NATIONAL LABORATORY QUALITY POLICY MANUAL FOR SOUTH SUDAN

NATIONAL LABORATORY QUALITY MANAGEMENT SYSTEM PROGRAMME

June 2021

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Foreword

The Republic of South Sudan has a dynamic society that needs quality policies and services that fit with their ever-expanding lifestyles. Quality health care is a basic right, not a privilege, of each and every South Sudanese citizen irrespective of social status, tribe, physical ability and geographical location. The constitutional requirements call for all stakeholders in the health sector, including medical laboratories, to establish a framework for implementing services that balance coverage, quality and safety that meet the needs of service providers and users. Achieving, maintaining and improving accuracy, timeliness and reliability of laboratory results and products, South Sudan has committed themselves to build national capacities to improve quality of laboratory services. This laboratory quality policy manual which guides implementing the requirements of ISO-15189:2012 to assure laboratory quality and competence nationwide will help the country achieve improved quality of laboratory services. Only sound management of quality in health laboratories will enable South Sudan to produce test results that the international community will trust in cases of international emergency.

Our aspiration is for our laboratories to be accredited and recognized among the best diagnostic laboratories in the health care industry both locally and internationally, and to prosper from a reputation of relevance, excellence and efficiency that we aspire to earn through continually improving our quality management systems.

This quality policy manual which is based on both ISO 15189 and CLSI GP26-A3 documents, is intended to provide a comprehensive reference on Laboratory Quality Management System for all stakeholders in health laboratory processes, from management, to administration, to bench-work laboratorians. In order for this policy to be successful, our laboratories must work together with various institutions, both public and private, in areas such as provision of supplies and technical expertise. I therefore extend my gratitude to the laboratory professionals and partners including the Centers for Disease Control and Prevention (CDC), and ICAP for their technical assistance and for facilitating this noble cause.

I thereby approve this Quality Policy as an expression of my commitment and that of the Ministry of Health in the support of the smooth implementation of the National Laboratory Quality Management System.

Hon Elizabeth Acuei Yor
Minister of Health
Republic of South Sudan

Preface

As part of Health Sector Reform (HSR) Strategy and in line with the South Sudan Ministry of Health Policy 2007 and Ministry of Health Strategic Plan (MHSP) 2010, the Ministry of Health (MOH) strives to provide better and guaranteed access to quality services for conditions that largely affect the populations in South Sudan.

With these intentions, initiatives include HIV/AIDS diagnosis and treatment, tuberculosis and malaria diagnosis, safe blood transfusion, maternal health and child care, control and response to epidemic-prone diseases, good laboratory practices, laboratory safety, and many others. These interventions require proficient and quality assured laboratory services at all tiers of the health care delivery system, guided by sound policy.

This National Laboratory Quality Policy Manual for South Sudan establishes overall policies for national quality management systems (QMS) for medical laboratory services nationwide. This policy has been developed in line with the International Organization for Standardization ISO 15189:2012 and ISO 17025:2005 standards, general requirements for competency in testing and calibrating laboratories, the Clinical Laboratory Standards Institute (CLSI) standards, and the Maputo Declaration of 2008. The accreditation process serves to provide objective documentation which confirms that each laboratory has the capacity to accurately detect, identify, and promptly report diseases of clinical and public health significance.

This quality policy manual defines the scope of the national QMS and documents the processes needed to implement the QMS to achieve quality laboratory services. This manual contains policy statements on all quality essentials which are intended to ensure the understanding and effective planning, operation and control of key QMS processes in all laboratories. Besides organizational management requirements, this policy manual describes the technical requirements for quality laboratory procedures before, during and after test procedures.

May I end by congratulating and acknowledging all the participants who developed this document. The list can be long but I cannot fail to mention the contributions of NPHL Leadership, CDC, and ICAP, the technical assistance of experts, the laboratory technical working group and the representatives from the ten states of South Sudan. Let us all join hands to make this document workable.

Dr Mayen M. Achiek
Undersecretary,
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NPHL would like to acknowledge with thanks all those who contributed to the development and review of National Laboratory Quality Policy Manual for South Sudan, more specifically

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We would also like to acknowledge those who participated in the final review of this historic document which will go a long way to strengthening and empowering laboratory quality systems in South Sudan.

Dr Lul Lojok Deng
Director General, Public Health, Clinical Laboratory, and National Blood Transfusion Service

List of Abbreviations

CAP	College of American Pathologists
CDC	Centers for Disease Control and Prevention
CPD	Continuing Professional Development
CV	Curriculum Vitae
DG	Director General
EQA	External Quality Assessment
GCLP	Good Clinical Laboratory Practice
IQC	Internal Quality Control
ISO	International Organization for Standardization
JTHL	Juba Teaching Hospital Laboratory
LIS	Laboratory Information System
MLT	Medical Laboratory Technology
MOH	Ministry of Health
NBTS	National Blood Transfusion Services
NEQAS	National External Quality Assessment Scheme
NGO	Non-Governmental Organisation
PHL	Public Health Laboratory
NQA	National Quality Assurance
NQAP	National Quality Assurance Programme
NRL	National Reference Laboratory
PDSA	Plan Do Study Act
PHCC	Primary Health Care Centre
PPE	Personal Protective Equipment
PT	Proficiency Testing
QA	Quality Assurance
QI	Quality Improvement
QATWG	Quality Assurance Technical Working Group
QC	Quality Control
QMS	Quality Management System
SOP	Standard Operating Procedure
SSHLS	South Sudan Health Laboratory System
TI	Training Institute
WHO	World Health Organization

Definitions

- **Accuracy** – how close a measure is to the true value
- **Corrective Action** – measures taken to correct a problem which may adversely affect the quality of the reported result and to prevent its recurrence
- **Incident –** A single distinct event
- **Internal audit –** audit conducted by laboratory personnel within that institution to establish the extent of conformity of the laboratory to documented requirements or standards
- **Non-conformance** – event that has not fulfilled the requirements of a specific standard
- **Occurrences** – actual instance where a situation arises
- **Preventive action** – long term improvements made by the laboratory to prevent non-conformances
- **Proficiency testing** – measure of a laboratory's performance in comparison to peers and reference standards
- **Quality assurance –** range of activities that enable laboratories to achieve and maintain high levels of accuracy and proficiency despite changes in test methods and volume of testing
- **Quality improvement-** A systematic approach that uses the scientific method to analyze and improve health system performance based on appropriate standards of care. Quality improvement uses a specific methodology to continuously plan, implement, and adapt solutions that lead to improved outcomes.
- Quality Planning- The process of establishing goals and standards for health system performance.
- **Quality management system** – management system to direct and control an organisation with regard to quality assurance
- **Reference (normal) range** – specified interval bound by two limiting values that contain 95% of the values found in healthy individuals
- Root Cause Analysis- a multidisciplinary participatory process to problem solving that minimizes individual bias while building a shared consensus in the identification of the root causes of quality challenges.
- **Turnaround time** – time taken from receipt of samples to the delivery of results as defined by the laboratory

- **Validation –** confirmation that the requirements for a specifically intended use or specific applications have been met through objective evidence
- **Verification -** confirmation that the analytical characteristics and data provided by a manufacturer, laboratory or reference institution have been reached through objective evidence provided by a given laboratory through the use of a specific measuring system
- **Work environment** – set of conditions such as temperature, humidity, noise, clutter, benches, dust under which work is done

1. Introduction

The MOH implements and monitors quality of public laboratory services through the National Public Health Laboratory, under the Directorate of Laboratory compliance & Quality Assurance / Quality Control. The program is responsive to the National Laboratory Policy and National Laboratory Strategic plan, targeting all the public health laboratories (Government, Non-government, and Private). It is therefore timely to institute standards to ensure uniform guidance to the delivery of laboratory services in the country. This is part of the Ministry of Health, South Sudan, measures to strengthen the laboratory network and address laboratory quality nationally

The South Sudan National Laboratory Quality policy Manual establishes the overarching quality policies for the laboratories within South Sudan. These policies have been extracted from international quality management systems standards (International Organization for Standards, ISO), CDC Laboratory Quality policy manual, WHO QMS and guidelines from Clinical and Laboratory Standards Institute, CLSI. The Laboratory Quality Policy manual is also aligned to measures outlined in the South Sudan National Medical Laboratory Policy (2020) and National Medical Laboratory Strategic Plan (2019–2023).

