MEDICAL LABORATORY SCIENCE COUNCIL OF NIGERIA

MLSCN GUIDE TO MEDICAL LABORATORY CONTINUOUS QUALITY IMPROVEMENT AND ACCREDITATION.

DECEMBER 2012

FOREWORD

The National Guideline for setting up Medical laboratories in Nigeria is a manual meant to serve as a guide that will appropriately enlighten potential laboratory owners on what they need to have in place to enable them set up a standard medical laboratory.

Prior to this time, there was no standard or specification for setting up medical laboratories at whatever level, whether primary, secondary or tertiary. This manual therefore sets out to fill in the existing gaps. It consists of details that should be in place starting from the space, the siting, the design, ceiling, floor, bench tops, furniture, essential equipment and even personnel.

With these, this manual is recommended as a necessary document that must be read by all potential medical laboratory owners whether private or government.

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.

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1.0 Introduction

1.1 Background

Laboratory services are an essential component in disease diagnosis and treatment.

Nigeria is in the process of reforming her health sector; the laboratory services being amongst the frontline of healthcare delivery. The need to improve on the broken-down infrastructure and poor services cannot be over emphasized. Nigeria needs to strengthen laboratory capacity for the purposes of effective health systems and sustainability.

Accreditation is an important milestone in the path of continuous quality improvement and has proved to be a useful tool in strengthening laboratory quality systems. Laboratory infrastructure and test quality for all types of clinical laboratories remain weak in Nigeria. MLSCN has commenced implementation of the laboratory accreditation standards and checklists as part of the Nigerian National Health Laboratory Accreditation Program. This program has been designed to offer gradual process of improvement on the quality management system of laboratories in Nigeria.

1.2 Procedure for Development

This manual has been developed following series of consultations, synthesis of evidence, suggestions, recommendations and contributions from a cross section of stakeholders across Nigeria bringing to bear current/ acceptable international standards while forecasting into the future as regards Medical Laboratory practice in Nigeria with an assessment of human resources, procedures and practices in both public and private sector, all with the aim of ensuring that the manual reflects the hopes and aspirations of all.

A technical working committee was constituted by MLSCN and included members from the academia, professional members, international development partners, and non-governmental organizations (NGOs). to develop this manual.

1.3 Strategic Objectives

This document is to serve as a user guide for:

a) Mentoring medical laboratories to establish quality management system, achieve and maintain Continuous Quality Improvement (CQI)

b) Mentoring medical laboratories to achieve maintain and improve accreditation.

This guide has been developed to help facilities offering medical and veterinary laboratory services in the following areas:

a) Achieve immediate measurable laboratory improvement using the MLSCN Continuous Quality Improvement (CQI) programme as it relates to patient care

b) Build confidence to seek certification/ accreditation

c) Improve on the level of accreditation already achieved and

d) Maintain as well as improve on their status

This document will give the medical laboratories options for Continuous Quality Improvement and /or accreditation in chosen areas of strength, interest or specialty with opportunity for understanding processes to improve on already existing accreditation.

2.0 CONTINUOUS QUALITY IMPROVEMENT (CQI)

2.1 Definition: CQI can be defined as 'a comprehensive management philosophy that focuses on continuous improvement by applying scientific methods to gain knowledge and control over variation in work processes' (Tindill and Stewart, 1993).

In the laboratory CQI is the management of organizational processes that emphasizes meeting (and exceeding) client needs and expectations, use of scientific methods to continually improve work processes, and the empowerment of all laboratory staff to engage in continuous improvement of their work processes.

ISO 15189 describes CQI as a set of activities for achieving continual improvement in the laboratory, which includes:

- identifying potential sources of system weakness or error;
- developing plans to implement improvement;
- implementing the plans;
- reviewing the effectiveness of the action through the process of focused review and audit;

- adjusting the action plan and modifying the system in accordance with the review and audit report..

