UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH, COMMUNITY, DEVELOPMENT GENDER, ELDERY AND CHILDREN (MoHCDGEC)

NATIONAL PUBLIC HEALTH LABORATORY (NPHL)

ISO15189:2012

QUALITY MANUAL

Author Name	Title:	Signature:	Date:
Seif Abdul	Quality Officer		27.07.2021
Reviewed By			
Ambele E Mwafulango	Laboratory Manager		28.07.2021
Approved By			
Medard Beyanga	Laboratory Director		28.07.2021
Next Review			30.07.2023

TABLE OF CONTENTS

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Medard Beyanga

Laboratory Director NPHL.

ABBREVIATIONS

Abbreviations as used in this Quality Manual

ADDS	Assistant Director Diagnostic Services
BSL	Biosafety Level
CLSI	Clinical Laboratory Standards Institute
DQO	Deputy Quality Officer
EQA	External Quality Assessment
EAPHLN	East African Public Health Laboratory Network
ISO	International Organization for Standardization
IQC	Internal Quality Control
MoHCDGEC	Ministry of Health Community Development Gender Elderly and Children
MSD	Medical Stores Department
MSDS	Material Safety Data Sheet
MU	Measurement Uncertainty
NC	Non conformance
NIMR	National Institute of Medical Research
NPHL	National Public Health Laboratory
QMS	Quality Management System
QO	Quality Officer
HCTS	Health Care Technical Services
LIS	Laboratory Information System
NIDC	National Information Data Centre
ICT	Information and Communication Technology
SCM	Sample Collection Manual
SLIPTA	Strengthening Laboratory Improvement Towards Accreditation
SADCAS	Southern African Development Community Accreditation Service
SANAS	South African Accreditation System
SOP	Standard Operating Procedure
SF	Safety
WHO	World Health Organization

DEFINITIONS

All definitions listed below are as defined inISO9000:2000 and ISO 15189:2012

Calibration

The set of operations which establish, under specified conditions, the relationship between values indicated by a measuring instrument or measuring system or values represented by a material measure, and the corresponding known values of a reference standard.

Corrective action

Action taken to eliminate the cause of an identified nonconformity or other undesirable situation

Documentation

All the written or electronic instructions and records, quality procedures and recorded test results involved in the manufacture of a product.

Non-Conformity

The non-fulfillment of a specified requirement

Quality

The totality of features and characteristics of a product, service or test method that bear on its ability to satisfy stated or implied needs.

Quality Assurance

All those planned and systematic actions necessary to provide adequate confidence that a product, service, test method will satisfy given requirements for quality.

Quality audit

A systematic and independent examination to determine whether activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are appropriate to achieve objectives.

Quality control

The operational techniques and activities that are used to fulfill requirements for quality

Quality management

Aspect of the overall management function that determines and implements the quality policy

Quality policy

Overall quality intentions and direction of an organization as regards quality as formally expressed and authorized by top management.

Quality system

The organizational structure, responsibilities, procedures and resources for implementing quality management

Specification

Document that states the requirements to which the product, service, or test method has to conform.

Traceability

Ability to trace the history, application or location of an item, activity or result by means of documented records.

Validation

The act of confirming a product, service, or test method that it meets the requirements for which it was intended

Laboratory

Clinical laboratory for the biological, microbiological, immunological, chemical, immune-hematological, cytological, pathological or other examination of materials derived from human body for the purposes of providing information for the diagnosis, prevention, prognosis, surveillance and treatment of disease in assessment of the health of human beings, and which may provide a consultant advisory service covering all aspects of laboratory investigation including the interpretation of results and advice on further appropriate investigation.

NPHL staff

All members of staff who work in the NPHL

Technical staff

Laboratory members of staff who performs laboratory testing

Laboratory Management

Comprises of Laboratory Director, Laboratory Manager, Deputy Laboratory Manager, Quality Officer, Deputy Quality Officer, Safety Officer, Deputy Safety Officer and Heads of Sections

1.0 SCOPE OF SERVICE

The NPHL provides technical expertise and quality assurance services to clinical and public health Laboratories. The service provided mainly focus in the following fields;

- **Clinical chemistry**
- **Haematology**
- **Serology and Immunology**
- **Bacteriology**
- **Parasitology**
- **Molecular Biology**

Specific tests offered in each discipline have been described in the sample collection manual.

2.0 QUALITY POLICY AND OBJECTIVES

2.1 QUALITY POLICY

The NPHLis committed to continual improvement of laboratory processes and services to achieve ongoing customer satisfaction. It is therefore our policy and commitment to:

- Consistently provide efficient and reliable referral and public health laboratory testing services that are fit for intended use and conforms to customer needs, national and international standard requirements.
- Ensure that all personnel are technically competent, qualified and committed to good professional practice for the tasks they perform, and that all personnel are trained and familiar with the quality system documentation and this Quality Policy statement for the effective implementation of the Quality Management System (QMS).
- Professionally and effectively perform public health and referral laboratory testing services to produce accurate, reliable, timely and precise results.
- Consistently comply with ISO 15189:2012 standard requirements to ensure quality public health and referral laboratory testing services, and to continually improve the effectiveness of the QMS.
- Reviews its Quality Policy for continuing suitability in order to keep abreast with knowledge and technological developments.
- Develop and review Quality Objectives on an annual basis during Management review meetings.

It is NPHL goal to encourage active participation of all employees in quality planning and continual improvement efforts to meet all quality services.

The NPHL management is committed to support the implementation of its QMS which includes, but are not limited to testing services, human resources management, client satisfaction and safety considerations. Management supports all laboratory personnel by providing them with the appropriate authority and resources to carry out their duties.

2.2 QUALITY OBJECTIVES AND PLANNING

The management of NPHL sets measurable quality objectives (specific, measurable, achievable, realistic and time bound) for different levels and functions of the laboratory and reviews them annually during management reviews. The management involves its staff in setting up of the quality objectives by collecting their suggestions prior to the management review. Quality objectives are approved by the Laboratory Director before being implemented (Quality objectives attached in appendix B). The Quality Officer (QO) ensures that the integrity of the QMS is maintained when changes are being planned and implemented.

3.0 INTRODUCTION

3.1 Introduction and Legal Identity

This Quality Manual describes the organizational quality system for the NPHL under Diagnostic Services Section (DSS) of the Ministry of Health, Community Development, Gender, Elderly and Children (MoHCDGEC), Tanzania. The plan to have NPHL was established in **2015** in order to strengthen the national effort to combat numerous infectious diseases as well as to improve overall public health across the country. The laboratory will contribute to improving laboratory service by introducing new technologies and systems to address weak health infrastructures and providing training opportunities to increase the number of skilled health care workers in Tanzania. NPHL also serves as a center for investigation and monitoring of rarely encountered, emerging and re-emerging pathogens including Ebola and Marburg hemorrhagic fever viruses, *Yersinia pestis*, *Rickettsia prowazekii,*Influenza, Corona virus and *Bartonellaquintana*.

The Government of the United Republic of Tanzania through the MoHCDGEC in collaboration with World Bank through the EAPHLN Project and using health sector basket fund, has built both Biosafety level 2 (BSL2) and Biosafety Level 3 (BSL3) laboratories in Mabibo, Dar es Salaam. On March 22, 2020 the NPHL was officially handed over to the MoHCDGEC and became established.

Currently, the legislation for the establishment of NPHL as an entity is within the MoHCDGEC portfolio. However, NPHL is mandated to assist the MoHCDGEC in fulfilling its public health responsibilities.

3.2 Corporate Strategies, Policies and Priorities

The creation of NPHL was a result of many consultations and reports that emphasized the growing concerns with regards to the capacity of Tanzania's public health system to anticipate and respond effectively to public health threats. It is within this context that NPHL has created within its mandate its:

- Goal
- Vision
- Mission and

- Values statement

Goal

The goal of the NPHL is to contribute to the achievement of the National Action Plan for Health Security Goal of 2017-2021 in prevention and control of public health threats.

Vision

To be a sustainable center of excellence in provision of reliable, accessible and quality public health and referral laboratory services in Tanzania and beyond.

Mission

To ensure provision of high quality, equitable, relevant, timely, reproducible, accessible and affordable health Laboratory services for the management of patients,prevention,controland surveillance of the disease, research and development towards achieving better for all people in Tanzania and beyond.

The NPHL has the following set of core values to guide its work and the manner in which it will pursue its mandate (**Table 1** refers):

CORE VALUES	OPERATIONAL DEFINITIONS
Collaboration	Ensure that the NPHL works with other stakeholders in fulfilling its overall mandate for the protection of public health
Customer satisfaction	Focusing on provisional of customer Centred services
Efficiency	Working with integrity, accountability, responsibility and professionalism
Innovation	Pioneering relevant research solutions and training
Privacy	Ensure confidentiality and protection of information related to any persons, families, organizations and communities
Reliability	Ensure all its clients can count on the NPHL for addressing their laboratory and information requirements as well as to facilitate technical staff to fulfil their mandates with accuracy and confidence
Timeliness	Ensure all clients have access to information and test results on a consistent basis and with the fastest turn-around time possible
Transparency	Ensure all persons are forthcoming with information related to decision making except where prohibited by legislation

TABLE 1: Core values and operational definitions

The NPHL provides several programs including public health and reference diagnostic services and related research functions for the detection and prevention of human infectious agents.

Because of the significance and infectious nature of these diseases, all work with live or infectious agents are carried out under vigorous bio-safety containment conditions. The NPHL contains laboratories which meet Containment Level (BSL) 2 and highly safety containment level BSL 3.

Financing

The MoHCDGEC provides the NPHL with financial resources, guidance and support.

Maintenance of facilities

NPHLmade up of two building facilities, The Public health laboratory located at Ubungo External,Mabibo area off Mandela road near Benjamin Mkapa Export processing zone centre and the Quality assurance and Training centre located at 2448 Luthuli Road/Sokoine drive in the 3rd and 4th Floors of the National Institute for Medical Research (NIMR) building. The organization has an internal equipment maintenance section which has the responsibility for maintaining the supply of electricity and water to the laboratory. Equipment maintenance is supervised by the equipment maintenance section. The building infrastructure maintenance is a dual responsibility of MoHDCGEC.

Contact information

National Public Health Laboratory (NPHL)
Ubungo External,Mabibo area near TMDA HQ office
Off Mandela Road
P.O BOX 9083
Dar es Salaam

4.0 MANAGEMENT REQUIREMENTS

4.1 Organization and Management Responsibility

4.1.1 Organization

4.1.1.1 **General**

NPHL satisfies the requirements of ISO 15189:2012 standard when performing laboratory work at its permanent facility through the documentation of its QMS and its effective implementation throughout the laboratory.

4.1.1.2 **Legal entity**

This Quality Manual describes the organizational quality system for the NPHL under the authority of DSS of the MoHCDGEC in Tanzania. Currently, the legislation for establishment of the NPHL as an entity is within the MoHCDGEC portfolio. NPHL satisfies all laws which are applicable to itslaboratory operations. Legal identity of NPHL is recognized by the notification/letter from the Permanent secretary of the MoHCDGEC with reference number HD 207/270/03/13, describing the identity and roles of NPHL.

4.1.1.3 **Ethical Conduct and Confidentiality**

a. NPHL management ensures that all its personnel are bound by the Ethical Code of Conduct (NPHL/ID/003) and must follow the procedure for protection of confidential information (NPHL/SP/15)to ensure that there is no involvement in any activities that could diminish confidence in the laboratory's competence, impartiality, judgment or operational integrity.
b. NPHL requires all members of staff to disclose any internal and external commercial, financial or other pressures and influences that may affect the quality of their work. Members of staff are free to approach any managerial staff in confidence and share their personnel pressures. It is the responsibility of both the laboratory management and staff to generate and report data objectively and therefore no staff has the authority to take any action or to require any action to be taken which interferes with the laboratory in discharging this responsibility, irrespective of the normal line of management.

c. Responsibilities of all laboratory personnel of NPHL are defined in order to identify conflict of interest. Where potential conflicts of interest exist, employee will complete and submitto management the Conflict of interest form (NPHL/M/FM026).

d. Sample management procedure (NPHL/SP/23) contains guidelines on how the ethical handling of human samples and all personnel are supposed to sign a pledge at the end of the ethical code of conduct to show that they have understood it.

e. Confidential information shall not be disclosed to any third party without written authority from the Laboratory Director. During orientation, all new members of staff are

trained and are required to sign a confidentiality and conduct undertaking form (NPHL/M/FM027) to ensure that confidential information are not disclosed to unauthorized persons. The organization also uses the NPHL/SP/15, Protection of confidential information Procedure to ensure that all the confidential information is sufficiently protected from abuse.

