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CHANGES

General document revision with policies and procedures update and/or clarifications. Accordingly, individual changes are not explicitly identified. It is the first OGC001 version for ISO/IEC 17025:2017 which both structural and content changes.

NOTE: This is a translation of the Portuguese version which prevails in all cases and for all purposes.
1. Introduction

This document provides guidance for application of ISO/IEC 17025:2017 (also referred to as ISO/IEC 17025 or as the standard). It is intended to be used by IPAC’s assessors and accredited and applicant laboratories. It includes interpretations, explanations and examples of implementation considering, among others, documents prepared by EA and ILAC as well as the experience accumulated by laboratories and IPAC. The content considered the inputs from interested parties, notably through the Laboratory accreditation Technical Committee (CTaL).

The guide is of general application (for all types of laboratory activities - testing, calibrations and associated sampling) and is structured in accordance with the clauses of ISO/IEC 17025 - it should be noted that it does not includes the standard text and SHALL always be used in conjunction with it). It contains:

- Interpretative notes (signalized with expressions as “It is interpreted” and “It is considered”);
- Examples of fulfilment of the requirements (signalized with expressions as “Can/may” and “For example/E.g.”);
- Non-binding recommendations (signalized with expressions as “It is recommended” and “Should”);
- Explicit accreditation criteria, or contractual additional requirements, both mandatory, signalized with “Shall”.

2. Bibliographic references

The following documents are the most relevant to the application of this document:

- DRC001 - General Regulation for Accreditation;
- DRC002 - Regulation for the Accreditation Symbols;
- DRC005 - Procedure for Accreditation of Laboratories;
- OGC002 - Guide for Accreditation of Chemical testing Laboratories;
- EA-4/02 - Expression of the uncertainty of measurements in calibration;
- EA-4/14 - The selection and use of reference materials;
- EA-4/16 - EA guidelines on the expression of uncertainty in quantitative testing;
- ILAC - G8 - Guidelines on assessment and reporting of compliance with specification;
- ISO/IEC 17065 - Conformity assessment -- Requirements for bodies certifying products, processes and services
- ISO/IEC 17025 - General requirements for the competence of testing and calibration laboratories;
- ISO/IEC 17000 - Conformity assessment -- Vocabulary and general principles;
- ISO 9000 - Quality management systems - Fundamentals and vocabulary;
- ISO 10012 - Measurement management systems - Requirements for measurement processes and measuring equipment;
- ISO 10015 - Quality management -- Guidelines for training;
- ISO 19011 - Guidelines for auditing management systems;
- ISO 31000 - Risk management - Guidelines;
- ISO/TR 10013 - Guidelines for quality management system documentation;
- ISO Guide 30 - Reference materials - Selected terms and definitions;
- ISO Guide 31 - Reference materials - Contents of certificates, labels and accompanying documentation;
- ISO 17034 - General requirements for the competence of reference material producers;
3. Definitions

For the purposes of this document, and in addition to the definitions in ISO/IEC 17025, the following definitions are adopted and/or referenced:

**Internal Calibration**: Calibration performed on the premises of the laboratory or organization to which it belongs, with its personnel and equipment and covered by the same management system according to ISO/IEC 17025.

**Request (consultation)**: Survey made by a potential client about the possibilities of providing laboratory services. Examples: budget requests, public consultations, etc.

**Maintenance**: Set of operations intended to maintain (preventive maintenance) or to reset (corrective maintenance) the equipment in its correct working condition, namely by replacement or inspection of parts, cleaning, etc.

**Standard method**: A test method that follows operations stated in a standard or equivalent normative document drawn up by a standardization body or a sectoral body comprising representatives of the technical sector. These methods are assumed to have been duly validated, are subject to periodic updating and are recognized by the national and international laboratory community. Examples: NP, EN, ISO, UNE, NF, etc.; sectoral standard ASTM, TAPPI, SMEWW, OIML, AOAC, etc. Methods issued or recognized by scheme owners and public authorities, where relevant, are considered as standard methods.

**Non-standard method**: This category covers methods not included in the definition of standard method, namely:

- Methods coming from adaptations or modifications of standard methods;
- Methods fully developed by the laboratory.

**Opinion and interpretation**: is the result of the process by which the applicability of the result of a test or calibration can be extended. The inferences concerned are made on the basis of the result and the knowledge and professional judgment of persons specifically authorized for that purpose. Opinions and interpretations SHALL be technically robust and supported by unambiguous evidence. Information related to the results, that are an integral part of the results and which are essential for their interpretation are not considered to be opinions or interpretations.

**Tender (proposal)**: response given by a laboratory to a request (consultation) with the purpose to celebrate a contract to perform the related laboratory activities and/or services.

**Contract**: documented agreement for providing testing, calibration and sampling services.

DRC001 contains definitions of cause analysis, correction and corrective action.

**VIM** contains, namely, the following definitions: calibration (see also DRC005), verification, uncertainty, error, correction, adjustment, traceability, standard (and related terms), reference material and certified reference material (for these last two definitions see also ISO 17034 and the related ISO/REMCO guides).

ISO/IEC 17000 includes the following definitions: accreditation, multilateral agreement, testing (see also DRC005), sampling (see also DRC005), and 1st, 2nd or 3rd party.

ISO 9000 contains, namely, the following definitions: non-conformity, correction and corrective action.

In this document the following abbreviations are used:

- BIPM - Bureau International des Poids et Mesures (www.bipm.org)
- CIPM - Comité International des Poids et Mesures (www.bipm.org)
- EA - European cooperation for Accreditation (www.european-accreditation.org)
- EPTIS - European PT Information System (www.eptis.bam.de)

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1. DRC005 includes the definition of sector scheme.
4. General Requirements

4.1. Impartiality

4.1.1 [Principle of impartiality]

4.1.2 [Management commitment]

4.1.3 [Responsibility and absence of undue pressures]

4.1.4 [Identification of risks to impartiality]

Situations that may threaten the impartiality of the laboratory or its personnel SHALL be considered as risks to the impartiality of the laboratory.

Threats to impartiality can be categorized as follows:

(a) self-interest threats: threats arising from a person or body acting in their own interest (financial, material or immaterial benefit) e.g. excessive reliance on a contract, fear of losing a client or becoming unemployed;

(b) self-assessment threats: threats that arise from a person or body evaluating their own work, e.g. evaluation of products for which they have carried out consultancy activities;

(c) advocacy threats: threats arising from the involvement of a person or body in the settlement of disputes involving their client organizations;

d) Threats of familiarity (or trust): threats that arise from a person or body that is too familiar or confident in the people performing the activity to objectively question and evaluate them;

e) threats of intimidation: threats that arise from a person or body with the perception of being coerced directly or indirectly, e.g. the threat of being replaced or reported to a superior;

f) Threats of competition: threats that arise from a person or body that evaluates products or services from its competitors.

The laboratory MUST have a mechanism for identifying the risks associated with its activities, its relationships, and the relationships of its personnel, using for example, organizational diagrams or other means.

For example, the following situations may be considered as risks to impartiality.

- Risks associated with laboratory’s activities:
  - Undue pressure caused by commercial objectives;
  - Requests for delivery of results with priority;
  - Reduced number of customers;

- Risks associated with laboratory’s relationships:

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The laboratory carries out conformity assessment activities for products whose responsibility for the design, manufacture, sale, maintenance or repair is of the of the entity to which the laboratory belongs to;

- The entity to which the laboratory belongs provides technical consulting services such as project design and validation of their suitability based on tests performed by the laboratory, with co-responsibility in obtaining results;
- The laboratory assesses the compliance of customer products that purchase other products or services to the laboratory (or the entity to which it belongs);
- The laboratory assesses the compliance of equipment used in business transactions in which the laboratory (or the entity to which it belongs) is an interested party.
- Complaints from customers or over-familiarity between the laboratory and customers;
- Relationship with regulatory entities;

- Risks associated with laboratory’s staff relationships:
  - Accumulation of duties and direct responsibilities of staff, whether performed inside or outside the laboratory or of the entity, individually or on behalf of others;
  - Self-interest (e.g. over-reliance on a contract, fear of losing a job or family relationships between different hierarchical positions).

The laboratory SHALL identify events that may impact the reassessment of risk analysis to its impartiality. Any change to the initially considered situations SHALL be promptly reassessed to confirm if the initially identified impartiality risks remain.