2.2 STEPS TO CONTINUOUS QUALITY IIMPROVEMENT

2.2.1 Scope for CQI: This encompasses all the processes and procedures involved in laboratory operations.

2.2.2 Components of MLSCN CQI Program

- Assessment(s)
- Mentoring
- Training
- Site visits
- Improvement Projects

The CQI process last a period of Eighteen (18) months and can be repeated depending on the gaps and non-conformities noted. New subjection 2.2.3 Application Requirement:

The facility is expected to fulfill all registration requirements with the Medical Laboratory Science Council of Nigeria. This includes:

- Corporate Affairs Commission business registration certificate
- Current practicing licenses of all employed Medical Laboratory Scientists, and registration certificates of all Medical Laboratory Technicians and Assistants
- Partnership agreement between the Proprietor and Medical Laboratory Scientist in-charge (if the proprietor is not a Medical Laboratory Scientist).
- Registration fee as applicable
- Completion of the application for registration and external quality assurance programme forms.
- Copies of floor plan, organizational chart as well as quality and safety manuals.
- Description of the services the laboratory undertakes and for which it seeks CQI;
- Relevant documents indicating the test procedures, methods, standard operating procedures
- Participatory information in external proficiency testing.

The facility is also expected to be familiar with the requirements of Nigerian National Standards for Medical Laboratories (ISO15189:2012E) Medical Laboratory – Particular Requirements for Quality and Competence;

2.2.4 Fees for various activities:

The Medical Laboratory facility is expected to apply in writing for CQI. On receiving the request for CQI from a facility by the Laboratory Accreditation Unit of the Council, a letter is sent to the facility acknowledging the receipt of such request. This letter also explains the step by step breakdown of fees and explanation of what each process fee is for as follows:

- Application fee: paid after approval for application has been granted.
- Documentation review fee: paid on submission of the relevant documents for the scope of CQI.
- Pre-assessment fee: paid by facilities applying for the first time
- This is to enable the assessment plan to be drawn up before the main assessment New bullet Assessor fee: paid for each assessor unit for duration of two (2) days which consists of: a team lead, a technical assessor/expert and the team secretary. This fee is for daily subsistence allowance.
- Additional assessor (per day) fee: paid in cases where the help of an additional assessor is required such as complex or wide systems and speciality areas.
- CQI Program fee: paid pre enrolment..

NB:

These fees may be reviewed as need arises.

2.2.5 Assessment team:

CQI assessment team consists of at least: team lead (lead assessor), a technical assessor/expert and the team secretary. Additional assessors maybe added depending on the size and complexity of the laboratory.

The members of the assessment team must be

- individuals trained on the Medical Laboratory Science Council of Nigeria National Laboratory Audit (MLSCN NLA) checklist and
- have technical knowledge to cover the desired scope ,
- knowledge in applying ISO 15189
- possess good communications and interpersonal skills to competently perform an assessment
- must also have background knowledge in good medical laboratory practice.

2.2.6 Assessment:

The stages of CQI assessment include the following:

a) Baseline Assessment:

This is an exercise required to give an overview of the facility and general preparedness of the laboratory for CQI. Members of the assessment team will formally be communicated to the laboratory for acceptance or rejection in cases of conflicts of interest.

b) Requisite Mentoring Program :

At the end of the baseline assessment, the team lead is required to develop an action plan detailing areas to be addressed and the different laboratory personnel requiring training. The report of the baseline assessment is forwarded to the Continuous Quality Improvement (CQI) /Mentoring Unit of the Council for enrollment into requisite mentoring on the deficient areas of the medical laboratory for a period based on the needs for each laboratory. The mentoring process is also offered based on needs of the laboratory.

c) Follow up assessment:

This will be carried out after the mentoring period to assess the extent of implementation of recommendations from baseline assessment, and to monitor improvement projects assigned during the mentoring period.

d) Assessment procedure :

This exercise is preceded by a courtesy visit to the management of the Medical Laboratory facility. The team shall examine all aspects of the implementation of the Quality System Essentials and documentation in the organization to verify that it meets the requirements of the standards and demonstrates competence.

