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ACCREDITATION
SERVICE

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Criteria for Accreditation of Chemical Testing Laboratories

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1 Background Information

1.1 Purpose

This document has been prepared by the Technical Committee on Testing and Calibration and authorized for adoption by KENAS. It supplements ISO/ IEC 17025 standard and provides specific guidance on the accreditation of chemical laboratories for use by assessors and by laboratories preparing for accreditation. It gives detailed guidance for those undertaking qualitative and quantitative examination of the composition, nature and properties of materials, products and substances.

1.2 Scope

This document covers the application of the ISO/ IEC 17025 for accreditation of chemical testing laboratories. This document should be read in conjunction with the Rules and Procedures of KENAS.

1.3 Role(s) and Responsibility

Role	Responsibility
All KENAS Technical Staff	Process owner
MEDO	Reviewer
CMLA	Recommender
CEO	Approval
Accreditation Committee	Compliance

2 Terms and Definitions

For the purpose of this manual, the following terms and definitions shall apply in addition to those given in ISO/IEC 17000 and the Kenya Accreditation Service Act 2019.

2.1 Acronyms and Abbreviations

CEO	Chief Executive Officer
CMLA	Chief Manager, Laboratories
KEBS	Kenya Bureau of Standards
KENAS	Kenya Accreditation Service
NMI	National Metrology Institute
NSB	National Standards Body

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MEDO	Medical Officer
TC	Technical Officer
MR	Management Representative

2.2 Definition of Terms

2.2.1 Accreditation

A third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks.

2.2.2 Committee

A group of people appointed for a specific function by a larger group or organization.

2.2.3 Selectivity

Selectivity of a method refers to the extent to which it can determine particular analyte(s) in a complex mixture without interference from the other components in the mixture. A method which is perfectly selective for an analyte or group of analytes is said to be specific. The applicability of the method should be studied using various samples, ranging from pure standards to mixtures with complex matrices. In each case the recovery of the analyte(s) of interest should be determined and the influences of suspected interferences duly stated. Any restrictions in the applicability of the technique should be documented in the method.

2.2.4 Range

For quantitative analysis the working range for a method is determined by examining samples with different analyte concentrations and determining the concentration range for which acceptable accuracy and precision can be achieved. The working range is generally more extensive than the linear range, which is determined by the analysis of a number of samples of varying analyte concentrations and calculating the regression from the results, usually using the method of least squares. The relationship of analyte response to concentration does not have to be perfectly linear for a method to be effective. For methods showing good linearity five different standards (plus a blank) are usually sufficient for producing calibration curves. More standards will be required where linearity is poor. In qualitative analysis, it is commonplace to examine replicate samples and standards over a range of concentrations to establish at what concentration a reliable cut-off point can be drawn between detection and non-detection.

2.2.5 Linearity

Linearity is determined by the analysis of samples with analyte concentrations spanning the claimed range of the method. The results are used to calculate a

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regression line against analyte calculation using the least squares method. It is convenient if a method is linear over a particular range but it is not an absolute requirement. Where linearity is unattainable for a particular procedure, a suitable algorithm for calculations should be determined.

2.2.6 Sensitivity

Sensitivity is the difference in analyte concentration corresponding to the smallest difference in the response of the method that can be detected. It is represented by the slope of the calibration curve and can be determined by a least squares procedure, or experimentally, using samples containing various concentrations of the analyte.

2.2.7 Limit of Detection

Limit of detection of an analyte is determined by repeat analysis of a blank test portion and is the analyte concentration whose response is equivalent to the mean blank response plus 3 standard deviations. Its value is likely to be different for different types of sample.

2.2.8 Ruggedness

Sometimes also called robustness. Where different laboratories use the same method they inevitably introduce small variations in the procedure, which may or may not have a significant influence on the performance of the method. The ruggedness of a method is tested by deliberately introducing small changes to the method and examining the consequences. A large number of factors may need to be considered, but because most of these will have a negligible effect, it will normally be possible to vary several at once. The technique is covered in detail by the Association of Analytical Communities (AOAC). Ruggedness is normally evaluated by the originating laboratory, before other laboratories collaborate.

2.2.9 Accuracy

The accuracy of a method is the closeness of the obtained analyte value to the true value. It can be established by analyzing a suitable reference material. Where a suitable reference material is not available, an estimation of accuracy can be obtained by spiking test portions with chemical standards. The value of spiking is limited; it can only be used to determine the accuracy of those stages of the method following the spiking. Accuracy can also be established by comparison with results obtained by a definitive method or other alternative procedures and via inter comparison studies.

