MEDICAL LABORATORY SCIENCE COUNCIL OF NIGERIA

NATIONAL GUIDELINES FOR SETTING UP A MEDICAL LABORATORY IN NIGERIA

DECEMBER 2012

Foreward

The World Health Organization (WHO) recognizes quality laboratory services as key to improving global health and reaching Millennium Development Goals. Strengthening the breadth of laboratory services accessible to clients, and ensuring that results are accurate, reliable, reproducible, and rapid enough to be useful, is crucial to improved health outcomes.

Until recently, however, the majority of public health laboratories in Nigeria delivered suboptimal service and were not in a position to contribute to a quality health system. Many performed poorly, hindered by dilapidated infrastructures, and poor development and implementation of quality management systems (QMS), including inadequate participation in external quality assessment (EQA) programs.

Council under section 4(h) and 19(d) of MLSCN Act 2003 is mandated to inspect, approve, monitor and accredit Medical Laboratories in the country. Council accreditation is a validation process established to ensure that Medical Laboratories deliver high quality services that meets the needs and requirement of their clients. It also demonstrates competence and impartiality while promoting national and international recognition. At present, through strong commitment and leadership by the Federal Ministry of Health (FMOH), the Medical Laboratory Science Council of Nigeria (MLSCN) in collaboration with international partners (CLSI, CDC) has adopted the ISO 15189 standard to improve the quality of medical laboratory services in Nigeria.

This document has been developed to regulate the accreditation processes of Medical Laboratory Services in Nigeria to ensure accuracy, reliability and sustainability in the quality of service delivery.

I therefore encourage all stakeholders both in public and private health sectors at all levels in Nigeria to use this guideline in setting up Medical Laboratories which is geared towards improving the quality of laboratory services in Nigeria.

Professor Anthony O. Emeribe
Registrar/CEO
MLSCN

Acknowledgment

The MLSCN sincerely appreciates the efforts of all that contributed to the successful development of this document.

We appreciate the tremendous efforts of the United States Government through US Centers for Disease Control and Prevention (CDC) for funding the MELTNA (Mentoring Laboratories towards National Accreditation) project. We also appreciate the technical and logistics support of all CDC, USAID and DOD implementing partners.

Dr. Lawrena C. Okoro
Director Laboratory Accreditation & Regulation
MLSCN

Abbreviations

AFB- Acid Fast Bacilli
ASV – Anodic Strip Voltameter
BSC – Biosafety Cabinet
CBC – Complete Blood Count
CHCs – Community Health Centers
CV - Curriculum Vitae
ELISA – Enzyme Linked Immunosorbent Acid
EQA – External Quality Assurance
EQAS – External Quality Assurance Scheme
ESR – Erythrocyte Sedimentation Rate
HB – Haemoglobin
HIV – Human Immunodeficiency Virus
IDSP – Integrated Disease Surveillance Programme
ISE – Ion Specific Electrodes
MLSCN – Medical Laboratory Science Council of Nigeria
MP – Malaria Parasite
PCR – Polymerase Chain Reaction
PCV – Packed Cell Volumn
PHC – Primary Health Centers
POCT – Point of Cure Testing
RST – Rapid Syphilis Test
SQA – Sperm Quality Analyzer
VCT – Vinyl Composition Tiles
WBC – White Blood Count

TABLE OF CONTENT

1.0 INTRODUCTION

In Nigeria, the laboratory services are integrated with the 3- tier public health system at the primary, secondary and tertiary levels. Besides these, there are Reference Laboratories, Research Laboratories and Disease Specific Reference Laboratories to provide services for complex and special tests. Both public and private sector provides laboratory support at all levels of health care both in rural and urban areas. Each laboratory should identify the scope, functions and the capacity of the services offered by it and appropriate infrastructure with requisite biosafety measures in place. Qualified and trained staff should be employed with periodic up- graduating of their skills.

Laboratory test results play an important and sometimes singular role in the diagnosis and treatment of disease processes. When combined with the history, physical examination, x-ray studies and other diagnostic procedures, laboratory diagnoses always lead to sound Medical Diagnostic judgments.

