INTERNATIONAL STANDARD

CD1 ISO/IEC 17025

General requirements for the competence of testing and calibration laboratories

Exigences générales concernant la compétence des laboratoires d'étalonnages et d'essais

Contents

Foreword

ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) form the specialized system for worldwide standardization. National bodies that are members of ISO or IEC participate in the development of International Standards through technical committees established by the respective organization to deal with particular fields of technical activity. ISO and IEC technical committees collaborate in fields of mutual interest. Other international organizations, governmental and non-governmental, in liaison with ISO and IEC, also take part in the work. In the field of conformity assessment, ISO and IEC develop joint ISO/IEC documents under the management of the ISO Committee on Conformity assessment (ISO/CASCO).

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO and IEC shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

ISO/IEC 17025 was prepared by the *ISO Committee on Conformity Assessment* (CASCO). It was circulated for voting to the national bodies of both ISO and IEC, and was approved by both organizations.

This third edition cancels and replaces the second edition (ISO/IEC 17025:2005), which has been technically revised.

Introduction

This International Standard has been drawn up with the objective of promoting confidence in the operation of testing and calibration laboratories.

This standard contains requirements for testing and calibration laboratories to enable them to demonstrate they operate laboratories competently, and are able to generate technically valid results.

This International Standard requires the laboratory to plan and implement actions to address risks and opportunities. Addressing both risks and opportunities establishes a basis for increasing the effectiveness of the quality management system, achieving improved results and preventing negative effects. The laboratory is responsible for deciding which risks and opportunities need to be addressed.

The acceptance of testing and calibration results between countries are facilitated if laboratories comply with this International Standard and if they obtain accreditation from bodies which have entered into mutual recognition agreements with equivalent bodies in other countries using this International Standard.

The use of this International Standard will facilitate cooperation between laboratories and other bodies, and assist in the exchange of information and experience, and in the harmonization of standards and procedures.

General requirements for the competence of testing and calibration laboratories

1 Scope

1.1. This International Standard specifies the general requirements for the competence and consistent operation of laboratories to carry out tests and/or calibrations, including sampling. It covers testing and calibration performed using standard methods and non-standard methods, including laboratory-developed methods.

1.2. This International Standard is applicable to all organizations performing testing and/or calibrations. These include laboratories with different levels of independence and organizations where testing and/or calibration forms part of inspection or product certification.

1.3. This International Standard is applicable to all laboratories regardless of the number of personnel or the extent of the scope of testing and/or calibration activities.

1.4. Laboratory customers, regulatory authorities, organizations and schemes using peer-assessment, accreditation bodies, and others can also use this International Standard in confirming or recognizing the competence of laboratories.

1.5. This International Standard covers technical competence requirements that are not covered by ISO 9001.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 9000, *Quality management systems — Fundamentals and vocabulary*

ISO/IEC 17000, *Conformity assessment — Vocabulary and general principles*

ISO/IEC Guide 99(JCGM 200:2012), *International vocabulary of metrology — basic and general concepts and associated terms (VIM)*, issued by BIPM, IEC, IFCC, ILAC, ISO, IUPAC, IUPAP and OIML

3 Terms and definitions

For the purposes of this document, the relevant terms and definitions given in ISO/IEC 17000 and ISO/IEC Guide 99 apply.

General definitions related to quality are given in ISO 9000, whereas ISO/IEC 17000 gives definitions specifically related to conformity assessment and laboratory accreditation. Where different definitions are given in ISO 9000, the definitions in ISO/IEC 17000 and ISO/IEC Guide 99 are preferred.

3.1
impartiality
presence of objectivity

Note 1 to entry: Objectivity is understood to mean that conflicts of interest do not exist, or are resolved so as not to adversely influence the activities of the laboratory.

Note 2 to entry: Other terms that are useful in conveying the element of impartiality are independence, freedom from conflicts of interest, freedom from bias, freedom from prejudice, neutrality, fairness, open-mindedness, even-handedness, detachment and balance

[SOURCE: ISO/IEC 17021-1:2015, 3.2]

3.2
complaints
expression of dissatisfaction other than *appeal* (ISO/IEC 17000 6.4,) by any person or organization to a laboratory, relating to the activities or results of that laboratory where a response is expected

[SOURCE: ISO 17000:2004, 6.5 — modified: *conformity assessment body* or *accreditation body* replaced by *laboratory* and added the term *results*.]

3.3
measuring equipment
measuring instrument, software, measurement standard, reference material or auxiliary apparatus or combination thereof necessary to realize a measurement process

[SOURCE: ISO 9000:2005, 3.10.4]

3.4
interlaboratory comparison
organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions

[SOURCE: ISO/IEC 17043:2010, 3.4]

3.5
proficiency testing
evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons

Note 1 to entry: For the purposes of this International Standard, the term "proficiency testing" is taken in its widest sense and includes, but is not limited to:

a) quantitative scheme — where the objective is to quantify one or more measurands of the proficiency test item;

b) qualitative scheme — where the objective is to identify or describe one or more characteristics of the proficiency test item;

c) sequential scheme — where one or more proficiency test items are distributed sequentially for testing or measurement and returned to the proficiency testing provider at intervals;

d) simultaneous scheme — where proficiency test items are distributed for concurrent testing or measurement within a defined time period;

e) single occasion exercise — where proficiency test items are provided on a single occasion;

f) continuous scheme — where proficiency test items are provided at regular intervals;

g) sampling — where samples are taken for subsequent analysis; and

h) data transformation and interpretation — where sets of data or other information are furnished and the information is processed to provide an interpretation (or other outcome).

Note 2 to entry: Some providers of proficiency testing in the medical area use the term "External Quality Assessment (EQA)" for their proficiency testing schemes, or for their broader programmes, or both.

[SOURCE: ISO/IEC 17043:2010, 3.7— modified: *the reference to the Annex and the last sentence of note 2 deleted.*]

3.6
method

published process associated with the test of an item

Note to entry: For calibration laboratories it is understood to be the term “measurement procedure” as defined in the VIM.

3.7
validation
confirmation through the provision of objective evidence that the particular requirements for a specific intended use or application are fulfilled

4 General requirements

4.1 Impartiality

4.1.1 Testing and calibration activities shall be undertaken impartially and structured and managed so as to safeguard impartiality.

4.1.2 The laboratory management shall be committed to impartiality.

4.1.3 The laboratory shall be responsible for the impartiality of its testing and calibration activities and shall not allow commercial, financial or other pressures to compromise impartiality.

4.1.4 The laboratory shall identify risks to its impartiality on an on-going basis. This shall include those risks that arise from its activities, or from its relationships, or from the relationships of its personnel. However, such relationships do not necessarily present a laboratory with a risk to impartiality.

NOTE 1 A relationship that threatens the impartiality of the laboratory can be based on ownership, governance, management, personnel, shared resources, finances, contracts, marketing (including branding), and payment of a sales commission or other inducement for the referral of new customers, etc.

NOTE 2 If the laboratory is part of an organization performing activities other than testing and/or calibration, defining the responsibilities of key personnel in the organization that have an involvement or influence on the testing and/or calibration activities of the laboratory can identify potential conflicts of interest.

4.1.5 If a risk to impartiality is identified, the laboratory shall be able to demonstrate how it eliminates or minimizes such risk.

