QUALITY MANUAL

MEDICAL LABORATORY SCIENCE COUNCIL OF NIGERIA (MLSCN)

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Appendix B. Staff Signatures

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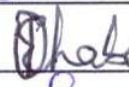
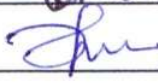
Mr. Tosan Erhabor		22/4/15
Mrs. Stella N. Udo		22/4/15
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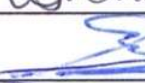
Mrs. Olufunmi Onakalu		22/4/15
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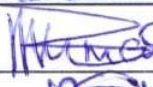
Nzeako Ihuoma N.		22/4/15
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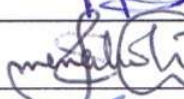
Nkemakolam Stanley		22/4/15
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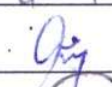
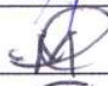
Ahunanya Ijeoma		22/4/15
Pius Lami		22/4/15
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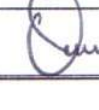
Deji .I. Ibrahim		22/4/15

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III Authorization by Registrar

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iii Abbreviations:

1.	MLSCN	Medical Laboratory Science Council of Nigeria
2.	FMoH	Federal Ministry of Health
3.	CDC	Centers for Disease Control and Prevention
4.	EQAP	External Quality Assessment Program
5.	APER	Annual Performance Evaluation Report
6.	CEO	Chief Executive Officer
2.	CLSI	Clinical and Laboratory Standard Institute
3.	FIFO	First In First Out
4.	ISO	International Organization for Standardization
5.	LIS	Laboratory Information Management System
6.	QM	Quality Manual
7.	QO	Quality Officer
8.	SOP	Standard Operating Procedure
9.	TAT	Turn Around Time
10.	ILAC	International Laboratory Accreditation Cooperation
11.	WHO	World Health Organization
12.	QMS	Quality Management System
13.	NEQAL	National External Quality Assessment Laboratory

iv. Glossary

Accreditation: Procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks. Reference: ISO 15189.

Audit: Systematic, independent, and documented process for gathering evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled.

Bio-safety: The active, assertive, evidence-based process that laboratorians use to prevent microbial contamination, infection, or toxic reaction as they actively manipulate live microorganisms or their products, thus protecting themselves, other laboratory staff, the public, and the environment.

Competence: Demonstrated ability to apply knowledge and skills.

Confidentiality: Pertains to the disclosure of personal information in a relationship of trust and with the expectation that it will not be divulged to others in ways that are inconsistent with the original disclosure.

Continual/Continuous Improvement: The cornerstone of quality management systems, allows the laboratory to gain insights from setting objectives, monitoring through audit and management review, addressing complaints and nonconformities, and performing facility satisfaction surveys. A recurring activity to increase the ability to fulfill requirements: Plan, Do, Check, Act.

Control Substances: That contain an established amount of the substance being tested – the analyte. Controls are tested at the same time and in the same way as patient samples.

Customer: Organization or person that receives a product or service from a supplier organization.

Customer Satisfaction: Customer's perception of the degree to which the customer's requirements have been fulfilled. It can vary from high satisfaction to low satisfaction. If customers believe that you have met their requirements, they experience high satisfaction. If they believe that you have not met their requirements, they experience low satisfaction.

Document: Information and its supporting medium; digital or physical. ISO identifies five types of documents: specifications, quality manuals, quality plans, records, and procedure documents. See Normative and Standard documents.

Documentation: Written material defining the process to be followed.

Examination: 1. Activities and steps related to performing laboratory examinations. 2. A set of operations having the object of determining the value or characteristics of a property to describe these processes. 3. One phase of the three-phase framework for the total testing process to describe issues related to the quality of laboratory testing. Also referred to as Analytical phase. See Pre- and Post-examination.

External Quality Assessment (EQA): A system for objectively checking the laboratory's performance using an external agency or facility.

Indicators: Established measures used to determine how well an organization is meeting its customers' needs as well as other operational and financial performance expectations.

Internal Audits: Internal quality audits are audits carried-out by the laboratory personnel who examine the elements of a quality management system in their laboratory in order to evaluate how well these elements comply with quality system requirements.

Management Review: Evaluation of the overall performance of an organization's quality management system and identification of improvement opportunities. These reviews are carried-out by the organization's top managers and are done on a regular basis.

Non-conformity: Failure to fulfill the requirements of a specified process, structure or service. May be categorized as major (complete) or minor (partial).

Occurrence: An event, accident or circumstance that happened without intent, volition, or plan.

Organization: Group of people and facilities with an arrangement of responsibilities, authorities and relationships.

Path of Workflow: (clinical laboratory) Sequential processes in pre-examination, examination, and post-examination clinical laboratory activities that transform a physician's order into laboratory information.

Policy: An overarching plan (direction) for achieving an organization's goals.

Post-examination (also Post-analytical Phase): Processes following the examination including systematic review, formatting and interpretation, authorization for release, reporting and transmission of the results, and storage of samples for the examinations. One phase of the three-phase framework for the total testing process to describe issues related to the quality of laboratory testing.

Pre-examination (also Pre-analytical Phase): Steps starting, in chronological order, from the clinician's request and including the examination requisition, preparation of the patient, collection of the primary sample, and transportation to and within the laboratory, and ending when the examination phase begins. One phase of the three-phase framework for the total testing process to describe issues related to the quality of laboratory testing.

Preventive Action: Planned steps that are taken to remove the causes of potential nonconformities or to achieve quality improvements. Preventive actions address potential problems, ones that have not yet occurred. In general, the preventive action process can be thought of as a risk analysis process.

Process: The use of resources to transform inputs into outputs. In every case, inputs are turned into outputs because some kind of work, activity, or function is carried out.

Proficiency Testing: ISO guide: 43 (EA-2/03) [1], proficiency testing schemes (PTS) are inter-laboratory comparisons that are organized regularly to assess the performance of analytical laboratories and the competence of the analytical personnel. (See EQA). CLSI definition: "A program in which multiple samples are periodically sent to members of a group of laboratories for analysis and/or identification; whereby each laboratory's results are compared with those of other laboratories in the group and/or with an assigned value, and reported to the participating laboratories and others".

Quality: Degree to which a set of inherent characteristics fulfill requirements.

Quality Assurance: A planned and systematic set of quality activities focused on providing confidence that quality requirements will be fulfilled.

Quality Control: A set of activities or techniques whose purpose is to ensure that all quality requirements are being met. Simply put, it is examining "control" materials of known substances along with patient samples to monitor the accuracy and precision of the complete examination process.

Quality Indicator: Established measures used to determine how well an organization meets needs and operational and performance expectations.

Quality Management: Coordinated activities that managers carry out in an effort to implement their quality policy. These activities include quality planning, quality control, quality assurance, and quality improvement. (See Quality System Essentials).

Quality Management Standards: (such as GP26 A4: 2011,ISO 15189:2012, ISO 17011:2004) are a series of policy statements.

Quality Management System (QMS): Management system to direct and control an organization with regard to quality.

Quality Manual: Document specifying the quality management system of an organization.

Quality Policy: Overall intentions and direction of an organization related to quality as formally expressed by top management.

Quality Record: Objective evidence, which shows how well a quality requirement is being met or how well a quality process is performing. It always documents what has happened in the past.

Quality System: The defined organizational structure, responsibilities, processes, procedures and resources for implementing and coordinating the Quality Assurance and Quality System Audit. A documented activity performed to verify, by examination and evaluation of objective evidence, that applicable elements of the quality system are suitable and have been developed, documented, and effectively implemented in accordance with specified requirements.

Quality System Essentials (QSE): The necessary infrastructure or foundational building blocks in any organization that need to be in place and functioning effectively in order to support the organization's work operations so that they proceed smoothly. (See Quality Management).

Referral Laboratory: External laboratory to which a sample is submitted for a supplementary or confirmatory examination procedure or for testing not performed in the originating laboratory.

Regulation: Any standard that is mandated by a government agency or authoritative body.

Root Cause: That which has the most impact on the problem being tackled.

Root Cause Analysis: A tool designed to help identify not only what and how an event occurred, but also why it happened.

Safety: Those processes implemented to protect laboratory workers, visitors, the public, and environment.

Sample (also Specimen): One or more parts taken from a system and intended to provide information on the system, often to serve as a basis for decision on the system or its production.

Specimen (see Sample)

Supplier: Organization or person that provides a product or service.

Test: Determination of one or more characteristics according to a procedure.

Traceability: Ability to trace the history, application or location of that which is under consideration.

Validation: Confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled.

Verification: Confirmation, through the provision of objective evidence, that specified requirements have been fulfilled.

Waste: Any activity that consumes resources and produces no added value to the product or service a customer receives.

1.0 General

1.1 Historical Background

The Medical Laboratory Science Council was established by Act 11 of 2003. The Act, apart from establishing the Medical Laboratory Science Council of Nigeria (MLSCN), also repealed Decree 54 of 1999, a decree that changed the name of the Institute of Medical Laboratory Technology of Nigeria to the Institute of Medical Laboratory Science and Technology of Nigeria.

In effect there had been progressive transformation from Institute of Medical Laboratory Technology of Nigeria through Institute of Medical Laboratory Science and Technology to Medical Laboratory Science Council of Nigeria.

Legal provision for the establishment of the Institute of Medical Laboratory Technology of Nigeria was made by promulgation of Decree No 56 of 19th November, 1968. This was the final result of some four (4) years of planning by a Working Committee of Medical Laboratory Scientists and Pathologists under the chairmanship of successive Chief Medical Advisers, including Dr S.O Awoniyi and Dr M. P. Otolorin. Under the decree, the Working Committee was constituted into an interim Council with Dr. M. P. Otolorin, Chief Medical Adviser to the Federal Government as chairman and Dr. S. L. Adesuyi then Deputy Chief Medical Adviser to look after the affairs of the Institute until the Statutory Council was formed. The first meeting was held on 3rd February, 1969. The statutory Council was formally inaugurated by the Honourable Federal Minister of Health, Dr. J. E. Adetoro on 10th March, 1970.

By a notice published in the Federal Gazette, October 1, 1969 was declared by the Hon. Minister to be the appointed day on which in accordance with Section 3 of Decree 56 of 1968, any group in Nigeria associated with an overseas body of Medical Laboratory Technology shall cease to exist as a group or branch in Nigeria and its functions and assets shall be vested in the Nigerian Institute unless otherwise agreed with the associated group.

Prior to the formation of the statutory Council, two medical laboratory scientists in succession served as Secretary/Registrar – Mr P. E. U. Idundun and Mr R. A. Johnson respectively.

These men could be regarded as part-time Registrars. In March 1970, Mr Edward Isidahome Madojemu assumed duties as the first full time Secretary/Registrar of the statutory Council of the Institute of Medical laboratory Technology Mr Madojemu passed on, on 3rd August, 1972 and was succeeded by Mr G. W. Park who assumed duty on 12th April 1973. Mr Park was succeeded by Dr. S. M. Osuoha and later Lady E. U. Okonkwo. The incumbent Registrar, Prof Anthony O. Emeribe succeeded Lady Okonkwo after her retirement in 2010.

