



KENYA PLANT HEALTH INSPECTORATE SERVICE

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KEPHIS HEADQUARTERS PLANT HEALTH LABORATORY (HQPHL)

QUALITY ASSURANCE MANUAL (POLICY) ISO/IEC 17025:2017

“General requirements for the competence of testing and calibration laboratories”

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Revision Number: 0		Effective Date:		

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1:0 INTRODUCTION

1.1 Background Information

KEPHIS Headquarters Plant Health Laboratory (HQPHL) is a department under the Directorate of Laboratory Services at the Kenya Plant Health Inspectorate Service (KEPHIS), a Kenyan state corporation situated in Karen, Nairobi off Nairobi – Ngong’ Highway. KEPHIS as a state corporation, was established under the KEPHIS Act No. 54 of 2012 with a core mandate of providing Kenya with a science-based plant regulatory service through the assurance of plant health, quality of agricultural inputs and produce for food security, globally competitive agriculture, and sustainable development. Vision of the institution is “Excellence in plant health and quality assurance in agriculture” and its motto is “Plant health our business”.

The HQPHL is charged with the responsibility of;

- i. Undertaking morphological and molecular identification and diagnosis of plant pests for Phytosanitary Certification.
- ii. Surveillance and detection of Genetically Modified Organism events and review of applications for contained use and environmental release authorization.
- iii. Collection and maintenance of biological reference materials and analysis of genetic materials for purity.
- iv. Identification and release authorization of Biological control agents.
- v. Supporting the Centre of Phytosanitary Excellence Africa (COPE) by offering training services on laboratory testing and diagnosis of plant pests.
- vi. Offering advisory services to farmers.
- vii. Training of interns and students on attachment.

In order to effectively serve our customers and undertake the above functions sustainably, HQPHL charges nominal fees for the services offered to its customers as stipulated in the Legal Notice No. 48 of 2009 on Plant Protection fees and charges. These funds are used to supplement the laboratory in the purchase of equipment, reagents, and reference materials and for the day-to-day operations. This KEPHIS Headquarters Plant Health Laboratory Quality Manual document outlines how the laboratory meets the requirements of the ISO/IEC 17025:2017 international standard, *General requirements for the competence of testing and calibration laboratories*, for the purpose of accreditation.

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1.2 Scope

The quality system described in this manual covers testing and diagnosis services provided to internal and external KEPHIS customers. To provide quality and efficient services to its customers, HQPHL develops necessary procedures, policies, systems, organization and controls on all factors to demonstrate competence to carry out diagnostic tests as per specified requirements according to ISO/IEC 17025:2017. Scope of HQPHL testing and diagnostic services currently includes;

- i. Testing and diagnosis of pathogenic plant viruses (Virology).
- ii. Testing and diagnosis of pathogenic plant fungi (Mycology).
- iii. Testing and diagnosis of pathogenic plant bacteria (Bacteriology).
- iv. Detection and Identification of insect vectors of plant pathology significance (Entomology).
- v. Detection and identification of nematodes of plant pathology significance (Nematology).
- vi. Molecular diagnosis of plant pests and monitoring and analysis of GMO events (Molecular Biology).
- vii. Analysis and verification of genetic material for purity (Genetic Purity).
- viii. Collection and maintenance of biological reference materials (Reference Collection).

2:0 MANAGEMENT SYSTEM IMPLEMENTATION AND DISTRIBUTION

2.1 Management System Awareness and Implementation

The management system documents and test methods described herein are included as training elements in the laboratory's staff training program. This ensures that the laboratory's staff are familiar with quality assurance documentation and fully implement appropriate quality policies and procedures while undertaking laboratory activities.

2.2 Management System Objectives

The objectives of this HQPHL management system include;

- i. To assure the validity and reliability of laboratory test results by strictly adhering to standardized protocols.
- ii. To establish and maintain national and international recognition by acquiring and retaining international accreditation.

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- iii. To meet or exceed the needs and expectations of its customers by providing timely and reliable services, and assuring information integrity and confidentiality.
- iv. To maintain the laboratory's reputation for accurate diagnosis by consistently delivering valid and reproducible test results.

2.3 Management System Strategies

To achieve HQPHL's management system objectives, the laboratory commits to;

- Train and retain competent personnel to conduct laboratory activities.
- Maintain equipment that is fit for purpose and ready for use.
- Calibrate equipment traceable to National and International standards.
- Verify that equipment operating outputs are within prescribed tolerances.
- Provide suitable accommodation and controlled environment that is fit for purpose.
- Apply methods of testing and diagnosis whose capabilities (accuracy, precision, robustness, specificity and repeatability) can be validated.
- Validate methods using standards or references of required accuracy and traceability.
- Verify the controlled performance of tests and methods by the use of in-house Quality Control procedures and external proficiency testing.

It is recognized that this level of quality assurance can only be achieved through the implementation of ISO/IEC 17025:2017 requirements and accreditation by an internationally recognized body. The accreditation body to which application is made for accreditation purposes is the Kenya National Accreditation Service (KENAS).

2.4 Controlled Distribution of Quality Assurance Documents

Quality assurance manager is responsible for the maintenance of the official master copies of this Quality Manual and other Quality Assurance Documents. This Quality Manual describes how HQPHL implements the required clauses of ISO/IEC 17025:2017 standard. Other quality assurance documents contain information on laboratory organization structure, roles and responsibilities, in addition to detailing procedures on how laboratory

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activities should be carried out. The distribution of these Quality Assurance materials for implementation is accomplished through the use of hard copies. They are reviewed biennially through the coordination of the quality assurance manager.

3:0 QUALITY POLICY STATEMENTS

3.1 Management Policy Statement

KEPHIS is a regulatory body mandated to undertake quality assurance services of Agricultural Inputs, Plant Variety Protection, and Plant Health.

The KEPHIS Board of Directors, Management and Staff at the Headquarters Plant Health Laboratory are committed to full implementation of ISO/IEC 17025:2017 standard requirements and KENAS accreditation requirements. In this regard;

- The KEPHIS management is committed to availing all necessary resources required to support the laboratory;
- HQPHL management is committed; to maintaining good professional practice, to meeting the requirements of ISO/IEC 17025:2017 international standard and to producing quality test results;
- All laboratory personnel commit to understanding the management system for all operations and to implementing the policies and procedures at all times;
- HQPHL manager and the quality manager commit to be responsible for establishing, implementing and maintaining the laboratory quality assurance system.

The above commitments are geared towards compliance with ISO/IEC 17025:2017 standard and to continually improve the effectiveness of the management system while meeting and even exceeding customer needs and expectations.

HQPHL management system objectives are continually reviewed for their adequacy, relevance and general suitability for provision of reliable test results.

Signed

Date

PROF. THEOPHILUS M. MUTUI; PHD

KEPHIS MANAGING DIRECTOR

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3.2 Laboratory Commitment Policy on Impartiality

The HQPHL management and the Laboratory Staff are fully committed to ensuring that all activities in the laboratory are carried out impartially and objectively. Therefore, the laboratory is committed in particular to;

- Continuously identifying risks to its impartiality, arising from its activities, its external relationships or internal relationships of its staff;
- Analysing, evaluating, treating, monitoring and documenting the identified risks and demonstrating how to eliminate such risks to impartiality.
- Providing staff with the knowledge required to operate in accordance with impartiality and requiring its staffs to sign a commitment to promptly reveal any situation that may constitute a conflict of interest.
- Do not allow commercial, financial or other pressure to compromise impartiality of HQPHL activities.

HQPHL is committed to providing quality testing and diagnostic services that meet the needs of both its customers and the requirements of ISO/IEC 17025:2017 and to continually improve the effectiveness of the management system. It is also committed to ensuring that test results are reported within stated limits of accuracy, precision, and consistency described in the methods used for testing and diagnosis. HQPHL commits to the full implementation of this Quality Assurance Manual and policies therein, and to maintaining its accreditation and compliance to ISO/IEC 17025:2017.

Signed

Date

MR. IVAN OBARE

HQPHL- LABORATORY MANAGER

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4.0 GENERAL REQUIREMENTS

4.1 Impartiality

4.1.1 HQPHL has established and enforced unbiased procedures, conducts regular internal audits, provide staff training on impartiality and has structured its management system in a way that prevent any undue influence or conflict of interest. This ensures its activities are undertaken impartially and safeguarded from impartiality.

4.1.2 HQPHL management is committed to impartiality by setting and enforcing policies that prioritize unbiased decision-making, regularly reviewing operations for conflict of interest, and ensuring all personnel understand and adhere to impartiality standards.