4.2 Confidentiality

4.2.1 The laboratory shall be responsible, through legally enforceable commitments, for the management of all information obtained or created during the performance of testing and calibration activities. The laboratory shall inform the customer in advance, of the information it intends to place in the public domain. Except for information that the customer makes publicly available, or when agreed between the laboratory and the customer (e.g. for the purpose of responding to complaints), all other information is considered proprietary information and shall be regarded as confidential.

NOTE Legally enforceable commitments can be, for example, contractual agreements.

4.2.2 When the laboratory is required by law or authorized by contractual arrangements to release confidential information, the customer or individual concerned shall, unless prohibited by law, be notified of the information provided.

4.2.3 The laboratory shall have policies and procedures to ensure the protection of its customers' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results.

4.2.4 Personnel, including any committee members, contractors, personnel of external bodies, or individuals acting on the laboratory's behalf, shall keep confidential all information obtained or created during the performance of the laboratory's testing or calibration activities, except as required by law.

5 Structural requirements

5.1. The laboratory shall be a legal entity, or a defined part of the legal entity, such that it can be held legally responsible for all its activities.

NOTE A governmental laboratory is deemed to be a legal entity on the basis of its governmental status.

5.2 It is the responsibility of the laboratory to carry out its activities in the laboratory's permanent facilities, at sites away from its permanent facilities, or in associated temporary or mobile facilities, or at a customer's facility, in such a way as to meet the requirements of this International Standard and to satisfy the needs of the customer, the regulatory authorities and the requirements of the organizations providing recognition.

5.3 A laboratory shall define its scope of operations or services which comply with this International Standard.

5.4 The laboratory shall normally perform itself the services it contracts to undertake.

5.5. The laboratory shall:

a) have managerial and technical personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including the implementation, maintenance and improvement of the management system, and to identify the occurrence of deviations from the management system or from the procedures for performing tests and/or calibrations, and to initiate actions to prevent or minimize such deviations ;

b) define the organization and management structure of the laboratory, its place in any parent organization, and the relationships between quality management, technical operations and support services;

c) specify the responsibility, authority and interrelationships of all personnel who manage, perform or verify work affecting the quality of the tests and/or calibrations;

d) have technical management which has overall responsibility for the technical operations and the provision of the resources needed to ensure the required quality of laboratory operations;

e) identify management who, irrespective of other responsibilities, shall have responsibility and authority that include the following:

   — ensuring that processes and procedures needed for the management system are established, implemented and maintained; and

   — reporting on the performance of the management system and any need for improvement.

5.6 Laboratory management shall ensure that:

a) appropriate communication processes are established between the laboratory and its stakeholders and within the laboratory;

b) communication takes place regarding the effectiveness of the management system;

c) the importance of meeting customer requirements as well as statutory and regulatory requirements is communicated to the laboratory personnel;

d) the integrity of the management system is maintained when changes to the management system are implemented.

6 Resource requirements

6.1 General

6.1.1 The laboratory shall have available personnel, accommodation and environmental conditions, measuring equipment, information system(s) and support services necessary to perform its laboratory activities.

6.1.2 When resources do not exist, and the laboratory subcontracts all or parts of the service, it shall ensure and be able to demonstrate that the subcontractor is competent to perform the activities in question and, where applicable, complies with the relevant requirements stipulated in this International Standard, in other relevant conformity assessment standards or customer requirements.

6.1.3 The laboratory shall use personnel who are employed by, or under contract to, the laboratory. Where contracted personnel are used, the laboratory shall ensure that such personnel are supervised and competent and that they work in accordance with the laboratory's management system.

6.1.4 All personnel of the laboratory, either internal or external, that could influence the laboratory activities, shall act impartially.

6.1.5 The laboratory shall manage the risk to impartiality arising from over-familiarity between its personnel and the customer.

6.2 Personnel

6.2.1 The laboratory shall define and document the competence requirements for all personnel involved in laboratory activities, including requirements for education, qualification, training, technical knowledge, skills and experience. The laboratory shall have a job description or other documentation for each function within its organization involved in laboratory activities and communicate to relevant personnel.

6.2.2 The personnel shall have relevant knowledge of the activities for which they are responsible and understand the significance of and response to deviations found with regard to the normal laboratory activities.

6.2.3 The laboratory shall communicate to each person their duties, responsibilities and authorities.

6.2.4 The laboratory shall have documented procedures for selecting, training, formally authorizing, and monitoring personnel involved in laboratory activities.

6.2.5 Authorizations shall be given to specific personnel to perform particular types of sampling, test and/or calibration, to issue test reports and calibration certificates, to give opinions and interpretations and to operate particular types of equipment.

6.2.6 The laboratory shall maintain records of monitoring, education, training, technical knowledge, skills, experience and authorizations.

6.2.7 The laboratory shall provide adequate supervision of testing and calibration personnel, including trainees, by persons familiar with methods and procedures, the purpose of each test and/or calibration, and with the assessment/ verification of the accuracy of the test or calibration results.

6.3 Accommodation and environmental conditions

6.3.1 Laboratory facilities for testing and/or calibration shall facilitate correct performance of laboratory activities. There shall be effective separation between neighbouring areas in which there are incompatible activities. Measures shall be taken to prevent cross-contamination, interference or adverse influence. Access to and use of areas affecting laboratory activities shall be controlled. The laboratory shall determine the extent of control based on its particular circumstances.

6.3.2 The laboratory shall ensure that the environmental conditions are suitable to realize the laboratory activities and do not invalidate the results or adversely affect the required quality of any measurement. Particular care shall be taken when sampling and tests or calibrations are undertaken at sites other than a permanent laboratory facility. The technical requirements for accommodation and environmental conditions that can affect the results of tests and calibrations shall be documented. Measures shall be taken to ensure good housekeeping in the laboratory. Special procedures shall be prepared where necessary.

6.3.3 The laboratory shall establish, monitor, control (where appropriate) and record environmental conditions as required by the relevant specifications, methods and procedures or where they influence the quality of the results. Tests and calibrations shall be stopped when the environmental conditions jeopardize the results of the tests and/or calibrations.

6.4 Externally provided products and services

6.4.1 The laboratory shall have a policy and procedure(s) for the selection and purchasing of products and services it uses that affect the quality of the tests and/or calibrations.

6.4.2 Procedures shall exist for the purchase, reception and storage of reagents and laboratory consumable materials relevant for the tests and calibrations.

6.4.3 The laboratory shall evaluate and record evidence of compliance for suppliers of critical consumables, supplies and services which affect the quality of testing and calibration, and shall maintain records of those approved.

6.4.4 The laboratory shall document all subcontractors it uses for tests and/or calibrations and maintain a record of the evidence of compliance with this International Standard for the work in question.

6.4.5 Purchasing documents for items affecting the quality of laboratory output shall contain data describing the services and supplies ordered. These purchasing documents shall be reviewed and approved for technical content prior to release.

NOTE The description may include type, class, grade, precise identification, specifications, drawings, inspection instructions, other technical data including approval of test results, the quality required and the management system standard under which they were made.

6.4.6 The laboratory shall ensure that purchased supplies and reagents and consumable materials that affect the quality of tests and/or calibrations are not used until they have been inspected or otherwise verified as complying with defined requirements. Records of actions taken to check compliance shall be maintained.