4.1.1.4 **Fraudulent Results**

NPHL management is responsible for the detection and prevention of fraudulent results, misappropriations and other irregularities. Each member of the management team is familiar with the type of improprieties that might occur within his or her area of responsibility, and must be alert for any indication or irregularity.

Any irregularity that is detected or suspected are reported immediately to the Laboratory Director or the Laboratory Manager who coordinates all investigations within the laboratory and other affected areas, both internal and external. All cases relating to fraud will be treated seriously and anyone found guilty will be disciplined accordingly after investigations.

4.1.1.5 **Laboratory Director**

The Laboratory Director is the Head of the NPHL. The Laboratory Director reports directly to the Assistant Director of Diagnostics Services in the MoHCDGEC. The responsibilities of the Laboratory Director include professional, scientific, consultative or advisory, organizational, administrative and educational matters relevant to the operations of the National Reference Laboratory testing services. The Laboratory Director maintains the ultimate responsibility for the overall operation and administration of the laboratory. Detailed job descriptions are available at the NPHL and describethe responsibilities of all personnel including Laboratory Director.

Responsibilities of the Laboratory Director include but not limited to the following:

- Provides effective leadership of the reference, public healthlaboratory service, including budgeting, planning and financial management, in accordance with institutional assignment of such responsibilities.
- Relates and functions effectively with stakeholders including accrediting and regulatory agencies, appropriate administrative officials, the healthcare community, and the patient population served, and providers of formal agreements, when required.
- Ensures that there are appropriate numbers of staff with the required education, training and competence to provide reference, public health laboratory services that meet the needs and requirements of the users.
- Ensure the implementation of the Quality Policy and the Quality Management System.
- Ensures a safe environment for provision of referral and public health services.
- Selects and monitors referral laboratory services as required.
- Ensure the provision of clinical and public health advice with respect to the choice of examinations, use of services and interpretation of examination results.
- Provides professional development programs for laboratory staff and opportunities to participate in scientific and other activities of professional interest.

- Defines, implements and monitors standards of performance and quality improvement of the referral and public health laboratory service or services.
- Designs and implements a contingency plan to ensure that essential services are available during emergency situations or other conditions when laboratory services are limited or unavailable.
- Plans and directs research and development, as appropriate for a referral and public health facility.
- Delegates responsibilities as appropriate to other managerial and supervisory staff.

4.1.1.6 **Human Resource Officer**

The Human Resource Officer reports to the Laboratory Director and is responsible for the following activities:

- Prepare,monitor and implement development plans for the staff of the NPHL.
- EducatesNPHL staff on work regulations and guidelines.
- Coordinates implementation of on-the-job training plans for the NPHLstaff.
- Innovate strategies for improving work performance at the NPHL.
- Monitors execution and performance of NPHLoperations.
- Conduct any other duties as assigned by the Laboratory Director of the NPHL.

4.1.1.7 **Procurement Officer**

The Procurement Officer reports to the Laboratory Director and is responsible for the following activities:

- Oversees and supervisesstaff and all activities regarding purchasing and inventory of laboratory items.
- Compiles and reviews with relevant staff the procurement plan for the purchase of laboratory equipment, services, and supplies.
- Complies withNPHL procurement policies and procedures.
- Liaises with respective sections on reviewing, comparing, analyzing and approving products and services to be purchased.
- Manages inventory and maintains accurate purchase and pricing records.
- Maintains and updates supplier information such as qualifications, delivery times, product ranges, etc.
- Conducts supplier evaluations as necessary.
- Maintains good supplier relations and negotiating contracts.
- Prepares budget, cost analyses and reports.
- Conducts any other duties as assigned by the Laboratory Director.

4.1.1.8 **Accountant Officer**

The Accounting Officer reports to the Laboratory Director and is responsible for the following activities:

- Maintains and reviews of financial records.
- Ensures compliance with accounts and tax laws.

- Advises and prepares budgets regularly.
- Monitors expenditure and provide reports.
- ManagesNPHL accounts and prepares financial statements.
- Conducts any other duties as assigned by the Laboratory Director.

4.1.1.9 **Laboratory Manager**

The Laboratory Manager reports to the Laboratory Director and is responsible for the following activities:

- Coordinates the establishment of the QMS based on ISO 15189:2012, supports its implementation and coordinates activities pertaining to quality.
- Supervises and direct work at sectional level.
- Coordinates and supervises staff induction, training and competence assessment.
- Monitors QMS implementation.
- Ensures that the safety requirements of the laboratory are being followed.
- Selects referral laboratories and monitors the quality of their services.
- Addresses any complaint, request or suggestion from staff and/or users of laboratory services.
- Monitors all work performed in the laboratory to determine that clinically public health relevant information is being generated.
- Identifies and addresses complaints, non-conformities and corrective actions.
- Advises the Laboratory Director in technical matters pertaining to the NPHL.
- Conducts any other duties as assigned by the Laboratory Director.

4.1.1.10 Laboratory Quality Officer

The QO is appointed by the Laboratory Director and ensures that the QMS is implemented and maintained throughout the laboratory. The QO has the responsibility and authority to ensure that the requirements of the QMS function effectively. The QO reports directly to the Laboratory Director.

The Quality Officer is responsible for the following activities:

- Chairs the Quality Committee and ensures that all quality related issues are addressed.
- Develop, implements and revise the QMS to ensure that it is up to date at all times.
- Organizes and facilitates internal staff training on QMS.
- Collects and monitors quality/performance indicators from each section and ensures that corrective and preventive actions are taken for tests that do not meet the target indicators.
- Prepares and presents updates of the QMS at weekly and monthly staff meetings
- Plans and coordinates internal audits of the laboratory in accordance with the SOP on conduct of audits.
- Identifies and addresses complaints, non-conformities and corrective actions.
- Interacts with the accreditation bodies on behalf of Laboratory Director.
- Plans, conducts and facilitates training, workshops and seminars.
- Organizes and coordinates Annual Management Review Meeting.

- Compiles and distributes performance reports from Management Review Meeting.
- Selecting referral laboratories and monitoring the quality of their services.
- Ensuring that processes needed for the QMS are established, implemented, and maintained.
- Reporting to laboratory management, at the level where decisions are made on laboratory policy, objectives, and resources, on the performance of the QMS and any need for improvement.
- Ensuring the promotion of awareness of users' needs and requirements throughout the organization.

4.1.1.11 Deputy Quality Officer

The Deputy Quality Officer is appointed by Laboratory management and reports to the Quality officer. The Deputy Quality provides support and works closely with the Quality Officer to ensure that all the activities listed under Quality Officer are realised.

4.1.1.12Safety Officer

The Safety Officer is appointed by Laboratory managementand reports to the Laboratory Manager and is responsible for ensuring the implementation of safe practices throughout the facility and for following up and taking corrective and preventive actions on all safety related incidents/accidents. The Safety Officer is responsible for the following activities:

- Reports to the Laboratory manager on the functioning and effectiveness of the safety measures as detailed in the Laboratory Safety Manual.
- Ensures implementation of the QMS in relation to safety issues.
- Trains and retrain staff on laboratory biosafety and biosecurity and ensures that safety practices are observed.
- Implements and maintains a safe work environment.
- Conducts safety related risk assessments for each laboratory process.
- Records and Monitors safety eventsand report to management.
- Implements corrective actions in response to safety incidents and accidents.
- Ensure safe and appropriate disposal of laboratory waste.
- Identifies and communicates safety lessons learned to all members of staff.
- Ensures that all staff receives safety orientation.
- Compile a list of all hazardous materials, chemicals and reagents used in NPHL, followed by Material Safety and Data Sheets (MSDS) for each hazardous substance.
- Implement a safe work environment by conducting annual safety audits to ensure compliance with good safety practices and applicable requirements.

4.1.1.13Deputy Safety Officer

The Deputy Safety Officer is appointed by Laboratory management and works closely with the Safety Officer to ensure that the activities listed above (under the responsibilities of the Safety Officer) are completed in a timely manner.

4.1.1.14Section Heads

All Section Heads are appointed by Laboratory management andreports to the Laboratory Manager and are responsible for the following activities:

- Supervise Medical Laboratory Technologist/Scientists within their respective sections.
- Identify and address complaints, non-conformities and corrective actions relating to their sections.
- Perform routine and specialized laboratory tests to the respective discipline.
- Review and approve all laboratory results before release.
- Comply with established QMS and safety procedures
- Train and orient new staff members within their sections.
- Plan and conduct competency assessments of the laboratory staff.
- Prepare monthly and quarterly reports.
- Order and monitor laboratory suppliers.

4.1.1.15Medical Laboratory Scientists/Technologists and other Laboratory staff

- The roles and responsibilities for all other members of staff are defined in their respective Job descriptions available in their personnel files.

NB:

- The job descriptions listed above only summarize the functions of each role, for further details, check their respective job descriptions.
- Section Heads are deputized by Laboratory Scientist/Technologists within their respective sections.

4.1.2 Management Responsibility

4.1.2.1 **Management Commitment**

Laboratory Management is committed to the development, implementation and continual improvement of its QMS and Clinical and Public Health Laboratory services. This requirement is achieved by**:**

- Communicating and ensuring that all laboratory personnel are aware of and comply with regulatory and accreditation requirements through well planned and scheduled laboratory training sessions.
- Ensuring that all laboratory personnel are aware of and comply with the needs and requirements of service users.
- Establishment of the Laboratory Quality Policy.
- Ensuring that quality objectives and quality management plans are in place to achieve these objectives.
- Defining the responsibilities, authorities and interrelationships of all personnel (Organizational chart and job descriptions).

- Establishment of effective communication processes with staff and also with the service stakeholders.
- Appointment of a Quality Officer.
- Ensuring that management reviews of the QMS occur on at least an annual basis.
- Ensuring that staff is competency assessed to provide assurance that they are competent to perform their assigned activities.
- Ensuring that there are adequate resources to enable the proper conduct of pre-examination, examination and post-examination activities.

4.1.2.2 **Needs of User**

Laboratory management regularly reviews the laboratory services including the advisory and interpretative services provided to ensure that it meets the needs of users served. Complaints received from users are fully investigated and any necessary corrective actions undertaken. Assessment of user's satisfaction and complaints is conducted on annual basis through customer Satisfaction survey and the findings presented in the annual management review**.**

4.1.2.3 **Quality Policy**

NPHL Quality Policy are described in section 2.1 of this Quality Manual

4.1.2.4 **Quality Objectives**

NPHLQuality Objectives are described in section 2.2 of this Quality Manual.

4.1.2.5 **Responsibility, authority and interrelationships**

Responsibilities, authorities and interrelationships of personnel are defined in the NPHL and MoHCDGECorganizational chart found in page 23 of this Quality Manual as well as in individual staff job descriptions. The specific roles and responsibilities of key personnel are as outlined in this Quality Manual. The roles and responsibilities for the rest of the staff are contained in their respective personnel files which are kept by the QO. NPHL management has also appointed deputies to key management and technical positions, which is QO and safety officer**.**

4.1.2.6 **Communication**

Communication is vital for effective performance as well as continual improvement of a QMS. It is in this regard that NPHL management has put in place communication mechanisms that will ensure that customer requirements (both internal and external) are met. All communications (outgoing and incoming) are logged or filed whichever is appropriate.

4.1.2.6.1 Internal Communication

To achieve collective ownership of the system by both management and staff, laboratory management involves all staff in every aspect of the development and implementation of QMS. For effective communication within the laboratory, management has put in place channels of communications, which includes but arenot limited to the following**:**

- Memos, letters, notices, email
- Meetings

- Telephonic
- Oral communication
- Verbal or written instructions (e.g. through Quality Manual, Lectures).

4.1.2.6.2 External Communication

Communication with external stakeholder is in the form of but not limited to electronic mail, fax, telephonic, video conference and meetings. Laboratory management is authorized to offer telephonic consultations on technical matters within the scope of their responsibilities to external clients. Records of all communications shall be kept thereof. Communication log (NPHL/M/FM005) is used to document details of communication both internal and external.