2.2.10 Precision

Precision of a method is a statement of the closeness of agreement between mutually independent test results and is usually stated in terms of standard deviation. It is generally dependent on analyte concentration, and this dependence should be determined and documented. It may be stated in different ways depending on the conditions in which it is calculated. Repeatability is a type of precision relating to measurements made under repeatable conditions, i.e. same method; same material;

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same operator; same laboratory; narrow time period. Reproducibility is a concept of precision relating to measurements made under reproducibility conditions, i.e. same method; different operator, different laboratories; different equipment; long time period.

2.2.11 Reference Material

A reference material (RM) is a material or substance one or more properties of which are sufficiently established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials.

2.2.12 Certified Reference Material

A certified reference material (CRM) is a reference material one or more of whose property values are certified by a technically valid procedure, accompanied by, or traceable to a certificate or other documentation which is issued by a certifying body.

2.2.13 Sample

A portion of material selected to represent a larger body of material.

2.2.14 Sample Handling

Manipulation to which samples are exposed during the sampling process, from the selection from the original material through to the disposal of all samples and test portions.

2.2.15 Sub-sample

A portion of the sample obtained by selection or division; an individual unit of the lot taken as part of the sample or; the final unit of multistage sampling.

2.2.16 Sample Preparation

A procedure followed to select the test portion from the sample (or sub sample) and includes: in laboratory processing; mixing; reducing; coning and quartering; riffling; and milling and grinding.

2.2.17 Test Portion

Actual material weighed or measured for the analysis.

2.2.18 Sampling Plan

Combination of sample size(s) to be used and associated lot acceptability criteria.

2.2.19 Spiked Sample

A sample to which a known amount of the analyte has been deliberately added

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3 Criteria

3.1 Scope of Accreditation

3.1.1 The scope of accreditation of a laboratory is the formal statement of the range of activities for which the laboratory has been accredited. The scope is recorded in detail on a laboratory's accreditation certificate. A laboratory's scope should be defined as precisely as possible so that all parties concerned know accurately and unambiguously the range of tests and/or analyses covered by that particular laboratory's accreditation. The schedule format should typically define the laboratory's accreditation in terms of;

a) The range of products, materials or sample types tested or analyzed
b) Types of tests or analysis carried out
c) The specification or method/technique used
d) The concentration range and accuracy/precision.

3.1.2 Where non-routine testing is carried out, it is recognized that a more flexible approach to scope may be necessary, but the scope must be as specific as is feasible and the quality assurance system maintained by the laboratory must ensure that the quality of the results is under control. Frequently, a single measurement technique may be used for different analytes in a wide variety of samples.

3.1.3 This measurement stage may be covered by a single method. However, the methods used to prepare the samples for subsequent analysis may vary considerably according to the nature of the analyte and sample matrix. Thus several methods may be required to cover each different analyte matrix combination. This is illustrated by gas chromatography, a technique applicable to a wide variety of analytes. Depending on the matrix, a diverse range of methods may be used to prepare analytes for gas chromatographic analysis; however, variation in the procedures involved in the final analytical stage is small.

3.1.4 Where a laboratory uses analytical tools such as mass spectrometry, NMR or FTIR, it may be appropriate to use the terms of qualitative and/or quantitative chemical analysis under the type of test heading. However, the onus will be on the laboratory to demonstrate to the assessors that in using these techniques, it is meeting all of the criteria for accreditation. In particular, the experience, expertise and training of the staff carrying out the tests and those interpreting the data involved will be a major factor in determining whether or not such analyses can be accredited.

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3.1.5 It is accepted that it is not practicable for laboratories to use a (fully documented) standard method in the conventional sense, which sometimes specifies each sample type and determinant. In such case, the laboratory must have its own method or procedure for the use of the instrument in question, which includes a protocol defining the approach to be adopted when different sample types are analyzed. Full details of the procedures, including instrument parameters, used must be recorded at the time of each analysis such as to enable the procedure to be repeated precisely in the same manner at a later date. Where a particular analysis subsequently becomes routine, a full method as required by KENAS must be written and followed.