6.4.7 For subcontracted work, the laboratory shall:

a) establish and apply criteria for the evaluation, selection, monitoring of performance and re-evaluation of external providers based on their ability to provide work in accordance with specified requirements;

b) retain appropriate records of the results of the evaluations, monitoring of the performance and re-evaluations of the external providers;

c) ensure that work is placed with competent subcontractors and that work conforms to specified requirements;

NOTE A competent subcontractor is one, for example, that complies with this International Standard for the work.

d) determine the controls for:

— externally-supplied measurement data and/or results that are intended for incorporation into the laboratory's own test and/or calibration reports;

— externally-supplied products and services that are provided directly to the customer(s) on behalf of the laboratory;

e) advise the customer of the arrangement in writing and, when appropriate, gain the approval of the customer. The laboratory shall ensure the customer's requirements are communicated and observed by the vendor.

6.5 Equipment

6.5.1 The laboratory shall have available all equipment, including measuring equipment, required for the correct performance of the laboratory activities and capable of achieving the accuracy required and complying with specifications relevant to the activities concerned. In those cases where the laboratory needs to use equipment outside its permanent control, it shall ensure that the requirements of this International Standard are met.

6.5.2 The laboratory shall have documented processes for appropriate handling, transport, storage, use and planned maintenance of equipment, where applicable, to ensure proper functioning and in order to prevent contamination or deterioration.

6.5.3 Before being placed into service (and after being placed into service) equipment (including that used for sampling) shall be verified to establish its performance characteristics and that it complies with the laboratory's requirements and complies with the relevant standard specifications.

6.5.4 A calibration programme shall be established for measuring equipment unless it has been determined that the associated contribution of the measuring equipment to the uncertainty of the measurement result is negligible.

6.5.5 All measuring equipment under the control of the laboratory and requiring calibration shall be labelled, coded or otherwise identified to allow the user of the equipment to readily identify the status of calibration.

6.5.6 Records shall be maintained for equipment significant to the laboratory activities. The records shall include at least the following:

a) the identity of the item of equipment and software;

b) the manufacturer's name, type identification, and serial number or other unique identification;

c) checks that equipment complies with the specification (see 6.5.3);

d) the current location, where appropriate;

e) calibration dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and the due date of next calibration;

f) where appropriate, to the performance of the equipment the maintenance and/or quality control plan, and maintenance carried out to date;

g) any damage, malfunction, modification or repair to the equipment.

6.5.7 Equipment that has been subjected to overloading or mishandling, gives suspect results, or has been shown to be defective or outside specified limits, shall be taken out of service. It shall be isolated to prevent its use or clearly labelled or marked as being out of service until it has been repaired and shown by calibration or test to perform correctly. The laboratory shall examine the effect of the defect or deviation from specified limits on previous tests and/or calibrations and shall institute the "Management of nonconforming work" procedure (see 7.8).

6.5.8 When, for whatever reason, equipment goes outside the direct control of the laboratory, the laboratory shall ensure that the function and status of the equipment are checked and shown to be satisfactory before the equipment is returned to service.

6.5.9 When intermediate checks are needed to maintain confidence in the status of the equipment, these checks shall be carried out according to a defined procedure.

6.5.10 Where documentation of reference materials establishes certified values and where calibrations give rise to a set of correction factors, the laboratory shall have procedures to ensure those values and factors (e.g. in computer software) are correctly updated and are used.

6.5.11 Measuring equipment and software shall be safeguarded from adjustments which would invalidate the test and calibration results.

6.5.12 The laboratory shall select and use reference materials that are fit for the specific purpose in the measurement process. The laboratory shall use reference materials which fulfil the technical requirements specified in ISO 17034.

NOTE 1 A multitude of names exist for reference materials and certified reference materials, including reference standards, calibration standards, standard materials, quality control materials. For the use in the measurement process only the fulfilment of the requirements for reference materials or certified reference materials, but not the naming, is important.

NOTE 2 Reference materials can be the final reference of the traceability chain for certain measurements. Examples include isooctane as reference for octane number determinations or certain World Health Organization (WHO) materials.

NOTE 3 Reference materials may differ with respect to their position in the traceability chain (primary, secondary etc. materials). The important aspect for their applicability is, however, the uncertainty of the assigned property value.

NOTE 4 Further guidance on the selection and use of reference materials is provided in ISO Guides 31 and 33.

6.6 Metrological traceability

6.6.1 General

6.6.1.1 The laboratory shall establish metrological traceability to the International System of Units (*SI*) (*Système international d'unités*). A laboratory shall establish and maintain metrological traceability of its measurement standards and measuring equipment by means of an unbroken chain of calibrations or comparisons linking them to relevant primary standards of the SI units of measurement. The link to *SI* units may be achieved by reference to national measurement standards or certified reference materials.

NOTE See Annex A for additional information on metrological traceability.

6.6.1.2 There are certain measurements that cannot, yet, be strictly made in SI units. In these cases the laboratory shall provide confidence in measurements by establishing traceability to appropriate measurement standards such as the use of:

a) reference materials provided by a competent supplier to give a reliable physical or chemical characterization of a material;

b) results of reference measurement procedures that are clearly described and agreed by all parties concerned;

c) specified methods and/or consensus standards that are clearly described and agreed by all parties concerned.

NOTE 1 See ISO Guide 99 for definition of metrological traceability and reference materials.

NOTE 2 See Joint BIPM, OIML, ILAC and ISO declaration on metrological traceability whenever there is a need to demonstrate metrological traceability requiring international acceptability.

6.6.2 Reference measurement standards

Reference measurement standards shall be calibrated and traceable to the SI. Such standards shall only be used for calibration of working measurement standards, unless it can be shown that their performance as reference measurement standards would not be invalidated. Reference standards shall be calibrated before and after any adjustment.

6.6.3 Intrinsic measurement standards

Traceability to the SI for intrinsic measurement standards shall be established through comparison directly or indirectly with other similar standards of a national metrology institute.

6.6.4 Reference materials

Reference materials (RM) shall, where possible, be traceable to SI units of measurement, or to certified reference materials (CRM).

NOTE ISO 17034 contains additional information on reference materials and reference material producers.

7 Process requirements

7.1 Review of requests, tenders and contracts

7.1.1 The laboratory shall establish and maintain policies and procedures for the review of requests, tenders and contracts. The policies and procedures for these reviews leading to a contract for testing and/or calibration shall ensure that:

a) the requirements are adequately defined, documented and understood (see 7.7.2);

b) the laboratory has the capability and resources to meet the requirements;

c) the appropriate test method and/or calibration procedure is selected and is capable of meeting the customers' requirements (see 7.7.2);

d) when the customer requests a verification of conformity to a specification or standard for the test or calibration (e.g. pass/fail, in-tolerance/out-of-tolerance):

— the specification is clearly defined in the procedure selected;

— the decision rule for conformity, its level of risk and statistical assumptions is documented in the test method/procedure or is documented by the laboratory and communicated to the customer;

— the decision rule is agreed to by the customer.

7.1.2 Any differences between the request or tender and the contract shall be resolved before calibration or testing activities commence. Each contract shall be acceptable both to the laboratory and the customer. Deviations requested by the customer shall not jeopardize the integrity of the laboratory or the results.

NOTE For internal customers, reviews of requests, tenders and contracts can be performed in a simplified way.

7.1.3 The laboratory shall advise the customer in writing of any arrangement when the test and calibration will be completed in part or in full by an external provider and demonstrate the approval of the customer.

7.1.4 The laboratory is responsible for the subcontractor's work, except in the case where the customer or a regulatory authority specifies which subcontractor is to be used.

