REPUBLIC OF KENYA

MINISTRY OF HEALTH

NATIONAL TUBERCULOSIS, LEPROSY AND LUNG DISEASE PROGRAM

NATIONAL QUALITY MANAGEMENT FRAMEWORK FOR TB DIAGNOSTIC LABORATORIES

2023 - 2028

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Table of Contents

FOREWORD

Through the Ministry of Health, the Government of Kenya has continuously shown its commitment to improving the quality of health care services in the country towards attaining the highest standard of health to all Kenyans as espoused in the Constitution of Kenya 2010. This is made possible by laying a firm foundation in the Kenyan Healthcare System for a progressive, responsive and sustainable quality of care.

Laboratories plays a crucial role in disease diagnosis and treatment monitoring achieved through various diagnostic platforms available in the country. To achieve, maintain and improve the accuracy, timeliness and reliability of tests remains a major challenge for medical laboratories. Through the department of laboratory services, the Ministry has committed to build national and county capacities for the detection of, and response to, public health disease concerns such as Tuberculosis in line with the desired quality and reliability of test services.

Appropriate management and coordination mechanisms will enable TB diagnostic laboratories to produce test results that facilitate timely surveillance and management of patients, this Quality Management Framework therefore, is an additional resource to complement the existing strategies in aligning the practice of laboratory testing of TB towards the reduction the disease burden.

I encourage the various stakeholders in TB laboratory diagnostic to make use of it as a reference resource to strengthen the administration and benchwork in TB diagnostic laboratories.

Nakhumicha S. Wafula
Cabinet Secretary
Ministry of Health

PREFACE

TB laboratories are often challenged to provide the services needed to maximize TB management. Public health laboratories' work is highly complex and requires high levels of accuracy, precision, reliability and confidentiality provided in a timely and cost-efficient manner. To achieve this high level of quality, laboratories must adopt a systematic approach to the organization, planning and review of their testing services.

The National QMF for TB labs in Kenya will be beneficial to integrate within a broader TB laboratory strengthening in line with the laboratory ISO standard 15189 and other related guidelines. This document will be used as a guide for QMS to all stake holders comprising of Management, administration and technical staff and also standardize the quality practices in TB testing. It employs quality system essentials (QSE) for improvement of quality within the diagnostic labs across the country and focuses on ensuring that the laboratories are capacity built on the appropriate WHO approved TB diagnostic methods which include among others; Smear microscopy, culture and drug susceptibility testing (DST), as well as molecular WRDs e.g. line probe assay (LPA), gene Expert/Rif Ultra, truenat, TB genome sequencing etc.

This document also provides references for further consultations for both policies and technical recommendations to help achieve concrete, time-delineated and target driven TB laboratory strengthening. It highlights the structure in which the national will work hand in hand with the county laboratories in the implementation. These will include availing of the required resources, training and mentorship to enable a smooth implementation.

Mary Muthoni Muriuki, HSC

Principal Secretary

Ministry of Health - State Department for Public Health and Professional Standards.

EXECUTIVE SUMMARY

A Quality Management Framework is a core structural document for any laboratory providing quality services. This Framework has been developed to provide guidance to the TB diagnostic laboratories in implementing and continued maintenance of laboratory quality management. Through it, the National TB Reference Laboratory has provided a comprehensive and standardized information for the quality management of TB diagnostic laboratories, in addition to meeting the general Laboratory QM essentials, the framework aims to;

1. Establish National Quality Performance indicators for TB diagnostic laboratories.
2. Establish quality of TB lab diagnostics and TB lab surveillance to all eligible TB patients.
3. Provide a reference standard for empowering laboratory personnel on quality TB diagnostics management.

This framework specifies the requirements for quality and competence management for all TB testing modalities both at point of care and in the laboratories. The QMF shall be used alongside the National Policy Guidelines for Medical Laboratory Services, the National Public Health, the National TB Reference Laboratory and the National TB Program Strategic Plans to aid users in the quality management of TB laboratory diagnostics by the following key persons;

1. Health care workers in private and public laboratories involved in TB diagnostics work.
2. Policy actors and implementing partners with an overarching framework for managing the quality of TB laboratory diagnostics work.
3. Laboratory users, regulatory and accreditation agencies to recognize and/or confirm the competency of the TB diagnostic laboratory

Designed in-line with Juran's Trilogy of Quality Planning, Quality Control and Quality Improvement its content corresponds to laboratory Quality System Essentials as laid out in ISO 15189 standards. The framework specifies the requirements for quality and competence in TB laboratory diagnostic work providing minimum requirements in all elements, these are described chapter by chapter in the QSE format as follows;

1. Introduction and Organization
2. Human resource/personnel
3. Documents and Records Management
4. Client Management Services
5. Process Control
6. Process Improvement
7. Occurrence and Incident Management
8. Facility Safety and Infrastructure
9. Equipment Management
10. Purchasing and Inventory Management
11. Audits and Assessment
12. Information Management
13. Monitoring & Evaluation (M&E).

The framework should be used by laboratory managers and implementing partners both at the National and Counties to facilitate management and improvement of quality practices in TB testing. As a key reference tool alongside other Laboratory Quality Management Guides, the National TB Reference Laboratory looks forward to its enrichment and continual improvement in the quality of TB testing in the country.

Dr. Patrick Amoth, EBS

Ag. Director General for Health

Ministry of Health

ACKNOWLEDGEMENT

The National Quality Management Framework for TB Laboratories in Kenya has been prepared to guide and facilitate country-level efforts for strengthening national TB laboratory systems and networks. This framework will support implementation and continued maintenance of laboratory quality management systems.

The National Tuberculosis Reference Laboratory would like to thank everyone who participated in the development and review process of this document. In particular, the NTRL would like to acknowledge all the individuals who participated in providing technical assistance and having worked tirelessly towards the development of this framework.

Special appreciation to the National and County Governments, NPHL, Global Fund through the Division of National Tuberculosis Leprosy and Lung Disease program (DNTLD-P), AMREF Health Africa, KEMRI, CDC and Center for Health Solutions-Kenya (TB ARC II) for financial assistance in the development and the printing of this framework.

Dr. Immaculate Kathure

Ag. Head, Division of National Tuberculosis Leprosy and Lung Disease Program

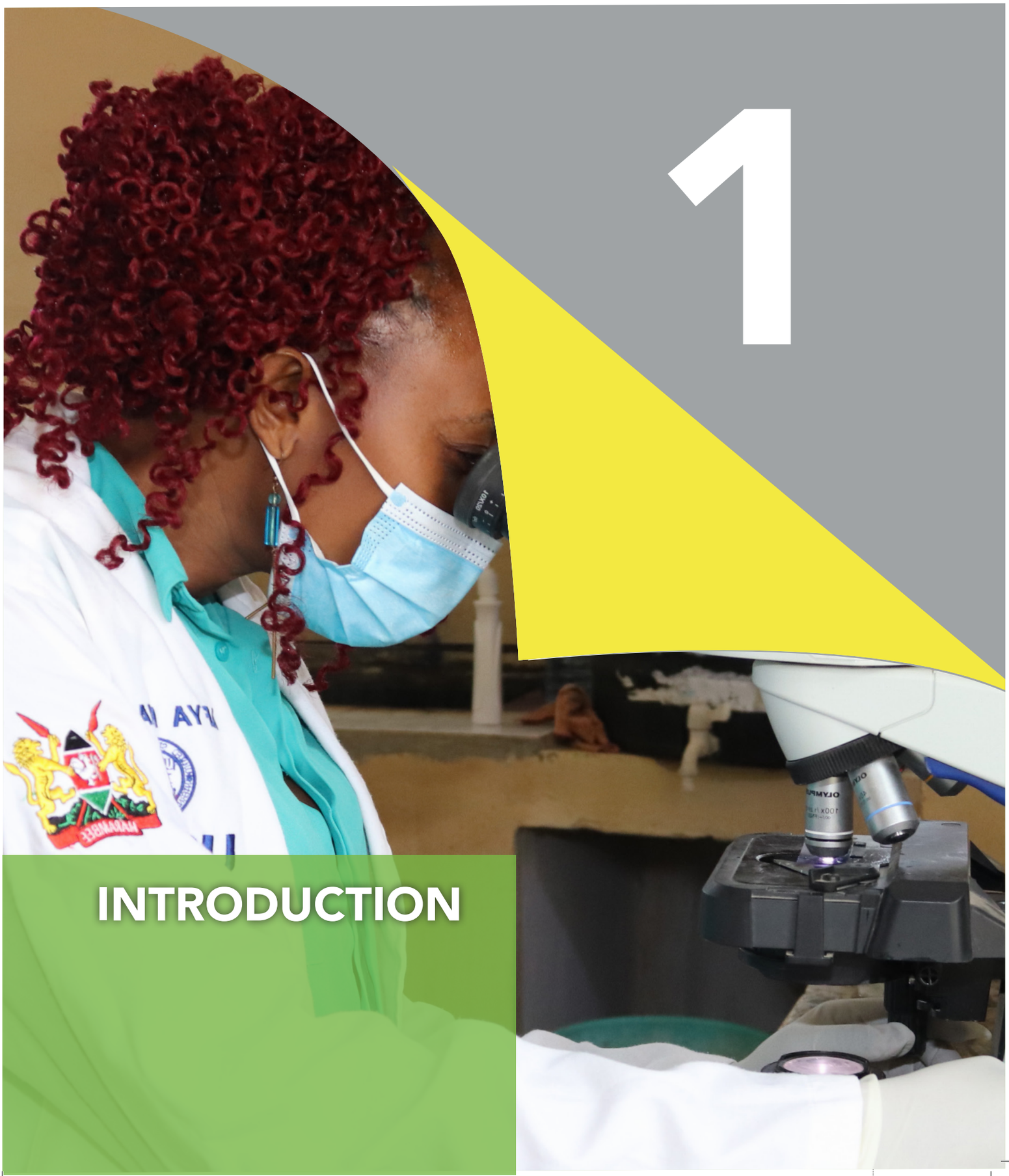
ABBREVIATIONS

BSC	Biosafety Cabinet
BSL	Biosafety Level
CAPA	Corrective Action Preventive Action
CDRR	Consumption Data Report and Request
CME	Continuous Medical Education
CMLC	County Medical Laboratory Coordinator
CQI	Continuous Quality Improvement
CTLC	County TB and Leprosy Coordinator
CXR	Chest X-Ray
DQA	Data Quality Audit
DST	Drug Susceptibility Testing
EQA	External Quality Assessment
FCDRR	Faciltiy Consumption Data Report and Request
GCLP	Good Clinical Laboratory Practice
HCW	Healthcare Worker
HRH	Human Resource for Health
HVAC	Heating, Ventilation and Air Conditioner
IA	Internal Audit
IPC	Infection Prevention Control
IQA	Internal Quality Audit
IQC	Internal Quality Control
ISO	International Organization for Standardization
KEMSA	Kenya Medical Supplies Agency
KENAS	Kenya Accreditaion Services
KHIS	Kenya Health Information System
KMLTTB	Kenya Medical Laboratory Technicians & Technologists Board
LIMS	Laboratory Information Management System
LPA	Line Probe Assay
NQMF	Laboratory Quality Management Framework
LQMS	Laboratory Quality Management System
LTBI	Latent TB Infection
M&E	Monitoring and Evaluation
MDR	Multi-Drug Resistance
MoH	Ministry of Health

MRM	Management Review Meeting
MSDS	Material Safety Data Sheet
MTB	Mycobacteria TB
NPHL	National Public Health Laboratory
NSP	National Strategic Plan
NTLDP	National TB Lung and Leprosy Disease Program
NTP	National TB Program
NTRL	National TB Reference Lab
PCP	Process Control Procedures
PCR	Polymerase Chain Reaction
PDSA	Plan, Do, Study, Act
PPE	Personal Protective Equipment
PT	Proficiency Testing
QC	Quality Control
QI	Quality Improvement
QSE	Quality System Essentials
QMS	Quality Management System
RCA	Root Cause Analysis
RIF	Rifampicin
SCMLC	Sub County Medical Laboratory Coordinator
SCTLC	Sub County TB and Leprosy Coordinator
SLA	Service Level Agreement
SOP	Standard Operating Procedure
SRS	Sample Referral System
TAT	Turn Around Time
TB	Tuberculosis
TiBU	Treatment Information from Basic Unit
WHO	World Health Organization
WRDs	WHO Recommended Rapid Diagnostic
XDR	Extensively Drug Resistance

DEFINITION OF TERMS

Administrative Relation	Labs that provides both administrative support
Audit	systematic, independent and documented process for gathering evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled.
Critical Results	A lab test result that represent a pathophysiologic state at such variance with normal (expected values) as to be life threatening unless something is done promptly and for which some corrective actions should be taken.
Error	A deviation from truth, accuracy or correctness; a mistake; a failure of planned action to be completed as intended, or the use of a wrong plan to achieve an aim.
H37RV	Mycobacteria Tuberculosis strain commonly used as controls for MTB identification in the laboratory.
Incident	An individual occurrence of brief duration or secondary importance.
Occurrence	An even, accident or circumstance that happened without intent, volition or plan.
Quality Assurance	A planed and systematic set of quality activities focussed on providing confidence that quality requirements will be fulfilled.
Quality Control	A set of procedures for continuously assessing laboratory work and emergent result.



1

INTRODUCTION

The medical laboratory is essential to patient care and the quality of laboratory services play a critical role in the overall improvement of health services. Laboratories provide information necessary for efficient use of medicines and for disease prevention. Laboratory testing as part of routine diagnostics for TB care, management and through surveillance programs provides data necessary for early diagnosis and detection. This guides effective responses to the reduction of TB disease burden, and promoting the life, wellbeing and productivity of TB patients.

Therefore, the need to strengthen laboratory services functionality as part of overall health systems improvement has been the basis for several global and regional accords/declarations[1,2].

Rationale

As provided for by the National Policy Guidelines[3], there is need for a National Quality Management Framework for TB diagnostic laboratories to facilitate management of quality practices. A Quality Management Framework is a core structural document for any laboratory implementing quality services.

Purpose of this Framework

This quality management framework provides guidance to the National, Counties and Sub Counties TB diagnostic laboratories in implementing and continued maintenance of laboratory quality management. By providing a comprehensive and standardized information for the quality management of TB diagnostic laboratories, the framework further aims to meet these key specific objectives;

1. To establish National Quality Performance indicators for TB diagnostic laboratories.
2. To establish quality of TB lab diagnostics and TB lab surveillance to all eligible TB patients.
3. To provide a reference standard for empowering laboratory personnel on quality TB diagnostics management.

Scope

This framework specifies the requirements for quality and competence management in both laboratory based and point of care TB testing modalities. It can also be used to develop quality management systems and assess service competency of any medical laboratory.

The QMF shall be used alongside the National Policy Guidelines for Medical Laboratory Services, the National Public Health, the National TB Reference Laboratory and the National TB Program Strategic Plans to aid users in the quality management of TB laboratory diagnostics by the following key persons;

1. Health care workers in private and public laboratories involved in TB diagnostics work.
2. Policy actors and implementing partners with an overarching framework for managing the quality of TB laboratory diagnostics work.
3. Laboratory users, regulatory and accreditation agencies to recognize and/or confirm the competency of the TB diagnostic laboratory.