3.1.6 The statement in the column of the methods schedule will normally take the form of "Documented In-House Methods" using GC-coupled mass spectrometry/NMR/FTIR, ICP-MS, etc. (Refer **ISO/IEC 17025 Para 5.4.2, 5.4.3, 5.4.4** and **5.4.5**).Whenever there are deviations from standard method or inadequate clarification in Standard Method, the laboratory needs to develop effective procedure for ensuring the quality of results.

3.1.7 The approach to extending or amending the scope of accreditation should be as flexible as possible. Normally the laboratory will give written notice to KENAS of the tests, which it wishes to add to its scope, quoting Standard method references (where applicable) and providing copies of documented validated in-house methods before surveillance and re-assessment.

3.2 Technical Requirements

(ISO /IEC 17025: Clause 5)

3.2.1 Personnel (ISO /IEC 17025: Clause 5.2)

The minimum qualification for the technical personnel shall be training in Analytical chemistry and related professional qualifications

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Graduates with Chemistry as one of the subjects or equivalent qualification in chemistry with relevant work experience chosen on the basis of ability and competence as determined by the laboratories management.

3.2.3 Technical Staff - Laboratory Assistants or Technicians

a) Diploma in Laboratory Technology in Chemistry and other relevant qualifications with one year relevant work experience.
b) The Laboratory should be able to ensure the competence of each technical staff member in performing applicable tests with documentary evidence and such level of competence shall be demonstrated to the Technical Assessor

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3.3 Environment And Accommodation Conditions

(ISO/IEC 17025: Clause 5.3)

3.3.1 Samples, reagents and standards should be stored so as to ensure their integrity. The laboratory should guard against deterioration, contamination and loss of identity.

3.3.2 The Laboratory shall meet the safety requirements applicable to the test procedure wherever the published standard specifications mention such requirements

3.3.3 It may be necessary to restrict access to particular areas of laboratory because of the nature of the work carried out there. Restrictions might be made because of security, safety, or sensitivity to contamination. Typical examples might be work involving explosives, radioactive materials, carcinogens, toxic materials and trace analysis. Where such restrictions are in force, staff should be aware of;

a) The intended use of a particular area
b) The restrictions imposed on working within such areas
c) The reasons for imposing such restrictions.

3.3.4 Frequently, it will be necessary to segregate certain types of work which are prone to interferences from other work, or which present particular problems or hazards. Examples are trace analysis (where physical separation from high-level is necessary) and carcinogen analysis.

3.3.5 When selecting designated areas for special work, account must be taken of the previous use of the area. Before use, checks should be made to ensure that the area is free of contamination. Once in use, access to such areas should be restricted, and the type of work undertaken there should be carefully controlled.

3.3.6 The laboratory shall provide appropriate environmental conditions and controls necessary for particular tests, including temperature, humidity, freedom from vibration, freedom from air borne and dust borne microbiological contamination, special lighting, radiation screening.

3.3.7 Critical environmental conditions should be monitored.

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3.3.8 One key responsibility of the laboratory management is to provide an adequate and safe working environment. Laboratory facilities should reflect due consideration of space, design, security, health and safety. It is recognized that laboratories will be required to comply with Government legislation related to building and occupational safety and health. The provisions of such legislation shall be considered as additional essential requirements.

3.3.9 Each employee must have adequate work space to accomplish assigned tasks. Sufficient space must be provided for storage of supplies, equipment and tools. Analysts/examiners must have space available for writing reports and other official communications. Where possible, there must be a clear delineation of areas used for the clerical aspects of laboratory work and the areas used for testing/examinations.

3.3.10 Adequate and appropriate space must be available for records, reference work and other necessary documents. Sufficient space must be available for each instrument to facilitate its operation.

3.3.11 Accessories should be preferably stored near each instrument to facilitate its use and operation. (Laboratories in which usable space falls below adequate levels may experience health and safety problems, compromised efficiency, adversely affected morale and productivity and an increased risk of mishandling and contaminating the evidence. In designing and planning for additional space or a new facility, future space requirements should also be projected.

3.3.12 The relative locations of functional areas should facilitate the use of equipment and instruments. Adequate and proper lighting of a minimum 100 lumen must be available for personnel to carry out assigned tasks. Adequate and proper plumbing and wiring must be available and accessible.

3.3.13 The laboratory must have proper ventilation, adequate heating, cooling and humidity control as per the requirements. Bench and floor surfaces must be appropriate for the work being performed. The design should maximize laboratory functions and activities, safeguard the physical evidence, protect the confidential nature of the laboratory operations and provide a safe and healthy environment. Lack of fiscal resources is not acceptable reasons for unacceptable laboratory practices.

