ISO/IEC 17025:2017 New requirements

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Learning Objectives

- History of the evolution of the ISO/IEC 17025 standard
- Managing risk in the quantitative and qualitative areas.
- Implementing Metrological traceability requirements.
- How the requirements of the standard affect other ISO 9001, ISO 13485, AS9100 and IATF 16949 registered customers of calibration and testing services.

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What is the ISO/IEC 17025 standard about?

As the title suggests:

General requirements for the competence of testing and calibration laboratories

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Evolution of calibration based standards

- MIL STD 45662A: 1962
- ISO Guide 25: 1990
- ISO 10012 Part 1 and 2: 1992
- ANSI Z540-1:1994
- ISO/IEC 17025:1999
- ISO 10012:2003
- ISO/IEC 17025:2005
- ANSI Z540.3:2006
- ISO/IEC 17025:2017

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The main changes compared to the previous edition

- Risk-based thinking applied in this edition has enabled some reduction in prescriptive requirements and replaced by performance-based requirements;
- Greater flexibility than in the previous edition in the requirements for processes, procedures, documented information and organizational responsibilities;
- Definition of “laboratory” has been added

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Basic verbal forms explained

- “shall” indicates a requirement;
- “should” indicates a recommendation;
- “may” indicates a permission;
- “can” indicates a possibility or a capability.

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Highlights - A new structure

- The Standard looks completely different from the 2005 edition.
- The 2005 edition was split into Management (4.0) requirements and Technical requirements (5.0).
- The 2017 version has a new structure, closely aligned with all recent 17000-series standards.

Highlights - New emphasis

- The large difference in structure does not, however, signal great changes in most of the familiar technical elements of 17025.
- Laboratories are still expected to train staff, to calibrate equipment properly, to validate their methods, and to evaluate and report measurement uncertainty where appropriate.

Highlights - New emphasis

- The distinction between reporting requirements for calibration and testing remains.
- What does seem to have changed is the emphasis on different elements.

Highlights - New emphasis

- The most prominent example of this is the new emphasis on metrological traceability
- In 17025:2005, the term '**metrological traceability**' was referenced as **measurement traceability**; metrological traceability was addressed by requirements for calibration.
- In **2017, metrological traceability has a whole new subclause of its own**, included into Resource requirements, and an informative Annex.

Highlights - New emphasis

- There is also an emphasis on **conformity assessment**; instead of the 2005 edition's occasional reference to statements of compliance with specifications (for example in the reporting requirements), **conformity assessment, too, has a detailed subclause on reporting statements of conformity and – unlike the 2005 edition – the detail applies in full to both testing and calibration reports.**

Highlights - New emphasis

- Although the practical change is not large, an explicit requirement to document the decision rule is used in conformity assessment. Establishing clear **decision rules is emphasized**.
- Managing **Probability of False Accept (PFA)** becomes more important.
- Engaging the customer will be even more critical to **know their requirements** (specifications).

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Highlights - New emphasis

- Another, smaller, shift in technical emphasis is on **sampling, where more detail is required for sampling and pre-treatment and a clearer set of factors to be recorded**.
- The standard also has a **stronger focus on information technologies and incorporates the use of computer systems**, electronic records and the production of electronic results and reports.

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Highlights - New management system options

- The big changes are in the management system parts of the Standard. The most obvious change is that two broad options are now set out (labelled as options A and B).
- The **first option (A)** is to comply with an explicit list of requirements, **which follow those in the 2005 edition**.

Highlights - New management system options

- The **second option (B)** is important for laboratories already meeting ISO 9001 requirements for management systems; **it simply requires a 9001-compliant management system that meets all the relevant requirements of the new ISO/IEC 17025.**

Highlights - New management system options

- This makes it simpler for laboratories to **manage implementation of the two standards**; it is much clearer that a laboratory can cover many of the management system requirements using 9001-compliant processes and documentation, **with no need for a separate set of documentation for ISO/IEC 17025.**

Highlights - New management system options

- This is also aided by the **“process approach”**, emphasized by the section on “process requirements”, which matches that of newer standards such as ISO 9001 (quality management), ISO 15189 (quality and competence of medical laboratories) and ISO/IEC 17021-1 (requirements for audit and certification bodies).