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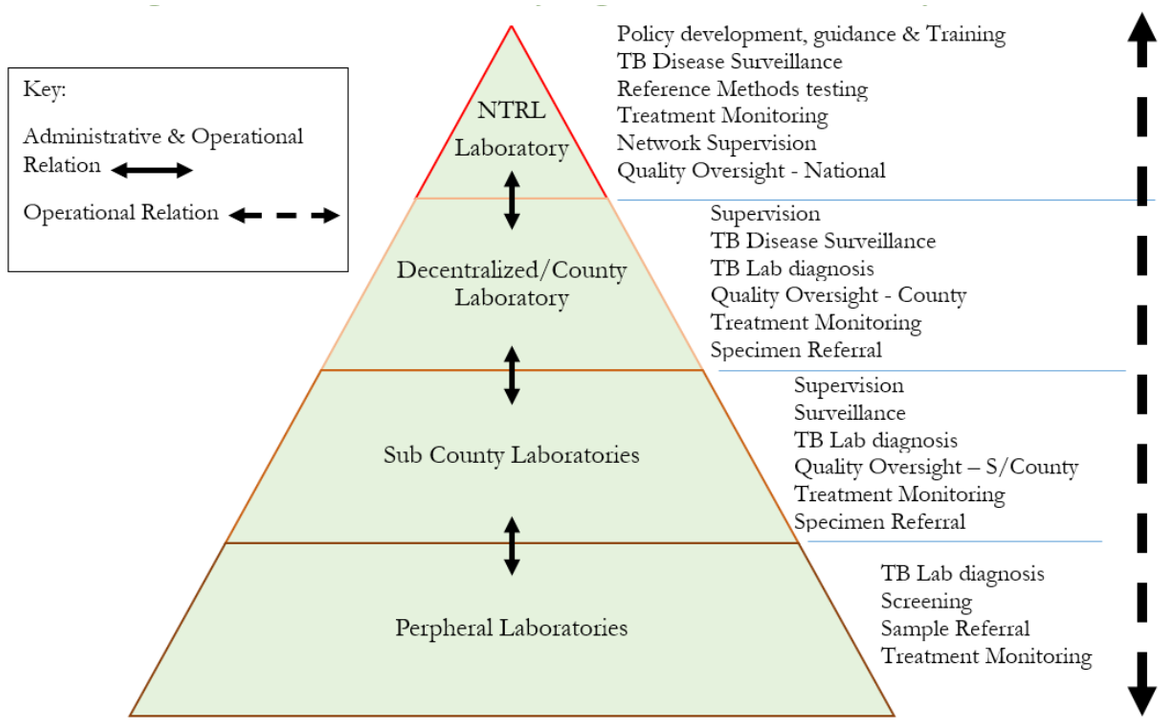
1 World Health Organization (WHO). The Maputo declaration on strengthening of laboratory systems.2008a. http://www.who.int/diagnostics_laboratory/Maputo-Declaration_2008.pdf
2 Yaoundé Resolutions 2008-2009
3 National Policy Guideline for Medical Laboratory Services in Kenya, 2006

Figure 1: Tiered network of laboratory Diagnostic for TB control in Kenya



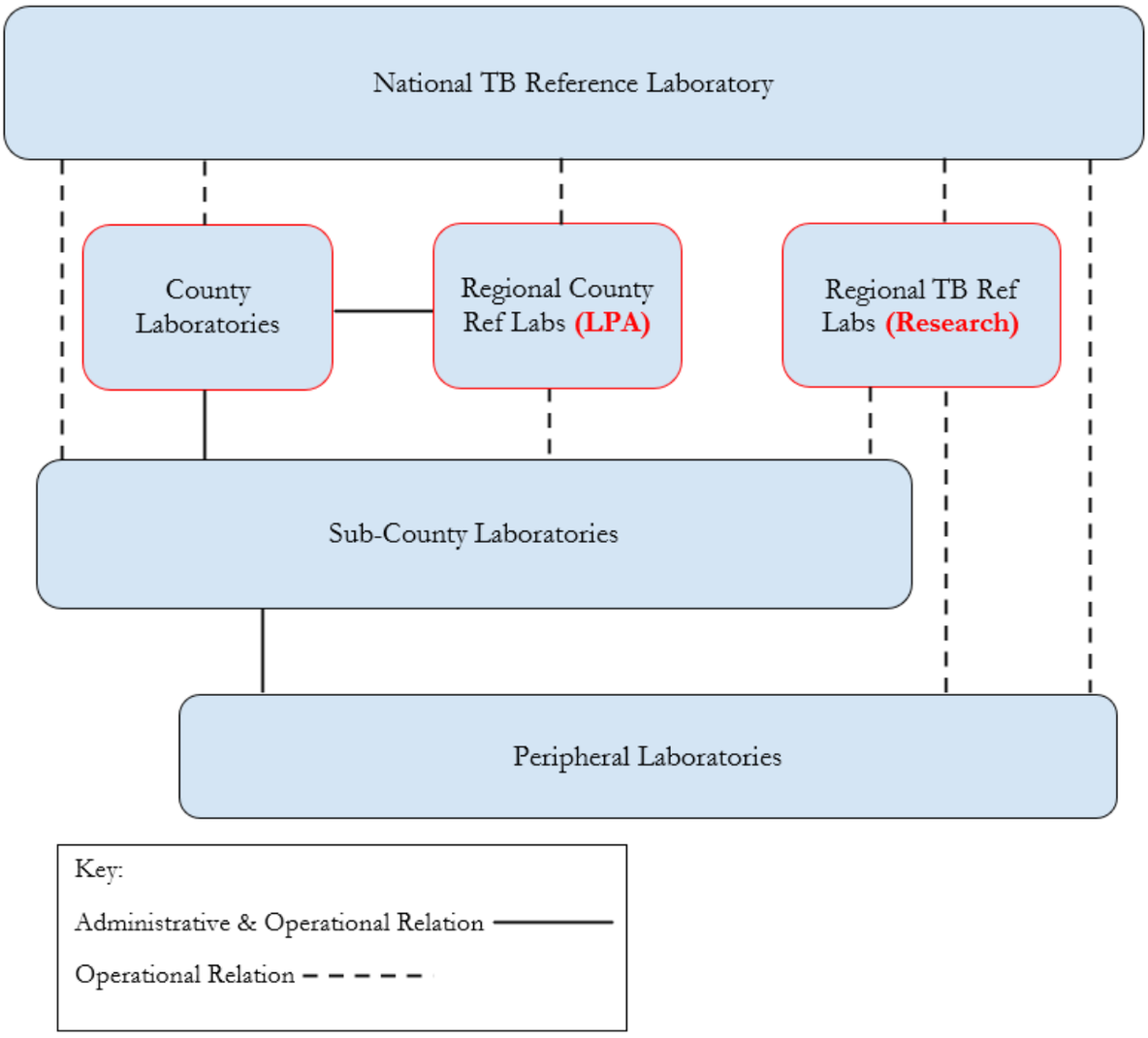
The Tiered laboratory Diagnostic network for TB control in Kenya shows the mandate and roles played by each level of laboratories in terms of diagnostics, surveillance and strengthening of the lab network.

The National Tuberculosis Reference Laboratory (NTRL)

The NTRL, a unit under the Division of National Public Health Laboratories shall provide policy formulation, national oversight and guidance in the implementation of this Framework in the TB Testing laboratories network. It is registered by KMLTTB as a public TB reference laboratory. It is accredited by KENAS on the ISO 15189:2012 and 17043:2010 in all TB scopes.

The NTRL, in collaboration with NTLDP and NPHL, has expanded its focus to include not only improving access to Tuberculosis diagnosis but also improving the quality of TB testing.

Figure 2: NTRL Organizational Relationship with other TB Diagnostic Laboratories



2

INTRODUCTION TO LABORATORY QUALITY

Laboratory Quality

Quality in diagnostic services can be defined as the accuracy, reliability and timeliness of reported test results[4]. It is with this in mind that this framework provides the NTRL with a system strengthening mechanism to ensure that results are as accurate as possible and that all aspects of the laboratory operations are reliable, with timely reporting practices in order to be useful in TB care.

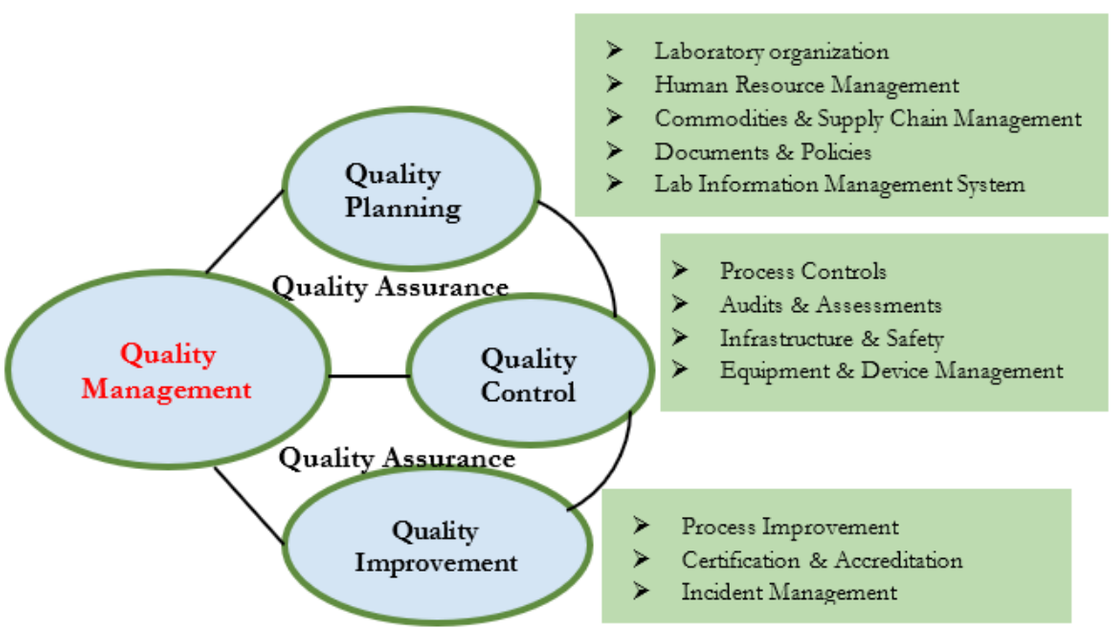
Strengthening quality management in the TB laboratory is of critical importance in ensuring people with TB get an accurate and timely diagnosis. The NSP (2019 - 2023) therefore supports the development and roll-out of a quality assurance system for all TB diagnostic tests.

NTRL shall realize this for TB Laboratory diagnostic network by;

i. Strengthening the implementation of external quality assurance (EQA) and IQC.
ii. Providing policy and guidance on methodologies for test and equipment verification.
iii. Development of algorithms and provision of guidance on SOPs.
iv. Capacity building lab personnel in collaboration with the Counties and sub-counties.
v. Auditing TB regional reference labs.
vi. Providing oversight in the implementation of TB WRD's in the country.

Quality Management Framework Overview

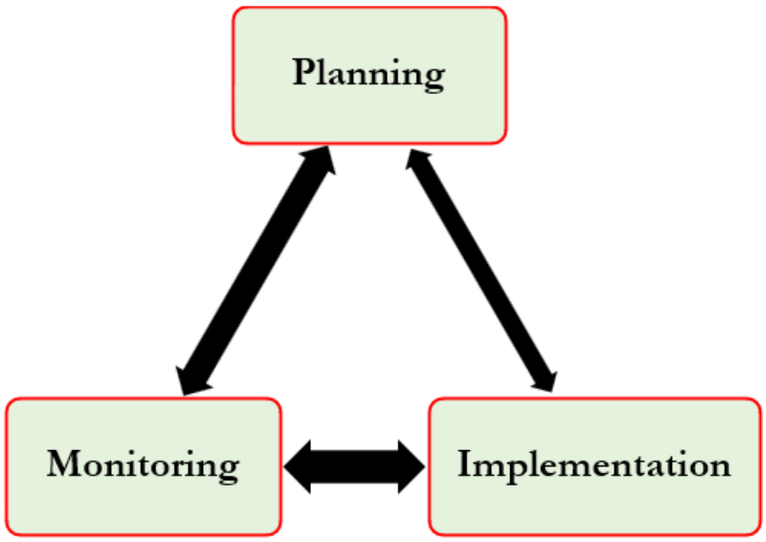
This NQMF is designed around the Juran Trilogy[5] of Quality Management with a three-legged stool of Quality Planning, Quality Control and Quality Improvement attached to Quality Assurance as the seating area with the System Quality Elements spread across the Trilogy.



4 WHO Laboratory Quality Management System: Handbook. 2011
5 Joseph M. Juran. The Quality Trilogy: A Universal Approach to Managing for Quality, 1986

Quality Management Functions

In managing quality of TB laboratory diagnostic services, a laboratory shall have in place mechanisms to carry out its quality management functions and support other diagnostic laboratories in its network along these key functions of a quality management system;



Planning

The laboratory management from National, Counties and partners shall establish mechanisms for joint planning to enable a common plan for the implementation of this framework. This should be contextualized to the relevant class of the laboratory. Making reference to this framework and the relevant National Policy Guidelines for Medical Laboratory services, NTRL shall guide and support TB diagnostic laboratories to plan and implement quality management activities towards improving the quality of laboratory diagnosis of TB patients.

Implementation

With the written plan in place each county shall detail a step-wise and practical implementation plan to ensure that all the elements of the QMS activities are carried out. The NTRL shall collaborate with the respective Medical Laboratory Services coordination structures at the National and County levels in the implementation of targeted approaches in improving the quality laboratory TB diagnosis.

Monitoring

To support the implementation process, the county laboratory services management shall establish a monitoring system for implementation of the quality system. This is key in establishing and sustaining continuous improvement as the overall goal of any QMS. NTRL shall provide technical and operational support to TB diagnostic laboratories in monitoring the implementation of quality management activities towards improving quality of diagnostic services.

3

HUMAN RESOURCE MANAGEMENT

Overview

Personnel form an integral part of quality management in any laboratory. Appropriate personnel qualifications must be established for all positions in the laboratory. Proper vetting of personnel before hiring is key in ensuring that they qualify in terms of professional training, and competence.

Recruitment and On-boarding

Recruitment and retention of qualified staff is essential in the maintenance of laboratory service quality, national and the county government shall ensure there are adequate staff in the laboratories who will cover TB testing services. Each laboratory should have a mechanism to determine its staffing needs, request for personnel placement or secondment and conduct a comprehensive orientation and induction for those joining TB diagnostic workstations.

Competency Assessment and Performance Appraisal

The specific laboratories should establish mechanisms to carry out competency assessment performance as per the ISO 15189 Standards. The NTRL shall assess the implementation of the competency assessment mechanism in place when performing support supervision to the TB diagnostic facilities.

The approach to competency assessment and performance appraisal shall include;

i. Knowledge grasp of medical laboratory practice with regards to TB diagnostics (both oral/written theory).

ii. Observation / witnessing practice within the workstation, and

iii. Outcomes/feedback of proficiency tests taken within the appraisal period.

Capacity Building - Training and Technical Support

The National, County and sub-county Laboratory services management shall design and establish capacity building programs for laboratory personnel engaged in TB diagnostic work. In so doing, NTRL shall coordinate these activities supported by the National TB Program, the County and subcounty laboratory systems and implementing partners for continuing education. This shall be done through;

i. Continuing education or structured academic programs in medical laboratory sciences

ii. On-site technical support/mentorship

NTRL shall emphasize the need for competence in the WHO recommended TB testing techniques.

4

DOCUMENTS AND RECORDS

Overview

Documents provide written information about policies, processes, procedures and understanding their relationship is key. Without accurate and complete documentation, the quality of TB diagnostic test results will be compromised. Documentation must address activities throughout the diagnostic cascade including documentation for clinical (e.g., specimen collection and referral) and laboratory analytical procedures, quality assurance and safety guidelines as per the WHO recommendations. The NTRL shall develop standardized documents for laboratory TB diagnostic work and disseminate to peripheral TB diagnostic Laboratories in the country. To avoid non-conformance these should be adopted as-is or customized to suit the end user (s) where necessary and they should ensure that the primary content is intact or not altered in any way.