The importance of quality in the function of health care laboratories is recognized worldwide. Poor quality laboratory results can lead to misdiagnosis, wrong treatment, wastages, and litigation among others.

In order to harmonize existing standards that ensure Medical Laboratories are producing quality test results, the international organization for standardization in 2004 officially announced ISO15189 for adaptation as the international quality standard for Medical Laboratories globally. The requirements of ISO 15189 are quite comprehensive and in a way tasking to achieve. However, very few laboratories conform to these standards because of inadequate knowledge of implementation.

This guideline is therefore being developed to guide stakeholders understand the requirements for setting up a medical laboratory in to Nigeria.

2.0 CATEGORIES OF LABORATORY SERVICES

2.1 Primary Laboratory

- Primary laboratory performs simple laboratory tests and could be managed by a registered a Medical laboratory Scientist or a Medical Laboratory Technician. They include primary healthcare laboratories, side Laboratories within clinics. Point of care testing They perform test such as:

- MP, Widal test, PCV/HB, Rapid serology test, urinalysis urine microscopy, and stool microscopy, pregnancy screening test

2.2 Secondary Laboratory

- These are labs that can carry out diagnostic services as may be required by the community and may serve as research centers and must be managed by a Medical Laboratory Scientist.

2.3 Tertiary Laboratory

- These are laboratories that can carry out diagnostic services as well as training and research at sophisticated level, and could also act as reference laboratories. It could have all or specialized disciplines/ department of medical laboratory services such as:
- Chemical Pathology, Haematology, Blood transfusion service, bacteriology, mycology, parasitology, virology, molecular diagnostics, histopathology, forensics laboratory, etc.

3.0 THE LABORATORY SPACE

- The laboratory has evolved from a service unit to a business entity and quality space must be provided to enhance quality services.
- Medical Laboratories shall not be located within two hundred meters radius of another laboratory, market or an environment where wastes from the facility could pose any form of HEALTH HAZZARD to the public.
- The laboratory space shall have enough working space and appropriate conditions to ensure quality services. The laboratory

space should be such that the contaminated area is well drafted and separated from the clean area. The laboratory shall monitor, control and document all environmental conditions which may affect the quality of its services. The laboratory shall design appropriate room/space for collection of samples which should not affect the quality of its services.

- The Laboratory shall have a clear procedure for waste management and environment protection.

	PRIMARY LABORATORY	SECONDARY LABORATORY	TERTIARY LABORATORY
Laboratory Site	a. Maybe attached to other health facilities or can be independent b. It should not be less than 300m from restaurants or eating houses and residential houses c. Proximity to other laboratory should not be less than 200m	Same as Primary Laboratory	Same as Primary Laboratory
Space	One room (5mx6m) or (16.4ft x19.7ft) which may be partitioned as may be required. Convenience **N/B**: These are minimum requirements	-Office of Director of Medical Laboratory Services Eight Rooms: 4 rooms of 12ft x 14ft in dimension and 4 rooms of 16 ft. x 19,7ft. The rooms are for the following 1. Reception 2. The manager's office 3. Media/wash-up room 4. Seminar / Training Room 5. Laboratories 6. Staff common room 7. Call duty room 8. Store convenience 9. **N/B:** These are minimum requirements	1. Office of Director of Medical Laboratory Services 2. Waiting room/space 3. Specimen collection/Dispatch 4. Minimum of 5 rooms for laboratory staff offices in each specialty 5. Record/I.T. offices 6. Seminar / Training Room 7. Conveniences 8. Staff common room 9. Call duty room 10. Wash-up room 11. Store 12. Main laboratory room 13. N/B Each dep artment. Should have a minimum of 5 laboratory rooms' space of 5m x6m each.
	-	-	
	-		

4.0 QUALITY SYSTEM REQUIREMENTS FOR MEDICAL LABORATORY SERVICES

The Laboratory shall develop and implement a quality management system that satisfies the requirement under the following twelve (12) clauses.