4.1.3 HQPHL is responsible for the impartiality of its activities by implementing strict governance policies that prohibit commercial, financial, or other pressure from influencing testing outcomes, while maintaining transparency and accountability through regular internal and external reviews.

4.1.4 HQPHL identifies risks to its impartiality on an ongoing basis by conducting continuous risk assessments, monitoring its activities and relationships, reviewing personnel associations, and implementing a system to flag potential conflicts of interest, while recognizing that not all relationships inherently pose a risk to impartiality.

4.1.5 HQPHL demonstrates how it eliminates or minimizes the identified risks to impartiality by documenting the implementation of corrective actions, such as adjusting workflows, enforcing conflict-of-interest policies, and enhancing oversight mechanisms to ensure unbiased operations.

4.2 Confidentiality

4.2.1 HQPHL is responsible for managing all information obtained or created during its activities through the implementation of legally enforceable agreements that protect confidentiality, informing the customer in advance of any information intended for public release, and treating all other data as proprietary unless otherwise agreed upon or made publicly available by the customer. The implemented legally

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enforceable agreements include the Official Secrets Act CAP 187 and the Confidentiality and Non-Disclosure Agreement Form.

- 4.2.2** When required by law or authorized by contractual arrangements to release confidential information, HQPHL ensures that the customer or individual concerned is notified by establishing a clear communication protocol that promptly informs them of the disclosure, unless prohibited by law.
- 4.2.3** HQPHL ensures that information obtained from sources other than the customer remains confidential by implementing strict data protection policies that restrict access to the source's identity, only sharing such information with the customer if explicitly agreed upon by the source.
- 4.2.4** HQPHL ensures that all personnel, including committee members, contractors, and external individuals acting on its behalf, maintain confidentiality of all information obtained or created during performance of laboratory activities by enforcing comprehensive confidentiality agreements and providing regular training on data protection policies, with clear consequences for breaches.

5.0 STRUCTURAL REQUIREMENTS

- 5.1** HQPHL is a plant health governmental laboratory under the directorate of laboratory services of the Kenya Plant Health Inspectorate Service (KEPHIS), a Government of Kenya statutory organization established through Legal Notice No. 305 of October 1996, and later operationalized through the Kenya Plant Health Inspectorate Service Act No. 54 of 2012. By virtue of being a governmental laboratory, the laboratory is deemed to be a legal entity on the basis of its governmental status.
- 5.2** HQPHL has identified management with overall responsibility by clearly outlining an organizational chart that specifies roles and responsibilities, designating a laboratory manager, and ensuring that management positions are formally documented in the laboratory's quality management system.
- 5.3** HQPHL has defined and documented the range of laboratory activities for which it conforms with ISO/IEC 17025:2017 by creating a comprehensive scope of accreditation that outlines specific tests, methods, and services provided, along with corresponding compliance with applicable standards and regulations.

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5.4 HQPHL ensure that its activities meet the requirements of ISO/IEC 17025:2017, as well as those of its customers, regulatory authorities, and recognizing organizations, by implementing a robust quality management system that includes standardized procedures, regular internal audits, comprehensive training for personnel, and documentation practices that apply to all operational environments, including permanent facilities, temporary sites, and customer locations.

5.5 HQPHL has;

- a. defined its organization and management structure, its place within KEPHIS, and the relationships between its management, technical operations, and support services by creating an organizational chart that illustrates hierarchical relationships, along with documented policies and procedures that outline roles, responsibilities, and communication pathways among different functions within the laboratory.
- b. specified the responsibilities, authorities, and interrelationships of all personnel involved in managing, performing, or verifying work affecting test results by developing a detailed organizational chart and job descriptions that clearly outline each role's functions and responsibilities, along with established communication protocols and reporting structures to ensure effective collaboration and accountability.
- c. documented its procedures by creating comprehensive standard operating procedures (SOPs) that detail each step of laboratory activities, including methodologies, equipment usage, safety protocols, and quality control measures, ensuring that these documents are regularly reviewed, updated, and accessible to all personnel to promote consistency and validity in results.

5.6 HQPHL ensures that it has personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties by establishing a documented procedure for the review of requests, tenders, and contracts, ensuring that it has the capability and resources to fulfil the requirements, and maintaining effective communication with customers to clarify any ambiguities before the work begins.

5.7 HQPHL management has ensured that;

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- a. communication takes place regarding the effectiveness of the laboratory's management system and the importance of meeting customers' and other requirements by conducting regular stakeholder meetings and trainings, distributing internal newsletters/brochures, and utilizing feedback mechanisms that keep all personnel informed and engaged in quality management processes.
- b. the integrity of the laboratory's management system is maintained during the planning and implementation of changes by conducting a thorough impact assessment, documenting the change process, involving relevant stakeholders, providing training on new procedures, and implementing a monitoring system to evaluate the effectiveness of the changes and ensure compliance with established standards.

6.0 RESOURCE REQUIREMENTS

6.1 General

HQPHL ensures the availability of necessary personnel, facilities, equipment, systems, and support services by conducting regular needs assessments, maintaining an effective recruitment and staff training program, investing in appropriate infrastructure and technology, and establishing clear operational procedures that outline resource allocation and utilization for laboratory activities.

6.2 Personnel

6.2.1 HQPHL ensures that all personnel, whether internal or external, act impartially, are competent, and adhere to the laboratory's management system by implementing rigorous hiring practices, providing comprehensive training on ethical standards and management system requirements, conducting regular performance evaluations, and establishing clear policies that promote accountability and impartiality in all activities.

6.2.2 HQPHL documents the competence requirements for each function influencing laboratory activity results by creating a detailed competency matrix/framework that outlines specific criteria for education, qualifications, training, technical knowledge, skills, and experience, and by regularly reviewing and updating these requirements in conjunction with job descriptions and performance evaluations.

6.2.3 HQPHL ensures that its personnel have the competence to perform their responsibilities and evaluate deviations by providing comprehensive training programs, implementing a structured on boarding process, conducting regular competency assessments, and fostering a culture of continuous professional development that encourages personnel to stay informed about relevant methods and standards.

6.2.4 HQPHL management communicates personnel's duties, responsibilities, and authorities by providing clear job descriptions, conducting staff orientation sessions, holding regular staff meetings to discuss roles and expectations, and using visual aids such as organizational charts and flowcharts to reinforce understanding within the laboratory's management system.

6.2.5 HQPHL establishes and retains records for procedures relating to determining competence requirements, selecting personnel, training, supervising, authorizing, and monitoring competence by implementing a comprehensive quality management system that includes documented protocols, standardized forms, and regular audits to ensure compliance and accessibility of all relevant documentation.

6.2.6 HQPHL authorizes personnel to perform specific activities, such as method development, modification, verification and validation, result analysis, and result reporting, by establishing clear criteria for competency and qualifications, documenting the authorization process, and maintaining records of each individual's specific permissions and training related to those activities.

6.3 Facilities and environmental conditions

6.3.1 HQPHL can ensure that facilities and environmental conditions are suitable for activities and do not adversely affect result validity by conducting regular assessments of the laboratory environment, implementing strict control measures for temperature, humidity, and cleanliness, and adhering to established guidelines and standards for laboratory design and maintenance.

6.3.2 HQPHL ensures that the requirements for facilities and environmental conditions necessary for laboratory activities are documented by developing a comprehensive facilities management plan that outlines specific requirements, procedures for maintaining conditions, and protocols for regular monitoring and review, all of which are stored in

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a centralized document management system for easy access and updates.

6.3.3 HQPHL monitors, controls, and records environmental conditions by implementing a robust environmental monitoring system that includes calibrated sensors and equipment to continuously measure parameters such as temperature, humidity, and air quality, along with procedures for regular checks, data logging, and analysis to ensure compliance with relevant specifications and prompt corrective actions when deviations occur.

6.3.4 HQPHL implements, monitors, and periodically review measures to control facilities by establishing access control protocols to limit entry to sensitive areas, developing standard operating procedures to prevent contamination and interference, and clearly defining physical separation between incompatible activities through spatial design and signage, while conducting regular audits and assessments to evaluate the effectiveness of these measures and making adjustments as necessary.

6.3.5 HQPHL ensures that when performing activities at sites or facilities outside its permanent control, it meets the requirements related to facilities and environmental conditions of ISO/IEC 17025:2017 by conducting thorough pre-assessment of the external site to verify compliance, establishing clear agreements with site owners regarding necessary conditions, implementing a monitoring plan to regularly evaluate the site conditions during the activities, and ensuring personnel are trained to adhere to standard protocols to maintain quality and integrity.