Policies, Standard Operating Procedures (SOPs), reporting and requesting forms plus other documents should be accurate, available and accessible to all testing sites.

Key Documents - Characteristics and Highlights

i. They should provide information from key TB strategy[6] and diagnostic guidelines

ii. They should communicate to all the relevant personnel including laboratory staff and the managers

iii. They should be subjected to a review process whenever policies regarding processes or procedure change

iv. They provide a standardized format for recording and reporting framework

The goal of documentation and record keeping is to find information whenever it is needed. The lab shall have QMS documents that include but not limited to;

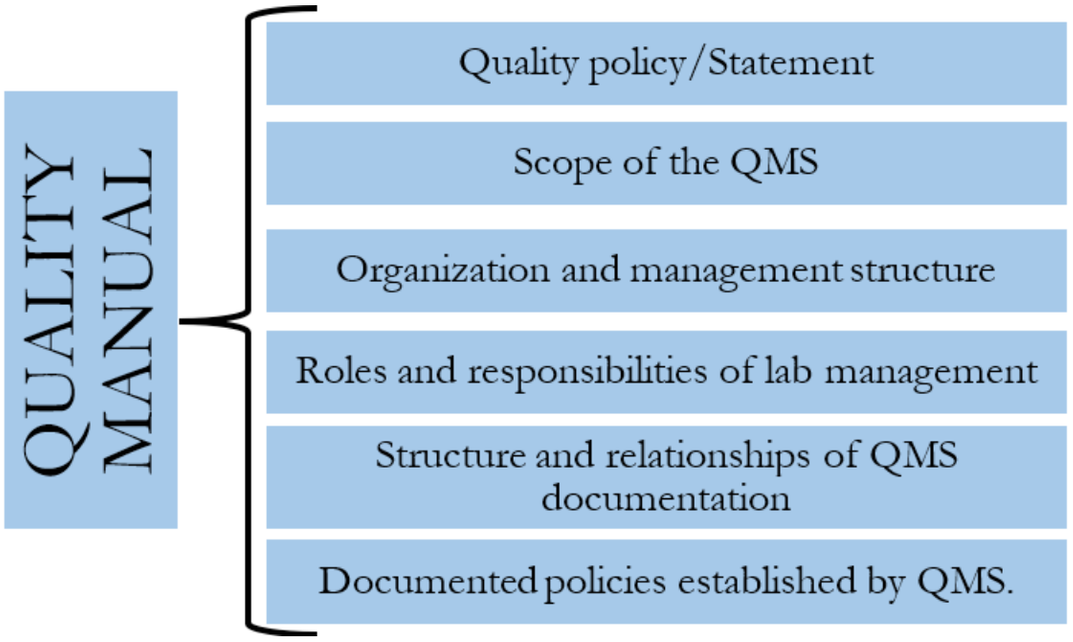
Regulatory & Policy	QMS & Operational	Standards & Guidelines	Operational Forms/ Registers
• KMLTTB Act • Waste Management Act • Human Tissue Act • Public Health Act	• Quality Policy Statement • Quality Manual • Safety Manual • Client Handbook • Standard Operating Procedures	• ISO Standards – e.g. 15189,17025,17043 • Laboratory Biosafety & Biosecurity Guidelines • National Policy Guidelines for Medical Laboratory Infrastructure • Healthcare Waste Management Guidelines	• Test Request form • Laboratory Register • Equipment inventory and maintenance logs • CAPA forms • TB diagnostic indicator reporting form • Temperature monitoring logs

[6] WHO END TB Strategy 2030

Regulatory & Policy	QMS & Operational	Standards & Guidelines	Operational Forms/ Registers
		• National TB integrated guidelines • Kenya WHO recommended Rapid TB Diagnostics Implementation Plan • National Guidelines for Integrated Laboratory Specimen Referral Network	• Training and competency assessments forms • Summary/ Reporting form • Commodity management tools

Laboratory Quality Manual

The quality manual gives direction to the laboratory leadership, personnel and describes the lab QMS. This includes quality work, meet regulatory standards and meets customer satisfaction. This being a key document for every laboratory, all persons in the laboratory should be made aware of its existence, instructed on its application/use. The Laboratory Quality Manual is always o document on review and mechanisms should be put in place to ensure an up-to-date version is in use.



Client / Clinician Handbook

A Clinician handbook is also in some cases referred to as laboratory handbook or service manual. It is a guide that is intended to provide information about the Lab services to the users and should be distributed to all service delivery points. This handbook should provide the following information in the minimum;

i. Name(s) and contacts of key personnel (e.g., Laboratory manager, Laboratory Quality manager, Laboratory safety officer or customer care officer where applicable)

ii. Name and address of the laboratory

iii. Physical location of the Laboratory.

iv. Operating hours of the laboratory.

v. Test menu.

vi. Detailed information on sample collection requirements.

vii. Sample transport requirements (if any).

viii. Expected turnaround times.

ix. Description of how to handle urgent requests.

Quality Policy

This document defines the quality intent in the QMS. The Laboratory management shall ensure that the quality policy:

i. is appropriate to the purpose of the laboratory.

ii. includes a commitment to good professional practice, examinations that are fit for the intended use, compliance with the requirements of the current accreditation, standardization practices and continual improvement of the quality of the lab services.

iii. provides framework for establishing and reviewing quality objectives.

iv. should be communicated and understood within the laboratory.

v. should be reviewed for continuing suitability.

Standard Operating Procedures and Records (SOPs)

These are step wise instructions compiled to help the lab personnel carry out routine operations. The personnel shall be trained on how to review and update procedures as scheduled and when need arises.

Categories of SOPs	Basic structure for an SOP should have
1. Management / mandatory SOPs	1. Title
2. Safety SOPs	2. SOP Identifier/ ID number
3. Technical SOPs	3. Author, reviewer and approval authority
4. Equipment use and maintenance SOPs	4. Effective Date
5. Reagent preparation SOPs	5. Next review date

NB: technical SOPs/forms shall be shared by NTRL then customized as per the need of the lab.

Operational Plan

This is a document that establishes a laboratory's business case and highlights operational aspirations around a set of Quality Objectives. Where applicable, a laboratory shall operationalize a Strategic Plan with specific measurable quality objectives which are consistent with its quality policy.

TB Lab Network Diagnostic Manual

The aim of this manual is to provide TB lab network members and other laboratories involved in the diagnosis of tuberculosis, with an agreed national list of key diagnostic methods and their protocols in various areas of TB diagnosis, ranging from microbiological diagnosis of active TB using the WRDs to the diagnosis of latent TB infection (LTBI).

This manual offers a single source of reference by compiling all methods, with a strong focus on standard (reference) and evidence-based methods as per the WHO guidelines.

Documents Control

A document control system is needed to ensure a regular review of quality management and to ensure the correctness of the documentation that supports laboratory testing. To prevent unintended use of obsolete documents, the laboratory shall have a documented procedure to control its QMS documents aligned to ISO 15189 standard.

5

CLIENT MANAGEMENT SERVICES

Overview

Client management services is a major element of a quality management system, and a significant focus in the International Organization for Standardization (ISO) standards. Being that the main product i.e., the Test Result has a greater bearing in the management of a customer's healthcare, it only means that laboratory that is not able to meet the expectations of its customers is not only harming the same customers but also not achieving the primary function of a diagnostic laboratory.

Key Aspects of TB Laboratory Client Management

Laboratory Clients

Effective and efficient communication is vital to customer experience and the laboratory should establish sustainable mechanisms to address the various needs of its customer population. The laboratory has many clients and the needs of all must be carefully addressed, key customer groups that the laboratory should address are;

- Clinicians – play central role in ordering laboratory services.
- Patients and family members – primary consumers of test services.
- Non-technical laboratory personnel – primary support systems for lab operations.
- Public health officials – provides support for disease surveillance/research roles of the lab.
- Health/hospital management teams – provides administrative support to the laboratory.
- Community members – consumers of public health disease surveillance information.
- 3rd party contracted service vendors/suppliers – supports un-interrupted continuity of laboratory services.

Managing client expectation and monitoring satisfaction

The assessment and monitoring of client management services and satisfaction rates forms a core element of continuous quality improvement program for the laboratory. In order to understand whether client needs are being met, the laboratory will need to establish a mechanism to gain feedback and information from clients. Complaints and compliments can be raised through customer surveys, emails, suggestion box, etc.

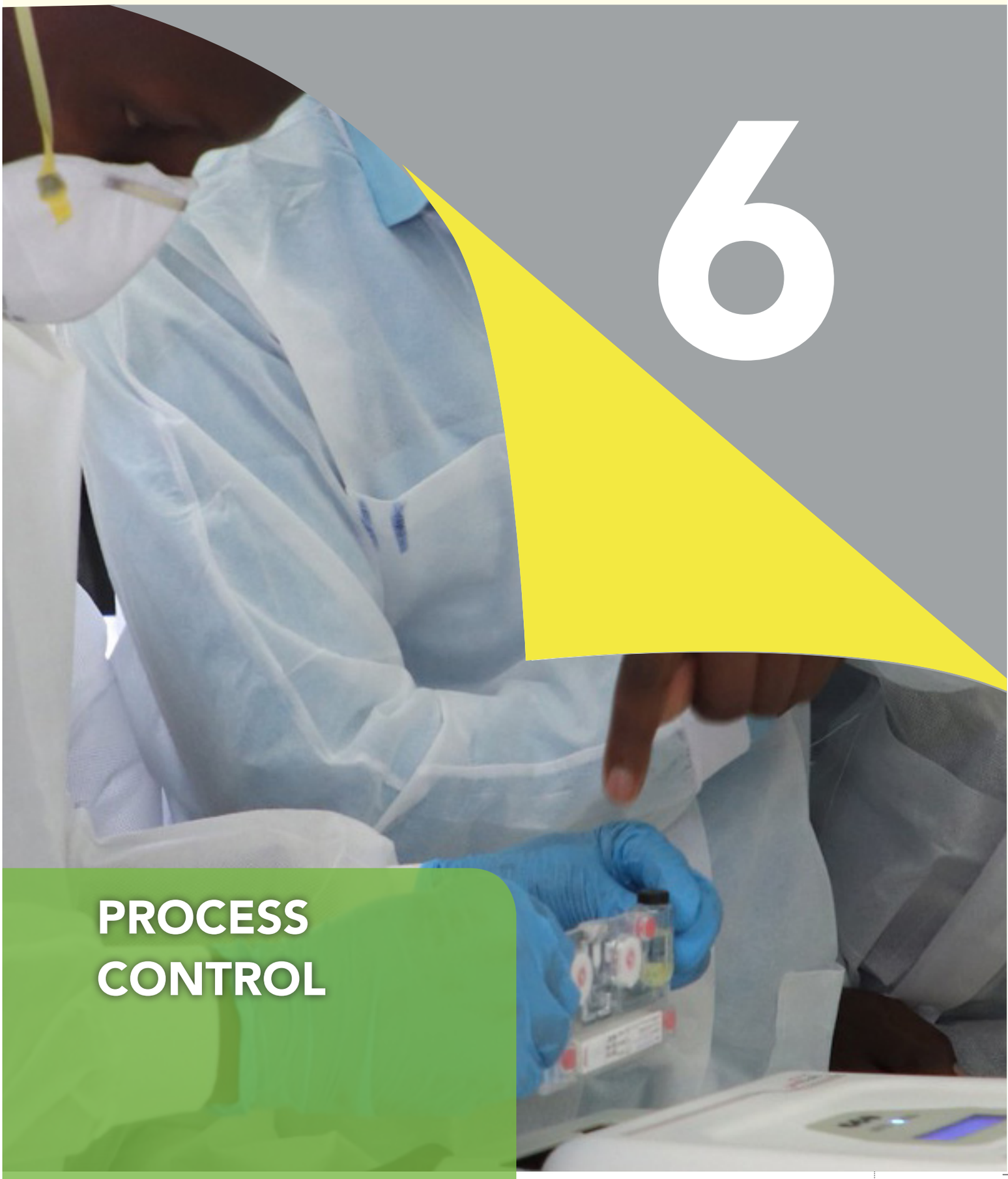
The identified system tools should be used proactively to seek information from customers, as opposed to reactive responses whenever clients contact the laboratory with concerns/ complaints. These are some key approaches for consideration by the laboratory to assess client satisfaction levels;

- Establishment of a complaint monitoring/tracking system. This should include recording of complaints received in the laboratory from its clients, addressing them and monitoring the effectiveness of the solutions taken to address the complaints.
- Utilization/tracking of quality indicators.

- TB laboratories shall establish and monitor performance indicators to identify trends that might affect client satisfaction. e.g, Turn Around Time (TAT) & Specimen rejection rates.
- Utilization of satisfaction surveys to gain client feedback.

Client Responsibilities: Service Charter

The Service Charter should highlight the client's responsibilities when they seek laboratory services that will help the service provider to deliver the best possible care to them. This includes information such as available tests, cost and turnaround time. The laboratory shall develop and display their service charter where it can be easily seen by the patients.



6

PROCESS CONTROL

Overview

Process control is an essential element of the quality management system, and refers to control of the activities employed in the handling of samples across all the phases[4]. QC assures the laboratory of the reliability of its test results. The main objective QC practices in the laboratory is to enable the laboratory detect, evaluate and correct errors before the test result is relayed to the clients, whether due to operator performance, system failures/inadequacy or prevailing environmental conditions.

The laboratory shall establish and maintain Quality Control mechanisms for all elements of the testing process, namely;

1. Pre-analytic phase
2. Analytic Phase
3. Post-Analytic phase

Sample Management Process

The reliability of test results is directly determined by the quality of the testing sample received at the laboratory; the laboratory should establish and utilize written policies/guides for sample management, this shall be part of the laboratory operations handbook defined in Chapter 4.

Pre analytical Phase

Every TB diagnostic laboratory shall establish and maintain mechanisms to ensure all the pre analytical activities are strictly followed to ensure that the output is valid. This may be inform of documented procedures that should be availed to all the sample collection sites. A standard request form should be available either hard or soft copy. All received samples and their request forms should be reviewed and sorted at the sample reception area.

Key quality control practices to be considered:

i. Sample collection, labelling and packaging: Laboratories shall develop SOPs on sample collection describing the steps needed to obtain a quality sample. Personnel involved in samples collection should be trained and assessed for competency as per the SOP. The lab management should ensure availability of adequate supplies/commodities.

ii. Sample storage: The lab should have SOP that address suitable specimen storage conditions and facilities to ensure that they remain stable and viable.

iii. Sample Referral System: there should be systems in place to ensure that samples are safely transported to the laboratory observing all the sample referral requirements. The sample should be accompanied by a test request form, tracking log. Systems should be in place to aid referring labs to identify referral labs within the SRS network. The samples should be triple-packaged to minimize risk during transportation. Transit TAT should be established and monitored by the referral lab.

iv. Sample protection: procedures and appropriate facilities for securing patient samples, ensuring sample integrity and preventing loss or damage during pre-examination activities, transportation, handling, preparation and storage.

v. Criteria for additional examination request on the primary sample - procedures shall include time limits for requesting additional examinations, or further examinations on the same primary sample.

vi. Sample stability: advise and considerations for the stability of the measurability of the primary sample, the time between sample collection and performing the examination shall be specified and monitored where relevant. The lab should have suitable specimen storage facilities to ensure that they remain stable and viable.

Analytical Phase

The laboratory shall ensure that all the necessary technical SOPs are available and up to date. All the reagents used should be verified in terms of Lot-to-lot verification. The laboratory should ensure that all the quality controls are run, analyzed and that they are acceptable before any sample analysis is done.