At inception, the Statutory Council was chaired by a non-medical laboratory scientist. The Board of the Institute inaugurated in 2000 was, however, chaired by a medical laboratory scientist – Chief D. I. Tabansi. Only two (2) out of the 15-member board were non-medical laboratory scientists- a Pathologist – Dr. O. S. Njoku and Alhaji Ibrahim Kankara nominated by the Federal Ministry of Health to represent public interest. The last 2 Boards that were dissolved in 2008 and 2011 had no Pathologist as a member. These were also chaired by a medical laboratory scientist in the person of Professor D. E. Agbonlahor. The present board of Council is chaired by Dr. N.N. Shidali, a Medical Laboratory Scientist.

At any rate, the Board inaugurated in 2000 did not have the necessary tools to function effectively. The Board of the Council constituted following the MLSCN Act 11 of 2003 was able to operate more effectively because of the enabling law. Furthermore, the current Registrar/Chief Executive Officer, Prof. A.O. Emeribe, being an astute scholar and a seasoned administrator has propelled the Council to greater heights. Under his administration, Council has been able to articulate its shared Vision, Mission, Core Values, Organizational Culture, Strategic Plan, and now the Quality Manual. These are necessary instruments for any organization as well as the hallmarks of quality practice.

There is training of staff across board to position them for actualization of quality practice. Few areas of its enabling laws that were not receiving attention hitherto are now being pursued vigorously. One of such areas is importation, marketing and production of reagents.

Equally, Council is working assiduously at advocacy in order to continuously engage its stakeholders despite gaining recognition as a leading Regulatory Authority both nationally and internationally.

Its efforts have also led to positive collaborations with donor agencies with a view to improving its services.

1.2 Introduction

The Medical Laboratory Science Council of Nigeria (MLSCN) functions as a Statutory Regulatory Agency. It regulates the practice of Medical Laboratory services in Nigeria and is a legal entity established by Act 11 of 2003 under public law reporting to the Federal Ministry of Health (FMoH). The Council is governed by a board which makes policies and it is headed by the Registrar/Chief Executive Officer who is in charge of the day to day running of the Council activities. The corporate headquarters is located at Durumi District Federal Capital Territory Abuja. It has offices in the six geo-political zones and some states. It has a National External Quality Assessment Laboratory (NEQAL) in Saye-Zaria, Kaduna State and an In-Vitro Diagnostics Control Public Health Laboratory in Yaba, Lagos State. As a regulatory agency we strive to maintain a culture of quality and we are committed to a systematic approach to provide effective and efficient services to our stake holders The Council has adopted and maintains a Quality Management System which is based on the international standard ISO 15189.and ISO 17011. Management and staff are committed and actively participate in this quality process. Quality policies, processes and procedures are documented in the Quality Manual to ensure that Council meet the needs of its stake holders and the requirements as established by National and International standards. This manual defines the quality management system addressing all Departments/Units. Responsibilities and assignments are clearly defined for all Departments/Units of the Council. It establishes the means for management and staff to improve the Council's performance.

1.3 Scope:

This quality manual outlines and communicates the MLSCN Quality Management System. The manual provides guidance to the Council and stakeholders on the MLSCN endeavours to consistently meet or exceed stakeholders' needs and expectations. Council efficiently and effectively fulfills its stated mission and objectives through the establishment of the Quality Management System.

- The policies set out in this manual are mandatory for all staff members. Quality System Essentials are explained to and are accessible to all Council staff and stake holders
- The document serves as an introduction of the quality system of our service to our stake holders
- Management is responsible for its content and all updates.
- Management is responsible for implementation of the quality manual.

- To reflect the current best practices and continuous improvements, changes or additions to the manual are documented on the revision history table
- The Quality Manual is accessible to all staff and management.

It is the responsibility of the Registrar/CEO to ensure that all staff are familiar with the manual's content as it relates to their work and responsibilities and that they are kept informed of any changes and updates.

1.4 Functions of the Council

- Determine from time to time the standard of knowledge and skill to be attained by persons seeking to become Medical Laboratory Scientist, Medical Laboratory Technicians and Assistants
- Regulates the practice of Medical Laboratory Science in Nigeria
- Regulates the training of Scientists, Technicians and Assistants in any institution in Nigeria and give periodic Accreditation to institutions
- Regulates the production, importation, sales and stocking of diagnostic laboratory reagents and chemicals
- Inspects, regulates and accredits medical laboratories
- Conducts examinations for Technicians and Assistants
- Assess, evaluate and register foreign graduates of Medical Laboratory Science

1.5 Approval, Revision and Distribution of the Quality Manual:

The Quality Manual is prepared by the MLSCN Quality Manual (QM) team with input from staff of all Departments/Units in consultation with CLSI Program Manager. The quality manual is approved by the Registrar/CEO. It will be reviewed bi-annually and revised as the need arises. The Registrar/CEO is responsible for maintaining the official master copy of the QM. General distribution of this manual is accomplished using a controlled document distribution list kept in the Registrar/CEO office.

1.6 Vision

To be a world acclaimed regulatory agency driving the culture of quality and efficient health laboratory care to the public and ensuring high academic standards in training institutions.

1.7 Mission

Strengthening health laboratory systems and professional practice for quality service through strategic regulation and accreditation.

1.8 CORE VALUES (PIECE-T)

1. **P**rofessionalism:
    - Application of skills and high standards
2. **I**ntegrity:
    - Firmness in more Principles,
    - Truthfulness at all time
3. **E**xcellence:
    - Outstanding feature or quality obtaining reliable results,
    - State of superiority or eminence.
4. **C**ommitment:
    - A pledge of promise or obligation
5. **E**fficiency:
    - The State or quality of being competent in performance,
    - Ability to accomplish a job with a minimum expenditure of time and effort
6. **T**eamwork:
    - Cooperative or coordinated efforts on the part of a group of persons acting together in the interest of a common course.

1.9 Quality Policy Statement

MLSCN is committed to continual improvement of medical laboratory services to achieve ongoing stakeholders' satisfaction. It is therefore our policy and commitment to:

- Consistently provide efficient and reliable services that conform to national and international standards.
- Ensure that all personnel are competent and qualified for the tasks they perform, and that all personnel familiarize themselves with quality system documentation in order to implement the policies and procedures in their work.
- Professionally and effectively perform our mandate
- Consistently comply with ISO 15189 and ISO 17011 to ensure quality service delivery and to continually improve the effectiveness of the Quality Management System.

- MLSCN reviews its quality policy for continuing suitability in order to keep abreast with knowledge and technological developments
- It is MLSCN's goal to encourage active participation of all employees in quality planning and continual improvement efforts to meet all quality, service and cost

1.10 Quality Objectives

1. To provide QMS continued educational classes quarterly with attendance of more than 95% of laboratory workers by December 2017.
2. To increase the number of trained assessors by 20% by December 2014.
3. To ensure that 90% of all applications for licence, transcripts are released within the established Council turnaround times by December 2015.
4. To maintain safe and healthy working conditions to all employees and ensuring zero working accidents per month by December 2016.
5. To reduce number of customer complaints every quarter by 10%.
6. To achieve complete computerization of Council activities by December 2015.

2. QSE: Organization

This section describes the overall Quality System including legal identity, organization and management arrangement at the Medical Laboratory Science Council of Nigeria.

2.1 Legal Entity:

The Medical Laboratory Science Council of Nigeria (MLSCN) functions as a Statutory Regulatory Agency. It regulates the practice, processes, diagnostics, education, and infrastructure of Medical Laboratory services in Nigeria and is a legal entity established by Act 11 of 2003 (Cap M25 LFN, 2004) under public law reporting to the Federal Ministry of Health (FMoH). The law clearly establishes the Council as an accrediting body. The Council is governed by a Board which makes policies and it is headed by the Registrar/Chief Executive Officer who is in charge of the day to day running of the Council activities. The corporate headquarters is located at Durumi District, Federal Capital Territory Abuja. It has offices in the six geo-political zones and some state offices. It has a National External Quality Assessment Laboratory (NEQAL) in Saye Zaria, Kaduna State and a Public Health In-Vitro Diagnostics Laboratory in

Yaba, Lagos State. As a regulatory agency Council strives to maintain a culture of quality and is committed to a systematic approach to provide effective and efficient services to stakeholders.

The Council has adopted and maintains a Quality Management System which is based on the international standards (ISO 15189.and ISO 17011). Management and staff are committed and actively participate in this quality process. Quality policies, processes and procedures are documented in the Quality Manual to ensure that Council meets the needs of its stakeholders and the requirements as established by National and International standards. This manual defines the quality management system addressing all departments/units. Responsibilities and assignments are clearly defined for all departments/units of the Council. It establishes the means for management and staff to improve the Council's performance.