The one who performs, reviews or approves laboratory activities (testing, calibration, sampling) on a particular object SHALL NOT have been, or involved in, the design, production, supply, installation, service and maintenance of that object. There may be provisions, however, that minimize the associated risks to an acceptable level, such as the use of uncharacterized samples or the definition of compassionate leave.

4.1.5 [Treatment of risks to impartiality]

For each impartiality risk, the laboratory SHALL define whether it has to be eliminated or minimized. Each identified risk SHALL correspond to one or more actions to eliminate or minimize it. Interruption of conflicting activities for a sufficiently long period of time can be considered as a sufficient mitigatory measure.

Records of risk identification and implementation of defined actions SHALL be maintained.

It is recommended to the laboratory to use an impartiality risk matrix where it identifies, for each risk, its identification, probability of occurrence, severity of occurrence, defined actions to eliminate or minimize the risk and the mechanisms for monitoring these actions.

4.2. Confidentiality

4.2.1 [Accountability and customer information]

It is understood that information placed in the public domain is information that can be accessed without requiring permission. It is clarified that the information provided to the regulatory entity (or regulator), as well as to IPAC, does not fit into that concept. The laboratory SHALL agree with the client which information it intends to treat as non-confidential, except that it involves access to the information by the relevant authorities (IPAC, courts, criminal investigation authorities, among others).

4.2.2 [Confidential Information]

It is understood that the information provided to the regulatory entity (or regulator) as well as to IPAC does not require notification to the client.

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3 It concerns changes to the type of threats to impartiality as the originally identified should have previously established actions.
4.2.3 [Other sources]

4.2.4 [Application to staff]

5. Structural requirements

5.1. [Legal personality]
The laboratory (or the entity to which it belongs) SHALL prove its existence by appropriate legal document. If only the entity that is part of the laboratory has a legal existence, this situation SHALL be described in a management system document or referenced by it.

5.2. [Management Identification]
Identification of laboratory management, including its members, SHALL be documented.
Laboratory management is the person or body responsible for deciding on the policies, assets and resources required to obtain and maintain laboratory accreditation.

5.3. [Laboratory activities]
The definition of laboratory activities SHALL unambiguously identify the scope of laboratory accreditation.
Accreditation of laboratory activities that are permanent (periods longer than six months) or systematically performed by external providers will not be accepted. However, this may occur on a temporary and sporadic basis in the event, for example, of breakdown, absence of staff or work overload.

5.4. [Applicable requirements]
The laboratory SHALL evidence that it meets the regulatory requirements applicable to its accredited and applicant scope, i.e. applicable to testing, calibration and sampling4.

5.5. [Structure, Responsibilities, and Documentation]
a) The laboratory SHALL have available an organization chart, or equivalent document, showing:
   • The insertion of the laboratory in the structure of the entity where it is integrated;
   • The internal organization of the laboratory, identifying the roles and lines of authority of laboratory personnel and, if applicable, sectors or departments and their responsible;
   • The integration of personnel referred to in sections 5.6 and 6.2.6 of the standard.
b) Any substitution of duties SHALL be described in a management system document clarifying the scope of the replacement, under what circumstances and the duration of the replacement, and the necessary competence.
c) The procedures mentioned are those referred to in other clauses of the standard and SHALL therefore be documented. The extent to which they need to be documented (i) depends on factors such as their complexity and the qualifications and experience of their users, (ii) SHALL ensure the reproducible performance of the procedure.

5.6. [Quality management]
Laboratory management SHALL identify the personnel responsible for the functions defined in this clause.

5.7. [Communication and change management]
a) It is recommended that the laboratory prioritize communication tools that produce records.

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4 The assessment of compliance with other legal requirements, such as contributory or social security obligations, is not considered to fall within the scope of ISO/IEC 17025.
6. Resource requirements

6.1. General

6.2. Personnel

Personnel authorized to perform the functions described in clauses 5.6 and 6.2.6 SHALL have a contractual relationship to ensure the presence and availability required. In order to establish and maintain a relationship of confidence between IPAC and the laboratory this relationship SHALL be stable (a minimum of one year is recommended).

6.2.1 [Principle of competence and impartiality]

In cases where the laboratory uses indirect contracting mechanisms, i.e. where the laboratory hires another body which then directly contracts personnel:

- The laboratory SHALL ensure that there is a contractual relationship between all parties (laboratory, organization that hires personnel and each indirectly hired person). The name of the person(s) SHALL be identified by the laboratory in the contractual provisions;
- The laboratory SHALL be responsible for integrating indirectly hired personnel into its management system;
- The laboratory SHALL be responsible for ensuring the necessary competence for the functions to be performed, as well as the training and supervision of indirectly hired personnel;
- The laboratory SHALL assume full responsibility for the tests performed by indirectly hired personnel;
- Contractual provisions SHALL establish that indirectly hired personnel fall under the laboratory's functional and hierarchical authority and subordination lines;
- Contractual provisions SHALL ensure that indirectly contracted personnel comply with the confidentiality and impartiality requirements;
- Contractual provisions SHALL clearly establish that they do not transfer any right to use accreditation symbols or reference to accredited entity status to the company directly hiring personnel, and that the contract will terminate automatically and immediately if this occurs.

6.2.2 [Competence requirements]

Personnel performing the functions described in clause 6.2.6 of the standard SHALL have adequate and sufficient professional experience in their technical area. Any legal requirements SHALL be fulfilled.

Personnel performing the functions described in clause 5.6 of the standard SHALL have adequate professional experience in management systems and competence in ISO/IEC 17025.

6.2.3 [Competence demonstration]

Competence demonstration methods should be proportional and appropriate to the capacity under evaluation - demonstration of different types of competences (education, qualification, training, technical knowledge, expertise, experience) usually requires the application of different methods as well.

Methods such as record review (for example curricula or activity records), information feedback (e.g. from former employers or clients), interviews, on-site observations, testing and exams, among others, may be used.

Demonstration of expertise, skills and technical knowledge can be done using periodical practical and/or theoretical performance tests, intra-laboratory comparisons with more experienced or qualified personnel or participation in proficiency tests. It is recommended that at least annually the expertise and technical knowledge of personnel is demonstrated.

6.2.4 [Communication]

Communication and recording of duties, responsibilities and authorities may be in the form of a qualification’s matrix (see 6.2.6).

6.2.5 [Procedure and records]

It is considered that supervision involves activities performed before personnel authorization where monitoring corresponds to activities performer after that authorization.
6.2.6 [Personnel authorization]
Authorizations SHALL be documented in the management system.

6.3. Facilities and environmental condition

6.3.1 [Suitability]

6.3.2 [Documented requirements]

6.3.3 [Monitoring: when]
Whenever environmental conditions control is necessary, the measuring equipment used for that purpose SHALL be suitable for use, be calibrated and available in accordance with ISO/IEC 17025 clause 6.4.6. Control may be done continuously over time or only when performing the laboratory activity. Whatever the case, it SHALL always be possible to demonstrate compliance with tolerances during its performance (and any periods of stabilization or conditioning).

There may be a need to develop environmental stability and homogeneity studies of facilities where laboratory activities are performed depending on their dimensions and accuracy control requirements.

6.3.4 [Monitoring: what]
Circumstances determining access control depend on the accessibility to the laboratory areas, possible disruption of laboratory activities and existing mechanisms to preserve the confidentiality of operations. The application of the principle of forward direction in microbiology or a segregation of testing areas (physically or temporarily) to avoid contamination are examples of possible measures.

6.3.5 [Facilities outside laboratory permanent control]

6.4. Equipment

6.4.1 [Access]
Access to equipment can be provided through ownership, loaning, renting, leasing, etc.

6.4.2 [Equipment outside permanent control]
An equipment is considered outside the laboratory permanent control when:

(a) It is temporarily transferred by the laboratory for use by persons or external bodies (e.g. for research, training or sharing with another department of the same entity); or

(b) The laboratory uses external equipment, provided by third organizations for use in the laboratory’s (or its customers’) facilities.

The laboratory SHALL define the methodology for others to use equipment outside its permanent control - item (a) above - in particular regarding:

- Conditions for hand over and use;
- Conditions of access to facilities where the equipment is located;
- Records regarding the use of equipment in those conditions.

In cases where the laboratory uses equipment provided by third parties - item (b) above - or put equipment into service after temporary external assignment - item (a) above - it is the responsibility of the laboratory to confirm the suitability of this equipment for its intended use (e.g. establishment of acceptance criteria, planning of calibrations and intermediate checks, and analysis of results and repercussions of the results of these activities).