The assessors shall record all details of observations and findings and this shall be acknowledged by the assessors by appending a signature. The assessment team shall summarize all their findings during their review meeting and making reference to relevant clauses of the standard, quality manuals and other supporting documents and regulations. The team lead shall ensure that the organization fully and clearly understands the non-conformities noted during debriefing as well as ensure that they are discussed with the representatives of the laboratory's management.

e) Communication of Assessment Report:
The written report shall be compiled indicating areas that require corrective action and submitted to the Council not later than one week after the assessment. This report must contain comments on competency and conformity of the laboratory as well as non-conformities and observations which must be addressed by the laboratory. The Council forwards the edited soft and hard copies to the management of the laboratory facility for further implementation. The Council will continue monitoring of the laboratory and reports will be submitted at intervals.

f) Training :
A minimum of three trainings will be conducted during the period of CQI program. Further trainings could be provided as needed.

g) Improvement projects:
These will be assigned after every training based on identified non conformities.

h) End of CQI assessment:
This will be performed at the end of the CQI Program and report forwarded to the Medical Laboratory facility. The Laboratory may wish to apply for National Accreditation by MLSCN depending on the outcome of the end of CQI assessment.

3.0 MEDICAL LABORATORY ACCREDITATION

3.1 Definition: Accreditation is a procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks ISO/IEC Guide 2:1991

3.2 Scope for Laboratory Accreditation:
The scope of accreditation has been tailored to meet the needs of each laboratory and they include the following;

* Number of Laboratory units/specialties e.g Heamatology, Microbiology, Chemical pathology, Parasitology, Immunology, Histopathology
* Group of services/level of tests e.g
* The entire laboratory services e.g

STEPS TO MEDICAL LABORATORY ACCREDITATION

3.2 Application Requirement:
The facility is expected to fulfill all registration requirements with the Medical Laboratory Science Council of Nigeria. This includes:

* Corporate Affairs Commission business registration certificate
* Current practicing licenses of all employed Medical Laboratory Scientists, and registration certificates of all Medical Laboratory Technicians and Assistants
*. Partnership agreement between the Proprietor and Medical Laboratory Scientist in-charge (if the proprietor is not a Medical Laboratory Scientist).
* Registration fee as applicable
* Completion of the application for registration and external quality assurance programme forms
* Copies of floor plan, organizational chart as well as quality and safety manuals.
* Description of the services the laboratory undertakes and for which it seeks accreditation;
* Relevant documents indicating the test procedures, methods, standard operating procedures
* Participatory information in external proficiency testing.

The facility is also expected to be familiar with the requirements of Nigerian National Standards for Medical Laboratories (ISO15189:2012E) Medical Laboratory – Particular Requirements for Quality and Competence;

3.3 Fees for various activities:
The Medical Laboratory facility is expected to apply in writing for accreditation. On receiving the request for accreditation from a facility by the Laboratory Accreditation Unit of the Council, a letter is sent to the facility acknowledging the receipt of such request. This letter also explains the step by step breakdown of fees and explanation of what each process fee is for as follows:

* Application fee: paid after approval for application has been granted.
* Documentation review fee: paid on submission of the relevant documents for the scope of accreditation the laboratory is applying for.
* Pre-assessment fee: paid by facilities applying for the first time.

This is to enable the assessment plan to be drawn up before the main assessment (this must be a day's activity).

