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Revision of the ISO/IEC 17025 standard

Olivier Pierson[1]*

A new version of the ISO/IEC 17025 standard, “General requirements for the competence of testing and calibration laboratories", will be published before the end of 2017. Since 1999, this document has been the reference for the accreditation of tens of thousands of laboratories around the world, but it is also used by an even greater number of industrial or research laboratories (or their customers) to benchmark their measurement and testing practices.

The standard covers all the activities for characterising samples or media through measurements or experimental observations, including where appropriate, sampling, the development of methods or the publishing of opinions and interpretations concerning the results.

The new version makes no changes to the standard’s scope: it covers all types of tests and all types of laboratories, irrespective of their size or status. Nevertheless, the standard can now be used to determine the competence of bodies that only carry out sampling, if the sampling is associated with subsequent testing or calibration. It will include the possibility of writing reports on the sampling, thus improving control of the different potential subcontracting systems between samplers and testing laboratories.

Keywords

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- Quality
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[1] ANSES, Quality & Internal Audit Department, Maisons-Alfort, France

* Corresponding author : olivier.pierson@anses.fr

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The basic principles of the standard remain unchanged:

- The selection, or possibly the validation of testing methods that are relevant and appropriate for the customer's needs;

- The reproducibility of results, based on the concepts of metrological traceability and measurement uncertainty, as well as on the qualification of the resources implemented;

- The ability to trace and control the laboratory activities, through a management system that includes the implementation of continuous improvement.

It was considered necessary to revise the current version, however.

Since 2005, when the standard was last updated, many terms and documents cited in the standard have evolved, thus making an update necessary. More fundamentally, analysis techniques, information systems, and procedures for transmitting results now offer opportunities that deserve to be taken into consideration. This is why a section has been introduced (among others) concerning information systems and the concept of reference data (commonly used in the fields of spectrometry or molecular biology). The format and the support medium for the information have been left as free as possible, including for the report itself.

As in 2005, the experts responsible for the revision have paid close attention to compatibility between ISO/IEC 17025 and ISO 9001. This is important, because many laboratories (including industrial laboratories) also seek ISO 9001 certification, because many quality tools and concepts are developed in an ISO 9001 environment, but especially because most laboratory customers are certified and expect their suppliers to be similarly organised.

The seven principles underlying ISO 9001:2015 have all been taken into account in the new version of ISO/IEC 17025. Some sections, such as the one relating to internal audits, have been closely aligned with ISO 9001. For the first time in the world of accreditation, the "risks and opportunities" approach has been incorporated, which should make it easier to scale implementation of the requirements according to the specific context of each laboratory. The process approach has been applied – strictly within the meaning of ISO 9001 – for activities involving sampling, testing or calibration, thus opening up many opportunities for laboratories to be integrated in a process-based management system. A notable result of this effort to reconcile the two reference standards is that ISO/IEC 17025 explicitly mentions that a laboratory conforming to ISO 9001 meets all the requirements of ISO 17025 concerning management systems.

Lastly, the general structure of the ISO/IEC 17025 standard has changed: it is now aligned with the structure of the recent standards for conformity assessment (including ISO 17020, for inspection activities). Here again, this choice reduces the effort required by organisations concerned by several such reference standards, and also presents a more pragmatic breakdown of requirements between resources, execution and management, better adapted for applying requirements in different contexts: industry, research, etc.

Plenty of good reasons, therefore, which explain the great interest aroused by the ISO/IEC 17025 standard (more than 2000 comments on average during each consultation) and a final 99% vote in favour among the Member States of the ISO committee concerned!

For reference laboratories, this new version will not introduce any mandatory fundamental changes, but may give more opportunities to take into account the specificity of their missions and their context, in particular by implementing the risk approach, digitising the results for data collection systems, and introducing the concept of reference data. The structure of the standard and the introduction of the process approach should also facilitate the management of other activities (training, proficiency testing, research) in the framework of a given management system.