7.1.5 The customer shall be informed of any deviation from the contract.

7.1.6 If a contract needs to be amended after work has commenced, the same contract review process shall be repeated and any amendments shall be communicated to all affected personnel.

7.1.7 The laboratory shall be willing to cooperate with customers or their representatives in clarifying the customer's request and in monitoring the laboratory's performance in relation to the work performed, provided that the laboratory ensures confidentiality to other customers.

NOTE 1 Such cooperation can include:

a) providing the customer or the customer's representative reasonable access to relevant areas of the laboratory for the witnessing of tests and/or calibrations performed for the customer;

b) preparation, packaging, and dispatch of test and/or calibration items needed by the customer for verification purposes.

NOTE 2 Customers value the maintenance of good communication, advice and guidance in technical matters, and opinions and interpretations based on results. Communication with the customer, especially in large assignments, should be maintained throughout the work. The laboratory should inform the customer of any delays or major deviations in the performance of the tests and/or calibrations.

7.1.8 Records of reviews, including any significant changes, shall be maintained. Records shall also be maintained of pertinent discussions with a customer relating to the customer's requirements or the results of the work during the period of execution of the contract.

NOTE For review of routine and other simple tasks, the date and the identification (e.g. the initials) of the person in the laboratory responsible for carrying out the contracted work are considered adequate. For repetitive routine tasks, the review need be made only at the initial enquiry stage or on granting of the contract for on-going routine work performed under a general agreement with the customer, provided that the customer's requirements remain unchanged. For new, complex or advanced testing and/or calibration tasks, a more comprehensive record is maintained.

7.1.9 Where the customer requires deviations, additions or exclusions from the documented sampling or sample taking procedures, these shall be recorded in detail with the appropriate sampling data and shall be included in all documents containing test and/or calibration results, and shall be communicated to the appropriate personnel.

7.2 Sampling

7.2.1 The sampling process or the sample taking shall address the factors to be controlled to ensure the validity of the test and calibration results. The laboratory shall have a sampling plan and procedures for sampling and sample taking when it carries out sampling of substances, materials or products for subsequent testing or calibration. The sampling plan as well as the sampling or sampling taking procedures shall be available at the location where sampling is undertaken. Sampling plans shall, whenever reasonable, be based on appropriate statistical methods.

7.2.2 Sampling procedures shall describe the selection of samples/sites, sampling plan, withdrawal and preparation of a sample or samples from a substance, material or product to yield the required information in testing or calibration. Once received into the laboratory, the laboratory sample may require further handling such as subdivision or treatment prior to analysis.

7.2.3 Where the laboratory has not been responsible for the sampling or sample taking stage (i.e. it has been provided by the customer), it shall state in the report that the samples were analysed as received. If the laboratory has conducted or directed the sampling or sample taking stage, it should

report on the procedures used and comment on any consequent limitations imposed on the results. Deviations requested by the customer shall not jeopardize the integrity of the laboratory or the results.

7.2.4 The laboratory shall have procedures for recording relevant data and operations relating to sampling or sampling taking that forms part of the testing or calibration that is undertaken. These records shall include:

a) the sampling or sample taking procedure used;

b) the identification of the sampler;

c) if relevant, environmental conditions; and diagrams or other equivalent means to identify the sampling or sample taking location necessary.

7.3 Handling of test or calibration items

7.3.1 The laboratory shall have procedures for the transportation, receipt, handling, protection, storage, retention, disposal and return of test and/or calibration items, including all provisions necessary to protect the integrity of the test or calibration item, and to protect the interests of the laboratory and the customer.

7.3.2 The laboratory shall have a system for identifying test and/or calibration items. The identification shall be retained while the item is under the care of the laboratory. The system shall be designed and operated so as to ensure that items cannot be confused physically or when referred to in records or other documents. The system shall, if appropriate, accommodate a sub-division of groups of items and the transfer of items within and from the laboratory.

7.3.3 Upon receipt of the test or calibration item, abnormalities or deviations from normal or specified conditions, as described in the test or calibration method, shall be recorded. When there is doubt as to the suitability of an item for test or calibration, or when an item does not conform to the description provided, or the test or calibration required is not specified in sufficient detail, the laboratory shall consult the customer for further instructions before proceeding and shall record the discussion. When the customer requires the deviating item to be tested the laboratory shall include a disclaimer in the report indicating that the results may be compromised.

7.3.4 The laboratory shall have procedures and appropriate facilities for avoiding deterioration, loss or damage to the item during handling, transport, testing or storing/waiting processes and preparation. Handling instructions provided with the item shall be followed. When items have to be stored or conditioned under specified environmental conditions, these conditions shall be maintained, monitored and recorded. Where a test or calibration item or a portion of an item is to be held secure, the laboratory shall have arrangements for storage and security that protect the condition and integrity of the secured items or portions concerned.

7.3.5 Where test items are to be returned into service after testing, the laboratory shall take special care to ensure that they are not damaged or injured during the handling, testing or storing/waiting processes.

7.4 Evaluation of uncertainty of measurement

7.4.1 A laboratory performing calibrations shall have and shall apply procedures to evaluate the uncertainty of measurement for all calibrations.

7.4.2 Testing laboratories shall have and shall apply procedures for evaluating uncertainty of measurement for all tests. In certain cases the nature of the test method may preclude rigorous calculation of uncertainty of measurement. In such cases the laboratory shall at least attempt to identify all the components of uncertainty and make a reasonable evaluation of their magnitude. Reasonable evaluation shall be based on knowledge of the performance of the method and on the measurement scope and shall make use of, for example, previous experience, quality control and validation data.

7.4.3 In those cases where a well-recognized test method specifies limits to the values of the major sources of uncertainty of measurement and specifies the form of presentation of calculated results, the

laboratory is considered to have satisfied clause 7.4.2 by following the test method and reporting instructions

Note For a particular test method used in testing laboratories where the relevant measurement uncertainty of test results obtained with the method is known, there is no need to estimate uncertainty of measurement for each test result, if the identified critical influencing factors are under control and remain unchanged.

7.4.4 When evaluating the uncertainty of measurement, all components which are of significance in the given situation shall be taken into account using appropriate methods of analysis.

NOTE For further information, see ISO 5725 and ISO/IEC Guide 98-3, the Guide to the Expression of Uncertainty in Measurement.

7.5 Reporting of results

7.5.1 General

7.5.1.1 The results shall be reported, usually in a test report or a calibration certificate (see Note 1), and shall include all the information requested by the customer and necessary for the interpretation of the test or calibration results and all information required by the method used. This information is normally that required by 7.5.2 and 7.5.3 or 7.5.4.

NOTE 1 Test reports and calibration certificates are sometimes called test certificates and calibration reports, respectively.

NOTE 2 The test reports or calibration certificates may be issued as hard copy or by electronic data transfer provided that the requirements of this International Standard are met.

7.5.1.2 In the case of tests or calibrations performed for internal customers, or in the case of a written agreement with the customer, the results may be reported in a simplified way. Any information listed in 7.5.2 to 7.5.4 which is not reported to the customer shall be readily available in the laboratory which carried out the tests and/or calibrations.