6.4.3 [Procedure for handling]
After transporting it may be necessary to confirm the equipment’s performance before use.
6.4.4 [Verification before use]

6.4.5 [Appropriate accuracy]

6.4.6 [General criteria for calibration]

It is considered that equipment that requires calibration includes, besides those explicitly referred to in the standard, also those which calibration is required by the methods (normative documents) used to perform the laboratory activities.

Calibrations can be performed externally by “competent entities” or internally by the laboratory (see this guide section 6.5.2).

Calibration (or testing) SHALL be understood as a mean to knowing the metrological and functional characteristics of the equipment. Even if the equipment has been calibrated it may have errors (or other characteristics) making it unsuitable for the intended use. Verification aims to establish compliance with specified requirements and confirm fitness for use.

Acceptance criteria (CA) SHALL be established for equipment (namely maximum or minimum acceptable values considering the intended use) that allow to analyse the results of calibrations performed and to make decisions regarding their suitability (to use without restrictions, restricted or partial use, reclassification, to repair or to adjust, to withdrawal from service).

It is recommended that, in the absence of specifications on how to assess conformity with the acceptance criteria established by normative documents, legislation, etc, the following evaluation methodology to be used:

- The sum of the Error modulus with the modulus of the associated uncertainty to be less or equal to the equipment’s acceptance criteria (i.e. \(|\text{Error}| + |\text{Uncertainty}| \leq |\text{CA}|\)).

6.4.7 [Calibration program]

The laboratory SHALL evidence that it has an updated calibration program (or plan) with the relevant information, namely, the equipment identification, the entity responsible for calibration, frequency and scheduled calibration date.

6.4.8 [Identification of the calibration status]

It is considered that the identification of the calibration (or validity) status can be made, for example:

- Through labels (or other marking) placed in visible parts of the equipment or on the respective storage boxes (if it does not cause ambiguities);
- By separation and/or storage of the equipment in specific locations, duly signalized and identified.

All restrictions on use (including measuring ranges) SHALL be clearly identified on the equipment (or in the identification mechanisms used).

6.4.9 [Out of service]

6.4.10 [Intermediate checks]

It is considered that normally the laboratory SHALL carry out intermediate checks of the metrological and functional characteristics of the measuring instruments (or standards) between calibrations (or tests) in order to control their drifts and suitability for use, allowing timely detection of faults or failures. It is recommended that the frequency of this control (daily, weekly, etc.) be established considering the following factors:

- Previous experience and trend analysis, obtained through the analysis of previous calibrations;
- Manufacturer’s recommendations;
- Indirect data about equipment behaviour (maintenance, interlaboratory comparisons, etc.);
- Frequency, type and conditions of the equipment utilization;
- Environmental conditions (temperature, humidity, vibration, etc.);

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5 To assess the conformity of an equipment considering only one limit (superior or inferior) for one of its parameters it may be more appropriate to compare the observed value with the limit value using an unilateral t test where the measurement standard deviation is replaced by the measurement standard uncertainty.
• Required accuracy.

Whenever the laboratory doesn’t perform intermediate checks, it SHALL technically justify it.

6.4.11 [Correction Factors]

6.4.12 [Unintentional adjustments]

Protection against adjustments does not prevent that they can be made to maintain, restore or improve the equipment operation. Examples of measures taken include the use of passwords and inviolability seals.

6.4.13 [Records]

d) It is considered appropriate to record the equipment’s location when its use is restricted to certain places or areas of the laboratory.

e) The laboratory SHALL keep records of malfunctions or deviations prior to adjustment, in order to assess, in particular, the magnitude of possible impacts on the tests and calibrations prior to the adjustment.

g) It could be appropriate to establish a preventive maintenance plan.

6.5. Metrological traceability

6.5.1 [Principle]

6.5.2 [Reference mechanisms]

a) IPAC considers as “competent entities” for the purposes of external calibration:

• Laboratories accredited by IPAC to perform the specific calibration - they are identified by the use of their accreditation symbol in the certificates issued (the identification of these laboratories can be done by consulting IPAC’s website);

• Laboratories accredited to perform the specific calibration by one of the accreditation bodies signatories of the EA or ILAC Multilateral Agreement (arrangement) - they are identified by the use of their respective accreditation symbol (consult the signatories and their respective websites at www.european-accreditation.org and http://www.ilac.org);

• National Metrology Laboratories (LNM) or Designated Institutes (ID) whose services are covered by the CIPM Mutual Recognition Agreement (MRA). These services are listed in Appendix C of the BIPM key comparison database (http://kcdb.bipm.org/appendixc/).

As an exception, when calibration capabilities are not available by (national or foreign) “competent entities”, calibrations made by other entities can be accepted, provided that the laboratory demonstrates that these entities are competent to ensure metrological traceability to SI units. IPAC will evaluate those evidences, which may involve witnessing laboratory audits to those entities. For further details, see Appendix A of ILAC-P10.

It is considered that internal calibrations SHALL meet the same requirements as those of an accredited calibration laboratory. Thus, when these calibrations are carried out by the laboratory itself, they SHALL be available to be assessed - for that purpose IPAC may introduce one or more additional members in the assessment team. As for accredited calibration laboratories, they SHALL also participate in proficiency testing activities recognized by IPAC (see section 7.7.2 of this document) in the technical areas subject to internal calibration.

Calibration certificates, or other documents for the same purpose, issued by other bodies, including manufacturers or companies (even with ISO 9001 certification), are not accepted.

If there are measuring instruments or standards subject to legal metrological control, that are also used for testing or calibrations within the accreditation scope, it is also necessary that these devices are calibrated by “competent entities” as defined above, except when the metrological control is an accredited activity.

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6 Requirements regarding internal calibrations in DRC005 SHALL also be considered.

7 It is considered as a measuring instrument or standard subject to a legal metrological control operation the one where a metrological control regulation is in place and when used directly for measurements foresee in the relevant legal framework.
These provisions are also applicable, with the appropriate terminological adaptations, to the performance of metrological and functional tests on standards, measuring instruments or devices subject to metrological characterization (e.g., thermo-regulated baths).

6.5.3 [Alternative mechanisms]

When the state of the art does not allow metrological traceability to the SI units, it is the responsibility of the laboratory to demonstrate this impossibility and the suitability of the implemented actions.

6.6. Externally provided products and services

6.6.1 [Suitable products and services]

b) It is recommended that testing, calibration and sampling services with the purpose to deliver their results directly to the customer are contracted to accredited laboratories.

6.6.2 [Verification of products and services]

b) Provider evaluation may involve, for example, audits performed by the laboratory. The conclusions on provider evaluation SHALL be made by product type and service type.

Quality of service, product quality, delivery time, certification or accreditation, as applicable, are examples of provider evaluation criteria.

The laboratory SHALL evaluate all relevant providers even in case of a unique provider (in order to be able to express their satisfaction and measure progress, and to be able to compare when there are more providers).

6.6.3 [Communication with providers]

b) The acceptance criteria may be related to product (or service), to the provider itself, or both, depending on the product or service concerned but also the reality of the relevant sector.

d) It is considered this requirement relates to activities performed by the laboratory regarding the provider’s qualification, such as, where applicable, performing second party audits of the provider by the laboratory.

7. Process requirements

7.1. Review of requests, tenders and contracts

7.1.1 [Procedure]

c) The use of external providers of testing, calibration and sampling services may fall into two distinct situations:

- The laboratory is accredited to perform the activity but due to unforeseen reasons it is not able to perform it timely. In these cases, the use of external providers SHALL not extend for more than six months (see 5.3);
- The laboratory is not accredited to perform the activity. These are cases where the laboratory acts as an intermediary for contracting the conformity assessment activities.

In both cases the report SHALL identify such activities as outside of the accreditation scope (see 7.8.1).

d) If applicable, the selected method SHALL satisfy the requirements of the regulatory entity. The laboratory SHALL be able to provide evidence that the customer has been informed of the selected method to realize the laboratory activity before its beginning.

It is considered that when the laboratory is accredited according only to a method for a specific activity (testing, calibration or sampling) it is not necessary to inform the customer of the method to be used, provided that the tender is duly accompanied by the current Technical Annex or reference to it.