6.4 Equipment

6.4.1 HQPHL ensures that it has access to necessary equipment for the correct performance of its activities by conducting a comprehensive needs assessment to identify required tools and materials, establishing relationships with reliable suppliers, maintaining an inventory management system to track equipment availability and condition, and implementing a scheduled maintenance and calibration program to ensure that all instruments and materials are functioning accurately and are readily accessible when needed.

6.4.2 HQPHL ensures that when using equipment outside its permanent control, it meets the requirements of ISO/IEC 17025:2017 by

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conducting thorough evaluations of the external equipment to verify its calibration status and suitability for the intended use, establishing agreements with the equipment owners to ensure compliance with relevant standards, training personnel on proper usage and maintenance, and implementing a system for monitoring and documenting the performance and reliability of the equipment during its use.

- 6.4.3** HQPHL ensures proper handling, transport, storage, use, and planned maintenance of equipment by developing detailed standard operating procedures (SOPs) that outline specific protocols for each phase of equipment management, providing training to personnel on these procedures, conducting regular audits to ensure compliance, and maintaining comprehensive records of equipment maintenance, inspections, and any incidences of contamination or deterioration to facilitate ongoing improvement and accountability.
- 6.4.4** HQPHL verifies that equipment conforms to specified requirements before being placed or returned into service by conducting a series of checks, including calibration against recognized standards, performance verification tests, inspection for physical damage or wear, and documentation of compliance with manufacturer specifications, ensuring that all results are recorded and reviewed by qualified personnel before the equipment is deemed suitable for use.
- 6.4.5** HQPHL ensures that measurement equipment achieves the required accuracy and/or measurement uncertainty by calibrating it against traceable reference standards, performing regular verification tests, conducting uncertainty analyses, and documenting calibration and performance data to confirm that the equipment meets the necessary precision levels for valid results before and during its use.
- 6.4.6** HQPHL ensures that measuring equipment is calibrated by implementing a scheduled calibration program that adheres to traceable reference standards, focusing on equipment whose measurement accuracy or uncertainty affects the validity of reported results or is essential for establishing metrological traceability.
- 6.4.7** HQPHL establishes a calibration program by setting regular calibration intervals based on equipment usage, manufacturer recommendations, and required accuracy levels, maintaining detailed records of each calibration, and periodically reviewing the program's effectiveness to

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make adjustments as needed, ensuring ongoing confidence in calibration status and measurement reliability.

- 6.4.8** HQPHL ensures that all equipment requiring calibration or with a defined validity period is labelled, coded, or otherwise identified by using visible tags or digital tracking systems that clearly indicate the equipment's calibration status, date of last calibration, and the next due date, allowing users to easily verify its readiness and compliance before use.
- 6.4.9** HQPHL ensures that equipment subjected to overloading, mishandling, questionable results or defects is taken out of service by implementing strict protocols for immediate isolation or clear labelling of the equipment as "out of service." The equipment remains inaccessible for use until it has been inspected and verified to perform correctly. Additionally, the laboratory assesses the impact of the defect or deviation on previous results and initiate a nonconforming work procedure to address any potential issues, including corrective actions and documentation.
- 6.4.10** HQPHL ensures that necessary intermediate checks on equipment are performed by developing a documented procedure that outlines the frequency, methods, and criteria for these checks, training personnel to follow the procedure, and maintaining records of the checks to verify that they are conducted consistently and effectively to maintain confidence in the equipment's performance.
- 6.4.11** HQPHL ensures that reference values and correction factors from calibration and reference materials are updated and implemented by regularly reviewing calibration data, applying any updated reference values or correction factors in accordance with the latest standards, and documenting these updates in relevant procedures and records to ensure that they are consistently applied during laboratory activities to meet specified requirements.
- 6.4.12** HQPHL ensures that unintended adjustments of equipment are prevented from invalidating results by implementing physical safeguards such as lockable settings, tamper-evident seals, or password protection for electronic equipment, and by training personnel on proper handling procedures, while regularly inspecting equipment to verify that no unauthorized changes have been made.

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6.4.13 HQPHL ensures that records are retained for equipment influencing laboratory activities by implementing a centralized record management system that systematically captures and updates the following information;

- a) the identity of the equipment, including software and firmware versions;
- b) the manufacturer's name, type identification, and unique serial number or identifier;
- c) evidence verifying that the equipment meets specified requirements;
- d) the current location of the equipment;
- e) calibration dates, calibration results, adjustments made, acceptance criteria, and the next calibration due date or interval;
- f) documentation of reference materials used, results obtained, acceptance criteria, relevant dates, and the validity period;
- g) the maintenance plan and records of all maintenance performed to date, relevant to the equipment's performance;
- h) details of any damage, malfunction, modifications, or repairs done to the equipment.

6.5 Metrological traceability

6.5.1 HQPHL establishes and maintains metrological traceability of its measurement results by implementing a documented calibration management system that includes maintaining an unbroken chain of calibrations linked to national or international standards, ensuring that each calibration step is recorded with details on the measurement uncertainty, and regularly reviewing and updating calibration procedures and records to reflect changes in reference standards or equipment used.

6.5.2 HQPHL ensures that measurement results are traceable to the International System of Units (SI) by;

- a. obtaining calibration services from a competent laboratory that meets the necessary standards and requirements, ensuring that the calibration results are documented and linked to SI units.
- b. using certified reference materials (CRM) from competent producers who have stated metrological traceability to the SI, which provide certified values that can be used for calibration and validation of measurement results.

- c. ensuring direct realization of SI units by conducting comparisons with national or international standards, either directly or indirectly, to verify the accuracy and traceability of measurement results.

6.5.3 HQPHL ensures metrological traceability to an appropriate reference when direct traceability to SI units is not technically possible by implementing the following approaches:

- a) utilizing certified reference materials with certified values from a competent producer, ensuring that these materials are appropriate for the specific measurements being performed and are accompanied by documentation demonstrating their traceability to the appropriate references.
- b) employing results from reference measurement procedures, specified methods, or consensus standards that are clearly documented and accepted as providing reliable measurement results fit for their intended use. This includes ensuring that these methods are validated through suitable comparisons with established references or through inter-laboratory studies to confirm their accuracy and reliability.

6.6 Externally provided products and services

6.6.1 HQPHL ensures that only suitable externally provided products and services that affect laboratory activities are used by implementing the following measures:

- a) for products and services intended for incorporation into the laboratory's own activities, the laboratory establishes criteria for evaluation and selection based on their quality, reliability, and compliance with relevant standards, conducting assessments of the external providers to verify their capability and performance.
- b) for products and services provided directly to customers by HQPHL as received from external providers, HQPHL ensures that these products and services are sourced from reputable suppliers with a documented history of quality and reliability, along with maintaining records of their compliance with applicable specifications.
- c) for products and services used to support operations of the laboratory, HQPHL regularly reviews and monitors their performance, ensuring that they meet established quality standards and are fit for their intended use through a documented evaluation process.

6.6.2 HQPHL ensures that it has a procedure and retains records for managing externally provided products and services by establishing a

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comprehensive documented process that outlines the definition, review, and approval of requirements; criteria for evaluating, selecting, and monitoring of external providers; methods for verifying conformity to established requirements before use or delivery; and procedures for taking actions based on evaluations and performance monitoring, while systematically maintaining records of each step to ensure traceability and compliance.

6.6.3 HQPHL communicates its requirements to external providers by clearly documenting and conveying specifications for;

- a) the products and services to be provided;
- b) detailing acceptance criteria;
- c) outlining competence and any necessary qualifications of personnel;
- d) specifying the activities that HQPHL or its customer intends to perform at the external provider's premises,
- e) ensuring that this information is shared through formal agreements or contracts to promote understanding and compliance.

7.0 PROCESS REQUIREMENTS

7.1 Review of requests, tenders and contracts

7.1.1 HQPHL ensures that it has a procedure for the review of requests, tenders, and contracts by;

- a) establishing a documented process which verifies that requirements are adequately defined and understood;
- b) assessing its capability and resources to meet those requirements;
- c) applying the necessary criteria for using external providers while advising customers on specific activities performed externally and obtaining their approval;
- d) ensuring that appropriate methods or procedures are selected to fulfil the customer's requirements effectively.

7.1.2 HQPHL informs the customer when the requested method is considered inappropriate or out of date by proactively communicating through formal channels, such as email or a meeting, to explain the reasons for the concern, provide alternative method recommendations, and discuss the potential impact on results, ensuring that the customer understands the rationale and has the opportunity to make informed decisions.