Supporting Documents

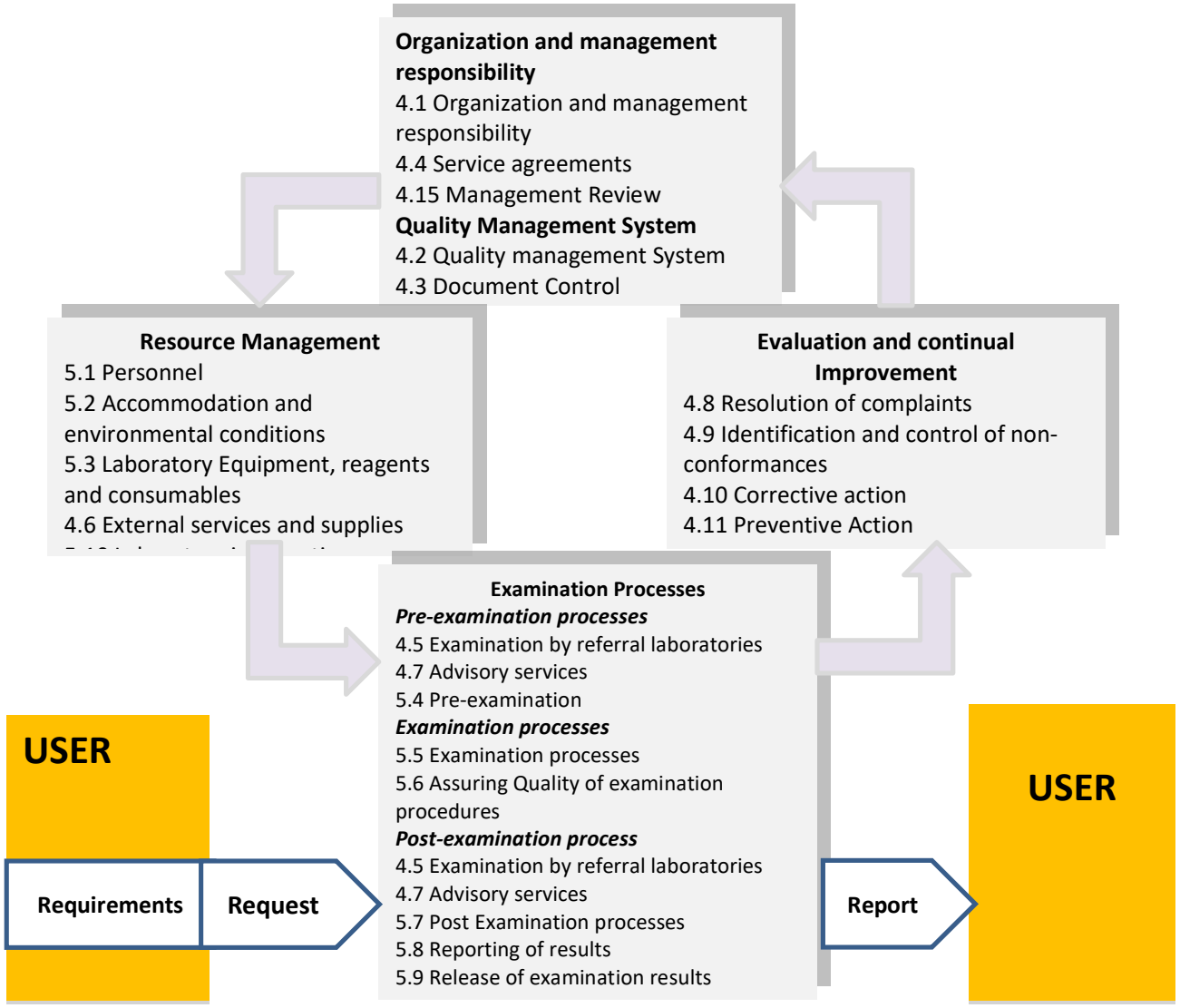
NPHL/SP/15Protection of confidential information Procedure
NPHL/SP/23 Sample management procedure
NPHL/M/FM005 Communication log
NPHL/M/FM026Conflict of Interest disclosure form
NPHL/M/FM027Confidentiality and Conduct undertaking form
NPHL/ID/003 Ethical Code of Conduct
JD-Job Descriptions
Legal Identity letter from MOHCDGEC (HD 207/270/03/13)

4.2 Quality Management System

4.2.1 General Requirements

Through the creation of this quality manual laboratory management has provided documentary evidence of the existence of a QMS. Laboratory management will endeavour to improve the effectiveness of this QMS in accordance with the requirements of International Standard ISO 15189:2012 Requirements for Quality and Competence. The Laboratory has determined the following processes needed for the Quality Management System.

Figure 1 Interaction of Laboratory processes



The NPHL has developed Quality Indicators for the different laboratory processes to ensure that both the operation and control of these processes are effective. Quality indicators are available on NPHL/ID/002_List of Quality indicators. Laboratory management also ensures the availability of resources and information necessary to support the operation and monitoring of these

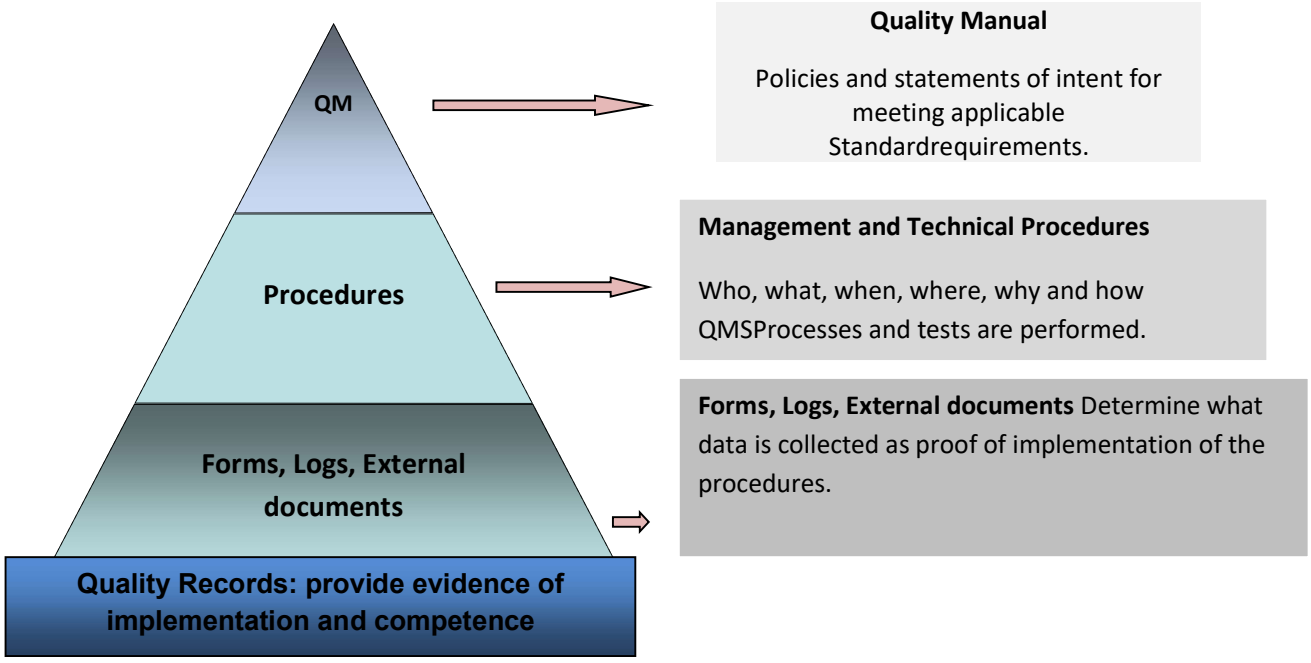
processes. The Quality indicators are regularly monitored and the required action is implemented to achieve planned results and continual improvement of these processes.

4.2.2 Documentation requirements

4.2.2.1 General requirements

NPHLuses a 4-tier documentation structure of the Quality Management System that consist of Quality manual, procedures, forms, logs and records as shown below.

Figure 2 Quality System Documentation



The Quality Manual is the governing document that defines the quality system policies and statements of intent by the NPHL and is based on ISO 15189:2012 requirements as well as Document Control Procedure (NPHL/SP/02).

Management and Technical Procedures describe who, what, when, where and how quality management system and testing processes are performed. Personnel are required to sign a reading and understanding form at the back of each manual or procedure as proof that they have read and understood the documents.

Forms and Logs, are used for collecting data for the executed procedures.

External documents: Documents of external origin are also recognized in the system and these include documents like textbooks, ISO standard and kit inserts.
Records give data and evidence of activities that have been performed. At this level, forms that have been developed are being filled in to generate records. Laboratory Management ensures that all members of staff have access to and are instructed in the use and application of the QMS and all the referenced and supporting documents. This is evident by signing the read and understood acknowledgement form found at the end of manuals and procedures, and the training records. It is the responsibility of the Quality Officer to keep the quality manual up to date.Quality Records are retained as objective evidence of compliance to the requirements of ISO 15189:2012 and NPHL management and technical procedures per Record Control Procedure NPHL/SP/10.

4.2.2.2 **Quality Manual**

This Quality Manual outlines the general form of the Quality System in operation at NPHL laboratory identifying the general arrangements for ensuring that the Quality Policy is adhered to by staff at all times. It describes the QMS for the benefit of laboratory management and staff and provides information for users and for accreditation bodies. The sections of the Quality Manual are arranged so that they equate with the ISO 15189:2012. Under each of the standards is a brief description of the way in which the laboratory seeks to comply with the particular standard. Appropriate procedures and forms are referenced to support the description.

Figure 3: MoHDCGEC organization structure

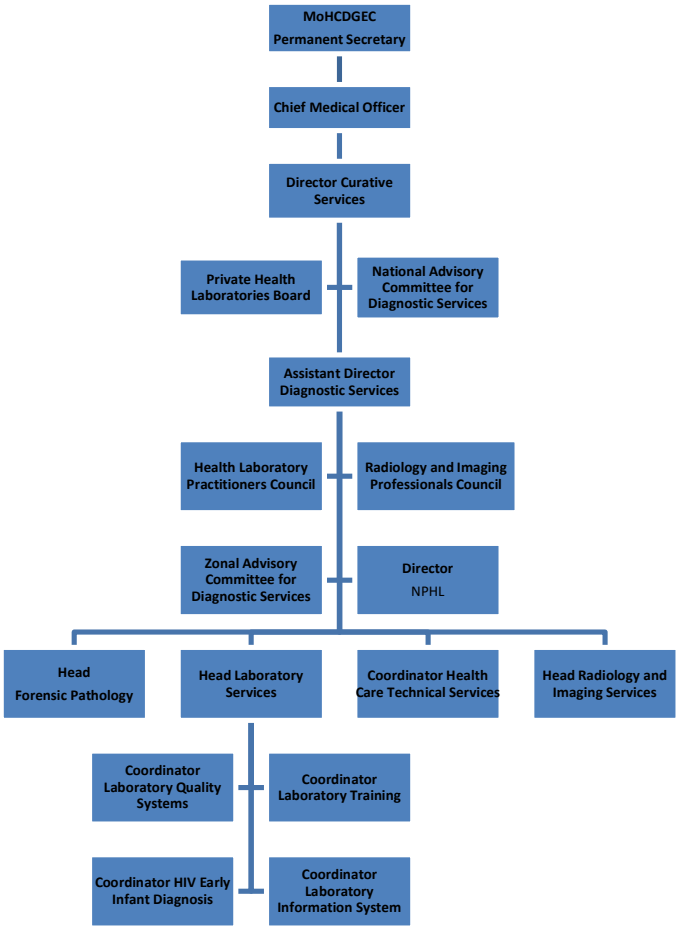
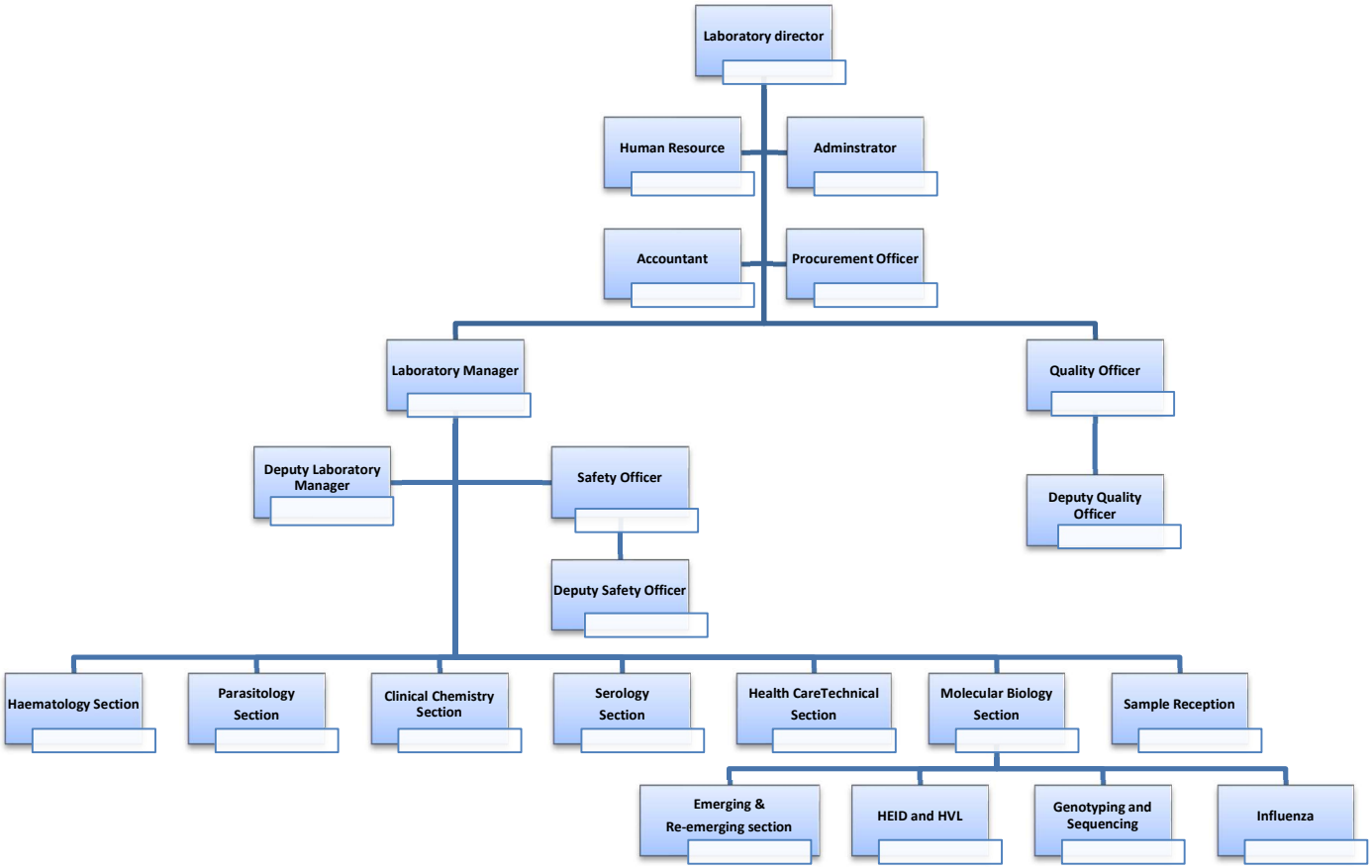