Type of Organization: Government Regulatory Agency

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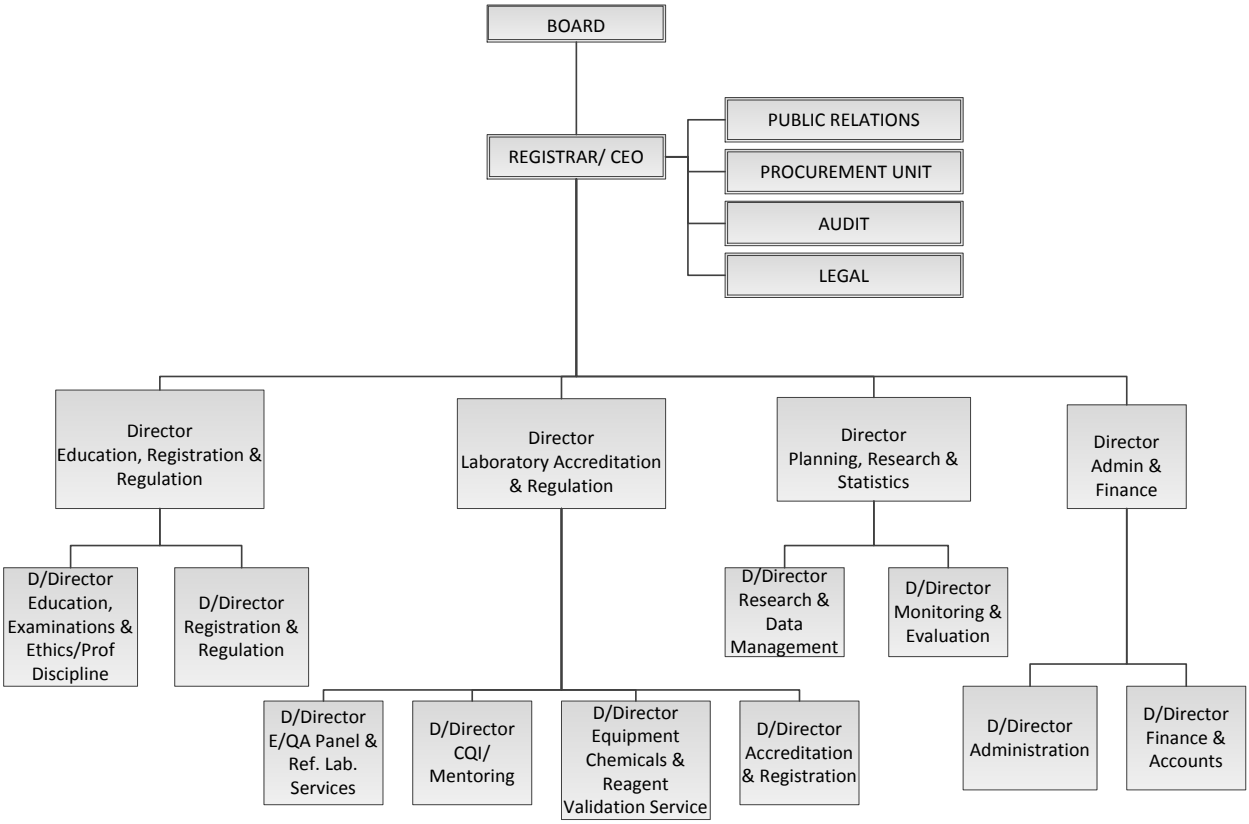
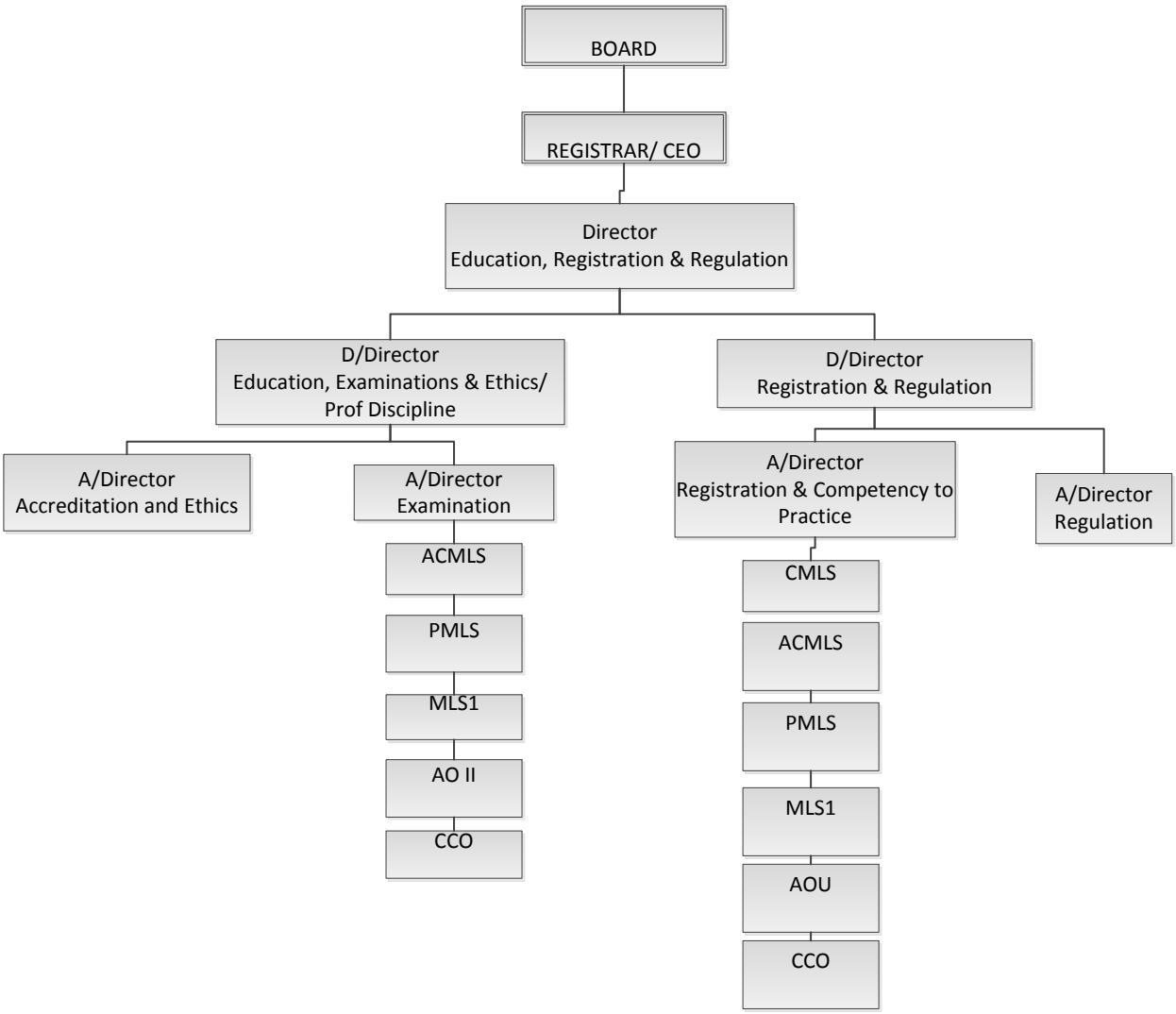
2.2 Organizational Structure

MLSCN is managed under the leadership of the Registrar/CEO with the support of senior management team comprising of Heads of Departments and other Principal Officers who oversee all activities of the Council. Each Department of the Council is under the supervision of Directors and Deputy Directors.