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- 7.1.3** HQPHL ensures that when a customer requests a statement of conformity to a specification or standard, it clearly defines the specification or standard and the associated decision rule by documenting the criteria for conformity, providing a detailed explanation of the decision rule, and communicating this information to the customer in writing. Additionally, HQPHL engages in discussions to confirm the customer's understanding and agreement on the decision rule prior to the execution of the tests, ensuring mutual clarity and alignment on expectations.
- 7.1.4** HQPHL ensures that any differences between the request or tender and the contract are resolved before commencing laboratory activities by implementing a structured review process that involves a thorough comparison of the request and contract terms, facilitating discussions between HQPHL and the customer to clarify and negotiate any discrepancies, and documenting any agreed-upon changes or deviations in a revised contract. This process also includes an assessment to confirm that any requested deviations do not compromise the integrity of HQPHL or the validity of the results, ensuring that both parties are aligned and satisfied before proceeding.
- 7.1.5** HQPHL ensures that the customer is informed of any deviation from the contract by establishing a formal communication protocol that mandates timely notification to the customer regarding any changes or deviations. This protocol includes clear documentation of the nature of the deviation, its potential impact on the results or services, and any proposed solutions or adjustments.
- 7.1.6** HQPHL ensures that if a contract is amended after work has commenced, the contract review is repeated by implementing a structured change management process that includes a formal review of the amended contract to assess its implications on ongoing activities. This process also involves promptly communicating the amendments to all affected personnel through meetings, written notifications, or internal memos, ensuring that everyone understands the changes and their responsibilities related to the revised contract.
- 7.1.7** HQPHL cooperates with customers or their representatives in clarifying requests and monitoring performance by actively engaging in open communication to discuss and refine the customer's requirements, providing reasonable access to relevant laboratory areas for them to witness specific activities, and ensuring transparency throughout the

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process. HQPHL also facilitates cooperation by efficiently preparing, packaging, and dispatching items needed by the customer for verification purposes, thereby fostering a collaborative relationship that enhances trust and satisfaction while ensuring alignment on objectives and performance metrics.

7.1.8 HQPHL ensures that records of reviews, including any significant changes, are retained by implementing a robust document management system that systematically archives all review records, discussions, and relevant communications with customers in a secure and organized manner. This system includes clear procedures for categorizing and storing test items, specifying retention periods in compliance with regulatory and organizational requirements, and ensuring that all personnel are trained on the importance of documentation and record-keeping practices. Regular audits of the document management system also help maintain the integrity and accessibility of these records over time.

7.2 Selection, verification and validation of methods

7.2.1 Selection and verification of methods

7.2.1.1 HQPHL ensures the use of appropriate methods and procedures for all laboratory activities, including evaluation of measurement uncertainty and statistical techniques for data analysis, by systematically selecting validated methods that comply with recognized standards and scientific principles. HQPHL documents these methods and regularly review them for continued suitability. HQPHL also provide training to personnel on applying these methods correctly and employ statistical techniques to analyse data and quantify measurement uncertainty, ensuring the accuracy, reliability, and validity of the results.

7.2.1.2 HQPHL ensures that all methods, procedures, and supporting documentation are kept up to date and readily available to personnel by implementing a centralized document control system. HQPHL regularly reviews and update all relevant documents to reflect the latest standards, instructions, and reference data. HQPHL ensures that these documents are accessible to personnel through digital platforms and/or physical copies in designated areas, while also providing clear communication and training on updates to ensure compliance and proper use of the latest procedures in laboratory activities.

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- 7.2.1.3** HQPHL ensures that it uses the latest valid version of a method by establishing a systematic process for regularly reviewing and updating methods in line with the latest standards and guidelines. This process includes subscribing to relevant technical updates from standards bodies and maintaining close communication with method developers or regulatory authorities. When it is not appropriate or possible to use the latest version, HQPHL documents the reasons for using an alternative method and, if necessary, supplementing the method with additional detailed instructions to ensure consistent and accurate application across all laboratory personnel.
- 7.2.1.4** HQPHL ensures that when the customer does not specify the method, it selects an appropriate one by following a formal method selection procedure that prioritizes methods from recognized sources such as international, regional, or national standards, reputable technical organizations, or relevant scientific literature. HQPHL also considers manufacturer-recommended methods or validated laboratory-developed and modified methods. Once the method is selected, HQPHL promptly informs the customer of the chosen method, explaining its suitability and ensuring alignment with the customer's expectations and requirements.
- 7.2.1.5** HQPHL verifies that it can properly perform methods before introducing them by conducting a thorough method validation or verification process. This involves testing the method under the laboratory's specific conditions to confirm that it meets the required performance criteria, such as accuracy, precision, and reproducibility. The results of the verification are documented and retained as records. If the method is revised by the issuing body, HQPHL repeats the verification to the extent necessary to ensure continued compliance with the updated method, and updates the records accordingly.
- 7.2.1.6** HQPHL ensures that method development is a planned activity by assigning the task to competent personnel with the necessary expertise, equipment, and resources. HQPHL outlines a detailed development plan that includes clear objectives, timelines, and milestones. Periodic reviews are conducted to assess progress and confirm that the method still meets the customer's requirements. Any modifications to the development plan are formally documented, reviewed, and authorized by the appropriate management to ensure

that changes align with both technical needs and customer expectations.

7.2.1.7 HQPHL ensures that deviations from methods occur only when properly controlled by establishing a formal procedure that requires all deviations to be documented, technically justified, and reviewed by competent personnel. HQPHL ensures that a deviation must be authorized by laboratory management or a designated authority, and the customer must be informed and provide explicit acceptance of the deviation before any laboratory activities proceed. This ensures transparency and safeguards the integrity of the results while meeting both technical and customer requirements.

7.2.2 Validation of methods

7.2.2.1 HQPHL validates non-standard methods, laboratory-developed methods, and standard methods used outside their intended scope or modified by conducting a comprehensive validation process. It evaluates key performance characteristics such as accuracy, precision, repeatability, reproducibility, sensitivity, specificity, and measurement uncertainty. The extent of validation is determined by the method's intended application or field of application. The validation results are compared against predefined criteria to ensure they meet the necessary technical requirements, and detailed records of the validation process, results, and conclusions are retained to demonstrate that the method is fit for its intended purpose.

The techniques used for method validation is one of, or a combination of, the following:

- a) calibration or evaluation of bias and precision using reference standards or reference materials;
- b) systematic assessment of the factors influencing the result;
- c) testing method robustness through variation of controlled parameters, such as incubator temperature, volume dispensed;
- d) comparison of results achieved with other validated methods;
- e) interlaboratory comparisons;
- f) evaluation of measurement uncertainty of the results based on an understanding of the theoretical principles of the method and practical experience of the performance of the sampling or test method.

7.2.2.2 HQPHL ensures that changes made to a validated method are properly managed by implementing a procedure that requires an

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evaluation of the potential impact of the changes on the method's performance. It conducts a risk assessment to determine if the changes affect the original validation parameters such as accuracy, precision, or measurement uncertainty. If the changes are found to influence the method's validity, a new validation process is initiated to confirm that the modified method still meets the required performance criteria. All findings, assessments, and re-validations are documented to maintain traceability and compliance.

7.2.2.3 HQPHL ensures that the performance characteristics of validated methods align with customer needs and specified requirements by actively engaging with customers during the method selection and validation process. It conducts consultations to understand the specific requirements and intended applications of the methods, as well as reviewing relevant specifications or standards. HQPHL regularly assesses the performance characteristics, such as accuracy, precision, and sensitivity, against the established criteria that meet customer expectations. Feedback from customers regarding the applicability and effectiveness of the methods in meeting their needs is sought and incorporated into the laboratory's continuous improvement process, ensuring that all methods remain relevant and effective.

7.2.2.4 HQPHL retains records of validation by systematically documenting the validation procedure, specifications of requirements, performance characteristics determination, obtained results, and a statement of validity in a secure and organized manner, ensuring easy access for review and compliance with applicable retention policies.

7.3 Sampling

7.3.1 HQPHL ensures it has a sampling plan and method by developing a documented procedure that outlines the factors to be controlled during the sampling process, ensuring the availability of this plan at the sampling site, and basing the sampling plans on appropriate statistical methods whenever feasible to maintain the validity of subsequent testing or calibration results.

7.3.2 HQPHL ensures that the sampling method describes the selection of samples or sites, the sampling plan, and the preparation and treatment of samples by documenting detailed procedures that outline each of these components, ensuring that all personnel involved in the sampling process are trained on these procedures, and regularly

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reviewing and updating the documentation to reflect any changes in methods or best practices.