Laboratory test results are important for the diagnosis and treatment of illnesses, surveillance and prevention of diseases, disease outbreak investigation and health research. Therefore, it is paramount that as the country develops its laboratory networks, attention is paid to ensuring that the quality of laboratory testing meets set standards of quality.

The main objective of the National Laboratory Quality Policy Manual for South Sudan is to guide and inform the National Quality Assurance Programme (NQAP) to ensure high quality laboratory services are provided that meet the expectations of all its customers & stakeholders. The Program is dedicated to ensuring test results meet national and international standards and to continually improve Laboratory Quality Management Systems (QMS). This National Laboratory Quality Policy Manual (NLQPM) spells out the laboratory standards that have been set to enable the health LQMS ensure reliable results at all levels of health care delivery as described and or defined in the document

1.1 Scope of the Health Laboratory Quality Policy for South Sudan

The scope of this policy applies to laboratories at all levels in the country, including public, faith-based and private laboratories, including technical staff working in these laboratories who will be required to implement the policy. This policy seeks to provide guidelines on the organization and management of the

National Laboratory Quality Assurance Programme (NLQAP) and monitoring of the quality of laboratory services. The Department of Laboratory Compliance/ IQC/EQA, supported by the QA Technical Working Group (QATWG) is responsible for leading and monitoring the implementation of the policy. It is envisaged that laboratories setting up quality management systems (QMS) and participating in accreditation schemes will find it an essential reference for developing their own internal quality manuals. Additionally this policy will provide guidelines on those support services that impact on health laboratory services and are dependent on or controlled from national or state levels such as procurement, budgeting and personnel recruitment, among others.

1.3 Purpose of the National Laboratory Quality Policy Manual (NLQPM)

The purpose of this policy is to:

i. Define the National Laboratory Quality Assurance Policy
ii. Define roles and responsibilities of the NLQAP staff at every level with respect to quality management
iii. Document the elements of the South Sudan Laboratory Quality Management System
iv. Provide the vision and framework for the organization, management, implementation and monitoring of the NLQAP in South Sudan.
v. Provide Laboratory customers and stakeholders information that ensures their confidence in the quality of laboratory products and services.

The National Laboratory Quality Policy Manual (NLQPM) represents the highest formal quality directive supported by MOH of South Sudan. They provide the overall intentions and directions for quality of all the laboratories and laboratory staffs in South Sudan

This policy, although mandated by the overall National Laboratory Policy and Strategic Plan, is primarily driven by the increasing demand from stakeholders, laboratory users, including the general public, for quality laboratory test results, and the push for accreditation of laboratories. Individual laboratories are expected to use this document to develop and implement their QMS.

1.4 Policy Goal

i. To ensure and continuously improve the quality of laboratory testing in support of clinical care / treatment and research by:
    1. Setting a solid quality testing system and foundations through Quality System Essentials
    2. Continuously monitor those systems and processes.
ii. To identify deviations in these systems in a timely manner and to provide prompt resolution and corrective action to ensure the problems do not reoccur.
iii. To not only monitor and be satisfied with the set systems, but to continuously evaluate the system for improvement to ensure deviations do not occur and to introduce better and improved quality assurance systems.
iv. To comply with regulations, policies, directives, and standards established by the governing bodies.

2.1 Policy Framework

To align its vision, mission, and core values within the one national laboratory system, this policy has adopted the existing vision and mission of the National Laboratory Policy and Strategic Plan 2020.

2.2 Vision

A comprehensive quality laboratory system that is appropriate, equitable, accessible, affordable and promotes the health of the people of South Sudan.

2.3 Mission

To provide effective, efficient, accessible, equitable, affordable and relevant quality laboratory services that support the diagnosis and management of patients, clinical and public health disease surveillance, disease prevention and control, training and research, and monitor the standards of laboratory practice in South Sudan.

2.4 Core values and guiding principles

Laboratories in South Sudan shall adhere to a number of values and principles in their efforts to fulfill their mission.

- ***Values:*** solidarity, patriotism, equity, ethics, cultural identity, gender-specific respect, transparency and accountability
- ***Principles:*** acceptability and quality, safety, cost-efficiency, inter-sectoral cooperation, coordination, community participation, decentralization, dependability, integration

2.5 South Sudan Laboratory Quality Management System (QMS) Framework

The PHL approach to quality is led through the Department of Laboratory Compliance IQC/EQA, supported by the QA Technical Working Group (QATWG) which delineates the policy objectives and sets the goals for implementing the NQAP in the country.

This NLQPM explains the quality system elements that provide a framework for establishing and sustaining a QMS. These elements are inter-related and incorporated collectively to provide the framework for the South Sudan Laboratory QMS. Through understanding the details of each element, Laboratorians are able to develop policies, processes and procedures that are appropriate to their individual laboratory products and services.

A QMS provides a framework for managing and monitoring activities to address quality standards and achieve organizational goals. NLQPM is that part of the overall management system that establishes, documents, and implements the organizations quality policy and related processes and procedures for providing products and services that meet or exceed customer quality requirements. The QMS framework outlined in this manual consists of the following quality essentials elements:

11 Essential Quality Elements

1. Structure & Organization
2. Documents and Records
3. Process Control & Improvement
7. Laboratory Equipment
8. Purchasing and Inventory
9. Information Management

4. Assessments/ Lab Audits
5. Personnel
6. Facilities and Safety
10. Occurrence Management
11. Customer Service

3.0 South Sudan Laboratory QMS Elements

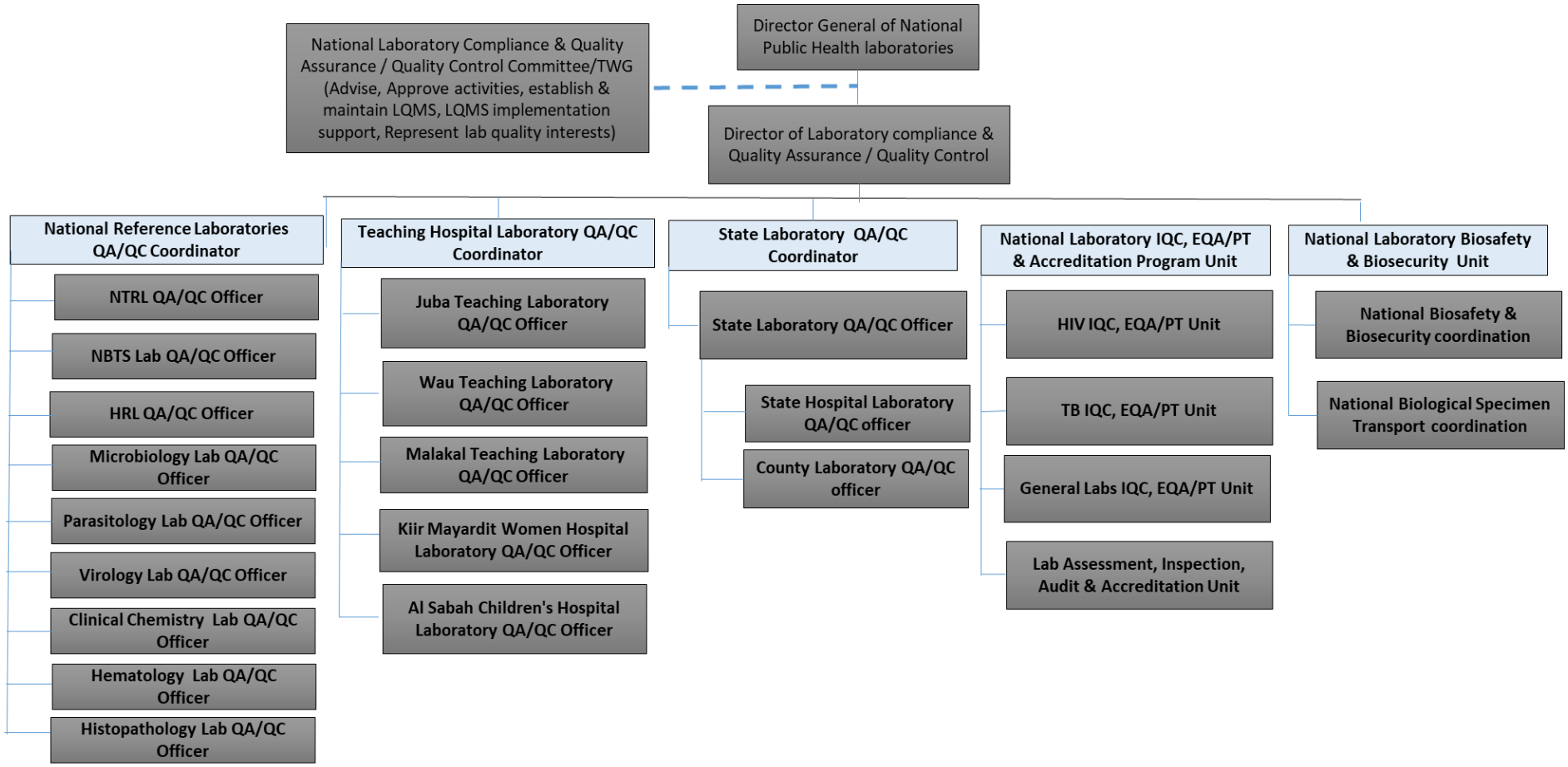
3.1.1 Element 1: Structure and organization

The intention of the organization element is to ensure that an organizational structure is established which supports quality functions in laboratories across the country and that resources are provided to ensure quality laboratory services and products.