2.2.1 MLSCN Management Organogram

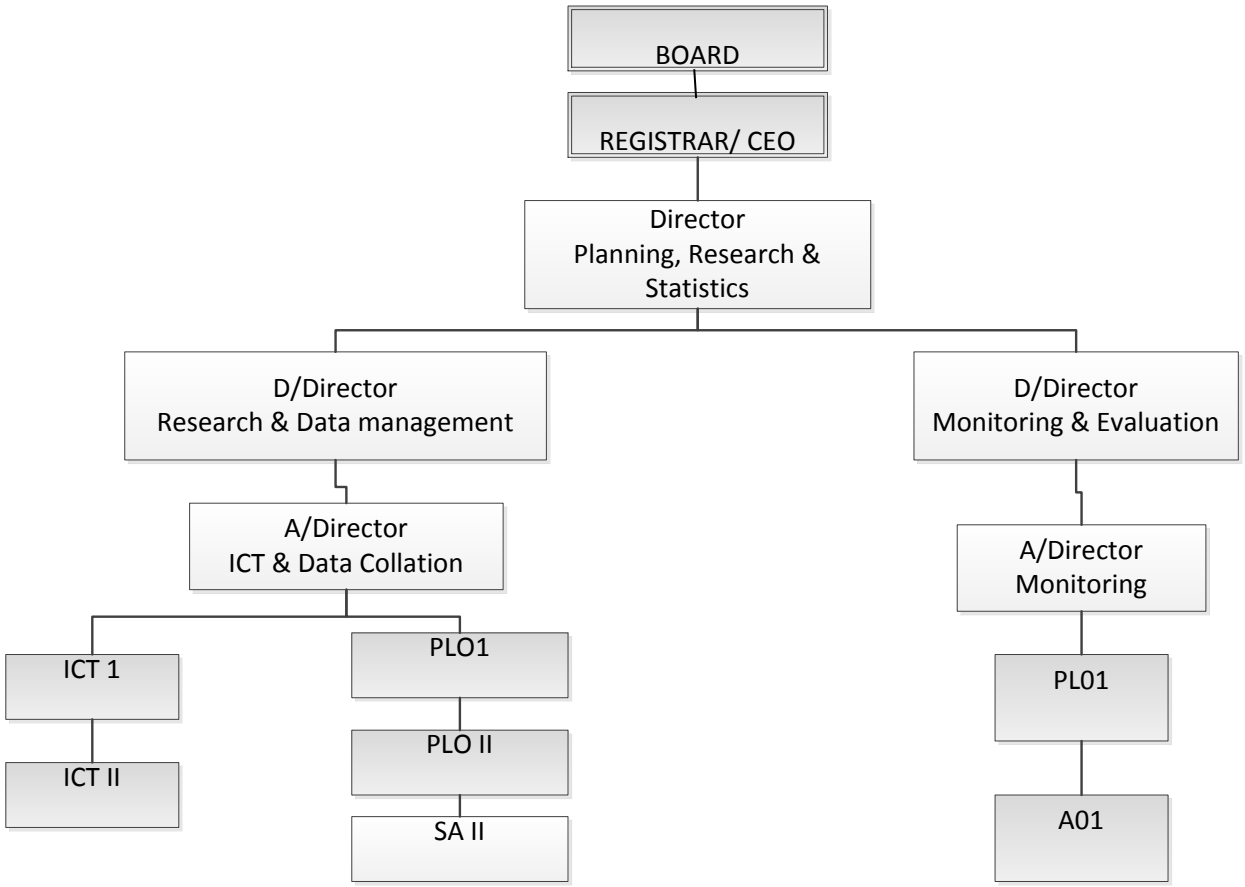


2.2.2 Department of Education, Registration and Regulation Organogram

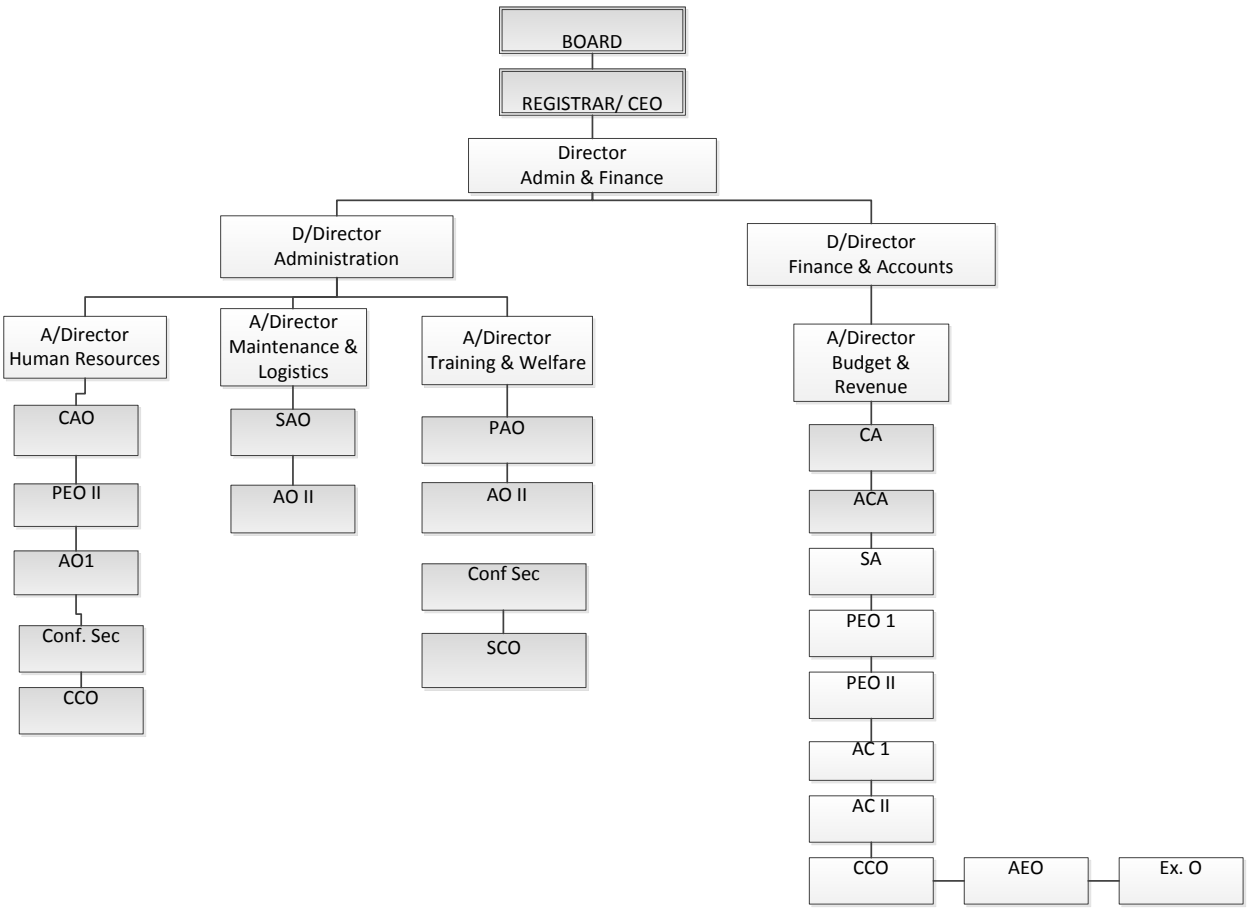


2.2.3 Department of Laboratory Accreditation and Regulation

2.2.4 Department of Planning Research and Statistics



2.2.5 Department of Administration and Finance



2.3 Maintenance and Disclosure of Confidential Information/Conflict of Interest

2.3.1 The MLSCN maintains a high level of confidentiality in its operations. An undertaking is obtained from the employees, assessors, contracted personnel and other third parties, to the maintenance and disclosure of confidential information. Any breach of confidentiality is viewed and handled appropriately.

2.3.2 MLSCN requires all personnel (employees, assessors, technical experts) who may have interest related to their activities, to ensure the highest integrity and public confidence in their activities. MLSCN requires that all personnel disclose any circumstances that could give rise to a potential conflict of interest related to the subject of the activity in which they will be involved. All assessors, including contracted personnel must disclose any circumstances that could represent a potential conflict of interest.

2.4 Authority:

All members of staff are given authority by the Registrar/CEO to perform their activities, and on behalf of MLSCN in areas which they have been deemed competent. Authorizations are generally documented in their individual job descriptions and followed by competence assessment forms.

2.5 Resources:

Adequate human and financial resources are provided by management to ensure that MLSCN general operations are not compromised which would affect the quality of service delivery

2.6 Confidentiality

Council has put in place at all levels adequate arrangement to safeguard the information obtained in the process of its accreditation activities including committees and individuals acting on its behalf. Council will not disclose classified official information about a particular institution without written consent of the institution, except where the law requires such information to be disclosed without such consent.

2.7 Impartiality

To ensure the credibility and validity of the accreditation process, MLSCN has put in place measures to safeguard the objectivity and impartiality of its activities. MLSCN ensures balanced representation of

qualified persons in constituting accreditation teams. MLSCN ensures its accreditation services are accessible to all applicants whose requests for accreditation fall within the activities and the limitations as defined in the policies and rules. MLSCN has an Independent Advisory Committee (IAC) whose responsibility is to consider and approve accreditation reports. Complaints on the accreditation process are referred to the Governing Board of the Council which has in its fold an Arbitration Panel.

2.8 Internal and External Pressure:

MLSCN encourages all members of staff to disclose any internal and external commercial, financial or other pressures and influences that may affect the quality of their work. Members of staff are free to approach any managerial staff in confidence and share their personal pressures.

2.9 Communication:

Communication is vital for the effective performance as well as continual improvement of a Quality Management System. It is in this regard that MLSCN management has established communication mechanisms that will ensure that stake holders requirements (both internal and external) are met. All communications (outgoing and incoming) are logged or filed whichever is appropriate.

2.10 Internal Communication

To achieve collective ownership of the system by both Management and staff, MLSCN management involves all staff in every aspect of the development and implementation of the QMS. For effective communication within the Council, Management has adopted channels of communication, which include but not limited to the following:

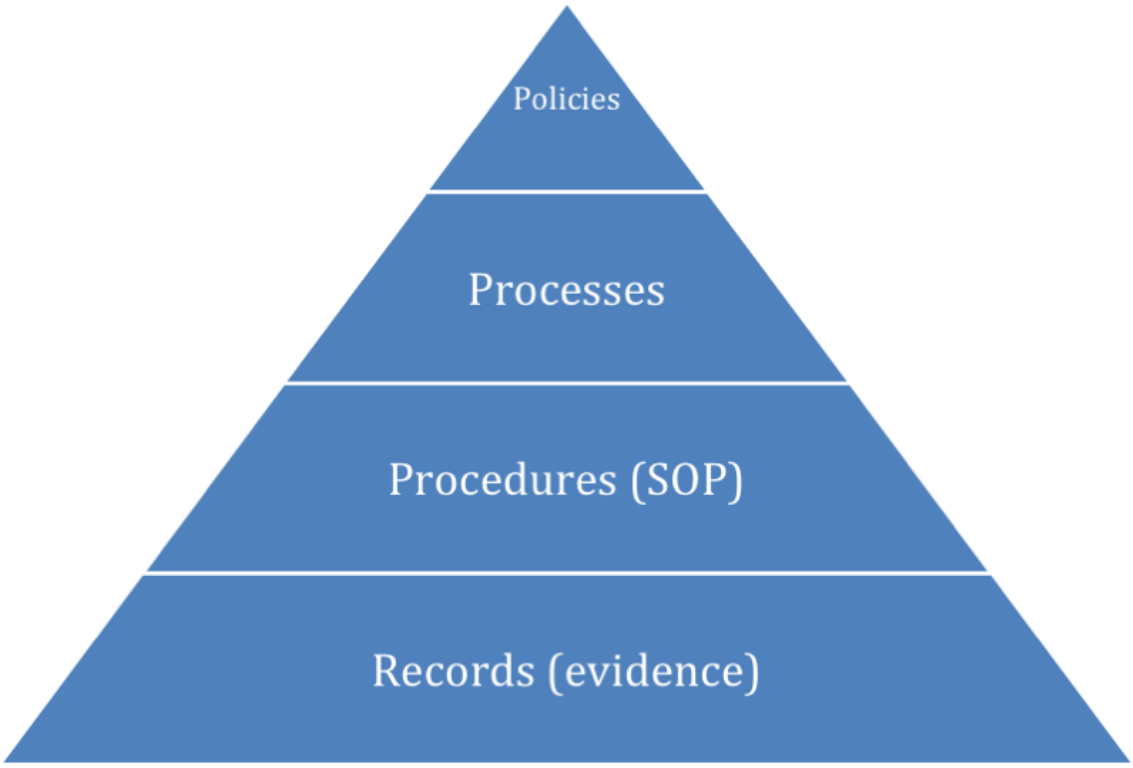
- Memos, letters, notices
- Meetings
- Oral communication
- Verbal or written instructions (e.g. through Quality Manual, Lectures).
- Periodicals (Bulletin)

2.11 External Communication:

Communication with external stakeholder is in the form of but not limited to letters, newspaper publication, electronic mail, telephone and meetings. Council staff are authorized to offer telephonic consultations on technical matters within the scope of their responsibilities to external facilities. Records of all communications shall be kept thereof.

2.12 Quality Management System:

The MLSCN has a documented Quality Management System which comprises of policies, procedures, instructions, forms, job descriptions, external reference and regulatory documents and records. The MLSCN management ensures that all members of staff have been trained on QMS and understood it upon employment and as when necessary. All relevant QMS documents are made available at each Department/Unit for easy implementation. The following diagram outlines the Quality Management System documentation Structure.



The Quality Manual is the governing document that defines the quality system policies and statements of intent by MLSCN and is based on ISO 15189:2012 and ISO 17011 requirements.

Quality Policies……..Describe what we do

Quality Processes…….How we make it happen

The Quality Procedures (SOPs) and Instructions describe who, what, when, where and how quality management system and processes are performed.

Quality Forms related to quality procedures are used for data collection.

Quality Records are retained as objective evidence of compliance to the international requirements and MLSCN processes and procedures.

Supporting Documents:

PR01_Document control procedure
PR10_Record Control Procedure

2.13 The Governing Board

The Governing Board of the MLSCN is headed by a Chairman and 19 other members drawn from:

- Federal Ministry of Health (1)
- Association of Medical Laboratory Scientist of Nigeria (12, two from each geo-political zone)
- Nigerian Universities offering Medical Laboratory Science as a course (2).
- Representative of the Association of Medical Laboratory Scientists (1).
- A representative from a non-governmental organization with bias for health representing public interest (1).
- A representative of the Guild of private practitioners of Medical Laboratory Sciences (1).
- The Registrar/CEO (Secretary)

Responsibility of the Board is to make policies for the activities of the Council.

2.14 Registrar/CEO

The Registrar/CEO is the Chief Accounting Officer of the Council and is responsible for:

- Keeping the records and conducting all correspondences of the Council
- Preparing and maintaining in accordance with the rules made by Council a register of names, address, qualifications and other particulars of persons entitled for registration.
- Issuance of licences and tags to qualified Scientist, Technicians and Assistants

- Issuance of transcripts and evaluation of certificates
- Conducting of examinations for Technicians, Assistants and foreign graduates
- Conducting accreditation exercises for training institutions and Laboratories
- Inspecting and monitoring of Medical Laboratories
- Publishing and updating the names of practitioners as well as those in default of payment of annual subscriptions
- Publishing of the Scientist news bulletin.
- Striking off the names of deceased members from the register

2.15 Heads of Departments

Responsible for:

- Coordinating the establishment of the quality management system based on ISO 15189 and ISO 17011 supporting its implementation and coordinating activities pertaining to quality.
- Supervising and directing the work at departmental/unit levels.
- Coordinating and supervising staff orientation, training and competence assessment.
- Monitoring quality management system (QMS) implementation.
- Ensuring the safety requirements of the MLSCN are being followed.

2.16 Heads of Units

Responsible for:

- Assisting the Heads of Department in providing advice to those requesting information about Councils activities
- Assisting the Heads of Department in supervising and overseeing the technical functions of the Council.
- Assisting the Heads of Department in advising the Registrar/CEO in technical matters pertaining to the Council
- Serving as an active member of the management team.
- Assisting the Heads of Department in monitoring all works performed in the Council to determine that reliable data are being generated in the Council.