7.5.2 Test reports and calibration certificates – common requirements

Each test report or calibration certificate shall include at least the following information, unless the laboratory has valid reasons for not doing so, thereby minimizing any possibility of misunderstanding or misuse:

a) a title (e.g. “Test Report” or “Calibration Certificate”);

b) the name and address of the laboratory, and the location where the tests and/or calibrations were carried out, if different from the address of the laboratory;

c) unique identification of the test report or calibration certificate (such as the serial number), and on each page an identification in order to ensure that the page is recognized as a part of the test report or calibration certificate, and a clear identification of the end of the test report or calibration certificate;

d) the name and address of the customer;

e) identification of the method used;

f) a description of, the condition of, and unambiguous identification of the item(s) tested or calibrated;

g) the date of receipt of the test or calibration item(s) where this is critical to the validity and application of the results;

h) the date(s) of performance of the test or calibration;

i) the date of issue of the test report or calibration certificate;

j) reference to the sampling plan and procedures used by the laboratory or other bodies where these are relevant to the validity or application of the results;

k) a statement to the effect that the results relate only to the items tested or calibrated, where relevant;

l) the test or calibration results with, where appropriate, the units of measurement;

m) the name(s), function(s) and signature(s) or equivalent identification of person(s) authorizing the test report or calibration certificate.

NOTE It is recommended that laboratories include a statement specifying that the test report or calibration certificate shall not be reproduced except in full, without written approval of the laboratory.

7.5.3 Test reports – specific requirements

7.5.3.1 In addition to the requirements listed in 7.5.2, test reports shall, where necessary for the interpretation of the test results, include the following:

a) deviations from, additions to, or exclusions from the test method, and information on specific test conditions, such as environmental conditions;

b) where relevant, a statement of compliance/non-compliance with requirements and/or specifications;

c) where applicable, uncertainty of measurement presented in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent). Information on uncertainty is needed in test reports when it is relevant to the validity or application of the test results, when a customer's instruction so requires, or when the uncertainty affects compliance to a specification limit.

d) where appropriate and needed, opinions and interpretations (see 7.5.5);

e) additional information which may be required by specific methods, authority, customers or groups of customers.

7.5.3.2 In addition to the requirements listed in 7.5.2 and 7.5.3, reports containing the results of sampling shall include the following, where necessary for the interpretation of test results:

a) the date of sampling;

b) unambiguous identification of the substance, material or product sampled (including the name of the manufacturer, the model or type of designation and serial numbers as appropriate);

c) the location of sampling, including any diagrams, sketches or photographs;

d) a reference to the sampling plan and procedures used;

e) details of any environmental conditions during sampling that may affect the interpretation of the test results;

f) any standard or other specification for the sampling method or procedure, and deviations, additions to or exclusions from the specification concerned.

7.5.4 Calibration certificates– specific requirements

7.5.4.1 In addition to the requirements listed in 7.5.2, calibration certificates shall include the following, where necessary for the interpretation of calibration results:

i) the conditions (e.g. environmental) under which the calibrations were made that have an influence on the measurement results;

j) the uncertainty of measurement presented in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent)and/or a statement of compliance with an identified metrological specification or clauses thereof;

k) evidence that the measurements are traceable (see Annex A, General).

7.5.4.2 The calibration certificate shall relate only to quantities and the results of functional tests. If a statement of compliance with a specification is made, this shall identify which clauses of the specification are met or not met. When a statement of compliance with a specification is made omitting the measurement results and associated uncertainties, the laboratory shall record those results and maintain them for possible future reference. When statements of compliance are made, the uncertainty of measurement shall be taken into account.

7.5.4.3 When an instrument has been adjusted or repaired, the calibration results before and after adjustment or repair, if available, shall be reported.

7.5.4.4 A calibration certificate (or calibration label) shall not contain any recommendation on the calibration interval except where this has been agreed with the customer. This requirement may be superseded by legal regulations.

7.5.5 Opinions and interpretations

When opinions and interpretations are included, the laboratory shall ensure that only personnel authorized for expression of opinions and interpretations releases the respective statement in the reports. The laboratory shall document the basis upon which the opinions and interpretations have been made. Opinions and interpretations shall be clearly marked as such in a test report.

NOTE 1 Opinions and interpretations are not to be confused with inspections and product certifications as intended in ISO/IEC 17020 and ISO/IEC 17065.

NOTE 2 Opinions and interpretations included in a test report can comprise, but not be limited to, the following:

a) an opinion on the statement of compliance/noncompliance of the results with requirements;

b) where necessary, a statement to ensure that the opinion based on testing or calibration of a sample or a single item is not misused or mistaken for product certification of a range or type (see Note 1 above);

c) fulfilment of contractual requirements;

d) recommendations on how to use the results;

e) guidance to be used for improvements.

NOTE 3 In many cases it might be appropriate to communicate the opinions and interpretations by direct dialogue with the customer. Such dialogue can be written down.

7.5.6 Testing and calibration results obtained from external provider

When the test report contains results of tests provided externally, these results shall be clearly identified. The laboratory shall require the subcontractor to report the results in writing or electronically. When a test or calibration has been subcontracted, the contracting laboratory shall have appropriate contractual arrangements to receive calibration/testing certificate from the subcontracted laboratory.

7.5.7 Electronic transmission of results

In the case of transmission of test or calibration results by any electronic means, the requirements of clauses 4.2 and 7.10 of this International Standard shall be met.

7.5.8 Format of test reports and calibration certificates

The format shall be designed to accommodate each type of test or calibration carried out and to minimize the possibility of misunderstanding or misuse.

NOTE 1 Attention should be given to the lay-out of the test report or calibration certificate, especially with regard to the presentation of the test or calibration data and ease of assimilation by the reader.

NOTE 2 The headings should be standardized as far as possible.

7.5.9 Amendments to test reports and calibration certificates

7.5.9.1 Material amendments to a test report or calibration certificate after issue shall be made only in the form of a further document, or data transfer, which includes the statement:

> "Supplement to Test Report [or Calibration Certificate], serial number... [or as otherwise identified]",

or an equivalent form of wording.

Such amendments shall meet all the requirements of this International Standard.

7.5.9.2 When it is necessary to issue a complete new test report or calibration certificate, this shall be uniquely identified and shall contain a reference to the original that it replaces.

7.6 Assuring the quality of results

7.6.1 The laboratory shall have procedures for monitoring the validity of activities undertaken and the quality of the laboratory output. The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to the reviewing of the results. This monitoring shall be planned and reviewed and shall contain both internal and external activities as applicable.

7.6.2 Internal quality control activities are those actions that routinely monitor the quality of the laboratory output and can include, but not be limited to, the following:

a) regular use of certified reference materials and/or reference material and/or quality control material;

NOTE It is recommended to use certified reference material from producers that meet ISO 17034. ISO Guide 33 provides guidance on the selection and use of reference materials.

b) regular use of traceable instrumentation;

c) functional check of measuring and testing equipment;

d) use of check standards with control charts;

e) periodic intermediate checks on measuring equipment;

f) replicate tests or calibrations using the same or different methods;

g) retesting or recalibration of retained items;

h) correlation of results for different characteristics of an item;

i) review of reported data by qualified laboratory personnel;

j) intra-laboratory comparisons (i.e. organized within a laboratory).

7.6.3 External quality assurance activities are those actions that monitor the quality of the laboratory output. External quality activities shall comprehensively cover the laboratory output over a defined period. Such activities can include, but not be limited to the following:

a) participation in proficiency tests where such activities are available and appropriate;

NOTE It is recommended to use proficiency tests that are organized by providers that meet the requirements of ISO/IEC 17043

b) participation in interlaboratory comparisons other than proficiency testing.