National Public health laboratory is committed to planning and providing quality laboratory services by defining roles, responsibilities, and authorities within the QMS describing a reporting structure, training personnel for proficiency, meeting and adhering to internal and external organizational quality system requirements, allocating necessary resources for laboratory QMS, and continually improving, through periodic review and revision, the status and effectiveness of the QMS

The organizational structure for quality complements the management structure and provides independent credibility and authority. This structure will be further developed as the QMS is established and matures throughout the country.

3.1 National Laboratory Quality Management Program Organizational Chart



3.1.2 Responsibilities, and Functions

There are several stakeholder institutions that will be involved in contributing to the quality of laboratory testing in South Sudan. Each of these institutions will have separate but complementary roles.

Position/Personnel	Description of Responsibilities
NPHL	The NPHL is the highest level laboratory in the country and provides leadership and reference laboratory services Budgeting and financial management Licensing and regulation of health facilities and laboratories Licensing and registration of health personnel Support building of Lab professionalism and ethical conduct
National QMS TWG	Shall be the National Laboratory Quality technical advisory body for all laboratory quality assurance activities and shall meet monthly. Shall be composed of representatives from training institutions, NPHL, Teaching hospital laboratories, national reference laboratories, National Blood Transfusion Services (NBTS), partners supporting laboratory activities, disease control programmes and the private sector. Advise the Quality Assurance Unit on implementation of quality assurance activities, including setting priorities. Assist the QA Unit in resource mobilization. Assist in the development of policies, standards and guidelines Assist in the monitoring of quality of laboratory services Conduct regular meetings to discuss QMS activities and generate reports and recommendations to improve service delivery.
Partners supporting Laboratory Services & Products	A number of partners provide technical support to the national laboratory services. This support includes human resource capacity building, equipping of laboratories, infrastructure improvement, specimen referral systems and many other types of support. Partners therefore contribute significantly to the provision of quality laboratory services including mobilizing resources for laboratory activities. These partners include PEPFAR, CDC, Global Fund, and UNDP, WHO, MSF, ICAP, non-governmental organizations (NGOs) and many other bilateral organizations. Apart from membership of the QATWG they are also expected to play the following roles: Provide technical and material support to the QA unit and facilities Include quality assurance activities as outlined in the National Quality Assurance Programme within their programmes and activities. Follow the national guidelines in provision of QA activities. Participate in the national coordination mechanism for laboratory QA activities.

Department of Laboratory Compliance, QA/QC	With the authority over and responsibility for ensuring that LQMS requirements are effectively established and maintained Facilitates LQMS implementation and maintenance, including planning, training, assessing and continually improve the quality system and performance measurement outcomes Provides for independence and authority necessary to perform these LQMS tasks Develop an annual work plan and budget that support and maintenance of the QMS. Serve functions: i. Develop and review the National Quality Assurance Policy ii. Provide strategic leadership and oversight in the implementation of the policy through the National Quality Assurance Programme iii. Develop and oversee implementation of national laboratory standards. iv. Develop and monitor national laboratory quality assurance indicators v. Mobilise resources for implementation of the National Quality Assurance Programme vi. Facilitate capacity building and skills development of staff responsible for implementing the National Quality Assurance Programme vii. Advise and support the national supply chain system of the Ministry of Health on laboratory supplies approved for use in the country.
Director Laboratory Compliance, QA/QC	Has the primary responsibility for the quality of the Laboratory services and products in South Sudan, and as such, holds the authority to ensure laboratory staff comply with the NLQPM policies and applicable standards. Serve as chair on the National QMS TWG The Director delegates the authority for quality management to the Quality coordinating team for Central, states, NPHL & Teaching hospitals
National Laboratories EQA/IQC Coordinator National Reference Laboratories QA/QC Coordinator Teaching Hospital Laboratories QA/QC Coordinator State Laboratories QA/QC Coordinator	Represents the Director of Laboratory Compliance, QA/QC Department Sets direction for the future success of the respective LQMS through clear definition and communication of QMS responsibilities and authorities Facilitates LQMS implementation and maintenance, including planning, training, assessing and continually improve the quality system and performance measurement outcomes Serve on the National QMS TWG Delegates responsibilities and authority for the NLPQM to specific laboratories QA/QC officers

Laboratory QA/QC officers	Assist laboratory Staff in developing and documenting appropriate policies, processes and procedures for their unique activities Conduct periodic QMS assessments Provide QMS training Communicate information about QMS and distribute quality tools to the laboratories Assign responsibility for quality system elements as appropriate for their laboratories, and ensure these responsibilities are clearly communicated and documented

3.2 Element 2: Documents and Records

3.2.1 Purpose

Several types of documents are important for the proper management and implementation of the laboratory QA program. These include regulatory documents (policies, manuals, procedures) and records (logs, registers, forms, work sheets, IQC summary sheets, raw data, and reports). Records may be computerized or kept as hard copies (paper-based). Where data is computerized, systems shall be put in place for routine data back-up to avoid loss of data in case of hardware failure.

It is extremely important therefore that documents and records are secured and controlled to avoid interference, loss or unauthorized use. The laboratory must have a system of identifying documents, authorizing them and controlling their circulation and use.

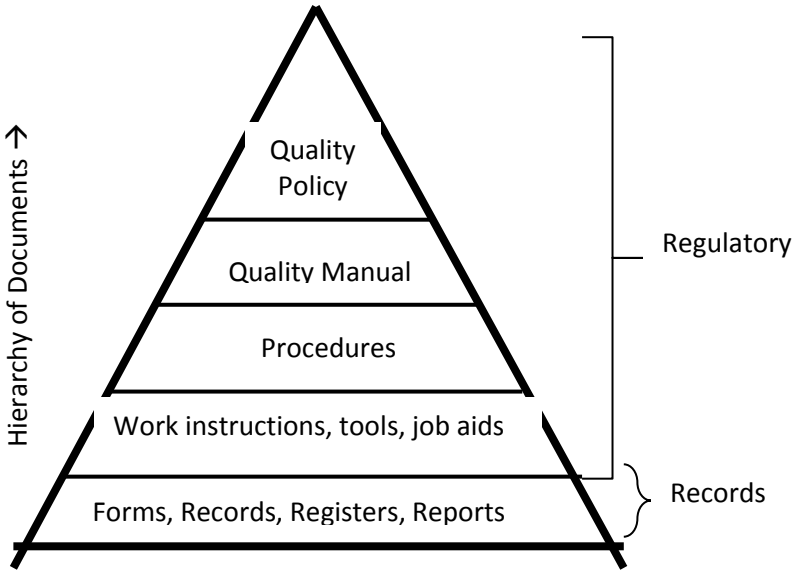
Process and procedure documents serve to outline the laboratory workflow and provide work instructions. Records serve to provide objective evidence of the results of performing the processes and procedures

Laboratories are expected to maintain current documents and records that are updated and periodically reviewed and managed in a controlled, systematic way.

Records are generated to document activities and are stored so they can be retrieved for the required time period.

Every laboratory should have procedures for archiving and time frame for disposal of old records

3.2.2 Hierarchy of documents



3.3 Element 3: Process Control, & Improvement: Internal quality control and external quality assessment

3.3.1 Purpose

To support the quality of laboratory products and services, understanding and controlling operations in the path of workflow enhances the effective and efficient use of resources and facilitates compliance with laboratory quality requirements.