- Assisting the Heads of Department in providing effective and efficient administration of the Council including budget planning and control with responsible financial management, in accordance with the Federal Government financial regulations
- Assisting the Heads of Department in Providing continuous professional development programs for the staff
- Assisting the Heads of Department in planning and performing research appropriate to the council.
- Assisting the Heads of Department in selecting and monitoring all medical laboratories for the quality of service in conjunction with the quality officer in the facilities
- Assisting the Heads of Department in Identifying and addressing complaints and corrective actions to satisfy stake holders' needs.
- Assisting the Heads of Department in advising on various developments and review of policies and programs of the MLSCN
- Assisting the Heads of Department in Planning, issuing orders or instructions, providing leadership, enforcing discipline, handling grievances, controlling outputs, maintaining work conditions and preserving records.
- Assisting the Heads of Department in implementing a safe working environment in compliance with good practice and applicable regulations.
- Assisting the Heads of Department in accountability for the implementation of the quality management system.
- Assisting the Heads of Department in coordinating the planning and implementation of training workshops and seminars.
- Assisting the Heads of Department in scheduling and organizing of management review meetings in consultation with the Registrar/CEO.
- Assisting the Heads of Department in compilation and distribution of performance reports for Management review
- To perform any other duties as assigned by the Heads of Department from time to time.

Supporting Documents
MLSCN/DR/2/1_Confidentiality and Conduct form
MLSCN/DR/2/2 _Protection of confidential information Procedure
MLSCN/DR/2/3_Activities That Diminish MLSCN Operational Integrity

MLSCN/DR/2/3_Ethical Code of Conduct
MLSCN/DR/2/4_Business Commercial Interests Disclosure form
MLSCN/DR/2/5-Records of Minutes
MLSCN/DR/2/6-Memoranda
MLSCN/DR/2/7_Communication log
MLSCN/DR/2/8_Conflict of interest
MLSCN/DR/2/9_Review of the general organization
MLSCN/DR/2/10_Procedures
MLSCN/DR/2/11_Meetings management procedure
MLSCN/DR/2/12_Internal board communication
MLSCN/DR/2/13_Ethics and conflict of interest
MLSCN/DR/2/14_Organization review
MLSCN/DR/2/15_Forms/Logs
MLSCN/DR/2/16_Meeting minutes
MLSCN/DR/2/17_Conflict of interest and ethics form

3.0. QSE: Documents and Records

3.1 Policy:

The Medical Laboratory Science Council of Nigeria establishes and maintains as part of its quality management system these documents:

- Quality Manual
- Standard Operating Procedures
- Forms and logs
- Guidelines, standards or regulations
- Check-lists, licenses, tags, transcripts etc.

3.2 Purpose

This policy ensures that documents and records are managed in a consistent manner and only current and approved documents are used by staff. All documents are managed according to ISO 15189 and ISO 17011 standards and also national laws or regulations.

3.3 Responsibility:

Management and staff of MLSCN all have a responsibility for the management and control of documents and records.

3.4 Documents and Records:

- MLSCN controls all documents in its QMS from the creation, distribution, printing, reviewing, revision and destruction.
- Handwritten amendments to documents are permitted only by those personnel authorized to do so. (MLSCN/DR/3/2_ Procedure for making changes to documents or records)
- All records are stored in a safe environment to avoid deterioration and confidentiality.
- All documents are uniquely identified according to title, revision, number of pages, and authority for use and source identification.
- MLSCN retains or archives documents according to the document retention time in this manual.
- All documents are reviewed and revised if necessary on an annual basis and if need arises by the Registrar/CEO or designee.
- All documents deemed obsolete are destroyed and documented. (added to retired Master Log)

3.5 Archiving

The Registrar/CEO is responsible for proper archiving of documents and records according to procedure MLSCN/DR/3/4.

MLSCN respects national laws concerning the retention time of all records.

3.6 Document Control:

Registrar/CEO or designees have ultimate responsibility for establishing and maintaining the document control system

3.7 Document Review and Revising:

There is bi-annual review for every document.

3.8 Review of Contract:

- All contracts are reviewed to ensure availability of competence and resources to provide services
- All records are maintained

- There is a contract review process

Supporting Documents:

MLSCN/DR/3/0	Procedure for identification and control of documents and records
MLSCN/DR/3/1	Procedure for the creation, review and approval of new documents
MLSCN/DR/3/2	Procedure for making changes to documents or records
MLSCN/DR/3/3	Procedure for periodic review of documents
MLSCN/DR/3/4	Procedure for archival, storage and retention of documents and records
MLSCN/DR/3/5	Procedure for Contract review process
MLSCN/DR/3/6	Procedure for creating, identifying, revising, reviewing and approving new documents
MLSCN/DR/3/7	Procedure for Document Control
MLSCN/DR/3/8	Form for Master Index for identifying documents
MLSCN/DR/3/9	Procedure Manual Minor Correction
MLSCN/DR/3/10	Master Documents file form
MLSCN/DR/3/11	Master index Number
MLSCN/DR/3/12	Document Retention Schedule
MLSCN/DR/3/13	Document change request form
MLSCN/DR/3/14	Manual Minor Correction form
MLSCN/DR/3/15	Standard Operating Procedure template
MLSCN/DR/3/16	Retired Master Log

QSE: 4.0 Purchasing and Inventory

4.1 Policy:

The MLSCN follows procurement policies and processes in purchasing office equipment, consumables and supplies. The mechanism for purchases is established by the procurement regulations according to the Bureau of Public Procurement (BPP) Act.

4.2 Responsibility:

The procurement unit in conjunction with the tenders board establishes selection of qualifying suppliers, approved vendor listing, and contract reviews.

4.3 Identification of Needs:

The Head of unit, with input from staff, identify and document needs prior to purchase.

4.4 Acquisition:

The Registrar/CEO and Heads of department participate in the capital office equipment purchasing process.

4.5 Purchasing:

The MLSCN follows the established purchasing process for the selection and use of external services, equipment, consumables and supplies that affect the quality of service. National regulations are followed.

4.6 Receipt of Supplies:

The MLSCN receiver performs an inspection of all received supplies. Those that meet the inspection criteria are placed in the storage areas, while those that failed are rejected and returned to the supplier.

4.7 Storage:

All items are stored according to the manufacturer's recommendations and all storage facilities are monitored for temperature to ensure that temperature will not affect the stored items.

4.8 Inventory Management:

The MLSCN has procurement officers who act as a liaison between the Council and the suppliers/vendors to ensure efficient delivery of office equipment and supplies.

4.9 Advisory Service:

The tenders' board evaluates suppliers of office equipment and consumables, and maintains records of these evaluations and list of those approved.

Supporting Documents:

MLSCN/DR/4/0	Procedure for External services and supplies procedure
MLSCN/DR/4/1	Procedure for Inventory Control Procedure
MLSCN/DR/4/2	Form for Supplies Quality Control form
MLSCN/DR/4/3	Inventory Control form
MLSCN/DR/4/4	Receiving and Inspection checklist
MLSCN/DR/4/5	Reagent Daily Monitoring Log
MLSCN/DR/4/6	List of providers
MLSCN/DR/4/7	List of referral laboratories
MLSCN/DR/4/8	Stock log
MLSCN/DR/4/9	Inventory log

5.0. QSE: Non-conforming Event Management

5.1 Policy

The policy of non-conforming event management includes nonconforming cases detection, identification, classification, documentation, investigation (analysis), solving the problem and reporting. The occurrences

are classified as either internal or external and appropriate corrective actions are planned and implemented for removing the root cause of the problem.

MLSCN have procedures for documentation and reporting of any problem emerging in and outside the Council, or issues that may interfere with the delivery of quality service in our certified laboratories. Such problems can be identified through any of the following means:

- practitioner complaints
- stake holders complaints
- non-conforming external quality assessment results
- nonconforming reagents, equipment or consumables
- staff comments
- findings from internal or external audits
- management reviews

All event records are collected and analyzed during Management Reviews.

All events are addressed within a period not exceeding 30 days.

5.2 Responsibilities

All MLSCN staff are responsible for recognizing and reporting non-conforming events which could have adverse implications for stake holders and employees.

The MLSCN departments are responsible for investigating occurrences, identifying and implementing appropriate corrective action. The departmental heads are responsible to fill out forms and enter occurrence information into the database. It is emphasized that all incidents are documented.

MLSCN staff reports the incident to their heads of unit. The Head of Departments review reports developed by unit heads and conducts an investigation of the non-conforming event, implements corrective action if required and develops a final report. The Quality Management Team (QMT) in

conjunction with the Registrar/CEO is responsible for periodic review of the Quality Management System, compiling statistics, and trending to monitor the effectiveness of corrective action and the Quality Management System.

5.3 Identification of Non-conformities

The MLSCN has established a standardized mechanism for the Council's internal and external non-conforming event management processes which includes the following activities:

- nonconforming events detection and notification
- documentation of each episode of nonconformity
- recall of nonconforming correspondences
- immediate remedial action
- definition of further corrective actions to be taken
- designation of personnel responsible for resolving the problem

5.4 Corrective Action

The MLSCN management allows quick and regular identification of non-conformities and facilitates the implementation of Corrective Actions by using MLSCN/DR/5/0_Corrective Action procedure when non conformities are noted. Root cause analysis shall be conducted for every non-conformance noted before corrective action is implemented. Corrective action (s) selected to eliminate the root cause of the non-conformance shall be appropriate to the magnitude of the problem and commensurate with possible risks.

Whenever changes are to be made as a result of corrective actions, the changes are documented and communicated to the affected members of staff. The results of corrective action taken shall be monitored, in order to ensure that they have been effective in overcoming the identified problem(s). The result of corrective actions shall be forwarded to management review meeting.

Supporting documents:

MLSCN/DR/5/0 Corrective Action Procedure
MLSCN/DR/5/1 Corrective action records

5.5 Preventive Action

The MLSCN shall take action to prevent non-conformance which shall be identified from potential sources, whether technical or affecting quality management system. When a potential non-conformance is identified, the organization shall follow the Preventive action procedure to come up with the preventive action plan. The preventive action implementation shall be monitored to verify that the needed improvements have been realized and effective in reducing the likelihood of the occurrence of nonconformance.

The Council shall utilize information derived from Quality Indicator data, surveys and any other source to take action to prevent nonconformance. The organization shall also utilize information about identified non-conformances by external assessment and quality audits to effect preventive action.

Preventive action shall include the use of data from external assessments, internal audit results, quality records and complaints to detect, analyze and eliminate potential causes of nonconformities.

Supporting Documents

MLSCN/DR/5/1 Preventive Action Procedure
MLSCN/DR/5/2 Preventive Action Plan

5.6 Continuous Improvement

MLSCN management continually improves its QMS in accordance with MLSCN/DR/5/22_Improvement procedure. All operational and technical procedures are reviewed annually. The quality system shall be reviewed for redundancies and inherent weaknesses especially in areas that have frequent nonconformance's or facility complaints, closer scrutiny or tighter control will be applied. Each unit implements quality indicators for the activities they perform.