3.3.14 Where a laboratory exists within a host agency facility, documented procedures may be required to permit entry during off hours for emergencies. The laboratory should have a fire detection system wherever applicable. In keeping with any relevant statutory requirements appropriate fire extinguishing devices must be available and policies and procedures of laboratory security must be clearly documented. Laboratory personnel should be trained in fire fighting

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3.3.15 Health and safety aspects are to be taken seriously.

3.4 Test And Calibration Methods And Method Validation

(ISO/IEC 17025: Clause 5.4)

3.4.1 Available Standards will be used to assess the Test methods of Chemical Testing Laboratories. Laboratory, whenever using non-standard methods or a standard method beyond the stated limits of operation, is required to validate such test methods. Validation of a method establishes by systematic laboratory studies, that the performance characteristics of the method meet the specifications related to the intended use of the analytical results. The performance characteristics determined include;

a) Selectivity and specificity
b) Range
c) Linearity
d) Sensitivity
e) Limit of Detection
f) Limit of Quantitation
g) Ruggedness
h) Accuracy
i) Precision

3.4.2 Above parameters should be clearly stated in the documented method so that the user can assess the suitability of the method for their particular needs. Any other relevant parameters should be included.

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3.4.3 In theory the development should include consideration of all of the necessary aspects of validation. However, the responsibility remains firmly with the user to ensure that the validation documented in the method is sufficiently complete to fully meet his or her needs. Even if the validation is complete, the user will still need to verify that the documented performance can be met.

3.4.4 Test and calibration methods and method validation/verification published by American Society of Testing and Materials (ASTM), Association of Analytical Communities (AOAC), etc. may apply.

3.4.5 A laboratory seeking accreditation for a more open set of terms of accreditation must have fully documented procedures covering elements such as: method selection, method development, method validation or verification, acquisition of appropriate reference standards or reference materials and staff training. Records of the application of these procedures will be reviewed as part of each assessment.

3.4.6 When standard methods are used, laboratories should verify their own satisfactory performance against the documented performance characteristics of the method, before any samples are analyzed. Records of the verification must be retained. For published test methods that do not include precision data, the laboratory must determine its own precision data based on test data. All methods should include criteria for rejecting suspect results.

3.4.7 Where a test can be performed by more than one method there must be documented criteria for method selection. Where relevant the degree of correlation between the methods should be established and documented.

3.4.8 Methods developed in-house must be validated and authorized before use. Where they are available, certified reference materials should be used to determine any systematic bias, or where this is not possible results should be compared with other technique(s), preferably based on different principles of analysis.

3.4.9 All methods shall be fully documented including procedures for quality control, and the use of reference materials. It is preferable that a common format be adopted for writing up methods and suitable guidance **(ISO 78-2:** Layout for Standards – Part 2 – Standards for Chemical Analysis).

3.4.10 Developments in methodology and techniques will require methods to be changed from time to time. Obsolete methods should be withdrawn but must be retained for archive purposes and clearly labeled as obsolete. The revised method must be fully documented, and under whose authority the new method was issued/should be indicated (signed and dated).

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3.4.11 Where a change in method involves only minor adjustments, such as sample size, different reagents, the amended method should be validated and the changes brought to the attention of KENAS at their next visit. Where the proposed change in method involves a change of scope, such as a significant change in technology or methodology, the laboratory shall inform KENAS for appropriate action.

3.4.12 Laboratories are required to estimate uncertainty of measurement for the tests being carried out. This should be on the basis of standard methods which include uncertainty factors; laboratories may use them for the estimates.

3.5 Use of Computer

(ISO/IEC 17025: Clause 5.4.7)

3.5.1 In chemical testing laboratories, computers have a wide variety of uses including;

a) Control of critical environmental conditions
b) Monitoring and control of inventories
c) Calibration and maintenance schedules
d) Stock control of reagents and standard materials
e) Design and performance of statistical experiments
f) Scheduling of samples and monitoring of work throughput
g) Control chart generation
h) Monitoring of test procedures
i) Control of automated instrumentation
j) Capture, storage, retrieval, processing of data, manually or automatically
k) Matching of sample and library data
l) Generation of test reports
m) Word processing
n) Communication

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3.5.2 The chemical testing environment creates particular hazards for the operation of computers and storage of computer media. Advice can usually be found in the operating manuals, however particular care should be taken to avoid damage due to chemical, microbiological or dust contamination, heat, damp and magnetic fields.

