INTERNATIONAL STANDARD

CD2
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

This document contains obligatory ISO/CASCO PAS language highlighted in grey in the CD2. Please note that comments to modify these sections will not be considered, as this is mandatory CASCO language that cannot be deleted or changed, unless approved by the CPC.

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.

The first edition (1999) of this International Standard was produced as the result of extensive experience in the implementation of ISO/IEC Guide 25 and EN 45001, both of which it replaced. It contained all of the requirements that testing and calibration laboratories have to meet if they wish to demonstrate that they operate a management system, are technically competent, and are able to generate technically valid results. The first edition referred to ISO 9001:1994 and ISO 9002:1994. When those standards were superseded by ISO 9001:2000, an alignment of ISO/IEC 17025 was necessary. In the second edition of this International Standard, clauses were amended or added only when considered necessary for alignment with ISO 9001:2000.

Introduction

This International Standard has been developed with the objective of promoting confidence in the operation of laboratories.

This International Standard contains requirements for laboratories to enable them to demonstrate they operate competently, and are able to generate valid results.

The acceptance of results between countries is facilitated if laboratories conform to 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.

Laboratories that conform to this International Standard will also operate in accordance with the principles of ISO 9001.

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 management system, achieving improved results and preventing negative effects. The laboratory is responsible for deciding which risks and opportunities need to be addressed.

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.

In this International Standard, the following verbal forms are used:

- “shall” indicates a requirement;
- “should” indicates a recommendation;
- “may” indicates a permission;
- “can” indicates a possibility or a capability.

Further details can be found in the ISO/IEC Directives, Part 2.

General requirements for the competence of testing and calibration laboratories

1 Scope

1.1 This International Standard specifies the general requirements for the competence, impartiality and consistent operation of laboratories as defined in the standard.

1.2 This International Standard is applicable to all organizations performing laboratory activities. These include laboratories with different levels of independence and organizations where laboratory activities form 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 laboratory 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.

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

(CASCO Secretariat is in process of determining which version is correct, ISO/IEC Guide 99 or JCGM 200:2012).

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. Where different definitions are given in ISO 9000, the definitions in ISO/IEC 17000 and JCGM 200:2012 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 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
complaint
expression of dissatisfaction by any person or organization to a laboratory, relating to the activities or results of that laboratory where a response is expected

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

3.3
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]

3.4
intralaboratory comparison
organized within a laboratory, performance and evaluation of measurements or tests on the same or similar items in accordance with predetermined conditions

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

[SOURCE: ISO/IEC 17043:2010, 3.7— modified: *the reference to the Annex and both notes deleted.*]

3.6
validation
verification, where the specified requirements are adequate for an intended use

EXAMPLE A measurement procedure, ordinarily used for the measurement of mass concentration of nitrogen in water, may be validated also for measurement of mass concentration of nitrogen in human serum.

[SOURCE: VIM: 2012, 2.45]

3.7
verification
provision of objective evidence that a given item fulfils specified requirements

EXAMPLE 1 Confirmation that a given reference material as claimed is homogeneous for the quantity value and measurement procedure concerned, down to a measurement portion having a mass of 10 mg.

EXAMPLE 2 Confirmation that performance properties or legal requirements of a measuring system are achieved.

EXAMPLE 3 Confirmation that a target measurement uncertainty can be met.

Note 1 to entry: When applicable, measurement uncertainty should be taken into consideration.

Note 2 to entry: The item may be, e.g. a process, measurement procedure, material, compound, or measuring system.

Note 3 to entry: The specified requirements may be, e.g. that a manufacturer's specifications are met.

Note 4 to entry: Verification in legal metrology, as defined in VIML and in conformity assessment in general, pertains to the examination and marking and/or issuing of a verification certificate for a measuring system.

Note 5 to entry: Verification should not be confused with calibration. Not every verification is a validation.

Note 6 to entry: In chemistry, verification of the identity of the entity involved, or of activity, requires a description of the structure or properties of that entity or activity

[SOURCE: VIM: 2012, 2.44]

3.8
working standard
standard that is used routinely to calibrate or check material measures, measuring instruments or reference materials

Note to entry: Working standards are also called check standards.

[SOURCE: ISO/TR 16015:2003, 3.4.2]

3.9
laboratory
body that performs one or more of the following activities:
— calibration
— testing
— sampling, associated with subsequent calibration and testing

3.10
decision rule
documented rule that describes how measurement uncertainty will be accounted in statements of compliance with regard to accepting or rejecting an item, given a specified requirement and the result of a measurement

[SOURCE: ISO Guide 98/4, 3.3.12— modified: *added "in statements of compliance".*]

4 General requirements

4.1 Impartiality

4.1.1. Laboratory 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 laboratory 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 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.

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 ensure the protection of its customers' confidential information and proprietary rights, including protecting the electronic storage and transmission of results.

4.2.2. The laboratory shall be responsible, through legally enforceable commitments, for the management of all information obtained or created during the performance of laboratory 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.

4.2.3. 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.

4.2.4. Information about the client obtained from sources other than the customer (e.g. complainant, regulators) shall be confidential between the client and the laboratory. The provider (source) of this information shall be confidential to the laboratory and shall not be shared with the customer, unless agreed by the source.

