



KENYA PLANT HEALTH INSPECTORATE SERVICE (KEPHIS)

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ANALYTICAL CHEMISTRY LABORATORY AND FOOD SAFETY DEPARTMENT

QUALITY MANUAL PART 1A: QUALITY POLICY (ISO/IEC 17025:2017)	
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1.0 Introduction

1.1 Background Information

The Analytical Chemistry Laboratory and Food Safety (ACL&FS) is a department of the Directorate of Laboratory Services at Kenya Plant Health Inspectorate Service (KEPHIS), a statutory organization situated in Karen, Nairobi. KEPHIS mandate includes the protection of plant resources from pest and diseases, assuring the quality and safety of agricultural inputs and produce to prevent adverse impact on the economy, the environment and on human health. KEPHIS was established through the Legal Notice No. 305 of October 1996 and later through the KEPHIS ACT No. 54 of 2012. The vision of the institution is ““Excellence in plant health and quality assurance in agriculture.” The Analytical Chemistry Laboratory and Food Safety (ACL&FS) is a multi-purpose facility charged with the responsibility of monitoring the quality of agricultural inputs, pesticide residues in agricultural produce, chemical and microbial contaminants of human health importance in the environment, food and animal tissue. The laboratory offers advisory and testing services to farmers, exporters and other stakeholders in the agriculture and environment sector.

This Analytical Chemistry Laboratory and Food Safety’s Quality Manual document outlines how the laboratory meets the requirements of the ISO/IEC 17025:2017 Standard for purposes of accreditation.

1.2 Service Scope

The quality system described in this manual covers testing and analytical services provided to customers both internal and external to KEPHIS. The scope of the ACL&FS testing service currently includes;

- i. Pesticides residues analysis in Agricultural crops
- ii. Pesticides residues analysis in environmental samples
- iii. Portable water analysis
- iv. Plant tissue analysis
- v. Food and feed analysis
- vi. Soil fertility testing
- vii. Irrigation Water suitability testing
- viii. Mycotoxin analysis
- ix. Pesticides formulation analysis
- x. Fertiliser and manure analysis
- xi. Heavy metal contaminants
- xii. Food Microbiology

2.0 Management System Awareness and Implementation

2.1 Controlled Distribution of the Quality Manual

Quality assurance officer is responsible for maintaining the official master copy of the Quality Manual. The

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Quality Manual describes the organisation of the staff in the laboratory, their responsibilities, the layout of the laboratory and general equipment and testing guidelines. The Quality Manual is divided into three main parts; Part one (1A) describes the implementation of the required clauses of ISO/IEC 17025 while Part one (1B) gives details of Organisation structure, roles and responsibilities; part two (2) contains procedures including sops, methods and record forms comprising of the Standard Operating Procedures (SOPs). General distribution of this manual is accomplished using hard copy. Biennial review is coordinated by quality assurance officer.

3.0 Quality Policy Statement

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 Analytical Chemistry Laboratory and Food Safety department are committed to full implementation of ISO /IEC 17025:2005 standard requirements and KENAS accreditation requirement. In this regard;

- The KEPHIS management is committed to avail all necessary resources required to support the laboratory;
- The laboratory management is committed to good professional practice, to a quality management system based on the ISO/IEC 17025:2017 Standard and to producing quality test results;
- All laboratory personnel shall understand the management system for all operations and implement the policies and procedures at all times;
- The Deputy Director (DD) in charge of the department and the Quality Assurance Officer (QAO) shall be responsible for establishing, implementing and maintaining the quality assurance system in the laboratory;
- The laboratory management is committed to ensure that all activities are carried out impartially and objectively

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

The quality objectives will be continually reviewed for their adequacy, relevance and general suitability for provision of reliable test results.

Signed

Date

PROF. THEOPHILUS M. MUTUI; PHD
MANAGING DIRECTOR

3.2 Laboratory Commitment and Policy on Impartiality

The Analytical Chemistry Laboratory and Food Safety (ACL&FS) management is committed to ensuring that all activities are carried out impartially and objectively. For this reason it is committed in particular to;

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- Continuously identify risks to the impartiality of the ACL&FS department, arising from its activities, its external relationships or internal relationships of its staff;
- Analyse, evaluate, treat, monitor, and document the identified risks and demonstrate how to eliminate such risks to impartiality;
- Provide staff with the knowledge required to operate in accordance with impartiality and require its staff to sign a commitment to promptly reveal any situation that may constitute a conflict of interest
- Do not allow commercial, financial or other pressures to compromise impartiality of ACL&FS activities

The laboratory is committed to providing quality testing services that meet both the needs of the customers and the requirements of ISO/IEC 17025:2017 and to continually improve the effectiveness of the management system. Test results are reported within stated limits of accuracy, precision, and detection limits as described in the methods used for analysis. The laboratory pledges commitment to the Quality Assurance Manual and policies therein, and its implementation to maintain the accreditation to ISO/IEC 17025:2017

Signed.....

Date.....

PETER M. KAMUTI

DEPUTY DIRECTOR, ANALYTICAL CHEMISTRY LABORATORY AND FOOD SAFETY DEPARTMENT

3.3 Management System Objectives

The objectives of the management system established by ACL&FS department is;

- To assure the accuracy of laboratory results so that they are reliable, interpretable, repeatable, and defensible.
- To establish and maintain national and international recognition through compatibility with the requirements of relevant standards.
- To strive to meet or exceed the customer's needs and expectations.
- To maintain the laboratories reputation for quality by promoting continuous process improvement and problem prevention.

These objectives are considered as part of the reviews performed by management.

3.4 Management System Strategies

In order to achieve these objectives and assure itself and its client of the reliability of its work, the ACL&FS department commits to;

- Train personnel to achieve competency in analytical work
- Maintain equipment that is fit for purpose
- Maintain calibrated equipment traceable to National and International standards
- Verify that equipment operating outputs are within prescribed tolerances

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- e) Have suitable accommodation and environment that is fit for purpose
- f) Apply methods of test whose capabilities (detection, accuracy, precision, etc.) can be demonstrated
- g) Validate methods used in testing
- h) Verify the controlled performance of tests by the use of in-house Quality Control procedures and external proficiency testing
- i) Apply suitable sampling plans and procedures where relevant
- j) Apply methods of test item handling that will maintain the integrity of the test item, the interest of the laboratory and the client
- k) Provide an appropriately controlled environment for carrying out laboratory analysis

Recognition of this level of quality assurance can only be achieved through accreditation to the requirements of ISO/IEC 17025:2017; general requirements for the competence of testing and calibration laboratories. The accreditation body to which application is made for accreditation purposes is the Kenya National Accreditation Service (KENAS)

3.5 Management System Awareness and Implementation

The management system documents and test methods are included as training elements in the laboratory's training program addressed in the laboratory training procedure. This ensures that staff is familiar with quality documentation and implement the quality policies and procedures in their work.

4.0 General Requirements

4.1 Impartiality

- 4.1.1 The laboratories activities are structured and managed so as to safeguard impartiality (conflicts of interest, pressures, and influences). The laboratory staff are familiar with and observe the Public Officers Ethics ACT CAP 183 and the KEPHIS Human Resources and Procedures Manual (2021)
- 4.1.2 The laboratory management is committed to sustaining impartiality of all personnel by enforcing existing Human Resources policies and procedures through trainings and itemizing discussions on ethics and corruption in laboratory meetings.
- 4.1.3 The laboratory shall ensure that risks to impartiality are continuously reviewed and eliminated or minimized to ensure there is no compromise to the objectivity of staff engaged in laboratory activities. Staff are familiar with and observe the Public officer ethics Act CAP 183. Staff shall not use the laboratory for private gain and shall act impartially and not give preferential treatment to any private organization or individual pressures that would adversely affect the quality of the technical work of the laboratory.
- 4.1.4 Risks to impartiality are identified during its audits and through customer complaints/feedback reviews.

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- 4.1.5 When laboratory employees or processes pose a risk to impartiality, an assessment is made of the nature of the risk and appropriate corrective actions are taken by the laboratory as per SOP G0529 on risk and opportunity assessment, management and communication

4.2 Confidentiality

- 4.2.1 The laboratory is legally obligated to provide protection of confidential and or proprietary information obtained or created during the performance of its laboratory activities. All permanent laboratory staff, contract personnel, interns, attachees shall abide by Official Secrets Act CAP 187 of the laws of Kenya and sign a Confidentiality and Non-Disclosure Agreement Form CA01.