Figure 4: Current NPHL organization structure



4.3 Document Control

NPHL has Document control procedure (NPHL/SP/02) that provides guidelines on how to control all documents in the QMS, whether internally generated, externally generated or computerized. A copy of each document in the QMS is archived for later reference. All quality documents are retained for a minimum period as defined in the Minimum Retention Times – Documents, and Records (NPHL/ID/001).A master copy of each quality document is maintained electronically and as and hard copy under the authority of the QO. For dailyuse, hard copies are available in each section. All staff needs to sign and date the original hard copy indicating that they have read and understood the procedure and will implement as required.

The Quality Manual, Sample collection manual and System/Management procedure are created by the Quality Officer; reviewed by Laboratory Manager and approved for use by the Laboratory Director. Safety manual and safety related procedures are developed by safety officer, reviewed by Quality officer or Laboratory manager or and approved for use by Laboratory Director. All technical procedure are prepared by competent technical staff, reviewed by Quality Officer and approved for use by Laboratory Manager. All Documents issued to personnel are approved by the Laboratory Director prior to use. The QO maintains the master index (NPHL/M/FM001) which shows the current revision status and their distribution. The organisation ensures that only current authorised versions of appropriate documents are available for use at each work station.All documents are periodically reviewed and updated every two years or whenever necessary. All obsolete documents are removed from the workstations and destroyed to prevent inadvertent use. One copy of the obsolete documents is retained as softy copy dated and watermarked with word **"OBSOLETE"** on all pages. The laboratory does not allow changes to be done by hand to all documents. Changes to documents are done following Document Control Procedure NPHL/SP/02. All obsolete documents are stored electronically for the period stated in the Minimum Retention Times – Documents, Records (NPHL/ID/001)

All documents are uniquely identified with the following identifiers: Title; Date, Current version number and date; Pages number to total number of pages; Authority for issue.

Supporting Documents

NPHL/SP/01Document Control Procedure
NPHL/SP/10 Record Control Procedure
NPHL/M/FM001 Master List Index
NPHL/M/FM008 Quality Management Plan
NPHL/ID/002 List of Quality Indicators
NPHL/ID/001Minimum Retention Times – Documents, Records

4.4 Service Agreements

All reviews for service agreements shall be done prior to commencement of work. The NPHL uses guidelines outlined in Service agreement procedure (NPHL/SP/03) to review all agreements it enters into for provision of laboratory services. Service agreement for individual samples will be done upon receipt of the sample and the associated request form. For large sample size that may be associated with research projects and special studies, the client requesting for laboratory services shall provide their protocol for examination and approval prior to testing of the samples. The NPHL management will determine whether the organization has the capacity and resources to process the samples. The NPHL's capacity to meet the agreement requirements in terms of human resources, space, reagents, other logistics and procedures including availability of specific human skills and expertise will be considered. Consideration is also given to specimen collection, management, testing timelines and modalities of reporting results. In case of any deviation in contracts, the Laboratory Director or the Laboratory Manager will inform clients through a letter/ written memo.

Supporting Documents

NPHL/SP/03Service agreement procedure

4.5 Examination by Referral Laboratories

4.5.1 Selecting and evaluating Referral Laboratories and Consultants

The NPHLmay need the services of a referral laboratory for tests that are not performed at the NPHL or in cases where back up services are required. Before such laboratories are used, they must be evaluated. The NPHLuses the Selection and Evaluation of Referral laboratories procedure (NPHL/SP/04) for evaluating and selecting the services of referral laboratories. All referral laboratories are evaluated and selected on any of the following basis, in their order of priority:

1. Accreditation to relevant ISO or equivalent standards
2. Audit conducted by NPHL or a recognized body (Technical requirement ISO 15189:2012)
3. Satisfactory performance in relevant External Quality Assessment/Proficiency Testing or Interlaboratory comparison schemes.
4. Acceptable results for known samples.

For Consultants who provide technical advice and opinions on test procedure and results, the selection criteria are based on:

1. Qualification certificate and curriculum vitae.
2. Good performance in EQA results participated.

NPHL shall enter into an agreement with an evaluated and approved referral laboratory for the referral of samples. The NPHL maintains a register of all selected referral laboratories with their contact details and the type of tests referred. Referral laboratories are reviewed once after two years. All referred tests will be recorded in NPHL/M/FM011Sample Referral Log which will be kept by referring sections.

4.5.2 Provision of examination results

The NPHL will be responsible for ensuring that examination results and findings from referral laboratories are provided to the person making the request (NPHL). The reports from accredited referral laboratories shall be sent to the requested clinicians without alterations, but the reports from non-accredited referral laboratories are subject to alterations to meet the minimum requirements for the ISO 15189:2012 standard clause 5.8. However, alterations shall not alter the clinical interpretations of the results.

Supporting Document

NPHL/SP/04Selection and Evaluation of Referral laboratories procedure

NPHL/M/FM011 – Sample Referral Log

4.6 **External Services and Supplies**

The NPHL follows procurement regulations from the Government of Tanzanian when purchasing equipment, reagents and consumable supplies. All required items are purchased

through the Medical Stores Department (MSD) as it is the sole supplier of the MoHCDGEC. However, other NPHL approved/listed suppliers are normally used as a backup for MSD. NPHLconducts evaluation of MSD and other approved/listed suppliers once a year to ensure that the final supplies received are of acceptable quality. This procedure is performed following guidelines outlined inExternal Services and Supplies procedure NPHL/SP/18.

The NPHL performs inspection on all items received to ensure that they meet the inspection criteria and then placed in storage facilities according to manufacturer's recommendations. All storage facilities shall be adequately maintained to ensure cleanliness and clutter are monitored for temperature control. Qualitycontrol tests are conductedon reagents and test kits according to procedure for Reagent and consumables Management procedure (NPHL/SP/19). The reagents and test kits that pass quality control shall be accepted for use, and those thatfail shall be rejected and returned to the MSD. Storage and inventory of purchased items are performed according to guidelines outlined procedure for Reagent and consumables Management procedure (NPHL/SP/19). The laboratory maintains a record of all laboratory supplies, including reagents and consumables, this information includes:

- Identity of the reagent or consumable
- Contact information for the supplier or the manufacturer
- Date of receiving and date of entering into service
- Condition when received (e.g. acceptable or damaged)
- Manufacturer's instructions
- Records that confirmed the reagent's or consumables initial acceptance for use
- Performance records (IQC) that confirm the reagents or consumables ongoing acceptance for use.

All reagents that are prepared within the laboratory, such as media, must contain batch numbers, expiry dates, and the name/s of the person who prepared it.

The NPHL has a focal officer who acts as a liaison between the NPHL, MoHCDGECprocurement unit and MSD to ensure efficient delivery of reagents and supplies.

Supporting Documents

NPHL/SP/18 External Services and Supplies

NPHL/SP/19 Reception, Storage, acceptance testing and Inventory Management procedure

4.7 Advisory Services

The Laboratory management shall provide advisory services on choice of testing, use of laboratory services, repeatfrequency and required type of sample via its Sample collection manual. Advisory services are offered via e-mail, letters, fax, phone and meeting with customers as perAdvisory Service Procedure (NPHL/SP/17).

The Laboratory Director, Laboratory Manager, Deputy Laboratory Manager, Quality Officer, Deputy Quality Officer, Safety Officer and Deputy Safety Officer will give recommendations on selection of testing services and proper samples for the client and interpretation of results where appropriate. Section heads or laboratory scientist, technologists with experience in each field are given responsibility for providing advice to patients, nurses and clinicians on the use of laboratory services as shown on NPHL Authority matrix (Appendix B).

NPHL has a Sample Collection Manual that is also used to provide information to clinicians for sample collections, copies of which have been distributed to all the sample collection sites.

The details of provided advisory services offered must be recorded on the Advisory service form (NPHL/M/FM007). When changes are made on testing services, new services become available or a testing method has been changed, the Laboratory Director shall communicate this to the service users (laboratories, physicians, nurses or others). This communication (minutes of meetings or memo)is documented and filed.

Supporting Documents

NPHL/SP/17 - Advisory service Procedure
NPHL/M/FM007 - Advisory service form
Sample Collection Manual
NPHL Authority matrix (Appendix B)

4.8 Resolution of complaints

The NPHL uses the resolution of complaints procedure (NPHL/SP/06) for handling and managing all internal and external complaints. Complaints can be received as feedback via phone, e-mails, verbal or written from its service users (Clinicians, patients or other parties) and through the suggestion box at the laboratory. All complaints are recorded on the Complaint Form (NPHL/M/FM013), and registered in a Non-Conformity register (NPHL/M/FM016), where a complaint number is given and recorded in the complaint form. The received complaints are classified according to its severity in affecting the QMS. The complaints are analysed, Root cause analysis(RCA) performed, corrective and preventive actions taken according to the Corrective Action Procedure (NPHL/SP/08). All complaint records are collected and analysed at the Management Review meetings. All complaints shall be addressed within a period not exceeding 14 working days.

The laboratory conducts client satisfaction survey of its service users once a year to receive positive and negative feedback which facilitates continual improvement.

Supporting Documents

NPHL/SP/06 Resolution of complaints procedure

NPHL/SP/08 Corrective Action Procedure
NPHL/M/FM013 - Complaints Form
NPHL/M/FM016 – Non-conformity register

4.9 Identification and control of nonconformities

Non-conformities (NCs) are identified by all staff of the NPHL during their examination processes (Pre-examination, examination and post-examination) when they are not in compliance with their procedures or policies as stated in the QMS. All NCs are addressed according to Identification and control of nonconformity procedure (NPHL/SP/07). The identified NCs shall be classified as major or minor, depending on the clinical significance of the examination. The clinician requesting the examination shall be notified of the nonconformity identified.

If the identified NC is classified as major, and directly affects patient results, the Laboratory Director or the Laboratory Manager shall stop the examination and all reports shall be withheld until the problem is resolved and corrective actions taken. The resumption of testing shall be authorized by the Laboratory Director or the Laboratory Manager after the problem is resolved. If the results of nonconforming examinations were released, the client will be informed and all the results involved in that NC will be recalled. The NPHL reviews all non-conforming results and releases them according to the procedure for Identification and control of nonconformities NPHL/SP/07. All identified nonconformities shall be recorded and forwarded to management review where in-turn shall initiate preventive actions

Supporting Document
NPHL/SP/07 - Identification and control of nonconformities procedure

4.10 Corrective Action

The NPHL management allows quick and regular identification of NCs and facilitates the implementation of Corrective Actions by using NPHL/SP/08-Corrective Action Procedure when NCs are noted. Root cause analysis (RCA) shall be conducted for every nonconformity noted before corrective action is implemented. Corrective action (s) selected to eliminate the root cause of the NC shall be appropriate to the magnitude of the problem and commensurate with possible risks.

