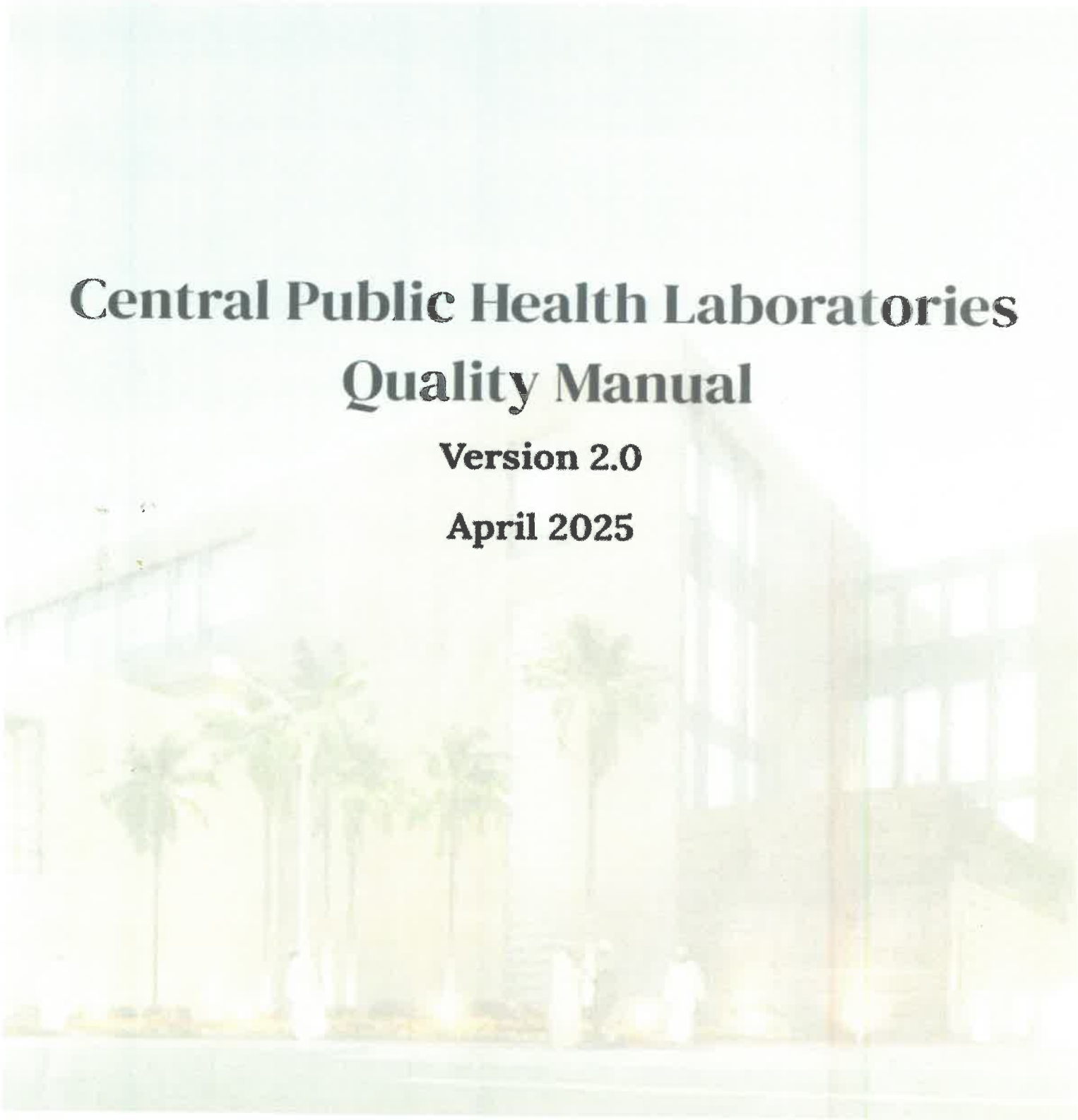
Central Public Health Laboratories
Quality Manual

Version 2.0

April 2025



CDCP/CPHL/QM/04/Vers.02

Department of Central Public Health Laboratories
Center for Disease Control & Prevention
Ministry of Health
Sultanate of Oman

Ministry of Health
Center for Disease Control & Prevention

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Document Author	Dr Salim Al Kiyumi
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Prepared by		**Validated &Approved by**	
Name	Dr. Salim Al Kiyumi	**Name**	Dr Hanan Al Kindi
Designation	Quality Chairperson	**Designation**	Director of the CPHL
Signature		**Signature**	
Date		**Date**	

Preface

Ensuring quality in laboratory practices is not only essential for producing accurate and reliable results—it is also a fundamental responsibility that safeguards public health, supports clinical decision-making, and upholds professional integrity. In recognition of this, the Department of Central Public Health Laboratories (CPHL), under the Ministry of Health, Sultanate of Oman, is committed to the implementation and continual improvement of a robust Quality Management System (QMS) across all laboratory operations.

This revised Laboratory Quality Manual reflects our alignment with international best practices, particularly those outlined in the World Health Organization (WHO) Laboratory Quality Management System while also being adapted to the specific needs and operational scope of CPHL. The manual serves as a comprehensive reference, detailing the policies, procedures, and quality standards necessary for the effective management of biological safety, chemical handling, waste disposal, and physical hazard control within laboratory environments.

A well-functioning QMS is built on the principles of standardization, risk management, continuous improvement, and staff competency. This manual is designed to support laboratories in achieving these principles by promoting a culture of quality, where standard operating procedures (SOPs), risk assessments, internal audits, training, and corrective actions are part of routine operations. The successful implementation of the QMS requires the active involvement of laboratory leadership, supervisors, and staff, each of whom plays a vital role in maintaining quality standards and ensuring regulatory compliance.

Moreover, this manual serves as a guiding framework for governorates public health laboratories to develop and enhance their own quality systems, tailored to their specific technical capabilities and resources. Through consistent application of quality practices, we aim to strengthen the credibility, efficiency, and safety of laboratory services across the nation.

We acknowledge the invaluable contributions of CPHL staff in the preparation and continuous refinement of this manual, and we reaffirm our commitment to upholding the highest standards of laboratory quality in service to public health.

Dr Hanan Al Kindi ,
Senior consultant, MD, DMTH, FRCPath in clinical virology (UK)
Director of Department of Central Public Health Laboratories
Centre for Disease Control and Prevention
Ministry of Health
Sultanate of Oman

Table of Contents

1 Acronyms and definitions

1.1 Acronyms

S. No.	Abbreviation	
1	CPHL	Department of Central Public Health Laboratories
2	CDCP	Center for Disease Control & Prevention
3	IQ	Installation Qualification
4	OQ	Operational Qualification
5	MOH	Ministry of Health
6	QM	Quality Manual
7	QMS	Quality Management System
8	PQ	Performance Qualification

1.2 Terms and definitions:

- **Bias measurement:** Estimate of a systematic measurement error.

Note: This *definition only applies to quantitative measurements)*

- **Biological reference interval reference interval:** Specified interval of the distribution of values taken from a biological reference population.

Note1: *A reference interval is commonly defined as the central 95% interval. Another size or an asymmetrical location of the reference interval could be more appropriate in particular cases.*

Note 2*: A reference interval can depend upon the type of primary sample and the examination procedure used.*

Note 3*: In some cases, only one biological reference limit is important, usually an upper limit, "x", so that the corresponding biological reference interval would be less than or equal to "x".*

Note 4*: Terms such as 'normal range', 'normal values', and 'clinical range' are ambiguous and therefore discouraged.*

- **Clinical decision limit:** Examination result that indicates a higher risk of adverse clinical outcomes, or is diagnostic for the presence of a specific disease.

Note 1*: Clinical decision limits for therapeutic drugs are called "therapeutic range".*

Note 2*: It is used to determine risk of disease, to diagnose or to treat.*

- **Commutability of a reference material:** Property of a reference material, demonstrated by the closeness of agreement between the relation among the measurement results for a stated quantity in this material, obtained according to two given measurement procedures and the relation obtained among the measurement results for other specified materials.
  Note 1*: The reference material in question is usually a calibrator and the other specified materials are usually routine samples.*
  Note 2*: It is typical that there are more than two measurement procedures available and comparison among all applicable measurement procedures is desirable.*
  Note 3*: Closeness of agreement of measurement results is defined in terms of fitness for purpose as appropriate for the intended use of the reference material.*
  Note 4*: A commutability statement is restricted to the measurement procedures as specified in a particular comparison.*

- **Competence:** Demonstrated ability to apply knowledge and skills to achieve intended results.
- **Complaint:** Expression of dissatisfaction by any person or organization to a laboratory, relating to the activities or results of that laboratory, where a response is expected.
- **Consultant:** Person who provides expert advice professionally.
- **Examination:** Set of operations having the objective of determining the numerical value, text value or characteristics of a property.
  Note 1*: An examination may be the total of a number of activities, observations or measurements required to determine a value or characteristic.*
  Note 2*: Laboratory examinations that determine a numerical value of a property are called "quantitative examinations"; those that determine the characteristics of a property are called "qualitative examinations".*
  Note 3*: Laboratory examinations are also called "assays" or "tests".*

- **Examination procedure:** Specifically described set of operations used in the performance of an examination according to a given method.
  Note*: In the IVD medical device industry and in many laboratories that use IVD medical devices, an examination procedure for an analyte in a biological sample is commonly referred to as an analytical method, analytical procedure or test procedure.*

- **External quality assessment EQA:** Evaluation of participant performance against pre-established criteria by means of inter-laboratory comparisons.

  Note 1*: Also known as proficiency testing (PT)*

- **Impartiality:** Objectivity with regard to the outcome of tasks performed by the medical laboratory.