4.2.5. 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 a legal entity, such that it can be held legally responsible for all its activities.

NOTE For the purpose of this international standard a governmental laboratory is deemed to be a legal entity on the basis of its governmental status.

5.2. The laboratory shall identify management who have overall responsibility for the laboratory.

5.3. It is the responsibility of the laboratory to carry out its activities in the laboratory's permanent facilities, or 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.

5.4. The laboratory shall have adequate provision (e.g. insurance or reserves) to cover liabilities arising from its activities.

5.5. The laboratory shall define the range of laboratory activities for which it conforms with this International Standard.

5.6. 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 management system, 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 laboratory activities;

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

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 to laboratory management on the performance of the management system and any need for improvement.

5.7. Laboratory management shall ensure that:

a) internal and external communication mechanisms are established;

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

c) the importance of meeting customer and other 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

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

6.2 Personnel

6.2.1. All personnel of the laboratory, either internal or external, that could influence the laboratory activities shall act impartially, be supervised and competent and shall work in accordance with the laboratory's management system.

6.2.2. The laboratory shall define and document the competence requirements for each function involved in laboratory activities, including requirements for education, qualification, training, technical knowledge, skills, experience, duties, responsibilities and authorities.

6.2.3. The personnel shall have the competence to execute the activities for which they are responsible and understand the significance of and response to deviations found with regard to the laboratory activities.

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

6.2.5. The laboratory shall have documented process(es) for:

a) selecting;

b) training;

c) supervising;

d) authorizing; and

e) ongoing monitoring of personnel involved in laboratory activities.

6.2.6. The laboratory shall authorize specific personnel to:

a) develop modify, verify and validate methods;

b) perform particular types of sampling, test or calibration;

c) analyze results, including statements of conformity or opinions and interpretations;

d) issue test reports and calibration certificates.

6.2.7. Records of competence, such as education, training, technical knowledge, skills, experience, authorizations and monitoring for all personnel involved in laboratory activities, shall be maintained.

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

6.3 Laboratory facilities and environmental conditions

6.3.1. The facilities and environmental conditions shall be suitable to realize the laboratory activities and do not adversely affect the validity of results.

6.3.2. In those cases where the laboratory needs to use facilities outside its permanent control, it shall ensure that the requirements of this International Standard are met.

6.3.3. There shall be effective separation between areas in which there are incompatible laboratory activities.

6.3.4. The facility and environmental requirements necessary for the performance of the laboratory activities shall be documented.

6.3.5. Measures shall be taken to control the facility and environmental requirements. These measures shall be monitored and periodically reviewed and include, but not limited to:

a) access to and use of areas affecting laboratory activities;

b) processes to prevent contamination, interference or adverse influences on the laboratory activities.

NOTE Influences that can affect the quality of results include biological sterility, dust, electromagnetic disturbances, radiation, humidity, electrical supply, temperature and sound and vibration levels.

6.3.6 Records of the ongoing monitoring and periodic review with respect to the facility and environmental requirements shall be maintained.

6.4 Equipment

6.4.1. The laboratory shall have access to all equipment required for the correct performance of the laboratory activities. Equipment shall include software, measurement standards, reference materials, reagents and consumables or auxiliary apparatus or combination thereof necessary to realize a measurement process and which may influence the measurement result.

6.4.2. 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.

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

NOTE Particular attention should be paid to measurement reference standards.

6.4.4. The laboratory shall verify that equipment complies with specified requirements before being placed into service and when equipment has been outside the direct control of the laboratory.

6.4.5. The laboratory shall identify equipment used for measurements and capable of achieving the accuracy required and complying with the specifications relevant to the laboratory activities concerned. It shall establish a documented calibration program for such equipment to ensure metrological traceability of the measurement results.

NOTE Types of equipment having an effect on the accuracy of the measurement may include:

— those used for the direct measurement of the measurand, for example, use of a balance to perform a mass measurement;

— those used to make corrections to the measured value, for example, temperature measurements;

— those used to obtain a measurement result calculated from multiple measurements.

6.4.6. All equipment requiring calibration shall be labelled, coded or otherwise identified to allow the user of the equipment to readily identify the status of calibration.

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

a) the identity of equipment, software and firmware version;

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

c) the manufacturer's instructions;

d) evidence of verification that equipment complies with specified requirements;

e) the current location, where appropriate;

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

g) dates, results and copies of documentation and certificates of reference materials, acceptance criteria, and the period of validity;

h) the maintenance plan, and maintenance carried out to date, where relevant to the performance of the equipment;

i) details of any damage, malfunction, modification or repair to the equipment.

6.4.8. Equipment that has been subjected to overloading or mishandling, gives questionable results, or has been shown to be defective or outside specified requirements, 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 to perform correctly. The laboratory shall examine the effect of the defect or deviation from specified requirements and shall institute the “Management of nonconforming work” procedure (see 7.11).

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

6.4.10. When calibration and reference material data include reference values or correction factors, the laboratory shall have procedures to ensure the correction factors and reference values are updated and implemented, as appropriate, to meet specified requirements.