Whenever changes are to be made as a result of corrective actions, the changes are documented and communicated to the affected members of staff. NPHL Quality Committee members (preferably trained Internal auditors) reviews and monitors all corrective actions during the internal audit to ensure that they have been effective in overcoming the identified problem, to detect any trends and to ensure that NCs do not recur. Such reviews

are documented and actions arising from them are presented at the annual management review meetings.

Supporting document
NPHL/SP_08 - Corrective Action Procedure

4.11 Preventive Action

The NPHL shall take action to prevent NC which shall be identified from potential sources such as review of quality indicators, NCs identified by internal and external audits and complaints, whether technical or affecting the QMS. When a potential NC is identified, the organization shall followPreventive action procedure NPHL/SP/09to investigate and develop the preventive action plan (NPHL/M/FM018). The preventive action implementation shall be monitored to verify that the needed improvements have been realized and effective in reducing the likelihood of the occurrence of nonconformity.

The NPHL shall utilize information derived from any other source to take action to prevent nonconformity. The organization shall also utilize information about identified non-conformities by external assessment and quality audits to effect preventive action.

Supporting Documents
NPHL/SP/09 Preventive Action Procedure
NPHL/M/FM018Preventive Action Plan

4.12 Continuous Improvement

The NPHL continuously improves its QMS by the review of all its operational policies and procedures by laboratory management as per Document control procedure NPHL/ SP/02,and Preventive Action ProcedureNPHL/SP/09 or whenever a new version of the standard is issued. During these reviews, potential sources of non-conformity or other opportunities for improvement in the QMS or technical practices are identified and action plans for improvement are developed, documented, implemented and monitored.

Actions taken to improve the quality of service are periodically reviewed for effectiveness. Such reviews include monitoring the levels of non-conformities traceable to the area or activity the quality improvement action is associated with. The outcome of such actions shall be submitted to the laboratory management for review and implementation of any changes to the quality management system.
The laboratory implements quality indicators in every section of the laboratory for systematic monitoring and evaluation of the laboratory's contribution to patient care, and if an opportunity for improvement is identified through the review of quality indicators, the laboratory management shall use this information to conduct quality improvement projects to address the identified issues.

NPHL management communicates with all staff about improvement plans and related goals. Moreover,NPHL management provides access to suitable educational and training opportunities for laboratory personnel and relevant users of laboratory services so as to improve in areas with high incidences of non-conformities.

Supporting Documents

NPHL/SP/02 Document Control Procedure

NPHL/SP/09 Preventive Action Procedure

4.13Control of records

The NPHL uses a Record Control procedure (NPHL/SP/10) in identification, collection, indexing, access, storage maintenance and disposal of quality and technical records. All records are created concurrently with the performance of each activity that affects the quality of the examination.

All records are readily retrievable and prevented from fire, water, rodents and from loss by locking in the metal cupboards and no records are accessed without authorization. All records are legibly written in ink before storage and personnel shall make any changes or amendments according to the Record Control Procedure (NPHL/SP/10) all records are stored either in hard or soft copies for the period shown in the Document and Records retention Guidelines (NPHL/ID/001).

Supporting Documents

NPHL/SP/10 Record Control procedure

NPHL/ID/001 Documents and record retention Guidelines

4.14. Evaluation and Audits

4.14.1 General Requirements

The NPHLhas developed a Quality Management Plan (NPHL/M/FM008) to implement the evaluation and internal audit processes needed to:

- Demonstrate that the pre-examination, examination, post-examination and supporting processes are being conducted in a manner that meets the needs and requirements of users.
- Ensure conformity to the QMS.
- Continually improve the effectiveness of the QMS.

The results of evaluation and improvement activities are reviewed at to the annual management review meeting.

4.14.2. Periodic review of requests and suitability of procedures and sample requirements

Audits of the laboratory's test list are conducted once in a year to ensure that the tests offered remain clinically appropriate for users and the local population. These audits require suitable consideration of sample volumes, the collection devices used and any preservative

requirements to ensure optimal sample collection and preservation of the sample measurand.

4.14.3. Assessment of user feedback

The NPHL conducts customer satisfaction survey throughout the year using a Customer satisfaction survey form (NPHL/M/FM020). Results are analyzes and the findings used to determine whether the service has met the needs and requirements of users. Should the laboratory identify opportunities for improvement, these are implemented as improvement projects.

Supporting Documents

NPHL/M/FM020 - Customer satisfaction survey form
NPHL/M/FM008 - Quality Management Plan

4.14.4. Staff suggestions

The NPHLis committed to ensuring that staff feels suitably empowered to make suggestions for quality improvement. Staff can make suggestions at weekly staff meetings and during the training sessions. Staff can also have one to one discussions with their section heads or the laboratory management. A record of all staff suggestions are recorded on the Staff suggestions form (NPHL/M/FM021).

Supporting Document

NPHL/M/FM021Staff suggestions form

4.14.5 Internal Audits

The NPHL uses the internal audit procedure (NPHL/SP/11) to formally plan and conduct Internal Audits to evaluate the compliance to its QMS, including pre-examination, examination, and post-examination to ensure that the QMS:

a) Conforms to the requirements of this International Standard and to requirements established by the laboratory, and

b) Are implemented, effective, and maintained.

The auditing is conducted by members of Staff who is independent of the area being audited, trained to assess the performance of managerial and technical processes of the QMS. Each area of QMS is audited at least once in every twelve months following the internal audit schedule (FM22). The auditing shall be conducted by using updated versions of checklists i.e. NPHL/ED/002_SADCAS Management checklist, NPHL/ED/003_SADCAS Vertical checklist, and NPHL/M/FM060 _Witnessing Activity form. The auditing method shall be horizontal, vertical or witnessing depending on the choice of the internal auditor. The Quality Officer is responsible for planning and organizing all internal audits within the NPHL. Before conducting internal audits, internal auditors will review corrective action of the previous non-conformities.

The NPHL shall use the Internal Auditing reports for improving its QMS whenever deficiencies or noncompliance are found. Appropriate Corrective and Preventive actions will be taken within agreed time and documented in Corrective Action Form. All internal auditing reports shall be submitted for management review.

Supporting Documents

NPHL/SP/11Internal Auditing procedure
NPHL/M/FM022Internal Auditing schedule
NPHL/M/FM060 - Witnessing Activity form
NPHL/M/FM60Witnessing activity Form
NPHL/ED/002_SADCAS Management Checklist
NPHL/ED/003_SADCAS Vertical Checklist

4.14.6. Risk management

A comprehensive risk assessment process is in place which considers risk to service provision as well as to health and safety associated risks. Risk assessment is conducted using the procedure (NPHL/SP/55). Any significant or high risks are recorded via the Risk Assessment form (NPHL/M/FM024) with regular updates provided to management on any progress taken to mitigate these risks. Any audit findings which have a potential impact upon patient safety are prioritized for urgent action in order to mitigate this risk. Findings from risk assessments are reviewed at the annual Management Review Meeting.

Supporting Document

NPHL/SP/55Risk Assessment Procedure
NPHL/M/FM024Risk Assessment form

4.14.7 Quality indicators

The NPHL has determined a number of quality indicators which are used to evaluate performances in the pre-examination, examination and post-examination processes.

The NPHL has a plan for monitoring of quality indicators, which includes establishing the objective, methodology, interpretation, limits, action plan and duration of measurement.

Quality indicators in use are documented within each section on formNPHL/ID/002 - List of NPHL Quality Indicators.
Quality indicators are reviewed in the annual management review meeting. Feedback on performance of these indicators is also used to assist in the determination of laboratory quality objectives and improvement projects.

4.14.8. Reviews by external organizations

Any nonconformity identified following a review of the laboratory service undertaken by an external organization is handled using the Identification and control of non-conformity

procedure (NPHL/SP/07) and the Corrective Action ProceduresNPHL/SP/08). The NPHL may be assessed by the following external organizations:

- Accrediting bodies such as SADCAS
- Ministry of Health Community Development Gender Elderly and Children
- World Health Organisation (WHO)

Supporting Document

NPHL/ID/002 List of NPHL Quality Indicators
NPHL/SP/07 Non-conformity Procedure
NPHL/SP/08 Corrective Action Procedure

4.15. Management Review

4.15.1 General Requirements

The NPHL management conducts management reviews at least once per year following the procedure for conducting management reviews. The dates of the management review meeting are indicated on the Quality management plan (NPHL/M/FM008). The list of input items to the management review process is listed in the Management review procedure (NPHL/SP/12). The review process involves analysis of the input information for causes of non-conformities, trends and patterns that indicate problems. This review process also includes assessing the opportunities for improvement and the need for changes to the QMS, including the quality policy and quality objectives. The quality and appropriateness of the laboratory's services is also evaluated.

The output of the management review meeting is minutes of the meeting which are designed in such a way that they have the discussions and decisions made, actions to be done, responsibility, target date and status. It is the responsibility of the Quality Officer to plan and organize management reviews.

Laboratory staff shall be informed of findings from management review at a staff meeting within 2 weeks after the management review meeting. Required actions from management reviews shall be addressed in an appropriate and agreed-upon time and it is the responsibility of the Quality Officer to follow up on action items at least once a month. Results of the review are entered into the management review minutes and dated appropriately.

Supporting Documents
NPHL/SP/12Procedure for conducting management reviews
NPHL/M/FM008 QualityManagement plan

5. TECHNICAL REQUIREMENTS

5.1 Personnel

5.1.1 General requirements

The NPHL uses a Personnel Management procedure (NPHL/SP/20) for the management of all personnel who work in the laboratory. The laboratory maintains records for all personnel in each individual's personnel file kept by the Quality Officer. The list of records required for each member of staff is identified on the first page of the personnel files.

5.1.2 Personnel qualifications

The NPHL management has defined personnel qualifications for each positional level and these qualifications are available on each job description. The qualifications are appropriate to the tasks performed by the individual and reflect education, training, experience and demonstrated skills. The NPHLensures that personnel making judgments with reference to examinations have the applicable theoretical and practical experience.

5.1.3 Job descriptions

The NPHL has developed job descriptions that describe responsibilities, authorities and tasks for all personnel. Laboratory staff are given two copies of job descriptions, which are signed and documented. One signed copy is retained in the relevant staff personnel file.

5.1.4 Personnel introduction to the organizational environment

The NPHL has developed an orientation program for introducing new staff to the organization. Staff is oriented on the section in which he/she will work the terms and conditions of employment, staff facilities, health and safety requirements (fire and emergency) and occupational health services. This program is detailed in the Personnel Management procedure (NPHL/SP/20) and orientation conducted is documented on Orientation checklist form (NPHL/M/FM019) for all personnel.

5.1.5 Training

The NPHL offers internal training to all personnel, which covers the following thematic areas:

a) The quality management system
b) Assigned work processes and procedures
c) The laboratory information system
d) Health and safety, including the prevention or containment of the effects of adverse incidents
e) Ethics
f) Confidentiality of patient information.

It is the duty of the Quality officer to coordinate and review effectiveness of training programme to all personnel. Staff under orientation program, will always be supervised and will not process patient samples until they are deemed competent.

5.1.6 Competence assessment

All new recruited technical staff are trained and competence assessed on technical procedures before they are allowed to process patient samples by Section Heads. Competency assessment may be conducted if there is introduction of new method or procedure. The Laboratory Manager or any competent personnel is authorizedto conduct competency assessment to Section Heads. Competence assessments are conducted using any combination or all of the following approaches:

a) Direct observation of routine work processes and procedures, including all applicable safety practices using existing SOPs.
b) Direct observation of equipment maintenance and function checks using SOPs or equipment manuals.
c) Monitoring the recording and reporting of examination results.
d) Review of work records.
e) Assessment of problem solving skills.
f) Examination of blinded samples, such as previously examined samples, inter-laboratory comparison materials (proficiency testing), or split samples.

The NPHL management may include other methods for conducting competence assessment depending on the requirements of each procedure. Re-assessment shall take place if there is modification of method, procedure or ISO standard; however, retraining shall be conducted anytime if there is evidence that a staff member is no longer familiar with the method in use. The NPHL uses Personnel Management Procedure NPHL/SP/20for conducting competence assessment to both Managerial and Technical staff.

5.1.7 Reviews of staff performance appraisal

The NPHL conducts annual staff performance reviews and this is in line with the Government of Tanzania staff performance review system or Specific program annual staff performance reviews. The reviews of staff performance consider the needs of the NPHL and of the individual in order to maintain or improve the quality of service given to the users and encourage productive working relationships.