  Note 1: Objectivity can be understood as freedom from bias or freedom from conflicts of interest.

  Note 2: Other terms that are useful in conveying the element of impartiality include "independence", "lack of prejudice", "neutrality", "fairness", "open-mindedness", "even-handedness", "detachment", "balance".

- **Inter-laboratory comparison:** Organization, performance and evaluation of measurements or examinations on the same or similar materials by two or more independent laboratories in accordance with pre-determined conditions.

- **Internal quality control IQC:** Internal procedure which monitors the testing process to verify the system is working correctly and gives confidence that the results are reliable enough to be released.

- **In vitro diagnostic medical device IVD:** Device, whether used alone or in combination, intended by the manufacturer for the in vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes and including reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles.

- **Laboratory management:** Person(s) with responsibility for, and authority over a laboratory.

  Note 1*: Laboratory management has the power to delegate authority and provide resources within the laboratory.*

Note 2*: The laboratory management includes the laboratory director(s) and delegates together with individuals specifically assigned to ensure the quality of the activities of the laboratory.*

- **Laboratory user:** Individual or entity requesting services of the medical Laboratory.

- **Management system:** Set of interrelated or interacting elements of an organization to establish policies and objectives, and processes to achieve those objectives.
  Note 1*: This was formerly referred to and is synonymous with "quality management system".*
  Note 2*: The management system elements establish the organization's structure, roles and responsibilities, planning, operation, policies, practices, rules, beliefs, objectives, and processes to achieve those objectives.*

- **Measurement accuracy:** Closeness of agreement between a measured quantity value and a true quantity value of a measurand.
  Note 1: *The concept 'measurement accuracy' is not a quantity and is not given a numerical quantity value. A measurement is said to be more accurate when it offers a smaller measurement error.*
  Note 2: *The term "measurement accuracy" should not be used for measurement trueness and the term measurement precision should not be used for 'measurement accuracy', which, however, is related to both these concepts.*

  Note 3: *'Measurement accuracy' is sometimes understood as closeness of agreement between measured quantity values that are being attributed to the measurand.*

- **Measurement uncertainty MU:** Non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used.
  Note 1: *MU includes components arising from systematic effects, as in the case of corrections to the assigned quantity values of measurement standards. Sometimes estimated systematic effects are not corrected for, but instead, the associated MU components are incorporated.*

Note 2: *The parameter may be, for example, a standard deviation (SD) called standard MU (or a specified multiple of it), or the half-width of an interval, having a stated coverage probability.*

Note 3: *MU comprises, in general, of many components. Some of these may be evaluated by Type A evaluation of MU from the statistical distribution of the quantity values from series of measurements and can be characterized by SD. The other components, which may be evaluated by Type B evaluation of MU, can also be characterized by SD or evaluated from probability density functions based on experience or other information.*

Note 4: *In general, for a given set of information, it is understood that the MU is associated with a stated quantity value attributed to the measurand. A modification of this value may result in a modification of the associated uncertainty.*

Note 5: *All measurements have bias and imprecision. For example, replicate measurements of a sample performed under repeatability conditions generally produce different values for the same measurand. Because the different values could all be reasonably attributed to the same amount of measurand, there is uncertainty as to which value should be reported as the value of the measurand.*

Note 6: *Based on available data about the analytical performance of a given measurement procedure, an estimation of MU provides an interval of values that is believed to include the actual value of the measurand, with a stated level of confidence.*

Note 7: *Available data about the analytical performance of a given measurement procedure typically comprise uncertainty of calibrator assigned values and long-term imprecision of IQC materials.*

Note 8: *In medical laboratories, most measurements are performed in singleton, and are taken to be an acceptable estimate of the value of the measurand, while the MU interval indicates other results that are also possible.*

- **Medical laboratory:** Entity for the examination of materials derived from the human body for the purpose of providing information for the diagnosis, monitoring, management, prevention and treatment of disease, or assessment of health.

  Note 1 to entry: The laboratory can also provide advice covering all aspects of examinations including appropriate selection, the interpretation of results and advice on further examinations.

Note 2 to entry: Laboratory activities include pre-examination, examination and post-examination processes.

Note 3 to entry: Materials for examination include but are not limited to, microbiological, immunological, biochemical, immunohaematological, haematological, biophysical, cytological, tissue and cells, and genetic material.

- **Patient:** Person who is the source of material for an examination.

- **Post-examination processes:** Processes following the examination including review of results, formatting, releasing, reporting and retention of examination results, retention and storage of clinical material, sample and waste disposal

- **Pre-examination processes:** Processes that start, in chronological order, from the user's request and include the examination request, preparation and identification of the patient, collection of the primary sample(s), transportation to and within the laboratory, ending when the examination begins.

- **Primary sample:** Discrete portion of a body fluid or tissue or other sample associated with the human body taken for examination, study or analysis of one or more quantities or characteristics to determine the character of the whole.

  Note 1*: The International Medical Device Regulators Forum (IMDRF) uses the term specimen in its harmonized guidance documents to mean a sample of biological origin intended for examination by a medical laboratory.*

- **Quality indicator:** measure of the degree to which a large number of characteristics of an object fulfils requirements.

  Note 1*: Measure can be expressed, for example, as % yield (% within specified requirements), % defects (% outside specified requirements), defects per million occasions (DPMO) or on the Six Sigma scale.*

  Note 2*: Quality indicators can measure how well an organization meets the needs and requirements of users and the quality of all operational process.*

- **Referral laboratory:** External laboratory to which a sample or data is submitted for examination.

  Note 1*: A referral laboratory is one to which laboratory management chooses to submit a sample or subsample for examination, data for analysis or interpretation, or when routine examinations cannot be carried out.*

  Note 2*: This differs from a laboratory to which submission of samples is required by regulation, or a so called reference laboratory, e.g. public health, forensic, tumour registry, or a central (parent) facility to which submission of samples is required by structure.*

- **Sample:** One or more parts taken from a primary sample.

- **Measurement trueness:** Closeness of agreement between the average of an infinite number of replicate measured quantity values and a reference quantity value.

  Note 1: Measurement trueness is not a quantity and thus cannot be expressed numerically, but measures for closeness of agreement are given in ISO 5725-1.

  Note 2: Measurement trueness is inversely related to systematic measurement error, but is not related to random measurement error.

  Note 3: 'Measurement accuracy" should not be used for 'measurement trueness'.

  Note 4: For qualitative examinations, trueness of measurement (closeness of agreement) can be expressed in terms of concordance (i.e. percent agreement with a reference examination).

  Note 5: Trueness is a property of the examination procedure that reflects the bias of the measurements from the expected or target value. It is described qualitatively as good or bad. An examination procedure has good trueness if the bias of the measurements is acceptable.

- **Turnaround time:** Elapsed time between two specified points through pre-examination, examination, and post-examination processes.

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

Note 1: *Objective evidence can be obtained through observation, measurement, examination or by other means.*

Note 2: *The word "validated" is used to designate the corresponding status.*

Note 3: *Specified requirements of an examination method may include the following performance specifications: measurement trueness, measurement precision including measurement repeatability, and measurement intermediate precision, analytical specificity, including interfering substances, detection limit and quantitation limit, measuring interval, clinical relevance, diagnostic specificity and diagnostic sensitivity.*

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

  EXAMPLE 1 Confirmation that performance specifications of a measuring system are achieved.

  EXAMPLE 2 Confirmation that a target measurement uncertainty can be met.

  Note 1: Verification is the process by which the laboratory confirms that the established performance claims of a measuring system, e.g. trueness, precision, reportable range, can be replicated in the laboratory before human sample examination is performed.

  Note 2: The objective evidence needed for a verification can be the results of an inspection, or other forms of determination, such as performing alternative calculations or reviewing documents.

  Note 3: Verification may be sufficient to implement a new IVD device under circumstances where the examination is performed and used in the manner as directed in the package insert.

2 Introduction

2.1 Laboratory Background

CPHL is part of Ministry of Health serves as a national, regional, and global center in the field of surveillance and investigation of diseases, emerging infectious diseases and public health. There are several sections within the CPHL performing a wide range of laboratory tests using different techniques, for disease diagnosis, surveillance and surveys, epidemic or pandemic preparedness and outbreaks (See figure 1). CPHL has the following core functions:

- Disease prevention, control and surveillance
- Reference and specialized testing
- Environmental health and related food safety
- Emergency response
- Public health related research
- Quality assurance
- Information management and communication
- Policy development, networking and advocacy
- Training and education
- Partnerships and communication

The laboratory operates for seven hours a day, five days a week. However, during special circumstances such as an outbreak, it may function beyond regular hours with extended timings. The scope of tests offered by the laboratory is detailed in the Primary Sample Manual (Laboratory Handbook).

2.2 Vision

To be a center of excellence, most innovative, quality and safety focused national, regional and a global reference public health laboratory.

2.3 Mission

To promote health and prevent disease by providing: leadership in laboratory science, support to public health & environmental activities, networking and rapid response.

2.4 Values

Our values are focused on:

- End user satisfaction
- Competence
- Integrity
- Team work
- Accountability
- Continual improvement

2.5 Purpose of Quality Manual

To document the CPHL Quality Management System and establish a framework to ensure consistent quality in products and services. This version of the manual is compliant with ISO certification standard 15189: 2022.

3 Structure of Quality Manual

This quality manual is based on the structure provided in the table of contents. The numbering of the quality manual corresponds directly to the numbering of ISO 15189: 2022 standard requirements. It describes the quality management system under the stated quality policy and objectives, whereas the processes and activities required to implement the quality management system are described in procedures.

If any amendment is necessary, only the specific page is replaced, not the entire clause. The revised page is recorded in the amendment record sheet below. Amended pages of the quality manual are subject to approvals from the Director/Quality Chairperson.