6.4.11. Equipment shall be safeguarded from adjustments which would invalidate the test and calibration results.

6.4.12. The laboratory shall select and use reference materials that are fit for the specific purpose in the measurement process.

NOTE 1 Reference materials from producers meeting the requirements of ISO 17034 has specified technical characteristics.

NOTE 2 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 3 Reference materials can be used for a number of purposes in the measurement process including calibration, method validation and assessment of bias of a method within a laboratory. ISO Guide 33 gives guidance on the selection and use of reference materials, and reference material producers that meet the requirements of ISO 17034 are considered as competent.

6.5 Externally provided products and services

6.5.1 General

6.5.1.1 The laboratory shall ensure that externally provided products and services conform to requirements.

NOTE Products can include, for example, measurement standards and equipment, auxiliary equipment, consumable materials and reference materials. Services can include, for example, calibration services, sampling services, testing services, facility and equipment maintenance services and assessment and auditing services.

6.5.1.2 The laboratory shall control externally provided products and services when:

a) these are intended for incorporation into the laboratory's own activities;

b) these are provided, in part or full, to the customer(s) by the laboratory directly as provided by the external provider.

6.5.2 Control of externally provided products and services

6.5.2.1. The laboratory shall ensure that externally provided products and services do not adversely affect the laboratory's ability to consistently deliver technically valid results to its customers.

6.5.2.2. The laboratory shall:

a) ensure that externally provided products and services remain within the control of its quality management system;

b) define both the controls to apply to an external provider and those to apply to the products and services;

c) take into consideration:

— the potential impact of the externally provided products and services on the laboratory's ability to consistently meet requirements;

— the effectiveness of the controls applied by the external provider;

d) verify that the externally provided products and services meet the laboratory's established requirements before they are used or directly provided to the customer.

6.5.2.3. The laboratory shall have a procedure for evaluating external providers on their ability to provide products and services in accordance with the laboratory established requirements including:

a) the controls applied;

b) the criteria for their evaluation, selection, monitoring of performance and re-evaluation;

c) any necessary actions arising from monitoring and (re)evaluations.

6.5.2.4. The laboratory shall retain records of the verification processes to ensure products and service conform to the laboratory established requirements and any necessary actions arising.

6.5.3 Communication of information to external providers

The laboratory shall communicate to external providers, to the extent necessary, its requirements for:

a) the products and services to be provided;

b) the acceptance criteria;

c) competence, including any required qualification of persons;

d) control and monitoring of the external provider's performance to be applied by the laboratory;

e) verification of activities that the laboratory, or its customer, intends to perform at the external provider's premises.

6.6 Metrological traceability

6.6.1. The laboratory shall establish and maintain metrological traceability of its measurement results by means of a documented unbroken chain of calibrations or comparisons each contributing to the measurement uncertainty, linking them to an appropriate reference.

NOTE 1 Metrological traceability is often referred to as measurement traceability.

NOTE 2 See JCGM 200:2012 for definition of metrological traceability.

NOTE 3 See Annex A for additional information on metrological traceability.

6.6.2. Where it is technically possible, the laboratory shall demonstrate that the appropriate reference is a direct realization of, or traceable to the International System of Units (SI) (Système international d'unités). The link to SI units shall be achieved by comparison or reference to national or international measurement standards or certified reference materials with stated metrological traceability to the SI.

NOTE See *SI* Brochure: The International System of Units (*SI*) published by BIPM.

6.6.3. Where metrological traceability to the SI units is not technically possible, the laboratory shall demonstrate metrological traceability to an appropriate reference such as:

a) certified reference materials provided by a competent producer;

NOTE 1 ISO 17034 contains additional information on competence of reference material producers.

NOTE 2 Reference materials can differ with respect to their position in the metrological traceability chain (primary, secondary, etc. materials). For example, ISO 17511 describes metrological traceability chains in the field of laboratory medicine including those in which the top level stated reference is a certified reference material. The technical requirements to be met for such reference materials, in the field of laboratory medicine, are described in

ISO 15194. The important aspect for their applicability is, however, the uncertainty of the assigned property value.

b) results of reference measurement procedures that are clearly described and accepted by an appropriate authoritative body as providing measurement results fit for their intended use;

c) specified methods or consensus standards that are clearly described and accepted by an appropriate authoritative body as providing measurement results fit for their intended use.

6.6.4. Metrological traceability of measurement results shall be assured through calibrations by laboratories that can demonstrate competence, measurement capability and traceability.

NOTE Calibration laboratories fulfilling the requirements of this International Standard are considered to be competent.

7 Process requirements

7.1 Review of requests, tenders and contracts

7.1.1 General

7.1.1.1 The laboratory shall establish and maintain procedures for the review of requests, tenders and contracts. The procedures for these reviews leading to a contract for laboratory activities shall ensure that:

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

b) the laboratory has the capability and resources to meet the requirements and where external providers are necessary, the requirements of clause 6.5.2 shall be met;

c) the appropriate methods or procedures are selected and are capable of meeting the customers' requirements.

