



MEDICAL AND DENTAL COUNCIL OF NIGERIA (MDCN)

APPROVED GUIDELINES ON CLINICAL LABORATORY ACCREDITATION

Practice in Nigeria

**MEDICAL & DENTAL COUNCIL OF NIGERIA,
ABUJA, NIGERIA**



MEDICAL AND DENTAL COUNCIL OF NIGERIA (MDCN)

Approved Guidelines on Clinical Laboratory Accreditation

Practice in Nigeria

Revised 2010

MEDICAL & DENTAL COUNCIL OF NIGERIA,
ABUJA, NIGERIA

Table of Contents

| | Page |
|---|------|
| Section 1: Introduction | 1 |
| Section 2: Scope | 3 |
| Section 3: The Standard | 4 |
| Section 4: The Accrediting Body..... | 5 |
| Section 5: The Assessors..... | 7 |
| Section 6: The Laboratory..... | 8 |
| Section 7: The Checklist..... | 9 |
| Section 8: Implementation Plan and the Accreditation Process | 12 |

INTRODUCTION

- 1.1 Modern medicine places a huge premium on clinical laboratory services. Where it is practiced, it is believed that over 60% or more of decisions concerning diagnosis and treatment are based on laboratory medicine consultation. Given the consequences that may attend such decisions, clinical laboratories must produce results that are consistently accurate, reliable and reproducible over time. There are globally accepted laboratory quality standards, which define requirements for quality and competence in the provision of laboratory service. These are encapsulated in the International Standards Organization (ISO) 15189:2007 (or as may be reviewed or modified from time to time). The verification of the implementation of the requirements of this standard or any other nationally accepted standard in a laboratory is the process of accreditation. The overall goal of accreditation is the improvement of the standards of practice.
- 1.2 In much of sub-Saharan Africa, fulfilling the requirements of international accreditation schemes is not commonly perceived as immediately feasible because of the current state of the quality of testing in most public laboratories, lack of trained laboratory experts, and the high cost of participation in international accreditation schemes. Recognizing this, the World Health Organization African Regional Office (WHO AFRO), has established a

step wise accessible, affordable, scalable and sustainable scheme to improve the quality of laboratory services in the region. The WHO AFRO - scheme is not intended to be an alternative to the ISO 15189 accreditation, but a path to it. Laboratories with the highest ratings on this scheme are to be encouraged to seek accreditation based on the requirements of the ISO 15189 standard.

- 1.3 The Medical and Dental Council of Nigeria (MDCN) is mandated by the Medical and Dental Practitioners Act Cap M8 2004, Laws of the Federation of Nigeria to make regulations for the operation of clinical laboratory practice in the field of Pathology and all of its sub-disciplines that involve testing of specimens from healthy individuals or patients of any age. Such sub-disciplines include, but are not limited to, Surgical pathology, Forensic Pathology, Autopsy pathology, and Cytopathology, Clinical Cytogenetics, Haematology, Medical Microbiology and Medical Parasitology, Chemical Pathology, Clinical Chemistry, Immunology, Coagulation or Haemostasis, Molecular Pathology, Tissue-typing, Transfusion Medicine or Blood Banking and Medical Virology. As part of this regulatory function, the MDCN has adopted the tiered WHO AFRO accreditation scheme as the instrument to guide the process of accreditation in Nigeria with the intent of raising the quality of Laboratory Medicine practice in the country. Training institutions shall be

required to enrol in laboratory accreditation processes and make continuous progress as a condition for attaining and retaining accreditation at both the undergraduate medical education and internship programmes. It is expected that the postgraduate medical colleges will also adopt this stand on accreditation.

2. SCOPE

This document specifies policies and procedures of the MDCN with regards to the process of clinical laboratory accreditation in Nigeria. It is based on the tiered WHO AFRO Accreditation scheme and will be applicable to both public and private laboratories in Nigeria. It encompasses and applies to laboratory services delivered at all levels of care - primary, secondary and tertiary.

This document addresses the 4 main elements of the accreditation process, and an overview of the checklist

- 2.1 The Standard
- 2.2 The Accrediting Body
- 2.3 The Assessors
- 2.4 The Laboratory
- 2.5 The Checklist

3. THE STANDARD

This refers to the document containing the requirements with which laboratory has to comply in order to gain accreditation.

3.1 The WHO AFRO Accreditation checklist will serve as the adopted standard of the MDCN accreditation program

3.2 The requirements of the standard will be applicable to all public and private laboratories in Nigeria.

3.3 The criteria for accreditation will be:

3.3.1 Internal quality control practices

3.3.2 Performance in MDCN approved proficiency testing programs

3.3.3 Volume of testing and its adequacy to assure continuous competency of personnel to carry out such testing

3.3.4 Turnaround time for reporting of tests

3.3.5 Scores obtained during inspections by external assessors

4. THE ACCREDITING BODY

This is the body that oversees the assessments, grants accreditation, and may also be involved in setting the standards.