The laboratory's path of workflow is performed under controlled conditions to ensure the quality of products and services.

The need for improvement exists in all processes. NPHL respond to information from many sources in identifying and effecting needed improvements. All South Sudan laboratories shall participate in quality improvement activities and systematic review of processes identifying potential nonconformities and implementing preventive action to effectively improve our products and services.

The need for improvement is necessary in all processes. Laboratories should always be alert to opportunities for improvement which may come through:

- Analyses of non-conformances
- Feedback from customers and staff
- Performance in audits (internal and external) and quality indicators
- Monitoring internal quality control processes.

- Participation in external quality assessment schemes.
- Risk assessments
- Analyses of occurrences.

3.3.2 Responsibilities

Position/ Personnel	Description of Responsibilities
Laboratory Managers	Systematically review at regular intervals potential sources of nonconformance or other opportunities for improvement in the QMS or laboratory practices Develop and implement performance measures for monitoring and evaluating laboratory processes Develop corrective and preventive actions plans Ensure corrective and preventive actions are implemented and evaluated for effectiveness Address opportunities and implement preventive action and other processes for improvement Provide educational and training opportunities where relevant Hold monthly staff/department meetings to review implementation of QMS
Laboratory Staff	Identify and communicate concerns Submit suggestions for process improvement to management Implement corrective action preventive actions plan

3.3.3 Preventive and corrective actions

It should be expected that problems or incidences will occur in any process. One of the principal functions of good quality management systems is to put in place procedures for identifying problems and acting on them. Observations, trends and information from sources that provide opportunities for improvement may require the laboratory to initiate preventive actions, while non-conformances require corrective actions. Preventive and corrective actions are part of the overall quality improvement process.

3.3.4 Policy

Preventive and corrective actions shall be communicated, documented and evaluated for effectiveness using such tools as the “Plan Do Check Act” (PDCA) Cycle.

The laboratory shall institute systems to identify problems when they occur including a resolution mechanism using tools such as brainstorming and root cause analysis.

The laboratory shall have a system for documenting occurrences and evaluating the effectiveness of the corrective actions taken.

The laboratory shall define quality indicators for monitoring performance.

The laboratory shall identify and implement potential quality improvement projects.

3.3.5 Internal quality control and external quality assessment

The laboratory shall frequently assess the effectiveness of its quality management system (QMS). This can be done in a number of ways including participation in proficiency testing (PT) schemes, specimen rechecking programmes, customer surveys, audits and use of quality indicators. PT schemes serve as external validation of the quality of laboratory results and as a valuable self-monitoring tool. The national Public Health Laboratory with support from ICAP, is in the right direction with efforts to strengthen South Sudan National External Quality Assessment scheme (SSNEQAS), phased for all diagnostic tests.

In view of this:

- All laboratories shall participate inter-laboratory comparison programme(s) such as recognised PT schemes, according to the tests being performed.
- The laboratory shall conduct periodic customer satisfaction surveys as one major quality performance evaluation tool.
- The laboratory shall define quality indicators against which it will periodically monitor and evaluate its performance.
- The laboratory shall conduct periodic quality audits that are planned and scheduled as per the Quality Manual, including risk assessments.
- Laboratory management shall review all audit findings and monitor the effectiveness of the corrective actions.
- The laboratory must resolve customer complaints in an appropriate, systematic and timely manner.

3.3.5.1 Internal quality control

The laboratory shall put in place a plan for an internal quality control (IQC) programme for all laboratory examinations. This shall include:

- Records of date received and expiry, source, specification and storage requirements of IQC materials
- The process of validating and verifying IQC materials against manufacturers' target values

- Acceptance criteria for results obtained on IQC materials in use (where applicable)
- Handling out-of-range control results to ensure corrective action is implemented. All IQC results shall be documented including any corrective action taken, and regularly reviewed
- All IQC and calibration results shall be documented. For automated instruments, quality control and calibration results shall be printed monthly with each page reviewed and filed.

Internal quality control shall be carried out through various approaches including blinded rechecking of samples, repeat sample testing and use of control samples to check systems and personnel performance.

In addition to using inbuilt quality control, materials for qualitative tests, and external true positive and negative controls shall be included with each batch according to the frequency established by the laboratory.

A designated laboratory technical staff shall review and verify internal quality control and calibration results at appropriate times before laboratory results are reported. The procedure for reviewing and verifying results shall be documented.

All quality control charts for quantitative assays shall be plotted on Levi-Jennings charts to easily detect and identify trends and shifts. Levy-Jennings charts shall be interpreted using Westgard rules and appropriate corrective and preventive actions shall be initiated and followed up. The section head in collaboration with the quality manager shall review and sign all Levy-Jennings charts on a monthly basis.

3.3.5.2 External Quality Assessment (EQA)

External Quality Assurance (EQA) is the objective evaluation by an outside agency of the performance by a number of laboratories on materials of known pathology. The national Public Health Laboratory is in the right direction with efforts to strengthen South Sudan National External Quality Assessment scheme (SSNEQAS). With Support from ICAP, the SSNEQAS has started for HTS-PT using DTS, Blood bank-PT using DTS for all the TTI and EID-EQA for GeneXpert near Point of Care testing points across the country.

The quality manager shall explore and implement the following:

- Enroll in EQA programmes that are recognised nationally, regionally or internationally
- Engage in peer comparisons with other laboratories, especially for tests that are not supported by EQA
- Establish procedures for handling non-satisfactory EQA results. Corrective and preventive actions shall be taken when the performance of EQA is unsatisfactory, and all actions documented.
- Prepare and maintain a database of all EQA results.

3.3.6.0 Pre-analytical procedures (specimen management)

Patient specimens are the primary inputs into laboratory processes and generation of test results. It is important to maintain the integrity and quality of specimens from collection, transport, processing, storage and eventually disposal.

3.3.6.1 Policy

The laboratory shall have written policies and procedures in place for specimen collection, labelling, transporting, testing, reporting of results, storage and archiving. These procedures shall ensure that the right specimen is received and analysed correctly in a timely manner.

The laboratory shall develop and disseminate a specimen management policy that outlines procedures for:

- Patient identification.
- Collection of appropriate and quality specimens.
- Labelling of specimens.
- Timely transportation of specimens to the laboratory.
- Receipt and accessioning of specimens.
- Processing of specimens for analysis.
- Correct interpretation and reporting of results.
- Maintaining accurate records of specimen receipt, procedure and results.
- Short and long term storage of specimens.
- Safe disposal of specimens.

The clinician in collaboration with the laboratory staff shall utilize standard laboratory requisition forms with the following minimum information:

- ❖ Patient names (three names), age, gender, residence
- ❖ Unique patient/client registration number
- ❖ Name of hospital, clinic, ward where results will be sent
- ❖ Type of specimen and test requested
- ❖ Date and time of collection
- ❖ Relevant clinical information, including relevant drug use

- ❖ Name and signature of requesting clinician
- ❖ Test results
- ❖ Date, time, name and signature of laboratory technician

- The label on the specimen and its aliquots shall have the same information as appears on the requisition form accompanying the specimen.
- Aliquots shall be labelled in such a manner as to be traceable to the primary specimen.
- Specimens shall be packaged and transported in accordance with national and international regulations such as IATA regulations.
- Each laboratory shall develop and adhere to strict specimen receipt and rejection criteria.
- Rejected specimens shall be recorded in a specimen rejection register that includes the patient's name, unique registration number, facility name, type of specimen, date and time of collection and reason for rejection
- The relevant unit shall be immediately informed in the case of specimen rejection.
- The laboratory shall inform the laboratory users on specimen management processes, and conduct training and orientation if necessary.

3.3.7.0 Analytical procedures

The laboratory shall have written policies and procedures in place for analysis of samples. These procedures shall ensure that the right protocols and techniques are followed for sample analysis at all times.

The laboratory shall develop a policy and standard operating procedures that address the following:

- The laboratory shall have easily accessible, approved SOPs for each test.
- Only competent staff shall perform laboratory testing.
- Expired reagents shall never be used.
- Equipment should be calibrated and undergo regular care and maintenance.
- The laboratory shall validate test methods before they are put into use.
- The laboratory shall perform and document Internal Quality Control (IQC) procedures and verify results before release.
- IQC results shall be monitored and reviewed and corrective actions taken where results exceed the acceptable range.