The laboratory shall inform the customer in advance of the information it intends to publish in the public domain except for information that the customer makes publicly available or when agreed between the laboratory and the customer.

- 4.2.2 The laboratory does not release confidential customer information unless this is required by law or is a contractual agreement. The customer or individual concerned shall unless prohibited by law be notified through email of the information provided by the lab manager.
- 4.2.3 Information about the customer obtained from sources other than the customer shall be confidential between the customer and the laboratory. The provider (source) of this information shall be confidential to the laboratory and shall not be shared with the customer unless agreed by the source.
- 4.2.4 The laboratory is a controlled-access building to further ensure protection of data. Names and purpose of laboratory visitors are provided to security and recorded in Visitors Register KEPHIS/HQ/ACL/043 prior to a planned visit. Visitors are accompanied by a designated laboratory staff and allowed only in areas of interest to safeguard information from being compromised. Additionally, personnel, contractors, personnel of external bodies, or individuals acting on the labs behalf shall sign the confidentiality and non-disclosure agreement CA01 as a commitment to keep and use confidential information obtained or witnessed during their duties

5.0 Structural requirements

5.1 Laboratory as a legal entity

The Analytical Chemistry Laboratory (ACL) is a department of the Directorate of Laboratory Service (DLS) of the Kenya Plant Health Inspectorate Service (KEPHIS), a Government of Kenya statutory organization situated in Oloolua Ridge, Karen, in Nairobi. KEPHIS is the agency in Kenya mandated to protect Kenya's agriculture from pests and diseases that could impact upon the environment, economy and human health. KEPHIS was established through Legal Notice No. 305 of October 1996 and later through the Kenya Plant Health Inspectorate Service ACT No. 54 of 2012.”

5.2 Laboratory Management

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The Deputy Director in charge of the Analytical Chemistry Laboratory and Food Safety has overall responsibility for the laboratory

5.3 Scope of Accredited Laboratory Activities

Laboratory activities encompass all processes starting from the contract review process at the time of receiving samples from a customer, to sample handling and storage, processing, equipment operation, procurement of goods and services, data handling, verification and reporting within the laboratory. The laboratory has documented procedures on training, proficiency testing, and method validation. In order to ensure consistency of processes, approved documents are controlled and maintained to provide guidance in all processes and records retained. These also provide the basis to evaluate risks and improvements where gaps are identified through non-conformances, complaints, and annual management review of the inputs and outputs of operations.

The range of testing activities that conform to ISO/IEC 17025 are as shown in table 1.below

S/No.	Test Method Name	Matrix	Accredited Parameters	Test Method Number
1.	Multi-residue method for analysis of pesticides residues (QuEChERS) using GCMSMS and LCMSMS	High water and low fat agricultural matrices	300 pesticides molecules	M0326
2.	Determination of mycotoxins by LC-MS/MS using the solid-liquid extraction method	High starch, low water and low fat agricultural matrices	Aflatoxins: B1, B2, G1, and G2), Fumonisin B1 and B2 and Ochratoxin A	M0334
3.	Determination of mycotoxins by HPLC using the solid-liquid extraction method	High starch, low water and low fat agricultural matrices	Aflatoxin B1, B2, G1, and G2), Fumonisin (B1&B2) and Ochratoxin A	M0335
4.	Determination of the total organic carbon in soils by colorimetric method	Soil	Soil organic carbon	M0314

5.	Determination of pH, exchangeable acidity (Hp) and electrical conductivity (EC) in Soil	Soil	pH and EC	M0315
6.	Determination of Metal Elements using ICP-MS	Soils, sediments and biological tissue matrices	Pb, Hg, Cd, Cr, As, Ni, Se, Al, Fe, Cu, Zn, Ba, Ca, Mg, Mn, Na., K, Sr, Li, Rb, Sb, Bo, Mo, Be, V, Co, Ga, Ag, Cs. Tl, Bi, Th, U.	M0333
7.	Determination of macro and micro nutrients in mineral fertilizers	Chemical fertilizers	N, P, K, S, B, Ca, Mg, Cu, Zn, Fe, Mo and Mn.	M0331

Table 1: Range of accredited laboratory methods

5.4 Laboratory requirements

KEPHIS ACL&FS department laboratory permanent facilities are situated in Oloolua Ridge, Karen, Nairobi and it operates its analytical testing work based on the following requirements:

- i. KEPHIS Performance Contract and its work plan
- ii. ISO/IEC 17025:2017
- iii. ACL&FS Quality Manual
- iv. Customer contracts
- v. Accreditation Bodies policies
- vi. Kenyan laws and regulations

5.5 Laboratory Organizational Structure and Procedures

- a) The laboratory is a department within the Directorate of Laboratory Service (DLS) of the parent organisation called KEPHIS and is depicted in the larger KEPHIS organogram. The organization and the relationships between the laboratory management, technical operations, and support personnel is reflected in the laboratory's organogram. The organisational chart is included in Annex 1 of this manual while the laboratory organogram and responsibilities matrix is defined in Part 1B of the Quality Manual.
- b) The laboratory has managerial staff with authority to discharge their duties as defined in respective job descriptions for the laboratory. This authority includes the implementation, maintenance, and improvement of the management system. Job responsibilities for laboratory employees are documented in the management system procedures and operating instructions. Position descriptions are maintained by the Human Resource Office (HRO).

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c) The laboratory quality management system is outlined in the following documents:

- i. Quality manual,
- ii. Written Procedures,
- iii. Work Instructions,
- iv. Forms and Records.
- v. References

This management system is established to address the requirements in ISO/IEC 17025:2017. Each entity establishes and maintains documents per the procedure for document control. The quality policy and quality objectives for ACL laboratory are included in Part 1A of the Quality Manual. The documents listed above are accessible to all personnel and are included in the laboratory's training program.

5.6 Personnel Responsibilities and Authority

The Laboratory has personnel who irrespective of other responsibilities as outlined in QAM Part 1B have the authority and resources needed to carry out their duties including:

- (a) Quality Assurance Officer (QAO) ensures that the management system is established, implemented, maintained and improved in conformance with the requirements of ISO/IEC 17025:2017
- (b) Technical Team Leader(s) is/are responsible for identifying deviations from management system or from procedures for performing laboratory activities.
- (c) Laboratory analysts have the authority to execute and to identify and report deviations from the management system or procedures for laboratory activities.
- (d) The QAO is responsible for monitoring the laboratory's management system and reporting its performance and any need for improvement to laboratory management.
- (e) The Deputy Director in charge of the laboratory is responsible for ensuring the effectiveness of all the technical operations of the laboratory.

5.7 Communication and Integrity of the Management System

- a) The Deputy Director in charge of the laboratory ensures that there is communication on the effectiveness of the management system and the importance of meeting customer, statutory, and regulatory requirements. This is done through either an email communication highlighting the minutes from a management review or during a staff meeting.
- b) The Deputy Director in charge of the laboratory ensures that the integrity of the laboratory management system as defined in this manual is maintained when changes are planned and implemented.

6.0 Resource Requirements

- 6.1** The laboratory has evaluated and put in place personnel, facilities, equipment, systems and support services necessary for the management and performance of laboratory activities to ensure defensible data and conformity to the requirements of ISO/IEC 17025:2017.