Other means that contribute to the continual improvement of the QMS include but not limited to:

- Review of the preventive actions once every quarter.
- Systematic monitoring of quality indicators once every quarter including;
    - Customer Satisfaction Survey
    - MLSCN turnaround times
    - Percentage of sealed medical laboratories
    - Percentage of institutions failing accreditation
    - Percentage of students failing MLSCN conducted examination
    - Number of complaints received
    - EQA results/performance by participating medical laboratories

When opportunities for improvement are identified, MLSCN management shall address them accordingly regardless of where they occur. All members of staff are provided with an opportunity to attend planned educational and training courses to ensure the continuous improvement of the system.

Supporting Documents

MLSCN/DR/5/21 Improvement Procedure
MLSCN/DR/5/22 Quality Indicator records

5.7 Management Review

In accordance with Management Review procedure (MLSCN/DR/5/22), MLSCN management conducts a review of the Councils QMS and all the activities annually. The frequency of the reviews shall be increased depending on recommendations by the management review committee. The management review committee shall include and not limited to the Registrar/CEO, Heads of Departments and Quality Management Team. It is up to the Registrar/CEO discretion to invite relevant stakeholders for the management review meetings. The agenda for the management review is detailed in the management review procedure.

The ability of the QMS to meet the MLSCN objectives is evaluated and any changes or improvements that may be essential implemented. The quality and appropriateness of the Council contribution to public and stake holders needs shall be monitored and evaluated objectively. The results of the review shall be captured and incorporated into a plan that includes goals, objectives and action plans. Action plans shall be executed within an appropriate and agreed upon time. Results of the management review are communicated to all members of staff at least 2 weeks after the management review meeting.

Supporting Documents

MLSCN/DR/5/22 Management Review Procedure
MLSCN/DR/5/23 Management review Schedule

6.0. QSE: Human Resource:

6.1 Personnel Associated with MLSCN

6.1.1 General

The availability of sufficient, qualified, competent human resources forms the backbone of a credible accreditation service. The Council shall have sufficient number of competent personnel with requisite education, training, technical knowledge, skills and experience to effectively manage the type, volume and scope of activities offered.

6.1.2 MLSCN shall have access and maintain a pool of assessors, including lead assessors, technical experts, through Council stakeholders, internal technically qualified staff and contracted personnel that are conversant with current standards, for its accreditation activities.

6.2 Assessment Personnel

6.2.1 Responsibilities and procedures for the selection and contracting of assessment personnel will be as defined in MLSCN/DR/6/6.

6.2.2 Prospective assessors shall be selected on the basis of Council's need for assessors, qualifications, experience and competence in the relevant field of expertise.

6.2.3 Where feasible, Council shall certify/designate Lead Assessor(s) for accreditation programmes. Council may also use external MLSCN registered Lead Assessors.

6.2.4 Due to the nature of assessment, technical assessors and experts need to maintain competence within a given field. MLSCN will therefore not employ full time technical assessors/experts but will use Council registered, contracted external Technical Assessors / experts on a need-be basis.

6.2.5 Responsibilities and procedures for the training and qualifying of assessors will be as defined in MLSCN/DR/6/7_Requirements for MLSCN Assessors / Experts.

6.3 Responsibilities of the Assessment Team

6.3.1 MLSCN shall ensure that assessors are aware of their duties, responsibilities and authorities.

Table 6.1 describes the types of assessor and their function. Specific responsibilities and methods of conducting assessments will be defined in procedures listed below

Table 6.1

TYPES OF ASSESSORS	FUNCTION
Lead Assessor	• He/she is the leader of the assessment team. • Prepares the assessment plan; • Makes decisions relating to the conduct of the assessment; • Conducts assessment of the Management requirements; and • Coordinates and submits the final assessment pack. • May also act as a Technical Assessor provided he possesses the necessary technical competence in the required field assessed.
Technical Assessor	A team member, who conducts the assessment of the technical competence for specific area(s) of the desired scope of accreditation. These include: • Conducting the assessment of the Technical requirements and scope of activity using various methods as defined in MLSCN procedures. • Reports to the Lead Assessor.
Assessor	• Person assigned by an accreditation body to perform, alone or as part of an assessment team. • He/she performs assessment of a laboratory or conformity assessment. • Reports to the lead assessor.

Case Officer	• MLSCN personnel who provides advice on the policies, procedures and regulations of the Council. • May act as a lead assessor, technical assessor or technical expert, if he/she has the relevant assessor qualifications.

6.4 Personnel Records

6.4.1 MLSCN maintains personal records of relevant qualifications, training, experience and competence for all staff, contracted personnel and committee members associated with the Council. Records of training, experience and monitoring of each person involved in Council activities are kept up to date.

6.4.2 The MLSCN keeps up-to-date records on assessors, experts, committees, and other contracted personnel. The file contains the following; Name and address, position held and for external assessor and experts, the position held in their own organization, educational qualification and professional status, work experience, training in management systems, assessment and conformity assessment activities, competence for specific assessment tasks and experience in assessment and results of their regular monitoring.

6.5 Staff competency

Staff competencies cover technical, practical skills and general knowledge. Process for competency assessment after initial training and periodically thereafter, is established. Employees must successfully demonstrate competence in the skills and working knowledge for which they were trained. Competency assessment applies to all employees including probationary and confirmed employees.

Employees are encouraged to seek for opportunities to improve assigned tasks where appropriate.

6.6 Competency assessment

Competency assessment of each person to perform assigned duties occurs initially following training (within the probationary period of the employee) and annually thereafter at the time of annual performance review.

List of core competencies have been defined for each job description. The competency assessment carried out as detailed in procedure competency assessment.

6.7 Personnel Performance Appraisal:

The MLSCN management establishes, and maintains a process of periodically and objectively assessing individual performance. Each staff has an annual performance assessment with the approved Annual Performance Evaluation Report (APER) form rated by their immediate supervisors and counter signed by the heads of departments.

Propositions are made for staff's promotions taking into account objective criteria and indicating an order of priority if several staff are qualified. Trainings or continuous education are discussed with staff for performance and personnel promotion. The head of department documents an interview support for each staff.

6.8 Training:

Training and assessment of competence for all staff members take place at several levels including the following areas: quality management system, safety, and computer system and job tasks.

Training on new technical methods and procedures follows a documented plan for pre-analytic, analytic, and post-analytic aspects of testing including any relevant information systems procedures that must be performed for EQA and Public Health Laboratory.

The defined areas for training are documented as explained in procedure "Training" (MLSCN/DR/6/0).

The skills checklist is signed by both employee and supervisor at the completion of the training.

6.9 Continuous education:

The MLSCN supports and provides opportunities for continuous education and encourages employees to seek on their own as well as to advance their current skills. This fosters personnel growth, meets professional practice requirements and improves customer service.

***Supporting Documents*:**

MLSCN/DR/6/0	Orientation-Training–Performance assessment process
MLSCN/DR/6/1	Competency assessment process
MLSCN/DR/6/2	Continuing education process
MLSCN/DR/6/3	Personnel record maintenance process
MLSCN/DR/6/4	Orientation-Training-Performance procedure
MLSCN/DR/6/5	Competency assessment form
MLSCN/DR/6/6	Procedures for the selection and contracting of assessment personnel
MLSCN/DR/6/7	Requirements for MLSCN Assessors / Experts

6.10 Accommodation and environmental conditions

The MLSCN management shall ensure that there is adequate space to perform its work efficiently to ensure quality service delivery and safety of personnel. The Registrar/CEO shall provide enough resources to support quality service delivery and that the Council maintains a functional and conducive work climate. Access to the Council is controlled and limited to authorized personnel only through the use of identifications tags. All visitors require clearance from the security personnel to access the offices. All hazardous/biomedical waste is discarded into appropriate biohazard waste containers that are handled and disposed of in accordance with the MLSCN/DR/6/6_Safety practices procedure and in compliance with MLSCN Laboratory Safety Manual. All work surfaces shall be maintained in clean condition and records of daily cleaning and swabbing shall be recorded for the EQA and public health laboratories.

Supporting documents:

MLSCN/DR/6/6 Safety practices procedure
MLSCN/DR/6/7 Cleaning of laboratory environment procedure
MLSCN/DR/6/8 laboratory environment temperature chart
Laboratory safety manual

7.0. QSE Continual Improvement

7.1 Policy:

The MLSCN participates in quality improvement activities that contribute positively to outcomes for Council and laboratory services. It reviews periodically and maintains guidelines, validated processes and procedures to ensure quality services.

7.2 Purpose:

Opportunities for improvement are an ongoing process that is fundamental to the Quality Management System. Information is reviewed and appropriate action is taken to implement necessary action to improve processes and procedures.

7.3 Responsibility:

Everyone is responsible for continual improvement. Management is responsible to take an active role to advocate appropriate action to improve all practices in the Council. The Registrar/CEO and top management team take a lead role in reviewing and preparing reports from vital information collected that monitors activities for improvement. The staff has the responsibility to document or make suggestions for improvements without fear of retribution.

7.4 Sources of Information for Continuous Improvement:

A systematic review of QMS processes and respective documents is performed periodically to keep abreast of technologic changes.

Systemic review of laboratory processes to identify the process to be improved by applying a set of criteria derived from Quality Indicators as stated previously:

NOTE: Refer to QSEs: Non-Conforming Event, Customer Service and Satisfaction, Assessments: External and Internal

7.5 Evaluation of Effectiveness of Actions taken.

Appropriate action following the review of any non-conformance is submitted to Council management for review and implementation of any needed changes to the quality management system.

Corrective action is documented and evaluated for effectiveness with follow-up audits and reviews.

Supporting Documents

MLSCN/DR/7/0	Process for continual improvement
MLSCN/DR/7/1	Procedure to identify opportunity for improvement
MLSCN/DR/7/2	Quality indicator selection
MLSCN/DR/7/3	Opportunity for improvement form

8.0. QSE: Equipment

8.1 Policy:

MLSCN management ensures that the Council and its laboratories are committed to the selection, acquisition, validation, maintenance, replacement and disposal of obsolete equipment to provide quality service delivery

Note: This ISO standard considers instruments, reference materials, consumables, reagents and analytical systems as laboratory equipment.

8.2 Purpose:

The policy provides guidance for the purchase of office/laboratory equipment, installation and use according to the department's policies and procedures.

8.3 Responsibility:

Management ensures that the technical staff and other essential support service providers within the organization including purchasing, receiving, service engineers and maintenance staff are all given consideration in the selection and acquisition of equipment.

8.4 Equipment Qualification:

A program is established that defines the installation and use of new equipment that includes the vendor in the set-up which assures that its performance meets the specifications for relevant analysis.

The laboratory validates and verifies that the instrument functions according to established requirements by the manufacturer's instructions, operators' manuals or documentation. The elements addressed by this process are performance verification, function verification and instrument maintenance.

All pre-performance procedures and data are documented and submitted and reviewed by the Quality Officer for approval before the equipment can be utilized for testing for EQA and Public Health laboratories.

