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General requirements for the competence of testing and calibration laboratories

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

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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 Agreement on 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. ISO/IEC 17025 was aligned with ISO 9001:2000 in 2005. Since then ISO 9001 has been revised twice.

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.

Laboratories that conform to this International Standard will also operate generally 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. The acceptance of results between countries is facilitated if laboratories conform to this International Standard.

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, regardless of the number of personnel, performing laboratory activities (see 3.6).

1.3 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 document is 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.

JCGM 200:2012, International vocabulary of metrology — basic and general concepts and associated terms (VIM), 3rd edition issued by BIPM, IEC, IFCC, ILAC, ISO, IUPAC, IUPAP and OIML

3 Terms and definitions

For the purposes of this document, the following terms and definitions given in ISO/IEC 17000 and JCGM 200:2012 and the following apply[1].

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at http://www.iso.org/obp

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.

[1] Where there is more than one definition for the same term, the definitions in ISO/IEC 17000 and JCGM 200:2012 take precedence.

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 removed 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
organization performance and evaluation of measurements or tests on the same or similar items, within the same laboratory, 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 notes deleted.*]

3.6
laboratory
body that performs one or more of the following activities:
— calibration
— testing
— sampling, associated with subsequent calibration or testing

3.7
decision rule
a rule that describes how measurement uncertainty will be accounted for when stating conformity with a specified requirement

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

4.2.5 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 laboratory 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, that is 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 The laboratory shall carry out its activities in such a way as to meet the requirements of this International Standard, its customers, regulatory authorities and organizations providing recognition. The laboratory shall be responsible for activities performed in all its permanent facilities, at sites away from its permanent facilities, in associated temporary or mobile facilities or at a customer's facility.

5.4 The laboratory shall define and document the range of laboratory activities for which it conforms with this International Standard. The laboratory shall only claim conformity with this International

Standard for the range of laboratory activities, which excludes externally provided laboratory activities on an ongoing basis.

5.5 The laboratory shall:

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

b) specify the responsibility, authority and interrelationship of all personnel who manage, perform or verify work affecting the results of laboratory activities;

c) document its procedures to the extent necessary to assure the consistent application of its activities and validity of the results.

5.6 The laboratory shall have personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including:

a) implementation, maintenance and improvement of the management system;

b) identification of deviations from the management system or from the procedures for performing laboratory activities;

c) initiation of actions to prevent or minimize such deviations;

d) reporting to laboratory management on the performance of the management system and any need for improvement; and

e) ensuring the required validity of laboratory activities.

5.7 Laboratory management shall ensure that:

a) the integrity of the management system is maintained when changes to the management system are implemented;

b) communication takes place regarding the effectiveness of the management system and the importance of meeting customer and other requirements.

6 Resource requirements

6.1 General

The laboratory shall have available the personnel, facilities, equipment, systems 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 document the competence requirements for each function influencing the results of laboratory activities, including requirements for education, qualification, training, technical knowledge, skills, experience.

6.2.3 The laboratory shall ensure that the personnel have the competence to perform the laboratory 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 procedure(s) and maintain records for:

a) determining the competence requirements;

b) selection of personnel;

c) training of personnel;

d) supervision of personnel;

e) authorization of personnel;

f) monitoring of competence of personnel.

6.2.6 The laboratory shall authorize personnel to:

a) develop, modify, verify and validate methods;

b) perform specific laboratory activities;

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

d) report results.

6.3 Laboratory facilities and environmental conditions

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

6.3.2 The requirements for facilities and environmental conditions necessary for the performance of the laboratory activities shall be documented

6.3.3 The laboratory shall monitor, control and record environmental conditions as required by the relevant specifications, methods and procedures or where they influence the validity of the results.

6.3.4 Measures to control facilities shall be implemented, monitored and periodically reviewed and shall include, but not be limited to:

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

b) prevention of contamination, interference or adverse influences on the laboratory activities;

c) effective separation between areas in which there are incompatible laboratory activities.

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

6.3.5 When the laboratory performs activities at facilities outside its permanent control, it shall ensure that the requirements related to facilities and environmental conditions of this International Standard are met.

6.4 Equipment

6.4.1 The laboratory shall have access to equipment required for the correct performance of the laboratory activities. Equipment includes measuring instruments, software, measurement standards, reference materials, reference data, reagents and consumables or auxiliary apparatus or combination thereof necessary for laboratory activities and which can influence the result.