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6.2 Personnel

- 6.2.1 All laboratory activities shall be performed by competent laboratory personnel, either internal (permanent) or external (e.g. contractual) who act impartially in performing the required tasks and shall work in accordance with the laboratory management system.
- 6.2.2 The competence requirements for each laboratory function influencing the laboratory's activities including requirements for education, qualification, knowledge, experience, skills and trainings have been documented
- 6.2.3 Laboratory management ensures that laboratory personnel have the competence to perform laboratory activities for which they are responsible for and are capable of evaluating the significance of deviations. Laboratory personnel undergo a training program in accordance with the laboratory's training procedure. The trainee is considered competent after the specified criteria have been successfully met. In case where personnel under contract are required, these shall be approved by the Deputy Director and shall also fulfil the requirements of its quality system.
- 6.2.4 The Deputy Director in charge of the laboratory shall communicate the duties, responsibilities and authorities outlined in the job descriptions to laboratory personnel. Communication from management will include but is not limited to, memos, emails, minutes, official letters, presentations, or verbal.
- 6.2.5 The laboratory procedure for determining personnel competence requirements, selection of personnel, training of personnel, supervision of personnel, authorization of personnel, monitoring the competence of personnel are defined in the laboratory's Training procedure G0525 and these records are retained in the laboratory
- 6.2.6 The laboratory management has authorized laboratory personnel to perform specific laboratory activities including but not limited to method development, modification, verification and validation, analysis of results, including statements of conformity or opinions and interpretations, reports, review and authorization of results etc. Records of these authorizations, demonstration of competence, education, training, and experience are maintained by the laboratory in the training files and are dated.

6.3 Facilities and Environmental Conditions

- 6.3.1 **The** laboratory environmental conditions facilitate the correct performance of analytical testing. The laboratory monitors critical environmental conditions (e.g. Lighting, dust, microbial contamination, vibrations, humidity, temperature etc.) to ensure that results and the quality of the measurement are not adversely affected or invalidated.
- 6.3.2 Specific requirements for facilities and environmental conditions necessary for the performance of tests are documented in test methods and environmental monitoring procedures used by the laboratory.
- 6.3.3 Where the environment condition control is required to ensure that results and the quality of the measurement are not adversely affected or invalidated, monitoring, control and recording of the environmental conditions in done as per the relevant specifications, methods or procedures in the

laboratory.

- 6.3.4 All areas of ACL laboratory are subjected to controls. Only ACL laboratory staff are permitted to access and use all areas of the ACL laboratory. Other parties may not access the ACL laboratories without permission from the Deputy Director in charge of the Department. Visitors are to be accompanied by the assigned laboratory staff. Laboratory spaces are maintained clean and orderly to prevent contamination of samples and to facilitate the efficiency of laboratory operations. Separate areas are maintained for incompatible activities. Measures taken to prevent cross-contamination include, but are not limited to: sample receiving and storage are conducted in designated areas; separate storage for standards.
- 6.3.5 In the event staff perform laboratory activities at sites outside of the laboratory's control, facility and environmental requirements are met.

6.4 Equipment

- 6.4.1 The laboratory has sample processing, preparation, measurement and test equipment for the correct performance of the tests. The Deputy Director (HoD) determines the requisite equipment needs for consideration by KEPHIS top management to provide prioritized requests for funds to develop or purchase equipment. The HoD is also responsible for the maintenance, calibration, storage, safe, proficient operation and documentation of all equipment. An inventory of all equipment is maintained in the laboratory equipment register. Procedures on the use of various laboratory equipment are also maintained in the laboratory individual equipment register.
- 6.4.2 When the laboratory uses a piece of equipment outside its permanent control, it ensures that the equipment meets the requirements of the ISO/IEC 17025 standard to assure the correct performance of test activities.
- 6.4.3 The laboratory has procedures for the safe handling, transport, storage, use and planned maintenance of equipment to ensure proper functioning and to prevent contamination or deterioration as described in SOP NO. G0523. The maintenance schedule of the equipment and instructions for specified maintenance operation are included in the SOPs describing the equipment and individual equipment register.
- 6.4.4 The laboratory ensures that equipment performance is verified, and verification records are maintained. Equipment has to meet the laboratory's testing parameters and conform to standard specifications before being placed or returned into service.
- 6.4.5 Equipment and its software used for testing are to achieve the accuracy expected, measurement uncertainty required, and comply with specifications of the testing concerned. The uncertainty contributions are addressed in SOP M0323 on determination of expanded Uncertainty in analytical methods. Measuring equipment is calibrated when the measurement accuracy or uncertainty affects the reported results and/or calibration of the equipment is required to establish metrological

traceability of the reported result as per SOP G0523 on Equipment (General). The laboratory management shall ensure that all equipment used in the laboratory that could affect the accuracy of results are calibrated.

- 6.4.6 The laboratory has an equipment calibration program which is defined in SOP No. G0523 on Equipment (General) in order to establish that it meets the laboratory's specification requirements for accuracy. The program is reviewed and adjusted as necessary to maintain confidence in the status of calibration.
- 6.4.7 Equipment supporting measurement service activities requiring periodic calibration, or having a defined period of validity, are identified in a manner that readily indicates to staff the status of calibration or period of validity. This is achieved by a sticker placed on the equipment indicating the when calibration was done and the next calibration.
- 6.4.8 Equipment that has been subjected to overloading or mishandling, gives suspect results, or has been shown to be defective or outside specified limits, is taken out of service. It is isolated to prevent its use or clearly labelled or marked as being "Out of Service" to prevent its use until it has been repaired and shown by calibration or test to perform correctly. Laboratory personnel examine the effect of the defect or departure from specified limits on previous tests according to SOP G0523 on Equipment
- 6.4.9 Intermediate calibration confirmation checks are performed to maintain confidence in the calibration status of the equipment. These checks are conducted according to the procedure described for the individual equipment.
- 6.4.10 Where calibrations give rise to a set of correction factors, these factors are updated and implemented to meet specified requirements.
- 6.4.11 Test and calibration equipment, including both hardware and software, are safeguarded from adjustments that would invalidate the test or calibration results. Safeguards are provided using access control to the laboratory and the use of the equipment.
- 6.4.12 Records of all equipment and its software that may significantly affect the performance of the analysis are kept on Equipment Registers. These indicate the status of use of equipment, unique identification number of the equipment, its location, its service status and main procedure for its operation. The maintenance schedule of the equipment and instructions for specified maintenance operation are included in the SOPs describing the equipment

6.5 Metrological Traceability.

- 6.5.1 Measuring equipment including reference standards and reference materials having a significant effect on the accuracy and validity of the result of measurement and should be calibrated before putting to use. The program for calibration of equipment demands that calibrations and measurements made by the laboratory are traceable to the International System of Units.

Calibration laboratories providing services to ACL laboratory are to provide evidence of measurement

traceability of its own measurement primary standards and measuring instrument to the SI. Such primary standards are those used by national measurement standards.

Calibration certificates issued by calibration laboratories are to include the measurement results, including the measurement uncertainty and a statement of conformance with an identified metrological specification.

6.5.2 Traceability to SI units shall be ensured by;

- a) Calibration laboratories providing services to ACL laboratory are to provide documentation demonstrating measurement capability and competence to perform the calibration services requested.
- b) Reference standards and materials are traceable to national or international standard reference materials (SRMs), such as National Institute of Standards and Technology (NIST), or certified reference materials (CRMs) from competent suppliers of reference materials.
- c) The measurement integrity of internal reference materials generated by the laboratory is evaluated against either standard reference materials or certified reference materials from an independent source when it is technically and economically possible
- d) The measurement traceability to SI units may be achieved by measurements related to national measurement standards. National measurement standards may be used as primary standards that are primary realizations of the SI units or agreed representations of SI units.

6.5.3 Where traceability to the SI Units is not possible, ACL will establish traceability through the use of certified reference materials provided by a competent supplier or the use of specified methods and/or consensus standards and ensured by suitable comparison.

6.6 Externally provided products and services

6.6.1 The laboratory ensures that only suitable externally provided products and services that affect laboratory activities are used when they are intended for incorporation into the laboratory's activities and/or used to support the operation of the laboratory as outlined in SOP G0507 on subcontracting of test work. The laboratory does not subcontract routine analyses within the scope of accreditation

6.6.2 The procurement of materials, supplies and services that critically affect the quality of the tests or calibrations is conducted by KEPHIS procurement department as per procedure DOC. NO. SOP/KEPHIS/SUP/01 and laboratory procedure for the Procurement of Goods and Services SOP G0504

- a) Purchasing documents for items affecting the quality of laboratory output describe the services or supplies ordered. These purchasing documents are reviewed and approved for technical content prior to submission. Records of supplier evaluations are maintained in KEPHIS procurement department.
- b) The laboratory's purchasing procedure describes how purchased equipment, supplies, services, reagents, and consumable materials that critically affect the quality of tests or calibrations are

inspected or verified prior to use. Inspection or verification criteria are used to establish conformance with requests made, included in standard specifications.