Internal Quality Control

Table 1: Quality Control Reference for TB Tests

Test	IQC	Frequency
Microscopy	Positive control (actual or 1+) Negative control	As per schedule
mWRDs	Positive and negative control (provided by an IQC provider) or as defined by the manufacturer's instructions	As per schedule
Culture	Positive control (H37RV) Negative control (Artificial sputum)	Periodically Per Batch/weekly
DST	Positive control (H37RV) plus Growth Control Tube	Per Batch of drugs

The lab must also put in place systems to ensure that the analyzed samples have valid results by having a system that evaluates results since the last acceptable quality control. The laboratory shall make provisions to handle these key quality control elements of sample analysis;

i. Selections and identification of the examination method to be used for each test request.

ii. Verification and validation – establish mechanisms to verify and validate examination methods in use whether derived from the laboratory or adapted.

iii. Reference intervals and clinical decision limits – establish and define biological reference intervals and clinical decision limits to aid interpretation of examination results.

iv. Documentation of examination procedures - the laboratory shall document its examination procedures to the extent necessary to ensure the consistent application of its activities and the validity of its results.

v. Ensuring the validity of examination results – established IQC procedures for monitoring the ongoing validity of examination results, as per the defined criteria, that verifies the attainment of the intended quality and ensures consistent validity pertinent to clinical decision-making.

vi. Use of characterized standard materials to prepare IQCs may be preferred to ensure traceability of source and minimize variations in results

vii. Test result benchmarking - establish and maintain mechanism to ensure test results are benchmarked with peer laboratory through activities like EQA, blinded rechecking and parallel testing using other platforms.

The laboratory should also establish mechanisms that ensures monitoring and control of environmental conditions to ensure that all systems are conducive for the samples, equipment and the personnel working in the laboratory.

Table 2: Guidance on estimated number of tests that can be performed during an 8-hour workday[7]

Procedure	No. of tests per day	Unit of Measure
AFB light microscopy	20–25b	Per technician
AFB fluorescence microscopy	40–50b	Per technician
Culture (liquid/solid media, including specimen processing)	20–40c	Per technician
DST (using liquid media)	10–20	Per technician
DST (using solid media)	10–20	Per technician
FL-LPA (manual method)	48-96	Per instrument
SL-LPA (manual method)	48–96	Per instrument
Loopamp MTBC detection (TB-LAMP) test	Up to 70	Per instrument
Xpert MTB/RIF, Ultra or MTB/XDR assay (using four module instrument)	12–16	Per instrument
Truenat MTB, MTB Plus and MTB-RIF Dx (using Quatro instrument)	Up to 36	Per instrument
RealTime MTB and MTB RIF/INH	Up to 94	Per instrument
FluoroType MTB and MTBDR	Up to 288	Per instrument
BD MAX MDR-TB	Up to 48	Per instrument
Cobas MTB and MTB RIF/INH	384–1056	Per instrument
Genoscholar PZA-TB (using Multi-Blot NS-4800)	Up to 48	Per instrument

[7] WHO GLI Practical Manual on Tuberculosis Laboratory Strengthening. 2022

External Quality Assessment

NTRL being charged with the central mandate to coordinate TB laboratory diagnostic quality shall establish and maintain a mechanism to provide and manage EQA platforms for the diagnostic network. The laboratory shall have a system in place for enrolling peripheral labs for participation in EQA or an alternative approach. The diagnostic laboratories in the network shall participate in at least one or all of the following EQA exercises in a calendar year;

Blinded rechecking

- All labs to store all smears done until sampling is done. Labs shall be enrolled for EQA at the sub-county level
- Random sample collected using Lot Quality Assurance Sampling (LQAS) by Sub - County TB and Leprosy coordinators (SCTLCs) from TB labs conducting AFB microscopy for re-checking and verification.
- County TB and Leprosy coordinators (CTLCs)will follow the same procedure to sample slides from county/sub county referral hospitals for re-checking and verification
- The National level shall establish systems to monitor the effectiveness of blinded rechecking
- Sampled slides taken to sub county laboratories for the rechecking by a 1 controller
- Discrepant results will be subjected to a second controller
- Feedback reports are given to the testing facilities and CAPA done

Proficiency testing (PT)

- NTRL distributes PT samples to enrolled facilities according to scheduled calendar.
- Facilities enrolled shall run the samples in the same manner as patient samples.
- Results are sent back to the NTRL for analysis.
- Feedback of the PT performance is shared with the participating facilities.
- For unsatisfactory EQA results, the laboratory must have in place mechanisms to conduct root cause analysis, institute appropriate corrective measure to fix the problem and eventually monitor the same to confirm effectiveness.

On-site evaluation

Routine on-site evaluation of the TB diagnostic labs shall be conducted by either county TB coordinators, NTRL and the national TB program to address key aspects such as.

- Sample collection, handling and storage
- Sample analysis
- EQA performance, and related CAPAs
- Waste management

- Documentation practices.
- Performance indicators (e.g. TAT)

Post Analytical Phase

The output in terms of results must be well documented and verified before releasing to the patients. They must be assented to for ownership by the personnel running the test and the one verifying. The lab must also ensure that there is a system in place on how amendments are done in patients' results. The results must be traceable to a certain method.

These are some of the key aspects of post-analysis phase that the laboratory should manage for quality control purposes;

1. Result reporting according to the National guidelines.
2. Common requirements for reports.
3. Release of results including critical results that should be handled with urgency and escalated to higher authorities e.g.;
    - Urgent request from clinicians based on patient's clinical state.
    - Critical results such as Pre-XDR, XDR.
4. Amendments to reports.
5. Automated selection, review and reporting of results.
6. Post-examination handling of samples.

All the patient data must be archived in a safe manner and their access must be well controlled. There should also be a clear authorization matrix indicating those authorized to access patient reports, review patient reports, amend or revised patient reports that would ensure outpost confidentiality. The lab must also have a documented procedure guiding on release and management of patient results for both electronic and paper-based system.

The procedure on how to handle human samples, tissues or their remains as per the country regulations should be well documented. This could be implemented through strengthening the biorepository management at the laboratories.

7

PROCESS IMPROVEMENT

Overview

Continuous Quality Improvement is a core element in a functional quality management system, the laboratory shall establish a mechanism for continual improvement of all operational processes to ensure quality. Through the Kenya Quality Model for Health[8] the Ministry of Health has provided divisions and programmes with an overarching framework[9] for managing the quality of care, alongside this, the DNLTD-P has packaged a Quality Improvement framework as a reference and guide for the implementation of Continuous Quality Improvement activities across the cascade of service delivery in TB prevention, management and control.

The two guiding frameworks for process improvement have adopted approaches that are key in the continuous quality improvement of laboratory services;

i. Work Environment Improvement – 6S

   This is a provider-focused strategy for improving the 'work environment'. The model engages and supports health workers to acquire skills and competencies required to embrace and effect 'change' within the workplace.

   1. Sort – Eliminating unnecessary processes or items in the work environment
   2. Set – Establishing order of tasks/processes or commodities for efficiency during use
   3. Shine – Cleaning and establishing order in the workplace
   4. Standardize – Establishing standard protocols and procedures in the workplace for improvement implemented
   5. Sustain – Establishing improvements gained as part of common practice
   6. Safety – Assuring safety of staff & patients with every task in the improvement cycle

ii. Model for Improvement – Plan, Do, Study, Act (PDSA)

   This is a strategy used to accelerate improvement activities by conducting small-scale tests of change in real settings by using the PDSA cycle which denotes;

   i. Plan a change
   ii. Do it in a small test
   iii. Study its effects
   iv. Act on what is learnt from implementation

This shall be the guiding principle for continuous quality improvement activities and each lab should establish mechanisms to institute and implement activities through the cycle. Several small PDSA test cycles can be linked (tested concurrently) until ready for scale-up.

8 KQMH Implementation Guidelines 2011
9 TB QI Framework 2022

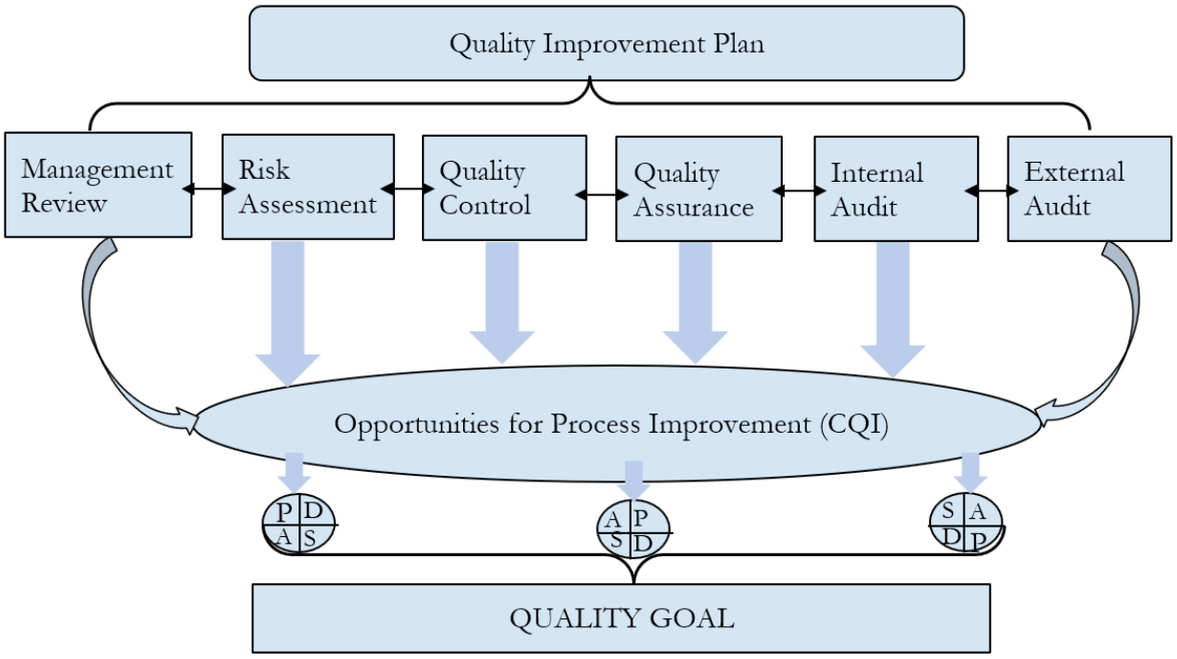
The laboratory shall therefore establish continuous quality improvement program by;

i. Establishing a Process/Work/Quality Improvement Team

ii. Quality Improvement Plan

The established process improvement mechanism should enable the laboratory management to evaluate and review outcomes of CQI initiatives on a regular basis to provide the management with the needed information on the opportunities for improvement.

Figure 4: Process Improvement Cycle



The Process Improvement Cycle Activities

i. Quality Assurance activities are a means of establishing standards (diagnostic/testing protocols and guidelines, quality management standard operating procedures) and consistently using these as a basis for assessing performance in the lab. Outcomes of QA activities are opportunities for quality improvement processes. This shall be observed in the various and specific labs following the ISO 15189 and the quality manual and plan systematic activities which will focus on providing confidence that quality requirements are fulfilled.

ii. Quality Control practices are designed to ensure that the level of performance of the laboratory remains stable, or in 'control' within new and agreed performance limits. QC helps to elevate quality of testing in the lab and sustains excellence. Routine QC practices enables a lab to identify areas of improvement. This shall be measured by the accuracy, reliability, and timeliness of the reported test results.

iii. Risk Assessment exercises enables a lab to identify potential hazards and determine controls that can be implemented in the improvement process to eliminate or reduce any risks to staff, operations, and/or property. A new risk assessment should be completed and documented each time a new potentially hazardous test is introduced. After QC measures are implemented, SOPs should be developed followed with staff training should follow to establish awareness of the correct sequential actions to take in ensuring test quality.

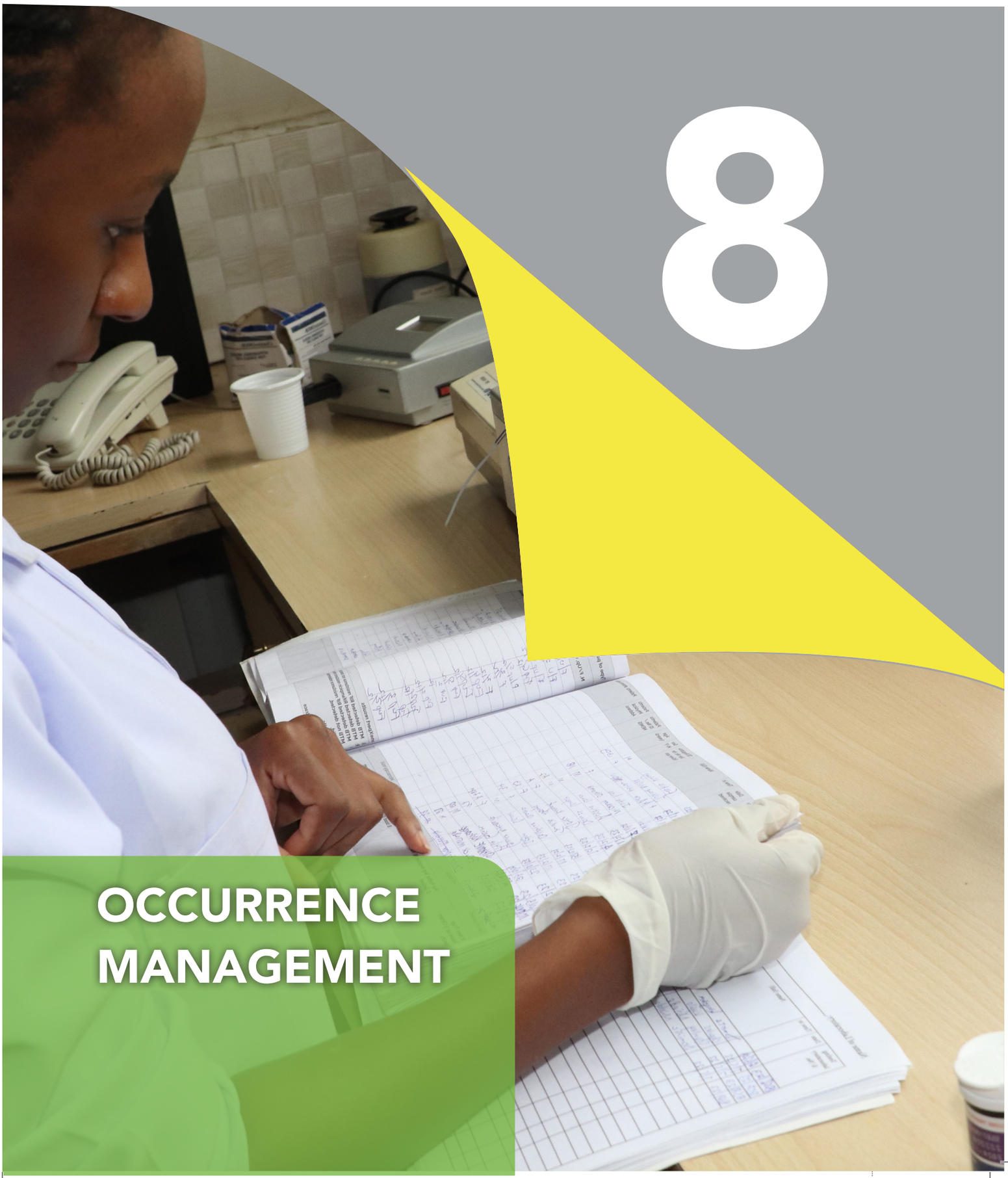
iv. Management Review: the laboratory management team shall routinely monitor, evaluate and review the operational performance against goals set the previous year. The goals for the next year will be discussed and set- in the meeting. This will ensure continuity in the implementation, maintenance and improvement of the quality management system. The management review reports and minutes shall serve as input for the new Quality Improvement Plan for the following year.

v. Internal Audit: staff working in one area of the laboratory should routinely conduct systematic examination of the lab or part of it. This provides the lab with information on how the laboratory is performing and whether it is in compliance with policy, regulatory or standards requirements. Internally, the laboratory staff shall realise gaps that present opportunities for improvement.

vi. External Audit: Systematic examination of the lab ca also be conducted by management/operational entitiess or agencies from outside the laboratory. This may be for regulation, operational or accreditation purposes which may generate improvement opportunities for the lab.