1. Organization and Management
2. Personnel
3. Equipment
4. Purchasing and Inventory
5. Process Control
6. Documents and Record
7. Occurrence Management
8. Assessment
9. Process Improvement
10. Client Management
11. Information Management
12. Facility and Safety

4.1 Organization and Management

The organization of the Medical Laboratories shall be legally identifiable. All services of the Medical Laboratories shall meet relevant requirement, and the scope of service shall be defined.

- The Medical Laboratory management shall be responsible for the design implementation, maintenance and improvement of the quality management system.
- Quality policies, procedures, and manual shall be documented and communicate to all relevant personnel. The management shall ensure that the documents are understood and implemented.
- Laboratory management shall review internal audit reports, surveillance reports, quality index results, laboratory services evaluation reports, and complaint records for management planning. The management reviews shall be documented.
- The quality index for quality monitoring shall be specified.

4.2 Personnel

- Policies and plans for employing sufficient staff shall be implemented. The laboratory shall have sufficient number of registered medical laboratory scientists proportional to the work load and shall be available at all times.
  The head of the Laboratory shall be experienced professional medical Laboratory Scientist and must be registered member of MLSCN. He or she will be responsible for duties related to instructing, managing, advising, training, budgeting, etc.

Personnel qualification shall be specified in relation to the job description.

- There shall be staff development and appropriate continuing education program available at all levels of organization to upgrade the knowledge attitudes and skills of staff.
- Work performance evaluation shall be regularly monitored for designing the training plan.
- Curriculum vitae, training records and other relevant records of laboratory personnel shall be maintained.
- Person(s) who can have access to the confidential laboratory data stored in computers or in files shall be defined.
- Annual medical checkup and vaccinations shall be supported.

4.3 Laboratory Instrument and Equipment

These include equipment, reference materials, reagents and test kits.
The analytical and logistic technology has to be available on a level which fulfills the minimal requirements for quality diagnostic services. The equipment shall be operated only by authorized personnel. It is important to stress that, most recent sophisticated equipment and technology without the support of the local suppliers and easy access to reagents is a negative critical success factor and will not make the recommended equipment list.

4.4 Procurement and External Services

4.4.1 Procurement

The Laboratory shall define and document its policy and procedure for selection of suppliers. There shall be inventory control system for suppliers of critical reagents and services that affect the quality of test result. The laboratory shall maintain records of approved suppliers.

4.4.2 External Services

The Laboratory shall define and document procedures for selection of the referral Laboratories and advisory matters. The list of referral Laboratories and advisory matters shall be documented.

The Laboratory shall establish procedures to ensure that the reports received from external Laboratories are correct. A copy shall be maintained for an appropriate period of time.

4.5 Process Control

The Laboratory shall implement internal quality control for monitoring the quality system and record all factors affecting the quality of services. The testing procedures shall be calibrated using reference material The Laboratory shall participate in External Quality Assessment Scheme EQAS

The Laboratory shall develop a specimen collection manual which, among others shall include procedures for collection, transporting, storage, handling, acceptance or rejection of specimens.

The Laboratory shall use only the standard or validated methods for specimen testing. The procedures for all test methods shall be documented and maintained..

The reporting procedures shall be clearly established including reporting via computer network and reporting the critical results.

The report form shall be designed with appropriate format stating clearly;

- The name of the Laboratory and Logo
- Name and age of the patient
- The hospital number of the patient
- The Laboratory number of the patient.
- Test request
- Nature of specimen

- Specimen receiving date
- Reporting date
- Test result and SI units
- Name and signature of laboratory scientist reporting the result
- Name and signature of laboratory scientist authorizing release of the result
- Biological reference where applicable

The Laboratory shall maintain copy of report for an appropriate period of time.

4.6 Document and Record Control

A list of all documents shall be maintained. The document shall be reviewed and approved by authorized persons. Obsolete or discontinued documents shall be labeled and archived / removed. Only authorized personnel shall access to the laboratory records and data.