- All laboratories shall participate in inter-laboratory comparison programme(s) such as a recognised Proficiency Testing (PT) schemes covering the tests performed in the laboratory.
- The laboratory shall review its performance in inter-laboratory comparison schemes and implement corrective actions when unsatisfactory results from inter-laboratory comparison schemes are recorded.
- The laboratory shall check and verify environmental conditions to ensure they are conducive to staff comfort and laboratory testing operations.
- The laboratory shall define acceptable ranges for temperature controlled equipment and procedures.

3.3.8.0 Post-analytical procedures

The laboratory shall have written policies and procedures in place for correct recording, reporting and submission of results within the stipulated turnaround time.

The laboratory register for recording test results and report forms shall include the following minimum information:

- Patient name, date, age, gender, unique patient registration number
- Location (hospital, ward, clinic).
- Laboratory accession number.
- Name of attending clinician to whom the results will be sent
- Tests requested and type of sample submitted
- Test results and reference (normal) range where applicable
- Laboratory comments and interpretation
- Laboratory technicians and supervisors' signatures and date.

- Laboratory results shall be written legibly and only universally accepted abbreviations shall be used.
- Before releasing results, test results shall be cross-checked against test requests to ensure they have been fully addressed.
- The laboratory supervisor or designee shall review all laboratory results to ensure there are no errors in reporting before dispatch.

- The laboratory in consultation with clinicians shall determine critical values for each analysis. Critical value notifications shall be done in accordance with laboratory policy including policy for telephone notification of results.
- The laboratory must establish procedures for return of urgent and emergency results.
- The laboratory shall establish turnaround time (TAT) for every test.
- Laboratory test results and records shall be retained for at least ten years.

3.3.9 Management review

Laboratory management review meetings are critical to the successful implementation of the laboratory's quality management system (QMS). The laboratory in its organisational structure must identify who forms part of the laboratory management. Management must own and commit to support the implementation of the QMS.

Suggested composition of the laboratory management team: Laboratory Manager or Director and Deputy, Quality Assurance (QA) Officer, Safety Officer, section heads

Laboratory management shall perform the following functions:

- Develop an annual workplan and budget that support laboratory testing operations and maintenance of the QMS.
- Routinely, through designated individuals, review all quality and technical records.
- Conduct annual reviews of the QMS.
- Conduct management review meetings at least annually.
- Identify and facilitate personnel development plans.
- Establish internal quality control (IQC) procedures for all tests and participate in relevant external quality assessment (EQA) schemes.
- Identify and implement laboratory improvement projects.
- Put in place procedures for identifying and undertaking corrective and preventive actions.
- Establish a system for regular communication with higher management including intra- and inter-laboratory communication.

The results of the reviews shall be incorporated into plans that includes goals, objectives and time-bound action plans.

3.3.10 Laboratory Quality Improvement (QI) Implementation Approach

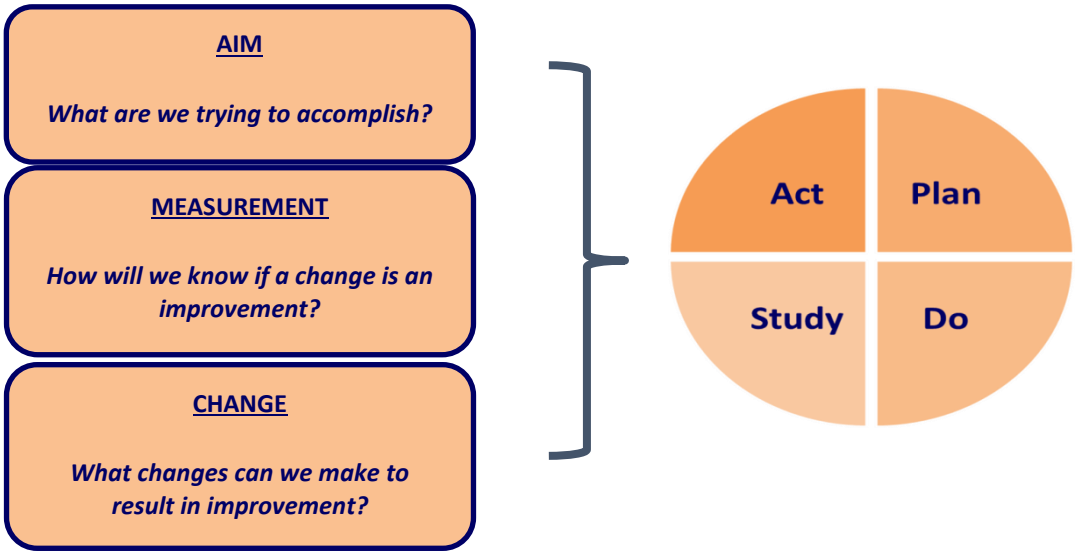
"While all changes do not lead to improvement, all improvement requires change"

Procedure to Support Laboratories implement Improvement approach

When the Laboratory is faced with improvement challenges, the improvement Model described in this quality policy manual is the most commonly used improvement framework in health care internationally (adopted from ICAP QI tool kit, 2016). It is comprised of two main parts:

(1) Three fundamental questions, and
(2) The Plan, Do, Study, Act (PDSA) cycle.

The Model for Improvement provides organizations and health care teams with a framework for developing, testing, and implementing changes that lead to improvement. This framework takes an action-oriented approach to improvement, encouraging teams to ask questions, generate change ideas, perform tests, and implement change ideas while measuring progress.



Langley G, Nolan T, Norman C, Provost L (1996) The Improvement Guide

Use of the Model for Improvement Approach

The Model for Improvement is composed of two key steps: (1) Asking questions, and (2) Taking action. Three key improvement components, aim, measurement, and change, guide the three key questions of the Model that are outlined below:

1. **[AIM] What are we trying to accomplish?**
   The outcome of answering this question is to produce an agreed upon and documented aim statement. Typically written in a SMART format (Specific, Measureable, Achievable, Realistic, Time-bound), the aim statement articulates an improvement goal and describes project boundaries.

   While an aim statement should be aligned with participating organizations' missions, visions, and strategic goals, it is more targeted and action-oriented than these organization-specific guides. It may take several meetings for stakeholders to reach an agreed-upon aim statement. However, this step cannot be skipped or abridged. Project success demands group consensus on the answer to this question.

   Examples of good aim statements include:
   - Within the next 6 months, Facility HRL will reduce the VL TAT from 5 days to 2 days
   - Within the next 6 months, JTH Laboratory will have developed and started use of all the test menu SOP

2. **[MEASUREMENT] How will we know if a change is an improvement?**
   The purpose of answering this question is to produce a family of indicators that will help teams to measure progress toward the aim over time. The "family" includes a set of outcome, process, and balancing indicators. While there is no magic number of indicators to measure change, the "family" should be designed to provide a well-rounded view of an intervention's impact without imposing undue burden in terms of data collection or analysis. Limiting the number of indicators chosen is recommended, as is selecting from available data that is already being collected.

   The PDSA cycle methodology emphasizes the use of measurement to indicate if a change is leading to improvement. This process is the basis for the "science of improvement" and facilitates team learning as teams can quickly see where and how their efforts are affecting a situation. Run charts are the essential QI tool utilized to present indicator data and monitor change over time.

3. **[CHANGE] What changes can we make that will result in improvement?**
Answering this question requires an in-depth consideration of what is causing the problem and generating related change ideas that the aim statement seeks to solve. Ideally, change ideas are prioritized by feasibility and anticipated impact. Change ideas are then tested in small cycles. A number of tools, such as the Driver Diagram, Fishbone Diagram and Process Map, can facilitate the process of generating change ideas. These tools are described in more detail later in this toolkit.