6.4.2 In those cases where the laboratory uses equipment outside its permanent control, it shall ensure that the requirements for equipment of this International Standard are met.

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

6.4.4 The laboratory shall verify that equipment complies with specified requirements before being placed into service.

6.4.5 The equipment used for measurement shall be capable of achieving the measurement accuracy and measurement uncertainty required to provide a valid result.

6.4.6 When the measurement accuracy and measurement uncertainty affect the validity of the reported result, or metrological traceability is a requirement, measuring equipment shall be calibrated.

NOTE Types of equipment having an effect on the validity of the reported results 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.

6.4.7 The laboratory shall establish a calibration program to ensure metrological traceability of the measurement results is maintained. The calibration program shall be reviewed and adjusted as necessary in order to maintain confidence in the status of calibration.

6.4.8 All equipment requiring calibration or which has a defined period of validity shall be labelled, coded or otherwise identified to allow the user of the equipment to readily identify the status of calibration or period of validity.

6.4.9 Records shall be maintained for equipment which can influence the laboratory activities. The records shall include at least the following:

a) the identity of equipment, including software and firmware version (where available) ;

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

c) evidence of verification that equipment conforms with specified requirements;

d) the current location, where appropriate;

e) calibration dates, results of all calibrations, adjustments, acceptance criteria, and the due date of next calibration or the calibration frequency;

f) dates, results and documentation of reference materials, acceptance criteria, and the period of validity;

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

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

6.4.10 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 verified to perform correctly. The laboratory shall examine the effect of the defect or deviation from specified requirements and shall initiate the management of nonconforming work procedure (see 7.10).

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

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

6.4.13 The laboratory shall ensure practicable measures are taken to prevent unintended adjustments of equipment which would invalidate results.

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

NOTE A multitude of names exist for reference materials and certified reference materials, including reference standards, calibration standards, standard materials, quality control materials. Reference materials from producers meeting the requirements of ISO 17034 come with a product information sheet/certificate that specifies, amongst other characteristics, homogeneity and stability for specified properties and, for certified reference materials, specified properties with certified values, their uncertainty and traceability.

6.5 Metrological traceability

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

NOTE 1 See JCGM 200:2012 for the definition of metrological traceability.

NOTE 2 See Annex A for additional information on metrological traceability.

6.5.2 The laboratory shall ensure that measurement results are traceable to the International System of Units (SI) through:

a) calibration; or

b) certified values of certified reference materials with stated metrological traceability to the SI; or

c) direct realization of the SI units which conform with the *mises en pratique*, as described in the SI Brochure, and ensured by comparison, directly or indirectly, with national or international standards.

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

a) certified values of certified reference materials provided by a competent producer; or

NOTE Reference material producers fulfilling the requirements of ISO 17034 are considered to be competent.

b) results of reference measurement procedures, 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 and ensured by suitable comparison.

NOTE The Joint Committee for Traceability in Laboratory Medicine (JCTLM) is an example of an authoritative body.

6.6 Externally provided products and services

6.6.1 The laboratory shall assure the suitability of externally provided products and services that affect laboratory activities, when they:

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

b) are provided, in part or in full, directly to the customer by the laboratory, as received from the external provider;

c) are used to support the operation of the laboratory.

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, proficiency testing services and assessment and auditing services.

6.6.2 The laboratory shall have a procedure and records for:

a) defining, reviewing and approving the laboratory's requirements for externally provided products and services;

b) defining the criteria for evaluation, selection, monitoring of performance and re-evaluation of the external providers;

c) ensuring that externally provided products and services conform to the laboratory's established requirements or when applicable, the relevant requirements of this International Standard; before they are used or directly provided to the customer;

d) taking any actions arising from evaluations, monitoring and re-evaluations.

6.6.3 The laboratory shall communicate to external providers, its requirements for:

a) the products and services to be provided;

b) the acceptance criteria;

c) competence, including any required qualification of personal;

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

7 Process requirements

7.1 Review of requests, tenders and contracts

7.1.1 General

7.1.1.1 The laboratory shall have a procedure for the review of requests, tenders and contracts. The procedure 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 used, the requirements of clause 6.6 are met;

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

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

7.1.1.2 The laboratory shall inform the customer when the method requested by the customer is considered to be inappropriate or out of date.