- c) Records of unsatisfactory materials and supplies and their disposition are maintained. These records establish trends in vendor performance and ensure that continuing quality material is accepted. A vendor is considered unacceptable and is not used when the quality of product or service does not meet expectations or specifications.

6.6.3 Critical specifications and requirements are developed by the laboratory and are clearly described on the purchasing requests and are communicated to external providers by the procurement department.

These requirements include:

- a) The products and services to be provided;
- b) The acceptance criteria;
- c) Competence, including any required qualification of personnel

7.0 Process requirements.

7.1 Review of requests, tenders and contracts

7.1.1.1 The policy of the laboratory is to provide its customers with a range of services to meet their needs, while maintaining the quality of its service in accordance to ISO/IEC 17025 as described in SOP G0503 on contract review

- a) The Deputy Director in charge of the laboratory or the authorised officer(s) shall review the contract with the customer to ensure that the requirements are well defined and confirm that the laboratory has the capability and resources to do the analysis and complete it within the required time.
- b) The receiving officer shall indicate the method used (e.g. GC-MS, GC-ECD, GC-FID, Flame-AAS, ICP-MS, ICP-OES, Flame photometry, AAS-GTA, UV-Vis spectrometry etc.).
- c) Where subcontracting is to be carried out the approval of the client is sought in writing prior to offering such a service.

7.1.2 The laboratory informs the customer during the contract review process when the suitability of the method proposed by the customer is considered to be the incorrect choice or the incorrect revision for the intended purpose.

7.1.3 If the customer requests for a statement of conformity in the reporting of the results, the decision rule applied shall be agreed upon with the customer and indicated as such in the sample reception/contract review form CR03. The decision rule applied shall be obtained from the Decision Rules Form CR10.

7.1.4 The laboratory ensures that during contract review there is no conflict between the customer request and the laboratory contract and any difference is resolved prior to commencement of laboratory activities. The contract shall be acceptable to both parties and any deviations requested by the customer shall not impact the labs integrity or validity of its results

7.1.5 The laboratory shall inform the customer of any deviation from the contract by email

7.1.6 In case of any changes and amendments to the contract after work has commenced, both parties shall be notified, preferably in writing; and the request for the change recorded in the request file or on the contract review.

7.1.7 With a written approval by Deputy Director in charge of the of the laboratory, a customer can request to visit the laboratory's analytical area to verify or monitor the laboratory's performance or copies of chromatograms or any other information related to a particular analysis provided such information will be solely used by the customer and shall not in any way, means or form be transferred to a third party.

7.1.8 The customer will take the duplicate (carbon copy) of the contract review/sample reception form, while the original is retained in the laboratory and filed in the appropriate contract review file

7.2 Selection, verification and validation of methods

7.2.1 Method selection and verification

7.2.1.1 The laboratory has established, implemented and maintains procedures used to carry out various test work in the laboratory (QAM Part 2) and the estimation of the uncertainty of measurement is addressed in SOP No. M0323 on Determination of Expanded Uncertainty in Analytical Methods.

7.2.1.2 Laboratory methods and supporting documents are controlled according to SOP No. G0501 SOP on Control of documentation.

7.2.1.3 Laboratory methods are selected to meet the customer's need as addressed in SOP on Contract Review G0503. The laboratory ensures that it uses the latest valid version of analytical methods unless not appropriate or possible to do so. Standard methods are preferred for use and are verified for use in the laboratory. A standard method may be supplemented with additional details in the form of a laboratory procedure to ensure consistent application. Those methods specified by the manufacturer of the equipment are considered as standard methods. The laboratory also has a procedure outlining method validation practice and outlining acceptance criterion of various methods (SOP G0520).

7.2.1.4 Customers will be informed of the methods available at the time of contract review depending on the test requested (SOP no. G0503 on Contract Review). If the customer does not specify the method to be used a standard method is preferred for use. If a standard method is not found, the laboratory may use either a non-standard method or modify a method for use with the concurrence of the customer. The laboratory informs the customer when the method proposed by the customer is considered to be the incorrect choice or the incorrect revision for the intended purpose. This is done as part of contract review.

7.2.1.5 Standard methods are verified according to the procedure SOP No. G0520 on Analytical Methods and Method Validation. Non-standard methods are selected for use when a customer request cannot be addressed with the use of a standard method. Such methods are subject to agreement with the customer and a clear specification of the customer's work requests, including the purpose of the test, is made.

7.2.1.6 Method Validation is done as per SOP No. G0520, Analytical Methods and Method Validation.

7.2.1.7 Deviations from test methods are documented, technically justified, authorized, and where circumstances call

for it, accepted by the customer

7.2.2 Method validation

- 7.2.2.1 The laboratory validates non-standard methods, laboratory developed methods, and modified standard methods to include their use outside the intended scope when modified. Validation is conducted to confirm that the methods are fit for the intended use, relevant to the customers' needs, and consistent with specified requirements. The validation is as extensive as is necessary to meet the needs of the given application or field of application.
- 7.2.2.2 When changes are made to a validated method, the influence of such changes shall be determined and where they are found to affect the original validation, a new method validation is performed.
- 7.2.2.3 The validation process addresses the needs of the given field of application. The basic performance characteristics are outlined in SOP G0520 on Analytical Methods and Method Validation.
- 7.2.2.4 The assigned laboratory analyst(s) records the results according to SOP G0520 on Analytical Methods and Method Validation. The validation results include a statement as to whether the method is fit for the intended use. The needs of the customer define the intended use of the method.

7.3 Sampling

- 7.3.1 The ACL laboratories do not routinely perform sampling in the sense of collecting a representative sample from a product lot to represent the whole. Sample collection is mostly conducted by the Customer. However, some regulatory test samples are obtained and sent to the laboratory staff in which case the instructions for sample collection, including methods and sampling plans are provided for specific applications.
- 7.3.2 The sampling method describes the selection of samples and sites as well as the sampling plan and any special sample treatment or preparation to secure the sample integrity.
- 7.3.3 The staff collecting the sample enter information in the sampling form on; sampling method used, date sampling, data to identify and describe the sample (e.g. number, amount, name), name of the personnel performing sampling, environmental or transport conditions, diagrams or other equivalent means to identify the sampling location, when appropriate, and deviations, additions to or exclusions from the sampling method and sampling plan.

7.4 Handling of test or calibration items

- 7.4.1 The laboratory procedure SOP No. G0513 on Sample Handling and Analysis describes the receipt, processing, protection, storage, retention and disposal of samples. This procedure also provides the details for handling and protecting test items from deterioration, loss or damage during storage and processing. The laboratory has arrangements for storage and security that protect the condition and integrity of samples. Sample security arrangements apply both in the laboratory and in the custodial areas.
- 7.4.2 The laboratory has a system for uniquely identifying samples as described in procedure SOP no. G0503 on

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Contract Reviews. The sample number is used to track its progress from the time the sample is collected in the field until the analysis is completed and the sample is disposed. The sample number is also used to provide traceability between the sample and the data.

- 7.4.3 When samples received do not meet established acceptance criteria, for example, contract/program specifications, analysis requested, abnormalities or departures from normal or specified conditions these deviations are recorded according to SOP no. G0503 on Contract Review. The customer is consulted prior to commencement of analysis for further instructions and a disclaimer will be included in the test report when customer acknowledges deviation but requests for the test to be carried out anyway. All communication with the customer is recorded in accordance to SOP no. G0503 on Contract Review.
- 7.4.4 When samples items have specific environmental conditions, those conditions are maintained, monitored and recorded. Monitoring records are collected according to established procedures.

7.5 Technical records

- 7.5.1 Technical records for all activities that contribute to data reporting, depending on the type of analysis, include the original observations, derived data, calculations, standard preparation, instrument printouts, and results as per SOP G0517 on recording of raw data. These records contain the date each activity is completed and the identity of all persons who perform each activity throughout the process, including those who review the data and results. Observations, data, and calculations are recorded at the time they are made and are identifiable to the activity performed. The records of each test contain sufficient information to repeat the test under conditions as close as possible to the original. This information includes environmental conditions that affect the test and factors that affect the measurement results and its associated measurement uncertainty. Staff records, equipment calibration, and verification reports are retained in accordance with the laboratory's control of records procedure. These records contain sufficient information to establish an audit trail.
- 7.5.2 ACL laboratory ensure changes to technical records can be tracked to the previous version or to original observations. Both the original and amended data and files are retained, including the date the record was changed, an indication of what was changed and the person responsible for the alteration as describe in procedure SOP G0517 on recording of raw data.