Quality Improvement Plan

Each of the above quality management activities in the improvement cycle when implemented separately or collectively should enable a laboratory to identify opportunities for improvement. The lab shall develop a quality improvement plan based on the opportunities for improvement. Subsequent monitoring of the implementation process of these activities should enable the lab to develop a new implementation plan for continual improvement.



8

OCCURRENCE MANAGEMENT

Overview

Occurrence management remains a core element of continuous improvement, every laboratory shall therefore establish a functional and sustainable occurrence management programme to support the identification of incidents and errors. The aim of this program should also make provisions for correcting errors during testing processes or any form of communication incidents that arise from an event with an objective of future-proofing the processes from repeated occurrences.

Consequences and Sources of Errors in TB Laboratory

The laboratory is a critical partner in all health systems, and it must perform its functions well in order to help ensure good outcomes of health programmes and interventions. A failure in the laboratory role can have a significant effect.

Errors encountered in the TB laboratory may lead to the following;

- inadequate or inappropriate management of TB patient
- inappropriate public health action towards TB control
- undetected TB disease outbreaks
- mismanagement of available resources
- the death of the TB patient
- missed or delayed diagnosis

The Lab shall establish mechanisms to identify errors arising across the entire testing process as per the following key points that errors may occur at:

Pre-Analysis - Some examples of common sources of errors that are frequently seen include;

- incomplete or wrong patient details in the request forms.
- inability to collect quality sample for testing.
- mis-labeled or unlabeled sample.
- incorrect sample storage prior to testing leading to sample deterioration.
- inappropriate transportation of the sample under conditions that damage the samples or that endanger staff and public safety.
- improper storage of reagents damaging the reagents or test kits. by storing them improperly.

Analysis - A list of common sources of errors that occur during the testing process include;

- failure to follow an established standard operating procedure.
- personnel incompetency.
- reporting of results when the quality control material fails.

- use of inadequate sample.
- incorrect measuring of the sample or reagents.
- use of reagents that have been improperly stored, or after their expiration date.
- equipment/device failure.

Post-Analysis - Most of the common laboratory errors occur following the testing of the sample, and some of these may be more difficult to detect. Common examples of these kinds of errors include;

- transcription errors when preparing test reports.
- producing a report that is illegible, usually caused by poor handwriting, but sometimes by damage to the report form.
- sending the report to the wrong location, which often results in complete loss of the report.
- failure to send test report.

Investigating and Detecting Occurrences

The laboratory should develop a mechanism to promptly investigate every laboratory incidence, problem and error. These are some of the various approaches that the TB lab should make use in investigating and detecting, investigating and reducing occurrences;

Occurrence Detection	Occurrence Investigation	Occurrence Reduction
• risk assessment • internal/external assessments • internal quality control • proficiency testing	• root cause analysis • internal/external audits	• staff training • proper preventive maintenance of equipment • validation/verification of test method • development of standard operating procedures • continuous improvement

The management process for dealing with errors or occurrences involves several steps.

1. Establish a process to routinely and actively detect problems and errors arising in the laboratory
2. An up-to-date error log to enable the laboratory keep a management history of all problem events that occur and accompanying investigative activities and resolutions

3. Investigate the cause of any problem that is detected and carefully analyze the information that is available. This is done using the established program and process
4. Take the necessary action (remedial and corrective)—if the problem is detected before the error actually occurs, take preventive action.
5. Monitor and observe for any recurrence of the original problem, keeping in mind that there may be a systemic problem.
6. Provide information to all those who need it, and to those who are affected by the error

Follow up

Upon completion of any incident investigation and subsequent action, follow up should include verification that corrective and preventive actions undertaken fully address the incident and its root causes. This check should be performed periodically with sufficient time-in-between to allow for actions to be implemented and incorporated into the system or process. If examinations were halted, any changes in practice or reagents should be evaluated prior to resuming testing.

9

FACILITY, SAFETY AND INFRASTRUCTURE

Overview

Facility safety and infrastructure design is an essential component of a laboratory Quality Management System. A Safety program is important in order to protect the lives of employees, users, laboratory equipment maintenance, facilities in optimum operable condition and to protection to the environment. Every laboratory shall establish and maintain a safety program that covers the entire scope of its operations. Kenya has a National Laboratory biosafety biosecurity guideline that provides regulations, procedures and processes to ensure quality safety measures in TB Laboratories. TB Laboratories are classified based on risk levels, i.e.

Table 3: Risk Hierarchy for TB Diagnostic Laboratory[10]

Risk levels	Lab Category	Performed Processes/ Procedures	Assessment of Risk	Minimum Requirements
Low risk TB Labs	BSL 1	Direct smear microscopy, Xpert MTB/RIF assay, Truenat test	Low risk of generating infectious aerosols from specimen; low concentration of infectious particles	Appropriate TB lab benches, adequately ventilated areas, Proper PPE'S, good lab practice, eyewash, emergency showers, running clean water, sinks
Moderate risk TB Labs	BSL 2	Direct smear microscopy, Smear concentrate microscopy, Xpert MTB/RIF assay, Sample processing for inoculation	Moderate risk of generating infectious aerosols from specimen; low concentration of infectious particles	In addition to what is in BSL 1, unidirectional airflow, BSCs,
High risk TB Labs	BSL 3	Direct smear microscopy, Smear concentrate microscopy, Xpert MTB/RIF assay, Sample processing for inoculation, Direct DST(PCR), Culture manipulations	High risk of generating infectious aerosols from specimen; high concentration of infectious particles	Ante room, complete containment maintained at absolute negative pressure (HVAC System Negative Airflow)

Infrastructure

The laboratory design layout, equipment and infrastructure all combined must support safety of laboratory personnel and the environment. The workflow in the laboratory should move from spaces designated for less infectious tasks to highly infectious tasks based on risk assessment.

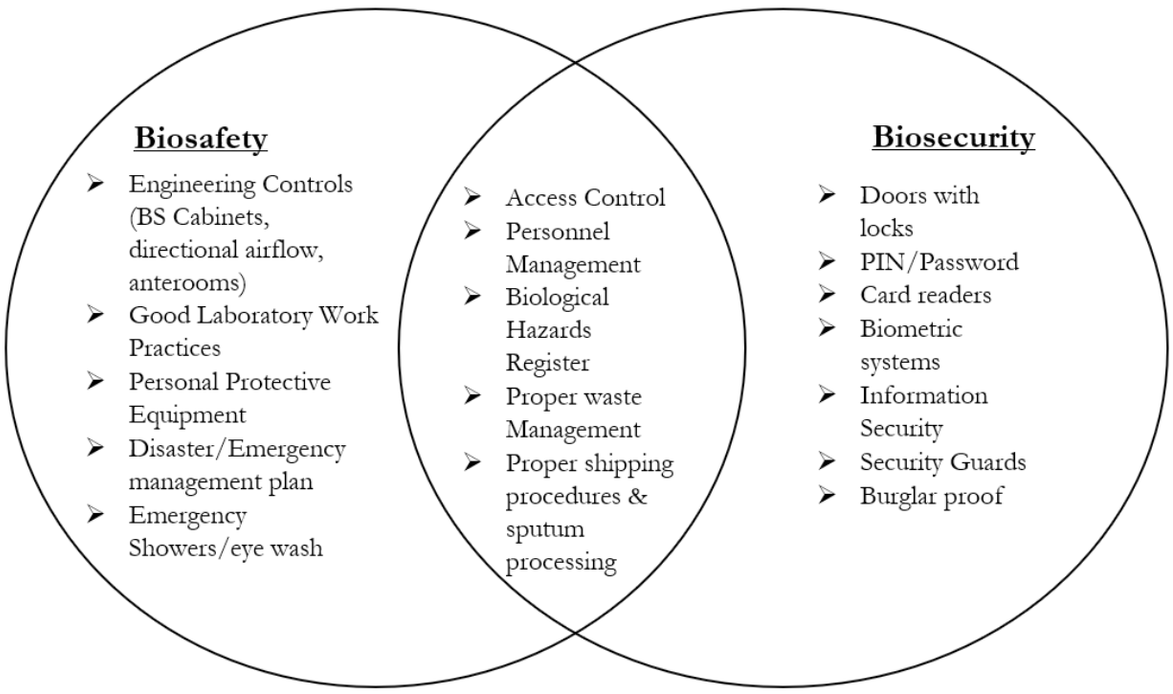
10 Guidelines for TB Infection Prevention and Control 2021

WHO has adopted an approach that assesses the risks associated with different technical procedures performed in different types of TB laboratory. The biosafety manual[11] describes the minimum requirements for facilities and the safe working practices that can be adopted following a risk assessment. Additionally, laboratory personnel must be trained on safe use of laboratory infrastructure and equipment including conducting competency assessment to ensure full understanding of safety procedures.

Biosafety and Biosecurity

The laboratory shall establish and maintain a mechanism to apply available knowledge, skills, techniques, expertise and equipment to prevent potential exposure of personnel, clients and the environment to infectious agents or biohazards from and within the laboratory. The containment conditions under which laboratory workers can safely manipulate infectious agents has been extensively highlighted in the Laboratory Biosafety and Biosecurity Guideline and shall be the reference point for risk assessment and management . The containment measures shall cover the fourteen core elements of Biosafety and Biosecurity as recommended by the World Health Organization (WHO)[12].

Figure 5: Core Elements of Laboratory Biosafety and Biosecurity



Infection Prevention and Control (IPC)

The probable risk of laboratory acquired infection poses adverse effects in healthcare, a major problem in public health and impacts morbidity, mortality and quality of life. In all TB diagnostic Laboratories, there is a risk of occurrence and spread of infection and the management should

11 National Policy Guidelines for Medical Laboratory Physical Infrastructure 2015
12 Laboratory Biosafety and Biosecurity Policy Guidelines for Kenya

establish and maintain infection prevention and control measures. Infection prevention and control (IPC) is a critical component of a laboratory quality management system as it primarily focuses on decreasing the risk of TB infection and transmission, in a health care setting.

Every facility shall establish an IPC committee that has representation from the laboratory, clinical areas and administration and must be actively meeting to review risk gaps including proactively addressing these gaps.

Key responsibilities of the laboratory management and by extension the Lab safety Officer;

Task	Rationale
Facility Safety Programme	Provides overall guidance in managing safety practices
IPC Committee	Provides the laboratory management with a central coordinating unit for the safety program
Personal Protective Equipment	Ensures that HCWs are provided with appropriate PPEs when on duty e.g., respirators when performing any aerosol-generating procedures associated with pathogen transmission
Post Exposure Prophylaxis Procedure[13]	Enable medical evaluation of laboratory staff as part of TB disease surveillance, prevention and treatment
Waste Management Plan	Provides a guide on the segregation, decontamination, transportation and disposal of hazardous waste
Emergency Contact details	Provides the laboratory staff with the go-to person in the event of emergency incidents
Safety Training and Orientation	Builds staff capacity to identify and handle safety concerns that in the laboratory, job specific training to lab staff on safety, safety plan orientation to staff and visitors facilitates structured response to emergencies involving non-lab personnel
Safety Audit & Risk Assessment	Enables the laboratory personnel to recognize and identify risk scenarios for all the operations

Waste Management

Laboratory waste has a hazard risk to the lab personnel, community and environment. Core biosafety/biosecurity guidelines and requirements for the handling of TB contaminated waste material require that processes for the identification and segregation of contaminated materials be adopted before decontamination and/or disposal. The lab therefore, shall establish a waste management plan and SOPs to address all these processes. To minimize risk of exposure lab waste should be decontaminated onsite, however Laboratories without the capacity to perform waste decontamination and disposal should have an approved waste management plan.

Emergency Management

Safety and security considerations of the lab shall be incorporated into the incident and emergency response plans, investigation of incidents and implementation of corrective actions. The emergency management protocol should detail how reports on incidents or suspicious

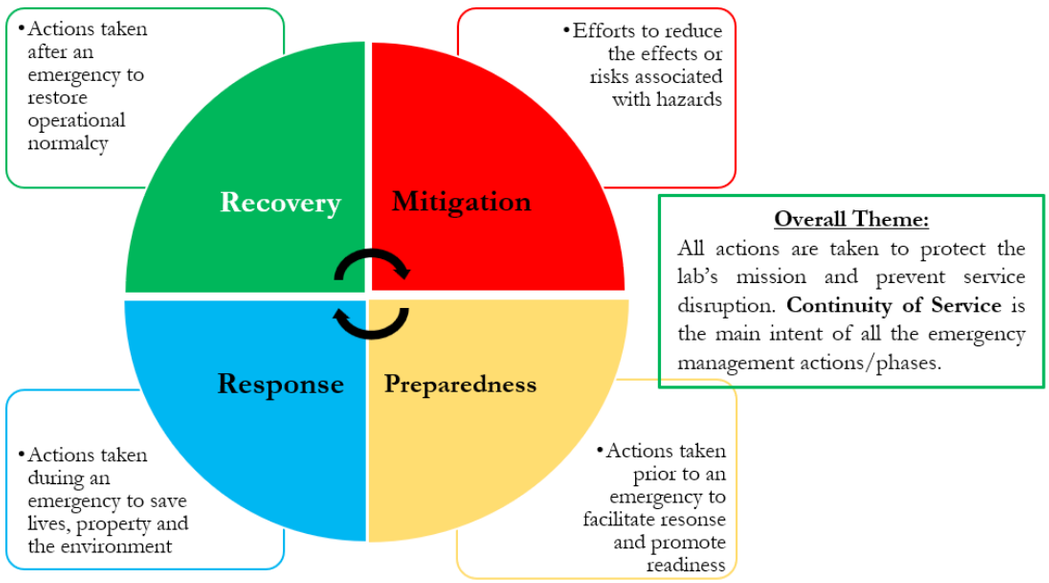
13 NTP LTBI Guidelines

activities shall be established and disseminated to staff and visitors.

The lab shall establish and maintain an up-to-date Safety Data Sheet (SDS) listing its potential hazards and precautionary measures, this should be used to identify these categories of hazards;

- Physical hazards – electricals, fire, infrastructure status, radiation.
- Biological hazards – microorganisms / aerosols, culture media, reagents.

Figure 6: Emergency Preparedness and Management Pathway



10

EQUIPMENT MANAGEMENT

Overview

Proper management of the equipment in the laboratory is necessary to ensure accurate, reliable and timely testing. To ensure uninterrupted service delivery, the national and county governments shall establish a sustainable equipment management plan to ensure that TB diagnostic equipment and associated devices used in the lab are maintained in a functional state.

Maintenance Program

The National, County, partners and stakeholders in laboratory management shall monitor the implementation of a sustainable equipment maintenance program to assure the quality of TB laboratory diagnostic services in Kenya.

The laboratory shall achieve this through engagement with partners to;

i. Establish a routine maintenance plan

ii. Establish Service Level Agreements for key diagnostic equipment with suppliers/ vendors

iii. Ensure routine calibration, servicing and repairs for relevant TB diagnostic laboratory infrastructure is done. The laboratory shall have a documented procedure for the calibration of equipment that directly or indirectly affects examination results taking into account conditions of use and the manufacturer's instructions and guidance.