3.5.3 If a testing instrument cannot be isolated from the data processing system, the system as a whole must be calibrated either statically or dynamically. Each such system will have to be examined individually.

3.5.4 If the testing instrument can be isolated from the data processing system, the opportunity is available to calibrate each component of the system separately. The testing instrument can be calibrated (again, statically or dynamically) in the conventional manner and a separate verification of the data processing system can be undertaken incorporating the A/D converters and interfacing systems.

3.6 Computer Controlled Automated System

(ISO/IEC 17025: Clause 5.4.7)

3.6.1 Such systems will normally be validated by checking for satisfactory operation (including performance under extreme circumstances) and establishing the reliability of the system before it is allowed to run unattended. An assessment should be made of the likely causes of system malfunction. Where possible the controlling software should be tailored to identify and highlight any such malfunctions and tag associated data. The use of quality control samples and standards run at intervals in the sample batches should then be sufficient to monitor correct performance on a day-to-day basis. Calculation routines can be checked by testing with known parameter values.

3.6.2 Electronic transfer of data should be checked to ensure that no corruption has occurred during transmission. This can be achieved on the computer by the use of `verification files' but wherever practical the transmission should be backed up by a hard copy of the data.

3.7 Laboratory Information Management Systems (LIMS)

(ISO/IEC 17025: Clause 5.4.7)

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3.7.1 LIMS systems are increasingly popular as a way of managing laboratory activities using a computer. LIMS is a software package allowing the electronic collation, calculation and dissemination of analytical data, often received directly from other instruments and it incorporates word-processing, database, spreadsheet and data processing capabilities. It can perform a variety of functions, typically sample registration and tracking; processing captured data; quality control; financial control; report generation.

3.7.2 Particular validation requirements include control of access to the various functions and audit trials to catalogue alterations and file management.

3.8 Equipment

(ISO/IEC 17025: Clause 5.5)

3.8.1 General

3.8.1.1 As part of its quality system, a laboratory is required to operate a programme for the maintenance and calibration of equipment used in the laboratory. Equipment normally found in the chemical laboratory can be categorized as;

3.8.1.2 General service equipment not used for making measurements or with minimal influence on measurements (e.g. Hotplates, stirrers, non-volumetric glassware and glassware used for rough volume measurements such as measuring cylinders) and laboratory heating or ventilation systems;

3.8.1.3 Volumetric equipment (eg. flasks, pipettes, burettes etc.).

3.8.1.4 Measuring instrument/equipment (eg. hydrometers, U-tube viscometers, thermometers, timers, spectrometers, chromatographs, electrochemical meters, balances etc).

3.8.1.5 Physical standards (weights, reference thermometers).

3.8.2 General Service Equipment

3.8.2.1 General Service equipment is maintained by appropriate cleaning and checks for safety as necessary. Calibrations or performance checks will be necessary where the setting can significantly affect the test or analytical result (eg. the temperature of a muffle furnace or constant temperature bath).

3.8.3 Volumetric equipment

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3.8.2.2 The correct use of volumetric equipment is critical to analytical measurements and it shall be suitably maintained and calibrated. The correct functioning of some specialist volumetric (and related) glassware is dependent on particular factors, e.g. the performance of U-tube viscometers is dependent on 'wetting' and surface tension characteristics, which may be affected by cleaning methods etc. Such apparatus may therefore require more regular calibration, depending on use.

3.8.2.3 For the highest accuracy, measurements can often be made by mass depending on properly calibrated weighing mechanism with traceability to the NMI (KEBS) or through other accredited calibration laboratories rather than by volume.

3.8.2.4 Attention should be paid to the possibility of contamination arising from the equipment or cross-contamination from previous use. The type used (glass, PTFE, etc), cleaning, storage, and segregation of volumetric equipment is critical, particularly for trace analyses when leaching and adsorption can be significant.

3.8.3 Measuring Instrument / Equipment

3.8.3.1 Correct use combined with periodic servicing, cleaning and calibration will not necessarily ensure an instrument is performing adequately. Where appropriate, periodic performance checks should be carried out (e.g. to check the response, stability and linearity of sources, sensors and detectors, the separating efficiency of chromatographic systems, the resolution, alignment and wavelength accuracy of spectrometers etc.).