7.6 Evaluation of measurement uncertainty

- 7.6.1.1 The laboratory identifies all the contributions to measurement uncertainty whether from sampling (Where applicable) and those arising from its testing activities for every test method during the validation process. This shall be recorded and documented in respective standard operating procedure or validation reports.
- 7.6.2 ACL laboratories do not perform calibration activities
- 7.6.3 The laboratory has a procedure for determination of Expanded Uncertainty in Analytical Methods
- 7.6.4 SOP No. M0323. This document describes how estimation of uncertainty of measurement for all

Analytical methods will be identified, quantitated and reported. It also describes how uncertainty of sampling will be identified, evaluated and reported when the laboratory is involved in sampling and subsequent testing and where the customer provides the uncertainty due to sampling.

7.7 Ensuring the validity of results

- 7.7.1 The laboratory has quality control procedures to validate the results of tests undertaken according to SOP No. G0512 on assuring the quality of analytical results. The monitoring data is recorded in such a way that trends may be detected using statistical process control charts. Monitoring techniques may include, but are not limited to, the following:
- (a) Scheduled use of certified reference materials or quality control materials;
 - (b) Use of alternative instrumentation calibrated to provide traceable results;
 - (c) Functional check(s) of measuring and testing equipment;
 - (d) Use of check or working standards with control charts;
 - (e) Intermediate checks on measuring equipment;
 - (f) Replicate tests using the same or different methods;
 - (g) Retesting of reference materials and retained customer samples;
 - (h) Correlation of tests results conducted for different characteristics of a sample;
 - (i) Review of reported results;
 - (j) Scheduled participation in proficiency-testing or inter-laboratory comparison;
 - (k) Testing of blind samples.
- 7.7.2 ACL laboratories participates in proficiency testing programs and/or inter-laboratory comparisons other than proficiency testing, where available and appropriate.
- 7.7.3 The laboratory SOP G0512 on assuring the quality of analytical results has defined the criteria for quality control data and performs analysis by such means as control charting. When data is found to be outside the established criteria, action is taken in accordance with the procedure for non-conforming work SOP no. G0505

7.8 Reporting of results

7.8.1 General

Test reporting is addressed in the ACL Laboratory by the procedure SOP No. G0516 on reporting of results.

- 7.8.1.1 Laboratory results are reviewed and authorized for release by supervisors or designees. Reports are reviewed for accuracy, clarity and objectivity. This procedure SOP G0516 on reporting of results gives details on reporting data using consistent reporting formats to ensure that test results are reported as accurately, clearly, unambiguously and objectively as possible in a test. Test and sampling reports include all information provided and agreed with the client necessary for interpretation of the results as well as information pertaining to the method.

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7.8.1.2 ACL provides its clients with documented reports either in hardcopy or electronic form which convey the test and or sampling data in a clear and an unambiguous way. Copies of issued reports are retained.

7.8.1.3 The format for laboratory worksheets is designed to accommodate the type of test conducted to minimize the possibility of misunderstanding or misuse. These enable description of the sample as received, including any information provided by the customer, on the sample worksheet. When information supplied by the customer can affect the validity of the results, a disclaimer statement is included on the worksheet.

7.8.2 Common requirements for test reports

7.8.2.1 The following information is included in test reports;

- a) A title,
- b) Name and address of the laboratory;
- c) Unique identification that all its components are recognized as a portion of a complete report and a clear identification of the end;
- d) The name and contact information of the customer;
- e) Identification of the method used;
- f) A description, unambiguous identification,
- g) The date(s) of performance of the laboratory activity;
- h) The date of issue of the report;
- i) A statement to the effect that the results relate only to the items tested,
- j) The results with, where appropriate, the units of measurement;
- k) Identification of the person(s) authorizing the report

7.8.2.2 The laboratory shall be responsible for all the information provided in the report, except when information is provided by the customer. Data provided by a customer shall be clearly identified. In addition, a disclaimer shall be put on the report when the information is supplied by the customer and can affect the validity of results. Where the laboratory has not been responsible for the sampling stage, it shall state in the report that the results apply to the sample as received.

7.8.3 Specific requirements for test reports

7.8.3.1 Where necessary for the interpretation of results, the following additional information may be provided on request at the time of contract review;

- a) Information on specific test conditions
- b) A statement on the estimated uncertainty of measurement is given in the test report and any deviations and measurements uncertainties that will affect compliance shall be specified (e.g. positive samples for pesticide residues) and reported in the test report.
- c) Where opinions and interpretations are included in the test report, the laboratory shall provide the disclaimer indicating that opinions and interpretations are not included in the schedule of

accreditation.

d) Where relevant, after request by a customer, a statement of conformity to a specification or standard shall be provided. The decision rules applied shall be agreed with the customer as outlined in the ACL form CR10 on Decision rules.

e) Additional information that may be requested by methods, customers or groups of customers.

7.8.3.2 When the laboratory conducts sampling such as when collecting a representative sample from a product lot to represent the whole, the requirements for test reports will meet the minimum requirements of the ISO 17025 standard

7.8.4 Specific requirements for calibration certificates

The laboratory only conducts in-house calibration activities on measuring and test equipment only and, therefore, do not issue calibration certificates. In-house calibrations are documented by a report, or sticker, or other suitable method

7.8.5 **The** laboratory maintains suitable procedures for sampling in the field, and used where appropriate when requested by the client. However, a majority of the samples received in the laboratory are submitted by customers.

7.8.6 Reporting of statements of conformity

7.8.6.1 Statements of conformity to a specification or standard require the use of a decision rule to take into account the uncertainty associated with method. Decision rules for the laboratory are documented in form no. CR10

7.8.6.2 The statements of conformity reported by the lab clearly identify;

- i. The results the statement applies to;
- ii. Which specifications or standards were met, or not met;
- iii. The decision rule applied (unless it is defined in the specification or standard)

7.8.7 Reporting opinions and interpretations

The laboratory expresses its opinion and interpretation of the compliance or non-compliance of the test results through the laboratory classification assigned to each sample. Records are maintained of conversations expressing opinions and interpretations about a sample with the customer.

7.8.8 Amendment to reports

The laboratory may re-issue results due to certain instances, which warrant a recall of the original report. In this instance also, a statement indicating that the previous report has been superseded by the re-issued report shall be included on the front page of the re-issued report also as a disclaimer. The sample code of the re-issued report shall have a letter “R” added to it to indicate that the report is re-issued.

7.9 Complaints

- 7.9.1** The laboratory management has established a procedure describing the handling of complaints and compliments received from any party (G0506). In addition to the resolution of these complaints, improvement in the area of concern is addressed and implemented in most cases.
- 7.9.2** The procedure for handling customer complains SOP G0506 gives a description of the complaint handling process and will be made available to any interested party on request. Upon receipt, the complaint is evaluated by the officer responsible for handling complaints or any other designated officer, to establish whether it relates to laboratory activities or not. The result of the evaluation shall be recorded in the space provided in the Customer complaints form, DCOMP03. However, the laboratory management is responsible for all decisions at all levels of the resolution process.
- 7.9.3** This procedure details how complaints concerning the service offered by the laboratory shall be received, validated, investigated, actioned and communicated. The complaints shall be tracked and records shall form a basis for identifying opportunities for improvement.
- 7.9.4** The section in the laboratory receiving the complaint shall be responsible for gathering and verifying all necessary information to validate the complaint. The investigation reports is submitted to the officer responsible or Head of laboratory for evaluation and review of the proposed corrective actions. The proposed corrective actions are reviewed and approved by the Quality Officer, and confirmed as the action to be taken.
- 7.9.5** Whenever possible the laboratory shall acknowledge receipt of the complaint and a communication of the same given to the complainant.
- 7.9.6** The outcomes to be communicated to the complainant shall be made by, or reviewed and approved by, individual(s) not involved in the original laboratory activities in question. After all the corrective actions and other actions are completed, the Head of laboratory or person delegated this responsibility completes the closure of the complaint by filling in Section F. A final formal notice of the end of the complaint handling is communicated to the customer.
- 7.9.7** The outcomes to be communicated to the complainant shall be made by, or reviewed and approved by, individual(s) not involved in the original laboratory activities in question.