7.3.3 HQPHL retains records of sampling data by implementing a robust documentation system that includes templates for recording relevant information, ensuring that all personnel are trained to accurately complete these records, regularly auditing the records for completeness and compliance, and securely storing the records in a manner that allows for easy retrieval and review when needed. These records include;

- a) reference to the sampling method used;
- b) date and time of sampling;
- c) data to identify and describe the sample (e.g. number, amount, name);
- d) identification of the personnel performing sampling;
- e) identification of the equipment used;
- f) environmental or transport conditions;
- g) diagrams or other equivalent means to identify the sampling location, when appropriate;
- h) deviations, additions to or exclusions from the sampling method and sampling plan.

7.4 Handling of test items

7.4.1 HQPHL establishes a comprehensive procedure for the transportation, receipt, handling, protection, storage, retention, and disposal or return of test items by ensuring that protocols are documented, personnel are trained on these protocols, and specific measures are implemented to prevent deterioration, contamination, loss, or damage during all stages of handling. This includes following handling instructions provided with the item, using appropriate protective measures and storage conditions, and regularly reviewing and updating the procedures to ensure they align with best practices and customer requirements.

7.4.2 HQPHL implements a robust system for the unambiguous identification of test items by assigning unique identifiers to each item upon receipt, which are clearly labelled and recorded in the laboratory's management system. This system includes procedures for tracking items throughout their lifecycle, ensuring that identifiers are maintained and visible while the items are under the laboratory's

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responsibility. It accommodates sub-divisions of items or groups and include clear protocols for the transfer of items, thereby preventing any physical confusion or discrepancies in records or documentation. Regular audits and reviews of the identification system further enhances the effectiveness and reliability of this system.

7.4.3 HQPHL ensures that deviations from specified conditions are recorded upon receipt of test items by establishing a standardized procedure for inspecting and documenting the condition of each item. This process includes a checklist for assessing compliance with specified conditions and a section for noting any deviations. When doubts arise regarding the suitability of an item or its conformity to the provided description, HQPHL promptly consult the customer for further instructions, documenting the consultation's details and outcomes. If the customer insists on proceeding with testing despite the deviation, HQPHL includes a clear disclaimer in the report, specifying which results may be impacted by the noted deviations, thereby maintaining transparency and protecting both the laboratory and customer interests.

7.4.4 HQPHL ensures that items requiring specific environmental conditions for storage are maintained, monitored, and recorded by implementing calibrated monitoring equipment, maintaining automated climate control systems, and keeping detailed logs of environmental parameters to ensure compliance with the specified requirements.

7.5 Technical records

7.5.1 HQPHL ensures that technical records for each laboratory activity are comprehensive and well-organized by implementing a systematic documentation process that includes: consistently recording results, reports, and detailed information related to factors affecting measurement results and associated uncertainties; including identification of the date and personnel responsible for each activity; ensuring original observations, data, and calculations are documented in real-time and linked to specific tasks; and regularly reviewing these records for completeness and accuracy to facilitate repeatability under similar conditions.

7.5.2 HQPHL ensures that amendments to technical records are traceable by implementing a robust document control system that includes version control mechanisms, which require that both original and amended

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data are retained; clearly marking changes with timestamps and annotations indicating the altered aspects; documenting the identity of personnel responsible for the changes; and maintaining a comprehensive audit trail that allows for easy retrieval and comparison between current and previous versions of the records.

7.6 Evaluation of measurement uncertainty

7.6.1 HQPHL identifies contributions to measurement uncertainty by systematically reviewing all potential sources of variability in the measurement process, including those related to sampling, equipment calibration, environmental conditions, and operator influence, and by employing established methodologies such as uncertainty budgets and/or the Guide to the Expression of Uncertainty in Measurement (GUM), which outlines the steps for quantifying and combining these contributions to calculate the overall measurement uncertainty.

7.6.2 HQPHL evaluates the measurement uncertainty for all calibrations by systematically identifying and quantifying all potential sources of uncertainty, combining these contributions using statistical methods, and documenting the process to ensure transparency and traceability.

7.6.3 HQPHL evaluates measurement uncertainty by identifying all relevant sources of uncertainty associated with the testing process, quantifying their contributions, and applying statistical methods to combine these contributions; if the test method does not allow for a rigorous evaluation, the laboratory estimates the uncertainty based on theoretical principles or practical experience with the method's performance.

7.7 Ensuring the validity of results

7.7.1 HQPHL establishes a procedure for monitoring the validity of results by systematically recording data to detect trends, applying statistical techniques for analysis, and ensuring planned reviews that incorporate;

- a) use of reference materials or quality control materials;
- b) use of alternative instrumentation that has been calibrated to provide traceable results;
- c) functional check(s) of measuring and testing equipment;
- d) use of check or working standards with control charts, where applicable;

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- e) intermediate checks on measuring equipment;
- f) replicate tests or calibrations using the same or different methods;
- g) retest of retained items;
- h) correlation of results for different characteristics of an item;
- i) review of reported results;
- j) intralaboratory comparisons;
- k) testing of blind sample(s).

7.7.2 HQPHL monitors its performance by comparing its results with those from other laboratories through planned and reviewed activities such as participating in proficiency testing and engaging in interlaboratory comparisons beyond proficiency testing, ensuring that both methods are utilized to assess and improve measurement accuracy and consistency.

7.7.3 HQPHL ensures that data from monitoring activities are analysed and utilized to control and improve its operations by establishing a systematic process for data review, setting predefined criteria for performance evaluation, and implementing corrective actions promptly if the analysis reveals results that fall outside these criteria, thereby preventing the reporting of incorrect results.

7.8 Reporting of results

7.8.1 General

7.8.1.1 HQPHL ensures that results are reviewed and authorized prior to release by implementing a defined procedure that includes a multi-tiered review process, where designated personnel verify the accuracy and completeness of the results against established criteria, and require documented authorization from a qualified individual before the final results are issued to customers.

7.8.1.2 HQPHL ensures that results are provided accurately, clearly, unambiguously, and objectively by adhering to standardized reporting formats that include all agreed-upon information with the customer and essential for interpreting the results, and all information required by the method used. All issued reports are systematically reviewed for compliance before release and retained as technical records for future reference.

7.8.1.3 HQPHL ensures that when results are reported in a simplified way, it establishes clear communication with the customer to confirm the

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specific information to be included or excluded, while maintaining a system to keep all relevant data readily accessible for reference; this ensures that any omitted information specified in sections 7.8.2 to 7.8.7 is still available for review if needed.

7.8.2 Common requirements for reports (test, calibration or sampling)

7.8.2.1 HQPHL ensures that each report includes relevant information by implementing a standardized reporting template that mandates the inclusion of essential details while regularly training staff on the importance of thoroughness and accuracy in report generation to minimize misunderstandings or misuse. The laboratory's reports contain essential details such as;

- a) a title (e.g. "Test Report", "Calibration Certificate" or "Report of Sampling");
- b) the name and address of the laboratory;
- c) the location of performance of the laboratory activities, including when performed at a customer facility or at sites away from the laboratory's permanent facilities, or in associated temporary or mobile facilities;
- d) unique identification that all its components are recognized as a portion of a complete report and a clear identification of the end;
- e) the name and contact information of the customer;
- f) identification of the method used;
- g) a description, unambiguous identification, and, when necessary, the condition of the item;
- h) the date of receipt of the test or calibration item(s), and the date of sampling, where this is critical to the validity and application of the results;
- i) the date(s) of performance of the laboratory activity;
- j) the date of issue of the report;
- k) reference to the sampling plan and sampling method used by HQPHL or other bodies where these are relevant to the validity or application of the results;
- l) a statement to the effect that the results relate only to the items tested, calibrated or sampled;
- m) the results with, where appropriate, the units of measurement;
- n) additions to, deviations, or exclusions from the method;
- o) identification of the person(s) authorizing the report;
- p) clear identification when results are from external providers.

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7.8.2.2 HQPHL ensures responsibility for all information in the report, except when provided by the customer, by implementing a clear policy that requires all customer-supplied data to be distinctly identified in the report, accompanied by a disclaimer highlighting that such information may affect the validity of results; furthermore, when the laboratory has not conducted the sampling, the report explicitly state that the results pertain solely to the sample as received, ensuring transparency and clarity for all report recipients.