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 or standard, and the decision rule shall be clearly defined. Unless inherent in the requested specification or standard, the decision rule selected shall be communicated to the customer.

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 impact the integrity of the laboratory or the results.

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

7.1.1.6 If a contract is amended after work has commenced, the contract review 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 Such cooperation can include:

a) providing reasonable access to relevant areas of the laboratory to witness customer-specific laboratory activities;

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

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 laboratory activities.

7.1.2 Externally provided laboratory activities

7.1.2.1 The laboratory's procedure 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 specific laboratory activities to be performed by the external provider and gain the customer's approval.

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

a) when 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) when the laboratory does not have the resources or competence to perform the activities.

7.1.2.2 The laboratory is responsible for externally provided laboratory activities, except in the case where the customer or a regulatory authority specifies the provider to be used. The laboratory shall ensure that laboratory activities which are externally provided meet the customer requirements and the relevant requirements of this International Standard.

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 laboratory activities and, where appropriate, for evaluation of the measurement uncertainty as well as statistical techniques for analysis of 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 JCGM 200 : 2012.

7.2.1.2 All methods, procedures and supporting documentation, such as instructions, standards, manuals and reference data relevant to the laboratory activities, 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 Customer acceptance of deviations can be agreed in advance in the contract.

7.2.1.4 The laboratory shall use methods for laboratory activities which meet customer requirements and which are appropriate for the laboratory activities it undertakes. The laboratory shall ensure that it uses the latest valid edition of a method unless it is not appropriate or possible to do so. When necessary, the application of the method shall be supplemented with additional details to ensure consistent application.

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

7.2.1.5 When the customer does not specify the method to be used, the laboratory shall select an appropriate method and inform the customer of the method chosen.

NOTE 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 can also be used.

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

7.2.1.7 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.

7.2.2 Validation of methods

7.2.2.1 The laboratory shall validate non-standard methods, laboratory-developed methods and standard methods used outside their intended scope (modified standard 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 method validation can be one of, or a combination of, the following:

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

b) systematic assessment of the factors influencing the result;

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

d) comparison of results achieved with other validated methods;

e) interlaboratory comparisons;

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

7.2.2.2 When changes are made to any validated methods, the influence of such changes shall be documented and, if appropriate, a new validation shall be performed.

7.2.2.3 The range and accuracy of the values obtainable from validated methods as assessed for the intended use, shall be relevant to the customers' needs and consistent with specified requirements.

NOTE Examples of performance criteria can include the measurement range, the measurement uncertainty of the results, limit of detection, limit of quantification, selectivity of the method, linearity, repeatability or reproducibility, robustness against external influences or cross-sensitivity against interference from the matrix of the sample or test object, trueness.

7.2.2.4 The laboratory shall record the following as evidence of validation:

a) the validation procedure used;

b) specification of the requirements;

c) determination of the performance characteristics of the methods;

d) results obtained;

e) verification that the requirements can be fulfilled by using the method; and

f) a statement on the validity of the method, detailing its fitness for the intended use.

7.3 Sampling

7.3.1 The sampling procedure shall address the factors to be controlled to ensure the validity of subsequent testing or calibration results. The laboratory shall have a sampling plan and procedure for sampling when it carries out sampling of substances, materials or products for subsequent testing or calibration. The sampling plan and procedure 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 or 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 can require further handling such as subdivision or treatment prior to analysis .

7.3.3 The laboratory shall record relevant sampling data 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 required, time of sampling;

c) relevant data to identify and describe 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 appropriate.

7.4 Handling of test or calibration items

7.4.1 The laboratory shall have a procedure for the transportation, receipt, handling, protection, storage, retention, and disposal or return of test 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 calibration, storing/waiting and preparation. Handling instructions provided with the item shall be followed.

7.4.2 The laboratory shall have a system for identifying test 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 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 an item or 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 results of this consultation. When the customer requires the item to be tested or calibrated acknowledging a deviation from specified conditions, the laboratory shall include a disclaimer in the report 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.

7.5 Technical records

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

7.5.2 The laboratory shall ensure that amendments to technical records can be tracked back to either previous versions and to original observations. Both the original and amended data and files shall be kept, including indication of the altered aspects and those responsible for alterations.

