ISO/IEC 17025:2017

GENERAL REQUIREMENTS FOR THE COMPETENCE OF TESTING AND CALIBRATION LABORATORIES

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REVISION PROCESS

CASCO WORKING GROUP 44

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~150 experts

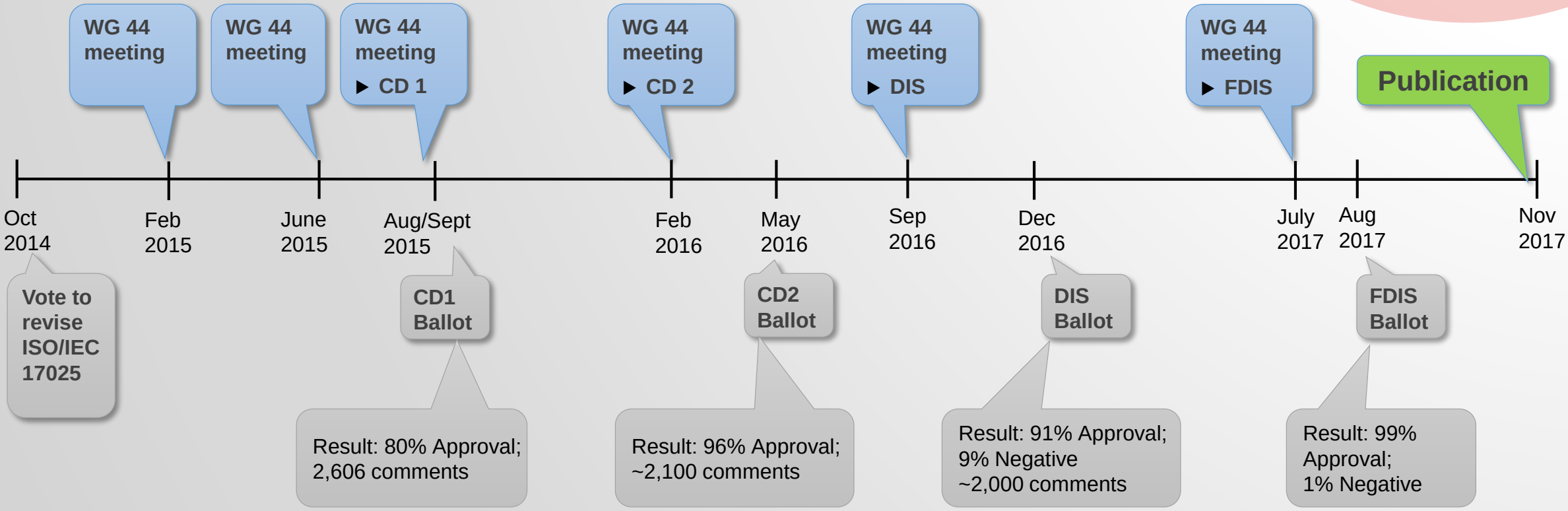
129 Committee members

21 Liaison members

FIFTH MEETING OF WORKING GROUP 44, 20-23 SEPTEMBER 2016 ISO HEADQUARTERS, GENEVA

SYSMAC Management Consultant

REVISION TIMELINE



OBJECTIVES OF REVISION

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- Align structure and content with other recently revised ISO standards
  - CASCO QS-CAS-PROC/33, Common elements in ISO/CASCO Standards
  - Other CASCO toolbox standards
  - ISO 9001:2015
- Focus on outcomes rather than prescriptive requirements
- Update language to reflect current practices and technologies
- Retain language from 2005 version whenever possible

MAIN CHANGES

MAIN CHANGES

From the Foreword of ISO/IEC 17025:2017:

- the risk-based thinking applied in this edition has enabled some reduction in prescriptive requirements and their replacement by performance-based requirements;
- there is greater flexibility than in the previous edition in the requirements for processes, procedures, documented information and organizational responsibilities;
- a definition of “laboratory” has been added.

MAIN CHANGES

- Scope of the standard: laboratory activities
  - Testing, calibration, sampling associated with subsequent testing
- Defined range of activities for laboratory
  - Excludes externally provided laboratory activities on an ongoing basis
- Emphasis on “Impartiality” vs. “Independence”
- Process orientation
- Information Technology: Risks, data integrity, confidentiality, validation of software, considering electronic documents
- Metrological traceability
- Decision Rules for statements of conformity (pass/fail)

DETAILED REVIEW OF CHANGES AND UPDATES

NEW STRUCTURE

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

1 SCOPE

This document specifies the general requirements for the competence, impartiality and consistent operation of laboratories.

This document is applicable to all organizations performing laboratory activities, regardless of the number of personnel.

Laboratory customers, regulatory authorities, organizations and schemes using peer-assessment, accreditation bodies, and others use this document in confirming or recognizing the competence of laboratories.

3 TERMS AND DEFINITIONS

3.4
intralaboratory comparison

- organization, performance and evaluation of measurements or tests on the same or similar items, within the same laboratory (3.6), in accordance with predetermined conditions
- [New, based on ISO/IEC 17043:2010 definition for “interlaboratory comparison”, which is included as 3.3 in ISO/IEC 17025:2017]

3.5
proficiency testing

- evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons (3.3)
- [SOURCE: ISO/IEC 17043:2010, 3.7, modified — Notes to entry have been deleted.]