4.7 Control of Non-Conformities

The criteria and procedure for the control of non-conformance shall be defined. Root cause analysis should be undertaken to forestall future occurrence. Testing may be stopped and results held until the nonconformance is resolved, depending on the nature and criticality of the nonconformance. Results reported during the nonconformance should be recalled when the nonconformance is of a critical nature to patient care.

4.8 Internal Audit

The laboratory quality system must undergo internal audits to verify that the laboratory is in compliance with the quality system. The laboratory management shall ensure that the internal audit is done at least once a year.

4.9 Continual Quality Improvement

All operational procedures shall be systematically reviewed by laboratory management at regular intervals in order to identify any potential sources of nonconformance or other opportunities for improvement in the quality management system or technical practices. Action plans for

improvement shall be developed, documented and implemented, as appropriate. Laboratory management shall ensure that the laboratory participates in continual improvement activities that encompass relevant areas and outcomes of patient care.

4.10 Client Management

The Laboratory shall develop a process for monitoring clients' satisfaction and complaint. Procedures shall be developed for receiving client feedback, opinion analysis, reporting to laboratory personnel and top management. An implementation plan shall be developed to address all complaints.

5.0 Laboratory Finishes and Furniture

5.1 Bench height:

Laboratory work benches should be between 28-35 inches above the floor and should have adequate leg and knee clearance under the workbench. Work benches should be 4-6 inches below elbow height while practitioner is seated on the stool. Laboratory stool, chairs with height 20''-25'' and should not have rollers.

5.2 Bench-Top materials:

The top materials for work benches should be made of Epoxy resin, silica, and chemically resistant plastic laminate. Stainless steel is good for glass wash rooms and cold rooms. However, work bench top materials must have chemical, impact, moisture, and bacteria resistance. Floor tiles and kitchen granite work tops are not recommended.

6.0 Laboratory fittings:

6.1 Laboratory windows:

The windows must be glass (opaque, translucent/tinted) but devoid of window blind drabs. The windows must be positioned in a way that good cross ventilation is achieved. The windows must be secured and netted. Fans should not be allowed in the laboratory.

6.2 Lighting system:

The laboratory must be well lit at all times. Multiple white energy saving or fluorescent tubes are recommended.

6.3 Plumbing system:

The plumbing for water and gas must be conduit wiring devoid of crisscrossing to avoid accidents. The tap must be elbow and sink enamel. The drainage must be connected to soak-away, sited away from the laboratory and domestic water source. There must be constant running water available.

6.4 Laboratory floor and ceiling:

No form of carpeting is acceptable. The floor can be tiled with vinyl composition tiles (VCT), sheath vinyl, rubber floors, or monolithic flooring. Floors must be mopped not swept.

Acoustic type ceiling is recommended for high sound absorbance. Ceiling must be solid, no liquid penetration, no access panels. Open ceiling is acceptable if there are no exposed ducts/tapes. It should be free from decorations and high enough for free movement.

6.5 Electrical system:

Electrical sockets should be placed on the laboratory benches or walls proximal to the workbench depending on the bench design. Crisscrossing of wires should be avoided, while conduit wiring or surface trunking is recommended.

If local electricity supply is intermittent or inadequate a generator of adequate capacity should be provided.

7.0 Waste management system:

Laboratory wastes should be separated appropriately into hazardous, non-hazardous and sharps. Liquid waste should be either heat- treated or chemically treated before being discarded into the drainage system.
There must be incinerator, needle destroyer or pit. All microbial wastes must be sterilized before incineration.

8.0 HUMAN RESOURCES /PERSONNEL

8.1 The medical laboratory shall be managed by a licensed Medical Laboratory Scientist certified by the Medical Laboratory Science Council of Nigeria.

8.2 In areas where Medical Laboratory Scientists are not available a MLSCN certified Medical Laboratory Technician with a three (3) years training on clinical laboratory sciences quality control and laboratory management, may manage a primary category clinical laboratories with supervision by a licensed Medical Laboratory Scientist.

8.3 The clinical laboratory shall employ qualified and adequately trained personnel for the level of service. Work assignment shall be consistent with the qualification of the concerned personnel.