3.1 Amendment record sheet

S. No.	Page No.	Section / clause / paragraph / line (as applicable)	Date of amendment	Reasons of amendment	Signature of person authorizing the amendment

4 Management Requirements

4.1 General requirements

4.1.1 Impartiality

a. CPHL ensures impartiality in all laboratory activities.

b. CPHL is committed to the Ministry of Health Code of Conduct for Medical Laboratory Personnel (MoH/DGSMC/P /001/Vers.01) which is communicated to all laboratory personnel. The document is followed by laboratory personnel for maintaining impartiality of laboratory activities.
c. CPHL is responsible for the impartiality of its activities and does not allow any commercial, financial or other pressures on the examination personnel to compromise impartiality. The activities such as payments is taken care by Directorate General of Finance/Administration and Finance unit. Laboratory personnel are responsible only for technical activities.
d. Laboratory personnel are required to read and follow the Code of Conduct for Medical Laboratory Personnel.
e. If a risk to impartiality is identified, CPHL address it and take corrective action.

Related Documents

Document Title	Document Number
Ministry of Health Code of Conduct for Medical Laboratory Personnel	MoH/DGSMC/P /001/Vers.01

4.2 Confidentiality

4.2.1 Management of information

CPHL is responsible for the management of all patient information during the performance of laboratory activities. Management of patient information includes privacy and confidentiality related to all information obtained.

4.2.2 Release of information

Personnel in CPHL can only release the information to the requester/ HCW involved directly in patient/ public health care, where appropriate.

4.2.3 Personnel responsibility

All laboratory personnel have access to laboratory information have to keep confidential all information obtained or created during the performance of laboratory activities as mentioned in the related documents.

Related Documents

Document Title	Document Number
Ministry of Health Code of Conduct for Medical Laboratory Personnel	MoH/DGSMC/P /001/Vers.01

Confidentiality	QPR/4.2

4.3 Requirements regarding patients

CPHL does not deal direct with patients, however, it ensures:

a) Providing helpful information (in the handbook) to the user to aid the selection of the examination, and the interpretation of the examination results.

b) Providing the users with approximate time required to release the examination results.

c) Periodic review of the examinations offered by CPHL to ensure that the examinations are clinically appropriate and necessary.

d) Treatment of the samples, or remains, with care and respect.

Related Documents

Document Title	Document Number
CPHL Handbook	MH/CPHL/ 01/V2/July 2023
Request forms	File 4.3

5 Structural and governance requirements

5.1 Legal identity

CPHL is a part of the Ministry of Health and it is legally registered for scope performed in its permanent facility.

5.2 Laboratory Director

5.2.1 Laboratory director competence

The Director of CPHL, is a holder of a fellowship or equivalent certification or recognition from relevant professional bodies in the field of medical laboratory science and with minimum of 8 years experience in the field medical laboratory management with and least 5 years' experience in a leadership role.

5.2.2 Laboratory director responsibilities

The duties and responsibilities are detailed in the relevant job description. The director is competent to discharge the following responsibilities:

a. Plan, set goals, and allocate resources.

b. Provide effective and efficient administration of the service.
c. Monitor all work performed in the laboratory to determine that reliable data is being generated.
d. Provide advice on the use of the laboratory service, information about the choice of tests and interpretation of laboratory data.
e. Ensure that there are sufficient qualified personnel with adequate documented training and experience to meet the needs of the laboratory.
f. Implement a safe laboratory environment in compliance with good practice and applicable regulations.
g. Define, implement, and monitor standards of performance and quality improvement for laboratory services.
h. Provide educational programs for the personnel and participate in the educational programs of the department.
i. Address any complaint, request, or suggestion from users of laboratory services.
j. Ensure good staff morale.

5.2.3 Delegation of duties

The Director has delegated selected duties or responsibilities to the head of the sections, bio-safety chairperson and quality chairperson for effective operation of laboratory activities and day to day laboratory operations.

5.3 Laboratory activities

5.3.1 General

CPHL perform range of laboratory examinations at the permanent facility (please refer to the handbook). CPHL claims conformity with ISO 15189:2022 for the range of examination in stated in section 2.6 of this quality manual.

5.3.2 Conformance with requirements

The examinations listed in section 2.6 of this quality manual are carried out in such a way to meet the requirements of ISO 15189:2022, the users and regulatory authorities.

5.3.3 Advisory activities

CPHL's pre-examination information and turnaround time are provided to the user in handbook. The Department also communicates with users via all means, including meetings, to provide required advice, which includes:

a. Provision of professional judgments on the interpretation of results generated

b. Promotion of the effective use of laboratory services
c. Consultation on scientific or logistical matters, e.g. Failure of samples to meet minimum criteria.
d. Individual clinical cases

5.4 Structure and authority

5.4.1 General

Figure 1 represents organizational structure of CPHL and how it fits in the Ministry of Health. The chart organizes the flow of authority, information, and decision making from top to bottom through various levels of hierarchy. The Director is the head of the organization and has ultimate responsibility for the overall operation and administration of the department. CPHL is divided into sections where there is a head of section position in each section with specific responsibilities associated with activities within their section. Below each head of section there is a position of technical in-charge representing a link between the head and supervisor. There is a supervisor in each subsection of the section for the day-to-day operations to supervise work performance and maintenance of records. Laboratory technologist performs a variety of laboratory procedures of technical nature and reports the findings to the head of the section through technical in-charge/supervisor. In both the quality unit and biosafety unit, a chairperson has been assigned to develop and manage the implementation of quality management and biosafety requirements, with direct supervision from the director. To ensure the compliance with the standards and implementation of the plans, each of the chairpersons is working with a committee which is made of representatives from all the sections. The administration & finance unit is responsible for all financial and related administrative matters. Table 2 provides short description of the duties/tasks and responsibilities of each position.

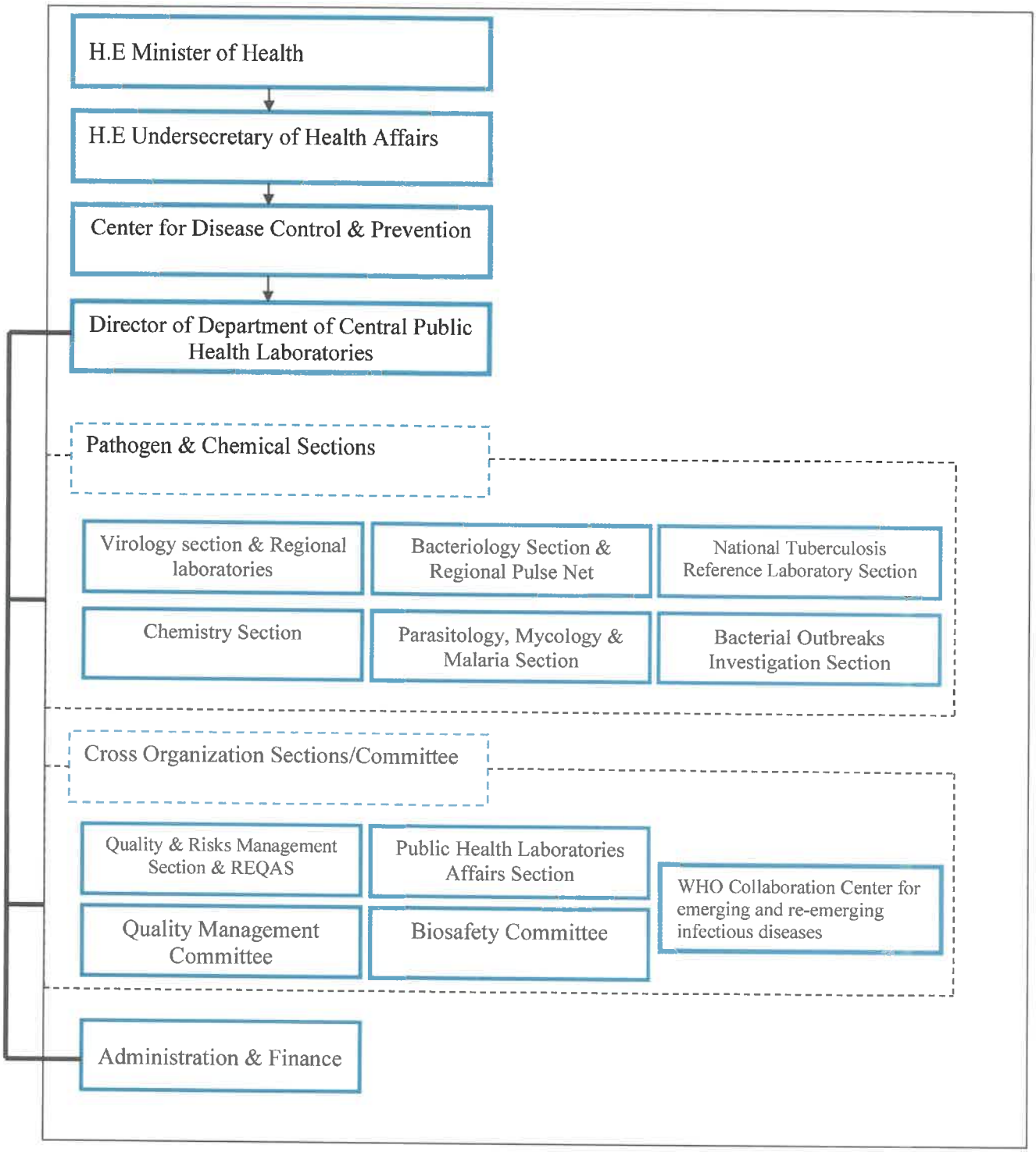

Figure 1: Represents the organizational structure of the Department of Public Health Laboratories.