7.8.3 Specific requirements for test reports

7.8.3.1 HQPHL ensures that test reports include necessary information for interpreting test results by establishing comprehensive reporting protocols that mandate the inclusion of;

- a) information on specific test conditions, such as environmental conditions;
- b) where relevant, a statement of conformity with requirements or specifications;
- c) where applicable, the measurement uncertainty presented in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent) when:
 - it is relevant to the validity or application of the test results;
 - a customer's instruction so requires, or
 - the measurement uncertainty affects conformity to a specification limit;
- d) where appropriate, opinions and interpretations;
- e) additional information that may be required by specific methods, authorities, customers or groups of customers.

7.8.3.2 HQPHL ensures that test reports meet the requirements listed in 7.8.5 for sampling activities it is responsible for by implementing a structured reporting process that includes comprehensive details on the sampling method, conditions, and relevant information about the sample, as well as maintaining clear records of the sampling process. This includes documenting the sampling plan, any deviations or changes, the date and personnel involved, and the environmental conditions during sampling, thus providing a complete context for interpreting the test results.

7.8.4 Specific requirements for calibration certificates

7.8.4.1 HQPHL do not perform calibration services, hence does not issue calibration certificates.

7.8.5 Reporting sampling – specific requirements

HQPHL ensures that, where it is responsible for sampling activity, in addition to clause 7.8.2 requirements, laboratory reports include necessary details for interpreting results by establishing a standardized reporting format that mandates the inclusion of specific information, such as;

- a) the date of sampling;
- b) unique identification of the item or material sampled (including the name of the manufacturer, the model or type of designation and serial numbers, as appropriate);
- c) the location of sampling, including any diagrams, sketches or photographs;
- d) a reference to the sampling plan and sampling method;
- e) details of any environmental conditions during sampling that affect the interpretation of the results;
- f) information required to evaluate measurement uncertainty for subsequent testing.

7.8.6 Reporting statements of conformity

7.8.6.1 HQPHL ensures that when providing a statement of conformity to a specification or standard, the decision rule employed is documented by clearly defining the rule, considering factors like the level of risk (e.g., false accept/reject rates and statistical assumptions) associated with the employed rule, and ensuring that the rule is consistently applied. The decision rule, along with its rationale, is reviewed and approved internally and communicated to the customer to ensure transparency and proper application during the conformity assessment process.

7.8.6.2 HQPHL ensures that a report on the statement of conformity clearly identifies;

- a) the specific results to which it applies;
- b) the relevant specifications or standards met or not met;
- c) the decision rule applied (unless inherent in the specification or standard).

7.8.7 Reporting opinions and interpretations

7.8.7.1 HQPHL ensures that opinions and interpretations are expressed only by authorized personnel by documenting the qualifications of these individuals, defining the basis for opinions and interpretations, and ensuring that the respective statements are released only by those authorized personnel, with the basis for such statements clearly documented.

7.8.7.2 HQPHL ensures that opinions and interpretations expressed in reports are based on the results obtained from the tested item by clearly distinguishing them from factual data, explicitly identifying them as opinions or interpretations, and linking them directly to the results from which they are derived.

7.8.7.3 HQPHL ensures that when opinions and interpretations are directly communicated through dialogue with the customer, a record of the dialogue is retained by documenting the details of the communication, including the date, time, content of the discussion, and the personnel involved. This record is then stored in the relevant technical or customer communication records for future reference.

7.8.8 Amendments to reports

7.8.8.1 HQPHL ensures that when an issued report needs to be changed, amended, or re-issued, any changes are clearly identified by marking or highlighting the modifications in the revised report, and where appropriate, including the reason for the change. The updated report is linked to the original, ensuring both versions are traceable, and the date of the amendment along with the personnel responsible for the change are also documented.

7.8.8.2 HQPHL ensures that amendments to a report after issue are made only in the form of an additional document or data transfer, which includes a clear statement such as "Amendment to Report, serial number... [or as otherwise identified]" to link the amendment to the original report. The laboratory ensures that this amendment comply with all report requirements, the amended report is properly tracked, justified, and the reasons for the changes are clearly documented.

7.8.8.3 HQPHL ensures that when it is necessary to issue a complete new report, the new report is uniquely identified with a different serial number or identifier from the original. It also includes a clear reference

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to the original report that it replaces, indicating that it supersedes the previous version. This helps to maintain traceability and transparency, ensuring that customers and relevant stakeholders are aware of the replacement and the reasons behind it.

7.9 Complaints

7.9.1 HQPHL establishes a documented process to receive, evaluate, and make decisions on complaints by creating a formal procedure that includes recording complaints, appointing responsible personnel for evaluation and investigation, deciding on corrective actions, communicating outcomes to the complainant, and maintaining records for future reference and continuous improvement.

7.9.2 HQPHL ensures that a description of the handling process for complaints is readily available to any interested party upon request by maintaining a clear and accessible document outlining the procedure, ensuring that personnel are trained to communicate this process, and confirming upon receipt of a complaint whether it pertains to laboratory activities under its responsibility, while retaining full accountability for all decisions made throughout the complaint handling process.

7.9.3 HQPHL ensures that the process for handling complaints includes a comprehensive description of the steps for receiving, validating, investigating complaints, and deciding on necessary actions by documenting each stage of the process in a standard operating procedure (SOP); implementing a system for tracking and recording all complaints along with the actions taken to resolve them in a centralized database; and establishing mechanisms for reviewing the outcomes to ensure that appropriate corrective and preventive actions are consistently implemented based on the findings from each complaint.

7.9.4 HQPHL ensures responsibility for gathering and verifying all necessary information to validate a complaint by implementing a structured complaint management system that includes designated personnel trained in complaint handling procedures; utilizing standardized forms or checklists to collect relevant details about the complaint; conducting thorough interviews with the complainant to clarify the issues; reviewing relevant records, reports, and data related to the complaint; and cross-checking information against established protocols or quality

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standards to confirm the validity of the complaint before proceeding with any further actions.

7.9.5 HQPHL ensures acknowledgment of complaints and provision of progress reports and outcomes by establishing a communication protocol that includes prompt acknowledgment of receipt, regular updates on the investigation status, and clear notification of the final outcome to the complainant.

7.9.6 HQPHL ensures that the outcome communicated to the complainant is made by, or reviewed and approved by, individuals not involved in the original laboratory activities by implementing a conflict-of-interest policy that mandates independent review of complaint resolutions, thereby ensuring objectivity and impartiality in the decision-making process.

7.9.7 HQPHL ensures that it gives formal notice of the end of the complaint handling to the complainant by establishing a documented procedure that includes notifying the complainant in writing once the investigation is complete, summarizing the findings, actions taken, and any further steps if necessary, thus providing closure and maintaining transparency in the complaint resolution process.

7.10 Nonconforming work

7.10.1 HQPHL ensures the implementation of a procedure for managing nonconforming work by;

- a) clearly defining responsibilities and authorities for the management of nonconforming work;
- b) establishing risk assessment protocols to determine appropriate actions such as halting or repeating work and withholding of reports;
- c) conducting thorough evaluation of the significance of the nonconforming work, including an impact analysis on previous results;
- d) making informed decisions regarding the acceptability of the nonconforming work;
- e) notifying the customer and recalling work when necessary;
- f) designating specific individuals authorized to approve the resumption of activities once corrective actions have been implemented.

7.10.2 HQPHL ensures the retention of records related to nonconforming work and actions by implementing a systematic documentation process that captures detail of the nonconformity, including the risk

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assessment results, evaluations of the significance and impact analysis, decisions on acceptability, customer notifications, and records of authorization for the resumption of work, all of which are stored in a secure, organized manner that allows for easy retrieval and review as needed.

7.10.3 HQPHL ensures the implementation of corrective actions by establishing a formal corrective action procedure that includes identifying the root cause of the non-conformance, assessing the potential for recurrence, documenting the evaluation results, and developing a specific action plan to address the identified issues; this process also involve assigning responsibilities, setting deadlines for implementation, and conducting follow-up reviews to verify the effectiveness of the corrective actions taken.

7.11 Control of data and information management

7.11.1 HQPHL ensures access to the necessary data and information for its activities by implementing a centralized document management system that includes standard operating procedures (SOPs), reference materials, historical data, calibration records, and relevant regulatory guidelines; this system is regularly updated, with clearly defined user access levels, ensuring that all personnel can retrieve the information efficiently while maintaining data integrity and confidentiality.

