The new ISO/IEC 17025:2017

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Introduction - Background information

ISO/IEC 17025 was first issued in 1999 by the International Organization for Standardization (ISO) and the International Electro-technical Commission (IEC). It is the single most important standard for calibration and testing laboratories around the world, with more than 50.000 laboratories accredited, globally.

At the International Laboratory Accreditation Cooperation (ILAC) General Assembly in October 2013 the Laboratory Committee (which is composed of stakeholder representatives of accredited testing and calibration) recommended that ILAC request that ISO/CASCO establish a new work item to comprehensively revise ISO/IEC 17025:2005. CASCO is the ISO committee that works on issues relating to conformity assessment. CASCO develops policy and publishes standards related to conformity assessment; it does not perform conformity assessment activities. CASCO's standards development activities are carried out by working groups made up of experts put forward by the ISO member bodies. The experts are individuals who possess specific knowledge relating to the activities to be undertaken by the working group.

The 6th ISO/CASCO WG 44 meeting was held on July 10-12, 2017 in ISO Central Secretariat, Geneva. The deliverable of this meeting was the FDIS version of the new ISO/IEC 17025 version. The document is expected to proceed to publication, planned for end November/December 2017.

Please note that throughout this article the term “the standard” refers to the new ISO/IEC 17025:2017.

About the New Standard

The format of the new standard has been significantly changed to be more in line with new ISO formatting guidelines. The basic format is similar to other new standards such as ISO/IEC 17020 and ISO/IEC 17065.

The new standard is now structured as follows:

1. Scope
2. Normative references
3. Terms and definitions
4. General requirements
5. Structural requirements

6. Resource requirements
7. Process requirements
8. Management requirements
    - Annex A – Metrological Traceability (Informative)
    - Annex B – Management System (Informative)
    - Bibliography

General Information

According to International Accreditation Forum (IAF) and the International Laboratory Accreditation Cooperation (ILAC), accreditation is defined as *"the independent evaluation of conformity assessment bodies against recognized standards to ensure their impartiality and competence."*

This standard was developed with the objective of promoting confidence in the operation of laboratories and contains requirements for laboratories to enable them to demonstrate that they operate in a competent and impartial way and that they are able to provide valid results.

During its development phase it has been tried to align the standard with the principles of ISO 9001, although this was not always practically possible. Still it is a fair statement to make that the laboratories complying with the standard will also, in general, comply with the principles of ISO 9001.

The standard can be used for accreditation purposes, for self-assessment of the laboratories and for second party assessments by laboratory customers, regulatory authorities, organizations and schemes using peer-assessment.

Its requirements are applicable to any organization that performs the activities of testing and/or calibration and/or sampling associated with subsequent testing or calibration. Therefore, accreditation to the new standard can be also achieved by organizations offering sampling associated with subsequent testing or calibration. When the standard uses the term "laboratory" is referring to any of the 3 options mentioned above (testing, calibration, and sampling).

The potential of performing only sampling activities is a new element in the standard. If, for example, a laboratory is performing tests and takes samples by its own capacity, it should meet all requirements related to both: sampling and testing. On the other hand, if any organization performs only sampling and then the samples are forwarded to a laboratory for testing, then this organization should comply with new standard requirements regarding sampling and its management system should ensure that the sampling activity doesn't affect negatively on test results. Requirements for sampling organizations are similar to testing and calibration laboratories: personnel shall be competent, equipment has to be maintained and calibrated, sampling procedure has to be validated, quality of sampling has to be assured etc. Confirmation of competence of organization to provide sampling can be provided through accreditation against the new ISO/IEC 17025.

Guide 99 ISO/IEC, *International vocabulary of metrology — basic and general concepts and associated terms (VIM)*, is referenced in the standard as a normative reference. The definitions also given in ISO/IEC

17000 are applicable. In addition, the standard provides the detailed definitions of the terms *impartiality, complaint, interlaboratory comparison, intralaboratory comparison, proficiency testing, laboratory, decision rule*.

Main Requirements

The Standard introduces its main requirements throughout the clauses 4 to 8.

Clause 4 - General requirements

Impartiality and Confidentiality requirements are discussed in clause 4. The risk-based thinking is evident throughout the standard. It should be noted that the new standard expects from the laboratory to plan and implement actions to address risks and opportunities. Although addressing risks and opportunities is laboratory's responsibility, the standard sets specific requirements. The first requirement of such risks and opportunities that is needed to be addressed is mentioned in clause 4, where the laboratory is required to identify and eliminate or minimize risks related to impartiality, on an on-going basis.

The confidentiality requirements include, among others, the responsibility of the laboratory to inform its customer in advance, of the information it intends to place in the public domain. It is also discussing how to handle the release of confidential information required by law or authorized by contractual arrangements. The confidentially requirement is also extended to laboratory personnel, including any committee members, contractors, personnel of external bodies, or individuals acting on the laboratory's behalf, even in the case that information is obtained from sources other than the customer (e.g. complainant, regulators).