Maintenance Documentation

As part of the quality management documentation, a laboratory shall establish procedures for equipment maintenance and maintain documentation and records of the maintenance program. Laboratory staff shall report all adverse incidents and accidents that are attributed to specific equipment to the manufacturer and appropriate authorities, as required This will enable thorough evaluation of any problems that arise during equipment use.

Each equipment will have specific maintenance logs uniquely designed as per its use taking into consideration the main parameters that need checking and maintenance such as;

- Name of the facility
- Name of the equipment
- Maintenance dates
- Reportable parameter
- Serial number
- Equipment unique identifier
- Personnel doing maintenance
- Frequency and type of maintenance e.g., daily, weekly, monthly

Equipment Inventory and Management

The laboratory should keep an inventory log of all equipment in the laboratory. The log should be updated with information on new equipment and include documentation of when equipment is retired. For each piece of equipment, the equipment inventory log should contain these key identifiers;

- Equipment name
- Model of the equipment
- Serial number of the equipment
- Name of the manufacturer
- Equipment Inventory number
- Location of the equipment in the lab
- Date received
- Date put in service
- Condition of the equipment when received
- Supplier contact person
- Lab developed unique identifier
- Date the equipment was serviced
- Next service due date
- Maintenance service provider
- Date of equipment decommissioning / retirement.

To facilitate continued services and ensure that the laboratory does not run out of replacement parts, the equipment inventory should be accompanied with an inventory record of most frequently used parts for each equipment. This record should on the minimum include;

- Part name and number
- Average use of the part, and the minimum to keep on hand
- Cost of acquisition
- Date when the part is placed into storage and when it is used (in and out stock log)
- Quantity of each part remaining in inventory.

11

COMMODITIES AND SUPPLY CHAIN MANAGEMENT

Overview

Availability and quality of laboratory commodities play a key role in determining the provision of diagnostic services. The laboratory shall establish processes for the selection, procurement, reception, storage, acceptance testing and inventory management of all commodities. Proper management of commodities inventory not only enables a laboratory to provide uninterrupted services to its clients but also helps in preventing expiration loses that result from improper storage and handling of commodities.

Laboratory Inventory Management System

As a core element of the quality management system, the laboratory shall establish and maintain a commodity purchasing and inventory management system with accompanying policies and procedures to enable it manage laboratory supplies in either electronic or paper-based formats, or both. Key components of a robust supply chain management system should address procedures;

- Tor vendor/manufacturer qualifications verification/assessment
- To manage/handle purchase agreements
- To manage commodity reception, inspection, testing, storage, and handling of materials—all purchased material should be inspected and appropriately tested to ensure that specifications are met, and guidance should be established for storing and handling materials as they are delivered to the laboratory
- For tracking materials to individual clients—the management system must allow for tracking materials to individual clients; that is, the laboratory should be able to identify specific test materials used for performing tests on any given day, so that if there is a problem with a patient result, the laboratory will know what reagents were used
- For assessing and maintaining supplies inventory
- For the management of commodity expiration periods
- For dissemination and dispatch supplies to peripheral laboratories

Quantification and Forecasting

The laboratory shall establish a mechanism to quantify and forecast inventory needs for optimum service delivery;

- Forecasting and quantification of laboratory diagnostic commodities shall be conducted at a frequency that enables the laboratory to determine annual commodity requirements with adequate review periods to cater for emerging needs within the year.

Commodity Management Logs

The laboratory shall develop appropriate recording and reporting tools to support the management of the supply chain inventory, some of the key tools for consideration are;

- Standardized log books/forms
- Inventory/bin cards
- Facility consumption data report and request forms (FCDRR)
- Electronic enterprise resource planning systems where possible

Whether a laboratory establishes a manual or electronic platform, the management system should on the minimum provide the following key details for each commodity/item;

- Date commodity or set of supplies are received
- Commodity lot numbers
- Pass or fail acceptance criteria
- Date the lot number or box of supplies was put into service or, if not usable, the date and method of disposition
- Reason for commodity disposition if not in use

Inventory Monitoring

The laboratory shall establish an inventory monitoring system that provides information on the following elements:

- Commodities in the supply chain pipeline
- Deliveries
- Monthly consumptions
- Current stock status
- Stock outs and expiries

General guidance on inventory monitoring can be obtained from various sources, Laboratory quality standard documents like ISO 15189 series, Ministry of Health Guidelines[14] on procurement of health products and technologies.

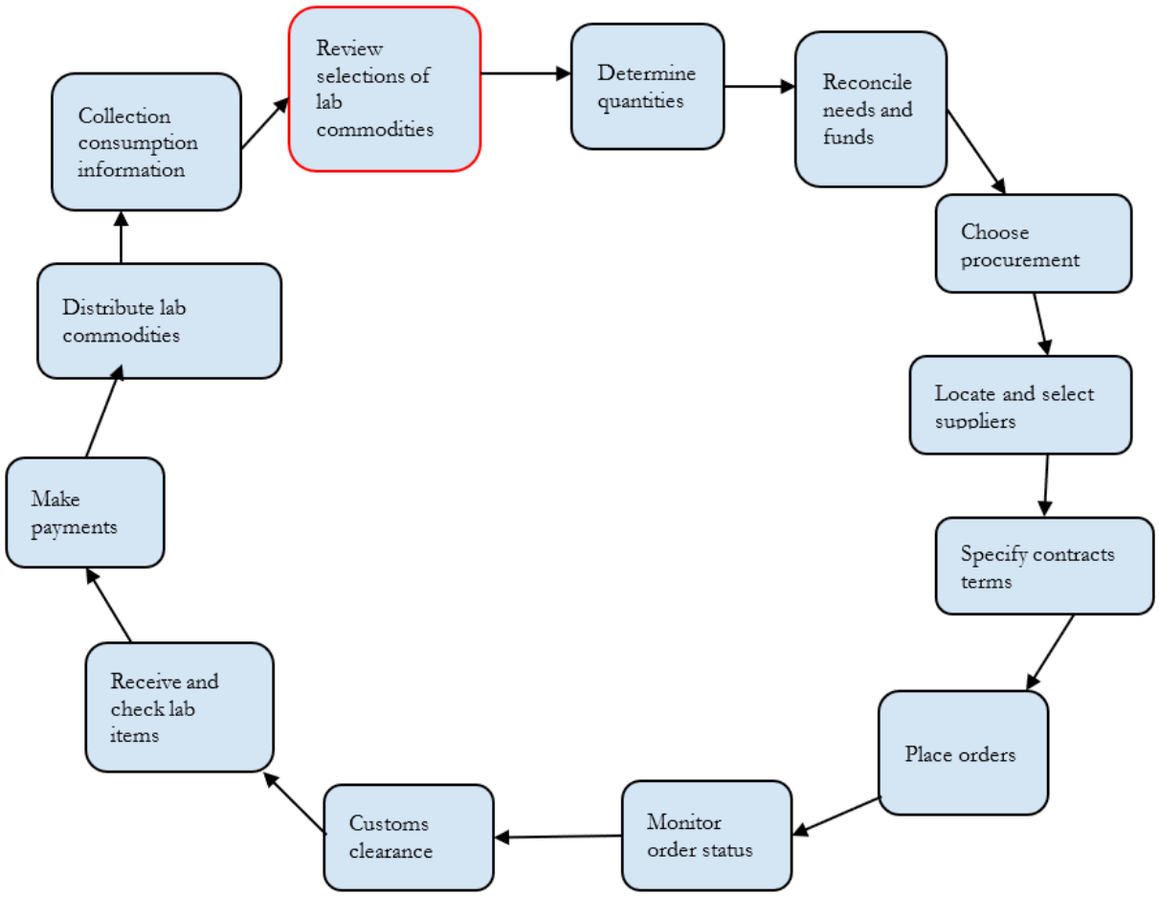
- Remote monitoring systems can facilitate inventory management, by allowing stocks to be entered at site-level and forecasting the anticipated stock-out date or potential expiring commodities based on the consumption rate using the LIMS system.

14 MoH Health Products and Technologies Supply Chain Strategy 2020-2025

Disposal of Expired and Unusable Commodities

The lab shall develop SOPs to guide the disposal of expired and unusable commodities, which should be disposed of promptly and removed from stock-keeping records.

Figure 7: TB Laboratory Commodities Procurement pathway



Commodities Reception

The laboratory shall establish and maintain procedures to provide guidance in the reception of commodities. All supplies and reagents shall be inspected as they arrive in the laboratory to be sure that they are in good condition and to verify that what is received is what was ordered. These procedures shall provide information regarding;

- The person receiving/verifying the commodities.
- Date each item is received.
- Note on expiration date.
- Commodity stock/bin card generation/record updates.

To ensure the quality of supplies, a quality check on the supplies shall be put in place to verify the LOT to LOT on new batches of supplies before use or distribution.

Commodity Storage

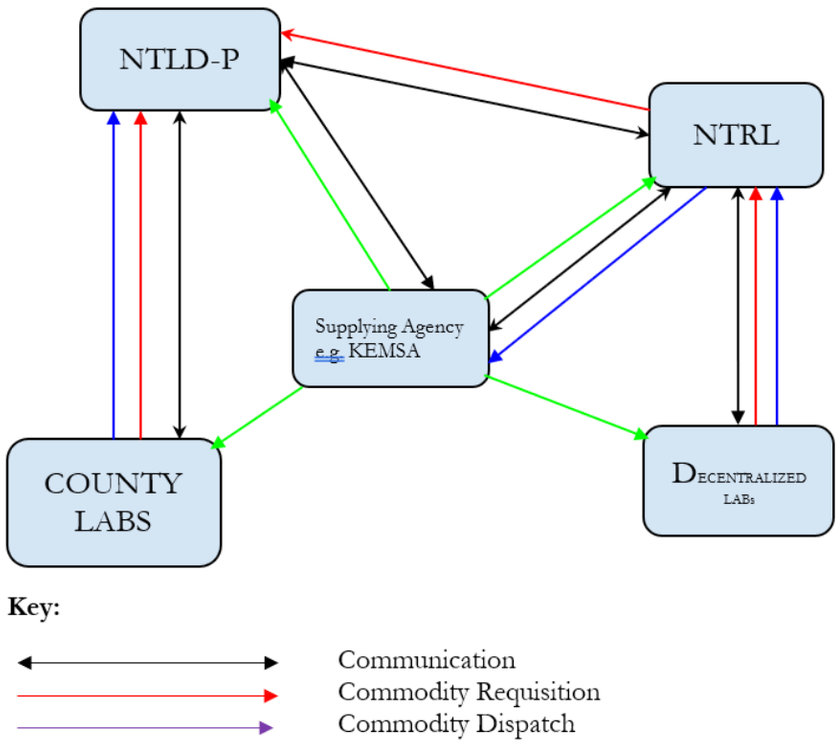
Storage of commodities is a very important part of inventory control. The laboratory shall establish appropriate storage SOPs in keeping with the respective manufacturer's instruction for each commodity. Some key recommended practices for consideration are;

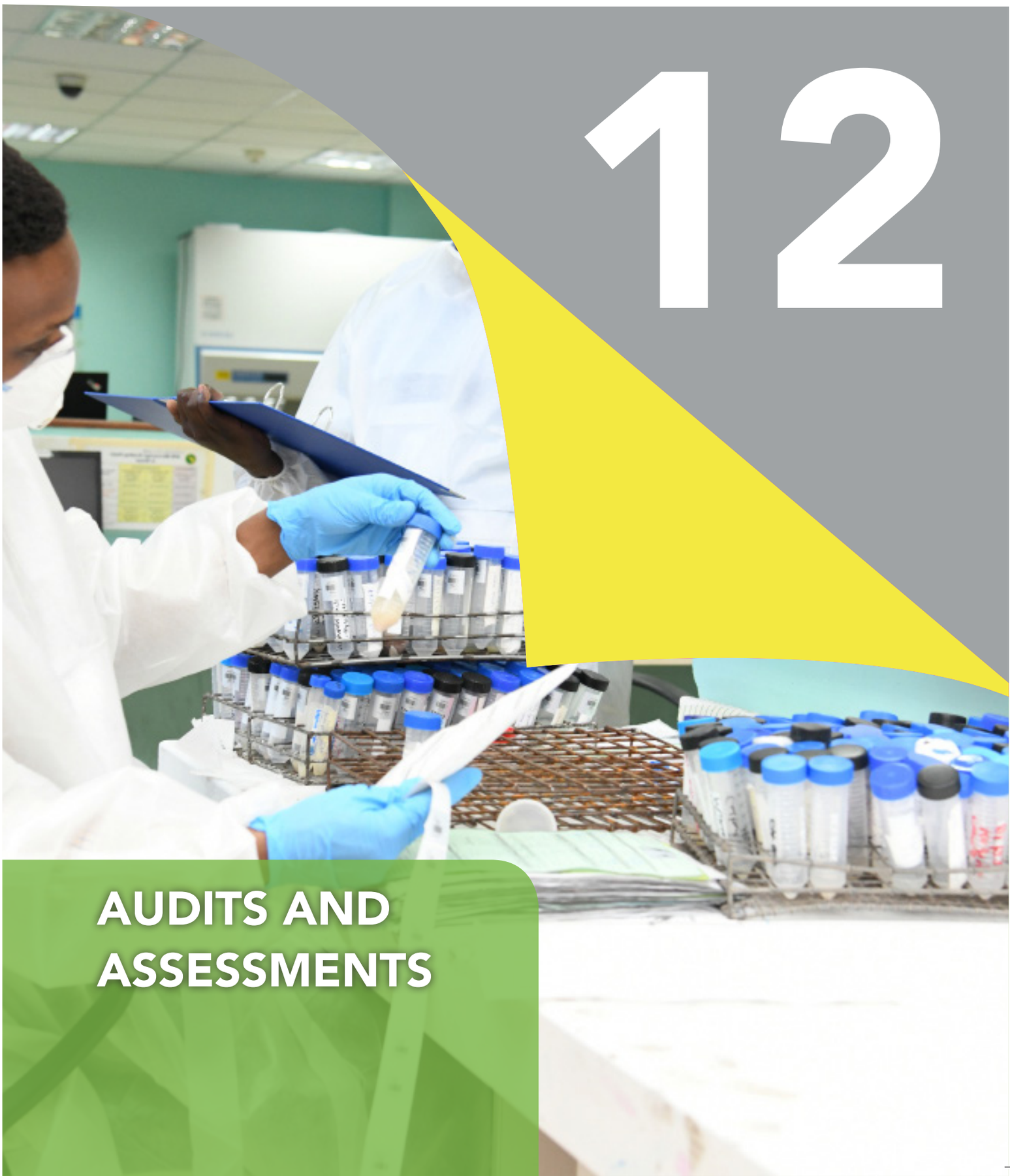
- Availability of appropriate storage and inventory spaces – designed to accommodate various commodity types.
- Commodities storage should be in accordance with the manufacturer's instructions, paying particular attention to any temperature requirements or other specifications, such as safety requirements.
- Use of appropriate supporting structures e.g., sturdy shelving for all categories of commodity weights.
- Appropriate storage practices to enable access and use.

Reporting and accessing of laboratory commodities

- All TB testing facilities shall be required to report commodity consumption through DHIS2 tool (FCDRR/MOH-643).
- County aggregate monthly consumption shall be reported using CDRR form (DHIS2).
- All commodity requisition shall be done at facility level.
- The lab shall be required to do commodity order validation before sending to the respective supplying agency/entity.