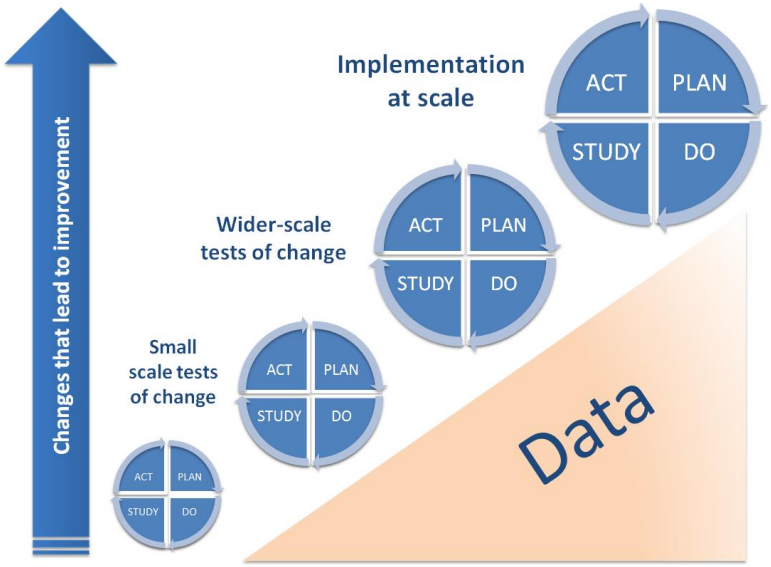
The Plan-DO-Study-Act (PDSA) Cycle Methodology

Walter Shewhart introduced the PDSA cycle in the 1920s in the manufacturing industry. The PDSA cycle methodology (also known as Rapid Cycle Improvement or Small Tests of Change) has successfully stood the test of time as the core of continuous quality improvement. PDSA cycle testing is an iterative and

continuous process that requires non-linear thinking. It emphasizes cycles, often performed simultaneously, rather than a straightforward progression from one step to another.

The three main uses of PDSA cycle testing are to test ideas of change, develop new knowledge, and implement promising ideas. It is not a single event, but a series of cycles — one leading to the next — as shown in the graph below.

Using PDSA cycle testing effectively can take some practice and requires discipline, but it can lead to rapid improvements. Like any applied skill, repeated practice can greatly enhance competence and confidence.



PSDA Cycle Testing

Plan – The QI team selects the change idea or ideas and develops the plan for implementation, documentation and time period. During the planning phase the team articulates clearly and precisely the what, when, when, how and who of the implementation plan for the change idea.

Do – The change idea (s) is implemented and documented according the plan. The "do" phase will have specific time frame.

Study – This stage is when the collected data must be organized and analyzed. The QI team must determine what lessons have been learned. Was the intervention a success? Were only some elements of it a success? If so, why? It is imperative that the team conducts a thorough and rigorous analysis of the data and agrees on lessons learned, as these lessons will directly affect the next stage.

Act – In this stage, the team determines whether to adopt, adapt, or abandon the change idea. If the data is positive, consider scaling it up and implementing it more widely. If features of the intervention were promising but weaknesses were discovered, then adapt the intervention as needed and start a new small-scale cycle. If the intervention was a complete failure, then document why it failed and move on to a new idea that has been discussed. Similar to the "Do" stage, this phase involves implementing an intervention, but this action is based on what has been learned from preceding stages. And, more importantly, this stage leads into another cycle of planning.

Quality improvement is an iterative process that continually uses previous actions and data to inform ongoing and future processes. Throughout the entire process, it is crucial to document decisions, actions taken, and data collected. Important lessons can be learned at each stage in the cycle to inform other parts

of a particular project as well as entirely new QI projects. Documentation can also serve a crucial role in codifying agreements, roles, and goals. It ensures that stakeholders share institutional memory of how a project evolved and minimizes confusion in future meetings.

3.4 Element 4: Laboratory Assessment

3.4.1 Purpose

To determine the effectiveness of the QMS, assessments (both internal and external), are performed by the NPHL, using the pool of internal and external auditors.

3.4.2 Policy

NPHL will periodically assess the effectiveness of the quality management system through scheduled review of the intent of the stated requirements, using both internal and external assessments.

Laboratory assessment, also known as audit, shall be conducted to measure laboratory performance and verify compliance with accreditation or certification and project requirements using internal, external and performance and management reviews. Based on audit reports the laboratory director or manager shall be notified of actions needed when events that cast doubt on the validity of laboratory results are identified.

3.4.3 Responsibilities

Position/Personnel	Description of Responsibilities
Audit Unit/ LQMS Team/ Lab Mangers	Coordinates the performance of periodic internal audits. Internal autists are conducted by the LQM team and other certified auditors Note: The LQM team coordinates internal audits only. External audits are conducted by regulatory and accrediting agencies Review audit findings (internal and external) Review corrective action reports and ensure corrective actions are effective Notify laboratory personnel of audit findings Ensure identified corrective actions are taken Identify key performance measures
Laboratory staff	Participate in internal and or external audits

	Track and trend designated performance measures evaluating path of workflow and operations

3.4.4 Internal Audit

An internal audit is the process of reviewing the laboratory by resident laboratory staff. Once a quality assurance programme has been developed and implemented, the only way a laboratory can verify its effectiveness is to carry out regular audits. Internal audits are performed regularly but may also be requested as the need arises based on findings from corrective actions, issues discovered during data review, complaints or data integrity concerns.

Internal audit shall be planned, conducted and documented in accordance with written procedures, using a standard checklist. Internal audits verify and evaluate, through objective evidence, that applicable elements of a quality assurance programme have been developed and documented, and are being implemented.

Internal audits shall be conducted quarterly by trained personnel who shall review all the elements of the quality management system.

Internal audits shall be conducted by the laboratory quality management team as directed by the quality manager and audit reports shall be evaluated to identify non-conformities which shall subsequently be addressed.

3.4.5 External Audit

Health authorities may assess laboratories to evaluate the quality of performance or compliance with licensing requirements and national regulations. They may also assess laboratories as part of a capacity strengthening plan of action, or for public health programme needs.

Accreditation bodies are organisations that provide accreditation or certification. When a laboratory seeks accreditation, an initial audit will be required to evaluate compliance with standards. To maintain accredited status, accreditation bodies require periodic audits of accredited laboratories.

Audits may be requested by major public health programmes or by agencies that provide funding for programmes. These groups need to ensure that quality standards are being met and that quality practices are in place. International programmes such as the WHO Polio Initiative regularly assess disease specific laboratories according to their own standards using their own checklists, for example, the WHO Polio laboratory accreditation standard and WHO measles accreditation standard.

3.5 Element 5: Personnel

3.5.1 Purpose

To ensure that both the quality of laboratory services and products and job satisfaction by laboratory staff, the laboratory follows processes and procedures to provide adequate, trained staff who have specific job descriptions and opportunities for professional growth and development

NPHL has established personnel policies to ensure employees have job descriptions and the necessary qualifications and adequate training to appropriately perform their roles and responsibilities in the lab. The employees and other staff within the NPHL realize their individual responsibilities for maintaining quality requirements, the lines of authority for their job functions, and the relationships among personnel with whom they work.

Laboratory personnel with appropriate qualifications and skills are an important part of ensuring the quality of laboratory testing. It is necessary that laboratories have adequate numbers of appropriately qualified staff equipped with the required knowledge, skills and competence. Even with these attributes, staff need to be well motivated in order to be productive.

3.5.2 Policy

Health laboratories shall be staffed with adequate and qualified staff that are well trained and motivated. Each staff member shall be appropriately appointed, designated and assigned specific tasks.

3.5.3 Roles and responsibilities of key staff

3.5.3.1 Laboratory Director or Head

The Laboratory Director or Head is the person who has overall responsibility and authority over the laboratory. He/she works closely with the laboratory management to implement the QMS. The Laboratory Director or Head will be responsible for:

- Appointing and deploying personnel to positions essential to meeting the laboratory's quality objectives.
- Defining lines of authority including communication.

- Establish and maintain job descriptions for each position
- Ensuring adequate numbers of skilled and competent staff to manage the workload.
- Ensuring commitment of the entire laboratory to quality and compliance with standards.
- Day to day management of the laboratory.
- Ensuring resources are available for laboratory activities and processes.
- Preparing a plan and budget for the laboratory quality programme.
- Determining laboratory requirements for equipment and supplies to ensure uninterrupted services.
- Leading in the selection and monitoring of laboratory suppliers.
- Establishing policies for proper receipt, handling and use of data.
- Communicating between the laboratory and other departments.
- Facilitating the training and mentoring of staff.
- Addressing customer complaints and acting on suggestions from staff
- Designing and implementing a contingency plan to ensure that essential services are available during emergency situations or other conditions when laboratory services are limited or unavailable.