7.6.4 Data from quality assurance activities shall be analysed and used to both control and improve the process of laboratory's activities. If the results of the analyses are found to be outside pre-defined criteria, appropriate action shall be taken to prevent incorrect results from being reported.

7.7 Selection, verification and validation of methods

7.7.1 General

7.7.1.1 The laboratory shall use appropriate methods and procedures for all tests and/or calibrations. These include procedures for sampling, handling, transport, storage and preparation of items to be tested and/or calibrated, and, where appropriate, for evaluation of the measurement uncertainty as well as statistical techniques for analysis of test and/or calibration data.

7.7.1.2 The laboratory shall have instructions on the use and operation of all relevant measuring equipment, and on the handling and preparation of items for testing and/or calibration, or both, where the absence of such instructions could jeopardize the results of tests and/or calibrations. All instructions, standards, manuals and reference data relevant to the work of the laboratory shall be kept up to date and shall be made readily available to personnel (see 8.3). Deviation from test and calibration methods shall occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer.

NOTE International, regional or national standards or other recognized specifications that contain sufficient and concise information on how to perform the tests and/or calibrations do not need to be supplemented or rewritten as internal procedures if these standards are written in a way that they can be used as published by the operating personnel in a laboratory. It can be necessary to provide additional documentation for optional steps in the method or additional details.

7.7.2 Selection of methods

7.7.2.1 The laboratory shall use test and/or calibration methods, including methods for sampling, which meet the needs of the customer and which are appropriate for the tests and/or calibrations it undertakes. The laboratory shall ensure that it uses the latest valid edition of a standard unless it is not appropriate or possible to do so. When necessary, the standard shall be supplemented with additional details to ensure consistent application.

7.7.2.2 When the customer does not specify the method to be used, the laboratory shall select appropriate methods. Methods published either in international, regional or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment are recommended. Laboratory-developed or modified methods or methods adopted by the laboratory may also be used if they are appropriate for the intended use and if they are validated. The customer shall be informed as to the method chosen.

7.7.2.3 The laboratory shall verify that it can properly operate standard methods before introducing the tests or calibrations by ensuring that it can achieve the performance characteristics of the standard methods. The records of the verification shall be maintained. If the standard method changes, the verification shall be repeated.

7.7.2.4 The laboratory shall inform the customer when the method proposed by the customer is considered to be inappropriate or out of date, unless specifically required by the customer, e.g. in tender material. Records of the communications shall be kept.

7.7.3 Non-standard methods

7.7.3.1 Non-standard methods, including modified standard methods or laboratory developed methods, shall be validated.

7.7.3.2 When it is necessary to use non-standard methods, these shall be subject to agreement with the customer and shall include a clear specification of the customer's requirements and the purpose of the test and/or calibration (see 7.1).

7.7.3.3 As method-development proceeds, periodic review shall be carried out to verify that the needs of the customer are still being fulfilled. Any change in requirements requiring modifications to the development plan shall be approved and authorized.

7.7.4 Validation of methods

7.7.4.1 The laboratory shall validate non-standard methods, laboratory-designed/developed methods and standard methods used outside their intended scope. The validation shall be as extensive as is necessary to meet the needs of the given application or field of application. The laboratory shall record the results obtained, the procedure used for the validation, and a statement as to whether the method is fit for the intended use.

NOTE 1 Validation can include procedures for sampling, handling and transportation.

NOTE 2 The techniques used for the determination of the performance of a method can be one of, or a combination of, the following:

- calibration using reference standards or reference materials;
- comparison of results achieved with other methods;
- interlaboratory comparisons;
- systematic assessment of the factors influencing the result;
- assessment of the measurement uncertainty of the results based on scientific understanding of the theoretical principles of the method and practical experience.

7.7.4.2 When some changes are made in the validated non-standard methods, the influence of such changes shall be documented and, if appropriate, a new validation shall be carried out.

7.7.4.3 The range and accuracy of the values obtainable from validated methods (e.g. the measurement uncertainty of the results, detection limit, selectivity of the method, linearity, limit of repeatability and/or reproducibility, robustness against external influences and/or cross-sensitivity against interference from the matrix of the sample/test object, trueness), as assessed for the intended use, shall be relevant to the customers' needs and consistent with legislation requirements, when required.

7.7.4.4 Records of validation shall include specification of the requirements, determination of the characteristics of the methods, a check that the requirements can be fulfilled by using the method, and a statement on the validity.

NOTE Validation is always a balance between costs, risks and technical possibilities. There are many cases in which the range and measurement uncertainty of the values (e.g. accuracy, detection limit, selectivity, linearity, repeatability, reproducibility, robustness and cross-sensitivity) can only be given in a simplified way due to lack of information.

7.7.4.5 The laboratory shall establish a plan to review validation data in order to verify that the requirements are still fulfilled

7.8 Management of nonconforming work

7.8.1 The laboratory shall have procedures that shall be implemented when any aspect of its testing and/or calibration work (e.g. laboratory equipment found to be out of tolerance, quality control results

fail to meet specified criteria), or the results of this work, do not conform to its own procedures or the agreed requirements of the customer. The procedures shall ensure that:

a) the responsibilities and authorities for the management of nonconforming work are designated;

b) actions (including halting of work and withholding of test reports and calibration certificates, as necessary) are defined and taken when nonconforming work is identified;

c) decision is taken on the acceptability of the nonconforming work;

d) an evaluation is made of the significance of the nonconforming work, including an impact analysis on previous results, and action taken as necessary, depending on the outcome on the test and /or calibration activity;

e) where necessary, the customer is notified and work is recalled;

f) the responsibility for authorizing the resumption of work is defined.

7.8.2 Where the evaluation indicates that the nonconforming work could recur or that there is doubt about the compliance of the laboratory's operations with its own policies and procedures, the laboratory shall implement corrective action.

7.9 Technical records

7.9.1 The records for each test or calibration shall contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty and to enable the test or calibration to be repeated under conditions as close as possible to the original. The records shall include the identity of personnel responsible for the sampling, performance of each test and/or calibration and checking of results (see 8.4). Observations, data and calculations shall be recorded at the time they are made and shall be identifiable to the specific task.

NOTE In certain fields it can be impossible or impractical to retain records of all original observations.

7.9.2 The laboratory shall develop and implement a procedure that ensures traceability to the original observations or amendments in records. Both the original and corrected file/data shall be kept, including indication of the altered aspects. All alterations to records shall be traceable.

7.10 Control of data – information management

7.10.1 The laboratory shall have access to the data and information needed to provide a service which meets the needs and requirements of the user.

7.10.2 The information management system(s) used for the collection, processing, recording, reporting, storage or retrieval of testing and calibration data shall be:

a) verified for functioning by the laboratory before introduction, with any changes to the system authorized, documented and verified before implementation;

NOTE Verification includes, where applicable, the proper functioning of interfaces between the laboratory information system and other systems such as with laboratory instrumentation.

a) protected from unauthorized access;

b) safeguarded against tampering or loss;

c) operated in an environment that complies with supplier specifications or, in the case of non-computerized systems, provides conditions which safeguard the accuracy of manual recording and transcription;

d) maintained in a manner that ensures the integrity of the data and information and includes the recording of system failures and the appropriate immediate and corrective actions;

e) in compliance with national or international requirements regarding data protection.

NOTE In this International Standard, "information management systems" includes the management of data and information contained in both computer and non-computerized systems. Some of the requirements can be more applicable to computer systems than to non-computerized systems.

