REVISION OF ISO/IEC 17025

GENERAL REQUIREMENTS FOR THE COMPETENCE OF TESTING AND CALIBRATION LABORATORIES

Presented August 10, 2017 to

Environmental Measurement Symposium

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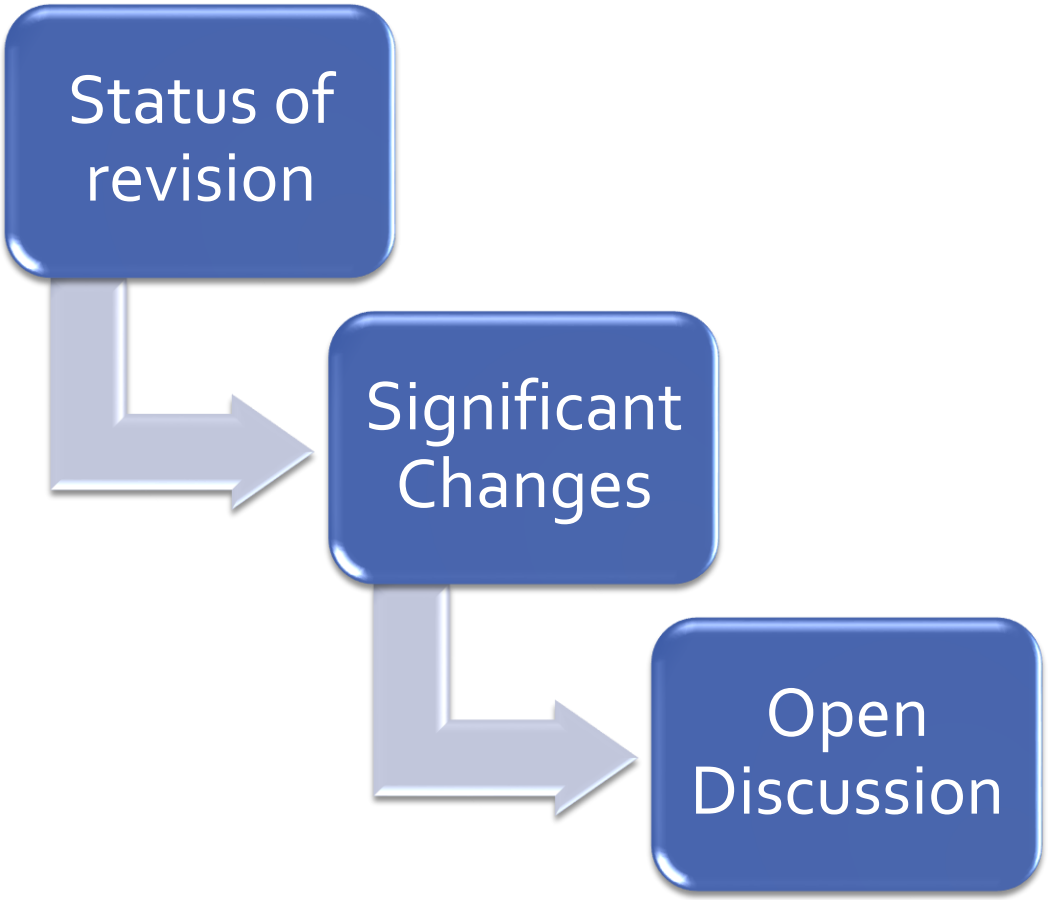
Overview