Position	Short Description of the Duties/Tasks and Responsibilities
Director	The Director is a competent individual with responsibility for, and authority over the whole CPHL. The Director ensures that all aspects of the CPHL including personnel, premises and environment, equipment, information systems, materials, safety, quality and pre- and post- examination processes function correctly. This is achieved in co-ordination with the head of the sections, administration supervisor, bio-safety chairperson and quality chairperson.
Acting	
Head of Section	This position is responsible for planning and managing the work of the section. The position is also responsible for setting objectives and priorities, providing guidance to members of the section, as well as supervising and reporting on the section's work. Work is performed under the direction and supervision of the director.
Acting	
Technical in-Charge	This position work closely with the head of the section and supervisor, and is responsible for all laboratory technical aspects including personnel competency, equipment management, inventory management, method verification.
Acting	
Supervisor	This is a hands-on position responsible for the day-to-day operations and ensures a balanced workload distribution and supervises work performance. Train junior staff on proper laboratory test procedures and performs the more technical and complex tasks relative to assigned area of responsibility.
Acting	
Laboratory technologist	This position performs a variety of laboratory procedures of technical nature and reports the findings to the head of the section through technical in-charge/supervisor.
Quality committee chairperson	This position is responsible for the establishment, implementation, and maintenance of a management system in accordance with the requirements of ISO 15189:2022. The position is also responsible for coordinating with the accreditation body on all matters related to accreditation.
Biosafety committee chairperson	This position is responsible for the establishment, implementation, and maintenance of a biosafety system in accordance with the standards. The position is also responsible for coordinating all matters related to biosafety.

Administration & finance supervisor	The administration & finance unit is responsible for all financial and related administrative matters.

Table 2: Provides short description of the duties/tasks and responsibilities of each position.

Note: all position ensures adherence to established quality management procedures and maintenance of records. For more details of these positions refer to the individual job descriptions.

5.4.2 Communication

CPHL has effective means of communication with its staff and stakeholders through communications systems (information technology, telephone, and written communications) and meetings. All communications are recorded in the form of minutes of the meeting.
Regular meetings are conducted as follows:

Management Meetings

- Chair: Director
- Representative: Head of Sections
- Frequency: Every two weeks or as required.

Departmental Meetings

- Chair: Director
- Representative: All Staff
- Frequency: Every two months or as required.

Quality Meetings

- Chair: Quality Chairperson
- Representative: Quality Management Team Members representing sections
- Frequency: Every two months or as required.

Biosafety Meetings

- Chair: Biosafety Chairperson
- Representative: Biosafety Team Members representing sections
- Frequency: quarterly and as required.

External Communications

- Chair: Director/Department Representative

- Representatives: health professionals, referral laboratories, suppliers, etc.
- Frequency: As required.

5.4.3 Quality management

CPHL has appointed a quality chairperson. The quality chairperson reports directly to the director and fulfills the role by:

a. Ensuring that the quality system is established, implemented, and maintained in accordance with the ISO 15189: 2022 standard.
b. Handling the maintenance and distribution of the quality manual and associated documents.
c. Maintaining a master list of current versions of quality documentation.
d. Training personnel on quality system activities.
e. Monitoring the quality system.
f. Managing the internal audit program.
g. Coordinating laboratory accreditation activities.

5.5 Policies and objectives

Quality Policy and Objectives
Quality Policy
CPHL is committed to meeting the needs of laboratory users by offering examination services that are of high quality, reliability, accuracy, and timeliness, and is constantly working towards improvement. CPHL is focused on achieving this by: ▪ Ensure compliance with ISO 15189:2022 requirements and striving for continual improvement of laboratory services through adhering to the established quality management system. ▪ Review the policy regularly to ensure its continuing suitability.
Objectives
▪ To implement evaluations needed to ensure compliance with ISO 15189:2022 requirements. ▪ To continually improve the effectiveness of the quality management system through the use of management reviews.

5.6 Risk management

CPHL has a risk management procedure in place. The department assesses the impact of work processes and potential failures on examination results as they affect patient safety and modifies processes to reduce or eliminate the identified risks and document decisions and actions taken. Risk assessments are performed in key areas of the pre-examination, examination and post-examination processes to identify potential risks and to put controls in place to support potential vulnerable areas. Biosafety risk assessment is incorporated in the examination procedures.

Related Documents

Document Title	Document Number
Risk management procedure	QPR/5.6
Risk assessment form	Form # 5.6

6 Resource requirements

6.1 General

CPHL has sufficient number of personnel, good facilities, all needed equipment, reagents, consumables and necessary supporting services to perform laboratory activities.

6.2 Personnel

6.2.1 General

a) CPHL has a sufficient numbers of personnel for timely completion of examination and timely reporting of results.

b) Personnel are competent and work in accordance with the CPHL management system documented as per ISO 15189:2022. For competence, the competence criteria are defined and established in the procedure for different levels considering the types of examination.

c) CPHL management communicates to all personnel, the importance of meeting the needs and requirements of user and the requirements of ISO 15189:2022.

d) CPHL has program to introduce personnel to the department. This includes the area where the person will work, time in and time out, personnel facilities, health and safety requirements, and available occupational health services. All such information is communicated to the newly joined personnel at the time of orientation.

6.2.2 Competence requirements

a) CPHL has specified competence requirements for each function influencing the results of

laboratory activities. Competence criteria are defined and established in the procedure.

b) CPHL ensures that all personnel have the required competence to perform laboratory activities for which they are responsible.

c) Personnel management procedure is in place for implementation of competence assessment. The competence assessment of all personnel is performed once in a year. Competence of laboratory personnel is assessed by using any of the listed below/combination or all of the following approaches:

- Direct observation of routine work processes and procedures, including all applicable safety practices.
- Direct observation of equipment maintenance and function checks.
- Monitoring the recording and reporting of examination results.
- Review of work records.
- Examination of specially provided samples, such as previously examined samples or inter-laboratory comparison materials. / PT

6.2.3 Authorization

CPHL has authorized personnel to perform specific laboratory activities, including but not limited to the following:

a) Accessing patient data and information, entering patient data and examination results, and changing patient data or examination results.

b) Review, release, and reporting of results.

c) Selection, development, modification, validation and verification of methods.

6.2.4 Continuing education and professional development

CPHL has a procedure (QPR/6.2.4) for continuing education and professional development and provides training sessions for personnel engaged in managerial and technical processes, and records are kept with the document controller. Each individual is responsible for maintaining their own certificates of attendance or completion of the training and continuing professional development (CPD) records. All personnel are encouraged to take part in these regular professional development activities.

Related Documents

Document Title	Document Number
Continuing education and professional development procedure	QPR/6.2.4

6.2.5 Personnel records

The records of the relevant educational and professional qualifications, training and experience, and assessments of competence of all personnel are maintained in different locations. The records maintained as follow:

- Introduction of new personnel to the laboratory environment at CPHL
- Job descriptions at CPHL
- Training in current job tasks at CPHL.
- Competency assessments at CPHL.
- Reviews of personnel performance in the Department of Personnel in the Ministry of Health.
- Reports of accidents and exposure to occupational hazards at CPHL
- Immunisation status at CPHL.
- Educational and professional qualifications in the Department of Personnel in the Ministry of Health
- Copies of certification in the Department of Personnel in the Ministry of Health.
- Previous work experience in the Department of Personnel in the Ministry of Health.
- Records of continuing education and achievements in the Department of Personnel in the Ministry of Health.
- Ejada approved goals and achievements should also be included in the records.

Related Documents

Document Title	Document Number
Continuing education and professional development procedure	QPR/6.2.4
Personnel management procedure	QPR/6.2

6.3 Facilities and environmental conditions

6.3.1 General

CPHL has appropriate facilities and environmental conditions to ensure the validity of results and the safety of laboratory personnel. The requirements for facilities and environmental conditions necessary for the performance of the laboratory activities are monitored, and recorded. Following environmental conditions which can adversely affect the validity of results are controlled:

- Electrical supply
- Temperature

- Humidity
- Dust
- Microbial contamination

6.3.2 Facility controls

Facility controls include:

a) Access control, taking into consideration safety, confidentiality and safeguarding medical information and patient samples.

b) Prevention of cross-contamination, where examination procedures pose a risk, or where work can be affected or influenced by lack of separation.

c) Provision of safety facilities and devices.

d) Maintenance of laboratory facilities in a functional and reliable condition.

e) Prevention of contamination, interference, or adverse influences on laboratory activities that can arise from ventilation and waste disposal.

6.3.3 Storage facilities

CPHL provides a proper storage space and conditions to ensure the continuing integrity of samples, reagents, consumables and any other items that could affect the quality of examination results. Samples and materials used in examination processes are stored in a manner to prevent cross contamination. Storage and disposal facilities for dangerous materials are appropriate to the hazards of the materials and as specified by biosafety requirements.

6.3.4 Personnel facilities

CPHL provides personnel with wash/change room, lockers, and a rest room. Space for personnel activities such as conference room and meeting room are also provided.

6.3.5 Sample collection facilities

Limited sample collection facility is available at CPHL.

6.4 Equipment

6.4.1 General

CPHL has documented procedures for the process of procurement, acceptance, management, use, maintenance, and decommissioning of equipment The Department is furnished with all equipment needed to the carry out its scope stated in the handbook.

6.4.2 Equipment requirements

CPHL selects its equipment with the specifications, ensures the capability of achieving the performance and that it complies with requirements relevant to any examinations.

Each piece of equipment is uniquely labeled with the identification number. The numbering system is decided by laboratory with the department of medical technology. List of equipment is maintained by biomed engineer. The department replaces equipment, as needed, to ensure the quality of examination results.