8.5 Equipment Inventory:

The laboratory maintains a master file that tracks the history of a given piece of equipment from selection to decommission.

Each item of equipment is uniquely labeled for identification purposes.

Records are maintained and readily available for the life span of the equipment or for any period required by national regulations.

8.6 Maintenance Program:

To ensure timely and preventative maintenance, a plan (according to manufacturer's instructions) exists that addresses:

- Schedules that specify frequency of performing maintenance
- Assignment of responsibilities
- Performing and recording maintenance activities
- Documenting routine service performed
- Recording non-routine service and repairs

All analytical instruments/equipment removed from direct control of the laboratory or undergo major service is validated before being permitted to be used for routine operations.

8.7 Equipment Use:

All equipment is used according to manufacturer's instructions and guidelines.

The laboratory prepares standard operating procedures for the operation of equipment according to manufacturer's instructions.

Training is provided to staff to ensure the proper operation of equipment.

Trained individuals perform and document all routine calibrations, maintenance and preventive service on equipment.

All laboratory equipment is regularly serviced, calibrated and tested for safety and efficiency.

Where calibrations result in a new set of correction factors, the laboratory ensures that copies of prior correction factors are updated.

All equipment is decontaminated (MLSCN/DR/8/5_Equipment decontamination procedure) before servicing, or retiring obsolete equipment.

All non-functioning equipment is appropriately identified to prevent its usage.

*issues concerning equipment are for the NEQAL and Public Health Laboratories

Supporting Documents:

MLSCN/DR/8/0	Procedure for selection, acquisition and purchasing of equipment
MLSCN/DR/8/1	Procedure for installation, operational and performance qualification
MLSCN/DR.8/2	Process for routine maintenance
MLSCN/DR/8/3	Procedure for decommission of equipment
MLSCN/DR/8/4	Procedure for troubleshooting, repair and service
MLSCN/DR/8/5	Procedure for equipment decontamination
MLSCN/DR/8/6	Procedure for selection and validation of new equipment.
MLSCN/DR/8/7	Procedure for the development and use of Master Index for identifying equipment.

MLSCN/DR/8/8	Procedure for repair or service of equipment
MLSCN/DR/8/9	Equipment Master file
MLSCN/DR/8/10	Preventative Maintenance forms
MLSCN/DR/11	Temperature charts
MLSCN/DR/12	Master Documents file form

9.0. QSE: Facilities and Safety:

9.1 Policy:

MLSCN is committed to provide and maintain a safe working environment which provides a safe, adequate and comfortable physical environment to ensure that the safety and health of employees and visitors are not compromised. The foundation of this policy is based on applicable laws, regulations and international laboratory safety standards.

9.2 Responsibility:

MLSCN Management is responsible for:

- Creating and maintaining a safe working environment
- Providing a clean and well lighted work space
- Providing sufficient space in configurations conducive to efficient handling of the workload
- Establishing a comprehensive Safety program
- Providing staff with the necessary Personal Protective Equipment (PPE)
- Ensuring all Council staff receive appropriate safety training.

MLSCN has a designated Safety Officer who is responsible to assess safety requirements, develop procedures, identify needs and assist in implementation. The NEQAL and Public Health Laboratories have a designated safety representative who is responsible to ensure that safety procedures and protocols are adhered to.

9.3 Policies and Procedures:

The Council documents policies and procedures to ensure the personnel safety as well as environmental safety in all facilities of MLSCN.

9.4 Health and Safety Policy and Safety Manual

The Council establishes procedures and guidelines in a Safety Manual which describes the policies and procedures relating to safety.

These procedures and guidelines are documented in the Council Safety Manual which is available and accessible in all the laboratories and departments. The Council Safety Manual is part of the controlled documents and is reviewed annually by all personnel.

9.5 Universal Precautions

Universal safety precaution posters are displayed in the Council and laboratories to remind staff of the basic personnel safety requirements.

9.6 Safety and First Aid Officers

The Council and laboratories have appointed safety representative. All staff members, through their safety representatives are involved in discussion concerning safety at work.

9.7 Safety committee(s**)**

A safety committee is nominated by the Registrar/CEO and those individuals are officially appointed. The members of the committee are responsible to oversee safety issues and attend scheduled Safety meetings.

9.8 Specific SOPs

Apart from the Safety Manual, various safety SOPs are available in each laboratory to describe decontamination of workbenches, staff hygiene, emergency response, handling of highly infectious and dangerous material, handling of safety equipment, etc.

9.9 Staff Health requirements

An accident / incident register is kept in the Council and each of the laboratories. All accidents / incidents must be recorded in this register, and appropriate documentation must be forwarded to the Safety Officer.

Safety risk assessments are conducted at least twice annually according to a plan developed and implemented by the Safety Officer.

9.10 Documentation

Specific staff safety issues are described in the Safety Policy, and the Safety Manual

The following records are kept by the -Safety Officer

- Records of Service of Safety Equipment
- Safety training record
- Incident / Accident reports
- Risk assessment reports
- Safety Inspection reports
- Analysis of accidents and preventive actions
- Fire emergency drill
- Minutes of safety meetings

9.11 Environment and Premises

MLSCN documents the minimum requirements for their testing laboratories. The lay-out and use of different areas is shown in the floor plan

MLSCN monitors environmental conditions to assure that test performance and equipment will not be negatively influenced

9.12 Access Control

MLSCN documents and controls access to the laboratories

9.13 Cleaning of the offices and laboratories

The offices and laboratories are cleaned by cleaning personnel according to documented procedures.

9.14 Waste Disposal

A procedure is in place for waste disposal

9.15 Documentation

General procedures and specific safety issues relating to infection control and hygiene of the environment are documented in the "Safety Manual" and relevant SOPs in the various departments and laboratories.

Supporting Documents:

MLSCN/DR/9/0 Facility Maintenance Procedure

MLSCN/DR/9/1 Waste Disposal Procedure

MLSCN/DR/9/2 Safety Incident Reporting Procedure

MLSCN/DR/9/3 Unsafe condition Follow-up Procedure

Documents

Safety Manual

Post Exposure Prophylaxis

Safety Training Plan

Logs/Forms

Safety Training Record

Evacuation/Fire Drill Record

Physical Facilities -General Outline

Safety Incident Reporting Form

Safety Audit Checklist

Floor plans

10.0. QSE: ACCREDITATION ACTIVITY:

10.1 Purpose and Scope

The purpose of this document is to provide the necessary information on the MLSCN accreditation and assessment process to enable applicants to apply for accreditation. This document should be read in conjunction with the field specific procedures on the accreditation process prior to submitting a formal application for accreditation.

10.2 Accreditation

MLSCN accreditation is the official recognition that a facility is competent to perform specifically defined functions and also has a documented Management System in place to facilitate this process. An accredited facility will have demonstrated through formal assessment that it is competent to perform the defined functions and that it satisfies

both national and international criteria in this respect. The requirements that have to be complied with for the various facilities are given in the MLSCN documents relevant to the field of accreditation.

Compliance monitoring is a regular inspection of test facilities by a Monitoring Authority (MLSCN) in order to evaluate the degree of conformity with ISO 15189 standards for Medical Laboratories to determine the integrity of data, and assure that resulting data are of adequate quality for assessment and decision making by Regulatory Authorities.
Note: All ISO/IEC and National documents and standards are only available from SON Standards.

10.3 Schedule of Accreditation

Every ISO 15189 accredited facility is issued with a certificate and schedule of accreditation detailing the scope of activities and functions for which accreditation is granted. This schedule will state each and every function accredited and the extent of the accreditation. The schedule will only contain/list those functions, which satisfy all the necessary accreditation requirements for the specific function. An accreditation schedule may refer to a single function or to any number of functions provided that all such functions satisfy the requirements.

Applicants are requested to complete a draft accreditation schedule as part of the application process. If any problem is experienced the applicant should contact the MLSCN office for further guidance. The schedule of accreditation will only be finalized after the initial assessment. Applicants who use the option of having a pre-assessment visit should discuss the schedule of accreditation with the assessor/inspector and try to finalise it as far as possible prior to the initial assessment/inspection.

No facility is permitted to use the MLSCN accreditation symbol until they have received written confirmation from MLSCN that they have been accredited.

An accredited organisation should consult MLSCN document on "Conditions for use of the Accreditation Symbol, prior to preparing any organisational material, which makes any reference to accreditation or the accreditation symbol.

10.4 General Application Information

The accreditation process and approximate time-lines are described in MLSCN Guide to Medical Laboratory Continuous Quality Improvement. All applications are processed internally in accordance with MLSCN procedures. Enquiries for application handled by the relevant officer, who will provide the potential applicant with the following documents:

- Programme specific application form;
- General Information on the Accreditation Process;
- Programme specific procedures, and standard of accreditation;
- Any additional Requirements, Technical or Technical Guidance applicable to the

application;

- Program specific forms / checklists to be completed and submitted to MLSCN together with the facility's Quality Manual; and
- The MLSCN Fees document.

Alternatively, the documents listed above are available on the MLSCN website at www.mlscn.gov.ng

10.5 Scopes of Accreditation as Offered by MLSCN

The Table below lists the programs and the applicable standards to which MLSCN offers accreditation. Accreditation is voluntary while inspection is regulatory, where the latter is required as part of the approval process.

Scopes of Accreditation & (MLSCN Document)	*Accreditation Standard/ Scheme*	*Voluntary or Regulatory Domain*	*Covered by:*	*Validity of Certificate of Accreditation*	*Accreditation is granted for:*
Medical Laboratories (P04)	ISO 15189	Voluntary	MRA	3 years	Tests performed on human biological

10.6 Application Information

10.6.1 A brief outline of the accreditation process and documents needed:

a) The facility writes and implements a management system based on the applicable standard. MLSCN Documentation and Policy Manual are available on the MLSCN website www.mlscn.gov.ng

b) The facility submits the relevant application form, and submits it together with their Quality Manual and required information and documentation.

- ***Note 1:*** Facilities are advised to read the relevant MLSCN documents for their scope of application prior to completing and submitting the MLSCN application form.
- ***Note 2:*** The applicant performs a self-assessment / internal audit by completing the applicable checklist(s) in detail, indicating references to where the requirements are addressed in the facilities' Quality Manual, to verify compliance with all the applicable requirements i.e. Regulatory, ISO 15189 standard and any additional MLSCN requirements.
- ***Note 3:*** Each field specific "Application Form" includes a list of requirements for application.

MLSCN documents and forms for completion can be accessed on the MLSCN website under accreditation, and may be submitted to MLSCN electronically (email addresses are available on the relevant application forms). Alternatively, the application and accompanying documentation may be marked for the ***ATTENTION: Director Laboratory Accreditation and Regulation*** and posted, couriered or delivered to:

Postal Address	***Courier / Physical Address***
MLSCN P.M.B. 771, Garki, Abuja	Medical Laboratory Science Council of Nigeria Plot 1166, Mohammed N. Umar Lane Durumi Phase 11 Garki, Abuja
MLSCN Telephone:	**(+234)806662043; 8086662349.**

c) MLSCN will review the application against the scope of accreditation applied for and clarify all outstanding issues with the applicant before proceeding to the next step.

