A new ISO/IEC 17025 for laboratories

Something is changing in the life of laboratories!

A significant revision has led to the publication of ISO/IEC 17025:2017. A three-year transition period is provided for all parties to fully implement the new version but some effort will be required to ensure a smooth transition. This applies to laboratories and national accreditation bodies. The latter will be supported by regional and international accreditation organisations which need to ensure a harmonised procedure for the implementation of the Standard, the assessment of laboratories and the peer review of the accreditation bodies. The structure of the Standard has changed extensively to be in line with the format of the new ISO/IEC 17000 series but the requirements for laboratories remain broadly similar.

What is changing?

- The structure (see Fig. 1)
- Sampling addressed as a standalone activity
- The use of a decision rule
- Risks and opportunities
- The management system
- Reference to new standards
- The Annexes

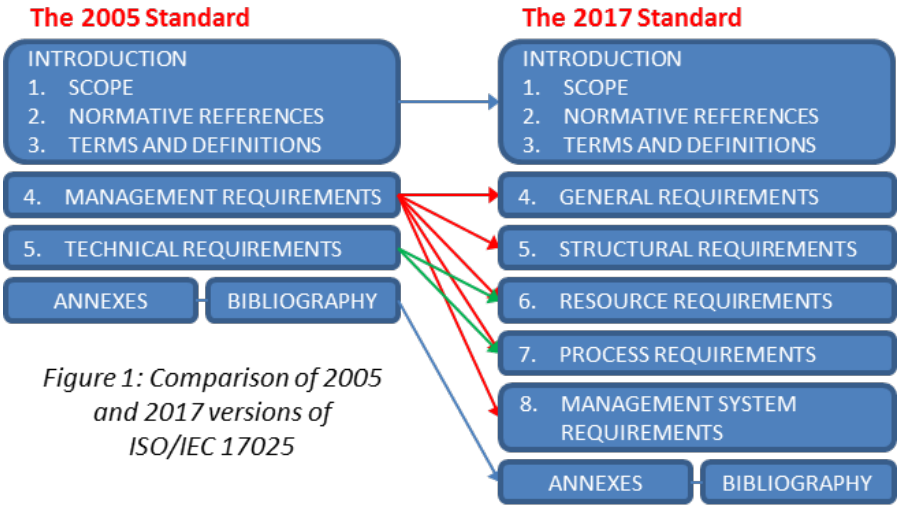

Figure 1: Comparison of 2005 and 2017 versions of ISO/IEC 17025

New definition of "laboratory"

A laboratory is defined as a body performing one or more of the following activities: testing; calibration; and sampling, associated with subsequent calibration or testing. The "subsequent calibration or testing" are not necessarily carried out in the same entity. This means that sampling as a standalone activity can be accredited against the Standard.

The decision rule

A decision rule describes how measurement uncertainty is accounted for when stating conformity with a specified requirement. It is the laboratory's responsibility to document the decision rule, including the statistical basis, and to communicate it to and agree it with the customer. Further information is available in ISO/IEC Guide 98-4 [1] and a guide published by Eurachem/CITAC [2].

Risks and opportunities

It is the laboratory's choice how to address risks. This requires deliberate consideration of what is important for the individual laboratory. The process involves identifying, evaluating and defining measures to control risks and enhance opportunities for the laboratory to achieve its purpose and objectives.

The Standard requires the laboratory to plan and implement actions to address risks and opportunities. This is reflected not only in a number of subclauses – i.e. on impartiality, statements of conformity, management of nonconforming work, and management reviews – but in its philosophy as a whole. No reference is made to "preventive actions" – risk-based provisions as well as clauses relating to improvement cover the need.

The management system

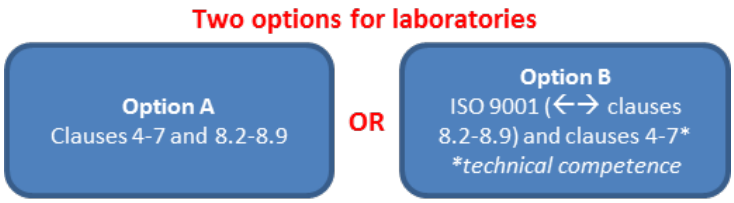

Figure 2: Management system options
Annex B gives more detailed information

There are two management system options (see Fig. 2).
Option A: Compliance with the provisions of clauses 4-7 and 8.2-8.9.
Option B: Laboratories implementing a management system in accordance with ISO 9001 need to comply with clauses 4-7 of ISO/IEC 17025.

Some other significant changes

- Clause on improvement now includes feedback from the customer.
- Emphasis on impartiality – defined as "presence of objectivity" – and confidentiality.
- Liability is covered in more detail; some of its aspects are addressed under confidentiality.
- Metrological traceability is addressed in more detail (reflecting the provisions of ILAC P10 [3]) with reference to relevant international agreements. Annex A provides further details.
- Specific requirements for reporting sampling activities.
- Requirement to take into account uncertainty from sampling.
- More detailed requirements on expression of opinions and interpretations.
- Additional tools are listed to ensure the validity of results. More strict requirements are set with regard to participation in proficiency testing.
- More detailed requirements for control of data and information management, taking into account new technology.
- Management review shall reflect the various changes, including risks and opportunities.
- A quality manual, as such, is not required.
- Additional requirements are set for externally provided products and services; according to a Note, the latter can include, among others calibration, sampling and testing services (i.e. subcontracting).
- "Laboratory management" is used instead of "top management". The terms "technical manager" and "quality manager" are not used; relevant responsibilities are to be assigned to competent personnel.

How can laboratories proceed smoothly?

- Obtain a copy of the new standard and have a clear understanding of its philosophy and provisions.
- Make a cross-reference table illustrating the link between existing processes and procedures and the relevant clause in the new standard.
- Examine existing procedures in light of the risk-based approach to evaluate whether they are still relevant for your laboratory.
- Identify any clauses that seem to require new procedures (gap analysis plus risk assessment).
- Communicate with the national accreditation body.
- Plan internal audit and management review to check the appropriateness of the revised system.

Useful information on the new standard…

Can be found in the Eurachem News article at bit.ly/ECNWS17025, the Eurolab "cookbooks" at bit.ly/ELCookbook, the ISO videos at bit.ly/17025VID1 and bit.ly/17025VID2, and the ISO brochure at bit.ly/ISOBROCHURE.

References

[1] ISO/IEC Guide 98-4:2012, Uncertainty of measurement – Part 4: Role of measurement uncertainty in conformity assessment (available as JCGM 106 from www.bipm.org)
[2] S L R Ellison and A Williams (Eds). Eurachem/CITAC guide: Use of uncertainty information in compliance assessment. First Edition (2007) (available from www.eurachem.org)
[3] ILAC P10:01/2013 ILAC Policy on Traceability of measurement results (available from www.ilac.org)

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