4.1 The MDCN shall operate as an accrediting agency in accordance with the requirements, criteria, rules and regulations laid down in the following documents and organizations

4.1.1 The Medical and Dental Practitioners Act Cap 221 Cap M8 2004, Laws of the Federation of Nigeria.

4.1.2 The requirements of the WHO AFRO Laboratory technical group

4.2 The Council of the MDCN delegates clinical laboratory accrediting authority to the head of the Clinical Laboratory Accreditation Unit (CLAU) of the MDCN, together with the responsibility to implement the MDCN policies concerned with laboratory testing service and governance of clinical laboratory practices in Nigeria.

4.3 The decision concerning the granting of accreditation and star ratings shall be made by the Coordinating Committee of CLAU

4.4 The appointment of the Head of the CLAU shall be made by the MDCN. This individual should have

detailed knowledge of issues related to the quality of laboratory testing.

4.5 The Clinical Laboratory Accreditation Unit shall function as a semi-autonomous unit of the MDCN. It shall be responsible for coordinating MDCN Clinical Laboratory Accreditation Programme (CLAP) nationwide. Its decisions shall be subject to review, where necessary, only by the General Council.

4.6 The CLAU may recognize the level of compliance of a Laboratory's performance with the expectations of the WHO AFRO scheme by awarding stars to the Laboratory according to its practices.

4.7 The number of stars awarded to a laboratory will correspond to the inspection checklist score. This will be graded as below

4.7.1 0 – 142 points (<55%) – No star

4.7.2 143 - 165 points (55 - 64%) – 1 star

4.7.3 166 - 191 points (65 - 74%) – 2 stars

4.7.4 192 - 217 points (75 - 84%) – 3 stars

4.7.5 218- 243 points (85 - 94%) – 4 stars

4.7.6 244 – 258 points (≥95%) – 5 stars

5. THE ASSESSORS

This refers to the individuals who are authorized to determine a laboratory's compliance with the standards by conducting an assessment.

5.1 The CLAU of MDCN shall maintain a list of persons qualified to serve as assessors.

5.2 Assessors shall have the following characteristics

5.2.1 Knowledge of the accreditation criteria

5.2.2 Knowledge and skill in applying the accreditation criteria in actual assessments

5.2.3 Technical knowledge of specific laboratory practices

5.2.4 Knowledge, skill and competence of assessors (lead or technical) shall be assured by demonstration of certificated training in the above by a body recognized by the CLAU of the MDCN

5.2.5 Assessors shall not be employees of the facility to be assessed nor have any personal conflict of interest nor demonstrate partiality in the pursuance of their duties.

5.3 Two types of assessors will be recognized by the MDCN

5.3.1 Lead Assessor

5.3.1.1 has overall responsibility for specified assessment activities

5.3.1.2 verifies that the facility meets all necessary clinical and regulatory needs including those of MDCN

5.3.2 Technical Assessor – conducts the assessment of the technical competence of the laboratory for the specific area of the desired scope of accreditation.

5.4 The MDCN CLAU register of assessors shall designate in which of the above capacities the individuals therein listed can serve.

6. THE LABORATORY

This refers to the specific clinical laboratory which seeks to comply with the national standards or standards as approved or adopted by the MDCN.

6.1 Enrolment in an accreditation scheme shall be considered imperative for all components of all public and private laboratories in Nigeria and any facility that does laboratory testing on specimens derived from humans to give information for the diagnosis, prevention, treatment of disease, or impairment of, or assessment of health.

6.2 The application for enrolment in the MDCN accreditation scheme can be obtained from the

MDCN CLAU headquarters as well as at the State Ministries of Health. Application forms can also be downloaded from the MDCN website.

6.3 The schedule of accreditation shall include all tests being offered at the laboratory. Accreditation shall not be done in part. A test is defined as any examination of any human body part or material withdrawn from such an individual by an appropriately qualified person.

6.4 Each laboratory should maintain a quality manual that documents clearly how it seeks to comply with the requirements of the accreditation scheme.

7. THE CHECKLIST

This checklist is a tool used by Assessors that specifies requirements for quality and competency aimed to develop and improve clinical laboratory services to raise quality to uniform national high standards in Nigeria. This is based on the WHO AFRO checklist which is, in turn, based on the current ISO standard 15189:2007(E) and, to a lesser extent, CLSI guideline GP26-A3.