3.5.3.2 Laboratory Quality Officer

The Laboratory Quality Assurance Officer shall be appointed and have delegated responsibility to oversee the laboratory's compliance with the quality management system (QMS). The Laboratory Quality Assurance Officer reports directly to Laboratory Director or Head and shall have appropriate knowledge and skills to maintain and continually improve the laboratory QMS. The Laboratory Quality Assurance Officer shall be responsible for scheduling, recording and coordinating audits within the laboratory as well as ensuring that any corrective or preventive actions required as a result of an audit are satisfactorily discharged. The Laboratory Quality Assurance Officer will:

- Monitor the implementation of the QMS as outlined in the Quality Manual.
- Ensure validation of equipment, supplies and methods.
- Coordinate performance evaluations and participation in external quality assessment schemes, including proficiency testing and external quality audits.
- Collaborate with technical staff in developing and documenting quality policies, procedures and processes.
- Document the competencies needed to ensure quality of laboratory services

- Oversee and review internal quality control data.
- Validate the Laboratory Information System (LIS) including relevant tools for collecting, storing, analysing and reporting data.
- Promote awareness of users' needs and requirements throughout the laboratory or institution.
- Monitor equipment use and maintenance, including maintaining equipment service records.
- Participate in procurement processes and purchases, and stock maintenance and control.

3.5.3.3 Safety Officer

The Safety Officer shall have overall responsibility for ensuring the safety of the laboratory premises, equipment, processes, staff, patients, clients and visitors. The Safety Officer shall implement the safety policies and guidelines and ensure that staff have been adequately trained on safety issues. The Safety Officer shall be responsible for:

- Conducting safety inspections and audits of laboratory facilities.
- Verifying that all safety equipment and supplies are available and in good working condition.
- Training of staff in safety procedures including the use of safety equipment.
- Maintaining an Incident Book in the laboratory.
- Ensuring appropriate action is taken in the event of a safety incident.

It is incumbent on all staff to report any safety incidents or accidents whether or not they may have resulted or have resulted in personal injury.

3.5.3.4 Technical staff

All technical staff working in the laboratory shall be responsible for:

- Sample reception.
- Preparation of reagents.
- Processing and analysing patient specimens, according to their various assigned duties.
- Providing quality, reliable and timely test results.
- Ensuring proper user care and optimum functioning of laboratory equipment.
- Following quality policies and procedures while performing any tasks.
- Performing internal quality control (IQC) procedures as defined by policy.
- Proper and complete information management.
- Preparing useful reports for clinicians and other customers.

3.5.3.5 Laboratory supervisor

The laboratory supervisor shall:

- Review and approve all technical laboratory reports
- Ensure staff perform internal quality control checks for all procedures and act on them, as necessary
- Be responsible for the documentation of all processes and operational activities.
- Prepare, update and orientate staff on SOPs for all laboratory processes.
- Monitor use of supplies.
- Regular and scheduled supervision by staff from laboratories at higher levels in the tiered system to laboratories at lower levels.

3.5.4 Staff training

The laboratory shall develop and implement regular training programmes for all staff. All training shall be documented both in the training records and individual personnel files. In addition to organised training, staff shall be required to participate in approved continuing professional development (CPD) programmes at least annually.

The laboratory shall hold regular staff meetings to review specific management and technical issues, as required.

3.5.5 Staff recruitment, orientation and induction

Staff should be appointed only to positions for which they are qualified, skilled and competent. It is necessary that qualifications and experience are assessed when recruiting personnel. Where qualifications and skills are not appropriate for the envisaged tasks to be performed, arrangements shall be made to provide adequate training for the staff and to ensure competency before they are allowed to undertake the tasks unsupervised. Each new staff member to the laboratory or to a section of the laboratory must undergo an orientation and induction covering laboratory policies and facilities, section rules and procedures. The orientation shall cover both a general lab and section or department specific orientation as shown below.

Laboratory Orientation Focus Areas

Laboratory orientation	Laboratory policies (quality, safety, personnel, communication)
	Organisational structure
	Interpersonal relations
	LQMS training
	Disaster preparedness and safety

	Laboratory tour Initial competency assessment and targeted training
Section and department orientation	Section and departmental rules and policies Work schedules and assignments Section and departmental tour Introduction to section and department staff

3.5.6 Competency assessment and performance appraisal

- Laboratories shall institute a system for regular staff competency assessments at least annually or whenever a new method is introduced. Competency assessments shall also be performed before staff perform a test for the first time. Records of competency assessments shall be maintained in individual personnel files.

- Laboratories shall institute a system of appraising performance of staff to maintain or improve the quality of services given to users, and to encourage productive working relationships.

3.5.7 Personnel records

- The laboratory shall maintain a personal file for each staff member with the following minimum details:

• Personal data • Education records • Employment history • Curriculum vitae • Job description • Letter of appointment • Appraisals	• Training records (courses, seminars, workshops, etc.) • Competency assessment records • License and/or Registration certificates • Induction and orientation records

Other documents such as cautionary letters, must also be retained in the personal file.

3.6 Element 6: Facilities and Safety

3.6.1 Purpose

To ensure adequate physical environments and the use of accepted safety practices for the safe handling of infectious agents and other hazardous materials, multiple units within PHL provide guidance and oversight and laboratory staff are routinely trained.

PHL Provides adequate space and facilities designed and constructed or renovated to optimize work efficiency, minimize the risk of injury and occupational illness, protect workers and visitors from recognized hazards, and meet applicable standards for facilities and environment

Laboratory facilities must be designed in such a way that the safety of all personnel as well as the quality of work are not compromised. There shall be adequate space for placement of equipment, movement of staff, work flow and sample analyses. The MOH is committed to providing a safe working environment for its employees, for patients and for visitors in both public and private laboratories.

3.6.2 Policy

The laboratory shall provide adequate and appropriate work areas for processing and analysing specimens, considering the safety of personnel, patients, clients and visitors to the laboratory.

- Laboratories shall be of adequate size and appropriately organised to facilitate optimal work flow and staff comfort.
- Patient and testing areas shall be distinctly separated.
- Work stations shall be free of clutter and set up for efficient operations.
- The laboratory shall be properly secured from unauthorised access.
- There shall be proper signage in all areas of the laboratory.
- The laboratory shall establish appropriate safety measures for the processing and testing of highly contagious samples.
- The laboratory shall have an updated Safety Manual that is available and accessible to all staff.
- There shall be procedures for the handling and disposal of sharps, spills, contaminated materials and laboratory waste.
- Appropriate Personal Protective Equipment (PPE) shall be available and used by all staff.
- There shall be proper procedures for storage and disposal of unserviceable and obsolete equipment.

The Laboratory Head or Director shall designate one person as the Safety Officer. The Safety Officer shall be responsible for ensuring the safety and security of the premises and personnel working in the laboratory. The Safety Officer shall ensure adherence to safety procedures as outlined in the Safety Policy.

The Safety Policy shall address the following:

❖ Fire emergencies ❖ Handling accidents in the laboratory ❖ First Aid	❖ Universal safety precautions including staff vaccination and access to post-exposure prophylaxis

❖ Use of Personal Protective Equipment	❖ Access control to facilities and information. ❖ Laboratory safety training

3.7 Element 7: Laboratory Equipment's

3.7.1 Purpose

Critical equipment items used to test, process, store, monitor, distribute or collect materials and quantitative data or product are identified and maintained according to manufacturer's instruction or applicable laboratory or regulatory requirements.

NPHL maintain processes and procedures needed to ensure equipment and instruments are appropriate, maintained and function according to established criteria. Critical equipment used to test, process, store, monitor, distribute or collect quantitative data or products is identified, monitored and maintained according to manufacturer's instructions or applicable regulation.

ISO 15189:2012 describes equipment including instruments, reference materials, consumables, reagents and analytical systems required for laboratory operations. Functional, well maintained and calibrated equipment is necessary for delivery of quality laboratory services.

3.7.2 Policy

The laboratory shall establish processes and procedures to ensure that appropriate equipment is procured and is correctly installed, maintained and used according to manufacturers' requirements. Equipment must be regularly calibrated.

- Laboratory equipment shall be installed according to operators' manuals. It is important that vendors are required to train staff on the use, care and preventive maintenance of equipment.
- Each item of equipment shall be uniquely labelled and identified.
- All equipment and methods must be validated or verified on-site, and records documenting the validation maintained in the equipment file.
- The laboratory shall keep an inventory of all equipment available in the laboratory.
- The laboratory shall keep a file of all equipment showing its make and model, serial number, unique identifier, maintenance records, service records and calibration records.
- The laboratory shall establish schedules for calibration of equipment including recording the metrological traceability of the calibration standard and the traceable calibration of the item of equipment.
- The laboratory shall establish a programme for routine equipment preventive maintenance by qualified and competent personnel supported by service contracts for analytical equipment.