8.3.1 A clinical laboratory shall have sufficient number of registered medical scientists, proportional to the work load and shall be available at all times during hours of laboratory operation. For hospital based clinical laboratory, there shall be at least one registered medical scientist per call duty to cover the laboratory operation.

9.0 EQUIPMENT/INSTRUMENT/SUPPLIES

1. There shall be sufficient number and types of appropriate equipment/instrument to undertake all the laboratory examinations and procedures for each test menu. All equipment/instrument shall comply with safety requirements. The head of the laboratory shall be responsible for overseeing the management of all equipment including point of care testing (POCT) devices irrespective of where they are located.
   NOTE: Please refer to appendix 1 for comprehensive list of equipment required for different laboratory levels.

10.0 Quality & Safety manual

The laboratory shall establish and maintain quality and safety manual. Refer to MLSCN for guidelines.

APPENDIX 1. LIST OF EQUIPMENT FOR EACH LABORATORY LEVEL

The list of equipment for each laboratory level shall be appropriate for the range of tests provided. Please refer to appendix for details.

PRIMARY LABORATORY	SECONDARY LABORATORY	TERTIARY LABORATORY
- Binocular mi croscope with (x100) objective - centrifuge - Hematocrit centrifuge, Reader - Refrigerator - ESR tubes & stand - Stop watch - Ambient room thermometer - Refrigerator thermometer - Glasswares - Automatic pipettes - Consumable & reagents/kits - Weighing balance	The following equipment are needed minimum depending on discipline/department: **Chemical Pathology** - Flame photometer or ISE - Colorimeter - Spectrophotometer - Refrigerator - Chemical balance - Automatic Pipette - Water bath - Water Distiller - Stopwatch **Haematology** - Haematocrit centrifuge & Reader - Binocular Microscope - Electric Centrifuge - Colorimeter - ESR stand & Tubes - Electrophoretic machine - And tank. - WBC Counter - Automatic Pipettes - Neubaeur Counting Chamber - Water Bath - Glasswares and Reagents - Staining Racks - Refrigerator, Freezer **Parasitology** - Binocular Microscope - Centrifuge - Hot air oven - Reagent & Consumable - Glasswares - Standing rack - Automatic Pipettes - Refrigerator - Stopwatch - Micro-ELISA Systems **Bacteriology** - Microscope - Autoclave - Hot air oven - Anaerobic Jar - Facility for Co2 incubation - Centrifuge - incubator - Refrigerator - Freezer	**In addition to the equipments in the seconday laboratory, the tertiary laboratory must have the following –** **Virology** Virology reagent and facility for viral culture ELISA System **HistoPathology** - Microtome - Tissue Incubator - Cryotome (Refrigerator Microtome - Slide Staining Rack (Assorter) - Binocular Microscope - Cytocentrifuge - Automatic Slide Staining Machine - COnsumables **Medical Microbiology** - Anaerobic Wink Station - Bacel Blood culture system - BSC II - ELISA Machine and Reader - Florescent Microscope - Carbon Dioxide Incubator - Inspissator - Laminar Flow Cabinet - Sperm Quality Analyser (SQA-V) - API Systems **Chemical Pathology** - This laye r Chromatography - Atomic Absorption Spectro - Photometer - Electrophoretic System - HPLC - ELISA System - Densitometric Scanner - Turbidometer - Autoanalysers (Chemistry) - Ion Specific Electrodes (ISE)