7.11.2 HQPHL validates its Laboratory Information Management System (LIMS) by establishing a comprehensive validation protocol that includes user requirements, functional specifications, and testing procedures to ensure all components work as intended, including interfaces; this validation is performed through systematic testing, such as installation qualification (IQ), operational qualification (OQ), and performance qualification (PQ) before implementation. Any changes to the system, including software configuration or modifications to commercial off-the-shelf software, undergo a formal change control process, which includes authorization, thorough documentation of the change, and re-validation of the system to ensure ongoing compliance and functionality.

7.11.3 HQPHL ensures that its information management system(s) is;

- a) protected from unauthorized access by implementing robust user authentication measures, such as strong passwords and multi-factor authentication, while conducting regular audits of user access rights.

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- b) safeguarding it against tampering and loss through regular data backups, encryption of sensitive information, and secure storage solutions.
- c) operating it in an environment that complies with both provider and laboratory specifications, ensuring physical security and climate control for digital assets, while also providing suitable conditions for manual recording and transcription in non-computerized systems.
- d) maintaining the integrity of data and information by conducting regular software updates, implementing version control, and monitoring for any anomalies.
- e) including a protocol for recording any failures, detailing the nature of the incident, immediate corrective actions taken, and follow-up measures to prevent recurrence, ensuring that any issues are promptly addressed and documented.

7.11.4 HQPHL ensures compliance by establishing a formal agreement or contract with external provider that explicitly outlines the expectations and requirements for data management and system maintenance, including adherence to relevant standards and regulations. Regular audits and assessments of the provider's operations are conducted to verify their compliance with the laboratory's requirements. HQPHL also implements a monitoring system to track the performance and security of the off-site information management system, including regular reviews of access logs and security protocols. It maintains clear communication with the provider to ensure that any changes in operations, software updates, or potential risks are promptly communicated and addressed, thereby safeguarding the integrity and security of the information management system.

7.11.5 HQPHL ensures that instructions, manuals, and reference data relevant to its information management system(s) are readily available to personnel by implementing a centralized digital repository or document management system where all relevant documents are stored and easily accessible. This repository is organized intuitively, allowing personnel to quickly find the information they need. HQPHL also provides training sessions and regular updates to familiarize staff with the system and the location of the materials. Access to these documents are supplemented with printed copies in strategic locations within the laboratory, along with clear communication regarding any changes or updates to the materials. To enhance accessibility, HQPHL has also created a user-friendly interface or a search function that

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enables personnel to locate information efficiently. Regular reviews of the document availability and relevance is conducted to ensure that all materials are current and useful.

7.11.6 HQPHL ensures that calculations and data transfers are checked systematically by implementing standardized procedures that include multiple layers of verification. This involves establishing clear Standard Operating Procedures (SOPs) for all calculations and data transfers, utilizing double-entry systems where critical data is entered by different personnel to catch discrepancies, and employing software with built-in error-checking features. HQPHL also incorporates peer reviews of calculations and data transfers, maintain detailed audit trails for traceability, and conduct regular training sessions for staff on the importance of accuracy further enhancing the reliability of these processes. Regular audits of the calculation and data transfer workflows also help identify and address any potential issues, ensuring ongoing compliance with best practices and data integrity.

8.0 Management system requirements

8.1 Options

8.1.1 General

HQPHL laboratory establishes, documents, implements, and maintains a management system capable of meeting ISO/IEC 17025:2017 requirements by defining its scope of testing, documenting procedures and policies that ensure compliance with the standard's clauses (covering impartiality, resource management, technical competence, and quality processes), and ensuring personnel competence. The system includes methods for controlling documents, conducting internal audits, managing equipment calibration, and handling non-conforming work. Regular internal audits and management reviews help monitor performance, identify risks, and drive continual improvement, ensuring consistent achievement of quality results.

8.1.2 Option A

The management system of HQPHL laboratory addresses the following;

- a) Management system documentation;
- b) Control of management system documents;
- c) Control of records;
- d) Actions to address risks and opportunities;

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- e) Improvement;
- f) Corrective actions;
- g) Internal audits;
- h) Management reviews.

8.1.3 Option B

HQPHL laboratory management has chosen to implement *Option A* management system as stipulated in ISO/IEC 17025:2017 international standard. Therefore, *Option B* on the implementation of a management system in accordance with the requirements of ISO 9001:2015 is already taken care of. This clause does not apply to the laboratory, inferring that the laboratory does not implement and is not audited as per ISO 9001:2015 requirements.

8.2 Management system documentation (Option A)

8.2.1 Laboratory management establishes, documents, and maintains policies and objectives in line with ISO/IEC 17025:2017 by developing clear, measurable goals that focus on quality, impartiality, and technical competence. The policies are documented in a quality manual, aligned with the standard's requirements, and communicated to all personnel through training, meetings, and accessible documentation.

8.2.2 HQPHL laboratory ensures that its policies and objectives address competence, impartiality, and consistent operation by aligning them with ISO/IEC 17025:2017 requirements, clearly defining roles, implementing rigorous training programs, and establishing procedures for impartial decision-making and standardized processes across all operations.

8.2.3 HQPHL management provides evidence of commitment to the development and implementation of its management system, and to continually improving its effectiveness, by setting quality objectives, allocating necessary resources, conducting regular management reviews, supporting internal audits, addressing non-conformities, and implementing corrective actions. The management also foster a culture of continual improvement by encouraging staff involvement, offering training, and staying engaged in the evaluation and enhancement of the system's processes and performance.

8.2.4 HQPHL ensures that all documentation, processes, systems, and records related to fulfilling ISO/IEC 17025:2017 requirements are included in, referenced from, or linked to the management system by establishing a comprehensive document control system. This system defines procedures for the creation, approval, distribution, and updating of all relevant documents, ensuring that they are easily accessible and traceable within the management system. Cross-referencing key documents, integrating them into a centralized digital platform, and regularly auditing to verify that all records and processes are up-to-date and compliant further ensures alignment with the management system.

8.2.5 HQPHL ensures that all personnel involved in laboratory activities have access to the relevant parts of the management system documentation by implementing a role-based access system that grants personnel access to the specific documents and information pertinent to their responsibilities. This is achieved through a centralized document management system where employees easily retrieve and review relevant procedures, policies, and records. The management also provides proper training on how to navigate the system, ensure that updates are communicated promptly, and regularly verifying that personnel are using the most current documents applicable to their roles.

8.3 Control of management system documents (Option A)

8.3.1 HQPHL controls internal and external documents relating to the fulfilment of ISO/IEC 17025:2017 by implementing a document control procedure that governs the creation, approval, distribution, review, and updating of all documents. This assign a responsible person or team to manage document control, ensuring documents are reviewed and approved before use, and maintaining a master list of current versions. The system also ensure that obsolete documents are clearly marked or removed to prevent accidental use. External documents, such as standards and regulations, are regularly monitored for updates, and staff are promptly informed of any changes. Document control is regularly audited to ensure compliance with the procedure.

8.3.2 HQPHL ensure effective document control by

- a) establishing a documented procedure that mandates approval of documents by authorized personnel before issuance;

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- b) scheduling regular reviews and updates;
- c) tracking changes and revision statuses;
- d) maintaining accessible and controlled distribution of current versions at points of use;
- e) assigning unique identifiers to each document;
- f) marking obsolete documents to prevent their unintended use while retaining them appropriately for reference.

8.4 Control of records (Option A)

8.4.1 HQPHL establish and retain legible records to demonstrate fulfilment of ISO/IEC 17025:2017 requirements by implementing a systematic record-keeping procedure that includes clear guidelines on the creation, maintenance, and storage of records. This procedure specifies formats for records to ensure legibility, outline responsibilities for record management, and establish retention periods based on legal and regulatory requirements. Records are stored in a controlled environment, whether physically or digitally, to prevent loss or damage, and backed up regularly to ensure data integrity. Regular audits are also conducted to verify that records are complete, accurate, and accessible for review when needed.

8.4.2 HQPHL implement controls for the identification, storage, protection, backup, archiving, retrieval, retention, and disposal of its records by establishing a comprehensive records management policy that outlines procedures for each area. This includes assigning unique identifiers to each record type for easy tracking, utilizing secure storage solutions to protect sensitive information, and implementing access controls to ensure confidentiality. Regular backups are conducted for digital records, with archived files stored securely but accessible for retrieval as needed. HQPHL define retention periods based on legal and contractual obligations, ensuring records are disposed of securely when no longer needed. By training staff on these procedures and regularly reviewing compliance, the laboratory ensures that records are managed effectively while remaining readily available to authorized personnel.