- The laboratory shall have in place back up procedures in case of equipment failure to ensure non-interruption of services.
- Equipment operator manuals shall be readily available to testing staff in the appropriate language.

Equipment should be installed away from direct sunlight, edge of the table, sink, mechanical vibration and air conditioners

3. 7.3 Selection of equipment

Equipment are heavy capital investment items. Care should therefore be taken in selection and procurement of equipment to ensure value for money. The following should be considered when deciding on the type of equipment for procurement:

• Available laboratory infrastructure, including availability and quality of utilities, such as power and water sources. • Environmental conditions at point of use (temperature, humidity, dust etc.). • Laboratory workload. • Skills and competence of available clinical and laboratory staff. • Availability of local support for training and maintenance.	• Analytical performance including technical specifications and sample throughput. • Open or closed systems. • Availability of back-up methods. • Running costs of the equipment. • Turnaround time.

3.8 Element 8: Purchasing, Supplies, and Inventory

3.8.1 Purpose

This element focuses on the process and procedures for purchasing and inventory control of supplies, equipment and services required to product the quality of products and services needed by NPHL

NPHL have systems in place to ensure the uninterrupted availability and quality of purchased materials, reagents, and services necessary to meet QMS requirements.

Proper laboratory supplies management will ensure commodity security and availability at point of use. This will also ensure that procured supplies are of the right quality and quantity. Laboratory personnel should be closely involved in all stages of supply chain management including forecasting, quantification, specification, tendering, receipt, warehousing, distribution and storage at facility level. The ordering of supplies from the national stores should meet laboratory needs and should be calculated to avoid stock outs and expiry in the laboratory.

3.8.2 Policy

The laboratory shall have a system in place to ensure uninterrupted availability of reagents and supplies of appropriate quality at point of use. The laboratory shall:

- Establish a system for accurately forecasting needs for supplies, consumables and reagents, including emergency buffer stocks.
- Establish a Logistics Information Management System (LIMS) to collect and manage information necessary for the proper management of the supply chain.
- Periodically review specifications of supplies and selection of suppliers.
- Put in place an inventory control management system and monitor levels of supplies.
- Have adequate and appropriate storage areas that are monitored for humidity and temperature fluctuations, and address safety, protection from rodents, cleanliness and security.
- Have a system for inspecting and testing commodities before they are put into use.

3.9 Element 9: Laboratory Information Management

3.9.1 Purpose

The purpose of this element is to assure the effective flow of information within and outside laboratory, confidentiality of data and information, as needed, and to comply with applicable regulatory and legal requirements.

NPHL manage incoming and outgoing data and information (verbal, written or electronic) to assure that the quality, security, and integrity of internal and external communications are addressed while complying with applicable regulatory and legal requirements. Confidentiality of information linked to personal identifiers, such as test result reports or data on clinical trial participants, is maintained at all times.

Laboratories by nature of their operations generate a large quantity of data, reports and information which is provided to and used by various people. The laboratory will develop a system to capture data for processing, storage and archiving if not for immediate use. The laboratory will utilize an appropriate medium depending on resources.

LIS is important for:

- Collection, processing and storage of data
- Generation of information and reports
- Archiving and retrieval of data

3.9.2 Policy

The laboratory shall establish a LIS to provide regular and accurate data for planning, evaluating and improving the quality of data.

In particular:

- Test results shall be legible, technically verified and authorised
- Test results shall be traceable to the equipment and personnel performing the test
- Archived results shall be securely stored and readily retrievable.
- Test results shall be validated, interpreted and released by appropriately authorised personnel.

3.9.3 Laboratory communication

The laboratory, by the nature of its operations, generates a large quantity of data and information that is useful to parties within and outside the laboratory. Often this information is private and confidential. There are also times when the laboratory may wish to communicate or request information that is of a general nature. It is necessary that this process is managed to ensure the integrity and confidentiality of the information.

The laboratory shall establish an effective system for managing both internal and external communications while ensuring the confidentiality of patients and staff.

Standard operating procedures require that laboratories have in place systems for communicating information to staff, management and other departments outside the laboratory.

3.9.3.1 Internal and external communication

This can be achieved through:

❖ Staff meetings ❖ Management meetings ❖ Quality review meetings ❖ Memos, circulars, newsletters	❖ Emails, blogs and websites ❖ Telephone calls and text messages ❖ Verbal communications that should be documented

The laboratory shall promote regular meetings with clinicians to discuss issues relevant to both parties such as testing services, types of specimens, test requests, result reporting, turn-around time, emergency requests, temporary interruption of testing, and introduction of new tests, among others. Information from these meetings may provide opportunities for improvement of services.

- All communications and proceedings of meetings shall be documented and signed by staff to signify that they have read and understood the communication.
- The laboratory shall have an SOP for conducting various meetings.

- The laboratory shall develop and make available a laboratory handbook (see Annex for contents) for laboratory users providing information on services offered, sample quality and turnaround times.
- The laboratory shall have a system for advising and communicating with clinicians on laboratory services and requirements.

Continuing Medical Education (CME) sessions jointly for both clinicians and laboratory staff are vital to improve knowledge and performance, and enhance good communication between the two cadres.

3.10 Element 10: Laboratory Occurrence and Incidence Management

3.10.1 Purpose

The purpose of an occurrence management program is to identify and analyze information about occasions when work is performed that is not in conformance with established policies, processes or procedures and incidents results in laboratory errors or other events in which the expected level of quality was not met.

NPHL identify, document and investigate nonconforming events and analyze the information to identify systematic problems and initiate corrective actions, as needed, to eliminate the cause and support quality improvement.

The purpose of occurrence and incidence management is to capture and analyse information from non-conforming events to identify systematic problems and gain the management's commitment to remove the cause.

3.10.2 Policy

The laboratory shall establish a system for capturing and analysing any occurrences to identify problems and institute measures to remove the cause(s).

- The laboratory shall document and report any aspects of its operations that does not conform to its own procedures and requirements of the QMS. Such occurrences may include customer complaints, breakdown in communication and adverse events. The staff that first discovers the problem shall take necessary steps to resolve the problem, document the action taken and report to the supervisor at the earliest opportunity.

- The laboratory shall maintain a register of all occurrences and actions taken.

3.11 Element 11: Laboratory Customer Service Management

3.11.1 Purpose

The purpose of this element is to ensure customer requirements are determined and are met.

NPHL meet or exceed the expectations of our customers and partners and responds to customer feedback and complaints

4.0 M&E Performance Framework for the implementation of the National Laboratory Quality policy manual

Ensure a national laboratory quality policy Manual is implemented to support country laboratory management system that meets national and international standards is in place at all laboratory levels					
Planned activities		**Time Frame (2021-2025)**		**Responsible partners**	**Outcomes and planned results**
1	Support the Director, Quality Assurance Department at the Public Health Laboratory to develop, implement and monitor the national laboratory quality management system, including internal quality control, external quality assessment, quality audits, updating relevant reference materials, and laboratory supervisory and mentoring systems, using standard guidelines and tools, in public and private			MOH, NPHL, Lab TWG PEPFAR/CDC, ICAP Implementing Partners, UNDP/ Global Fund	Functional national laboratory quality management system in place
2	Appoint Quality Assurance Officers at all laboratory levels and establish their roles and responsibilities			MOH, NPHL, Lab TWG PEPFAR/CDC, ICAP Implementing Partners, UNDP/ Global Fund	Quality Assurance Officers deployed at all laboratory levels; standard Job Descriptions for Quality Assurance officers available
3	Introduce the Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA) into laboratories at all levels for continuing laboratory improvement			MOH, NPHL, Lab TWG PEPFAR/CDC, ICAP Implementing Partners, UNDP/ Global Fund	Selected state laboratories are enrolled in the SLIPTA programme and achieve at least a 2 star rating
4	Establish an officially recognised national laboratory accreditation scheme for laboratories at all levels based on national standards. Encourage laboratories at national and state levels to seek international accreditation			MOH, NPHL, Lab TWG PEPFAR/CDC, ICAP Implementing Partners, UNDP/ Global Fund	Functional national laboratory accreditation scheme in place
5	Ensure quality management systems are included in all laboratory training programmes.			MOH, NPHL, Lab TWG PEPFAR/CDC, ICAP Implementing Partners, UNDP/ Global Fund	Quality management integrated into all laboratory training programmes

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