7.1.1.2 The laboratory shall only claim conformity with this International Standard for the range of laboratory activities defined in clause 5.5 and which excludes externally provided laboratory activities on an ongoing basis.

7.1.1.3 When the customer requests a statement of conformity to a specification or standard for the test or calibration (e.g. pass/fail, in-tolerance/out-of-tolerance) the specification and the decision rule shall be clearly defined and communicated.

7.1.1.4 Any differences between the request or tender and the contract shall be resolved before laboratory 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 1 For internal or routine customers, reviews of requests, tenders and contracts can be performed in a simplified way.

NOTE 2 Where a contract covers on-going work or a series of activities, each request should be reviewed against that contract.

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

7.1.1.6 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.

7.1.1.7 The laboratory shall 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.

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 in the performance of the laboratory activities.

7.1.1.8 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.

7.1.2 Externally provided laboratory activities

7.1.2.1 The laboratory's procedures for the review of requests, tenders and contracts shall cover laboratory activities from external providers. The laboratory shall, in particular, advise the customer of the arrangement about the external provider and gain its approval.

NOTE It is recognized that externally provided laboratory activities can occur:

a) where the laboratory has the resources and competence to perform the activities, however, for unforeseen reasons is unable to undertake these in part or full;

b) where the laboratory does not have the resources or competence to perform the activities.

7.1.2.2 The laboratory shall ensure that laboratory activities which are externally provided meet the customer requirements and where applicable, the relevant requirements of this International Standard.

7.1.2.3 The selection of external providers for laboratory activities shall be in accordance with clause 6.5.

7.2 Selection, verification and validation of methods

7.2.1 General

7.2.1.1 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.

NOTE For calibration laboratories, "method" as used in this International Standard can be considered synonymous with the term "measurement procedure" as defined in the VIM.

7.2.1.2 The laboratory shall have instructions on the use and operation of all relevant equipment, and on the handling and preparation of items, where the absence of such instructions could jeopardize the results. 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).

7.2.1.3 Deviation from methods and procedures for all laboratory activities 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.

7.2.2 Selection and verification of methods

7.2.2.1 The laboratory shall use methods for laboratory activities which meet the needs of the customer and which are appropriate for the laboratory activities 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 application of the standard shall be supplemented with additional details to ensure consistent application.

7.2.2.2 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 adapted by the laboratory may also be used if they are appropriate for the intended use and if they are validated (see 7.2.3). The customer shall be informed as to the method chosen.

7.2.2.3 The laboratory shall verify that it can properly perform methods before introducing them by ensuring that it can achieve the performance requirements. Records of the verification shall be maintained. If the method is revised, verification shall be repeated to the extent necessary.

7.2.2.4 The laboratory shall inform the customer when the method proposed by the customer is considered to be inappropriate or out of date. Records of the communications shall be kept.

7.2.2.5 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 laboratory activities (see 7.1).

7.2.2.6 When method development is required, this shall be a planned activity and shall be assigned to qualified personnel equipped with adequate resources. 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.

7.2.3 Validation of methods

7.2.3.1 The laboratory shall validate non-standard methods, laboratory-developed methods and standard methods used outside their intended scope (modified standards methods). 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:

a) calibration and/or bias and precision using reference standards or reference materials;

b) method robustness testing through variation of controlled parameters such as incubator temperature, volume dispensed, etc.;

c) comparison of results achieved with other methods;

d) interlaboratory comparisons;

e) systematic assessment of the factors influencing the result;

f) evaluation of uncertainty of measurement of the results based on scientific understanding of the theoretical principles of the method and practical experience.

7.2.3.2 When 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.

7.2.3.3 The range and accuracy of the values obtainable from validated methods (e.g. the measurement uncertainty of the results, limit of detection, limit of quantification, 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 specified requirements, when required.

7.2.3.4 The laboratory shall record the following:

a) the procedure used;

b) specification of the requirements;

c) determination of the characteristics of the methods;

d) results obtained;

e) a check that the requirements can be fulfilled by using the method;

f) a statement on the validity; and

g) a statement of fitness for intended purpose.

7.3 Sampling

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

7.3.2 Sampling procedures shall describe the selection of samples/sites, sampling plan, withdrawal, and preparation of a sample(s) 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 (see 7.4.2).

7.3.3 Where the laboratory has not been responsible for the sampling 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 stage, it shall report on the procedures used and comment on any consequent limitations imposed on the results.

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

a) the reference to the sampling procedure used;

b) date and, where appropriate, time of sampling;

c) relevant data to identify the sample (e.g. number, amount, name);

d) the identification of the sampler;

e) if relevant, environmental conditions; and

f) diagrams or other equivalent means to identify the sampling location when necessary.

7.4 Handling of test or calibration items

7.4.1 The laboratory shall have procedures for the transportation, receipt, handling, protection, storage, retention, and disposal or 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. Special care shall be taken to avoid 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.

7.4.2 The laboratory shall have a system for identifying test and/or calibration items. The identification shall be retained while the item is under the responsibility 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.

7.4.3 Upon receipt of the test or calibration item, abnormalities or deviations from specified conditions shall be recorded. When there is doubt about 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 or calibrated the laboratory shall include a disclaimer in the report or certificate indicating that the results may be compromised.