3.8.3.2 The frequency of such performance checks will be determined by experience and based on need, type and previous performance of the equipment. Intervals between checks should be shorter than the time the equipment has been found to take to drift outside acceptable limits.

3.8.3.3 It is often possible to build performance checks – system suitability checks – into test methods (eg. based on the levels of expected detector or sensor response to calibrates, the resolution of calibrates in separating systems, the spectral characteristics of calibrates etc).

3.8.3.4 These checks should be satisfactorily completed before the equipment is used.

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3.8.4 Physical Standards

3.8.4.1 Wherever physical parameters are critical to the correct performance of a particular test, the laboratory shall have or have access to the relevant reference standard, as a means of calibration.

3.8.4.2 Reference standards and accompanying certificates should be stored and used in a manner consistent with preserving the calibration status. Particular consideration should be given to any storage advice given in the documentation supplied with the standard.

3.9 Calibration And Measurement Traceability

(ISO/IEC 17025: Clause 5.5)

3.9.1 The overall programme for the calibration of measuring equipment in the chemical laboratory shall be designed to ensure that, where the concept is applicable, all measurements are traceable through certificates held by the laboratory, either to a national or international standard or to a certified reference material.

3.9.2 Where no such reference standard or certified reference material is available, a material with suitable properties and stability should be selected or prepared by the laboratory and used as a laboratory reference. The required properties of this material should be characterized by repeat testing, preferably by more than one laboratory and using a variety of methods (Refer **ISO Guide 35**: Reference Materials – General and Statistical Principles for Certification).

3.9.3 Analytical tests may be sub-divided into three general classes depending on the type of calibration required.

3.9.4 In general, standards exist for ensuring traceability to international or national standards for equipment used for the direct measurement of fundamental properties (e.g., mass, length, temperature and time) or the simpler derived properties (eg. area, volume and pressure). Where these properties have a significant effect on the results of an analysis, the requirements of **ISO/IEC 17025** shall be met.

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3.9.5 Where a test is used to measure an empirical property of a sample, such as flashpoint, equipment is often defined in a national or international standard method and traceable reference materials should be used for calibration purposes where available. New or newly acquired equipment should be checked by the laboratory before use to ensure conformity with specified design, performance and dimension requirements.

3.9.6 Instruments such as chromatographs and spectrometers, which require calibration as part of their normal operation, should be calibrated using chemicals of known and purity or reference materials of known composition.

3.9.7 Individual calibration programmes shall be established depending on the specific requirements of the analysis. Also, it may be necessary to check instrument calibration after any shutdown, whether deliberate or otherwise, and following service or other substantial maintenance. The level and frequency of calibration should be at least as recommended by the manufacturer.

3.10 Reference Materials And Chemical Standards

(ISO/ IEC 17025: Clause 5.6)

3.10.1 Reference materials provide essential traceability in chemical measurements and are used to demonstrate the accuracy of results, calibrate equipment and methods, monitor laboratory performance and validate methods, and enable comparison of methods by use as transfer standards. Their use is encouraged wherever possible.

3.10.2 Where matrix interferences exist, ideally a method should be validated using a matched matrix reference material certified in a reliable manner. If such a material is not available it may be acceptable to use spiked sample.

3.10.3 It is important that the Certified Reference Material (CRM) has been produced and characterized in a technically valid manner. Users of CRMs should be aware that not all materials are validated to the same standard. Details of homogeneity trials, stability trials, the methods used in certification, and the uncertainties and variations in the stated analyte values are usually available from the producer and should be used to judge the pedigree.

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3.10.4 For many types of analysis, calibration may be carried out using standards prepared within the laboratory from chemicals of known purity and composition. Some chemicals may be purchased with manufacturers certificates stating purity. Whatever the source, it is the users' responsibility to verify that quality of such standards is satisfactory. Normally a new batch of a standard should be checked against the old. All chemical standards should be subjected to inter/intra laboratory comparisons (amongst referred laboratories).

3.10.5 Standards for compounds (e.g. organic compounds) which are not available with international traceability, should be procured from reputed manufacturers with assured quality supported by certificate of analysis from the manufacturer

3.10.6 Reference materials and chemical standards should be clearly labeled so that they are unambiguously identified and referenced against accompanying certificates or other documentation. Information should be available indicating shelf-life, storage conditions, applicability, restrictions of use, etc.

3.10.7 Reference materials and standards should be handled in order to safeguard against contamination or loss of determinant. Training procedures should reflect these requirements.