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In order that the activity contracted to an external provider is considered the same as the one that the laboratory is accredited for, all technical descriptors established in the relevant scope description model must be identical. In the case of testing, for example, this corresponds to the determination of the same characteristic on the same product using the same method.
7.1.2 [Inappropriate methods]

7.1.3 [Statements of conformity]
When it is required to use a specific method for a laboratory activity (testing, calibration or sampling) a statement of conformity can only be made when that method has been used.

7.1.4 [Differences between request and contract]

7.1.5 [Deviations to the contract]

7.1.6 [Amendments to the contract]

7.1.7 [Cooperation with the customer]
a) Any permission to the customer to witness tests and calibrations SHALL take into account:
   - The operational and/or environmental conditions necessary not to invalidate the results;
   - Possible safety conditions;
   - The fulfillment of confidentiality and impartiality requirements.

b) It is advisable to have arrangements in place to return tested items to customers (when requested). It is also appropriate to establish a maximum deadline for returning the sample and to inform the customer in advance when the amount or perishability of the sample makes impossible to return it.

7.1.8 [Review records]
Records SHALL cover all relevant aspects including delivery results times, pricing, use of external testing (or calibration or sampling) providers and sampling responsibility.

7.2. Selection, verification and validation of methods

7.2.1 Selection and verification of methods

7.2.1.1 [Appropriate methods]

7.2.1.2 [Documented and available methods]

7.2.1.3 [Up-to-date methods]

See the provisions in DRC005 regarding obsolete methods (and related normative documents).

7.2.1.4 [Methods selected by the laboratory]

7.2.1.5 [Verification of methods]

It is considered that the verification of a method applies to standard methods, corresponding to the recorded demonstration that the implementation of the method in compliance with its performance characteristics and, if applicable, its suitability for the specific use required.

It is interpreted that the implementation referred in the standard concerns the method availability routinely.

7.2.1.6 [Development of methods]

Under the framework of the accreditation system managed by IPAC, it is considered that the provisions in this clause are not applicable to the fixed accreditation scope models. For the flexible scope models, the relevant requirements are addressed in DRC005.

7.2.1.7 [Deviations from methods]

In the context of the fixed description of the scope, when there are deviations from the accredited methods, the laboratory activities concerned SHALL be flagged as non-accredited in the reports (or certificates), indicating that a deviation has been made to the method. The approach to be adopted in context of flexible description SHALL be similar when the methods with deviations are not included in the respective testing lists under flexible accreditation.

7.2.2 Validation of methods

7.2.2.1 [Non-standard methods]
In order to validate a method, it may be necessary and convenient to perform some (or all) the studies listed below.

Indirect evaluation, by evidence of its characteristics:

- Study of the representativeness of the method, i.e. that the characteristics determined correspond to the objective of the laboratory activity in question;
- Study of the theoretical principles (fundamentals) of the method to point out its scientific basis;
- Studies of interferences and sources of error to delineate its applicability and to master its performance;
- Studies of optimization of the operating conditions and/or robustness of the method to allow an optimization and harmonization of its performance;
- Study of performance characteristics of the method (e.g.: field of application, accuracy, repeatability, robustness, intermediate precision, reproducibility, detection and quantification limits, uncertainty, etc.) to know the quality of its results.

Direct evaluation, by comparison with accepted references:

- Comparison with standard or reference methods;
- Comparison with standards or certified or reference materials;
- Interlaboratory comparisons.

In certain technical areas, the methodology or criteria for validating methods or establishing their equivalence or comparability may be described in normative (or legal) documents which SHALL be followed.

In certain technical areas (e.g. food microbiology) the validation of non-standard methods is sometimes carried out by a third-party using process certification methodologies. In such cases, that body SHALL be accredited in accordance with ISO/IEC 17065, for the particular activity concerned, by an accreditation body that is a signatory to the relevant EA or IAF multilateral agreement. The certificate issued SHALL have the relevant accreditation symbol.

7.2.2.2 [Revalidation of methods]

When a method has been validated by comparison with a standard method that has become obsolete, the comparison SHALL be reassessed against the new version and the method revalidated if necessary. Refer also to the provisions in DRC005 regarding obsolete methods.

7.2.2.3 [Validation relevant for the needs]

7.2.2.4 [Validation records]

a) The validation procedure only needs to be previously established for flexible scope description models (see DRC005).

7.3. Sampling

The requirements related to this activity - either including the sampling plan design or only the collection - will only be assessed if it is included in the accreditation scope.

Interested laboratories SHALL take into account the following provisions regarding other ISO/IEC 17025 clauses.

<table>
<thead>
<tr>
<th>7.1. Review of requests, tenders and contracts</th>
</tr>
</thead>
<tbody>
<tr>
<td>It SHALL explicitly provide the deadlines to consider to collect, transport and deliver samples. The laboratory SHALL keep the relevant records of the delivery of samples (e.g. date and hour).</td>
</tr>
<tr>
<td>The laboratory SHALL ensure the compatibility between sampling methods and determination methods.</td>
</tr>
<tr>
<td>If the laboratory only carries out sampling activities or has been contracted only for those activities, the operating conditions SHALL be clearly defined, namely the responsibilities and provisions concerning:</td>
</tr>
<tr>
<td>- The supply and conditioning of the container and other sampling material which may be from the laboratory that performs the tests;</td>
</tr>
<tr>
<td>- Preservation and conservation of the samples according to the methodology that will be used later in the tests;</td>
</tr>
</tbody>
</table>
Methodology and planning of sampling quality control, as well as the exchange of information on the results of quality control;
Fulfilment of the established deadlines.

7.4. Handling of test or calibration items
The laboratory that collects the sample SHALL carry out or ensure under their responsibility the transport to the laboratory that makes the determinations.

7.7. Ensuring the validity of results
The laboratory SHALL participate in proficiency testing or other interlaboratory comparisons that includes sampling (if available).
If the accreditation, or application, of the laboratory only includes sampling, the laboratory SHALL ensure that the determinations inherent to the validation and quality control are carried out in accredited laboratories for those determinations, when not carried out by the laboratory itself (and provided that the competence for such determinations by the laboratory has been assessed and accepted by IPAC).

### 7.3.1 [Sampling plan and method]

The use of statistical methods is considered to be “reasonable” when sampling is not made at 100% or when the homogeneity of the product influences the results. In other cases, the laboratory SHALL justify when does not use statistical methods.

The statistical methods used SHALL be recorded.

### 7.3.2 [Elements of the sampling method]

### 7.3.3 [Sampling records]

### 7.4. Handling of test or calibration items

#### 7.4.1 [Handling procedure]

#### 7.4.2 [Identification of items]

The system for identifying items to be tested or calibrated can be done, for example, through labels, marks, equipment code, customer reference.

It is considered implicit the existence of a registration system for items to be tested or calibrated.

It is considered appropriate to subdivide samples, for example, when a sample has to follow for different test or calibration sites simultaneously (chemistry and microbiology).

#### 7.4.3 [Deviations]

Testing or calibrating of an item that raises doubts about its suitability SHALL be performed only after customer acceptance. When it is unambiguous that the item does not meet the specific conditions and the results may be affected, it is considered that a deviation from the method is in place and the relevant results SHALL be signalized as non-accredited, indicating also that a deviation to the method had occur.

#### 7.4.4 [Storage]

### 7.5. Technical records

#### 7.5.1 [Complete records]

It may be not possible or not practicable to keep records of all original observations in cases where the equipment automatically performs several measurements, processes their results or signals and provides only a statistical summary (mean, standard deviation, etc.).

Records of laboratory activities can be made, for example, in specific templates, operator (or test) books, records provided by the equipment or in computerized information management systems.

It is recommended that, in order for records to be identifiable with the tasks, specific templates are used or otherwise records are made in a predefined manner. Records SHALL be intelligible not only by the persons who currently work in the laboratory, but also for those who will be involved in the future and may also have to interpret those records.
7.5.2 [Amendments to the records]

7.6. Measurement uncertainty evaluation

7.6.1 [General provisions]
The laboratory SHALL have records of uncertainty evaluations, including the identification of the main components to consider. It is recognized that there are cases where the rigorous quantification of these components is impossible and therefore, only approximate estimates can be made. In these cases, the laboratory SHALL evidence the impossibility of rigorous quantification of the components concerned.

It is considered that uncertainty evaluations are not necessary when:

- The results are qualitative (i.e. not expressed in numerical values) or semi-quantitative (i.e. expressed as a range of values);
- In standard methods where the situation described in Note 1 ISO/IEC 17025 clause 7.6.3 occurs (for example: tests according to OIML Regulations satisfying that note).