7.10.3 When the information system(s) are managed and maintained off-site or subcontracted to an alternative provider, laboratory management shall be responsible for ensuring that the provider or operator of the system complies with all applicable requirements of this International Standard.

7.10.4 The laboratory shall ensure that instructions, manuals and reference data relevant to the information management system are made readily available to personnel.

7.10.5 Calculations and data transfers shall be subject to appropriate checks in a systematic manner.

7.11 Complaints

7.11.1 The laboratory shall have a documented procedure to receive, evaluate and make decisions on complaints.

7.11.2 A description of the handling process for complaints shall be available to any interested party on request. Upon receipt of a complaint, the laboratory shall confirm whether the complaint relates to testing and calibration activities that it is responsible for and, if so, shall deal with it. The laboratory shall be responsible for all decisions at all levels of the handling process for complaints.

7.11.3 The process for handling complaints shall include at least the following elements and methods:

a) description of the process for receiving, validating, investigating the complaint, and deciding what actions are to be taken in response to it;

b) tracking and recording complaints, including actions undertaken to resolve them;

c) ensuring that any appropriate action is taken.

7.11.4 The laboratory receiving the complaint shall be responsible for gathering and verifying all necessary information to validate the complaint.

7.11.5 Whenever possible, the laboratory shall acknowledge receipt of the complaint, and provide the complainant with progress reports and the outcome.

7.11.6 The decision to be communicated to the complainant shall be made by, or reviewed and approved by, individual(s) not involved in the original testing and calibration activities in question.

7.11.7 Whenever possible, the laboratory shall give formal notice of the end of the complaint handling to the complainant.

8 Management requirements

8.1 Options

8.1.1 General

The laboratory shall establish, document, implement and maintain a management system that is capable of supporting and demonstrating the consistent achievement of the requirements of this International Standard and assuring the quality of the test and/or calibration results. In addition to

meeting the requirements of clauses 4 to 7 and the laboratory shall implement a management system in accordance with option A or option B.

8.1.2 Option A

As a minimum the management system of the laboratory shall address the following:

- management system documentation (see 8.2)
- control of management system documents (see 8.3)
- control of records (see 8.4)
- improvement (see 8.5)
- corrective action (see 8.6)
- internal audits (see 8.7)
- management review (see 8.8)

8.1.3 Option B

A laboratory that has established and maintains a management system, in accordance with the requirements of ISO 9001, and that is capable of supporting and demonstrating the consistent fulfilment of the requirements of clauses 4 to 7 of ISO/IEC 17025 also fulfils at least the intent of the management system section requirements (8.2 - 8.8).

8.2 Management system documentation (Option A)

8.2.1 The laboratory's management system policies related to quality, including a quality policy statement, shall be defined. The overall objectives shall be established and address at least the competence and quality of results of the laboratory. The quality policy statement shall be issued under the authority of laboratory management.

8.2.2 Top management shall provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness.

NOTE Documents, data and records are components of documented information as defined in ISO 9001. Control of document is covered in 8.3. The control of records is covered in 8.4. The control of data related to testing and calibration is covered in 7.10.

8.3 Control of management system documents (Option A)

8.3.1 The laboratory shall establish and maintain procedures to control all documents that form part of its management system (internally generated or from external sources), such as regulations, standards, other normative documents, test and/or calibration methods, as well as drawings, software, specifications, instructions and manuals.

NOTE In this context “document” could be policy statements, procedures, specifications, calibration tables, charts, text books, posters, notices, memoranda, software, drawings, plans, etc. These may be on various media, whether hard copy or digital.

8.3.2 The procedures shall ensure that:

a) documents are approved for adequacy prior to issue;

b) documents are reviewed and updated (as necessary) and re-approved;

c) changes and the current revision status of documents are identified;

d) relevant versions of applicable documents are available at points of use;

e) documents remain legible and readily identifiable;

f) documents of external origin are identified and their distribution controlled;

g) the unintended use of obsolete documents is prevented, and apply suitable identification to them if they are retained for any purpose.

8.4 Control of records (Option A)

8.4.1 The laboratory shall establish procedures to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of its records.

8.4.2 The laboratory shall establish procedures for retaining records for a period consistent with its contractual and legal obligations. Access to these records shall be consistent with the confidentiality arrangements.

Note Clause 7.5 contains additional requirements regarding technical records.

8.5 Improvement (Option A)

8.5.1 The laboratory shall have a procedure to improve the effectiveness of its management system requirements.

NOTE The improvement procedure can address the review of the operational procedures, the use of the quality policy, overall objectives, audit results, corrective actions, management review, risk assessment, analysis of data, and proficiency-testing results.

8.5.2 The laboratory shall seek feedback, both positive and negative, from its customers. The feedback shall be used and analysed to improve the management system, testing and calibration activities and customer service.

NOTE Examples of the types of feedback include customer satisfaction surveys and review of test or calibration reports with customers.

8.5.3 When improvement opportunities are identified, action plans shall be developed, implemented and monitored.

8.6 Corrective action (Option A)

8.6.1 The laboratory shall establish procedures for identification and management of nonconformities in its operations.

8.6.2 The laboratory shall also, where necessary, take actions to eliminate the causes of nonconformities in order to prevent recurrence.

8.6.3 Corrective actions shall be appropriate to the impact of the problems encountered.

8.6.4 The procedures shall define requirements for the following:

a) identifying nonconformities;

b) determining the causes of nonconformity;

c) correcting nonconformities;

d) evaluating the need for actions to ensure that nonconformities do not recur;

e) determining the actions needed and implementing them in a timely manner;

f) recording the results of actions taken;

g) reviewing the effectiveness of corrective actions.

8.7 Internal audits (Option A)

8.7.1 The laboratory shall conduct internal audits at planned intervals to provide information on whether the management system:

a) conforms to:
   - the laboratory's own requirements for its management system, including the testing and/or calibration activities;
   - the requirements of this International Standard;

b) is effectively implemented and maintained.

8.7.2 The laboratory shall:

a) plan, establish, implement and maintain an audit programme(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the laboratory, and the results of previous audits;
b) define the audit criteria and scope for each audit;
c) select competent auditors and conduct audits to ensure objectivity and the impartiality of the audit process;
d) ensure that the results of the audits are reported to relevant management;
e) take appropriate correction and corrective actions without undue delay;
f) retain records as evidence of the implementation of the audit programme and the audit results.

NOTE ISO 19011 provides guidance for internal audits.

8.8 Management reviews (Option A)

8.8.1 The laboratory management shall establish procedures to review its management system at planned intervals, in order to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the fulfilment of this International Standard.

8.8.2 These reviews shall be conducted at least once a year. Alternatively, a complete review broken up into segments (a rolling review) shall be completed within a 12-month time frame.

8.8.3 Records of reviews shall be maintained.

8.8.4 The inputs to management review shall include information related to the following:

a) changes in internal and external issues that are relevant to the laboratory;

b) fulfilment of objectives;

c) suitability of policies and procedures;

d) status of actions from previous management reviews;

e) the outcome of recent internal audits;

f) corrective actions;

g) assessments by external bodies;

h) the results of interlaboratory comparisons or proficiency tests;

i) changes in the volume and type of the work;

j) customer feedback;

k) complaints;

l) effectiveness of any implemented improvements ;

m) the adequacy of resources;

n) results of the risk identification;

o) other relevant factors, such as quality control activities and training.