Clause 5 - Structural requirements

In clause 5, main requirements are defined, including: Legal status of the laboratory, organization and management structure, identification of management, range of laboratory activities, documenting its procedures, availability of personnel responsible for the implementation and maintaining the integrity of the management system.

It should be noted that the new standard clearly requires (see clause 5.3) that the laboratory shall only claim conformity with this document for this range of laboratory activities, which excludes externally provided laboratory activities on an ongoing basis. This means that the laboratory is expected to be accredited, and include in the scope of accreditation only testing/calibration/sampling activities that is providing by utilizing its own resources.

In its 2005 version the standard allowed to subcontract tests and calibrations in the case that the laboratory was not in position to perform them. According to the new standard the laboratory can be accredited only for those laboratory activities, for which it is competent. Subcontracting is allowed only for outstanding situations, like overload of work, sickness of personnel, maintenance of equipment or other similar cases.

Clause 6 - Resource requirements

Resource requirements are considered to include personnel, facilities, equipment, systems and support services necessary to manage and perform the laboratory activities. It is expected that all internal or external personnel of the laboratory shall be competent and act impartially. The standard doesn't refer at this clause to ALL personnel, but only to personnel who could influence on the results of laboratory activities. This is not only personnel who is directly involved in testing/calibration/sampling activities, but also personnel who is indirectly involved, like technical personnel. For example, it can be personnel that perform maintenance of the equipment, or management system personnel, who evaluate suppliers and/or maintain the management system including internal auditing activities.

The competence requirements, which are expected to be documented, include education, qualification, training, technical knowledge, skills (like capacity to evaluate the significance of laboratory activities deviations) and experience. In addition, procedure and records are expected for selection, training, supervision, authorization and monitoring of competence of personnel. The standard also defines the cases where it is expected for the laboratory to authorize personnel to perform specific laboratory activities.

It is expected for the requirements for facilities and environmental conditions suitable for the laboratory activities to be documented, including the conditions related to monitoring, controlling and recording environmental conditions. The standard sets requirements to those environmental conditions which can effect on the results of laboratory activities. Depending on the nature of laboratory activities the same parameter can be or cannot be important for the testing results. For example, the value of the relative humidity that can be critical and shall be controlled during some textile testing, it is usually not critical during routine mechanical tests of plastics. Measures to control facilities may include access to and use of areas affecting laboratory activities, prevention of contamination and effective area separation, including sites or facilities outside of laboratory's permanent control.

A procedure for handling, transport, storage, use and planned maintenance of equipment is required. Equipment requirements are applicable to hardware, software, measurement standards, reference materials, reference data, reagents, consumables or auxiliary apparatus – whatever is required for achieving correct results during laboratory activities. It is also expected that the equipment used for measurement should achieve the required measurement accuracy or measurement uncertainty. The calibration requirements are described in details in clauses 6.4.6-6.4.13 including the requirements for relevant records.

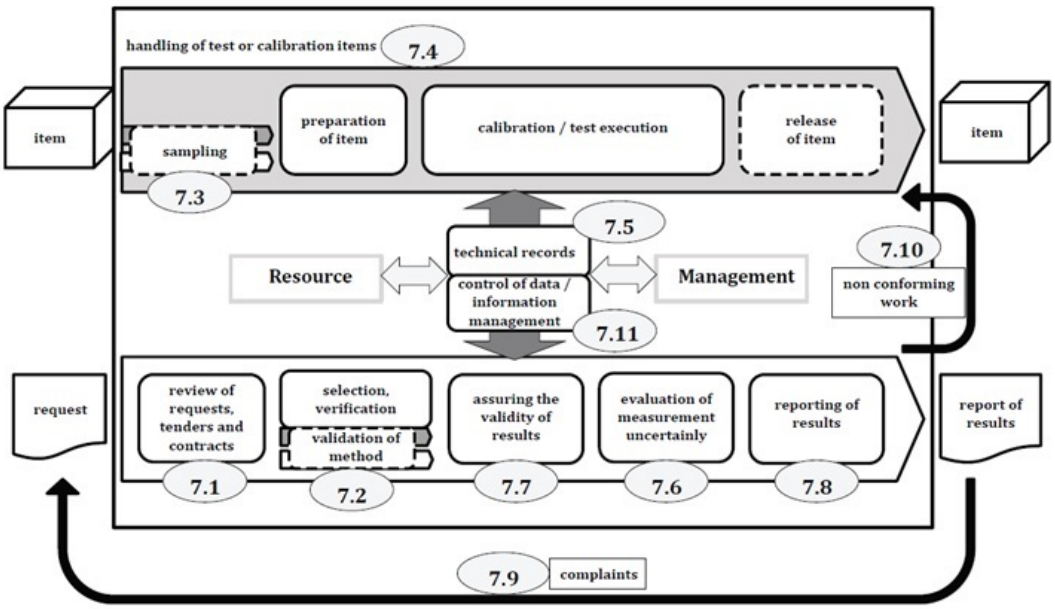
The standard is giving great attention to metrological traceability issues. In addition to the main requirements which are described in details in clause 6.5, an informative annex (Annex A) is available providing additional information, including guidance on how to establish and demonstrate metrological traceability.