7.6 Evaluation of measurement uncertainty

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

7.6.2 A laboratory performing sampling or testing activities shall evaluate measurement uncertainty. In certain cases, the nature of the sampling or test method may preclude rigorous calculation. In such cases the laboratory shall identify all the contributions to the measurement uncertainty and make a reasonable estimation of their magnitude based on an understanding of the theoretical principles of the method and practical experience of the performance of the sampling or test method.

NOTE In those cases where a sampling or test method specifies limits to the values of the major sources of measurement uncertainty and specifies the form of presentation of calculated results, the laboratory is considered to have satisfied clause 7.6.2 by following the sampling or test method and reporting instructions.

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

NOTE 1 For a particular method where the measurement uncertainty of the results has been established and verified, there is no need to evaluate measurement uncertainty for each result, if it can be demonstrated that the identified critical influencing factors are under control.

NOTE 2 Measurement uncertainty is different from systematic measurement errors (see JCGM 200:2012).

NOTE 3 For further information see ISO/IEC Guide 98-3 (GUM), ISO/IEC Guide 98-3/Suppl 1, ISO/IEC Guide 98-3/Suppl 2.

7.7 Assuring the quality of results

7.7.1 The laboratory shall have a procedure for regularly monitoring the validity of laboratory 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 materials from producers that meet ISO 17034. ISO Guide 33 provides guidance on the selection and use of reference materials. ISO guide 80 provides guidance to produce in house quality control materials.

b) regular use of alternative instrumentation that has been calibrated to provide traceable results;

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.

7.7.2 The laboratory shall monitor the quality of the laboratory performance by comparing with output of other laboratories, where available and appropriate. This monitoring shall be planned and reviewed and shall include, but not be limited to a selection from the following list:

a) participation in proficiency testing;

NOTE 1 ISO/IEC 17043 contains additional information on proficiency tests and proficiency testing providers.

NOTE 2 Proficiency test providers that meet the requirements of ISO/IEC 17043 are considered as competent

b) participation in interlaboratory comparisons other than proficiency testing.

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

7.8 Reporting of results

7.8.1 General

7.8.1.1 The results shall be provided accurately, clearly, unambiguously and objectively, usually in a report (e.g. test report or a calibration certificate or sampling report) (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 reports 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 Reports can be issued (hard copy or by electronic means) provided that the requirements of this International Standard are met.

7.8.1.2 In the case of a written agreement with the customer, the results may be reported in a simplified way. Any information listed in 7.8.2. to 7.8.6 which is not reported to the customer shall be readily available in the laboratory which carried out the laboratory activities.

7.8.2 Reports (test, calibration or sampling) – common requirements

7.8.2.1 Each report 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", "Calibration Certificate" or "Sampling Report");

b) the name and address of the laboratory;

c) the location of performance of the laboratory activities, including when performed at a customer facility or at sites away from the laboratory's permanent facilities, or in associated temporary or mobile facilities.

d) unique identification of the report 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 report and a clear identification of the end of the report;

e) the name and contact information of the customer;

f) identification of the method used;

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

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

i) the date(s) of performance of the laboratory activity;

j) the date of issue of the report;

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

l) a statement to the effect that the results relate only to the items tested or calibrated;

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

n) identification of the person authorizing the report;

o) clear identification when results are from external providers;

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

7.8.2.2 The laboratory shall be responsible for all the information provided in the test report or calibration certificate, except when information 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 information is supplied by the customer and can affect the validity of the test or calibration results. Where the laboratory has not been responsible for the sampling stage (e.g. the sample has been provided by the customer), it shall state in the report that the results apply to the sample as received.

7.8.2.3 Where the laboratory is responsible for the sampling stage, in addition to the requirements listed in 7.8.2.1 and 7.8.2.2, 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, and deviations, addition to or exclusions from the sample procedures;

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

f) information required to evaluate measurement uncertainty for subsequent testing or calibration.

7.8.3 Test reports – specific requirements

In addition to the requirements listed in 7.8.2, test reports shall, where necessary for the interpretation of the test results, include the following:

a) additions to deviations 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 (7.8.5);

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

d) where appropriate, opinions and interpretations (see 7.8.6);

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

7.8.4 Calibration certificates – specific requirements

7.8.4.1 In addition to the requirements listed in 7.8.2, calibration certificates shall include the following:

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

NOTE According to JCGM 200:2012 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) a statement identifying how the measurements are metrologically traceable (see Annex A);

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

7.8.4.2 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.