3.11 Sampling And Sample Preparation

(Iso/ Iec 17025: Clause 5.7)

3.11.1 Selection of an appropriate sample or samples from a larger amount of material is a very important stage in chemical analysis. It is rarely straight forward. Ideally, if the final results produced are to be of any practical value, the sampling stages should be carried out by, or under the direction of a competent person, with an understanding of the overall context of the analysis. Sampling is the operation of selecting part of the elements of a set, so that it precisely represents the distribution of the properties that we wish to measure in the total set. The selection of the elements constituting the sample is determined by means of a procedure known as the "Sampling Plan" (Quantity, Frequency, Preparation etc).

3.11.2 The various terms used in sampling are dealt with in detail in the recommendations published by International Union of Pure and Applied Chemistry (IUPAC).

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3.11.3 Where the test portion is not representative of the original material, it will not be possible to relate the analytical result measured to that in the original material as the final result may be dependent on the analytical method and the sampling process.

3.11.4 As analytical methodology improves and methods allow or require the use of smaller test portions the errors associated with sampling become increasingly important. Sampling errors cannot be controlled by the use of standards or reference materials. Sampling is always an error generating process and hence demands utmost care.

3.11.5 Sample packaging and instruments used for sample manipulation should be selected so that all surfaces in contact with the sample are essentially inert. Particular attention should be paid to possible contamination of samples by metals or plasticizers leaching from the container or its stopper into the sample. The packaging should also ensure that the sample can be handled without causing a chemical or microbiological hazard. The enclosure of the packaging should be adequate to ensure that there is no leakage of sample from the container and that contamination cannot enter.

3.11.6 The extent to which laboratories become involved in sampling varies. Some laboratories have no responsibility for sampling; others have partial involvement, while many have total responsibility for both sampling and testing. It is essential that the laboratory have available fully documented procedures for sampling. These may take the form of existing National or International Standards. For in-house procedures, these will be assessed on the basis of the suitability of the documented procedures for their intended purposes. All sampling equipment and devices specified in a procedure will need to be available, be well maintained and fully comply with dimensional and other tolerances specified in the relevant standard.

3.11.7 Supervisory staff, responsible for the design and documentation of sampling procedures, must be able to demonstrate the validity of the design of these procedures. The training and supervision of samplers must be shown to be satisfactory. Sampling procedures will usually be witnessed as part of on-site assessments of laboratories seeking such registration.

3.12 Handling Of Test / Calibration Items

(ISO/ IEC 17025: Clause 5.8)

3.12.1 Sample identification

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3.12.1.1 All samples must be uniquely and clearly identified. Identification labels must be secured and legible. Labeling on caps or lids is considered as poor practice as it can lead to possible mixing of sample identities during testing of like batches.

3.12.1.2 Containers should be leak-proof and impervious to possible contamination during transport.

3.12.1.3 Where specified, samples should be maintained within set temperature or other environmental tolerances during transfer to the laboratory and prior to testing. In some cases, it may be necessary for sample containers to be pre-tested prior to use to ensure freedom from contamination.

3.12.2 Sample registration

3.12.2.1 3.12.2.1On receipt, a sample must be registered into the laboratory records. The form of registration may vary. In most laboratories, a sample register will be used, but in some cases, the sample details may be written directly on worksheets or into workbooks.

3.12.3 Sample retention and storage

3.12.3.1 Sample retention criteria cannot be standardized due to the varying stability and storage considerations which apply for different materials. Each laboratory's sample retention and storage practices are, therefore, examined individually in the light of the types of materials tested, the use-life of the products or materials which the samples represent and the likely periods within which a recipient of the test results may request a retest.

3.12.3.2 Samples should be stored so that there is no hazard to laboratory staff and the integrity of the samples is preserved. Storage areas should be kept clean and organized so that there is no risk of contamination or cross-contamination, or of packaging and any related seals being damaged. Extremes of environmental conditions should be avoided, which might change the composition of the sample, for example, causing loss of analyte through degradation or adsorption. If necessary environmental monitoring should be used. An appropriate level of security should be exercised to restrict unauthorized access to the samples.

3.12.3.3 All staff concerned with administration of the sample handling system should be properly trained. The laboratory should have a documented policy for the retention and disposal of samples. The disposal procedure should take into account of the guidelines set out above.