5.1.8 Continuing education and professional development

The NPHL requires that all staff who participate in managerial and technical process to attend continuous education classes that are held internally once per week in the mornings before starting work. Continuing education classes are organized by the Quality officer. The program for continuing education is developed each year using Employee Training Plan (NPHL/M/FM036)

The effectiveness of the continuing education programme is reviewed at the end of each year and the review feedback is used to develop a new training program. External training courses are provided by the MoHCDGEC and partners; NPHL members who participate in these trainings are provided with training certificates, which are kept in their personnel files.

5.1.9 Personnel records

The NPHL keeps records for all staff in their respective personnel files. The list of records kept in the files satisfies the requirements of (a-k as listed below) and is kept on the first page for each individual personnel file.

a) Educational and professional qualifications
b) Copy of certification or license, when applicable
c) Previous work experience
d) Job descriptions
e) Introduction of new staff to the laboratory environment
f) Training in current job tasks
g) Competency assessments
h) Records of continuing education and achievements
i) Reviews of staff performance
j) Reports of accidents and exposure to occupational hazards, when applicable
k) Immunisation status, when relevant to assigned duties.

All personnel in the laboratory are required to be vaccinated against diseases they are exposed to, such as Hepatitis B Virus, and records of the vaccination are kept in their respective personnel files.

Supporting Documents

NPHL/SP/20 Personnel Management Procedure
NPHL/M/FM019 Orientation checklist
NPHL/M/ FM036Employee Training Plan
JD_ Job descriptions
NPHL/M/FM029 Staff training and Competency assessment form

5.2. **Accommodation and environmental conditions**

5.2.1 General requirements

The NPHL has adequate space for the performance of its work that is designed to ensure the quality, safety and efficacy of the service provided to the laboratory personnel and visitors. The Laboratory Director and the Laboratory Manager are responsible for allocating space and resources needed by the laboratory. The laboratory ensures conducive working environment for personnel and equipment.

5.2.2 Laboratory and office facilities

The laboratory facility was designed with the purpose of providing a suitable environment for the receipt, testing and result. The Laboratory access control system is designed to ensure that only staff with suitable authorization is permitted unescorted access to laboratory areas. All others (visiting maintenance personnel and other visitors to the laboratory) are only allowed access following approval and must not be left unaccompanied. Maintenance personnel must report to the main gate security personnel and obtain

permission to enter the laboratory after signing the visitors' book. Anyone not following this procedure shall be challenged by any member of staff to determine the reason for their presence.

Medical information, patient samples, and laboratory resources are safeguarded from unauthorized access. Only laboratory personnel have access and passwords to the laboratory information system (LIS) in use and are the only ones who can access patient information using appropriate access level. Laboratory samples, reports and reagents are accessed controlled and cannot be accessed by visitors unless permission is granted by the Management.

The NPHLfacilities have been designed to ensure provision of the following:

- adequate lighting
- adequate power supply (including contingency from the main hospital)
- adequate ventilation
- adequate water supply
- adequate waste disposal
- adequate staff communication systems (telephone, internet, fax machine, notice boards, meetings)
- Suitable safety systems (Showers, eye washes, fire hose, fire alarm system) are installed and their functioning is verified regularly.

5.2.3 Storage facilities

The NPHL has adequate storage space and conditions that ensure the continuing integrity of sample materials, documents, equipment, reagents, consumables, records and results. The storage conditions for different materials are indicated in the following table:

Item	Storage conditions
Sample materials	Temperature monitored refrigerators and freezers are available and prevented from unauthorised access. Used QC and samples slides are kept in the storage boxes and kept at room temperature.
Documents, records and Results	Stored in areas that prevent damage from fire, termites, water and unauthorised access. All records are filed in properly labelled files for easy identification.
Equipment	Equipment are installed according to manufacturer instructions.
Reagents and	Temperature monitored refrigerators and freezers are

Consumables	available. Same reagents and consumables are stored in the storerooms at between 18-25^{O}C (Monitored daily by using Room temperature chart(NPHL/M/FM040) Depending on the requirements of the materials.

Samples are stored for a minimum period that is defined in Sample Retention Schedule (NPHL/ID/004). Documents and records are stored for a minimum period that is defined in Documents and Records Retention Guideline (NPHL/ID/001). All freezers and refrigerators are temperature monitored and the records are kept. Clinical samples and materials used in examination processes are stored in a manner that prevents cross contamination. Dangerous materials are kept in a lockable metal cabinet kept in a secured and controlled area in accordance with the Material Safety Data Sheets (MSDS)

Slides and sharps are disposed in the sharps containers. Infectious materials are disposed in the properly labelled bins. Disposal facilities for dangerous materials are appropriate to the hazards of the materials and as specified by applicable MSDS requirements. All work surfaces shall be maintained in clean condition and records of daily cleaning and swabbing shall be recorded on Daily benches cleaning (NPHL/M/FM041).

5.2.4. Staff facilities

The NPHL facility has adequate staff toilet facilities and kitchen is available. The laboratory is provided with:

- Areas for hanging laboratory coats
- Storage area for clean laboratory coats
- Lockers for staff to store personal belongings
- Hand washingfacilities.

5.2.5. Patient sample collection facilities

The NPHL is referral and public health laboratory therefore samples are collected at referring laboratories and isolation centres and sent via couriers to the NPHL however whenever the need arises sample might be collected to the NPHL facility.

5.2.6. Facility maintenance and environmental conditions

The NPHLstaff are required to maintain good housekeeping practices throughout the laboratory at all times. The environment is required to be kept clean and tidy, in a manner that is compatible with the level of safety required for the operation of a laboratory handling samples for biological examination.

The NPHL requires the monitoring, recording and control of environmental conditions wherever they may impact upon the quality of the result obtained. Where the data from such recording are out of specification and there is an impact on the quality of the product or service provided, thennon-conformity is raised and any necessary corrective actions taken. The NPHL separates incompatible activities by providing separate rooms to prevent cross contamination.

Supporting documents

NPHL/M/FM041_Daily benches cleaning

NPHL/M/FM040_ Room temperature chart

NPHL/SM/001_ Laboratory safety manual

5.3 Laboratory Equipment, reagents and consumables.

5.3.1 Equipment

5.3.1.1 General requirements

The NPHL uses the Procedure for the Selection, Purchase and Management of Equipment procedure (NPHL/SP/21) for the management of all equipment within the laboratory. The NPHL is furnished with equipment needed for the provision of laboratory services. In situations where NPHL uses equipment outside its permanent control, the Laboratory Manager ensures that, the equipment maintenance and management satisfies the requirements of ISO 15189:2012. Laboratory equipment is replaced when it has been shown that the qualities of results are no longer reliable.

5.3.1.2 Equipment acceptance testing

All new equipment undergoes acceptance testing to verify that they are achieving the required performance and complying with requirements relevant to the examination concerned. The Laboratory Manager or Section Head generates the equipment acceptance testing protocol for each new equipment and conducts acceptance testing as per the protocol and records are kept within respective sections. Equipment acceptance testing is conducted following Method Validation and Verification procedure (NPHL/SP/22). All equipment in the laboratory is identified through the laboratory generated Equipment ID number

5.3.1.3 Equipment instructions for use

It is the policy of the NPHL that all equipment is operated at all times by trained and authorized personnel only. Personnel first undergo training and competency testing on the use of major types of equipment being used (e.g. Analyzers) before they are authorized to use such equipment. The list of personnel authorized to use equipment is available for each major type of equipment on the List of Equipment Authorized Users form (NPHL/M/FM044).

Current instructions on the use, safety and maintenance of equipment, including the operator manuals and directions for use provided by the equipment manufacturer are readily available in the respective sections. It is the responsibility of Section Heads to ensure

that the equipment operator manuals are readily available in their sections. The procedure for the safe handling, transport, storage and use of equipment to prevent contamination or deterioration is found within the Selection, Purchase and Equipment Management Procedure (NPHL/SP/21).

5.3.1.4 Equipment calibration and metrological traceability

The NPHL uses calibration laboratories that are accredited to ISO 17025 for the calibration of all laboratory equipment. In situation where there is no accredited calibration service provider, the NPHL will use providers whose calibration standards are metrological traceable to the national standards. The procedure for calibration of equipment is part of the Selection, Purchasing and Equipment management procedure (NPHL/SP/21). Records of the calibration status of equipment and the date of recalibration are kept on the Equipment Service and Calibration Schedule (NPHL/M/FM045) maintained by the Quality Officer.If possible, metrological traceability shall be to a reference material or reference procedure of the higher metrological order available. Where this is not possible or relevant, then other means for providing confidence in the results will be applied, for example:

- The use of certified reference materials
- Examination or calibration by another procedure

Records of the calibration status which includes calibration certificates & schedule are maintained by the quality officer, section Heads and HCT sections

5.3.1.5 Equipment maintenance and repair

Each equipment has a documented programme of preventive maintenance which at a minimum follows the manufacturer's instructions. Laboratory equipment is maintained in a safe working condition. At a minimum, manufacturer's schedules or instructions, or both, are used.

The NPHL management ensures that defective equipment are taken out of service and labelled, "**OUT OF SERVICE, DO NOT USE**, "which is dated and signed. Until it has been repaired and verified by calibration or through the use of quality control materials that it is in good working condition, then it can be brought back into use. The laboratory examines the effect that the defective equipment had on test results prior to its breakdown. If test results were affected, the laboratory implements immediate action or corrective action following the corrective action procedure.

It is the responsibility of the Section Head and staff to decontaminate all equipment before service, repair or decommissioning using the equipment decontamination form (NPHL/M/FM046). The Laboratory provides the biomedical engineers adequate personnel protective equipment and space for carrying out repairs. When equipment is removed from the direct control of the laboratory, for either calibration or service, the NPHL ensures that its performance is verified before being returned to laboratory use.

5.3.1.6 Equipment adverse incident reporting

Adverse incidents associated with the use of equipment are recorded are recorded as an incident using the Equipment Error/Service Log (NPHL/M/48).and these are assessed

periodically for trends. A serious equipment failure or trends observed, that indicate equipment issues will be communicated to the equipment supplier.

5.3.1.7 Equipment records

The NPHL maintains records for each item of equipment that contributes to the performance of examinations on the Equipment Inventory Record (NPHL/M/FM047) as per with the items listed below and these records are kept in the respective section.

a) Equipmentidentification (ID)
b) Manufacturer's name, model and serial number or other unique identification
c) Contact information for the supplier or the manufacturer
d) Date of receiving and date of entering into service
e) Location
f) Condition when received (e.g. new, used or reconditioned)
g) Manufacturer's instructions
h) Records that confirmed the equipment's initial acceptability for use when equipment is incorporated in the laboratory
i) Maintenance carried out and the schedule for preventive maintenance
j) Equipment performance records that confirm the equipment's ongoing acceptability for use
k) Damage to, or malfunction, modification, or repair of the equipment.

Supporting Documents

NPHL/SP/07 Non-conformities Procedure

NPHL/SP/21 Selection, Purchasing and Equipment management procedure

NPHL/SP/22 Method Validation and Verification Procedure

NPHL/M/FM044List of Equipment Authorized users

NPHL/M/FM045_Equipment Calibration/Service status

NPHL/M/FM046_Equipment decontamination form

NPHL/M/FM047_Equipment Inventory Record

NPHL/M/FM048Equipment Error/Service Log.

5.3.2 Reagents and consumables

5.3.2.1 General requirements

NPHLuses Reception, storage, acceptance testing and the inventory management procedure (NPHL/SP/19) for the management of all reagents and consumables within the Laboratory.

5.3.2.2 Reagents and consumables — Reception and storage

All received items are delivered at NPHL main store area; it is the responsibility of laboratory personnel who received the reagents or consumable to inspect all items and ensure that there is no damage or deterioration of the reagents. Inspection of good received is documented in Receiving and Inspection form (NPHL/M/FM032) .All reagents and consumables are stored according to the manufacturer's specifications in the respective storage area by the Storekeeper and or responsible laboratory personnel.

5.3.2.3 Reagents and consumables — Acceptance testing

New lots or new shipments of examination kits or new formulations of kits which have a change in reagent or procedure are verified for performance before they are used for examination. A similar approach is adopted for changes in consumables that may affect the quality of examinations.

5.3.2.4 Reagents and consumables — Inventory management

The NPHL has an inventory control system that is used to capture information like lot numbers, date of receipt, date of placing into service and expiry dates of all reagents and consumables. The inventory control system is carefully monitored by the Storekeeper and Section Heads to ensure that there are no stock-outs. The system for inventory control ensures that there is segregation of uninspected and unacceptable reagents and consumables from those that have been accepted for use upon receipt in the Laboratory store.