7.4.4 When items have to be stored or conditioned under specified environmental conditions, these conditions shall be maintained, monitored and recorded.

7.4.5 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.

7.5 Technical records

7.5.1 The laboratory shall ensure that records for each laboratory activity contain the report or certificate and sufficient information to facilitate, if possible, identification of factors affecting the uncertainty and enable the laboratory activity to be repeated under conditions as close as possible to the original. The records shall include the identity of personnel responsible for each laboratory activity and checking of results. Original observations, data and calculations shall be recorded at the time they are made and shall be identifiable with the specific task.

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

7.5.2 The laboratory shall ensure 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.

7.6 Evaluation of uncertainty of measurement

7.6.1 A laboratory performing calibrations, including of its own equipment, shall apply procedures to evaluate the uncertainty of measurement for all calibrations.

7.6.2 A laboratory performing testing activities shall apply procedures for evaluating uncertainty of measurement. 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 contributions to the uncertainty of measurement and make a reasonable estimation of their magnitude. Reasonable estimation 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.

NOTE 1 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 7.6.2 by following the test method and reporting instructions

NOTE 2 For a particular test method where the uncertainty of measurement obtained with the method is known, there is no need to evaluate uncertainty of measurement for each test result, if the identified critical influencing factors are under control and remain unchanged.

7.6.3 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 ISO/IEC Guide 98-3.

7.7 Analysis of the results

7.7.1 Statements of conformity

When statement of conformity to a specification or standard for test or calibration is requested, the laboratory shall:

a) document the decision rules employed taking into account the level of risk (such as false accept and false reject and statistical assumptions) associated with the decision rule employed;

b) apply the decision rule.

NOTE For further information see ISO/IEC Guide 98-4.

7.7.2 Opinions and interpretations

7.7.2.1 The opinions and interpretations expressed in test reports or calibration certificates shall be based on the results obtained from the tested or calibrated item.

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

7.7.2.2 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.

7.8 Assuring the quality of results

7.8.1 The laboratory shall have procedures for regularly 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 include, where appropriate, but not be limited to:

a) regular use of reference materials or quality control materials;

NOTE It is recommended to use 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 alternative metrologically traceable instrumentation;

c) functional check of measuring and testing equipment;

d) use of check or working standards with control charts, where applicable;

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 competent laboratory personnel;

j) intralaboratory comparisons;

k) blind test.

7.8.2 The laboratory shall monitor the quality of the laboratory output by comparing with output of other laboratories, where available and appropriate. This monitoring shall be planned and reviewed and shall include, where appropriate, but not be limited to:

a) participation in proficiency testing;

NOTE ISO/IEC 17043 contains additional information on proficiency tests and proficiency testing organisers.

b) participation in interlaboratory comparisons other than proficiency testing.

7.8.3 Data from monitoring activities shall be analysed and used to both control and improve the process of the 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.

7.9 Reporting of results

7.9.1 General

7.9.1.1 The results shall be provided accurately, clearly, unambiguously and objectively, usually in a test report or a calibration certificate (see Note 1), and shall include all the information agreed with the customer and necessary for the interpretation of the results and all information required by the method used. All issued test reports or calibration certificates shall be maintained as technical records.

NOTE 1 For the purpose of this International Standard 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 (hard copy or by electronic) provided that the requirements of this International Standard are met.

7.9.1.2 In the case of a written agreement with the customer, the results may be reported in a simplified way. Any information listed in 7.9.2 to 7.9.5 which is not reported to the customer shall be readily available in the laboratory which carried out the tests or calibrations.

7.9.2 Test reports and calibration certificates – common requirements

7.9.2.1 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 or calibrations were carried out, if different from the address of the laboratory;

c) unique identification of the test report or calibration certificate and that all its parts are recognized as a part of a whole, 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 contact information of the customer;

e) identification of the method used;

f) a description of , unambiguous identification of and, when necessary, the condition of the item ;

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

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) identification of person authorizing the test report or calibration certificate;

n) clear identification when results are from external providers.

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 approval of the laboratory.

7.9.2.2 The laboratory shall be responsible for all the information provided in the test report or calibration certificate, except when data is provided by the customer. When data is provided by the customer there shall be clear identification of it. In addition, a disclaimer shall be put on the report when the data is supplied by the customer and can affect the validity of the test or calibration results.

7.9.2.3 In addition to the requirements listed in 7.9.2.1 and 7.9.2.2, 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.

7.9.3 Test reports – specific requirements

In addition to the requirements listed in 7.9.2, 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 conformity with requirements or specifications;

c) where applicable, of the measurement uncertainty presented in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent);

NOTE: Information on measurement 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 measurement uncertainty affects compliance to a specification limit.

d) where appropriate and needed, opinions and interpretations (see 7.9.5.2);

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

7.9.4 Calibration certificates – specific requirements

7.9.4.1 In addition to the requirements listed in 7.9.2, calibration certificates shall include the following:

a) the measurement uncertainty presented in the same unit as that of the measurand or in a term relative to the measurand (e.g., percent);

NOTE According to ISO Guide 99 a measurement result is generally expressed as a single measured quantity value including unit of measurement and a measurement uncertainty.