* Scope extension fee: paid by a facility seeking accreditation on extension of the scope available.
* Assessor fee: paid for each assessor unit for duration of two (2) days which consists of: a team lead, a technical assessor/expert and the team secretary. This fee is for daily subsistence allowance.
* Additional assessor (per day) fee: paid in cases where the help of an additional assessor is required such as complex or wide systems eg??. (This should have been taken into consideration during the pre-assessment plan)
* Annual audit fee: this is paid once a year for every year in accreditation. For laboratories under suspension??, annual accreditation fee will continue to be paid. But laboratories on withdrawal status regardless of whether voluntary or forced will be charged at pro-rata basis considering the time of withdrawal. (This is very stringent and might discourage laboratories from applying for accreditation).
* Accreditation renewal fee: this is paid prior to renewal of current accreditation.

NB:
These fees may be reviewed as need arises.

3.4 Assessment team:

Accreditation assessment team consists of at least: team lead (lead assessor), a technical assessor/expert and the team secretary. Additional assessors maybe added depending on the size and complexity of the laboratory.

The members of the assessment team must be

* individuals trained on the Medical Laboratory Science Council of Nigeria National Laboratory Audit (MLSCN NLA) checklist and
* have technical knowledge to cover the desired scope of accreditation,
* knowledge in applying ISO 15189
* possess good communications and interpersonal skills to competently perform an accreditation assessment
* must also have background knowledge in good medical laboratory practice.

3.5 Assessment:

The stages of accreditation assessment include the following:

3.5.1 Baseline Audit:

This is an exercise required to give an overview of the facility and general preparedness of the laboratory for accreditation. Members of the assessment team will formally be communicated to the laboratory for acceptance or rejection in cases of conflicts of interest.

At the end of the baseline assessment, the team lead is required to develop an action plan detailing areas to be addressed. The report of the baseline assessment is forwarded to the facility for corrective action implementation.

3.5.2 Accreditation Audit:

This will be carried out to assess the extent of correction regarding non conformities previously identified.

3.5.3 Assessment procedure:

This exercise is preceded by a courtesy visit to the management of the Medical Laboratory facility. The team shall examine all aspects of the implementation of the Quality System Essentials and documentation in the organization to verify that it meets the requirements of the standards and demonstrates competence.

The assessors shall record all details of observations and findings and this shall be acknowledged by the assessee by appending a signature. The assessment team shall summarise all their findings during their review meeting and making reference to relevant clauses of the standard, quality manuals and other supporting documents and regulations. The team lead shall ensure that the organization fully and clearly understands the non-conformities noted during debriefing as well as ensure that they are discussed with the representatives of the laboratory's management.

3.5.4 Communication of Accreditation Assessment Report:

The written report shall be compiled indicating areas that require corrective action and submitted to the Council not later than one week after the assessment. This report must contain comments on competency and conformity of the laboratory as well as non-

conformities and observations which must be addressed by the laboratory. The Council forwards the edited soft and hard copies to the management of the laboratory facility for further implementation.

3.5.5 Granting of Accreditation:

The submitted report is forwarded to the Independent Advisory Committee of the Council for final editing and approval after which it is issued alongside an accreditation certificate. The certificate will specify the scope of accreditation. Accreditation could be withheld if requirement are not met. Should there be any complain, it is forwarded to the Board of MLSCN for resolution.

4.0 OTHERS

4.1 Use of Accreditation Symbol:

Accredited laboratories are to use appropriate accreditation symbols/logos specifying the scope of accreditation. This symbol/logo is allowed to be used on a laboratory's official documents. .

Accredited laboratories must fully conform to requirements for accreditation when making claims on the media and advertisement.

Upon suspension or withdrawal of accreditation, the laboratory is required to discontinue the use of all advertising material that contain any reference to accreditation status and not to allow the fact of its accreditation to imply that a test, analysis, method, process, system or person is approved by MLSCN.

4.2 Re-assessment, Surveillance and Extension:

The accreditation cycle is two (2) years after which a laboratory shall apply for re-accreditation. During the cycle, periodic re-assessment and surveillance activities shall be carried out at sufficient intervals (which is dependent on the stability of the services of the laboratory) to monitor the continued fulfillment by the laboratory of the requirements for accreditation.