The Checklist is in 4 parts:

Part I

7.1 Includes worksheets to determine and record laboratory performance for the 12 months preceding the initial application for accreditation. Selection of

the most recent 12-month period, rather than the most recent calendar year as a basis for calculation, provides an assessment of current performance and permits inspection of laboratories at any time during the calendar year.

Requirements for this part are:

7.1.1 That test results are reported by the laboratory on at least 75% of specimens within the turnaround time specified (and documented) by the laboratory in consultation with its clients. Turnaround time is to be interpreted as time from receipt of specimen in laboratory until results are reported.

7.1.2 That a sufficient number of tests are performed to maintain laboratory competency. Such volume as constitutes competency shall be determined by technical expert committees constituted by the CLAU of the MDCN or the report of expert professional bodies adopted by the MDCN.

7.1.3 That internal quality control (IQC) procedure(s) are practiced for all testing methods used by the laboratory. Quality Control data sheets and summaries of corrective actions are retained for documentation and discussion with the Assessor.

7.1.4 That the scores on the MDCN approved proficiency tests over the preceding year are 80% or better.

7.2 Proficiency test (PT) results must be reported within

30 days of panel distribution. Laboratories that receive a score of less than 80% on two consecutive PT challenges will lose their accreditation until such time that they are able to successfully demonstrate achievement of 80% or greater on two consecutive PT challenges. Unacceptable PT results must be addressed and corrective action taken.

7.3A laboratory that has failed to demonstrate achievement of 80% or greater on the two most recent PT challenges will not be awarded any stars, regardless of the checklist score they received upon assessment.

Part II:

Provides a profile of the laboratory and serves to identify resource needs.

Part III:

Contains the assessment checklist for evaluation of laboratory operating procedures and practices

Part IV:

Summarizes the findings of the accreditation assessment and action planning worksheet.

8. IMPLEMENTATION PLAN AND THE ACCREDITATION PROCESS

8.1 Given the complex scene of laboratory testing in Nigeria, the implementation of this accreditation programme will be done in phases as below

8.1.1 Federal, State and Private University Teaching Hospital Laboratories

8.1.2 All other laboratories in Federal Institutions

8.1.3 State General Hospital Laboratories

8.1.4 Private Hospital Laboratories/Private Laboratories

8.2 This is to enable laboratories at lower levels have higher level laboratories that could help prepare them for accreditation, and probably serve as their External Quality Assurance (EQA) partners. However, any of the institutions that apply for enrolment for accreditation shall be attended to accordingly.

8.3 The accreditation process shall be as follows:

8.3.1 The institution or laboratory to be assessed shall formally apply to the MDCN for enrolment through completing an enrollment form and returning same with a prescribed application fee. Once an institution

or laboratory is enrolled in the MDCN accreditation process it shall not at the same time enroll with another accreditation agency locally, unless it discontinues with the MDCN.

8.3.2 The MDCN shall write to the laboratories to be assessed formally through the chief executives of such institution. This will happen a minimum of 12 months before an actual inspection will take place.

8.3.3 In the period before an inspection, the laboratory shall implement and document a quality management system in accordance with the requirements of the MDCN-WHO AFRO laboratory accreditation plan.

8.3.4 Three to six months before the scheduled inspection, the laboratory shall obtain the MDCN accreditation checklist from the MDCN or the appropriate State Ministry of Health or downloaded from the MDCN website, and submit the same together with their quality manual and required information and documentation as required.

8.3.5 The CLAU of the MDCN will review the application and clarify all issues with the applicant.

8.3.6 The MDCN will quote and invoice the applicant with regards to the cost of the accreditation inspection and process.

8.3.7 Upon receipt of payment, the CLAU of the MDCN will appoint a lead assessor who will review the application documents of the laboratory. He will submit a written report of the review to the facility via the MDCN CLAU

8.3.8 The facility will correct any deficiency noted in the report and communicate the same to MDCN CLAU within 30 days of the scheduled inspection.

8.3.9 The assessment visit will be conducted by a lead assessor and technical assessor(s) as deemed necessary.

8.3.10 The assessment documentation will be submitted to the MDCN CLAU. The CLAU will then consider the reports to determine what star rating will be awarded to the inspected laboratory.

8.3.11 The star rating will be officially communicated to the chief executive of the institution by MDCN.

8.4 Accreditation status will be subject to review every 2 to 3 years.

8.5 It is required that institutions that have been inspected conduct documented yearly reviews of their facility. Such documentation will be part of subsequent assessments.

8.6 Laboratories that have been assessed by a recognized external accrediting agency and granted accreditation shall be granted concurrence accreditation status by MDCN.

8.7 Any laboratory with a current accreditation from a recognized foreign or international accreditation agency and which enrolls in the accreditation programme of the MDCN shall be considered for concurrence accreditation.