7.10 Nonconforming work

- 7.10.1** The ACL laboratory have a control of non-conforming work procedure SOP G0505 that is implemented when any aspect of it activities, or the results of this work, does not conform to requirements of the management system, testing methods, or the requests of the customer. This procedure describes among others the following;
- a) Responsibilities and authorities for the management of identified non-conforming work to include taking actions such as the halting of work and/or the withholding of test reports based upon risk levels established by the laboratory

- b) Actions are based upon the risk levels established by the laboratory;
- c) Evaluation of the significance of non-conforming work including an impact analysis on previous results and, if necessary, recall of work with notification to the customer.
- d) Remedial action taken, together with any decision about the acceptability of the non-conforming work

7.10.2 Records of nonconforming work and actions taken are maintained

7.10.3 Where the evaluation indicates that the nonconforming work could recur, or that there is doubt about the conformity of the laboratory's operations with its own management system, the laboratory shall implement corrective action in SOP G0505.

7.11 Control of data and information management

7.11.1 ACL laboratory have access to the data and information needed to perform laboratory activities through various electronic records management systems soft and paper records maintained according to procedure SOP G0517 on the recording of raw data.

7.11.2 ACL information management system applications used for the acquisition, processing, recording, reporting, storage or retrieval of data are validated prior to introduction. If computer software is developed by the user, its development is authorized, documented in detail. Changes to laboratory software configuration or modifications to commercial off -the-shelf software are also authorized, documented and validated prior to use.

7.11.3 The ACL laboratory have processes for the protection of data to include, but not limited to data integrity, data confidentiality during entry, collection, storage, transmission and processing. The processes also ensure safeguards are in place to prevent unauthorized access to or amendment of records.

7.11.4 Laboratory information systems managed and maintained off-site meet all applicable requirements of ISO 17025:2017.

7.11.5 Instructions, manuals and reference data relevant to the laboratory information systems are readily available to personnel through the document control process.

7.11.6 Calculations and data transfers are reviewed before the data is reported. All changes are identified and verified where they occur as detailed in SOP no. G0517, sop on the recording of raw data.

8.0 Management system requirements

8.1 Option A

The ACL laboratory management has chosen to implement the 17025 management requirements in accordance with Option A of the international standard.

8.1.1.1 KEPHIS ACL laboratories have established, documented, implemented, and maintained a management system capable of supporting and demonstrating the consistent achievement of the requirements of ISO/IEC 17025:2017 to assure the quality of laboratory results. The Quality Manual is divided into three main parts;

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Part one (1A) describes the implementation of the required clauses of ISO/IEC 17025 while Part one (1B) outlines the organisation structure, roles and responsibilities; Part two (2) contains procedures including Standard operating procedures, methods and record forms.

8.2 Management system documentation (Option A)

8.2.1 The policy of ACL is to offer analytical and related services in the fields of pesticide residues, agricultural inputs and formulations on a commercially viable basis and according to ISO/IEC 17025 requirements. The Quality Management System is established, implemented and maintained by the laboratory management and analysts. It is applicable in all fields of testing and other activities in which the laboratory is involved in and undertakes. The main objectives of the laboratory are to;

- a) Provide customers with a range of scientific analytical and advisory services under the KEPHIS mandated areas.
- b) To increase the volume and scope of analysis.
- c) Increase the laboratory's revenue base.
- d) To expand our customer base.
- e) To implement and comply to the requirements of ISO/IEC 17025:2005, thus be a competent laboratory
- f) To provide timely results to its customers.
- g) To periodically as need arises evaluate the test methods and propose changes to improve performance.
- h) To monitor the level of the laboratory's performance to implement possible areas of improvement.
- i) To ensure that all personnel are trained to a level of familiarity with the quality management system to the individual's degree of responsibility.

8.2.2 The policies and objectives address to the extent necessary the competence, impartiality and consistent operation of the laboratory and assure the quality of results generated.

8.2.3 Evidence of the laboratory's management commitment to the management system and its continual improvement in effectiveness is demonstrated by but not limited to; signed quality statement, participation of managers in the management reviews, performance of internal audits, proficiency testing, and the analysis of quality control samples.

8.2.4 All documentation, processes, systems and records related to the fulfilment of the requirements of ISO/IEC 17025:2017 have been included, referenced to the management system.

8.2.5 Relevant parts of the management system documentation is readily available and understood by implementing personnel.

8.3 Control of management system documents (Option A)

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- 8.3.1** The laboratory has a document control procedure SOP no. G0501 for control of documentation. The control system is based on the review, approval, issue and maintenance of documentation. The laboratory management maintains its documents on various media such as hard copy (paper) and electronic form. Only documents relevant to the quality system that may affect the output of operation are controlled.
- 8.3.2** The top management of the laboratory ensures that;
- a) Documents are issued to personnel in the laboratory as part of the management system are reviewed for adequacy and approved by authorized personnel prior to issue in accordance with the document control procedure
 - b) **The** quality system documentation is updated from time to time as the need arises and not less than once in one years.
 - c) Documents are reviewed per an established schedule and revised as necessary to ensure continuing suitability and conformance with the management system and ISO/IEC 17025:2017 requirements. These reviews should include an assessment of reference documents and pertinent background information.
 - d) Altered or new text is identified either in the document, document change history section, on a cover page, redline file, or in attachments. Changes can be described in general terms since the details can be demonstrated in the archived document. Document revision is recorded on each document and tracked within QMS.
 - e) Changes to any quality assurance documentation i.e. manuals, SOPs, forms etc. are proposed and recorded in Form DC01 as required by the document control procedure G0501.
- 8.3.3** This will constitute the Amendment list of the document.
- 8.3.4** The distribution of the documents to the designated analysts and sections/locations shall be done by the quality assurance officer (QAO) or the deputy. The distribution list shall have the following information: designated recipient, date received, and location of document or analyst to whom the document is issued, name of document (at the top of the list), copy number, and in particular for retrieval the revision number (or the period the document is revised).
- 8.3.5** All documentation will have a document unique identification number. The first page of the document shall bear the document identification, revision number, compiler (name and signature), authorised approver (name and signature) and effective date at the top of the page. All the pages of the document starting from first page shall have italicized footer bearing the text ‘Analytical chemistry Laboratory’, unique document identification number and page numbers at the centre of each paper.
- 8.3.6** Quality system documents are deemed obsolete once the document is revised or changed and approved by the Deputy Director in charge of laboratory and the appropriate copies made as per the distribution list.
- 8.3.7** All physical copies of the previous revision shall be withdrawn, and at least the original document filed in the “obsolete” documents file; and replaced with the new revision using the same procedure as before. The QAO shall monitor and confirm the previous revision has been retrieved and countersign the “CHECKED BY”

column in the system document issue and distribution list register RG 20.

8.4 Control of records (Option A)

- 8.4.1** The laboratory technical management has established and maintains procedures that outline the identification, collection, indexing, filing, storage, maintenance and disposal of the quality management system and technical records (SOP G0501 and the filing index FX01).
- 8.4.2** Quality records shall include reports from internal audits, minutes of management review as well as records of corrective and preventative actions. The laboratory management also established a procedure outlining archiving of raw data, obsolete documentation protocols, reports and test materials SOP G0521
- 8.4.3** The laboratory management shall define technical records, establish and maintain records of original observations and provide sufficient information to establish an audit trail. Calibration records, staff records and test reports shall also be maintained.

8.5 Actions to address risks and opportunities (Option A)

- 8.5.1** Laboratory management meet regularly to assess risks and opportunities associated with all laboratory activities to:
- Ensure the management system achieves its intended results;
 - Enhance opportunities to achieve the purpose and objectives of the laboratory;
 - Prevent, or reduce negative impacts and potential failures in laboratory activities;
 - Achieve improvement

Examples of areas evaluated consist of the following, although the list is not all inclusive:

- Turnaround times for data reporting
- Training and competency
- Structure to ensure impartiality of personnel
- Equipment issues
- Program requirements
- Facilities/Environment
- Effectiveness of corrective and preventive actions
- Outcomes of internal audits
- Complaints
- Processes to ensure confidentiality

- 8.5.2** Plans, final evaluation, actions and implementation of actions, improvement, and assurance of intended actions are outlined in section 8.9 below on Management Reviews
- 8.5.3** Actions taken to address risks and opportunities are proportional to the potential impact on the validity of laboratory results.

