

PROTOCOL FOR INSPECTION OF MEDICAL LABORATORIES IN NIGERIA BY THE MEDICAL LABORATORY SCIENCE COUNCIL OF NIGERIA

A. Introduction:

Medical Laboratory services are essential to patient care and therefore have to be available to meet the needs of all patients and the Physicians responsible for treatment and management of the patients. Therefore, the results emanating from the Laboratory should be reliable, accurate, reproducible, timely and cost effective. To achieve the above, the Medical Laboratory Science Council of Nigeria (hereinafter referred to as 'Council') is empowered by law to inspect, monitor, evaluate and accredit all Medical Laboratories in Public and Private Health facilities in Nigeria. This empowerment is statutorily provided in the MLSCN Act, CAP M25, LFN 2004 and the subsidiary legislations as published in the Federal Government of Nigeria Official Gazette No. 29, Vol. 102, Lagos dated 23rd March, 2015.

B. Objectives of the Inspection:

1. To ensure that Medical Laboratories generate accurate, reproducible reliable, timely and cost effective results for prompt treatment and management of patients.
2. To ensure international Good Laboratory and best Practice.

C. Pre-Inspection Activities:

1. Advocacy – To sensitize and create awareness amongst stakeholders in public and private Medical facilities, three (3) months before the inspection visit via print and electronic media.
2. Conduct pre-inspection workshop for stakeholders once annually.
3. Constitution of Inspection Team within 3 months of the advocacy.
4. Orientation workshop for the Inspection Team a day before the commencement of the inspection visits.

D. Procedure for Inspection:

The Medical Laboratory Inspection Checklist shall be used for the inspection of Medical Laboratories in Nigeria (for Primary, secondary and tertiary facilities). This checklist is available on MLSCN website: www.mlscn.gov.ng.

1. When an inspection team arrives any Medical Laboratory, it shall proceed as follows:
 - a. The team holds an opening/entry meeting with the Laboratory management in order to explain the purpose of the exercise.
 - b. Thereafter, the team proceeds with the inspection.
 - c. The team debriefs the Laboratory management on the outcome of the inspection and gives a timeline of maximum of 12 weeks depending on the complexity of the non-conformity observed to correct all deficiencies.
 - 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 MLSCN as well as participation in MLSCN's Proficiency testing scheme or any other accredited proficiency testing provider shall be regarded as having **passed** the inspection visit.
 - e. However, any **Registered** Medical Laboratory that scores less than 40% of the requirements listed on the checklist shall require corrective action in order to remedy the deficiencies and be given a time limit to rectify the identified non-conformities.
 - f. Notwithstanding the scores, any Medical Laboratory **not registered** with MLSCN shall be given a maximum of 12 weeks within which to get registered. The approved sum for laboratory registration is as follows:
 - Primary Facility: ~~₦~~50,000.00
 - Secondary Facility: ~~₦~~100,000.00
 - Tertiary Facility: ~~₦~~150,000.00
2. At the expiration of the time given for corrective action, failure to comply would attract automatic sealing of such facility by Council.

Where there is no Medical Laboratory Scientist and it is confirmed that the Medical Laboratory is operated by an un-registered/unqualified person, the Medical Laboratory shall also be sealed at once.

3. The inspection team upon conclusion of the inspection visit shall:
 - a. Forward the report of its finding with recommendations to the Council within 2 weeks.
 - b. The Council shall consider the reports of the inspection team and revert to the laboratories on the outcome within 2 weeks of receipt of the reports.

4. Upon the expiration of the period for regularization of nonconformities observed by the inspection team which shall not be less than 12 weeks depending on the complexities of the non-conformities observed, the Council's Zonal monitoring team will ensure compliance with the recommendations made by the inspection team and as approved by Council and report appropriately to the Council within 1 week of the monitoring visit.
5. When a sealed Medical Laboratory is ready to regularize its status, it shall:
 - a. Forward an application letter to the Registrar of Council requesting temporary access to the Medical Laboratory to enable it carry out the recommendations of the inspection team.
 - b. Present evidence of payment of a non – refundable fee of **₦100,000.00 (One Hundred Thousand Naira)** only representing penalty. This sum should be paid into Council's Treasury Single Account (TSA) with Central Bank of Nigeria (CBN).
 - c. Council shall respond to the request within 2 weeks of receipt of evidence of payment.
 - d. No request for opening of a sealed laboratory shall be considered during the inspection visits.
6. Where a Medical Laboratory that was previously closed is re-opened without recourse to the Council, the monitoring team shall close and seal the Laboratory and shall report the offender to the Nigeria Police for prosecution.
7. MLSCN will grant temporary registration for a period of three months (3) to a newly established medical laboratory awaiting pre-approval inspection provided all documents needed for registration have been submitted and reviewed for completeness.

SIGNED: MANAGEMENT