When evaluating uncertainty, it is acceptable to consider negligible the contribution of certain components and, as such, not to include them in the uncertainty budget. For this purpose, a criterion might be to consider negligible the contribution, in terms of the respective standard uncertainties, of components that together do not exceed 1/5 of the total contributions not disregarded. It is recommended that the assumed assumptions be periodically verified in order to confirm (or not) their validity.

The use of maximum values for certain components, based on documented studies, is also accepted, facilitating the determination of uncertainty in similar situations.

An overall evaluation or an evaluation of the main components can be made, based on experience, validation, interlaboratory comparisons and quality control data.

In order to support a consistent and harmonized approach to the evaluation of uncertainties, the state of the art is typified in the table below⁹ - it is expected that each laboratory will follow the state of the art for each type of test.

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Qualitative or semi-quantitative tests, where evaluation and reporting of uncertainties is not required – it may include components presence/absence tests or component identification tests. The sources of uncertainty SHALL be identified and, where possible, quantified.</td>
</tr>
<tr>
<td>2</td>
<td>Tests performed according to standard methods covered ISO/IEC 17025 clause 7.6.3 Note 1 – for these cases a regular and systematic uncertainty evaluation is dispensed, provided that the laboratory demonstrates to fulfill with the method provisions.</td>
</tr>
<tr>
<td>3</td>
<td>Tests where only the main sources of uncertainty are identified, and the uncertainty evaluation is often made through a global approach – these tests will often have only one or two main sources of uncertainty.</td>
</tr>
<tr>
<td>4</td>
<td>Tests where the sources of uncertainty are identified and where those with a contribution of less than 20% of the combined uncertainty (in terms of their standard uncertainties) can be ignored - an evaluation by grouping components (top-down) or an analysis by each component (bottom-up or a step-by-step) can be made.</td>
</tr>
<tr>
<td>5</td>
<td>Tests where all sources of uncertainty are identified and evaluated - in principle there are several significant sources of uncertainty and their value may vary from test to test. Most calibrations are covered by this situation.</td>
</tr>
</tbody>
</table>

7.6.2 [Calibration]
The principles, methodology and terminology to be followed by the laboratory to evaluate and report uncertainty in calibration SHALL be in accordance with EA-4/02 (OGC010).

It is expected that the uncertainties evaluated in routine will be close to the corresponding CMC (best uncertainty) - the laboratory SHALL be able to justify when this does not happen.

Internal calibrations of laboratory’s working standards can, provided that the relevant skills and resources are available, have an uncertainty smaller than the corresponding CMC. In these cases, the accreditation symbol SHALL NOT be apposed in a calibration certificate.

⁹ Even when the uncertainty evaluation is not required from the provisions in the table above, it may be necessary due to contractual or legal requirements which prevail.
7.6.3 [Testing]
The principles, methodology and terminology to be followed by the laboratory to evaluate and report uncertainty are established in document EA-4/16. However, given its generic nature, its application may be supported using sector standards or guides.

7.7. Ensuring the validity of the results

7.7.1 [Procedure]
Monitoring the validity of results SHALL be more frequent and exhaustive in areas where there is no metrological traceability to the SI, e.g. for some chemical and biological tests.

7.7.2 [Interlaboratory comparisons and proficiency testing]
Participation in other interlaboratory comparisons does not exclude the need to participate in proficiency testing, given the ILAC policy on the subject, included in DRC005. On the other hand, the unavailability of proficiency testing does not exclude participation in other interlaboratory comparisons that may be available. In these cases, when practicable, the laboratory SHALL participate in comparisons organized by third parties (e.g. for the development and characterization of standard methods or for method validation). As a last resource, the laboratory SHALL seek to organize comparisons with other accredited laboratories for the same scope. Records of searches and initiatives SHALL be kept for cases where it is not possible to participate in any comparison.

7.7.3 [Data-monitoring]
Examples of pre-defined criteria are acceptance and rejection criteria for duplicates, control standards, blanks, etc.

7.8. Reporting of results

7.8.1 General
7.8.1.1 [Review and authorisation]
7.8.1.2 [Unambiguous, accurate and objective presentation]

General conditions for the reproduction and use of the accreditation symbol (hereinafter referred to also as symbol) are established in DRC002.

As established in DRC002 it is a condition for the symbol to be apposed in a report that at least one of the reported laboratory activities has been performed by the laboratory under its accreditation scope.

Laboratory activities carried out by external providers (see 5.3 and 7.1.1) SHALL be identified as outside the accreditation scope of the emitting laboratory\(^\text{10}\). However, the use of an accredited external laboratory for those activities may be indicated, when applicable.

The laboratory SHALL be able to distinguish reports (test, calibration or sampling) and other documents where it invokes the status of an accredited body, namely by the use of the symbol, from those where it doesn’t. For this purpose, the laboratory can, for example, keep copies of that documents or keep a log of the use of the accreditation symbol.

The presentation of results by data transfer through electronic platforms SHALL ensure compliance with normative requirements. This is the case of those applicable to Technical records (clause 7.5 of the standard) and Control of data and information management (clause 7.11 of the standard).

When client platforms are used, they are also external providers of information management systems (see 7.11.4 of the standard). In cases where the laboratory is unable to ensure compliance of the platform with the normative requirements, the data transfer is considered as an additional service provided by the laboratory, without prejudice to the need to present results by other means that comply the normative requirements.

In cases where results are presented exclusively by data transfer, not using the accreditation symbol may be authorized, provided it is duly justified, in accordance with DRC002 provisions.

The table below summarizes the statements and remarks to be included in the reports (test, calibration or sampling).

\(^{10}\) Cases where sampling activities are the responsibility of the customer are included.
Declarations and remarks to include in reports (certificates)

<table>
<thead>
<tr>
<th>Aspect to consider</th>
<th>Sampling</th>
<th>Determination</th>
<th>Both</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. To signalize testing and calibration activities outside laboratory accreditation (7.8.1.2, DRC002 5.3.1)</td>
<td></td>
<td></td>
<td>•</td>
</tr>
<tr>
<td>2. To signalize sampling activities outside laboratory accreditation (7.8.1.2, 7.8.5, DRC002 5.3.1) (7.8.1.2, 7.8.5, DRC002 5.3.1)</td>
<td>•</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. To signalize activities and results issued by external providers, including sampling activities performed by the customer (7.8.1.2)</td>
<td></td>
<td></td>
<td>•</td>
</tr>
<tr>
<td>4. To signalize results presented in a simplified way as request by an external customer (7.8.1.3)</td>
<td></td>
<td></td>
<td>•</td>
</tr>
<tr>
<td>5. To declare that results refer only to items tested, calibrated or sampled (7.8.2.1 l)</td>
<td></td>
<td></td>
<td>•</td>
</tr>
<tr>
<td>6. To signalize the information provided by the customer (7.8.2.2)</td>
<td></td>
<td></td>
<td>•</td>
</tr>
<tr>
<td>7. To signalize deviations to methods as non-accredited scope (7.2.1.7, 7.4.3, 7.8.2.1 n)</td>
<td></td>
<td></td>
<td>•</td>
</tr>
<tr>
<td>8. To signalize opinions and interpretations (7.8.7)</td>
<td></td>
<td></td>
<td>•</td>
</tr>
<tr>
<td>9. To signalize caveats (sampling/determination) regarding presented measurement uncertainties (7.8.5)</td>
<td></td>
<td></td>
<td>•</td>
</tr>
<tr>
<td>10. To declare the meaning of equivalent methods.</td>
<td></td>
<td></td>
<td>•</td>
</tr>
</tbody>
</table>

Statements to be used:

1. Mandatory text (DRC002 5.3.1): “The [test] [calibration] marked with (e.g. *) is not included in the accreditation scope”.
2. Mandatory text (7.8.5): “The sampling [collection] carried out is not included in the accreditation scope”.
3. Mandatory text (7.8.1.3): “This Report [Certificate] does not contain all information, which may be provided upon request, required by ISO/IEC 17025, as agreed with the customer”.  
4. Recommend text: “Opinions / interpretations expressed in this Report (Certificate) are not included in the accreditation scope”.

7.8.1.3 [Simplified presentation]

A simplified presentation of results allows some of the elements discriminated in the standard not be included in the reports. These elements are discriminated in the table below and differentiate between the possible simplification for internal customers (within the same legal entity) and for external customers.