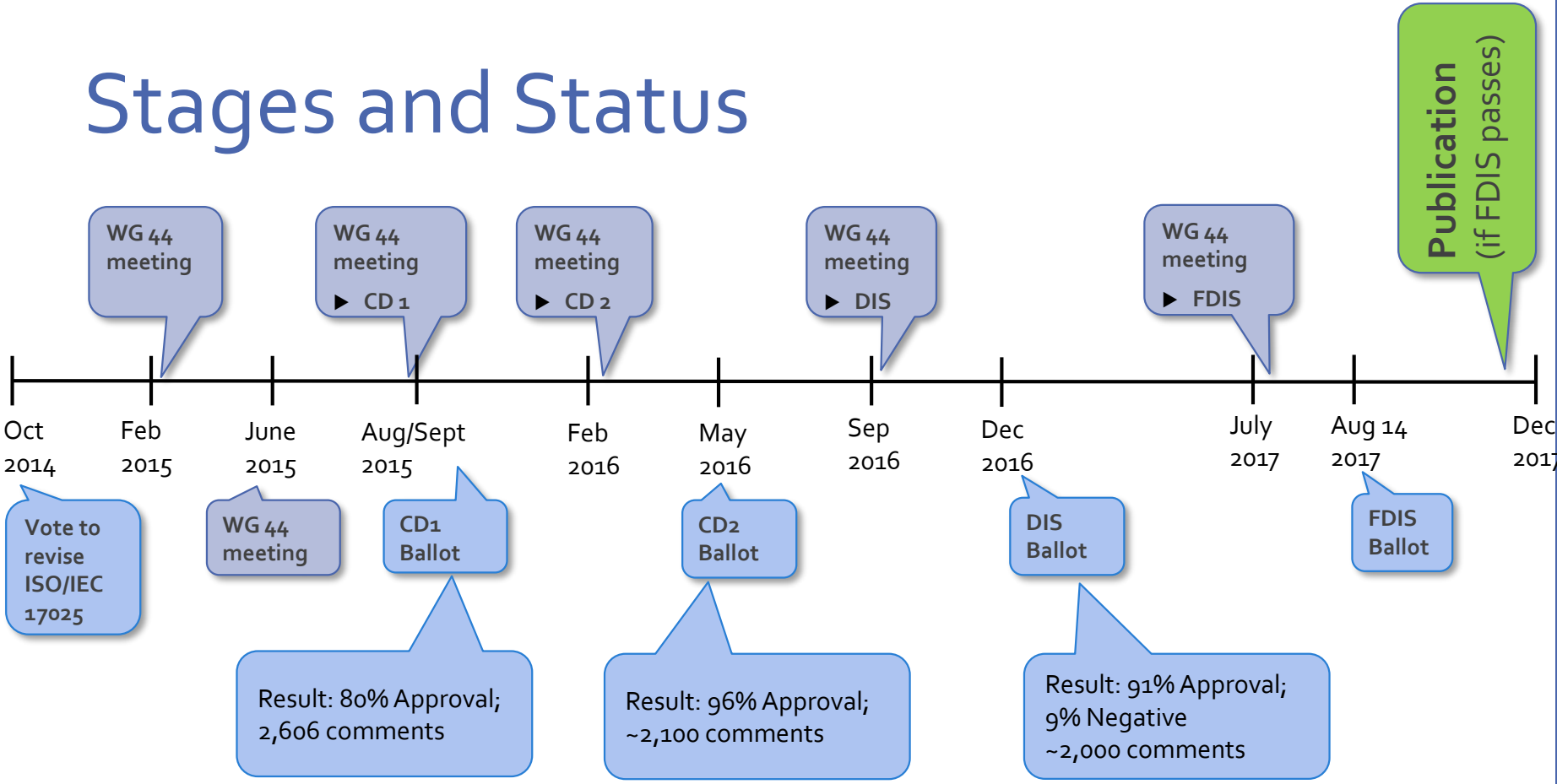


Objective…

Relax…

but get ready

Stages and Status



Nominal objectives of revision

- Align structure and content with other recently revised ISO standards
  - Other 17000-series CASCO documents
  - ISO 9001
- Focus on outcomes rather than prescriptive requirements
- Update language to reflect current practices and technologies
- Don't fix what isn't broken

Resulting key differences

- Now five clauses with requirements instead of two
- Focus on outcomes resulted in:
  - Less variety in terms used to describe required documentation
  - Elimination of some favorite terms (e.g., quality manual, quality manager, subcontracting, etc.)
  - More flexibility for laboratories
- Requirements for information systems/records more reflective of current technologies
- Many requirements are nearly verbatim from previous version, just in different places

New Structure

ISO/IEC 17025:2005

1. Scope
2. Normative references
3. Terms and definitions
4. Management requirements
5. Technical requirements

Annex A – Nominal cross-references to ISO 9001:2000

Annex B – Guidelines for establishing applications for specific fields

DIS ISO/IEC 17025

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

Annex B – Management system

Laboratory activities

3.9 laboratory

body that performs one or more of the following activities:

- testing
- calibration
- sampling, associated with subsequent testing or calibration

"Laboratory activities" used for requirements that apply to any of these

Management system options

8.1.1 General

The laboratory shall establish, document, implement and maintain a management system that is capable of supporting and demonstrating the consistent achievement of the requirements of this document and assuring the quality of the laboratory results. In addition to meeting the requirements of Clauses 4 to 7, the laboratory shall implement a management system in accordance with Option A or Option B.

Management system options

8.1.2 Option A

As a minimum the management system of the laboratory shall address the following:

- management system documentation (see 8.2)
- control of management system documents (see 8.3)
- control of records (see 8.4)
- actions to address risks and opportunities (See 8.5)
- Improvement (see 8.6)
- corrective action (see 8.7)
- internal audits (see 8.8)
- management reviews (see 8.9)

Management system options

8.1.2 Option B

A laboratory that has established and maintains a management system, in accordance with the requirements of ISO 9001, and that is capable of supporting and demonstrating the consistent fulfilment of the requirements of clauses 4 to 7, also fulfils at least the intent of the management system requirements specified in 8.2 to 8.9