8.6 Improvement (Option A)

- 8.6.1 The effectiveness of the laboratory's management system is improved by using the following activities: internal audits; management reviews; analysis of quality control data; corrective actions; preventive actions the quality policy; and the quality objectives.
- 8.6.2 The laboratory shall seek customer feedback on services and general performance. Records of the comments, both positive and negative, are maintained and are considered for identifying management system improvements during reviews performed by laboratory management as per SOP G0511 on Management reviews

8.7 Corrective actions (Option A)

- 8.7.1 The laboratory management has established, implemented and maintains procedures that define the actions to be taken in handling of non-conformances and corrective actions (G0505). Records of these also used to take up the necessary actions for improvement of the quality system.
- 8.7.2 The procedure describes process and designates the authorities for implementing corrective action when one of the following is identified:
- a) non-conforming work,
 - b) departures from the policies and activities outlined within the management system, and
 - c) departures from required technical operations

8.8 Internal audits (Option A)

- 8.8.1 The laboratory management shall establish, implement and maintain a periodic audit plan, outlined in procedure G0508. Internal audits are conducted to verify that operations continue to conform to the requirements of the management system and ISO/IEC 17025:2017.
- 8.8.2 The internal audit program is defined in SOP for Internal Audits (G0508). The program takes into consideration the importance of the laboratory activities concerned, changes affecting the laboratory, and the results of previous audits.
- 8.8.3 The procedure SOP G0508 defines the audit criteria and scope for each audit.
- 8.8.4 Results of the audits are reported to laboratory management.
- 8.8.5 When audit findings cast doubt on the effectiveness of operations or the correctness or validity of the laboratory's test or calibration results, the laboratory implements appropriate correction and corrective actions in a timely manner as per audit procedure SOP G0508
- 8.8.6 The area of activity audited, the audit findings, and corrective action that arise from them are recorded according the laboratory's audit procedure.

8.9 Management reviews (Option A)

- 8.9.1 The top laboratory management has established and implemented a procedure on review of the laboratory's management system and testing activities to ensure their continuing suitability and

effectiveness and to introduce necessary changes or improvements. (G0511). The review takes into account:

- a) The suitability of policies and procedures.
- b) Reports from managerial and supervisory personnel.
- c) Outcome of recent internal audits.
- d) Corrective and preventative actions.
- e) Assessments by external bodies
- f) Results of inter-laboratory comparisons or proficiency tests
- g) Changes in the volume and type of the work
- h) Customer feedback
- i) Complaints recommendations for improvement
- j) Quality control activities, staff training and resources.
- k) The minutes from such meetings shall be maintained and filed accordingly.

8.9.2 The minutes from such meetings shall be maintained and filed accordingly.

8.10 Amendment List

Amendment No.	Date approved	Nature of amendment
1	30/12/05	♣ Deletion of SOPs from the manual ♣ Deletion officers who have left service or deceased ♣ Amendment of the ACL laboratory floor plan ♣ Amendment of the organogram – to include Revision 1 of the manual ♣ Update of staff training ♣ Updating staff ♣ Update of staff responsibilities as per meeting of December 2005 ♣ Definitions of the laboratory technical management ♣ Definition of the management.
2	3/11/09	♦ Deletion of G. Muchemi in the organogram, staff initials and responsibility matrix, who left the laboratory
3	31/07/2021	➤ Amendment of the organogram ➤ Structural changes in manual format ➤ Adoption Albertus Extra font ➤ Change of lab name to analytical chemistry laboratory and food safety

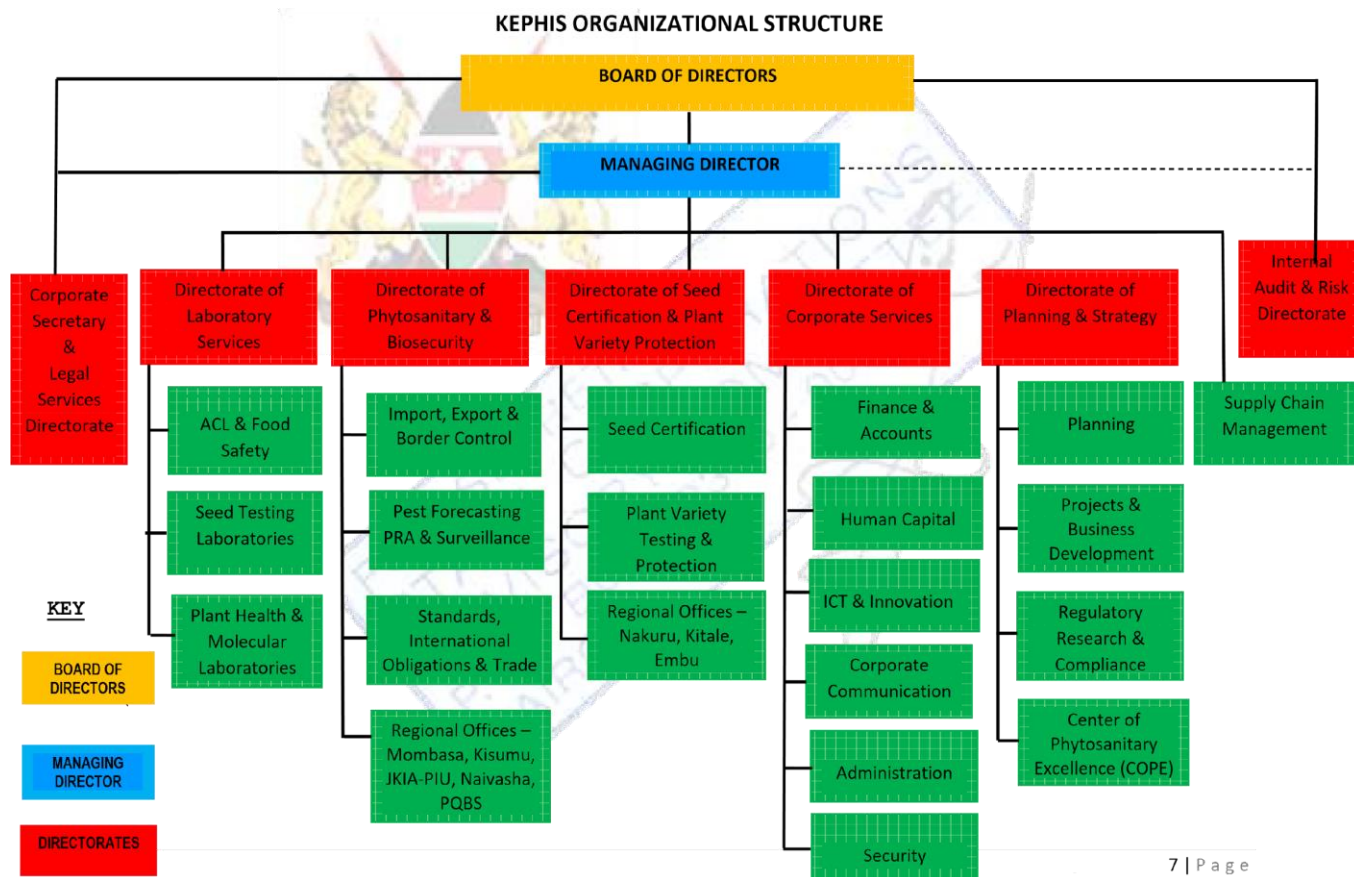
8.12.1 Revision List

Revision No.	Effective date	Nature of revision

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3	Dec 2005	-as above-
4	May 2007	Alignment of Quality Manual to the requirements of ISO/IEC 17025:2005 • Revision of the organisation's organogram and the laboratory's organogram. • Inclusion of responsibility matrix for the laboratory. • Inclusion of definition of responsibilities and job description of activities carried out in specific tasks. • Editing of the Management policy statement. • Inclusion of containers 1 and 2 in Annex layout of the laboratory. • Deletion of current qualifications and responsibilities. • Inclusion of the Scope of accreditation in Annex 4.
5	June 2009	Inclusion of new staff member (MO) amendment of responsibility matrix. Amendment of ACL organogram Inclusion of reference to an SOP on G0526.
6	January 2010	Removal of the responsibilities and ACL organ gram for inclusion in Part 1B on organisation and management. Deletion of the job description of analytical chemists (detail). Revision of documentation-KEPHIS organogram and ACL laboratory.
7	January 2011	Revision of Management Policy Statement and definition of committees. Improve numbering system (Part 1A).
8	May 2013	Changed issuer and authoriser.
9	February 2015	♣ Change of issuer and authoriser ♣ Revision of management policy statement ♣ Revision of manual to be in line with the new requirements and structural format of ISO/IEC 17025:2017
	July 2021	♣ Review of ACL&FS organogram ♣ Change of accreditation body from SANAS to KENAS
10	July 2023	Formatting of the cover page, revision change, provide for communication on effectiveness of the management system by use of either email, or staff meeting minutes in part 5.7 of the policy.
11	July 2024	Revision KEPHIS organogram and ACL&FS department.