5.3.2.5 Reagents and consumables — Instructions for use

Instructions for the use of reagents and consumables, including those provided by the manufacturers (kit inserts) are kept in the respective sections. Only one copy of the manufacturer instructions will be kept for reference if kits are of the same Lot number.

5.3.2.6 Reagents and consumables — Adverse incident reporting

Adverse incidents and accidents that can be attributed directly to specific lots of reagents or consumables are recorded as non-conformities and investigated as per Identification of Nonconformity procedure (NPHL/SP/07)and reported to the manufacturer.

5.3.2.7 Reagents and consumables — Records

Records of reagents and consumables that contribute to the performance of examinations are kept within the individual laboratory sections. These records include the following:

- Name of the reagent or consumable
- Manufacturer's name and batch code or lot number
- Contact details for the item supplier
- Date of receipt
- Date of expiry
- Date entered into service
- Date material was taken out of service
- Condition when received
- Manufacturer's instructions (if applicable)
- Records of confirmation of acceptance for use
- Records that confirm the reagent's or consumable's on-going acceptance for use
- For in-house preparations, details of the person undertaking the preparation and the date of preparation.

Supporting Documents

NPHL/SP/19 Reception, storage, acceptance testing and the inventory management procedure
NPHL/M/FM032 - Receiving and Inspection Form
NPHL/SP/07 Identification of Non-conformance procedure

5.4. Pre-examination processes

5.4.1 General requirements

The NPHL has Sample Management procedure (NPHL/SP/23) to ensure the validity of examination results.

5.4.2 Information for patients and user

The NPHL produces comprehensive information to the service users which contains procedures for sample collection that covers items as the requirement of the standard. This information is available in the Sample Collection Manual which has been distributed to all laboratories that refers specimen to NPHL.

5.4.3 Request form information

The NPHL has a request form (NPHL/M/FM063), designed to contain all information regarding patient, requester and clinical details.

The NPHL only accepts request forms that contain all the required information before testing is done. Critical information that must be indicated on the request forms includes but are not limited to patient's full name, sex, age, clinical history and address as well as the name and address of the requesting clinician. Detailed information on how to complete the request forms is found Sample Collection Manual.
The NPHL has a documented procedure concerning verbal requests for examinations (NPHL/SP/16), that includes providing confirmation by request form or electronic equivalent within a given time. The NPHL management and personnel are willing to cooperate with users or their representatives in clarifying the user's request.

Supporting Documents
NPHL/M/FM063Sample request form
NPHL/SP/23 Sample Management Procedure
NPHL/SP/16Verbal request for examinations procedure
NPHL/SCM/01 Sample Collection Manual

5.4.4 Primary sample collection and handling

5.4.4.1 General requirements

The NPHL has documented procedures for the proper collection and handling of primary samples and these are withinSample Collection Manual. The Sample Collection Manual is

available to those responsible for primary sample collection (referring laboratories and isolation centres).

Where the user requires deviations and exclusions from, or additions to, the documented collection procedure, these shall be recorded on the sample request form and included in all documents containing examination results and shall be communicated to the personnel carrying out and reviewing the tests.

In emergency situations, consent might not be possible; under these circumstances it is acceptable to carry out necessary procedures, provided they are in the patient's best interest.

5.4.4.2 Instructions for pre-collection activities

The NPHL instructions for pre-collection activities are defined in the Sample Collection Manual and these include:

- Completion of request form or electronic request.
- Preparation of the patient (e.g. instructions to caregivers, phlebotomists, sample collectors and patients).
- Type and amount of the primary sample to be collected with descriptions of the primary sample containers and any necessary additives.
- Special timing of collection, where needed.
- Clinical information relevant to or affecting sample collection, examination performance or result interpretation (e.g. history of administration of drugs).

5.4.4.3 Instructions for collection activities

Instructions for collection activities are available in the Sample Collection Manual and these include the following:

- Determination of the identity of the patient from whom a primary sample is collected.
- Verification that the patient meets pre-examination requirements.
- Instructions for collection of primary blood and non-blood samples, with descriptions of the primary sample containers and any necessary additives.
- In situations where the primary sample is collected as part of clinical practice, information and instructions regarding primary sample containers, any necessary additives and any necessary processing and sample transport conditions shall be determined and communicated to the appropriate clinical staff.
- Instructions for labelling of primary samples in a manner that provides an unequivocal link with the patients from whom they are collected.
- Recording of the identity of the person collecting the primary sample and the collection date, and, when needed, recording of the collection time.
- Instructions for proper storage conditions before collected samples are delivered to the laboratory.
- Safe disposal of materials used in the collection.

5.4.5 Sample transportation

Sample transportation is covered in the Sample Collection Manual. The NPHLalso has a Sample management procedure (NPHL/SP/23) which covers the monitoring of transportations of samples to ensure that they are transported under the correct conditions including:

- Within a time frame appropriate to the nature of the requested examinations and the laboratory discipline concerned.
- Within a temperature interval specified for sample collection and handling and with the designated preservatives to ensure the integrity of samples.
- In a manner that ensures the integrity of the sample, courier safety, general public and the receiving laboratory in compliance with established requirements.

The NPHL communicates with the sender immediately after receiving the specimen if the integrity was compromised or could have jeopardized the safety of the courier or the public this will be documented in the Communication Log NPHL/M/FM005.

5.4.6 Sample reception

All samples are brought to the laboratory reception area for the reception process. The NPHL has documented Sample management procedure NPHL/SP/23 which is used for sample reception. All samples are evaluated against the criteria for acceptance and rejection of samples to determine if they will be accepted for testing within NPHL. For samples that do not match the acceptance criteria but are clinically critical, irreplaceable or outbreak sample testing may be undertaken but all results will be issued with an alert indicating the nature of the problem and advising that necessary caution must be applied when interpreting the results. All portions of the primary sample shall be unequivocally traceable to the original primary sample through unique registration numbers.

5.4.7 Pre-examination handling, preparation and storage

All samples received are stored within the laboratory in compliance with each section procedures. These procedures are designed to ensure that samples are stored securely to prevent sample damage, loss or deterioration during pre-examination activities.

Time limits for requesting additional or further examinations on already received samples are described within Sample collection manual and must follow Verbal request for examination Procedure (NPHL/SP/16)

Supporting Documents

NPHL/SP/23 Sample Management Procedure
NPHL/SP/16Verbal request for examinations procedure
NPHL/M/FM005Communication Log
NPHL/SCM/01 Sample Collection Manual

5.5. Examination processes

5.5.1 Selection, verification and validation of examination procedures

5.5.1.1 General requirements

The NPHL uses validated examination procedures for their intended use. Prior to validation a set of performance requirements are established based upon the intended use for that examination. Preference is given to examination procedures based upon:

- Instructions provided for use in vitro medical devices
- Methods published in established/ authoritative text-books, peer-reviewed texts or journals, or nationally or regionally agreed methods

The testing process for NPHL ensures that the identities of persons performing activities in examination processes are recorded and are available for traceability purposes.

5.5.1.2 Verification of examination procedures

The NPHL verifies all examination procedures following Method Validation and Verification Procedure (NPHL/SP/22). Manufacturer validated examination procedures used without modifications are subject to independent verification by the NPHL before being introduced into routine use. However, laboratory will obtain information/ data from the manufacturer/method developer for confirming the performance characteristics of the procedure. The NPHL conducts its own verification to confirm that the performance claims for the examination procedure have been met. The performance claims for the examination procedure confirmed during the verification process shall be those relevant to the intended use of the examination results. Section Head documents the protocol used for the verification and record the results obtained. The Laboratory Manager and the Quality Officer are responsible for reviewing the verification results and the Laboratory Director will approve the method for use.

5.5.1.3 Verification and validation of examination procedures

The NPHL verifies all examination procedures following Method Validation and Verification Procedure (NPHL/SP/22). The section will produce a verification protocol for all the verifications, which has to be followed when conducting the verification studies. All the verification are extensive as is necessary and confirm, through the provision of objective evidence that the specific requirements for the intended use of the examination have been fulfilled.

The NPHL ensures that all the raw data and data analysis results for the verification studies are kept and produces a verification report which is reviewed by the Laboratory Manager and the Quality officer and approved by the Laboratory Director. When changes or modifications are made to examination procedure, the influence of such changes shall be documented and, validation shall be carried out.

5.5.1.4 Measurement uncertainty of measured quantity values

The NPHL determines measurement uncertainty (MU) for each measurement procedure in the examination phase used to report measured quantity values on patients' samples and control material by using Measurement Uncertainty procedure (NPHL/SP/05)The NPHL has defined the performance requirements for the measurement uncertainty of each measurement procedure and review estimates of measurement uncertainty once in every two years. It is a policy that the MU are not reported to the requester on a routine basis but are made available upon request.

5.5.2 Biological reference intervals or clinical decision values

NPHL has the biological reference intervals for all the parameters tested for the local population being served. The Normal ranges are available in the Sample Collection manual

5.5.3 Documentation of examination procedures

The NPHL ensures that all examination procedures are fully documented and addressed as per requirements. Examination procedures have been documented in English language and they are available at the appropriate work stations for use by staff.

All documents that are associated with the performance of examinations, including procedures, summary documents, condensed document format and product instructions for use, are subjected to the document control procedure NPHL/SP/02.

Supporting Documents

NPHL/SP/02 Document control procedure
NPHL/SP/22 Methods Validation and Verification procedure
NPHL/SP/05Measurement Uncertainty Procedure
NPHL/SCM/01 Sample Collection Manual

5.6 Ensuring quality of examination results

5.6.1 General

The NPHL ensures the quality of its examinations by performing them under suitably controlled conditions. This aim is supported by:

- A comprehensive quality control approach to pre-testing, testing and post testing processes.
- The approach to quality control is based on principles of in-process Quality Control checks.

The details of the Quality Control programme are found in the respective examination/technical procedures. The NPHL does not fabricate any results. All results are produced through verified test method under defined conditions for each test.

5.6.2. Quality Control (QC)

5.6.2.1 General requirement

The NPHL reviews all quality control results by using Reviewing of Quality Control procedure (NPHL/SP/13)

5.6.2.2 Quality control materials

The NPHL uses QC materials that will react in a manner as close as possible to patient samples. QC materials are examined at defined interval based on the testing procedure on stability and the risk of harm to the patient from an erroneous result. The frequency of running the QC material is defined in the respective examination procedure.

5.6.2.3 Quality Control data

The NPHL uses Reviewing of Quality Control procedure (NPHL/SP/13) for reviewing all QC results. Review of qualitative tests is performed by checking whether the QC results produce the expected positive or negative results.

Reviewing of Quality Control (NPHL/SP/13) results procedure details how to use Westgard rules in order to prevent the release of patient results in the event of quality control failure. When the QC rules are violated and indicate that examination results are likely to contain clinically significant errors, the results are rejected and relevant patient samples re-examined after the error condition has been corrected. Laboratory also evaluates the results from patient samples that were examined after the last successful QC event.

QC data are also reviewed once quarterly by the Quality Committee during the Preventive action review meeting in order to identify trends that may indicate deterioration in examination procedure performance so that suitable corrective action can be initiated. Trends noted in this way and the subsequent actions are recorded and corrected through the actions agreed by the Quality Committee.

5.6.3 Inter-laboratory comparisons

5.6.3.1 Participation

The NPHL participates in different external quality assessment (EQA) programmes or proficiency testing (PT) programme which are appropriate to the examination and interpretations of examination results. Priority is given to PT programs that are accredited to ISO 17043:2010. Participation and Review of EQA (NPHL/SP/14) procedure defined responsibilities and instructions for participation, and any performance criteria that differ from the criteria used in the inter-laboratory comparison Programme.

The NPHL selected these EQA Programme(s) that provides clinically relevant challenges that mimic patient samples and have the effect of checking all process, including pre-examination procedures, examination and post-examination procedures, where possible.

5.6.3.2 Alternative approaches

The NPHL may develop other approaches and provide objective evidence for determining the acceptability of examination results in situations where Interlaboratory comparison is not available, or when there is need to augment the EQA participation. The following methods may be used:

- Samples previous examined
- Exchange of samples with other laboratories
- Certified reference materials

5.6.3.3 Analysis of inter-laboratory comparison samples

The NPHL examines EQA samples following the rules for analysis of EQA samples, these are documented in the procedure for Participation and Review of EQA (NPHL/SP/14), and all samples are registered in the Laboratory information system (LIS) or EQA Sample receiving register (NPHL/M/FM055) when the system is down.

5.6.3.4 Evaluation of laboratory performance

The Quality Officer and Section Head together with the relevant staff are responsible for the review of performance in inter-laboratory comparisons as a team. When predetermined performance criteria are not fulfilled, staff shall use EQA Performance Review Form (NPHL/M/FM056) for the review of EQA performance and any non-conformances identified will be handled using the Identification and Control of Non Conformities Procedure (NPHL/SP/07) and relevant corrective action shall be implemented. The effectiveness of corrective action are monitored and returned results shall be evaluated for trends that indicate potential nonconformities.