3 TERMS AND DEFINITIONS

3.6
laboratory

- body that performs one or more of the following activities:
  - calibration
  - testing
  - sampling, associated with subsequent calibration or testing
- *Note 1 to entry: In the context of this document, "laboratory activities" refer to the three above-mentioned activities.*

3.7
decision rule

- a rule that describes how measurement uncertainty will be accounted for when stating conformity with a specified requirement

4 GENERAL REQUIREMENT

4.1 IMPARTIALITY

- Language taken from CASCO Procedure document (consistent with other conformity assessment standards)
- New/changed requirements:
  - Identifying and risks to impartiality on an on-going basis
  - Addressing risks to impartiality

4 GENERAL REQUIREMENT

4.2 CONFIDENTIALITY

- Language taken from CASCO Procedure document (consistent with other conformity assessment standards)
- New/changed requirements:
  - Stronger emphasis on customer awareness
  - More detail regarding specific cases where confidentiality could be affected

5 STRUCTURAL REQUIREMENT

- Removed terms “technical management” and “quality manager”
  - Retained same essential functions
- Introduced requirement for laboratory to identify range of laboratory activities for which it conforms with ISO/IEC 17025
  - Restricts claims of conformity to the defined range
  - Excludes externally provided laboratory activities on an on-going basis

5 STRUCTURAL REQUIREMENT

- 5.5 c) requires laboratory to “document its procedures to the extent necessary to ensure the consistent application of its laboratory activities and the validity of the results.”
  - Revised standard consistently uses term “procedure” when the intent is for laboratory to maintain documentation
  - The extend of detail in that documentation is up to the laboratory, subject to the conditions in 5.5 c)

6 RESOURCE REQUIREMENTS

6.1 GENERAL

"The laboratory shall have available the personnel, facilities, equipment, systems and support services necessary to perform its laboratory activities."

- Use of the term "available" indicates an approach in the revision to focus less on the status or ownership of resources and more on the relevant requirements for those resources
- Examples:
  - 6.2.1 refers to all personnel, internal or external [vs. 2005 version requiring personnel be employed by or under contract]
  - 6.4.1 requires laboratory to have access to equipment
  - [vs. 2005 version requiring laboratory be furnished with all items]

6 RESOURCE REQUIREMENTS

6.2 PERSONNEL

- Terminology and requirements have been updated and reorganized in the revision
- Otherwise, no significant changes to this clause compared to the 2005 version

6.3 FACILITIES AND ENVIRONMENTAL CONDITIONS

- Terminology and requirements have been updated and reorganized in the revision
- Otherwise, no significant changes to this clause compared to the 2005 version

6 RESOURCE REQUIREMENTS

6.4 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) that is required for the correct performance of laboratory activities and that can influence the results.

- Description of items considered as equipment is more inclusive than in 2005 version
- Notes provide more information regarding reference materials

6 RESOURCE REQUIREMENTS

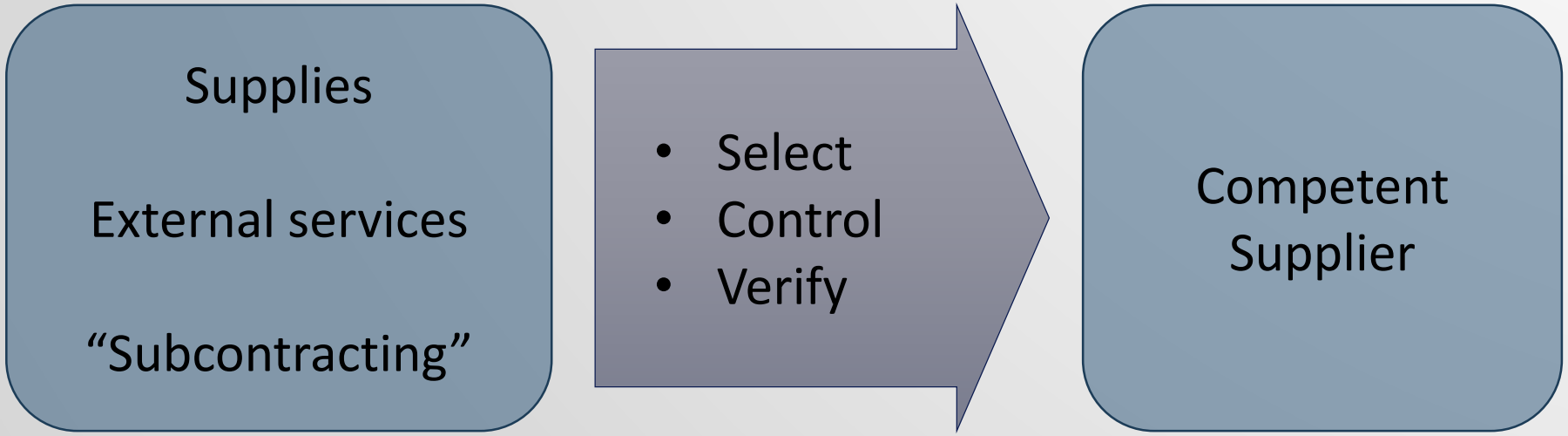
- 6.4.6 identifies two criteria that determine when calibration of equipment is requirement
  - the measurement accuracy or measurement uncertainty affects the validity of the reported results, or
  - calibration of the equipment is required to establish the metrological traceability of the reported result.
- These criteria apply for all laboratory activities [2005 version had different requirements for calibration and testing]
- Metrological traceability addressed in a separate clause (6.5) [2005 version included calibration in the traceability clause]