3.12.4 Reagents

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3.12.4.1 The laboratory should purchase reagents only from reliable and reputed manufacturers. The laboratory should also ensure that the quality of the reagents used is appropriate for the tests concerned. The grade of reagent used (including water) should be as stated in the method together with guidance on any specific precautions which should be observed in its preparation or use. These precautions include toxicity; flammability; stability to heat, air and light; reactivity to other chemicals; reactivity to particular containers; and other hazards.

3.12.4.2 Labelling of reagents should identify substance, strength, solvent (where not water), any special precautions or hazards, restrictions of use, and date of preparation and/or expiry if applicable. The person responsible for the preparation of the reagent shall be identifiable either from the label or from records.

3.12.4.3 Reagents used as primary standards for volumetric and gravimetric methods should have traceability to National and International standards. In cases where primary standards are not available the reagents should be analytical grade. Reagents used for volumetric analysis should be of periodically check for their strength and document properly. Records are maintained.

3.13 Assuring The Quality Of Test Results

(ISO/IEC 17025 :Clause 5.9)

3.13.1.1 Assurance and Quality Control

3.13.1.2 Analytical performance must be monitored by using quality control procedures appropriate to the type and frequency of the testing undertaken. The range of quality control activities available to laboratories include the use of:

a) Reference collections
b) Certified reference materials
c) Internally generated reference materials
d) Independent checks by other analysts/examiners
e) Statistical tables
f) Positive and negative controls
g) Control charts
h) Replicate testing
i) Alternative methods
j) spiked samples, standard additions and internal standards
k) Correlation of results for different characteristics of an item
l) Retesting of retained items

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3.13.1.3 Depending on the particular test/examination, one or more of these examples may be appropriate. Quality control procedures must be documented. A record must be retained to show that appropriate quality control measures have been taken, that quality control results are acceptable or, if not, that remedial action has been taken. Where appropriate, quality control data must be recorded in such a way that trends in analysis can be readily evaluated. It is desirable to participate in proficiency testing for better quality assurance of test results

3.13.2 Internal Quality Control

3.13.2.1 level adopted should be demonstrably sufficient to ensure the validity of the results. As a guide, for routine analysis the level of internal QC typically should be not less than 5% of the sample throughout, e.g. One in every twenty samples analyzed should be a QC sample. For more complex procedures, 20% is not unusual and on occasions even 50% may be required.

3.13.2.2 For analyses performed infrequently, a full system validation should be performed on each occasion. This may typically involve the use of a reference material containing a certified or known concentration of analyte, followed by replicate analyses of the sample and spiked sample. Those analyses undertaken more frequently should be subject to systematic QC procedures incorporating the use of control charts and check samples.

3.13.3 Applicable Products Groups in Chemical Testing

3.13.3.1 Adhesives & sealants, Resins

3.13.3.2 Air, gases & atmosphere

3.13.3.3 Biocides

3.13.3.4 Building Materials

3.13.3.5 Cement and related products

3.13.3.6 Clays, Ceramics and related materials

3.13.3.7 Coal, Coke & other solid fuels

3.13.3.8 Cosmetics & essential oils

3.13.3.9 Drugs & Pharmaceuticals

3.13.3.10 Explosives & pyrotechnics

3.13.3.11 Fertilizers

3.13.3.12 Industrial & fine chemicals

3.13.3.13 Inks, dyes & pigments

3.13.3.14 Leather & Leather Products

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3.13.3.15 Food & agricultural products

3.13.3.16 Metals & alloys

3.13.3.17 Oils & lubricants

3.13.3.18 Ores & Minerals

3.13.3.19 Organic chemicals

3.13.3.20 Paints & surface coatings

3.13.3.21 Petroleum products

3.13.3.22 Plastics & plastic products

3.13.3.23 Pollution & effluents

3.13.3.24 Pulp & Paper

3.13.3.25 Residues in water & food Products

3.13.3.26 Rubber & rubber products

3.13.3.27 Soaps & detergents

3.13.3.28 Solvents

3.13.3.29 Textile & related products

3.13.3.30 Water

4 Associated Documents

Ref	Document Identifier	Document Title
1.	ISO/IEC 17011	Conformity Assessment-General requirements for accreditation bodies accrediting conformity assessment bodies
2.	ISO/IEC 17025	Conformity Assessment – General requirements for Testing and Calibration Laboratories
3.	ACC-FM-28-01	Confidentiality Form

5 Revision/ Amendment Records

Date	Ver	Revised By	Reason for Revision
10/10/2022	01	RSQ	Newly developed/formatted document

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