7.8.5 Reporting statements of conformity

7.8.5.1 When a statement of conformity to a specification or standard for test or calibration is provided, the laboratory shall document the decision rule employed, taking into account the level of risk (such as false accept and false reject and statistical assumptions) associated with the decision rule employed and apply the decision rule.

7.8.5.2 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 specifications, standard or parts thereof are met or not met;

c) the decision rule applied (unless it is inherent in the requested specification or standard).

NOTE 1 For further information see ISO/IEC Guide 98-4.

NOTE 2 Where the decision rule is prescribed by the customer, regulations or normative documents, a further consideration of the level of risk is not necessary.

7.8.5.3 When reported information associated with a calibration includes a statement of conformity with a specification, omitting the measurement results and associated uncertainties, the reported information shall include a statement that the data is not intended to be used in support of the further dissemination of metrological traceability (e.g. to calibrate another device).

7.8.6 Reporting opinions and interpretations

7.8.6.1 The opinions and interpretations expressed in test reports or calibration certificates shall be based on the results obtained from the tested or calibrated item and shall be clearly marked as such.

7.8.6.2 When opinions and interpretations are expressed, 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.

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

7.8.7 Amendments to reports

7.8.7.1 When an issued report needs to be changed, amended or re-issued any change of information shall be clearly identified.

7.8.7.2 Amendments to a report after issue shall be made only in the form of a further document, or data transfer, which includes the statement:

> "Amendment to Report [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.

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

7.9 Complaints

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

7.9.2 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.

7.9.3 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.

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

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

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

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

7.10 Management of nonconforming work

7.10.1 The laboratory shall have a procedure 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. equipment or environmental conditions are out of specified limits, monitoring of results fail to meet specified criteria). The procedure shall ensure that:

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

b) actions (including halting or repeating of work and withholding of reports, as necessary) are based upon the risk levels established by the laboratory;

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

d) a 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) are recorded.

7.10.2 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.

7.11 Control of data – Information management

7.11.1 The laboratory shall have access to the data and information needed to provide laboratory activities.

7.11.2 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.

7.11.3 The laboratory information management system shall:

a) protect from unauthorized access;

b) safeguard against tampering or loss;

c) operate 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) maintain 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;

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.

7.11.4 When the laboratory information management 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.

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

7.11.6 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 of this International Standard 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 (see 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 the management system.

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, 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 and where necessary their distribution is controlled;

e) documents are uniquely identified;

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

8.4 Control of records (Option A)

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

8.4.2 The laboratory shall implement the controls needed for the identification, storage, protection, back-up, archive, retrieval, retention time, and disposal 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 the purpose and objectives of the laboratory;

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 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 identify 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 policies, 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 When a nonconformity occurs, the laboratory shall:

a) react to the nonconformity and, as applicable:

— take action to control and correct it;

— deal with the consequences;

b) evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:

— reviewing and analysing the nonconformity;

— determining the causes of the nonconformity;

— determining if similar nonconformities exist, or could potentially occur;

c) implement any action needed;

d) review the effectiveness of any corrective action taken;

e) update risks and opportunities determined during planning, if necessary;

f) make changes to the management system, if necessary.

8.7.2 Corrective actions shall be appropriate to the effects of the nonconformities encountered.

8.7.3 The laboratory shall retain records as evidence of:

a) the nature of the nonconformities, cause(s) and any subsequent actions taken;

b) the results of any corrective action.

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) ensure that the results of the audits are reported to relevant management;

d) implement appropriate correction and corrective actions without undue delay;

e) 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 The inputs to management review shall be recorded and 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 or in the range of laboratory activities;

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;

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

8.9.3 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) provision of required resources;

d) any need for change.

Annex A

(informative)

Metrological traceability

A.1 General

Metrological traceability is an important concept to assure comparability of measurement results both nationally and internationally. This informative Annex provides additional information on Metrological traceability.

A.2 Establishing metrological traceability

A.2.1 Metrological traceability is established by considering the following:

a) the specification of the measurand;

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

c) measurement uncertainty; for each step in the traceability chain measurement uncertainty is evaluated according to agreed methods;

d) each step of the chain is performed in accordance with appropriate methods, and the measurement results and associated, recorded uncertainties;

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

A.2.2 The systematic measurement error (sometimes called bias) of the calibrated equipment is taken into account when it is used to disseminate metrological traceability to measurement results in the laboratory. There are several mechanisms available to take into account the systematic measurement errors in the dissemination of measurement traceability.