The simplified presentation of results SHALL in any case be agreed with the customer.

For internal customers:

- The agreement SHALL include a commitment that reports are not disclosed outside the legal entity;
- When simplified reports released to internal customers do not include the accreditation symbol, they SHALL include the textual reference to accredited body status (see DRC002).

For external customers, reports SHALL include the following text in a way that it is legible and similar to the presentation of results:

- “This Report (Certificate) does not contain all the information required by ISO/IEC 17025, as agreed with the customer. The missing information may be provided upon the customer’s request”.

The simplifications systematized here do not prevail over the provisions of the normative documents that establish testing, calibration and sampling methodologies.
### Simplified presentation of results

<table>
<thead>
<tr>
<th>Relevant clause</th>
<th>Testing</th>
<th>Sampling</th>
<th>Calibration</th>
<th>Simplification</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.8.2.1 a) title</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.8.2.1 b) e) c) name and address of the laboratory the location of performance of the activity</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.8.2.1 d) Unique identification of the report (and its parts)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.8.2.1 e) name and contact information of the customer</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.8.2.1 f) identification of the method used (including the versions)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.8.2.1 g) Description, condition and identification of the item</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.8.2.1 h e) i) Date of receipt and date of performance of the laboratory activity</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.8.2.1 k) reference to the sampling plan and sampling method</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.8.2.1 l) statement to the effect that the results relate only to the items tested, calibrated or sampled</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.8.2.1 m) Results</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.8.2.1 n) Deviations</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.8.2.1 o) Identification of the persons authorizing the report</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.8.2.1 p) identification of the person(s) authorizing the report</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.8.3.1 a) information on specific test conditions e.g. environmental conditions</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.8.3.1 b) Statement of conformity, when relevant</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.8.3.1 c) Measurement uncertainty, when applicable</td>
<td></td>
<td></td>
<td></td>
<td>●</td>
</tr>
<tr>
<td>7.8.3.1 d) Opinions and interpretations, when appropriate</td>
<td></td>
<td></td>
<td></td>
<td>●</td>
</tr>
<tr>
<td>7.8.3.1 e) Additional information required by the method or the client</td>
<td></td>
<td></td>
<td></td>
<td>●</td>
</tr>
<tr>
<td>7.8.4.1 a) Measurement uncertainty</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.8.4.1 b) Conditions (e.g. environmental) under which the calibrations were made</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.8.4.1 c) Metrological traceability statement</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.8.4.1 d) Results before adjustment</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.8.4.1 e f) Statement of conformity, opinions and interpretations, where applicable</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.8.5 a) Date of sampling</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.8.5 b) Identification of the sampled material</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.8.5 c) Location of sampling</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.8.5 d) reference to the sampling plan and sampling method</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.8.5 e) details of any environmental conditions during sampling</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.8.5 f) information required to evaluate measurement uncertainty for subsequent testing or calibration</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The gray background cells in the Test, Sampling and Calibration columns identify the applicability of the requirement while the Simplification column identifies the simplification possibilities for internal and/or external customers. Elements that can be deleted for ● Internal and external customer, ○ Internal customer.

### 7.8.2 Common requirements for reports (test, calibration or sampling)

7.8.2.1 [Elements]

f) It is interpreted as “identification of the method” its (associated normative document) designation and its version. It is not necessary to indicate the test technique or the measurement principle, even when they are described in the scope of accreditation, except when necessary to identify the part of the applicable normative document. Descriptors used SHALL be those in the Technical Annex. For accreditations under flexible scope description models the method version SHALL be included in the report.

g) It is recommended that the description of the item and, when applicable, of the characteristic concerned refer to the terminology used in the Technical Annex. When this is not the case, it SHALL be possible to establish an unambiguous relationship with the activity as presented in the Technical Annex. It is considered that in the description of the “condition” SHALL be recorded any inappropriate conditions of the item identified during its reception. See also the provisions established in sections 7.2 and 7.4 of this document.

i) The dates of the performance of the laboratory activity may be recorded as an interval when this does not prejudice the interpretation of the results.
m) It is considered that for the presentation of quantitative test results to be clear for example when signalizing “non detected” or “non quantified”, the values of the detection limit or of the quantification limit (as applicable) SHALL also be indicated.

The number of significant digits used in the result SHALL be consistent with:

- The guidance given in the corresponding normative document (including legislation);
- The evaluated uncertainty for the result according to EA-4/02 for calibration and to EA-4/16 for testing. When the presentation of testing results does not include the uncertainty - see 7.8.3.1 (c) - the presentation SHALL be coherent with the variability and dispersion of results observed for that test or type of test (see 7.6. in ISO/IEC 17025) - the use of excessive significant digits induces false confidence in the customer, and the use of insufficient significant digits does not provide all the valid information available to the laboratory;

The result value SHALL be rounded to the last significant digit of the associated expanded uncertainty. The expanded uncertainty SHALL be presented with a maximum of two significant digits. E.g. if \( R = 10.05762 \) \( \Omega \) with \( U = 27 \) m\( \Omega \), \( R \) SHALL be rounded to \((10.058 \pm 0.027) \) \( \Omega \);

- In the case of calibration of a measuring instrument, when the measurement result includes or is limited to the presentation of the calculated error value (instrument indication value - reference value), it SHALL be rounded to the last digit of the Expanded Uncertainty value. If the measurement result includes the presentation of an average indication value of an instrument other than the object being calibrated (e.g. mass calibration) it SHALL be rounded to the last digit of the Expanded Uncertainty value.

7.8.2.2 [Information provided by the customer]

It is interpreted that the information that needs identification is the one that may have an impact on the results or their interpretation, thus excluding administrative information such as the one concerning customer contacts.

7.8.3 Specific requirements for test reports

7.8.3.1 [Elements]

b) It is considered relevant to include a statement of conformity when it comes from a contractual relationship established with the customer, or when foresee in the test standard or specification or applicable law.

c) Without prejudice of the normative provisions regarding reporting uncertainty in sampling - see in particular the table in clause 7.8.5 - for the cases 3, 4 and 5 in the table in section 7.6 test reports SHALL include the uncertainties, except when there are documented provisions issued by a regulatory authority that exempts the presentation of the uncertainty evaluation.11

d) See the definition of Opinion and Interpretation.

e) If adjustments are made to standards, measuring instruments or devices subject to metrological and functional tests (e.g. thermostategulated media), pre- and post-adjustment test results SHALL be available when the laboratory is the body performing the adjustment. The adjustment SHALL be done only after documented agreement with the customer. In cases where repair is performed as a supplementary service to testing by an organization to which the laboratory belongs, pre- and post-repair values SHALL be reported, if any.

7.8.3.2 [Cases involving sampling]

Consult to the normative provisions of clause 7.8.5 as well as the related interpretations and guidance in this document.

7.8.4 Specific requirements for calibration certificates

7.8.4.1 [Elements]

a) Uncertainties presented SHALL always be higher than or equal to the corresponding CMC (Best uncertainty) in the Technical Annex.

c) It is not relevant to state the metrological traceability except when necessary to interpret the calibration results. When this is the case, sufficient information SHALL be reported for such interpretation

11 The case where a decision rule establish that the uncertainty is not to be accounted for does not exempt the laboratory from evaluating it (see 7.6), nor does it exempt the laboratory from presenting it. When there is a statement of conformity where the decision rule establishes that the uncertainty is to be accounted, including the uncertainty in the report cannot be exempted.
and it is considered that such a statement SHALL include the identification of the reference above in the metrological chain or the body responsible for the calibration of the equipment or standard. Thus, in these circumstances, the reference standard(s) (relevant for the measurement) and the name(s) of the body(ies) having calibrated them SHALL be indicated. For example:

“Platinum thermometer calibrated in Lab NNN”; “E2 mass collection calibrated in Lab ABC”; “Gauge blocks calibrated in Lab XYZ”.

Being the metrological traceability one of the requirements of ISO/IEC 17025 it is considered that accredited laboratories evidence its suitability through the use of the accreditation symbols, so any further explanation is not necessary. In this way, the (mandatory) apposition of the respective symbol is sufficient. However, the laboratory may choose to make explicit how it obtains its traceability, or it may decide to add clarifying text - for example “The metrological traceability is assured by the laboratory accreditation”.

There may also be normative, contractual or legal provisions requiring making explicit metrological traceability; in such cases the applicable requirements SHALL be followed.

d) Calibration results before and after adjustment SHALL be available when is the laboratory that performs the adjustment. Adjustment SHALL be done only after documented agreement with the customer.