Figure 8: Lab Commodities and Information Flow Pathway





12

AUDITS AND ASSESSMENTS

Overview

The performance of internal and external audits and assessments provides an opportunity to determine the effectiveness of a laboratory's quality management system. Audit/assessment is not only a measure of performance appraisal but also a system strengthening mechanism for a laboratory's QMS and remains a core element of the quality system essentials. Assessment generally follows a systematic approach to the examination of some part (or sometimes all) of the quality management system to demonstrate to all concerned that the laboratory is meeting regulatory, accreditation and customer requirements.

Management of Audits and Assessments

The National and county laboratory management shall establish and maintain a mechanism to conduct;

1. Internal audits
2. External audits

Internal audit is also referred to as first party audits and are conducted by, or on behalf of, the laboratory itself. This means that the laboratory can through its trained auditors conduct the audit or invite qualified auditors form another organization to carry out the audit on their behalf.

External audit on the other hand includes those referred to as second- or third-party audits. Second party audits are conducted by parties having interest in the laboratories such as collaborators and customers. Third party audits are conducted by independent auditing organizations, such as those providing accreditation.

Audits should be done in line with the principles outlined in ISO 19011:2018 which include integrity, fair presentation, due professional care, confidentiality, independence, evidence-based approach and risk-based approach. Laboratories shall develop internal audit procedures and establish an audit plan to include the following key aspects

a. Objectives for the audit program
b. Calendar of activities
c. Risks and opportunities associated with the audit program
d. Scope (extent, boundaries, locations) of each audit within the audit program
e. Audit types (such as internal or external)
f. Audit criteria
g. Audit method to be employed
h. Criteria for selecting audit team
i. Audit reports – observations and non-conformance
j. Root Cause Analysis procedures
k. Corrective action procedures and timelines

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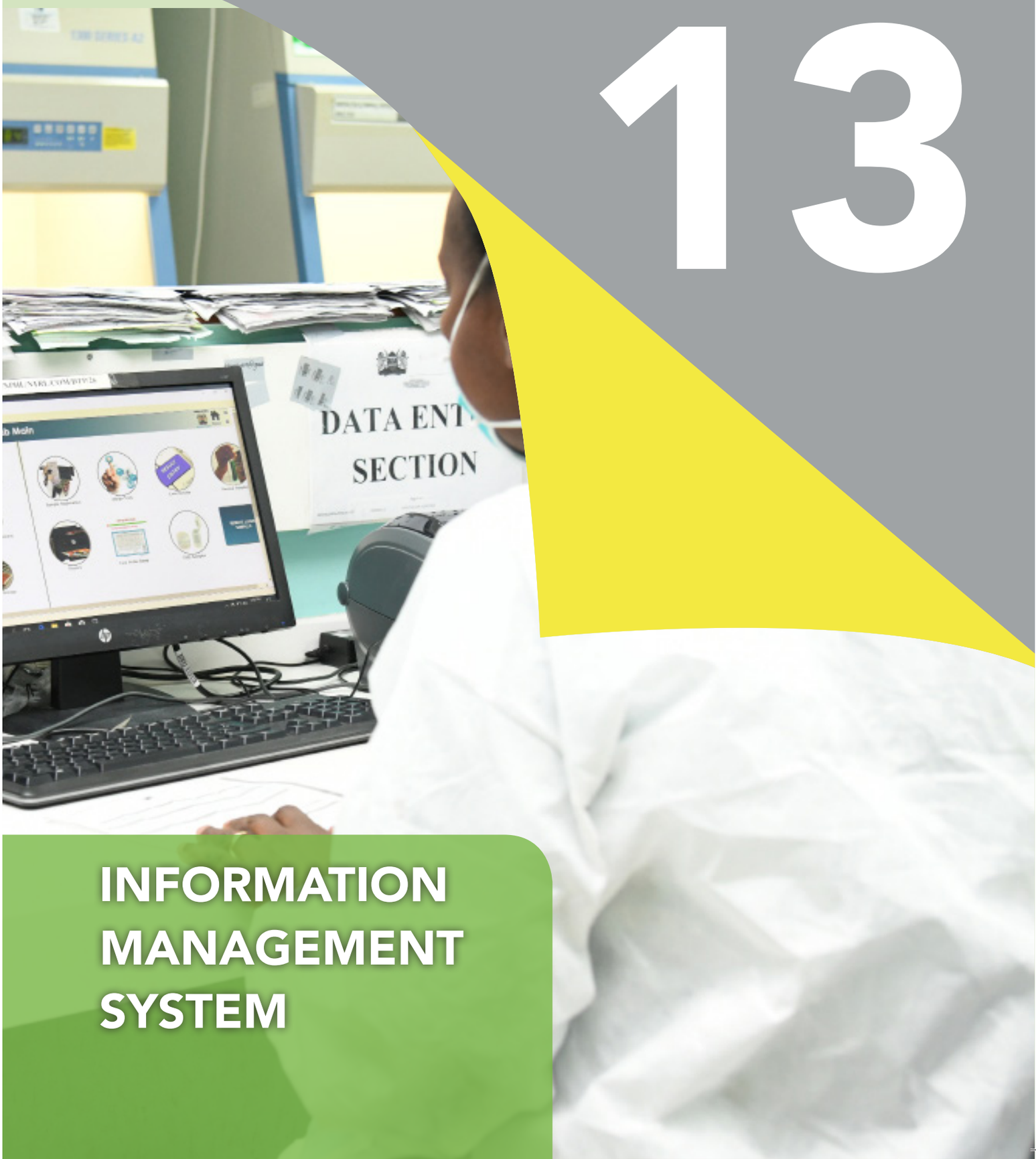


INFORMATION MANAGEMENT SYSTEM

Overview

Information management is a system that incorporates all the processes needed for effectively managing data, this being both incoming and outgoing client information[8]. The laboratory generates valuable data from various TB testing platforms, it's therefore, necessary for a laboratory to describe the processes of data capture and management during handling or processing of specimens received in the laboratory. This is key in maintaining confidentiality in the cascade of care and a good chain of custody of all laboratory generated results, archival and retrieval when the need arises.

Laboratory Responsibility

The laboratory shall establish and maintain an information management system and purpose to have it known and understood by all lab personnel, whether an entirely paper-based, computer-based, or a combination of both. Whichever mechanism that is employed, the information management system shall be in line with the laboratory's documents and records management principles. Some of the key elements the adopted information management system should address are;

- Procedures involved in Laboratory Data Management.
- Sample reception and logging.
- Results authorization and release of reports.
- Priority results dispatch procedure.
- Alternate results receiving officer.
- Results amendment procedure.

Some key elements of an efficient and effective information management system for consideration are[4];

- Ability to provide unique identifiers for patients and samples.
- Availability of standardized test request forms (requisitions).
- Availability of standardized logs and worksheets.
- Ability to check the laboratory processes to assure accuracy of data recording and transmission.
- Ability to provide protection against loss of data.
- Protection of patient data for confidentiality and privacy.
- Availability of effective reporting systems.
- Provisions for effective and timely communication.

Laboratory Information Management System

Where an electronic LIMS is adopted, the laboratory shall ensure that the system;

- As validated and licensed for use
- Allows flexibility, adaptability, interoperability, ease of evolution, off-site technical support and system speed

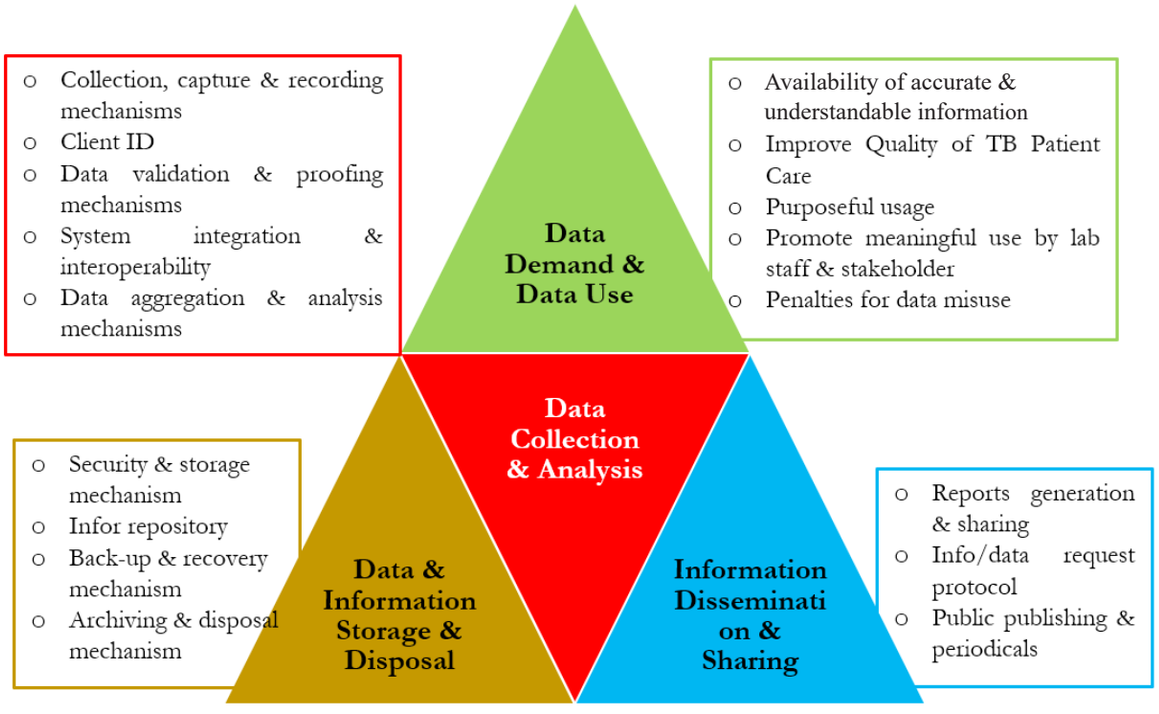
Enables the control and traceability of personnel logging-in accessing the laboratory information.

Where manual/paper-based system is used, the lab shall ensure that it addresses the components of inputs, processing, storage and reporting of information. This will include use of test request form, TB registers, logs and worksheets and test report forms. The laboratory shall ensure that these key features are properly addressed and standardized for ease of utilization.

Archiving and disposal of records shall be guided by MoH and accompanying data regulations in Kenya[15,16].

The information management framework below provides key elements that the TB lab should focus on when establishing the LMIS.

Figure 9: Guide to Information System Design



[15] The Health Records and Information Managers Act No. 15 Of 2016
[16] Kenya Health Information System Policy 2013

14

MONITORING AND EVALAUTION

Overview

The laboratory quality management framework shall be systematically and objectively observed to gather information on its implementation in TB diagnostic laboratories on all aspects of the framework. This will enable the respective laboratory management and NTRL to identify and resolve problems and gaps in operational performance that may hinder the provision of quality TB Laboratory diagnostic services.

Monitoring the TB Labs NQMF Implementation

The laboratory management shall contextualize the technical/operational level of the respective laboratory and focus monitoring and evaluation activities on the key NQMF that is relevant for the laboratory. The management should select the activities and indicators to monitor based on the laboratory's scope of TB diagnostic platforms, level of priority or importance and capacity to monitor.

To ensure progress towards achieving the quality objective and reliability in TB laboratory diagnostic in the country, this monitoring and evaluation framework shall enable constant tracking of the implementation process. To support implementation, the NTRL being the national oversight entity together with partners and stakeholders shall;

i. Develop an assessment criteria and checklist for TB Diagnostic laboratories
ii. Establish a coordinating mechanism involving all parties involved in TB Lab diagnostic
iii. Develop a capacity building plan to enable NQMF implementation across the TB Lab network
iv. Develop a sustainable implementation plan integrated with the relevant laboratory system strengthening approaches in place in the respective units
v. Develop an evaluation criterion for the implementation of this NQMF for TB Lab

Selecting the entire indicator pack in the M&E matrix beyond the laboratory's scope or too many activities will detract the team from problem identification and system strengthening which can make the entire process counterproductive. To effectively monitor and evaluate the NQMF, the laboratory should categorize and focus on performance indicators through logic framework below;

Table 4: TB NQMF Implementation Logic Framework

Approach	Input	Process	Output	Outcome
Structural	1. Policies, Guidelines, Manuals, SOPs 2. Personnel 3. Finance 4. Equipment 5. Commodities 6. Infrastructure – Software/ Hardware	1. Implementation 2. Recruitment & Capacity Building 3. Resource mobilization 4. Equipment management 5. Inventory management 6. Infrastructure management	1. Operational efficiency 2. Availability of competent staff 3. Resource optimization 4. Equipment efficiency 5. Commodity availability 6. Facility safety	1. Reliable diagnostic services 2. Responsive human resource 3. Reduction in resource waste
Indicators	Defined System Quality Elements – 12 QMS components	1. Quality Control 2. Continuous Quality Improvement	1. Quality conformance rates 2. Number of CQI initiatives implemented	Performance measurement of the Laboratory Quality Management Framework
Data Sources	1. Administrative Sources • Management Reports, Databases, Inventory Reports, Equipment Management Inventory 2. Operational Reports • Laboratory Assessments/Audits • Laboratory Capacity assessment • Laboratory Information Management System / KHIS2 / TiBU			
Knowledge Manage-ment	1. Analysis and synthesis of data through; DQA and implementation progress reports. 2. Communication and Feedback through; Routine management review meetings, stakeholder forums and laboratory performance dashboards			

The NQMF M&E indicators are drawn from the 12 QSE as illustrated below;

Table 5: Monitoring and Evaluation Matrix for the Laboratory Quality Management Framework

Thematic area	Indicator	Indicator Description	Source Documents	Frequency	Responsibility/Level of M & E
	Proportion of counties with detailed NQMF implementation workplan	Number of counties with implementation work plans for NQMF/ Total number of counties x 100	• Workplan for the implementation	Annually	National
NQMF Implementation	Proportion of staff trained on QMF	Number of lab staff trained/total number of lab staff * 100	• Training Reports • Staff returns • HRH documents	Biennial	National County Sub county Laboratory
	Number of participants who attended QMF CMEs/ training sessions done	Number of participants who attended sessions done	• Attendance logs/ Forms	Quarterly	National County Sub County Facility
	Proportion labs with TB NQMF integrated with other QI programs in the health facility	Number of labs with TB NQMF integrated with other QI programs within the health facility / Total number of TB labs * 100	• QI/QMS action plans, • Minutes, • QI/QMS attendance forms • Action plans	Annual	National County Sub county Laboratory and health facility
	Proportion of QI projects/activities recommended and implemented	Number of projects activities implemented / Number of projects/activities recommended * 100	• Minutes • Action plans • Reports	Quarterly	National County Sub county Laboratory
Documents and records	Proportion of TB testing labs with SOPS for all TB tests offered	Number of SOPs available / Number of TB testing platforms available * 100	• SOP master list Service charter (TB test menu)	Annual	National County Sub county Laboratory
	Proportion of bare**(as defined in chapter 4) minimum policies and guidelines available in the TB lab (by lab level)	Number of policies and guidelines available / Number of expected policies and guidelines by lab level	ISO standards Master SOP list Guideline documents Policy documents	Annual	Laboratory level
Management review and management responsibilities	Proportion of labs that routinely review their technical and operational performance	Number of labs that reviewed their performance / Total number of TB labs * 100	Management review meetings (MRM) agenda Minutes MRM reports	Annually	National County Sub county Laboratory