6.4.3 Equipment acceptance procedure

CPHL has procedure (QPR/6.4.3) for equipment acceptance which emphasis on verifying all equipment upon installation and before use to ensure that the equipment is capable of achieving the necessary performance and that it complies with requirements relevant to any examinations. The evidence of conformance with the specified acceptability criteria before being placed in to services are maintained.

The evidence of conformance in terms of capability of measuring equipment to achieve the measurement accuracy or measurement to provide a valid result are maintained in the sections. At the time of installation of new equipment, the installation qualification (IQ), operational qualification (OQ) and performance qualification (PQ) are performed and documented. Records of all such qualification are maintained. The equipment is uniquely labeled, marked or otherwise identified.

6.4.4 Equipment instructions for use

CPHL ensures the following:

a. The supplier has safeguarded equipment appropriately to prevent unintended adjustments of equipment that can invalidate examination results. All control or set points of the mechanism are locked to prevent any changes in the settings.
b. Equipment is operated by trained, authorized, and competent personnel only.
c. Operating instructions for the use of equipment are prepared and maintained near the equipment for the safe and proper functioning of equipment. Instructions on the use; safety and maintenance of equipment, including manuals for use (provided by the manufacturer of the equipment) are made readily available near the equipment.
d. Equipment is used according to the manufacturer's instructions.

6.4.5 Equipment maintenance and repair

CPHL has a documented program of preventive maintenance. All items of equipment are covered under the preventive maintenance and detailed preventive maintenance schedule is prepared and followed. All equipments are verified against the defined preventive maintenance check points on monthly and yearly basis, at a minimum. All such preventive maintenance check points are prepared based on the manufacturer's instructions. Deviations from the manufacturer's schedules

or instructions are recorded.

Equipment is maintained in a safe working condition and in working order. This includes examination of electrical safety, emergency stop devices, where they exist, and the safe handling and disposal of chemical, radioactive and biological materials by authorized persons. At a minimum, manufacturer's schedules or instructions are used for disposal.

a) Defective equipment is removed from service immediately and labeled as **"Out of service"**. It is ensured that defective equipment is not used until it has been repaired and shown to meet specified acceptance criteria. CPHL examines the effect of any defects on previous examinations and take corrective action as per the procedure for corrective action.
b) CPHL ensure decontamination of equipment before service, repair or decommissioning. When equipment is removed from the direct control of the laboratory, it is ensured that its performance is verified before being returned to laboratory use.

6.4.6 Equipment adverse incident reporting

Any adverse incidents or accidents that attributed directly to specific equipment is investigated and reported to the supplier, and the department medical technology, as required.

CPHL has a procedure (QPR/6.4.6 & 6.6.7) for responding to manufacturer's recall and taking actions recommended by the manufacturer whenever required.

6.4.7 Equipment records

CPHL maintains records for each piece of equipment contributing to the performance of examinations. These equipment records include, but not limited to the following:

a) Identity of the equipment.
b) Manufacturer's name, type identification and serial number or other unique identification.
c) Supplier's name contact person and telephone number.
d) Date of receiving.
e) Current location.
f) Condition when received (e.g. new, used or reconditioned).
g) Manufacturer's instructions or reference to their retention.
h) Equipment performance records that confirm the equipment's suitability for use.
i) Warranty (Also if calibration is the part of the contract with supplier)
j) Routine maintenance (includes calibration records)
k) Maintenance carried out and that planned for the future.

All the information as mentioned above maintained in the equipment file and relevant records are

made readily available for the lifespan of the equipment.

Related Documents

Document Title	Document Number
External Services and Supplies	QPR/6.8.3
Equipment acceptance procedure	QPR/6.4.3
Equipment procedure	QPR/6.4
Responding to manufacturer's recall	(QPR/6.4.6 & 6.6.7)

6.5 Equipment calibration and metrological traceability

6.5.1 General

CPHL is implementing calibration and traceability standards to ensure the validity of examination results. The calibration of equipment (other than analyzers) is carried out at calibration laboratories accredited under ISO/IEC 17025 to establishing metrological traceability. The calibration of the equipment (analyzer) used for quantifying a measured analyte involves the use of certified reference materials to fulfill calibration metrological traceability requirements.

6.5.2 Equipment calibration

CPHL has a documented procedure (QPR/6.5) for calibrating equipment that can impact examination results, either directly or indirectly.

6.5.3 Metrological traceability of measurement results

CPHL is maintaining metrological traceability through a documented unbroken chain of calibrations. Metrological traceability is established by using reference measurement standards and reference materials.

Related Documents

Document Title	Document Number
Procedure for equipment calibration	QPR/6.5
Calibration status of equipment	File 6.3

6.6 Reagents and consumables

6.6.1 General

CPHL has a procedure (QPR/6.6) for the reception, acceptance testing, storage, adverse incidents reporting and inventory management of reagents and consumables.

6.6.2 Reagents and consumables (Receipt and storage)

CPHL has adequate storage facilities where reagent and consumables are received and stored in a manner that prevents damage or deterioration. The storage temperature requirements of reagents and consumables are according to manufacturer's specifications. All storage environment conditions (room temperature, refrigerators, and freezers) are monitored and recorded.

6.6.3 Reagents and consumables (Acceptance testing)

CPHL performs acceptance test of new/ new formulation/ new lot shipment of reagent before using in examinations.

It verifies consumables that can affect the quality of examinations before use in examinations. The department maintains the records of the acceptance of the reagents and consumables.

6.6.4 Reagents and consumables inventory management

CPHL uses the Ministry of Health tailored healthcare information system (Al-Shifa) which includes an inventory management platform. A minimum stock level for each reagent and consumables is established and maintained. The records of receipt and issued reagents and consumables are maintained.

The inventory management system makes sure that consumables and reagents that have been approved for usage are kept apart from those that have not been inspected. All consumables and reagents that have not been inspected or are deemed unsatisfactory are kept apart and are either tagged or kept in the appropriate storage location.

6.6.5 Reagents and consumables (Instructions for use)

CPHL ensures that the instructions for the use of reagents and consumables, including those provided by the manufacturers, are readily available. Reagents and consumables are used according to the manufacturer's specifications.

6.6.6 Reagents and consumables (Adverse incident reporting)

CPHL investigated adverse incidents and accidents that attributed directly to reagents or consumables reported to the Directorate General of Medical Supplies, as required.

CPHL follows the manufacturer's recall mechanism in case of adverse incident and taking actions recommended by the manufacturer.

6.6.7 Reagents and consumables (Records)

CPHL maintains records for each reagent and consumable. These records include but not limited to the following:

a. Identity of the reagent or consumable.

b. Manufacturer's name and batch code or lot number.

c. Contact information for the supplier.

d. Date of receiving, the expiry date.

e. Condition when received.

f. Manufacturer's instructions.

g. Records that confirmed the reagents or consumables initial acceptance for use.

Related Documents

Document Title	Document Number
Reagents and Consumables	QPR/6.6
Al Shifa inventory management software	Al Shifa platform

6.7 Service agreements

6.7.1 Agreements with laboratory users

CPHL consider each electronic or paper based request received from health institutions within Oman as a service agreement. The Department uses the Ministry of Health tailored healthcare information system (Al-Shifa platform) for electronic request. Both electronic and paper based request forms are designed to capture sufficient information to identify the patient, the authorized requester as well as patient clinical data. Personnel receiving the sample review the sample and request to ensure that the examinations identified by the user is correctly entered in the request form. The forms specify the information needed on the request to ensure appropriate examination and result interpretation.

The arrangement for the service agreements for researches, services or examination requested from outside Oman please refer to the service agreement procedure (QPR/6.7).

Related Documents

Document Title	Document Number
Service agreement procedure	QPR/6.7.
Al Shifa & paper based request forms	Al Shifa platform

6.8 Externally provided products and services

6.8.1 General

CPHL ensures that any products or services from external sources are according to the specifications decided by the department.

6.8.2 Referral laboratories and consultants

CPHL does not refer samples to any referral laboratory for any laboratory services.

6.8.3 Review and approval of externally provided products and services

CPHL has a procedure (QPR/6.8.3) for the selection and acquiring of external services, equipment, reagents and consumable supplies that affect the quality of examination. CPHL process involves:

a) Defining, reviewing, and approving the laboratory's requirements for all externally provided products and services.
b) Defining the criteria for qualification, selection, and evaluation of performance and re-evaluation of the external providers.
c) CPHL selects and approves suppliers of externally provided products and services based on their ability to supply external supplies or services. It collaborates with other departments as mentioned in the procedures QPR/6.8.3.
d) CPHL monitors the performance of suppliers to ensure that purchased services or items consistently meet the stated criteria. All the suppliers of services and supplies are evaluated for their performance according to the procedure (QPR/6.8.3). Records of supplier re-evaluation are maintained.

Related Documents

Document Title	Document Number
External services and supplies procedure	QPR/6.8.3
External services and supplies	Form 6.8.3

7 Process requirements

7.1 General

CPHL has a procedure (QPR/5.6) for identifying potential risks to patient care in the pre-examination, examination and post-examination processes. The risks are assessed and mitigated to the extent possible.

The identified risks and effectiveness of the mitigation processes is monitored and evaluated according to the potential harm to the patient.

CPHL also identify opportunities to improve patient care and developed a framework to manage these opportunities in the risk and opportunity sheet.