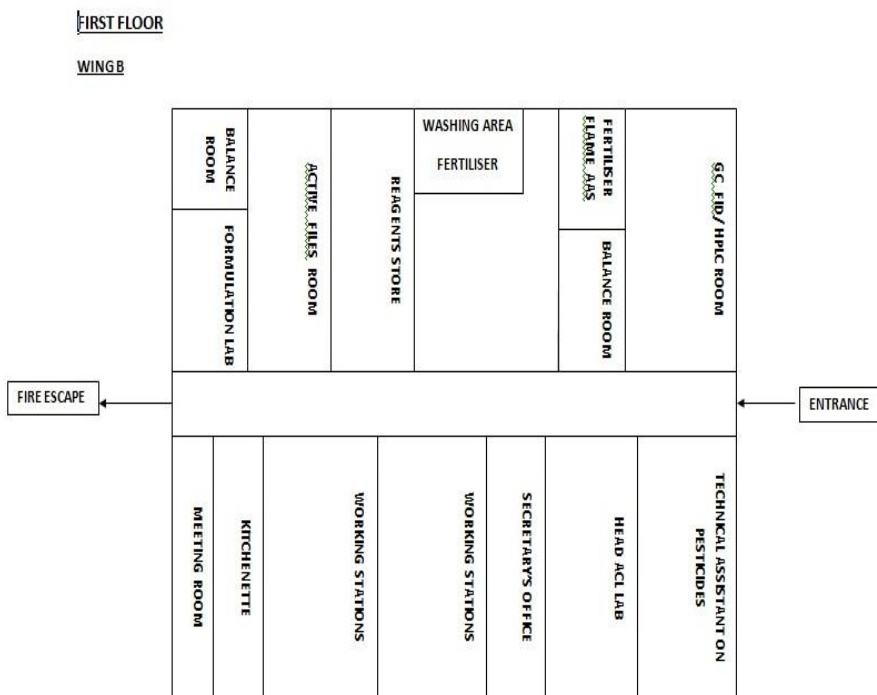
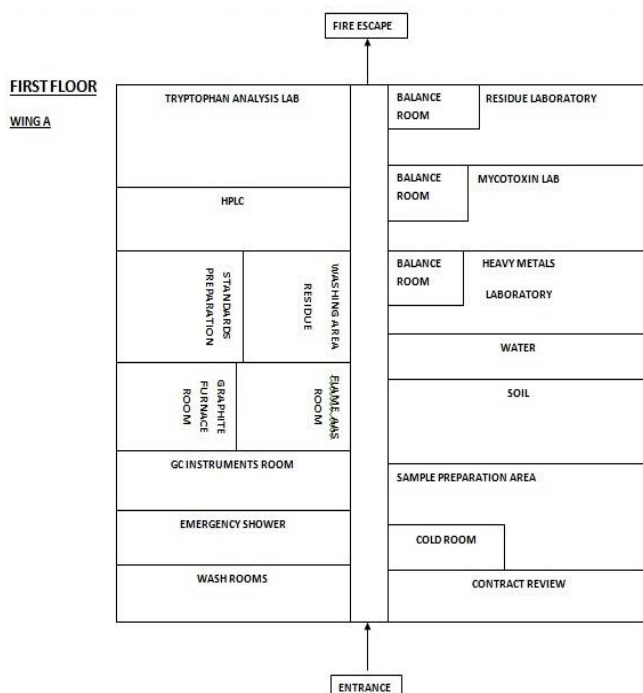
ANNEX 1: MANAGEMENT SYSTEM: KEPHIS ORGANOGRAM



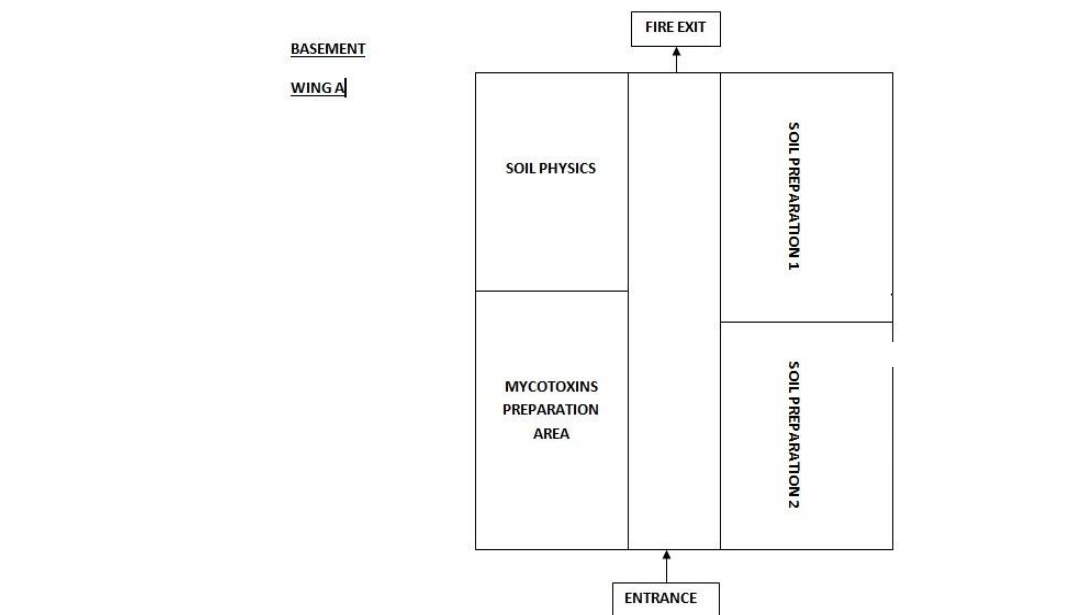
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ANNEX 2: ANALYTICAL CHEMISTRY LABORATORIES COMPLEX SITE LAYOUT

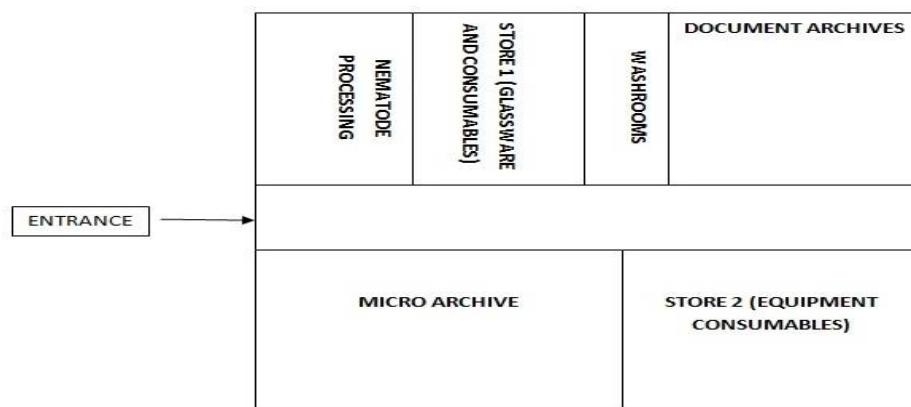


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BASEMENT FLOOR

WING B



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