8.8.5 The outputs from the management review shall record decisions and actions related to:

a) improvement of the effectiveness of the management system and its processes;

b) improvement of the laboratory related to the fulfilment of the requirements of this International Standard;

c) resource needs;

d) any need for changes.

Annex A

(Informative)

Metrological traceability

General

Traceability to SI units of measurement may be achieved by reference to an appropriate primary standard (ISO Guide 99/VIM) or by reference to a natural constant, the value of which in terms of the relevant SI unit is known and recommended by the General Conference of Weights and Measures (CGPM) and the International Committee for Weights and Measures (CIPM).

Establishing traceability

A laboratory establishes metrological traceability to the SI of its measurement standards and measuring equipment by means of an unbroken chain of calibrations or comparisons linking them to relevant primary standards of the SI units of measurement. The link to SI units may be achieved by reference to national measurement standards or certified reference materials (CRM). National measurement standards may be primary standards, which are primary realizations of the SI units or agreed representations of SI units based on fundamental physical constants. National measurement standards may also be reference standards which are calibrated by a peer national metrology institute or the BIPM.

Laboratories that maintain their own primary standard or representation of SI units based on fundamental physical constants can claim traceability to the SI system once these standards have been compared, directly or indirectly, with other similar standards of a national metrology institute.

The International Bureau of Weights and Measures (BIPM), established through the Metre Convention, has the mission of establishing world uniformity of measurement and the General Conference on Weights and Measures (CGPM) has the authority of approving the definitions of the SI. In order to assure the international recognition of NMIs the International Committee for Weights and Measures (CIPM) drew up a Mutual Recognition Arrangement, the CIPM-MRA. The CIPM-MRA provides a framework within which all participants (National Metrology Institutes and Designated Institutes (DI)) validate and recognize the Calibration and Measurement Capabilities (CMCs) published in the KCDB database of BIPM (http://kcdb.bipm.org/).

Traceability to national measurement standards does not necessarily require the use of the national metrology institute of the country in which the laboratory is located. To establish traceability, laboratories should select a national metrology institute (NMI) that actively participates in the activities of BIPM either directly or through the Regional Metrology Organisations (RMOs). The unbroken chain of calibrations or comparisons may be achieved in several steps carried out by different laboratories that can demonstrate traceability and competence.

Traceability of measurement can be assured by the use of calibration services (internal or external) from laboratories that can demonstrate competence, measurement capability and traceability. Laboratories fulfilling the requirements of this International Standard are considered to be competent.

Maintaining traceability

A laboratory can maintain traceability by implementing an effective calibration program. A calibration program should include established calibration intervals, as well as participation in a suitable interlaboratory comparisons, process control and intermediate checks.

Calibration intervals are highly dependent on the stability and usage of the standard. There are many guidance documents available to help laboratories determine the appropriate interval for each standard and instrument. Participation in a suitable interlaboratory comparisons, process control and intermediate checks can be used to justify adjusting the calibration interval. Provisions for suitable interlaboratory comparisons are available in ISO/IEC 17043 and other documents.

Reference materials

The values assigned to CRMs produced by NMIs and DIs and included in the BIPM KCDB or produced by other competent Reference Material Providers (RMP) are considered to have established traceability. Producers complying with ISO 17034 are considered to be competent.

The majority of RMs and CRMs are produced by other RMPs. These can be considered as critical consumables and the laboratory may demonstrate that each RM or CRM is suitable for its intended use as required in clause 6.6 of this International Standard.

Annex B

(Informative)

Management system

Growth in the use of management systems generally has increased the need to ensure that laboratories which form part of larger organizations or offer other services can operate to a quality management system that is seen as compliant with ISO 9001 as well as with this International Standard. As a result, this International Standard provides two options for the requirements related to the implementation of a management system.

Option A lists the minimum requirements for implementation of a management system in a laboratory. Care has been taken to incorporate all those requirements of ISO 9001 that are relevant to the scope of testing and calibration services that are covered by the laboratory's management system. Testing and calibration laboratories that comply with clauses 4 to 7 of ISO/IEC 17025 and implement option A of clause 8 will therefore also operate in accordance with the principles of ISO 9001.

Option B allows laboratories to establish and maintain a management system in accordance with the requirements of ISO 9001 in a manner that supports and demonstrates the consistent fulfilment of clauses 4 to 7 of ISO/IEC 17025. Testing and calibration laboratories that implement option B of clause 8 will therefore also operate in accordance with ISO 9001. Conformity of the quality management system within which the laboratory operates to the requirements of ISO 9001 does not of itself demonstrate the competence of the laboratory to produce technically valid data and results. This is accomplished through compliance with clauses 4 to 7 of ISO/IEC 17025.

Both options are intended to achieve the same result in the performance of the management system and compliance with clauses 4 to 7.

Bibliography

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[2] ISO 5725-2, *Accuracy (trueness and precision) of measurement methods and results — Part 2: Basic method for the determination of repeatability and reproducibility of a standard measurement method*

[3] ISO 5725-3, *Accuracy (trueness and precision) of measurement methods and results — Part 3: Intermediate measures of the precision of a standard measurement method*

[4] ISO 5725-4, *Accuracy (trueness and precision) of measurement methods and results — Part 4: Basic methods for the determination of the trueness of a standard measurement method*

[5] ISO 5725-6, *Accuracy (trueness and precision) of measurement methods and results — Part 6: Use in practice of accuracy values*

[6] ISO 9000:—[1)], *Quality management systems — Fundamentals and vocabulary*

[7] ISO 9001:2000, *Quality management systems — Requirements*

[8] ISO/IEC 90003, *Software engineering — Guidelines for the application of ISO 9001:2000 to computer software*

[9] ISO 10012:2003, *Measurement management systems — Requirements for measurement processes and measuring equipment*

[10] ISO/IEC 17011, *Conformity assessment — General requirements for accreditation bodies accrediting conformity assessment bodies*

[11] ISO/IEC 17020, *General criteria for the operation of various types of bodies performing inspection*

[12] ISO 19011, *Guidelines for quality and/or environmental management systems auditing*

[13] ISO Guide 30, *Terms and definitions used in connection with reference materials*

[14] ISO Guide 31, *Reference materials — Contents of certificates and labels*

[15] ISO Guide 32, *Calibration in analytical chemistry and use of certified reference materials*

[16] ISO Guide 33, *Uses of certified reference materials*

[17] ISO Guide 34, *General requirements for the competence of reference material producers*

[18] ISO Guide 35, *Certification of reference materials — General and statistical principles*

[19] ISO/IEC Guide 43-1, *Proficiency testing by interlaboratory comparisons — Part 1: Development and operation of proficiency testing schemes*

[20] ISO/lEC Guide 43-2, *Proficiency testing by interlaboratory comparisons — Part 2: Selection and use of proficiency testing schemes by laboratory accreditation bodies*

[21] ISO/IEC Guide 58:1993, *Calibration and testing laboratory accreditation systems — General requirements for operation and recognition*

1) To be published. (Revision of ISO 9000:2000)

[22] ISO/IEC Guide 65, *General requirements for bodies operating product certification systems*

[23] GUM, Guide to the Expression of Uncertainty in Measurement, issued by BIPM, IEC, IFCC, ISO, IUPAC, IUPAP and OIML

[24] Information and documents on laboratory accreditation can be found on the ILAC (International Laboratory Accreditation Cooperation): www.ilac.org