7.2 Pre-examination processes

7.2.1 General

CPHL has documented procedures and information for pre-examination activities to ensure the validity of the results of examinations. (Please refer to laboratory handbook)

7.2.2 Laboratory information for users

CPHL has detailed information available for user of the laboratory services in Handbook. The information includes as appropriate:

a. The location of the laboratory
b. Types of clinical services offered by the laboratory
c. Working hours of the laboratory and means of contact
d. The examinations offered by the laboratory including, as appropriate, information concerning samples required, sample volumes, sample storage and special precautions.
e. Instructions for completion of the request form
f. Instruction for preparation of the patient
g. Instructions for patient-collected samples
h. Instructions for transportation of samples, including any special handling needs
i. The laboratory's criteria for accepting and rejecting samples

7.2.3 Requests for providing laboratory examinations

7.2.3.1 General

CPHL consider each electronic or paper based request received from health institutions within Oman as a service agreement. The Department uses the Ministry of Health tailored healthcare information system (Al Shifa platform) for electronic request. Both electronic and paper based request forms are designed to capture sufficient information to identify the patient, the authorized requester as well as patient clinical data. The required information related to laboratory examination to be performed is specified in the request for examination. The request forms allow spaces for the inclusion of, but not limited to, the following:

a. Unique identification of the patient including gender and date of birth for interpretation purposes.

b. Name of the physician or other person legally authorized to request examinations or use medical information together with the destination for the report. The requesting institution and address.
c. Type of primary sample and the anatomic site of origin, where appropriate.
d. Examinations requested.
e. Clinical information relevant to the patient, for test justification and result interpretation purposes.
f. Date and time of primary sample collection.
g. Date and time of receipt of samples by the laboratory.

7.2.3.2 Oral requests

- Every test that is conducted ought to be documented in Al Shifa. Any tests that are added later on by oral request must to be added electronically to the Al Shifa system as well.

7.2.4 Primary sample collection and handling

7.2.4.1 General

CPHL has provided the documented instructions for the proper collection and handling of primary samples to the users. All the instructions are compiled in the handbook.

7.2.4.2 Information for pre-collection activities

CPHL provides information and instructions for pre-collection activities with sufficient detail to ensure that the integrity of the sample is not compromised.

7.2.4.3 Patient consent

Patient consent is only applicable when the samples are specifically intended for research or survey purposes.

7.2.4.4 Instructions for collection activities

CPHL does not directly collect samples from the patients. However, it provides its user all the information (in the handbook) necessary to ensure accurate and appropriate sample collection and pre-examination storage. The handbook ensures the following:

a. Instructions for clinicians to meet pre-examination requirements.
b. Instructions for collection of primary samples with descriptions of the primary sample containers and any necessary additives.
c. Instructions for labelling of primary samples in a manner that provides an unequivocal link with the patients from whom they are collected.

d. Instructions for proper storage conditions before collected samples are delivered to the laboratory.

7.2.5 Sample transportation

CPHL has provided its user with the requisite instructions (in the handbook) for sample transportation. This instruction includes:

a) Information, to ensure the timely and safe transportation of samples:
   - Packaging of samples
   - Maintaining the temperature interval specified for sample collection and handling
   - Any specific requirements to ensure integrity of samples, e.g., use of preservatives.
   - Instructions for transporting infectious materials

CPHL take the following actions:

a. When sample integrity is compromised and the safety of the carrier or the general public is placed at risk, the institution responsible for the transport of the sample is notified immediately and measures taken to mitigate the risk and to avoid recurrence with the whole process is clearly documented
b. Establishing and periodically evaluating the sample transportation systems.

7.2.6 Sample receipt

7.2.6.1 Sample receipt procedure

CPH has documented general sample receipt procedure (QPR/7.2.6) that specify the general criteria for acceptance and rejection and handbook (CPHL handbook) for specific examination sample acceptance and rejection.

7.2.6.2 Sample acceptance exceptions

a) CPHL has a process that considers the best interests of the patient in receiving care, when a sample has been compromised due to:
   - Sample identification (Includes unlabeling or mislabeling)
   - Sample instability due to, for example, delay in transport or not receiving the sample in triple pack)
   - Incorrect storage or handling temperature.
   - Inappropriate container.
   - Insufficient sample volume.
   - Sample leakage or contaminated.

b) When a compromised clinically critical or irreplaceable sample is accepted, after consideration of the risk to patient safety, the final report indicates the nature of the problem and where applicable, advising caution when interpreting results that can be affected.

7.2.7 Pre-examination handling, preparation, and storage

7.2.7.1 Sample protection

CPHL has a procedure (QPR/7.2.7.1) and appropriate facilities for securing patient samples, ensuring sample integrity and preventing loss or damage during, handling, preparation and storage.

7.2.7.2 Criteria for additional examination requests

The procedures include time limits for requesting additional examinations on the same sample.

7.2.7.3 Sample stability

Considering the stability of the examination in a primary sample, the time between sample collection and performing the examination is monitored in the procedure.

Related Documents

Document Title	Document Number
CPHL handbook	MH/CPHL 01/V2/July 2023
Procedure for sample receipt	QPR/7.2.6
Al Shifa & paper based request forms	Al Shifa platform

7.3 Examination processes

7.3.1 General

CPHL uses only examination methods that have been validated for their intended use to assure the clinical accuracy of the examination for patient testing. No in-house developed method is included in the scope for accreditation.

7.3.2 Verification of examination methods

CPHL has a procedure for the planning of the verification of examination methods used without modification. The procedure defines the process for planning and reporting of verification studies. The aim is to provide a clear plan for the entire verification study, covering the performance characteristics that will be studied, the target value for each performance characteristic, the

materials that will be analyzed, the level of replication and order of the experiments, any statistical analysis that will be used, and how the method will be judged as being fit for purpose. The planning and reporting document is structured in such a way that when the experimental work has been completed, it can be easily converted into a verification report. The Head of the section/Technical in-charge reviews and approves the verification plan, results and report.

7.3.3 Validation of examination methods

CPHL's scope for accreditation includes examination methods which are validated only.

7.3.4 Evaluation of measurement uncertainty (MU)

CPHL has procedure (QPR/7.3.4 to be completed) for evaluation of measurement uncertainty for the quantitative examination.

7.3.5 Biological reference intervals and clinical decision limits

The examination procedures specify the biological reference intervals and clinical decision limits for interpreting examination results, which are then communicated to users through the examination reports.

7.3.6 Documentation of examination procedures

CPHL has examination procedures, in the form of standard operating procedures. The procedures are kept at the work station where the test and examination performed and/or electronically. The procedures are based on instructions for use from the manufacturer.

a. The procedures are based in whole or in part on the instructions for use (e.g. package insert).
b. Any deviation is reviewed and documented. Additional information that could be required to perform the examination is also documented.
c. Each new version of examination kits with major changes in reagents or procedure is verified for performance and suitability for intended use.
d. Any procedural changes are dated and authorized.
e. The Head of each Section is responsible for ensuring that the contents of examination procedures are complete, current and have been thoroughly reviewed.

7.3.7 Ensuring the validity of examination results

7.3.7.1 General

CPHL ensures the quality of examinations by performing them under conditions defined in the examination procedure and using internal quality controls to verify the quality of the results. The frequency of running quality control materials is based on the manufacturer's recommendation, the stability of the procedure, and the risk of harm to the patient from an erroneous result.

7.3.7.2 Internal quality control

CPHL has a procedure (QPR/7.3.7.2) in place to prevent the release of patient results in the event of quality control fails the acceptability criteria defined in the examination procedure. In case the quality control defined acceptability criteria are not fulfilled and indicate results are likely to contain significant errors, the results are rejected and relevant patient samples re-examined after the error has been corrected. CPHL evaluates the results from patient samples that examined after the last successful quality control event. Quality control data is reviewed with defined acceptability criteria at regular intervals to detect trends in examination performance that may indicate problems in the examination system. Root cause analysis is performed when trends are noted and preventive actions are taken and recorded.

7.3.7.3 External quality assessment

CPHL participates in an external quality assessment program that is appropriate to the examination and interpretation of examination results. In the absence of a formal inter-laboratory comparison program, the laboratory seeks possible alternatives, such as the exchange of samples with other laboratories. The results of the external quality assessment program are monitored, and when predetermined performance criteria are not achieved, corrective actions are implemented.

7.3.7.4 Comparability of examination results

CPHL compare examination results using different methods or equipment whenever is necessary. The use of patient samples when comparing different examination methods can avoid the difficulties linked to the limited commutability of IQC materials.

Related Documents

Document Title	Document Number
Procedure for planning verification of examination method	QPR/7.3.2
Method verification report	Form 7.3.2
Procedure for evaluation of measurement uncertainty (MU)	QPR/7.3.7.2
Procedure for monitoring the validity of results	QPR/7.3.7
IQC Analysis report	Form 7.3.7.2

7.4 Post-examination processes

7.4.1 Result reporting

7.4.1.1 General

CPHL reports examination results accurately, clearly, unambiguously and in accordance with any specific instructions defined in the examination procedure and reporting (QPR/7.4.1). The report

includes all available information necessary for the interpretation of the results. In case of examination results delays, the user is notified according to the procedure.

7.4.1.2 Result review and release

Results are reviewed and authorized as per the reporting procedure (QPR/7.4.1) or examination procedure prior to release. CPHL ensures that authorized personnel evaluate the results against IQC and, as appropriate, available clinical information and previous examination results.

7.4.1.3 Critical result reports

When examination results fall in the established critical decision limits:

a. The end-user is notified as soon as relevant, based on clinical information available.
b. Actions taken are documented, including date, time, responsible person and person notified along with contact details.

7.4.1.4 Special considerations for results

When results are transmitted as a preliminary report, the final report is always forwarded to the user.

7.4.1.5 Automated selection, review, release and reporting of results

CPHL is not implementing automated selection, review, releasing and reporting of results. The results are reviewed and authorized as per the reporting procedure (QPR/7.4.1) or examination procedure prior to release.