A.3 Demonstrating metrological traceability

A.3.1 Laboratories are responsible for establishing metrological traceability in accordance with this International Standard. Calibration results from laboratories conforming with this International Standard provide metrological traceability. There are various ways to demonstrate conformity with this International Standard, i.e. self-assessment, external assessment by customers, or third party recognition. Internationally accepted paths include:

a) Calibration and measurement capabilities that have been subject to peer- review processes under international arrangements such as the CIPM MRA (Comité international des poids et mesures Mutual Recognition Arrangement). Services covered by the CIPM MRA can be viewed in Appendix C of the BIPM (Bureau international des poids et mesures) KCDB (Key Comparison Database) include the range and uncertainty for each listed service.

b) Calibration and measurement capabilities that have been subject to accreditation by an accreditation body subject to the ILAC (International Laboratory Accreditation Cooperation) Arrangement or by Regional Arrangements recognised by ILAC have demonstrated metrological

traceability. Scopes of accredited calibration laboratories are publically available from their respective accreditation bodies.

A.3.2 The Joint BIPM, OIML (International Organization of Legal Metrology), ILAC and ISO Declaration on Metrological Traceability provides specific guidance when there is a need to demonstrate international acceptability of the metrological traceability chain.

Annex B

(informative)

Management system

B.1 Growth in the use of management systems generally has increased the need to ensure that laboratories can operate a management system that is seen as conforming to 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.

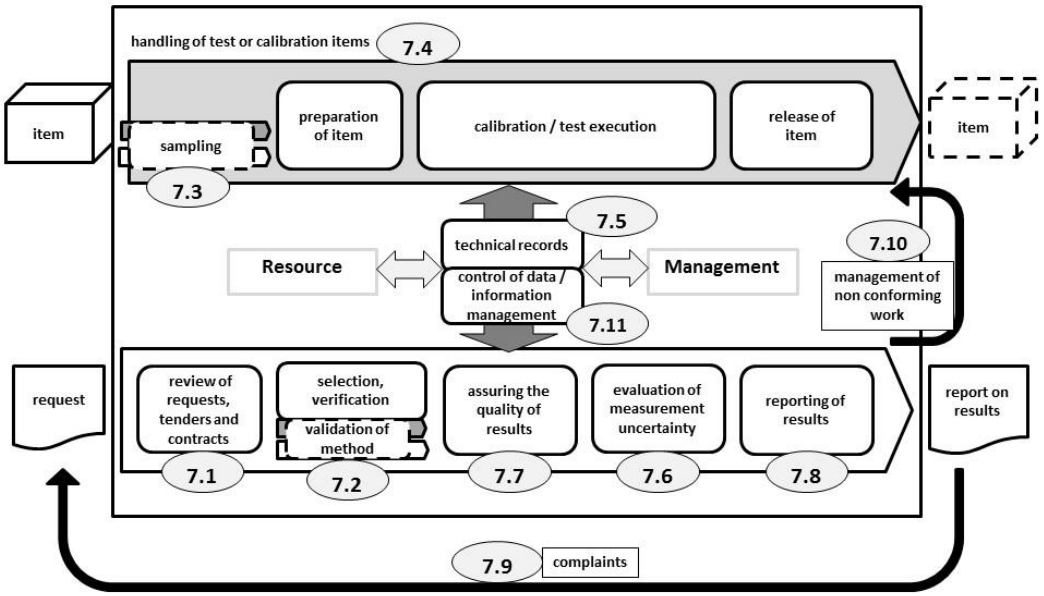
B.2 Option A lists the minimum requirements for implementation of a management system in a laboratory. Care has been taken to incorporate all those requirements of ISO 9001 that are relevant to the scope of laboratory activities that are covered by the management system. Laboratories that comply with clauses 4 to 7 of ISO/IEC 17025 and implement option A of clause 8 will therefore also operate generally in accordance with the principles of ISO 9001.

B.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.

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

NOTE Documents, data and records are components of documented information as used in ISO 9001 and other management system standards. Control of documents is covered in 8.3. The control of records is covered in 8.4 and 7.5. The control of data related to the laboratory activities is covered in 7.11.

B.5 Clause 7 of ISO/IEC 17025 is following the logic of a process, consistent with the process approach and requirements of ISO 9001. Hereafter is given a possible representation of this process.



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