The laboratory is given a period of time to implement corrective actions if non conformities are identified during surveillance/re-assessment. Continuation of the accreditation will be confirmed by MLSCN after due consideration.

A laboratory may apply to extend the scope of accreditation already granted but all assessment activities shall be undertaken to determine whether or not the extension may be granted.

4.3 Suspension, Withdrawal and Reduction of Accreditation Scope:

The MLSCN procedure for Suspension, Withdrawal and Reduction of Accreditation Scope are as follows:

4.3.1 Suspension of Accreditation:

* A laboratory's accreditation shall be suspended by MLSCN on any of the following conditions;
* non-payment of specified fees
* Critical non-conformance (deficiencies that may pose a substantial risk of harm to patients or to laboratory personnel, use of unqualified personnel),
* presence of numerous deficiencies that cannot be corrected within a reasonable period
* misuse of accreditation symbols/logos, etc;
* The Medical Laboratory's accreditation shall be suspended on approval by the Independent Advisory Committee based on reports of assessments and investigations or facts that justify the suspension;
* The Chief Executive of the Council shall inform the laboratory in writing regarding the suspension and detail the reasons. The letter shall also stipulate the maximum period of the suspension and the corrective action(s) required to be undertaken by the laboratory;
* The laboratory facilities that are under suspension shall have their directory entries as accredited facilities removed from the MLSCN website and only re-instated once they fulfill the requirement;
* A medical laboratory facility under suspension for non-conformance with the requirements shall:
* Undergo on-site assessment prior to reinstatement;
* Be re-instated only when positive recommendation by the assessment team is given and approved by the accreditation committee;
* Meet all the associated costs.

4.3.2 Withdrawal of Accreditation:

* The Independent Advisory Committee shall withdraw accreditation of a medical laboratory facility on the grounds of:
* Failure to adhere to the condition and terms for accreditation;
* The reasons for suspension are not address within the specified period.
* Failure to make specified payment;
* Closure due to liquidation, or change of ownership.
* failure to meet the Standards for Laboratory Accreditation
* The laboratory shall remove all the publicity materials and advertisement(s) on accreditation.
* The laboratory may appeal the decision of withdrawal within 30 days of receiving documented notice from Council.
* For the laboratory to be re-instated, it shall make a new application and meet all the associated costs.

4.3.3 Reduction of Scope of Accreditation:

* The Independent Advisory Committee shall reduce the scope of accreditation when:
* There is no demonstrated competence;
* There is no evidence to guarantee that the scope shall be covered as per specified requirements.

4.3.4 Communication of suspension, withdrawal or reduction of scope of accreditation:

* Withdrawal, suspension, or reduction of scope of accreditation shall be formally communicated by the Chief Executive of MLSCN to affected laboratories using a track able registered mail (courier), as well as an electronic mail where available.

The laboratory shall ensure that all claims made on accreditation are within the scope that is granted.

REFERENCES

Nigerian National Standards for Medical Laboratories (ISO15189:2012E) Medical Laboratory – Particular Requirements for Quality and Competence;
Clinical Laboratory Standard Institute- Application of Quality Management System Model for laboratory services; Approved guideline GP26- A3 3rd Edition