In cases where repair is performed as a service in addition to calibration by an organization to which the laboratory belongs to, the values before and after repair SHALL be reported, if any.

7.8.4.2 [Cases involving sampling]
7.8.4.3 [Not to recommend calibration intervals]

7.8.5 Reporting sampling - specific requirements

If the laboratory has done the sampling and is not accredited for that, and its performance is implied (by indication of locations, dates of collection or when contractually established), it SHALL include the following text, legibly and similar to the presentation of results, in the corresponding reports with the accreditation symbol:

“The sampling [collection] carried out is not included in the scope of accreditation”.

IPAC’s provisions regarding the presentation of the evaluation of uncertainty, and related information, is summarized in the table below considering the type of work reported and its coverage by the accreditation scope.

<table>
<thead>
<tr>
<th>Does the report include information about sampling?</th>
<th>Does the report include information about determination?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes, accredited</td>
<td>The uncertainty resulting from the combination of the uncertainties from the two activities SHALL be presented while the uncertainties from each contribution may be presented. Alternatively, only the uncertainties from the two contributions may be presented and, additionally, also the mechanism to combine them.</td>
</tr>
<tr>
<td>Yes, accredited</td>
<td>The information required in ISO/IEC 17025 clause 7.8.5 f) SHALL be presented.</td>
</tr>
<tr>
<td>Yes, accredited</td>
<td>The information required in ISO/IEC 17025 clause 7.8.5 f) SHALL be presented.</td>
</tr>
<tr>
<td>Yes, not accredited</td>
<td>The uncertainty resulting from the combination of the uncertainties for each activity may be presented. However, it SHALL be signalized that the combination and the determination uncertainty are not covered by accreditation.</td>
</tr>
<tr>
<td>No</td>
<td>The information required in ISO/IEC 17025 clause 7.8.5 f) SHALL be presented.</td>
</tr>
</tbody>
</table>
Does the report include information about sampling? | Does the report include information about determination?
---|---
Yes, not accredited. | The uncertainty from the determination SHALL be presented.
The uncertainty resulting from the combination of the uncertainties for each activity and/or the information referred to in 7.8.5 f) may be presented. However, it SHALL be signalized that the combination and that information are not covered by accreditation.
| It SHALL be clear that none of activities are covered by accreditation.
| It SHALL be clear that the sampling activity is not covered by the scope.
No | The uncertainty from the determination SHALL be presented.
| It SHALL be clear that the determination activity is not covered by accreditation.
| (Not applicable)

7.8.6 Issuing statements of conformity

7.8.6.1 [Decision rule]

It is interpreted that the issue of statements of conformity requires prior documented agreement with the customer.

It is recommended the consultation of ILAC G8 and JCGM 106 regarding the evaluation and statement of conformity.

The table below typifies different situations regarding the statement of conformity and associated decision rules.

<table>
<thead>
<tr>
<th>Case</th>
<th>Recommended action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>A statement of conformity is not required. Report only the results, including the measurement uncertainty.</td>
</tr>
<tr>
<td>2</td>
<td>A statement of conformity is required, and the decision rule is documented in legal and/or regulatory requirements. Use the decision rule established in legal and/or regulatory requirements. Report the results, measurement uncertainty and the statement of conformity.</td>
</tr>
<tr>
<td>3</td>
<td>A statement of conformity is required, and the decision rule is documented in normative documents (e.g. product standards). Use the decision rule established in the normative documents. Report the results, measurement uncertainty and the statement of conformity.</td>
</tr>
<tr>
<td>4</td>
<td>A statement of conformity is required and there is no documented decision rule as described in cases 2 and 3 above, but where the customer specifies a decision rule. Use the decision rule specified by the customer. Report the results, measurement uncertainty and statement of conformity.</td>
</tr>
</tbody>
</table>
Typical cases concerning statements of conformity and decision rules

<table>
<thead>
<tr>
<th>Case</th>
<th>Recommended action</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>A statement of conformity is required, and the customer requests the laboratory’s cooperation in defining it.</td>
</tr>
</tbody>
</table>

The laboratory SHALL cooperate with the customer establishing the decision rule that best takes into account both the risks of false acceptance as well as those of false rejection. Examples of possible approaches include:

(a) Use a guard band equal to the expanded uncertainty at 95% for the specific risk associated with the tested or calibrated object (classical approach in ILAC G8:2009);

(b) Use a null guard band and a certain TUR (Test Uncertainty Ratio)\(^{12}\) for the specific risk associated with the calibrated object (this is a frequent approach in calibration). A 4:1 TUR is frequently considered to provide sufficient confidence in certain applications. In this approach it is important to establish also complementary methodology in cases when the given TUR is below the specified reference value;

(c) Use a guard band that corresponds to a probability of false acceptance of less than 2% (global risk). It considers test or calibration results and information about the population of the object under test.

The definition of decision rule implies that it is established how the measurement uncertainty is accounted when issuing statements of conformity. This is understood as including cases where uncertainty is not to be accounted.

In order for a specification to be considered a decision rule, it SHALL be explicit regarding how uncertainty is, or is not, to be accounted. In the case of calibrations, and in accordance with ILAC P14, statements of conformity SHALL always take into account the measurement uncertainties.

For the situation 2 of the uncertainty evaluation table in section 7.6 of this document, the laboratory SHALL demonstrate that it has an appropriate uncertainty for the statement of conformity (see ILAC G8 §2.1). This appropriate uncertainty may be explicit in a standard or specification by indicating the maximum uncertainty value (i.e. the target uncertainty) (in this case it is sufficient to compare the uncertainty obtained with the one specified), or may be implicit if it indicates the characteristics (resolution, class, etc.) of the equipment(s) to be used for the calibration/test (and in these cases it is sufficient to verify conformity with these characteristics).

7.8.6.2 [Elements]

7.8.7 Reporting opinions and interpretations

7.8.7.1 [Authorized personnel]

7.8.7.2 [Related to results and identified]

See the definition of Opinion and interpretation.

It is considered that it is not currently possible to include the issuance of opinions and interpretations in the scope of accreditation. Therefore, ISO/IEC 17025 requirements associated with opinions and interpretations are not assessed.

However, the laboratory needs to signalize opinions and interpretations in the reports with the accreditation symbol, as established in DRC002.

Thus, when applicable, the following text, or equivalent, legible and similar to the presentation of results, SHALL be included in the corresponding reports:

“The opinions/interpretations expressed in this Report (Certificate) are not included in the scope of accreditation”.

The inclusion of opinions or interpretations on the results in other documents with the accreditation symbol is not accepted.

Opinions and interpretations should not be confused with statements of conformity with legal, regulatory or contractual requirements - a statement of conformity is limited to present fact(s).

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\(^{12}\) In English TUR: Test Uncertainty Ratio
7.8.7.3 [Oral opinions and interpretations]

7.8.8 Amendments to reports

7.8.8.1 [Identification and motivation]
The amendment SHALL unequivocally identify the information distinct from the originally reported.

7.8.8.2 [Amendments]

7.8.8.3 [Complete reports]
The amendment SHALL unequivocally identify the information distinct from the originally reported.

Test reports SHALL be reissued only for the correction of errors and the inclusion of omitted data available at the time of test. The unique identification of the sample SHALL be given and any manufacturers branding or labelling may also be shown and marked as such. The practice which consists for an accredited laboratory in reissuing a test report under accreditation when the trade name / trademark of the tested product has changed (without testing it again) is not permitted, even with a clear reference to the initial report that it replaces. The product tested has been clearly identified both in the contract review and in the test report. The laboratory SHALL not assume the responsibility for declaring that the product with the new trade name / trademark is strictly identical to the one tested; this responsibility belongs to the client.

7.9. Complaints

The laboratory SHALL consider as a complaint all manifestations of dissatisfaction with the services provided, whether oral or written

7.9.1 [Documented process]
The laboratory SHALL be prepared to record complaints where it contacts the public or carries out activities

7.9.2 [Description of the process available]

7.9.3 [Minimum process elements and methods]

7.9.4 [Responsibility]

7.9.5 [Feedback to the complainant during the process]

It is considered that normally it is possible to provide feedback to the complainant except where the complaint is anonymous or there are errors in the complainant’s contacts.