***Note*:** Failure to complete and submit the required supporting documentation may result in a delay in processing the application.

d) An Accreditation Agreement will be given to the applicant, which must be signed and submitted back to MLSCN.

e) MLSCN quotes and invoices the facility for the application fee as per MLSCN Fees documents.

f) MLSCN lead assessor / inspector is appointed, and on acceptance of the Lead Assessor by the facility, is given one month (from the date of receipt of the *completed* application) to evaluate the Quality Manual and, upon receipt of payment and the signed Accreditation Agreement, submits a report to the facility via the MLSCN office.

g) The facility corrects any deficiencies noted in the document review report and the programme specific checklists and submits these to MLSCN.

h) A Pre-assessment/Counselling visit is available at the request of the facility or may be required after review of the documents. This is at the cost of the facility.

i) Once the Quality Manual is acceptable, the relevant officer prepares a quote and the facility is invoiced for the pre-assessment / initial assessment / inspection. On receipt of payment, an assessment / inspection date is arranged. The facility must ensure that there are sufficient records to confirm the system is implemented prior to the assessment / inspection visit. MLSCN requires that a complete internal audit and management review be conducted prior to the assessment / inspection visit.

Note: *An application that has not proceeded to the initial assessment stage within 1 year from the date of application will lapse. Unless otherwise agreed with MLSCN, this may result in the laboratory having to re-apply for accreditation. All application fees will be applied for the re-application.*

j) The pre-assessment is a site visit by the lead assessor, whereas the initial assessment /inspection is a site visit by the lead and technical assessor(s) / inspector(s). These person/s names are made known to the facility prior to the planned visit.

k) Once non-conformance(s) recorded at the assessment / inspection are cleared, the assessment documentation is subjected to the Independent Advisory Committee, who determines whether accreditation can be granted for applicants in the voluntary domain.

10.7 The MLSCN Application Form and Requirements

The application form requires very comprehensive information on the applicant's organisation. This information is necessary to allow MLSCN to judge the extent that the organisation's documented Quality System satisfies the MLSCN Accreditation requirements. The applicant is required to complete all sections of the application form.

An organisation may submit to MLSCN a completed application form for the sole purpose of obtaining a detailed quotation. However, the application will not be processed further than the quotation stage without the submission of the organisation’s quality manual and application fee.

Refer to Appendix xxx for an estimate of the time required to process an application. Please note that times are approximate only and although MLSCN makes every effort to complete the various stages of the application within these times it is sometimes not possible. MLSCN will keep the applicant informed of any delays to any stage of the application process.

10.7.1 Application for Accreditation of Blood Transfusion Services

The following documents are required together with the application form:

- Copy of the Quality Manual (policies) and completed MLSCN forms and indicating where in the quality manual the requirements have been met;
- Appropriate application fee *;*

- Completed all relevant parts of application form;
- Completed "Application for Approval of Personnel";
- Copy of the relevant, authorised test method(s), i.e. : Procedures, Work Instructions, etc;
- Information regarding active participation in a proficiency testing scheme, where available;
- Procedure for validation of methods, an example of validation data.

10.7.2 Application for Accreditation of Medical Laboratories

The following documents are required together with the application form:

- Copy of the Quality Manual and completed MLSCN relevant form indicating where in the quality manual the requirements have been met.

(for ISO 15189 Medical Laboratories)

Appropriate Application Fee *(amount)*

- Completed all relevant parts of application form
- Information regarding active participation in a proficiency testing scheme, where available
- Procedure for validation of methods, an example of validation data

10.7.3 Application for Extension of Accreditation

Application for Extension of Accreditation applies to facilities which:

- Have already been accredited, where the facility wishes to extend the accredited scope of tests / inspections / certifications within the existing accredited field.
- Where an already accredited facility wishes to apply for accreditation in a new field altogether, but under the same management system.
- The facility completes the relevant application form and submits to the relevant officer at least **6 weeks** before the next scheduled assessment.
- Where possible, assessment or witnessing of extensions for accreditation will be carried out at the next surveillance or reassessment visit, but when requested by the facility, additional visits will be arranged. Annual fees may need to be revised.
- In this case a review of the quality manual does not need to be conducted.
- A quote is done and the facility is invoiced for the surveillance or re-assessment, including the extension where necessary. On receipt of payment, an assessment date is arranged. The facility must ensure that there are sufficient records for the extension to confirm the system is implemented prior to the assessment visit.
- The assessment is conducted on site visit by the lead and technical assessor/s. These person/s names are made known to the facility prior to the planned visit.
- Once all non-conformances recorded at the assessment are cleared, the

Independent Advisory Committee may grant accreditation, based on recommendations given in the report by the assessment Team.

10.8 Confidentiality

All information submitted to MLSCN in support of the application form shall be treated in confidence. All assessors used by MLSCN are required to sign the MLSCN Assessor Contract, as well as confidentiality agreements at each assessment performed. Any breach of confidentiality is treated extremely seriously. MLSCN will request written permission from all accredited facilities or applicants prior to releasing any information to a third party. MLSCN may be required to release confidential information in compliance with the law.

10.9 Time-scale for the Accreditation Process

MLSCN makes every effort to ensure that all applications are processed as efficiently as possible. The time taken to process an application depends on a number of factors, some of which are outside the control of MLSCN. The timing is dependent on:

- The quality of the applicant's documentation and the extent to which it complies with MLSCN and accreditation requirements. A delay can occur due to insufficient documented procedures and submission of inadequate Quality Manuals;
- The availability of suitable assessors;
- How efficiently the applicant organisation clears the non-conformances after the initial assessment;
- The availability of the resources within MLSCN.

Generally, accreditation takes place between 3 - 6 months from receipt of the application form with a good Quality Manual supplied, to the initial assessment.

10.11 SUBCONTRACTING THE ASSESSMENT

MLSCN as a matter of policy will not subcontract any of its accreditation activities because of issues of confidentiality and conflict of interest. Council will retain its full responsibility for granting, maintaining, extending, reducing, suspending or withdrawal of accreditation.

11.0. QSE: Process Management

11.1 Policy

MLSCN develops, designs, reviews and validates all of its processes to assure that they fulfill regulatory standards, customer requirements and organizational needs. The Council ensures that all developed processes in the implementation of its mandate are monitored for efficiency and effectiveness. This also includes internal and external quality assurance programs and

accreditation process to review MLSCN activities and laboratory performances, detect non-conformities and take corrective actions in the NEQAL and Public Health Laboratories.

11.2 Purpose**:**

Process control involves an active review of control records, test results and the use of other tools to detect system errors and correct them by improving the process.

11.3 Responsibility:

Management and staff all develop and monitor the processes for all twelve Quality System Essentials. The process flowcharts or tables are supported by procedures that have been developed and reviewed by all staff in the organization. Everyone is responsible for the development and the maintenance of the quality management system which is the essence of process control.

11.4 Developing Flowcharts/Tables:

The MLSCN identifies current or modified processes for design and modifications to ensure they fulfill the desired expectation or requirement.

Process flow charts are utilized to analyze or identify areas that may result in miscommunication or quality failures or inefficiencies.

11.5 Process Validation/Verification:

This applies to equipment, instruments, analytical systems, methods and reagents to be sure that the process works as intended before actual use.

11.6 Tools used to monitor processes:

11.6.1 Quality control:

MLSCN has a quality control program to verify its activities and test method performance in the laboratory. Quality control detects variations, errors and trends. Corrective measures and troubleshooting mechanisms are established.

11.6.2 EQA/PT

Participation in these programs provides an assessment of how well the NEQAL & Public Health laboratory is performing compared to its peers. It provides opportunity for improvement and means to review the process.

11.6.3 Quality Indicators:

Provide staff and management a means to monitor certain activities in the Council and laboratory for efficiency and effectiveness.

11.6.4 Statistical Tools:

Charts, graphs or Levy Jennings which can be utilized to review trends etc.

Changing and established process: refer to QSE: Process Improvement

Supporting Documents:

MLSCN/DR/11/0	Method validation
MLSCN/DR/11/1	Quality control
MLSCN/DR/11/2	Reporting
MLSCN/DR/11/3	Results validation
MLSCN/DR/11/4	Results reporting

Forms/Logs

MLSCN/DR/11/5	Quality control logs
MLSCN/DR/11/6	Validation reports
MLSCN/DR/11/7	Annual review of Quality Manual

12.0. QSE: Information Management:

12.1 Policy

MLSCN addresses the managing of information generated between Council and its laboratories. Security of accessing data information and the integrity of data transferred is managed in compliance with national guidelines.

12.2 Purpose:

This policy addresses processes and procedures for the management of MLSCN information to assure that confidentiality of the information is not breached.

12.3 Focus of Information Management System:

MLSCN information system is electronic and paper based and information can be disseminated verbally, e-mail or mail

12.4 External Communication:

Communication with external facilities is in the form of but not limited to electronic mail, telephones and meetings. MLSCN staff are authorized to offer telephone consultations on technical matters within the scope of their responsibilities to external facilities. Records of all communications are documented.

12.5 Computer Access and Security

MLSCN establishes and documents processes and procedures for:

- identifying appropriate levels of computer access
- assigning passwords and changing them at regular intervals
- changing data and updating information
- maintaining confidentiality

12.6 Data Integrity:

The MLSCN verifies the accuracy of information before its release.

Supporting Documents:

MLSCN/DR/12/0 Develop procedure to maintain privacy and confidentiality

MLSCN/DR/12/1 Develop procedure for transporting or transmitting of current documents

13.0 QSE: Customer Focus:

13.1 Policy

MLSCN management is dedicated to providing quality and timely service to all customers, both internal and external. The Council management commits to providing adequate resources to meet customers' requirements and to provide an on-going program for continual improvement.

13.2 Customers satisfaction measurement

Customer surveys are implemented. The objective is to assess the satisfaction of the stakeholders

The analysis of the results of this survey leads to the implementation of corrective actions where needed.

13.3 Facility management

Complaints are managed in order to lead to corrective or preventive actions (also refer to continual improvement chapter 12 and managing non-conforming events chapter 11).

The objective is to ensure continuous improvement of the quality system by taking into account the stakeholders concerns. The facility management will help tracking and investigating potential non-satisfaction of stakeholders

See 11. Non-conforming event management, 12.continual improvement

Supporting Documents:

MLSCN/DR/13/0 Customer survey

MLSCN/DR/13/1 Customer complaint

Forms/Logs

MLSCN/DR/13/2 Customer survey

MLSCN/DR/13/3 Incident report

Appendix A. Amendment Sheet

AMMENDMENT SHEET

Proposed by	**Section**	**Summary of Changes**

Appendix B. Staff Signatures

I have read, understood and agree to follow the manual as documented:

No	Name	Signature	Date