7.4.1.6 Requirements for reports

Each report includes the following information:

a) Unique patient identification, the date of primary sample collection and the date of the issue of the report.
b) Identification of the laboratory (CPHL) issuing the report.
c) Name of the user.
d) Type of primary sample and any specific information necessary to describe the sample (e.g., source, site of specimen).
e) Identification of the examinations performed.
f) Identification of the examination method used, where relevant.
g) Examination results with, where appropriate, the units of measurement, reported in SI units, units traceable to SI units, or other applicable units.
h) Biological reference intervals and clinical decision limits.

i) Identification of the person reviewing the results and authorizing the release of the report.

j) Indications of any critical results.

7.4.2 Additional information for reports

Following additional information may be provided based on the requirements:

a) When applicable, a report includes interpretation of results and comments on:

- Sample quality and suitability that can compromise the clinical value of examination results.
- Result significant changes over time.
- Any recommendations or comments on further testing.

7.4.3 Amendments to reported results

Procedure (QPR/7.4.1) is documented and implemented for the issue of amended or revised results and this procedure ensures that:

a) The reason for the change is recorded and included in the revised report.

b) Revised results are delivered only in the form of an additional document or data transfer, and clearly identified as having been revised, and the date in the original report is indicated.

c) The user is made aware of the revision with documentation of the name of user and date of calling the new result.

7.4.4 Post-examination handling of samples

CPHL retains all the samples for a period of retention time from the date of completion of examination. During storage, all such samples are kept under a controlled environment considering the type of sample to preserve the quality of sample from deterioration.

After the examination, it is ensured that the:

a) Suitability of the sample for additional examination is known.

b) Sample is stored in a manner that optimally preserves suitability for additional examination.

c) Sample can be located and retrieved.

d) Sample is discarded appropriately.

Related Documents

Document Title	Document Number

Procedure for reporting the results	QPR/7.4.1
Procedures for issue of amended or revised results	QPR/7.4.1
Procedures for identification, access, storage, preservation and safe disposal of clinical samples	QPR/7.2.6
Examination report	Al Shifa platform
Sample disposal records	File 7.4.2

7.5 Nonconforming work

CPHL has a procedure (QPR/7.5) for identifying, analyzing, reviewing, and addressing non-conformities. The responsibility for identifying, analyzing, reviewing, and addressing non-conformities lies with all personnel of CPHL.

Related Documents

Document Title	Document Number
Procedures for identification and control of non-conformities	QPR/7.5
Corrective action form	Form 8.7.1

7.6 Control of data and information management

7.6.1 General

Personnel of CPHL have access to the data and information needed to perform laboratory activities. The information management system is in both format computerized (Al Shifa platform) and non-computerized format for data receiving/entry, recording, reporting, storage, and retrieval. Al Shifa platform is validated for functionality, including the proper functioning of interfaces by the Directorate of General Information Technology (DGIT).

7.6.2 Authorities and responsibilities for information management

CPHL specifies the authorities and responsibilities for managing information systems, including maintenance and modifications that can affect patient care. The responsibility for the laboratory information systems lies with the department.

7.6.3 Information systems management

The Al Shifa platform used for the receiving/entry, recording, reporting, storage, and retrieval of examination data and information are:

a. Validated by CPHL for functionality before implementation. Before any changes are made to the system, including laboratory software configuration or modifications, they must be authorized and validated. The validation process ensures that the interfaces between Al Shifa platform and the laboratory equipment are functioning correctly and that the synchronization is working properly.
b. Documented by the Directorate of General Information Technology.
c. Implemented taking cyber-security into account, to protect the system from unauthorized access and safeguarded data against tampering or loss.
d. Operated in a controlled environment that meets the specified requirements.
e. 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.
f. Calculations and data transfers are checked in an appropriate and systematic manner.

7.6.4 Downtime plans

CPHL has a contingency plan to deal with information system failures/downtime during Al Shifa failure to maintain the operation of services. The plan is as follow:

a. Receives and process printed request forms sent along the samples.
b. Urgent and precious samples are given priority, as it can have an immediate impact on patient care.
c. Make it a practice to print examination reports from the analysers and verify patient identification before sending them to the requester whenever it's possible. This is done during the failure at the system.
d. Make sure that the examination reports are sent through the correct, authorized channel.
e. Once the system is back up and running, ensure that the samples that were processed during the failure are entered in Al Shifa and the results are transmitted.

7.6.5 Off site management

CPHL uses the Ministry of Health tailored healthcare information system (Al-Shifa) for electronic request. The system is used by healthcare professionals in the Ministry and administered by the Directorate of General Information Technology.

7.7 Complaints

7.7.1 Process

CPHL has a procedure (QPR/7.7) for handling complaints that includes the following:

a. The process for receiving, investigating, and responding to a complaint.
b. Ensuring appropriate action is taken.

7.7.2 Receipt of complaint

a. On receipt of a complaint, CPHL confirms whether the complaint relates to laboratory activities that the CPHL is responsible for and, if so, resolves the complaint.
b. CPHL is responsible for gathering all necessary information to determine whether the complaint is valid.
c. The department acknowledges complaints upon receipt and informs the complainant of the outcome.

7.7.3 Resolution of complaint

CPHL has a procedure for resolution of complaints or any feedback received from the user. All complaints are thoroughly investigated and corrective action taken as necessary. Impartiality is maintained during the resolution of complaint.

Related Documents

Document Title	Document Number
Complaints procedure	QPR/7.7
Complaints form	Form 7.7

7.8 Continuity and emergency preparedness planning

CPHL ensures that risks associated with emergency situations or other conditions when laboratory activities are limited, or unavailable, have been identified, and a coordinated strategy exists that involves plans, procedures, and technical measures to enable continued operations after a disruption. Procedure (QPR/7.8) for continuity and emergency preparedness planning is prepared and implemented.

Major Emergency Preparedness Plan is evaluated periodically by conducting mock drill and reviewed and updated based on the results of response against the plan.

CPHL:

a. Has established a planned response to emergency situations, taking into account the needs and capabilities of all relevant laboratory personnel.
b. Provides information and training as appropriate to relevant laboratory personnel.
c. Responds to actual emergency situations.

d. Takes action to prevent or mitigate the consequences of emergency situations, appropriate to the magnitude of the emergency and the potential impact.

Related Documents

Document Title	Document Number
Procedure for continuity and emergency preparedness planning	QPR/7.8
Major emergency preparedness plan	File 7.8
Mock drill records	File 7.8

8 Management system requirements

8.1 General requirements

8.1.1 General

CPHL is committed to the development and implementation of the management system and demonstrates the consistent fulfilment of the requirements of ISO 15189:2022. The management system includes the following:

- Responsibilities
- Objectives and policies
- Documented information
- Actions to address risks and opportunities for improvement
- Continual improvement
- Corrective actions
- Evaluations and internal audits
- Management reviews

8.1.2 Fulfillment of management system requirements

CPHL fulfil the requirements of management system in accordance with the requirements of ISO 15189:2022.

8.1.3 Management system awareness

The personnel of CPHL are aware of:

a. Relevant objectives and policies.
b. Their contribution to the effectiveness of the management system, including the benefits of improved performance.
c. The implications of not conforming with the management system requirements.

8.2 Management system documentation

8.2.1 General
To achieve the purposes of ISO 15189:2022, CPHL has established quality objectives and policies that are implemented at all levels of the department.

8.2.2 Competence and quality
The objectives and policies of CPHL are aimed at ensuring quality and competence.

8.2.3 Evidence of commitment
CPHL shows dedication to developing and implementing a management system and improving its effectiveness.

8.2.4 Documentation
CPHL maintains all documentation, processes and records, related to the fulfilment of the requirements of ISO 15189:2022.

8.2.5 Personnel access
CPHL personnel can access the relevant parts of the management system documentation and related information that are relevant to their responsibilities. The management system maintains all documentation, processes and records necessary for fulfilling ISO 15189:2022 requirements in either hard copy/soft copy. The documents that are relevant are distributed to the concerned personnel in a regulated manner as per the document control mechanism.

Quality Policy and Objectives
Quality Policy
CPHL is committed to meeting the needs of laboratory users by offering examination services that are of high quality, reliability, accuracy, and timeliness, and is constantly working towards improvement. CPHL is focused on achieving this by: ▪ Ensure compliance with ISO 15189:2022 requirements and striving for continual improvement of laboratory services through adhering to the established quality management system. ▪ Review the policy regularly to ensure its continuing suitability.
Objectives
▪ To implement evaluations needed to ensure compliance with ISO 15189:2022 requirements.

- To continually improve the effectiveness of the quality management system through the use of management reviews.

8.3 Control of management system documents

8.3.1 General

CPHL controls the documents that relate to the fulfillment of ISO 15189:2022.

8.3.2 CPHL ensures that:

a. Each document is having:
   - A title of document such as quality manual, quality procedure, examination procedure, etc. on the top of the document itself.
   - A unique identifier on each page, such as document number as per the detailed system given in the procedure for documents control.
   - The date of the current edition and edition number.
   - Page number to total number of pages (e.g., "Page 1 of 5," "Page 2 of 5," etc.).

b. CPHL reviews and approves all the documents before putting them in use as given below.