7.9.6 [Independence in conclusions]
When it is necessary to involve external personnel drafting conclusions, or reviewing and approving them, the laboratory SHALL establish competence requirements for such personnel

7.9.7 [Formal notice of closure]
It is considered that normally it is possible to provide feedback to the complainant except where the complaint is anonymous or there are errors in the complainant’s contacts.

7.10. Nonconforming work

7.10.1 [Procedures and their elements]
e) It is considered necessary to notify the customer if deviations are found that may affect the validity of the results. In such circumstances the work SHALL be repeated, if possible.

13 EA Resolution 2014(33)31.
7.10.2 [Records]

7.10.3 [Relations with corrective actions]

7.11. Control of data and information management

7.11.1 [Access]

7.11.2 [Systems validation]
Validation of software developed by the laboratory to perform calculations can be made, for example, by the description of the formulas and algorithms used and a representative comparison of the responses given by the system with those expected from the introduction of a known set of data.

7.11.3 [Specific requirements]

7.11.4 [External Providers]
The requirements directly applicable are those of clauses 7.11 and 4.2 (without prejudice of, depending on the functionalities, other normative provisions being also relevant relevant).

7.11.5 [Availability of information how to use]
The details that an information management system developed by the laboratory needs to be documented depends, in particular, on the knowledge of users and the implications of their use on the quality of results.

7.11.6 [Calculations and data transfers]
Systematic verification of calculations and data transfers SHALL always be performed regardless of how they are performed (with or without computerized systems). The periodicity of this verification SHALL be established on the basis of an analysis of the risks associated with the transfer, the complexity of the calculations involved as well as the robustness of the calculation and data transfer validation processes.

8. Management system requirements

8.1. Options

8.1.1 General
The management system documentation SHALL unambiguously identify which option is considered.

8.1.2 Option A

8.1.3 Option B
Option B allows laboratories that have implemented a management system conforming to ISO 9001 to use it to support to fulfil the management system requirements specified in clauses 8.2 to 8.9 of the standard. Option B does not require the laboratory management system to be ISO 9001 certified.
Since option B is an alternative to achieve the same goal, IPAC will assess its effectiveness against the requirements of clauses 8.2 to 8.9 (option A).

8.2. Management system documentation (Option A)

8.2.1 [Policies and objectives]

8.2.2 [Policies and objectives to include competence, impartiality and consistency]

8.2.3 [Management's commitment with improving effectiveness]
Laboratory management can demonstrate their commitment and participation in continuous improvement, for example, by participating actively in the management review and providing the resources needed to achieve the management system objectives.
8.2.4 [Traceability of information in the management system]

8.2.5 [Accessibility]

As the management system documentation (procedures, standards, instructions, etc.) SHALL be understood by those who use it, translations may be required.

It is recommended to use flowcharts as an alternative or in addition to text.

8.3. Control of management system documents (Option A)

8.3.1 [Principle]

It is the responsibility of each laboratory to keep under control the applicable external documents; however, it is not necessary to control mandatory EA and ILAC documents, except when explicitly stated, since their provisions are included in IPAC documents - in this regard see also the DRC005. It is recommended to consult EA-INF/01 (available at www.european-accreditation.org) and the ILAC website (www.ilac.org) for identification of relevant documents and their category.

EA and ILAC sectorial documents that provide relevant guidance for the accreditation of laboratories in those sectors are considered to be a proven way of meeting the relevant requirements of ISO/IEC 17025. Other approaches are acceptable but SHALL be technically justified and the laboratory SHALL keep records of such justifications, when applicable. Therefore, such documents SHALL be kept under control by the laboratory.

8.3.2 [Dispositions]

b) It is recommended to consider the need to review each document with maximum periodicity of 4 years;

c) It is considered necessary to identify the changes except where there is:

- A complete reformulation of the document;
- Typographical corrections or editorial formatting changes, without changing the technical content.

Changes may be signalized in several ways, for example by reference in an attached list or in the document itself using different colours, different formatting, sidebars, etc.

Is not recommended to identify changes using italic text, since some original text can be done in italic (e.g. variables).

Handwritten amendments are considered to be a change to the current version and SHALL be dealt with as such, especially when dealing with normative documents referred in the Technical Annexes.

f) Obsolete documents may be identified, for instance, with stamps, labels, graphics or segregation in specific directories.

It is recommended that the retention period for obsolete documents SHALL be 5 years or more.

8.4. Control of records (Option A)

8.4.1 [Principio]

It is considered that paper records SHALL be made permanently and indelibly, for example with ink.

8.4.2 [Provisions]

For the purpose of laboratory accreditation, the minimum period to storage are as following:

- Original and derived data: 5 years;
- Copies of reports: 5 years;
- Records: 5 years;
- It is considered that equipment records (e.g. calibration certificates) SHALL be retained during the equipment’s lifetime plus two years (in order to show compliance during the activity period)

These deadlines are independent of other (e.g. legal or contractual) provisions.

Archiving may be done in external facilities; however, archives SHALL be promptly accessible during the on-site assessments.
8.5. Actions to address risks and opportunities (Option A)

8.5.1 [Principle]
The laboratory can use tools such as SWOT analysis or FMEA amongst others.

It is noted (see introduction of the standard) that the laboratory is responsible for deciding the risks and opportunities that need to be addressed.

8.5.2 [Planning]
The laboratory should document the plan to address risks and opportunities.

8.5.3 [Proportionate actions]

8.6. Improvement (Option A)

8.6.1 [Principle]

8.6.2 [Feedback from customers]

8.7. Corrective actions (Option A)

8.7.1 [Process for handling nonconformities]

8.7.2 [Appropriate corrective actions]

8.7.3 [Records]

8.8. Internal audits (Option A)

It is recommended that the laboratory pays particular attention to this activity in order to detect and correct nonconformities as well as to keep improving the management system.

8.8.1 [Principle]

It may be interpreted that internal audits are not effective if the outcome from assessments performed by IPAC reveal systematic and significant deviations.

It is recommended that internal audits are at least performed annually Internal audits are recommended to be performed at least annually otherwise the laboratory SHALL provide valid technical reasons to justify larger intervals.

8.8.2 [Programme]

It is interpreted that “programme” presupposes the existence of a planning or schedule of the actions to be performed.

Internal audits can be performed by internal or external personnel provided that:

- The initiative to start and to close the audits belongs to the laboratory;
- The laboratory evidence that the audit team has competence for the scope to be audited and methods for performing the laboratory activities involved;
- Audits are effective.

It is recommended that mandates given to audit teams prevent conflicts of interest by appointing auditors independent of the specific activities to be audited.

The laboratory SHALL have evidences that:

- All ISO/IEC 17025 requirements are audited during an internal audit cycle14;

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14 An internal audit cycle is the period of time during which the laboratory SHALL audit in a representative manner all requirements of the standard and all types of relevant laboratory activities. It SHALL have at most the same duration as the accreditation cycle (however, it does not need to coincide temporally with the accreditation cycle).
- All technical areas\textsuperscript{15} covered by accreditation are audited at least once in an accreditation cycle\textsuperscript{16}.

Audit records SHALL include the identification of audited requirements, personnel involved, documents and records reviewed as well as audited laboratory activities (including their audit methods - witnessed, simulated, record review, ...).

8.9. Management reviews (Option A)

8.9.1 [Principle]

Management reviews are recommended to be at least annually. Otherwise, the laboratory SHALL provide valid reasons.

It is considered that the management review is carried out by the laboratory management when this:

\begin{itemize}
  \item Takes the initiative to nominate who, when and how to do will do it;
  \item Appoints an executive member to follow the process;
  \item Analyses results and draws or approves the conclusions.
\end{itemize}

8.9.2 [Inputs]

8.9.3 [Outputs]

It is recommended to disclose the relevant conclusions to all laboratory staff.


IPAC has developed a comparative analysis between the 2\textsuperscript{nd} and the 3\textsuperscript{rd} editions of the standard highlighting the key different in the last edition, as well as the potential impacts on a previously accredited laboratory. That analysis is available in the following link http://www.ipac.pt/docs/publicdocs/outros/alteracoes17025.asp. Any update to the analysis is performed independently of any updates to OGC001.

\textsuperscript{15} It is considered as belonging to the same technical the methods with similar attributes presuming similar competences - common scientific and technological grounds, including when applicable, the same principles of measurement, technology (equipment), validation, calibration, quality control, learning and training.

\textsuperscript{16} For initial and extension applications it should be evidenced that all technical areas were subject to internal audit prior to the corresponding IPAC on-site assessment.