Implications and options for options

- Standard permits either option equally
- Assessment of a management system established under Option B would require competence in ISO9001:2015
- Content of Option A requirements closely aligned with ISO 9001:2015
- Users of ISO/IEC 17025 have the ability to add specific requirements to supplement the standard

Risks and opportunities

- Revision incorporates "risked-based thinking"
- Not full risk management per ISO 31000
- Requires the laboratory to plan and implement actions to address risks and opportunities
- Laboratory is responsible for deciding which risks and opportunities need to be addressed

8.5 Actions to address risks and opportunities

8.5.1 The laboratory shall consider the risks and opportunities associated with the laboratory activities in order to:

a) give assurance that the management system achieves its intended results;

b) enhance opportunities to achieve the purpose and objectives of the laboratory;

c) prevent, or reduce, undesired impacts and potential failures in the laboratory activities;

d) achieve improvement.

8.5 Actions to address risks and opportunities

8.5.2 The laboratory shall plan:

a) actions to address these risks and opportunities;

b) how to:

— integrate and implement the actions into its management system;

— evaluate the effectiveness of these actions.

NOTE Although this document specifies that the organization plans actions to address risks, there is no requirement for formal methods for risk management or a documented risk management process. Laboratories can decide whether or not to develop a more extensive risk management methodology than is required by this document, e.g. through the application of other guidance or standards.

8.5 Actions to address risks and opportunities

8.5.3 Actions taken to address risks and opportunities shall be proportional to the potential impact on the validity of laboratory results.

NOTE 1 Options to address risks can include identifying and avoiding threats, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.

NOTE 2 Opportunities can lead to expanding the scope of the laboratory activities, addressing new customers, using new technology and other possibilities to address customer needs.

Requirements that include "risk"

4.1	Risks to impartiality
7.8.6	Level of risk associated with a decision rule used to make a statement of conformity to a specification (such as false accept and false reject and statistical assumptions)
7.10	Actions taken for nonconforming work based upon risk levels established by the laboratory
8.5	Actions to address risks and opportunities
8.7	Updated risks and opportunities when corrective action is taken
8.9	Management review includes results of risk identification

Equipment

6.4.1 The laboratory shall have access to equipment including, but not limited to, measuring instruments, software, measurement standards, reference materials, reference data, reagents, consumables or auxiliary apparatus which is required for the correct performance of laboratory activities and which can influence the result.

"Access" does not imply ownership

Much broader coverage than current standard, but requirements essentially the same

6.4.4 The laboratory shall verify that equipment conforms to specified requirements before being placed or returned into service.

Equipment calibration

6.4.5 The equipment used for measurement shall be capable of achieving the measurement accuracy or measurement uncertainty required to provide a valid result.

6.4.6 Measuring equipment shall be calibrated when:

- the measurement accuracy or measurement uncertainty affects the validity of the reported results, or
- calibration of the equipment is required to establish the metrological traceability of the reported result.

NOTE Types of equipment having an effect on the validity of the reported results can include:

- those used for the direct measurement of the measurand, e.g. use of a balance to perform a mass measurement;
- those used to make corrections to the measured value, e.g. temperature measurements;
- those used to obtain a measurement result calculated from multiple quantities.

Equipment calibration

6.4.7 The laboratory shall establish a calibration programme, which shall be reviewed and adjusted as necessary in order to maintain confidence in the status of calibration.

6.4.8 All equipment requiring calibration or which has a defined period of validity shall be labelled, coded or otherwise identified to allow the user of the equipment to readily identify the status of calibration or period of validity.

6.4.11 When calibration and reference material data include reference values or correction factors, the laboratory shall ensure the reference values and correction factors are updated and implemented, as appropriate, to meet specified requirements.

6.4.12 The laboratory shall take practicable measures to prevent unintended adjustments of equipment from invalidating results.

What's next with ISO/IEC 17025…

- FDIS ballot opens August 14th, closes October 9th
- Only editorial changes allowed for FDIS
- If ballot passes, publication by the end of 2017 (maybe as early as November)
- ILAC has adopted a 3-year transition period
- ISO/CASCO is developing materials explaining the differences between the revised standard and previous version
- Stay tuned…

Open discussion

1 Scope

2 Normative references

3 Terms and definitions

4 General requirements

4.1 Impartiality

4.2 Confidentiality

5 Structural requirements

Open discussion

6 Resource requirements

- 6.1 General
- 6.2 Personnel
- 6.3 Facilities and environmental conditions
- 6.4 Equipment
- 6.5 Metrological traceability
- 6.6 Externally provided products and services

Open discussion

7 Process requirements

7.1 Review of requests, tenders and contracts

7.2 Selection, verification and validation of methods

7.3 Sampling

7.4 Handling of test or calibration items

7.5 Technical records

7.6 Evaluation of measurement uncertainty

7.7 Ensuring the validity of results

7.8 Reporting of results

7.9 Complaints

7.10 Nonconforming work

7.11 Control of data and information management

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