8.5 Actions to address risks and opportunities (Option A)

8.5.1 HQPHL consider the risks and opportunities associated with its activities by conducting regular risk assessments to identify potential challenges and benefits, implementing preventive measures to

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mitigate risks, and developing strategies to capitalize on opportunities that align with its objectives and enhance overall performance. This helps the laboratory to;

- a) give assurance that the management system achieves its intended results;
- b) enhance opportunities to achieve the purpose and objectives of the laboratory;
- c) prevent, or reduce, undesired impacts and potential failures in the laboratory activities;
- d) achieve improvement.

8.5.2 HQPHL effectively plan actions to address risks and opportunities by first conducting a comprehensive risk assessment to identify and prioritize potential challenges and benefits, followed by developing a detailed action plan that outlines specific measures to mitigate risks and seize opportunities, along with assigned responsibilities and timelines. To integrate and implement these actions into its management system, HQPHL update relevant documentation, incorporate the measures into standard operating procedures, and provide training to ensure personnel understand and follow the new protocols. Finally, to evaluate the effectiveness of these actions, the laboratory establishes key performance indicators (KPIs) and conduct regular reviews, including internal audits and management assessments, to monitor progress and make adjustments as necessary, fostering a culture of continuous improvement.

8.5.3 HQPHL ensures that actions taken to address risks and opportunities are proportional to the potential impact on the validity of laboratory results by conducting a thorough risk assessment that evaluates both the likelihood of each risk occurring and the potential consequences on test results. This assessment prioritize risks based on their significance, allowing the laboratory to allocate resources and implement controls that are commensurate with the level of risk identified. Furthermore, the laboratory establishes a framework for regularly reviewing and updating risk assessments, ensuring that actions remain relevant and effective as conditions change. Engaging staff in the risk management process and utilizing feedback also help tailor actions to specific laboratory activities, ensuring that the focus remains on maintaining the integrity and reliability of results.

8.6 Improvement (Option A)

8.6.1 HQPHL identify and select opportunities for improvement by regularly analysing performance data, conducting internal audits, and soliciting feedback from staff and clients to pinpoint areas where processes can be enhanced. Once opportunities are identified, the laboratory evaluates them based on factors such as potential impact, feasibility, and alignment with overall objectives. After prioritizing these opportunities, the laboratory develops a structured action plan that outlines specific steps, assigns responsibilities, and sets timelines for implementation. HQPHL communicates these plans to all relevant personnel and provide necessary training to ensure successful execution. Following implementation, the laboratory monitors progress and evaluates the effectiveness of the actions taken, making adjustments as needed to drive continuous improvement.

8.6.2 HQPHL seek feedback from its customers by implementing structured methods such as surveys, questionnaires, and feedback forms that are distributed after service completion or during periodic check-ins. Additionally, the laboratory conducts interviews or focus groups with key customers to gain deeper insights into their experiences and perceptions. Once feedback is collected, both positive and negative responses are analysed systematically to identify trends and areas for improvement. This analysis informs adjustments to the management system, enhances laboratory activities, and improves customer service by addressing identified issues, reinforcing successful practices, and adapting services to better meet customer needs. Regularly communicating the outcomes of feedback initiatives to customers also demonstrate the laboratory's commitment to continuous improvement and customer satisfaction.

8.7 Corrective actions (Option A)

8.7.1 When a nonconformity occurs, HQPHL:

- a) reacts to the nonconformity and, as applicable:
 - i. take action to control and correct it;
 - ii. address the consequences;
- b) evaluates the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:
 - i. reviewing and analysing the nonconformity;
 - ii. determining the causes of the nonconformity;

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- iii. determining if similar nonconformities exist, or could potentially occur;
- c) implements any action needed;
- d) reviews the effectiveness of any corrective action taken;
- e) updates risks and opportunities determined during planning, if necessary;
- f) makes changes to the management system, if necessary.

8.7.2 HQPHL ensures that corrective actions are appropriate to the effects of nonconformities encountered by implementing a systematic approach that begins with a thorough investigation to identify the root cause and assess the severity of the nonconformity, including its impact on laboratory results and compliance with relevant standards. Based on this assessment, the laboratory develops a targeted corrective action plan that is proportionate to the severity and potential consequences of the nonconformity, ensuring that the actions effectively address the underlying issues to prevent recurrence. Responsibilities for implementation are clearly assigned, with specific timelines established to facilitate prompt resolution. Following the implementation, the laboratory monitors the effectiveness of the corrective actions through follow-up evaluations and performance metrics, documenting the entire process to provide a transparent record for future reference. This structured approach not only helps in effectively resolving current nonconformities but also fosters a culture of continuous improvement within the laboratory.

8.7.3 HQPHL retains records as evidence of the nature of nonconformities, their causes, and subsequent actions taken by systematically documenting each nonconformity incident, including detailed descriptions of the issue, root cause analysis, corrective action plans, and implementation timelines in a centralized nonconformity log or report. Additionally, to document the results of any corrective action, the laboratory maintains records that include follow-up evaluations, effectiveness assessments, and any relevant performance metrics or outcomes, ensuring these records are securely stored and easily retrievable for review and compliance purposes.

8.8 Internal audits (Option A)

8.8.1 HQPHL conducts internal audits at planned intervals to assess the conformity and effectiveness of its management system by

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implementing a systematic internal audit program. This process includes;

- a) developing an annual audit schedule that outlines the scope, objectives, and frequency of audits, ensuring comprehensive coverage of the laboratory's internal requirements and the ISO/IEC 17025:2017 standards.
- b) qualified and impartial auditors, trained in auditing techniques, are appointed to execute the audits, which involve evaluating the management system against defined criteria, reviewing relevant documentation, observing laboratory activities, and conducting interviews with personnel.
- c) findings from the audits are documented thoroughly, highlighting areas of conformity, nonconformity, and opportunities for improvement. The results are compiled into an audit report and communicated to management and relevant staff, including recommended corrective actions for any nonconformities identified.
- d) follow-up process has also been established to ensure that corrective actions are implemented effectively and within a specified timeframe.
- e) incorporating audit results into management review meetings allowing HQPHL to discuss trends, evaluate the effectiveness of the management system, and make informed decisions for continuous improvement.

8.8.2 HQPHL;

- a) effectively plans, establishes, implements, and maintains an audit program by developing a structured approach that includes determining the frequency of audits based on the importance of laboratory activities, potential risks, and changes affecting operations, while also considering the results of previous audits.
- b) clearly defines the methods to be used, designate responsibilities for auditors and auditees, and outline planning requirements, including necessary resources and timelines. Each audit's criteria and scope is established to focus on compliance with internal policies and relevant standards, ensuring that all critical areas are evaluated.
- c) ensures that results are compiled into comprehensive reports and promptly communicated to relevant management to facilitate timely action.

- d) implements appropriate corrections and corrective actions, in cases of identified nonconformities, without undue delay, ensuring that these measures address the root causes effectively.
- e) retains detailed records as evidence of the audit program's implementation and its results, including audit plans, reports, and records of corrective actions taken, all of which are organized, accessible, and securely stored to support ongoing compliance and future audits.

8.9 Management reviews (Option A)

8.9.1 HQPHL management reviews its management system at planned intervals by systematically evaluating performance data, audit results, customer feedback, and changes in internal and external factors, ensuring that the system remains suitable, adequate, and effective while also assessing the relevance of its policies and objectives in fulfilling the requirements of ISO/IEC 17025:2017.

8.9.2 HQPHL ensures that the inputs to its management review are effectively recorded and encompass all necessary information by implementing a structured and systematic approach. The laboratory establishes a standardized management review template that outlines the specific categories of information to be collected, including;

- a) changes in internal and external issues that are relevant to the laboratory;
- b) fulfilment of objectives;
- c) suitability of policies and procedures;
- d) status of actions from previous management reviews;
- e) outcome of recent internal audits;
- f) corrective actions;
- g) assessments by external bodies;
- h) changes in the volume and type of the work or in the range of laboratory activities;
- i) customer and personnel feedback;
- j) complaints;
- k) effectiveness of any implemented improvements;
- l) adequacy of resources;
- m) results of risk identification;
- n) outcomes of the assurance of the validity of results; and
- o) other relevant factors, such as monitoring activities and training.

8.9.3 HQPHL ensure that the outputs from the management review accurately record all decisions and actions related to;

- a) the effectiveness of the management system and its processes;
- b) improvement of the laboratory activities related to the fulfilment of the requirements of this document;
- c) provision of required resources;
- d) any need for change.

9.0 Amendment List

Amendment Number	Effective Date	Amender's Name	Nature of Amendment

10.0 Revision List

Revision Number	Effective Date	Reviewer's Name	Nature of Revision

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