	- Reagent and Consumable - Glass ware - Weighing balance - Automatic Pipettes Thermometer 70°C freezer - Facility for TB culture **Blood Transfusion Science** - Blood Bank - Facility for bleeding (Bleeding Couch) - Centrifuge - Microscope - Water Bath - Chemical balance - Refrigerator - Freezer - Plasma Extractor - Weighing Balance - Blood Pressure monitor - Bath Weighing Scale	- PH Meters - Mass Spectrometers - Pluorimeters - Chemiluminometers - Safety Hood - Anodic Strip Voltameter(ASV) - Lead Analysers - Votex Mixer - Microplate Reader - Osmometer - 70° Freezer - Chemistry Analyser - Immunology Analyser - Microplate Washer - Deionizer **Mycology** - Microscope - Incubator - Mycology reagents **Molecular LAB** Three rooms with unidirectional workflow for a manual PCR lab. - Safety hood /cabinet. - Standard work benches - (Thermocycler) - Automatic Pipettes designated for each room. - Area Specific Laboratory Coat - UV Transilluminator - DNA Sequencer - Ultracentrifuge - Gel Documentation System - Gel Turing device - Gel Electrtophoretic System - Fraction Collector

APPENDIX 2: LIST OF TESTS FOR EACH LABORATORY LEVEL (at a minimum)

LIST OF TESTS FOR EACH LABORATORY LEVEL		
PRIMARY LABORATORY	**SECONDARY LABORATORY**	**TERTIARY LABORATORY**
1. HIV Serology: Rapid Test 2. Hemoglobin/PCV 3. Urine Test for Pregnancy 4. Urinalysis 5. Stool microscopy/ occult blood 6. AFB 7. MP 8 9. Direct Microscopy 9. Rapid Syphilis Test (RST) 10 Other Rapid POC Tests	1. All the tests listed in primary level and the following: 2. Full blood count (FBC) 3. CSF analysis 3. CD4 4. Blood Chemistry 5. Bacteriology 6. Parasitology 7. Blood transfusion service	1. All the tests listed in secondary level and the following: 2. Histopathology 3. Mycology 4. Viral Load 5. DNA PCR 6. Drug resistance monitoring (DRM) 7. Immunology 8. Any other specialized assay

APPENDIX 3: QUALITY SYSTEM REQUIREMENTS FOR MEDICAL LABORATORY

The Laboratory shall develop and implement a quality management system that satisfies the requirement under the following ten (10) clauses. This section provides guidance on the requirements of a quality management system.

1) Organization and Management
2) Personnel
3) Equipment
4) Purchasing and Inventory
5) Process Control
6) Documents and Record
7) Occurrence Management
8) Assessment
9) Process Improvement
10) Client Management
11) Information Management
12) Facility and Safety

LIST OF CONTRIBUTORS

Dr. Lawrena Okoro	Director, Department of Laboratory Accreditation and Regulation, MLSCN
Professor Eugene Ikeh	University of Jos
Dr. Callista Osuocha	US Department of Defence, Walter Reed Program-Nigeria
Captain Ikechukwu Ogueri	Nigeria Ministry of Defence/Emergency Plan Implementation Committee
Kingsley Ochei	Family Health International 360
Sani Iliya	Department of Laboratory Accreditation and Regulation, MLSCN
Dr. Nkiru Nwokoye	Association of Medical Laboratory Scientists of Nigeria Lagos State Branch
Prof. John Anetor	University of Ibadan
Mr. Manason Rubainu	University of Abuja Teaching Hospital
Mrs. D. Oriaku	Federal Capital Territory Administration (FCTA) Health Management Board

Dr. Donald I. Ofili	Medical Laboratory Science Council Nigeria.
Dr. Jemikalajah D.J.	Delta State Hospital Management Board, Warri.
Dr. Josephine Akpotuzor	University of Calabar
Mr. Emmanuel Ojo	Achieving Health Nigeria Initiative (AHNi)
Prof. Nneka Agbakoba	Nnamdi Azikiwe University Awka
Mr. Efobi Henry	University of Calabar Teaching Hospital Calabar
Mr. Eke Ofuche	AIDS Prevention Initiative in Nigeria (APIN) Abuja
Mrs. Amaka Anoke	National Hospital Abuja
Mrs. Oyebimpe Balogun	Institute of Human Virology Nigeria (IHVN) Abuja
Mr. Tosan Erhabor	Medical Laboratory Science Council of Nigeria
M.O.O. Mbuko	Medical Laboratory Science Council of Nigeria
Professor Anthony O. Emeribe	Registrar/CEO MLSCN