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

c) evidence that the measurements are metrologically traceable (see Annex A);

d) the results before and after adjustment or repair, if available.

7.9.4.2 The calibration certificate shall relate only to quantities and the results of functional tests. When statements of conformity are made, the uncertainty of measurement shall be taken into account. If a statement of conformity with a specification is made, this shall identify which clauses of the specification are met or not met. When a statement of conformity with a specification is made omitting the measurement results and associated uncertainties, the laboratory shall include a statement that calibration certificate is not intended to be used in support of the further dissemination of metrological traceability (i.e. to calibrate another device).

7.9.4.3 A calibration certificate or calibration label shall not contain any recommendation on the calibration interval except where this has been agreed with the customer.

NOTE This requirement can be superseded by legal regulations.

7.9.5 Reporting of analyses of results

7.9.5.1 Reporting statements of conformity

The laboratory shall report on the statement of conformity such that the statement clearly identifies:

a) to which results the statement applies; and

b) which clauses of the specification are met or not met.

7.9.5.2 Reporting opinions and interpretations

Opinions and interpretations shall be clearly marked as such in a test report and calibration certificate.

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

7.9.6 Amendments to test reports and calibration certificates

7.9.6.1 When an issued test report or calibration certificate needs to be changed or amended any change of information shall be clearly identified.

7.9.6.2 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:

> "Amendment 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.

7.9.6.3 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.

7.10 Complaints

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

7.10.2 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 laboratory activities that it is responsible for and, if so, shall deal with it. The laboratory shall be responsible for all levels of the handling process for complaints.

7.10.3 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.

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

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

7.10.6 The outcomes to be communicated to the complainant shall be made by, or reviewed and approved by, individual(s) not involved in the original laboratory activities in question.

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

7.11 Management of nonconforming work

7.11.1 The laboratory shall have procedures that shall be implemented when any aspect of its laboratory activities or results of this work do not conform to its own procedures or the agreed requirements of the customer (e.g. laboratory equipment found to be out of specified limits, monitoring results fail to meet specified criteria). The procedures shall ensure that:

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

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) an evaluation is made of the significance of the nonconforming work, including an impact analysis on previous results;

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

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

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

g) nonconforming work and actions required as specified in b)-f) shall be recorded.

7.11.2 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.

7.12 Control of data – Information management

7.12.1 The laboratory shall have access to the data and information needed to provide laboratory activities which meet the needs and requirements of the user.

7.12.2 The laboratory information management system(s) used for the collection, processing, recording, reporting, storage or retrieval of data shall be validated for functionality, including the proper functioning of interfaces within the laboratory information management systems by the laboratory before introduction. Whenever there are any changes, including laboratory software configuration/modifications to commercial off-the-shelf software they shall be authorized, documented and validated before implementation;

NOTE Commercial off-the-shelf software in general use within its designed application range can be considered to be sufficiently validated.

7.12.3 The laboratory information management system shall be:

a) protected from unauthorized access;

b) safeguarded against tampering or loss;

c) operated in an environment that complies with supplier or laboratory 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 and security.

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

7.12.4 When the laboratory information systems are managed and maintained off-site or through an external provider, the laboratory shall ensure that the provider or operator of the system complies with all applicable requirements of this International Standard.

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

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

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

NOTE See Annex B for more information.

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)

— actions to address risks and opportunities (8.5)

— improvement (see 8.6)

— corrective action (see 8.7)

— internal audits (see 8.8)

— management review (see 8.9)

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 - 8.9).

8.2 Management system documentation (Option A)

8.2.1 Laboratory management shall establish, document, and maintain policies and objectives for the fulfilment of the purpose of this International Standard and shall ensure that the policies and objectives are acknowledged and implemented at all levels of the laboratory organization.

8.2.2 The policies and objectives shall address the competence, impartiality and consistent operation of the laboratory.

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

8.2.4 All documentation, processes, systems, records, etc. related to the fulfilment of the requirements of this International Standard shall be included, referenced, or linked to documentation of the management system.

NOTE Documents, data and records are components of documented information. Control of documents is covered in 8.3. The control of records is covered in 8.4. The control of data related to the laboratory activities is covered in 7.11.

8.2.5 All personnel involved in laboratory activities shall have access to the parts of the management system documentation and related information that are applicable to their responsibilities.

8.3 Control of management system documents (Option A)

8.3.1 The laboratory shall control the documents (internal and external) that relate to the fulfilment of this International Standard.

NOTE In this context "document" can 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 laboratory shall ensure that:

a) documents are approved for adequacy prior to issue by authorized personnel;

b) documents are periodically reviewed and updated (as necessary);

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 are uniquely identified and where necessary their distribution controlled;

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

8.4 Records (Option A)

8.4.1 The laboratory shall establish and maintain records to demonstrate fulfillment of the requirements in this International Standard.