Thematic area	Indicator	Indicator Description	Source Documents	Frequency	Responsibility/Level of M & E
	Proportion of management review meetings conducted with presence of top facility management	Number of labs that conducted MRMs with attendance of top facility management/ Total number of TB labs * 100	Management review report/minutes	Annual	National County Sub county Laboratory
	Proportion of recommendations implemented within the defined timelines	Number of recommendations implemented / Number of recommendations made * 100	Management review report Minutes Action plans	Annual	National County Sub county Laboratory
Organization and personnel	Level (Proportion) of staffing for the lab by level of service per MoH recommendations	Number of existing lab staff / Number of Recommended number of lab staff by level * 100	Staff records, personnel files MoH staffing recommendations	Annually	National County Sub county Laboratory
	Proportion of lab personnel with competency assessment and performance appraisal records	Proportion of lab staff appraised/Number of lab staff * 100	Staff records Appraisal forms	Annually	National County Sub county Laboratory
	Availability of an organogram that links the lab to parent organization and authorization matrix	Presence or absence of organogram	Organogram	Annual	Laboratory
	Proportion of labs with an updated staff training/capacity building plan	Number of labs updated staff training/ capacity building plan / Total number of TB labs * 100	Training needs assessment, training plan SOP on staff training or equivalent documents	Annual	National County Sub county Laboratory
Client management and customer service	Proportion of labs with a client management service information package	Labs with a client management service information package / Total number of TB labs * 100	Service charter, clinician handbook or other customer information packages	Annual	National County Sub county Laboratory
	Proportion of labs with a grievance / complains / issues solving mechanism	Presence of a grievance / complains / issues solving mechanism	Grievance/Complains register Complains resolution logbook	Annual	National County Sub county Laboratory
	Proportion of resolved issues	Number of issues resolved / Total number of issues raised * 100	Grievance/Complains register Complains resolution logbook	Quarterly	National County Sub county Laboratory
	Duration of service downtime in days	Date down time resolved – Date of service downtime	Communications register, Software downtown register Service interruption forms or equivalents documents	Quarterly	National County Sub county Laboratory

Thematic area	Indicator	Indicator Description	Source Documents	Frequency	Responsibility/Level of M & E
	Proportion of service downtime communicated to the relevant customers/ clients	Number of service downtimes communicated to the relevant customers/ clients / Total number of service downtimes	Communications register, Software downtown register, service interruption forms or equivalents documents	Quarterly	National County Sub county Laboratory
Equipment Management	Proportion of equipment with preventive/routine maintenance schedule	Number of equipment with preventive/routine maintenance schedule / Total number of equipment * 100	Inventory, Maintenance logs	Annually	National County Sub county Laboratory
	Proportion of equipment with calibration/service contracts/ certification maintenance schedule	Number of equipment with up-to date calibration/service contracts/ certification maintenance schedule / Number of equipment in the TB lab * 100	SLAs Calibration logs Calibration stickers Certification maintenance schedule Maintenance logs Equipment book of life	Depending on manufacturers standards or GCLP	National County Sub county Laboratory
	Proportion of equipment with calibrated/serviced/ done per schedule	Number of equipment with calibrated/serviced /certified per schedule / Number of equipment with calibration/service contracts/ certification maintenance schedule * 100	Service reported SLAs Calibration logs Calibration stickers Certification maintenance schedule Maintenance logs Equipment book of life	Annually	National County Sub county Laboratory
Assessment and Audits	Proportion of labs with SOPs on internal audits (IA) and external audit	Number of labs with SOPS on internal and external audits / Total number of TB labs	Master SOP list IQA & EQA SOPs	Annually	National County Sub county Laboratory
	Proportion of labs with risk assessment tool	Number of labs with risk assessment tool / Total number of TB labs * 100	Risk assessment tool	Annually	National County Sub county Laboratory
	Proportion of labs with risk assessment SOP	Number of labs with risk assessment SOP / Total number of TB labs * 100	Master SOP Risk assessment SOP	Annually	National County Sub county Laboratory
	Proportion of recommendations implemented	Number of recommendations implemented / Total number of recommendations made * 100	Risk assessment report IQA & EQA, CAPA reports	Annual	National County Sub county Laboratory

Thematic area	Indicator	Indicator Description	Source Documents	Frequency	Responsibility/Level of M & E
Purchasing and inventory	Proportion of labs with purchasing and commodity inventory SOP	Number of labs with purchasing and commodity inventory SOP / Total number of TB labs * 100	Master SOP SOP for purchasing and commodity inventory SOP	Biannual	National County Sub county Laboratory
	Proportion of reporting TB laboratories	Number of reporting TB laboratories / Total number of TB laboratories * 100	DHIS reports	Monthly	National County Sub county Laboratory
	Duration of stock outs (by lab commodity) in months	Months of stock outs	Bin/Stock cards TIBU LIMS (MTB RIF assays)	Annual	National County Sub county Laboratory
Process Control	Proportion of laboratories with Process Control Procedures (PCP)	Number of TB labs with PCP/Total number of labs * 100	SOPs on process control Quality Manuals	Annually	National County Sub county Laboratory
	Proportion of TB labs enrolled for EQA	Number of labs enrolled for EQA/ Total number of TB labs * 100	Microscopy workbook, TIBU LIMS EQA feedback reports	Quarterly	National County Sub county Laboratory
	Proportion of TB labs performing IQC for all TB lab diagnostic tests	Number of labs performing IQC all TB lab diagnostic tests / Total number of TB labs * 100	IQC records by testing method	Per the SOP depending on test	National County Sub county
Process Improvement	Proportion of TB labs with a CQI framework	Number of TB labs with a CQI framework / Total number of TB labs * 100	CQI Framework/Guide	Annually	National County Sub county Laboratory
	Proportion of Laboratories with Quality Improvement Plans (QIPs)	Number of TB labs with a QIPs / Total number of TB labs * 100	Quality Improvement Plans, CQI Schedule of Activities	Quarterly	National County Sub county Laboratory
	Proportion of QI recommendations implemented	Number of recommendations implemented / Number recommendations made * 100	Quality Improvement Plans, CQI Schedule of Activities CQI reports or equivalent documents	Quarterly	National County Sub county Laboratory
	Proportion of lab results released within the recommended TaT (by lab results)	Results released within the recommended time / Total number of results	TAT indicator tracking log TB lab register NTRL service charter Sample tracking log	Quarterly	National County Sub county Laboratory

Thematic area	Indicator	Indicator Description	Source Documents	Frequency	Responsibility/Level of M & E
Information Management	Proportion of labs with recording tools	Number of labs with recording tools / Total number of TB labs	Lab request forms Lab registers Sample tracking logs	Annually	National County Sub county Laboratory
	Proportion of labs with reporting tools	Number of labs with reporting tools / Total number of TB labs	MOH 706 MOH 643	Annually	National County Sub county Laboratory
	Proportion of labs with timely reporting	Number of labs reporting in a timely manner / Total number of TB labs * 100	DHIS reports TIBU LMIS reports/ dashboard	Annually	National County Sub county
Occurrence/Risk management	Proportion of labs with mechanisms for managing occurrences and incidences	Number of lab with mechanisms of managing occurrences and incidence/Total number of TB labs * 100	Occurrence (risk) management register	Quarterly	National County Sub county Laboratory
	Proportion of occurrences resolved	Number of occurrences resolved / Number of occurrences raised * 100	Occurrence management register	Quarterly	Laboratory
Facilities, safety and infrastructure	Proportion of labs with infrastructural layout	Number of labs with a layout / Total number of TB labs * 100	Infrastructural layout	Annually	National County Sub county Laboratory
	Proportion of labs with emergency exits	Number of labs with E/ exits/Total Number of TB Labs * 100	Infrastructural layout	Annually	National County Sub county Laboratory
	Proportion of labs with Service area workflows	Number of labs with a service area workflows / Total number of TB labs * 100	Service area workflows Presence of a patient care and testing area	Annually	National County Sub county Laboratory
	Proportion of labs with Laboratory access management	Number of labs with access management / Total number of TB labs	Access logs Restrictions of access Lockable access restrictions or equivalents	Quarterly	National County Sub county Laboratory
	Proportion of labs with a fire safety SOP	Number of labs with a fire safety SOP / Total number of TB labs * 100	Up to date Fire safety SOP	Biannually	National County Sub county Laboratory
	Proportion of labs with Emergency management and safety equipment (by level)	Number of labs with Emergency management and safety equipment / Total number of TB labs * 100	Equipment inventory Safety equipment maintenance logs Emergency and safety equipment checklist	Annually	National County Sub county Laboratory

Thematic area	Indicator	Indicator Description	Source Documents	Frequency	Responsibility/Level of M & E
	Proportion of labs with Personal protective Equipment for personnel and visitors (by level of the lab)	Number of labs with Personal protective Equipment for personnel and visitors / Total number of TB labs * 100	Stock cards	Quarterly	National County Sub county Laboratory
	Proportion of labs conducting Laboratory Medical surveillance and vaccination for lab staff	Number of labs with Laboratory Medical surveillance and vaccination for lab staff / Total number of TB labs * 100	National County Sub county Laboratory	Annual	National County Sub county Laboratory
	Proportion of staff with up-to date medical screening (including TB screening using CXR) and vaccination	Number of lab staff with up-to date medical screening and vaccination / Total number of lab staff * 100	National County Sub county Laboratory	Annual	National County Sub county Laboratory
	Proportion of lab staff trained on Laboratory Biosafety and Biosecurity	Number of lab staff trained on Laboratory Biosafety and Biosecurity / Total number of TB labs * 100	Biosafety training logs/ Attendance forms Verification forms (Certificates) in file	Annual	National County Sub county Laboratory
	Proportion of labs Laboratory/Facility with IPC committee	Number of labs with a functional IPC committee in the health facility/laboratory / Total number of TB labs * 100	IPC plans Minutes of the IPC committee	Annual	National County Sub county Laboratory
	Proportion of IPC recommendations implemented	Number of IPC recommendations implemented / Total recommendations made * 100	IPC plans Minutes of the IPC committee IPC reports	Annual	National County Sub county Laboratory
	Proportion of labs with waste management SOP	Number of labs with a waste management SOP / Total number of TB labs * 100	Master SOP list Waste management SOP	Annual	National County Sub county Laboratory

15

ANNEXES

Sample Tools:

INTERNAL QUALITY CONTROL LOG FOR MICROSCOPY

AURAMINE	CARBOL FUCSIN
ACID ALCOHOL	SULPHURIC ACID
POTASSIUM PERMANGANET	METHELYNE BLUE

METHOD: _____ BATCH NO: _____

DATE	POSITIVE CONTROL	NEGATIVE CONTROL	REMARKS	TECH INITIAL

REIEWED BY: _____ DATE _____SIGN_____

Ziehl-Neelsen (ZN) Stain Quality Control

Month/ Year _____

QC Date	Carbol Fuchsin		Decolorizer		Methylene blue		QC Results		Tech Initial	Section head Review	QA Review
	Batch #	Date prepared	Batch #	Date Pre-pared	Batch #	Date Prepared	(+) Con-trol	(-) Con-trol			

**Reagents expiry date: 6 months from preparation date.*

Instructions:

1. Perform Q.C. each time of use. Do not report patient results if QC failed. Document QC failure and inform supervisor immediately

QC Failure/Corrective Action (document, date and initial): _____
_____

Reviewed by----------Sign----------
Date----------

Occurrence Report Form

DATE OF OCCURRENCE _____ DATE OF REPORT_____

TIME OF OCCURRENCE _____ Requires immediate attention by manager __ Yes __No

PERSONNEL REPORTING OCCURRENCE_____

LOCATION OF OCCURRENCE_____

BRIEF DESCRIPTION OF OCCURRENCE

_____
_____
_____
_____
_____

IMMEDIATE ACTION TAKEN (If any) _____
_____
_____
_____
_____
_____

SIGNATURE and NAME OF REVIEWER _____

DATE_____

Reviewed by_____ Date_____

AUDIT SCHEDULE

Internal Audit Coordinator (QA manager):

AUDIT SCOPE: The audit all cover all the tests at NTRL for a period of 6 months.

AUDIT CRITERIA:

1. NTRL QMS Documents
2. SLIPTA Checklist Version 2:2015. (ISO 15189:2012 Requirements)
3. Other regulatory requirements as applicable

AUDIT OBJECTIVES:

1. To review effectiveness of corrective action from previous internal audit
2. To assess compliance of the documents to ISO 15189
3. Identify areas for improvement

AUDIT METHODS:

1. Horizontal assessment
2. Vertical method
3. Witnessing

TIME TABLE/Schedule:

Auditor	Audit Areas	Proposed dates	Audit Method	Auditee	Auditor's endorsement of plan

Prepared by (QA Manager): _____ Date: _____ Sign: _____

Approved by (Lab Manager): _____ Date: _____ Sign: _____

Reviewed by: _____ Date: _____ Sign: _____

1. Plan of action following internal audit

Date internal audit:

Audited section:

Technical and Management

List per finding from the audit report one or more actions. Let the numbering of the actions correspond to the numbering of the audit report, so that it is clear that all findings were considered. Please, motivate if it is decided not to take any action following a finding.				Date discussed:				
NC No.	Finding	Root Cause (Man, Measurements, Method, Material, Mother Nature, Machine)	Action/ corrective measures	Responsible person	Deadline (Time frame)	Date + initials of completion	Effectiveness of action Yes/No	Remarks

Date and initials: _____

Plan of action completed: _____

CAPA FORM

Corrective Action	Tick		Preventive Action			Tick	
Date of Occurrence:					Date of Reporting:		
Time of Occurrence:					Extent of Non-Conformance:		
Requires immediate attention of the lab Head?	YES		NO		MAJOR	MINOR	
Location of occurrence:					Particulars (Lab ID Number)		
Problem encountered (Brief description of occurrence):							
Initiated/reported by: Date:							
Immediate actions taken (if any):							
Results withheld: Yes ☐ No ☐ Results recalled: Yes ☐ No ☐ Testing halted: Yes ☐ No ☐							
Root Cause:							
• Pre-analytical • Analytical • Post-analytical							
Signature: Date:							
Corrective /preventive Action							
Assigned to: Date: Due Date:							
Authorize Resumption of test Date: Signature							
Signature: Complete Date:							
Effectiveness of the Corrective Action: YES ☐ No ☐ Date/Sign: _____							
Signature of Reviewer/Lab Manager:					Date		

ROOTCAUSE ANALYSIS

Attendance/Participants Date:……

1.

2.

3.

4.

5.

Method Used:

Underlying Root Cause

Corrective Action Suggested

Laboratory Equipment Inventory

Effective Date: _____

Equipment Inventory Number:

Equipment Name	Model	Serial No	Manufacturer	Location	Date Received	Condition when Received	Date Put in Use	Supplier Contact Person	Unique Identifier	Date Serviced	Next Service - due	Serviced By	Date Retired
Microscope	W44580	MG0841	BD	Microbiology	02/11/2011	New	13/01/2012	Vendor	XX/XX/XX	20/04/2013	20/04/2014	Stephen	N/A

Updated By: _____ Sign:_____ Date: _____

Checked/Verified By: _____ Sign:_____ Date: _____

DX System Monthly Maintenance Log

Month/Year _____

Equipment Unique #_____Serial #_____ Location _____

Abbreviations: ENT = Equipment not in use NP = Not performed

Date	Perform Daily maintenance	Perform Weekly /monthly maintenance	Tech initials	Section Head Review (Weekly)	QA Review (Monthly)

Instructions:

Perform maintenance as scheduled. Report any instrument failure and problems to the Section head.

Document problems

Daily: Remove used cartridges and disinfect bench working area with 70% alcohol.

Weekly: Restart the GeneXpert, computer and software.

Monthly: Disinfect the cartridge bay interior, GeneXpert surfaces and plungers.

Calibration: Calibrate the modules once a year or every 2000 runs/modules, whichever comes first.

List of Contributors

Name		Organization
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NATIONAL TUBERCULOSIS, LEPROSY
AND LUNG DISEASE PROGRAM

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