Requirements related to the control of and communication with, external organizations providing products and services affecting laboratory activities are described in clause 6.6. Procedure and records are required to define, review and approve the laboratory's requirements for externally provided products and services (purchasing requirements), setting the criteria for evaluation, selection,

monitoring of performance and re-evaluation of the external providers, ensuring that they conform to requirements and taking appropriate actions in the case that they don't.

Clause 7 - Process requirements

An example of a possible schematic representation of the operational processes of a laboratory as described in the Clause 7 is presented in informative Annex B:



A possible schematic representation of the operational processes of a laboratory

Process requirements are deployed as follows:

7.1 Review of requests, tenders and contracts

A procedure is required to address issues such as the level of understanding of requirements; laboratory's capability and resources to meet the requirements; implementation of appropriate control over external providers used (if any); and selection of appropriate methods to meet the customers' requirements. It is expected that the laboratory shall inform the customer when the required testing/calibration/sampling method is considered to be inappropriate or out of date. When a statement of conformity to a specification or standard is required, the decision rule (which specifies pass/fail criteria) selected shall be communicated to, and agreed with, the customer. Contract review procedure shall be applied also for any changes in the contract/tender/request. Relative review records are required.

7.2 Selection, verification and validation of methods

The term “method” in the standard is used to identify calibration method, testing/measurement procedure, sampling procedure. The laboratory is expected to ensure that it uses the latest valid version of a method, unless it is not appropriate or possible to do so. Methods used can include methods published 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 or laboratory-developed or laboratory-modified methods. The laboratory shall verify that it can properly perform selected methods. Deviations from methods shall occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer. Non-standard methods, laboratory-developed methods and modified standard methods are expected to be validated, and relevant records are expected to be kept.

7.3 Sampling

The requirements of this clause are applicable to the laboratories which perform just sampling activities as well as for testing and calibration laboratories which are responsible also for sampling. A sampling plan and a sampling method are expected to be available and implemented when the laboratory carries out sampling of substances, materials or products for subsequent testing or calibration. Records of sampling data should be retained per standard requirements.

7.4 Handling of test or calibration items

A procedure for the transportation, receipt, handling, protection, storage, retention, and disposal or return of test or calibration items should be drafted including a system for the identification of test or calibration items. Deviations from specified conditions are expected to be recorded and the customer to be consulted for next steps. In the case that some items have to be stored or conditioned under specified environmental conditions, these conditions shall be maintained, monitored and recorded.

7.5 Technical records

Requirements to retain technical records are in place to ensure the traceability of laboratory activities and to provide information for potential decision making. The technical records are expected to contain the results, report and sufficient information to facilitate, if possible, identification of factors affecting the measurement result and its associated measurement uncertainty and enable the repetition of the laboratory activity if required, providing traceability to previous versions or to original observations if amended.

7.6 Evaluation of measurement uncertainty

For testing laboratories it is expected to evaluate measurement uncertainty considering all contributions which are of significance, including those arising from sampling. It is noted in the standard that 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 the laboratory can demonstrate that the identified critical influencing factors are under control.

For calibration laboratories it is expected to evaluate the measurement uncertainty for all calibrations considering all contributions which are of significance, including those arising from sampling.

7.7 Assuring the validity of results

A procedure and records are required for monitoring the validity of results, which can include, among others: use of reference materials or QC materials; use of alternative traceable instrumentation; functional checks; use of standards with control charts; intermediate checks; replicate tests or calibrations; retesting or recalibration; correlation of results; review of reported results; intra-laboratory comparisons; testing of blind samples. Participating in PT's (Proficiency Tests) and/or ILC's (interlaboratory comparisons) is expected where available and appropriate. Such activities, according to the standard, must be planned and reviewed.

7.8 Reporting of results

Laboratory activity results shall be reported. The standard sets requirements for results review and authorization as retained in the relative technical records. The common information required to be included in the test, calibration or sampling reports is presented in details in clause 7.8.2. In addition, the specific information for test reports is presented in clause 7.8.3, for calibration certificates in clause 7.8.4, for reporting sampling in clause 7.8.5, for reporting statements of conformity in clause 7.8.6, for reporting opinions and interpretations in clause 7.8.7 and for amendments to reports in clause 7.8.8.