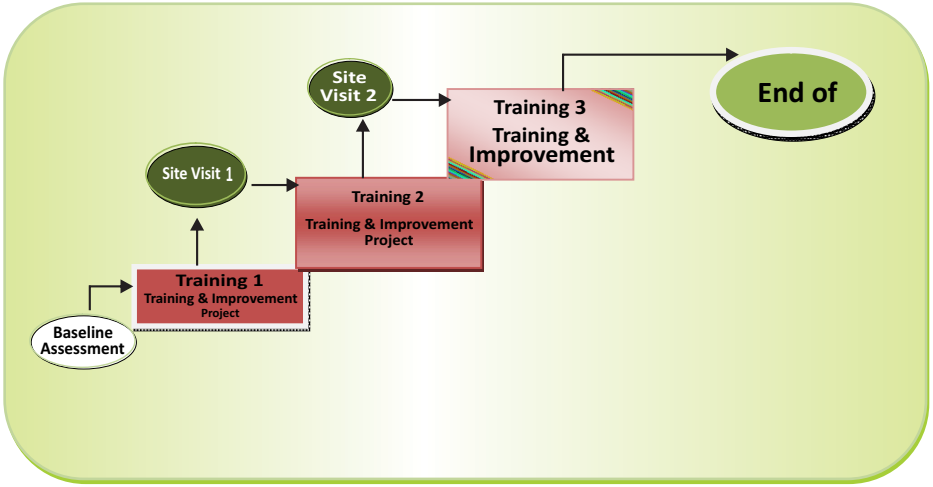
Tindill, B. S. and Stewart, D. W. (1993) Integration of Total Quality and Quality Assurance. In Al-Assaf, A. F. and Schmele, J. A. (eds) The Textbook of Total Quality in Healthcare. St Lucie Press, Delray Beach, FL, pp. 209–220.

WHO Laboratory Quality Management System Hand book 2011

WHO AFRO SLIPTA Checklist 2011

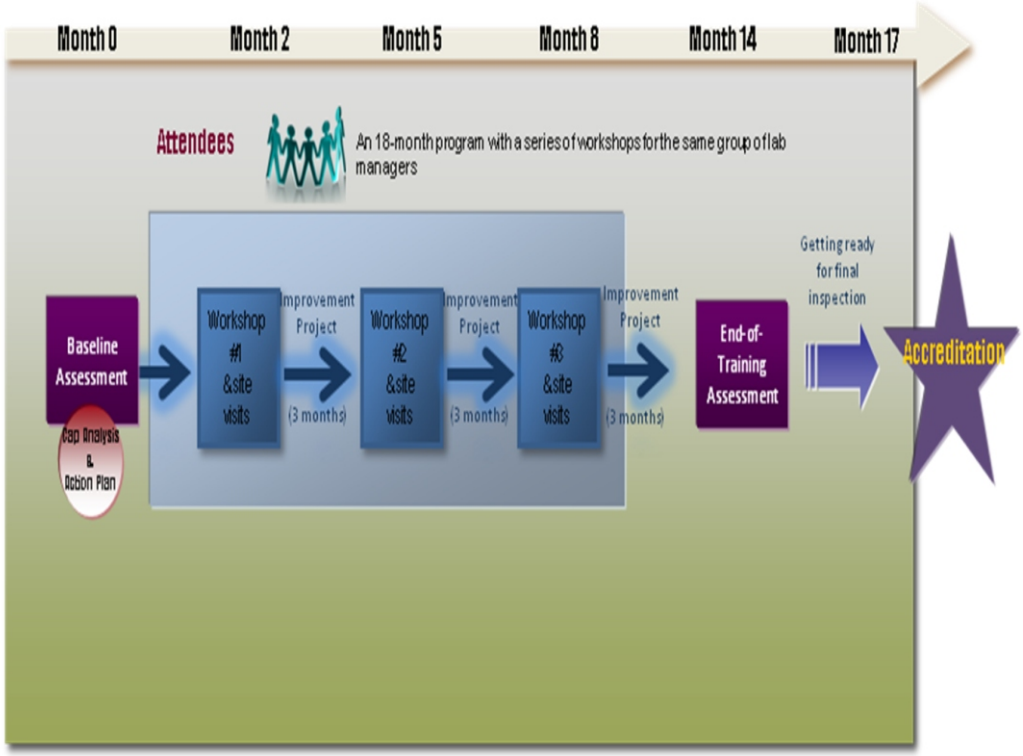
APPENDIX 1

MLSCN CQI PROGRAM



Appendix 2

MLSCN CQI Program Chart



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