Highlights - New management system options

- The other substantial shift – mainly affecting management system requirements – **is the appearance of a strong emphasis on "risk-based thinking".**
- The word "risk" appears over 30 times in the document, compared to only four appearances in the 2005 edition.

Highlights - New management system options

- In the **2017 edition, risk identification is included in management reviews, and there is a whole new subclause, “Actions to address risks and opportunities”, listing management system requirements for considering risks and opportunities.**

Highlights - New management system options

- As a result of this shift to risk-based thinking, **there is no longer any reference to "preventive actions";** this is essentially replaced by the new clause on addressing risks and opportunities.

Highlights - New management system options

- Although a **note makes it clear that there is no requirement for formal risk assessment methodologies, this new emphasis on consideration of risk will clearly have assessors looking for evidence of compliance with the new clause**.

Highlights - New management system options

- This should not necessarily place a new load on laboratories; those who already undertake regular management reviews that look at improvement opportunities are likely to find that they already meet most of the requirements here.

Highlights - New management system options

- But the idea of risk-based thinking does, according to the Standard's Foreword, "… [enable] some reduction in prescriptive requirements and their replacement by performance-based requirements". It remains to be seen whether laboratories will be able to use this extra flexibility in practice.

Highlights - More metrological traceability

- Returning to technical issues, there is more attention to the new and explicit emphasis on **metrological traceability**.

Highlights - More metrological traceability

- The main technical requirement, of course, is the same; laboratories are expected to calibrate their equipment appropriately, and that requirement already implied a need to demonstrate that suitable measurement references had been chosen. **The new Standard, however, includes a very clear requirement to have documentation of the calibration chain(s) for Metrological Traceability.**

Highlights - More metrological traceability

- This new paragraph may need some interpretation; if over-interpreted, it could have laboratories scrambling to prepare new, intricate, charts of traceability chains all the way back to the National Measurement Institute (NMI).

Highlights - More metrological traceability

- This may be challenging to testing laboratories– testing laboratories simply do not have that information – however, this is not the intent. The new requirement can largely be met from existing documentation.

Highlights - More metrological traceability

- Laboratories already have to document the source of their measurement standards, calibration and Certified Reference Material (CRM) supplies in order to show that they meet the 17025:2005 requirements; this already makes it possible to show a documented chain of calibrations from measurement results to the standards used in the laboratory.

Highlights - More metrological traceability

- And 17025:2017's new, informative Annex does make it clear that evidence such as **supplier accreditation to ISO/IEC 17025 can be used as evidence that the supplier has established metrological traceability**, making it unnecessary for the laboratory to require further documentation.

Highlights - More metrological traceability

- Supplier conformance to conformity assessment standards also appears in relation to reference material producers and proficiency testing providers.
- For both of these, notes in the new 17025 state that suppliers conforming to ISO 17034 and ISO 17043, respectively, can be considered as competent.

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Highlights - More metrological traceability

- In the case of ISO 17034:2016, a rather recent standard, this may take some time to establish unless accreditation bodies consider Guide 34 compliance in the transition period.

Highlights - Summary

- In summary, **ISO/IEC 17025:2017 differs much less from 17025:2005 than it appears at first sight**.
- **There are structural changes in the document**, but the **technical changes do not seem to be large, and most simply clarify existing requirements**.

Highlights - Summary

- The **changes in management system requirements, risk-based thinking and process orientation should leave laboratories with more flexibility in implementing the standard**.

Highlights - Summary

- More dialogue with testing and calibration laboratory customers to mitigate risk.
- More understanding by customers on risk based thinking.

Questions?

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