8.4.2 The laboratory shall implement the controls needed for the identification, display, storage, protection, back-up, archive, retrieval, retention time, and disposition of its records. The laboratory shall retain records for a period consistent with its contractual and legal obligations. Access to these records shall be consistent with the confidentiality arrangements and records shall be readily available.

NOTE Clause 7.5 contains additional requirements regarding technical records.

8.5 Actions to address risks and opportunities (Option A)

8.5.1 The laboratory shall consider the risks and opportunities associated with the laboratory activities in order to:

a) give assurance that the management system can achieve its intended results;

b) enhance opportunities to achieve laboratory's purpose objectives;

c) prevent, or reduce, undesired impacts and potential failures in the laboratory activities; and

d) achieve improvement.

8.5.2 The laboratory shall plan:

a) actions to address these risks and opportunities;

b) how to:

— integrate and implement the actions into its management system;

— evaluate the effectiveness of these actions.

8.5.3 Actions taken to address risks and opportunities shall be proportionate to the potential impact on the validity of laboratory activities and the quality of laboratory results.

NOTE 1 Options to address risks can include identifying and avoiding threats, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.

NOTE 2 Opportunities can lead to expanding the scope of the laboratory activities, addressing new customers, using new technology and other possibilities to address customer needs.

8.6 Improvement (Option A)

8.6.1 The laboratory shall determine and select opportunities for improvement and implement any necessary actions.

NOTE Opportunities for improvement can be identified through 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.

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

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

8.7 Corrective action (Option A)

8.7.1 The laboratory shall identify and manage non-conformities in its operations. The laboratory shall:

a) determine the causes of non-conformity;

b) evaluate the need for actions to ensure that non-conformities do not recur and, if so, determining the root causes of non-conformity;

c) determine the corrective actions needed,

d) implement corrective actions in a timely manner;

e) review the effectiveness of corrective actions.

8.7.2 The laboratory shall also, where necessary, take actions to eliminate the causes of non-conformities in order to prevent recurrence.

8.7.3 Corrective actions shall be appropriate to the impact and risk of recurrence of the non-conformities encountered.

8.8 Internal audits (Option A)

8.8.1 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 laboratory activities;
   - the requirements of this International Standard;

b) is effectively implemented and maintained.

8.8.2 The laboratory shall:

a) plan, establish, implement and maintain an audit programme including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the laboratory activities 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) implement 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.

8.9 Management reviews (Option A)

8.9.1 The laboratory management shall 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.

8.9.2 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.

8.9.3 Records of reviews shall be maintained.

8.9.4 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) outcome of recent internal audits;

f) corrective actions;

g) assessments by external bodies;

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

i) customer feedback;

j) complaints;

k) effectiveness of any implemented improvements;

l) adequacy of resources;

m) results of risk identification;

n) outcomes of the assurance of the quality of results (see 7.8. quality of results);

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

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

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

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

c) resource needs;

d) any need for change.

Annex A - Metrological traceability

(Informative)

With regards to the Annex A - Metrological traceability, due to the lack of time, the WG proposed the draft below and comments collected on Annex A during the CD1 ballot will be reviewed at the 5th WG44 meeting in September.

1 General concepts of traceability of measurements results

1.1 Traceability is characterized by:

a) unbroken chain of comparisons or calibrations; going back to stated and appropriate references. Appropriate references include, national or international standards, and intrinsic standards;

b) uncertainty of measurement; for each step in the traceability chain an evaluation of measurement uncertainty must be performed according to agreed methods and must be stated;

c) documented information; each step of the chain shall be performed in accordance with appropriate methods, the measurement results and associated uncertainties recorded;

d) competence; the laboratories performing one or more steps in the chain must supply evidence for their technical competence;

e) reference to SI units; the chain of comparisons must, where possible, end at primary standards for the realization of the SI units.

1.2 Fitness for purpose - whose service is suitable for the intended need:

1.2.1 Define the measurement results and uncertainty requirements (*incoming traceability)* necessary to support the measurements for the laboratory activities (including *outgoing traceability* for calibration laboratories).

1.2.2 Confirm that the incoming traceability meets the above requirements.

1.2.3 Metrological traceability is a measure of the trueness of a measurement result and is not only dependent upon the measurement uncertainty but also the systematic measurement error. The reported measurement uncertainty alone does not define the measurement accuracy, but the systematic measurement error needs to be considered as well. The measurement accuracy is defined either as the corrected error together with the reported measurement uncertainty, or the measurement uncertainty, expanded to include the uncorrected systematic measurement error.

[Insert an illustration to show how this works]

1.3 Appropriate Evidence of Incoming Traceability

1.3.1 To evaluate the technical competence of the calibration service provider and their claimed metrological traceability, an evaluation is likely to include but not be restricted to the following:

a) Records of calibration method validation;

b) Procedures for evaluation of uncertainty;

c) Documentation for traceability of measurements;

d) Documentation for assuring the quality of calibration results;

e) Documentation for competence of staff;

f) Documentation for facilities, environmental conditions, and equipment;

g) Audits.

1.3.2 Calibration and measurement capabilities that have been subject to peer review processes under international arrangements such as the CIPM MRA or accreditation by an Accreditation Body subject to the ILAC Arrangement or by Regional Arrangements recognised by ILAC have demonstrated metrological traceability.