5.6.4 Comparability of examination results

In situations where the NPHL has two or more different procedures, or equipment performing the same tests, then a comparison of these will be conducted using Method Comparability protocol (NPHL/M/FM131). The laboratory notifies users of any differences in comparability of results and discusses any implications for clinical practice when measuring systems provide different measurement intervals for the same measurand and when examination methods are changed.

The laboratory documents, records and quickly acts upon results from the comparisons performed and any problems or deficiencies identified are acted upon and records of actions retained.

Supporting Documents

NPHL/SP/07Identification and control of Non-conformance
NPHL/SP/08Corrective action procedure
NPHL/SP/13Procedure for reviewing quality control results
NPHL/SP/14 Procedure for Participation and Reviewing of EQA
NPHL/M/FM055 Sample receiving register

NPHL/M/FM056 EQA Performance Review Form
NPHL/M/FM131Method comparability protocol

5.7 Post-examination processes

5.7.1 Review of results

The NPHL uses Management of Result Procedure NPHL/SP/24 for the review of all the patient results. All reports undergo a data system check. Results are only authorized after complete satisfaction that the review criteria have been satisfied. Review of results is done by personnel who have been deemed competent to conduct the test under consideration. Authorization of results will be done by a second person who is deemed competent to a specific test. In situation where there is no second personnel to authorize results, the laboratory staff who performed the test will release results as preliminary results.

5.7.2 Storage, retention and disposal of clinical samples

The NPHL storage and disposal of sample procedure fully defines the identification, collection, retention, indexing, access, storage, maintenance and safe disposal of clinical samples. Retention periods of samples are in accordance with the laboratory developed timelines defined on Minimum retention times-Document, record (NPHL/ID/001). Safe disposal of samples is carried out in accordance with local regulations or recommendations for waste management.

Supporting Documents

NPHL/SP/23Management of samples Procedure
NPHL/SP/24 Management of Result Procedure
NPHL/ID/001Minimum retention Times-Document, record

5.8 Reporting of results

5.8.1 Generalrequirements

All the patient results for each examination are reported accurately, clearly, unambiguously and in accordance with any specific instructions documented in the examination procedures. The NPHL issues results in hard copy paper format and electronic. The management of results procedure (NPHL/SP/24) defines how the laboratory ensures the correctness of transcription of laboratory results. Where relevant, the reports shall include the information necessary for the interpretation of the examination results. In situations where the result is delayed and in a manner that could compromise patient care, the NPHL notifies the requester and explains the reason for the delay and this is documented in the communication log (NPHL/M/FM005). A comment is entered into the final report indicating the reason for the delay of the results and gives an indication of when the result may be available.

5.8.2 Report attributes

The NPHLensures that the following report attributes effectively communicate laboratory results and meet the users' needs:

a) Comments on sample quality that might compromise examination results.

b) Comments regarding sample suitability with respect to acceptance/rejection criteria.
c) Critical results, where applicable.
d) Interpretive comments on results, where applicable, which may include the verification of the interpretation of automatically selected and reported results in the final report.

5.8.3 Report content

NPHL reports include but are not limited to the content of ISO 15189:2012, Clause 5.8.3 (a-p).

5.9 Release of results

5.9.1 Generalrequirements

The Results Management procedure (NPHL/SP/24) defines who may release results and to whom. The following conditions are also met in the procedure.

- When the quality of the primary sample received is unsuitable for examination, or could have compromised the result, this is indicated in the report.
- Defined what happens when examination results fall within established “alert” or “critical” intervals.
- Results are legible, without mistakes in transcription, and reported to persons authorized to receive and use the information.
- When results are transmitted as an interim report, the final report is always forwarded to the requester.
- There are processes for ensuring that results distributed by telephone or electronic means reach only authorized recipients. Results provided orally are followed by a written report. There shall be a record of all oral results provided.

5.9.3 Revised reports

Management of results procedure NPHL/SP/24covers the situations where the reports are revised and resent to the requester.

Supporting Documents

NPHL/SP/24Management of results procedure

NPHL/M/FM005Communication log

5.10 Laboratory information management

5.10.1 Generalrequirements

The NPHL has access to the data and information needed to provide a service which meets the needs and requirements of the user through access to textbooks. The Procedure forProtection of confidential information NPHL/SP/15 is used by the laboratory to ensure that personnel treat all information and data they come across during their work as confidential at all times. All NPHL Staff are required to use LIS Laboratory Information System Procedure when using LIS;

Staff are aware that information that they have access to in the course of their duties, regarding patients, contracts and other work matters, must be considered confidential and should not be disclosed to others. All computers that are used within NPHL are maintained as per manufacturer instructions.

The NPHL ICT officers conduct a back-up of all LIS Data every day in the morning and data are synchronized with the National Internet Data Centre (NIDC).

5.10.2 Authorities and responsibilities

The NPHL management defined authorities and responsibilities for management of the information system, including the maintenance and modification to the information system(s) that may affect patient care. The authority and responsibility are available in each individual Job description who:

a) Access patient data and information;
b) Enter patient data and examination results;
c) Change patient data or examination results;
d) Authorize the release of examination results and reports.

5.10.3 Information system management

The NPHL Management ensures that the LIS used for collection, processing, recording, reporting, storage or retrieval of examination data and information are:

a) Verified as per NPHL/SP/27Laboratory Information System Validation Procedure by each section and verified for functioning by the laboratory before introduction, with any changes to the system authorized, documented and verified before implementation;
b) Documented, and the documentation, including that for day to day functioning of the system, readily available to authorized users;
c) Protected from unauthorized access;

d) Safeguarded against tampering or loss;
e) Operated in an environment that complies with supplier specifications
f) Maintained in a manner that ensures the integrity of the data and information and includes the recording of system failures and the appropriate immediate and corrective actions;
g) In compliance with national or international requirements regarding data protection.

The NPHL verifies all results of examinations, associated information and comments are accurately reproduced, electronically and in hard copy where relevant, by the information systems external to the laboratory intended to directly receive the information (e.g. computer systems, fax machines, e-mail, website, personal web devices).

When a new examination or automated comments are implemented, the NPHL verifies that the changes are accurately reproduced by the information systems external to the laboratory intended to directly receive information from the laboratory.

The laboratory has Sample management procedure NPHL/SP/23 and Results management procedure NPHL/SP/24to maintain services in the event of failure or downtime information systems that affects the laboratory's ability to provide service.

Supporting Documents
NPHL/SP/15 Protection of confidential information
NPHL/SP/23 Sample management procedure
NPHL/SP/24 Results Management Procedure
NPHL/SP/26 Laboratory Information System Procedure when using LIS.
NPHL/SP/27Laboratory Information System Validation Procedure
NPHL/M/FM005Communication log

5.11 Laboratory safety

The NPHL is committed to promote the upholding of highest safety standards for its employees and users of its services. To achieve this, the laboratory has developed a Safety Manual to ensure safe work practices and has appointed a Safety Officer who is responsible for enforcing safe working practices within the NPHL. In addition to the above-mentioned strategies, the following are to be implemented.

- Management ensures that all employees are well trained in laboratory safety, which covers all issues regarding bio-safety and bio-security in their work environment as well as corrective actions in cases of unexpected events.
- The NPHL management provides a safe work environment by compliance with the universal safety precautions and provision of appropriate personal protective equipment to all members of staff.

- Safety is the responsibility of everyone, therefore every employee while working in the laboratory, shall take reasonable care of his/her own safety and that of persons who may be affected by his action.
- All personnel who work in the laboratory shall be offered available immunization to prevent infections associated with organisms to which the personnel are likely to be exposed.
- All occupational illnesses, injuries, adverse incidents, accidents and consequential actions are reported to the Safety Officer, the Laboratory Manager or the Laboratory Director and documented in Work related injury report formNPHL/M/FM051. The records shall be kept in the staff personnel file. Employees who have had an occupational exposure to blood or other potentially infectious material shall follow the Post Exposure Prophylaxis procedure (NPHL/SP/56)and work practices outlined in the Safety Manual to mitigate the effects.
- All chemicals are stored according to the Material Safety Data Sheets (MSDS) instructions. Only authorized personnel have access to the laboratory using access cards. Management does not allow the use of mobile phones when working in the laboratory.
- The Safety Officer is responsible for ensuring that all staff adheres to safety guidelines in all operations of the laboratory.

Supporting documents

NPHL/SP/56 Post Exposure Prophylaxis procedure
NPHL/M/FM036 Employee Training Plan
NPHL/M/FM051Work related injury report form.
NPHL/SM/01 Safety manual

6. REFERENCES

ISO 15189: Medical laboratories — Particular requirements for quality and competence (2012) International Organization for Standardisation

7. AMENDMENT RECORD

NAME	DATE	SUMMARY OF CHANGES

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

No	Name	Signature	Date

Appendix A

Quality Objective	Desired outcome	Target date	Key activities	Responsibility
1. To apply for ISO 15189:2012 Accreditation by December 2021	Laboratory accreditation is attained	December 2021	a) Application of accreditation b) Implement Quality Management System (QMS) as documented c) Perform IQC regularly d) Participate in EQA schemes e) Conduct internal audit f) Focus on customer needs g) Identify nonconformities and take corrective action	Laboratory Director, Manager and Quality Officer
2. To provide QMS training as per NPHL plan and the attendance of the class to be more than 70% of Laboratoryworkers .	70% or more laboratory workers attended the class	December 2021	a) Conduct training need assessment to all employees b) Develop training plan according to the need c) Conduct training according to the plan d) Evaluate the impact of the training e) Take corrective action	Quality Officer
3. To participate in accredited EQA schemes and achieve 80% or more in performance for all registered	EQA performance of all registered tests achieved by 80% or more	December 2021	a) Ensure routine equipment maintenance b) Adhere to standard operating procedure c) Ensure internal quality control for all tests d) Ensure EQA participation for all tests e) Ensure IQC and EQA performed is monitored and reviewed. f) Perform staff competency assessment	Laboratory Director, Manager and Quality Officer

tests.				
4. All NPHL staff are deemed competent in QMS and technical procedures with pass mark of more than 80%	All NPHL staff are deemed competent.	December 2021	a) Train all staff on QMS and technical methods used at NPHL b) Adhere to competency assessment procedures c) Documentation of all technical competency records	Laboratory quality officer
5. All equipment downtime and reagents stock out is less than 10%(90% performance) per year .	No equipment downtime and reagent stock out	December 2021	a) Ensure equipment regular maintenance and calibration b) Ensure environmental temperature monitoring c) Ensure monthly physical count, daily monitoring of reagents. d) Timely ordering of reagents	Store officer Quality officer HCT section Head of sections
6. 80% of all customer results are released within established Turn Around Time .	All customer results are released within TAT	December 2021	a) Ensure availability of reagents b) Ensure regular equipment maintenance c) Proper sample and results management d) Perform staff competency assessment	Head of sections Quality officer

Appendix B: NPHL Advisory Services Authority Matrix

	Advisory Services												
Personnel responsible	**Selection of tests**	**Repeat frequency**	**Use of laboratory services**	**Interpretation of results**	**Rejecting/ accepting samples**	**Performing examination procedures**	**Operating analyzers**	**Data capturing (LIS)**	**Making changes to data in LIS**	**Releasing reports**	**Releasing revised reports**	**Issuing reports**	**Amending reports**
LD	×	×	x	x									
LM	×	×	x	×					×	×	×	×	×
DLM	x	x	x	x					x	x	x	x	x
QO/DQO	×	×	x	×	×	×	×	×	×	×	×	×	×
HOS	×	×	x	×	×	×	×	×	x	×	x	x	×
LS	x	x	x	x	×	×	×	×	x	×	x	×	×
LT	x	x	x	x	×	×	×	×	x	×	x	×	×
LA			x		×			×		×	x	×	
ICT / SU								×				×	
RCP					×			×	×			×	

Key:

LD - Laboratory Director QO - Quality Officer LS - Laboratory Scientist s

LM - Laboratory manager DQO - Deputy Quality Officer LT - Laboratory Technologists

DLM – Deputy Laboratory Manager HoS - Head of Sections LA – Laboratory Assistants

SU-Super UsersICT-Information and Computer Technology officer RCP-Receptionist

Appendix C

Laboratory Copy Numbers

Section	Copy Number
Quality Office	1
Laboratory manager	2
Laboratory Director	3
Safety office	4
Bacteriology	5
Clinical chemistry	6
Molecular Biology	7
Haematology	8
Parasitology	9
Serology	10
Reception	11
SADCAS	12