Responsibility Matrix for Documents			
Document Type	**Prepared by**	**Reviewed by**	**Approved by**
Quality Manual	Quality Chairperson	Director/ Section	Director
Quality Procedure	Quality Chairperson	Director/Section	Director
Standard Operating Procedures	Technical In-charge	Head of the Section	Head of the Section

a) CPHL reviews all documents (quality manual, quality procedures, and standard operating procedures) every 3 years and as required to ensure compliance with current practices. Record of document review is kept in document control database.

b) Distribution of documents is controlled and maintained by the quality chairperson who ensures availability of relevant versions at points of use.

c) Any changes or amendments made to documents are identified. To identify the latest changes, an asterisk (*) or appropriate marking is placed on the right or left of the affected text/paragraph, in addition to underlining the affected text/paragraph, etc. By using this marking, all laboratory personnel are made aware of the latest changes.

d) Documents are safeguarded from any unauthorized changes or deletion by putting it in shared folder, where it can only be read. Hard copy is provided to the quality management representatives of each section. This is documented in the master list excel maintained by the document controller. Whenever there are any changes made in the documents, it is replaced by newer version and the older version is taken back from the quality management representatives of the sections. The master list of documents is also shared in the shared folder so that the staff are aware of the latest version.

e) Documents are secured from any unauthorized access.

f) Obsolete documents are prevented from being used in unintended ways and are properly identified if kept for any reason. During issuance of the amended documents, the quality chairperson retrieves all outdated controlled documents from the controlled copy holder. To prevent further usage, all such documents are:
   - Shredding of individual paper for its permanent disposal in case of hard copy of documents.
   - Documents issued in soft copy are removed from the particular access point to prevent their further usage.

g) The master copy of document is identified by writing/stamping it as **"OBSOLETE"** on all the pages with the date when this document became obsolete.

Related Documents

Document Title	Document Number
Procedure for documents control	QPR/8.3
Master list and distribution list of documents	File 8.3

8.4 Control of records

8.4.1 Creation of records

CPHL has a procedure (QPR/8.4) for the maintaining legible records to demonstrate fulfillment of the requirements of ISO 15189:2022. For every activity that influences the examination's quality, a digital or paper form record is generated and maintained. Both digital and paper records can be easily accessed and are secure against unauthorized alterations.

8.4.2 Amendment of records

CPHL ensures that amendments to records can be traced to original observations in Al Shifa platform. The original and amended data are kept, along with the modification date and, if needed, the time, showing the altered aspects and the personnel responsible for the alterations.

8.4.3 Retention of records

a. CPHL has established the duration for retaining records related to the quality management system, which includes pre-examination, examination, and post-examination procedures. Retention period of all such records is maintained in the Master list of records. The retention period for each record is dependent on the activity.
b. Exam results that have been reported can be retrieved for as long as necessary or as required. All lab results are electronic and stored at Al Shifa platform.
c. The laboratory retains accessible records in in whichever medium and they are available for review by management throughout the retention period.

To avoid damage, deterioration, loss or unauthorized access, the storage of records is provided with appropriate adequate facilities, and a suitable environment. This is kept in the stores under the stores in charge supervision.

Related Documents

Document Title	Document Number
Control of records	QPR/8.4
Amendment of records	Al Shifa platform

8.5 Actions to address risks and opportunities for improvement

8.5.1 Identification of risks and opportunities for improvement

CPHL has a procedure (QPR/5.6) for the identification of risks and opportunities for improvement associated with laboratory activities, aiming to:

a. Prevent or minimize adverse effects and potential errors in laboratory activities.
b. Act on opportunities to for improvement.
c. Ensure the management system work towards its intended outcomes
d. Contribute to the laboratory's purpose and objectives.

8.5.2 Acting on risks and opportunities for improvement

CPHL is using a detailed risk assessment and opportunity sheet (excel sheet) to address identified risks and improvement opportunities. The actions to mitigate risks are based on their potential effects on laboratory results, patient safety, and personnel safety.

Related Documents

Document Title	Document Number
Risk assessment procedure	QPR/5.6
Risk assessment and opportunity sheet	Excel File 5.6

8.6 Improvement

8.6.1 Continual improvement

a. CPHL continually improves the effectiveness of the management system, including the pre-examination, examination and post-examination processes as stated in the objectives and policies.
b. CPHL make use of the reported nonconformities, internal audit findings, complaints, management reviews, personnel suggestions, user feedback, data analysis, external evaluation reports and EQA results for improvements.
c. The actions' effectiveness is evaluated upon improvement implementation.

8.6.2 Laboratory user feedback

CPHL collects information from user regarding whether the service has fulfilled their needs and requirements. The collected information is used to make necessary improvements.

Related Documents

Document Title	Document Number
User feedback form	File 8.6.2

8.7 Non-conformities and corrective actions

8.7.1 Actions when non-conformity occurs

CPHL responds to non-conformity by:

a. Taking immediate action to control the non-conformity.
b. Evaluating the need for corrective action to ensure that non-conformities do not recur. If corrective action is required, for the repetitive non-conformity, the department determine the corrective actions based on the root cause to prevent the occurrence of similar types of non-conformity in the future.

c. Implementation of corrective action.

d. Provide feedback to the initiator.

8.7.2 Preventive action

The preventive action is evaluated so that no incident will occur which was supposed to take place. Find all the measures to avoid any mishap from occurring.

8.7.3 Corrective action effectiveness

The corrective action is evaluated to ensure that it has effectively mitigated the identified cause and is appropriate for the non-conformity encountered.

8.7.4 Records of non-conformities and corrective actions

Documentation of non-conformities and corrective actions includes the nature of the non-conformity, the cause, any actions taken, and evaluation of corrective action effectiveness.

Related Documents

Document Title	Document Number
Corrective action procedure	QPR/8.7.1
Identification and control of non-conformities	QPR/7.5
Corrective action form	Form 8.7.1
Preventive action request form	Form # 4.11

8.8 Evaluations

8.8.1 General

CPHL conducts evaluations to ensure the processes meet ISO 15189:2022 requirements and user needs. The review of the same takes into account quality indicators and user feedback.

8.8.2 Quality indicators

The monitoring of quality indicators is planned and implemented on a periodically basis (according to procedure QPR/8.8.2), with consideration given to the types of quality objectives. The plan for monitoring consists of objectives, methodology, interpretation, limits, action plan and duration of monitoring. The appropriateness of the indicators is reviewed regularly.

8.8.3 Internal audits

Internal audits are carried out once a year/as required to gather information about whether the management system conforms to the requirements of ISO 15189:2022, and is effectively implemented and maintained.

Trained personnel conduct audits to evaluate the performance of managerial and technical processes within the quality management system. The audit program is designed, taking into

account the importance of the processes, technical and management areas that will be audited, and previous audit outcomes. Audit criteria, scope, frequency, and methods are documented and defined.

CPHL has a documented procedure to define the responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records of internal audit.

The internal audit schedule is prepared and shared with relevant individuals ahead of time. The plan includes the following:

a. Previously outcomes of audits, non-conformities, incidents, and complaints and potential identified risks.
b. Audit objectives, criteria and scope.
c. Selection of auditors who are qualified and authorized to assess the performance of the laboratory's management system.
d. Ensuring that the results of the audits are reported to relevant personnel in the form of internal audit observation report.
e. Head of the section for the section being audited must ensure that appropriate action is promptly undertaken when non-conformities are identified.
f. The implementation and effectiveness of corrective action are verified and documented through follow-up audit activities.
g. Upon satisfactory actions, auditor closes the non-conformity and the record is maintained in internal audit file.

Related Documents

Document Title	Document Number
Internal audit procedure	QPR/6.2.3
Audit report	File 6.2.3

8.9 Management reviews

8.9.1 General

CPHL reviews the quality management system **every year** (normally after completion of internal audit), to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the fulfillment of ISO 15189:2022. CPHL follows a documented procedure (QPR/8.9) for management review meetings. The director conducts regular management reviews which include the identification of opportunities for improvement.

8.9.2 Review input

The inputs for management review include evaluations of at least the following:

1.	Review of action decided in the previous meeting
2.	Review of the handbook requirements
3.	Review of assessment of user feedback
4.	Review of changes that could affect quality management system
5.	Review of staff suggestions
6.	Review of results of internal audits
7.	Review of risk management
8.	Review of use of quality indicators
9.	Review of results of external audits
10.	Review of results of participation in inter-laboratory comparison programs (PT/EQA)
11.	Review and monitoring and resolution of complaints
12.	Review of performance of suppliers
13.	Review of identification and control of non-conformities
14.	Review of results of continual improvement including current status of corrective actions and preventive actions
15.	Review of changes in the volume and scope of work, personnel, and premises that could affect the quality management system
16.	Review of recommendations for improvement, including technical requirements
17.	Review of end user survey

The analysis includes the opportunities for improvement and the requirement for changes to the quality management system, including the quality objectives and policy.

8.9.3 Review output

The management review outcome includes documentation of decisions and actions about:

a. Improving lab activities to comply with ISO 15189:2022 standards.

b. Provision of required resources as required.

c. Improving the quality of services offered to users.

Director ensures that actions arising from management review are completed within a defined timeframe. Quality team keeps track of all the actions and monitors them on regular basis. Management reviews' findings and actions are communicated to the concerned.

Related Documents

Document Title	Document Number
Management review procedure	QPR/8.9
Management review form	Form 8.9
Management review record	File 8.9

9 Reference

ISO 15189:2022, Medical laboratories – Requirements for Quality and Competence

ISO 15189:2012, Medical laboratories – Requirements for Quality and Competence

ISO 9000:2009, Quality Managements Systems – Fundamental and Vocabulary

ISO 9001:2000 Quality Management System – Requirements

Document Reviewers:

Name	**Designation /Job title**	**Signature**
Dr Amina Al Jardani	Senior Consultant- Medical Microbiologist	
Dr Aza Al Rashdi	Head of Section-Bacteriology/PMM/F&W	
Dr Intisar Al Shukri	Head of Section- Virology	
Dr Noora Al Balushi	Head of Section- Quality & Risk Management	
Ms Aisha Al Busaidy		
Ms Samiya Al Zidjali		