1.3.3 Services covered by the CIPM MRA can be viewed in Appendix C of the BIPM KCDB which includes the range and uncertainty for each listed service.

NOTE 1 Some NMIs may also indicate that their service is covered by the CIPM MRA by including the CIPM MRA logo on their calibration certificates, however the fixing of the logo is not mandatory and the BIPM KCDB remains the authoritative source of verification.

NOTE 2 NMIs from Member States participating in the Metre Convention may take traceability directly from measurements made at the BIPM. The KCDB provides an automatic link to the relevant BIPM calibration services (including the range and uncertainty). Individual calibration certificates issued by the BIPM are also listed.

NOTE 3 Some calibration laboratories indicate that their service is covered by the ILAC Arrangement by including the ILAC Laboratory Combined MRA mark on the calibration certificate. Alternatively, the accreditation symbol of the accreditation body that is a signatory to the ILAC Arrangement and/or a recognised regional MLA may be included on the calibration certificate. Both of these options may be taken as evidence of traceability.

2 Additional information on the SI

2.1. Metrological traceability is defined in ISO/IEC Guide 99(JCGM 200:2012), *International vocabulary of metrology — basic and general concepts and associated terms (VIM)* as the property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty.

2.2. The preferred reference is the International System of Units (*Système International d'Unités; SI*), which is defined in the SI Brochure, published by the BIPM[1]. At the highest level, the SI units are realized by following formal sets of instructions, the *mises en pratique*, which are developed by the CIPM Consultative Committees. These *mises en pratique* are published in electronic form on the BIPM website in Appendix 2 of the SI Brochure.

2.3. In practice primary measurement standards sit at the top of the traceability chain. These may be realized directly through a *mise en pratique* or established though a primary reference measurement procedure.

2.4. The National Metrology Institutes (NMIs) establish and maintain national measurement standards and disseminate metrological traceability via calibration and measurement services and certified reference materials. Some countries have a more distributed system and the term Designated Institute (DI) is used to describe additional institute(s) responsible for certain national measurement standards and associated services disseminating traceability not covered by the activities of the "traditional" NMI. National measurement standards are not necessarily primary standards, but may be secondary standards which are calibrated by a peer NMI or the BIPM.

2.5. The *Joint BIPM, OIML, ILAC and ISO Declaration on Metrological Traceability* provides specific guidance when there is a need to demonstrate international acceptability of the metrological traceability chain.

3 Reference material traceability

[1] The BIPM, established by the Metre Convention, operates under the authority of the General Conference on Weights and Measures (CGPM). The CGPM is made up of delegates of the governments of Member States, and observers from the Associates of the CGPM.

3.1 Some Certified Reference Materials are SI traceable while other cases this is not possible.

3.2 Reference materials can be used for a number of purposes in the measurement process including establishing metrological traceability, calibration, method validation and assessment of bias of a method within a laboratory. ISO Guide 33 gives guidance on the selection and use of reference materials, and reference material producers that meet the requirements of ISO 17034 are considered as competent.

Annex B - Management system

(Informative)

1.1 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.

1.2 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 laboratory activities that are covered by the laboratory's management system. 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.

1.3 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. Laboratories that implement option B of clause 8 will therefore also operate in accordance with ISO 9001. Conformity of the 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.

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

Bibliography

[1] ISO 5725-1, *Accuracy (trueness and precision) of measurement methods and results — Part 1 General principles and definitions*

[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 9001, *Quality management systems — Requirements*

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

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

[9] ISO/IEC 17020, *Conformity assessment — Requirements for the operation of various types of bodies performing inspection*

[10] ISO/IEC 17021-1, *Conformity assessment — Requirements for bodies providing audit and certification of management systems — Part 1: Requirements*

[11] ISO 19011, *Guidelines for auditing management systems* ISO Guide 30, *Reference materials — Selected terms and definitions*

[12] ISO Guide 31, *Reference materials — Contents of certificates, labels and accompanying documentation*

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

[14] ISO Guide 33, *Reference materials — Good practice in using reference materials*

[15] ISO 17034, *General requirements for the competence of reference material producers*

[16] ISO Guide 35, *Reference materials — General and statistical principles for certification*

[17] ISO/IEC 17043, *Conformity assessment — General requirements for proficiency testing*

[18] ISO/IEC 17065 *Conformity assessment — Requirements for bodies certifying products, processes and services*

[19] ISO Guide 98-3, *Uncertainty of measurement — Part 3: Guide to the expression of uncertainty in measurement (GUM)*

[20] *Joint BIPM, OIML, ILAC and ISO declaration on metrological traceability*.

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

[22] ISO/IEC Guide 98-4, *Uncertainty of measurement — Part 4: Role of measurement uncertainty in conformity assessmentISO 12207*

[23] ISO/IEC 12207, *Systems and software engineering — Software life cycle processes*

[24] *International Vocabulary of Terms in Legal (VIML)*

[25] ISO 17511, *In vitro diagnostic medical devices — Measurement of quantities in biological samples — Metrological traceability of values assigned to calibrators and control materials*