7.9. Complaints

A documented process is required for receiving, evaluating and making decisions on complaints. This process is expected to be available to any interested party upon request. The outcomes to be communicated to the complainant shall be made by, or reviewed and approved by, individual(s) not involved in the original laboratory activities in question.

7.10 Nonconforming work

A Nonconforming work procedure is expected to be in place ensuring that the responsibilities and authorities for the management of nonconforming work are defined, subsequent actions are taken considering the risk levels; an evaluation is made of the significance of the nonconforming work; a decision is taken on the acceptability of the nonconforming work; the customer is notified, if possible; work is recalled, if needed; and the responsibility for authorizing the resumption of work is defined. Halting or repeating of work and withholding of reports, as necessary can be considered among the required actions. Records of nonconforming work and relative actions are expected to me retained.

7.11 Control of data – Information management

This clause sets requirements for the laboratory information management system(s) used for the collection, processing, recording, reporting, storage or retrieval of data.

Clause 8 – Management System requirements

The laboratory can choose between implementing a management system in accordance with option A or option B. 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. Option B allows

laboratories to establish and maintain a management system in accordance with the requirements of ISO 9001. Laboratories that implement option B will therefore also operate in accordance with ISO 9001. Conformity of a laboratory to the requirements of ISO 9001 does NOT, by itself, demonstrate the competence of the laboratory to produce technically valid data and results. This is accomplished only through compliance to ISO/IEC 17025.

The requirements for documentation have been significantly reduced in clause 8. The documentation requirements related to the operation of the management system per clause 8 are:

- Management System policies and objectives (8.2.1)
- Analysis of Customer feedback (8.6.2)
- Corrective actions, non-conformities related records (8.7.3)
- Internal audit and results records (8.8.2)
- Management review input and output record (8.9.2)

It should be noted that there are no requirements any more for documented procedures related to management system activities referred in clause 8. There is also no requirement for Quality Manual.

By introducing the risk-based thinking in the standard some reduction in prescriptive requirements and their replacement by performance-based requirements was possible. Clause 8.5 that is dedicated on actions to address risks and opportunities is a new element added in the recent revision of the standard. This clause requires from the laboratory to consider the risks and opportunities associated with the laboratory activities. These activities are described throughout the standard and include risks related to impartiality (4.1.4), statements of conformity (7.8.6), nonconforming work (7.10.1), and corrective actions (8.7.1). It should be noted that the standard doesn't require a formal/specific method for risk management or a documented risk management process. Useful information can be found in ISO 31000, *Risk management - Principles and guidelines*, which is included as a reference in the bibliography.

Conclusion - Transition

Once the new standard's final version is published, expected by end of 2017, there will be a three year transition period. Accreditation bodies will need to have all laboratories assessed to the new standard by the end of 2020. Of course this doesn't mean that laboratories should wait for action until the end of the three years period. It is suggested to plan and initiate the transition process much earlier. The main transition steps to follow are:

- Decide on the overall timeline;
- Train he lab personnel who will be responsible for transition and implementation;
- Learn how to read, interpret and implement the new standard requirements;
- Conduct a gap analysis between the existing quality system and the requirements in the revised standard;
- Update management system's documentation. This includes updates to existing policies and procedures as required, plus the removal/modification/addition of policies and procedures.

Hint: Grab the opportunity that the new standard is providing to reduce management system documentation;

- Create a training plan and a communication plan for the laboratory personnel and;
- Implement the new and revised management system.

By careful preparation and timely action all accredited laboratories can ensure a successful transition to the new ISO/IEC 17025:2017.

About the Author

Dr. George Anastasopoulos (ganas@iasonline.org) is the Director of Conformity Assessment Accreditation Services, of the International Accreditation Service (IAS). He has also served to the Bonn-Germany based, Accreditation Panel of the United Nations Kyoto Protocol system UNFCCC/CDM and the Hellenic Accreditation System (ESYD).

He is a Mechanical Engineer with an MSc and a PhD in Applied Mechanics from Northwestern University, Evanston, Illinois. He is also member of ISO/TC176 and ISO/CASCO technical committees which developed the new ISO 9001:2015 and new ISO 17025.

Dr. George Anastasopoulos is awarded with the EOQ Presidential Georges Borel Award for international achievements being at the edge of the development, use and diffusion of quality at international level through his professional activities and behaviors, personally contributing to the development of the European Quality movement through his accomplishments with a global impact in the field of quality.

Dr. Anastasopoulos presented many papers in technical and financial conferences, magazines and newspapers and is the author of many articles and books. He also presented many lectures as keynote speaker in topics such as Management Systems, Business Process Reengineering, Telecoms-FTTH-IT, Quality Assurance and Process Auditing. He participated in numerous consulting and research projects sponsored by government and industry in USA, European Union and many other countries worldwide.