6 RESOURCE REQUIREMENTS

6.6 Externally provided products and services

Combines 4.5 Subcontracting and 4.6 Purchasing services and supplies from 2005 version

- In all cases, have requirements and controls
- Focuses on communication with customer



7 PROCESS REQUIREMENTS

7.1 Review of requests, tenders and contracts

New/updated requirements

- 7.1.3 requires statements of conformity and associated decision rules be addressed during contract review
- 7.1.4 states that deviations requested by the customer shall not impact the integrity of the laboratory or the validity of the results

7.2 Selection, verification and validation of methods

- Terminology and organization of clause updated from 2005 version
- Note after 7.2.1.1 clarifies that “method” as used in this document can be considered synonymous with the term “measurement procedure” as defined in ISO/IEC Guide 99.

7 PROCESS REQUIREMENTS

7.3 Sampling

- Definition of laboratory (3.6) clarifies that the sampling activity is associated with subsequent testing or calibration
- Otherwise, no significant changes to this clause compared to the 2005 version

7.4 Handling of test or calibration items

- 7.4.3 includes a new requirement:

  “When the customer requires the item to be tested or calibrated acknowledging a deviation from specified conditions, the laboratory shall include a disclaimer in the report indicating which results may be affected by the deviation.”

- Otherwise, no significant changes to this clause compared to the 2005 version

7 PROCESS REQUIREMENTS

7.5 Technical Records

- Technical records placed in this clause as process requirements
- Other types of records (e.g., management system records) addressed in Clause 8
- Otherwise, no significant changes to this clause compared to the 2005 version

7 PROCESS REQUIREMENTS

7.6 Evaluation of measurement uncertainty

- 7.6.1 requires all laboratories to identify contributions to measurement uncertainty
- 7.6.2 requires evaluation of measurement uncertainty for all calibrations, including those a laboratory performs on its own equipment (i.e. “in-house” calibrations)
- 7.6.3 includes essentially the same requirements for evaluation of uncertainty for testing as the 2005 version
- Note 2 applies to all laboratories, and clarifies that a laboratory is not required to calculate a unique uncertainty every time a test or calibration is performed provided the stated conditions are met

7 PROCESS REQUIREMENTS

7.7 Ensuring the validity of results

- Clause separates requirements for monitoring done within the laboratory (7.7.1) and those involving comparison with other laboratories (7.7.2)
- Data from internal activities (7.7.1) required to be recorded such that trends can be detected and, where practicable, statistical techniques applied
- Both required to be planned and reviewed, analyzed, used to control and (if applicable) improve laboratory activities
- Action required when results of analysis of data found to be outside pre-defined criteria

7 PROCESS REQUIREMENTS

7.8 Reporting of results

Language reflects current approaches to reporting

- New/updated requirements
  - 7.8.2.2 addresses data provided by a customer, including a disclaimer when those data can affect validity of results
  - 7.8.5 reporting sampling
  - 7.8.6 reporting statements of conformity

7 PROCESS REQUIREMENTS

7.9 Complaints

Language taken from CASCO Procedure document (consistent with other conformity assessment standards)

- New/updated requirements
- 7.9.2 requires a description of the complaints handling process be available to any interested party upon request
- 7.9.6 requires the outcomes to be communicated to the complainant be made by, or reviewed and approved by, individual(s) not involved in the original laboratory activities in question

7.10 Nonconforming work

- No significant changes to this clause compared to the 2005 version

7 PROCESS REQUIREMENTS

7.11 Control of data and information management

Extends and updates 5.4.7 in the 2005 version to address current laboratory practice

- 7.11.2 Note 1 clarifies that use of the term “laboratory information management system(s)” in this document includes both computerized and non-computerized systems
- 7.11.4 requires laboratory to ensure that off-site or external providers of information management comply with applicable requirements of ISO/IEC 17025

8 MANAGEMENT SYSTEM REQUIREMENTS

8.1 Options

The revision now provides two distinct options (A or B) for establishing a management system

- **Option A:** As a minimum the management system of the laboratory shall address the requirements in clauses 8.2 to 8.9
- **Option B:** Establish and maintain a management system in accordance with the requirements of ISO 9001

- Both options require that the management system is capable of supporting and demonstrating the consistent achievement of the requirements of ISO/IEC 17025 clauses 4 to 7 and assuring the quality of the laboratory results.
- Laboratories need only conform to one of the options (not both)

8 MANAGEMENT SYSTEM REQUIREMENTS

8.1.2 Option A

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

Similar to 2005 version

- 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) **New**

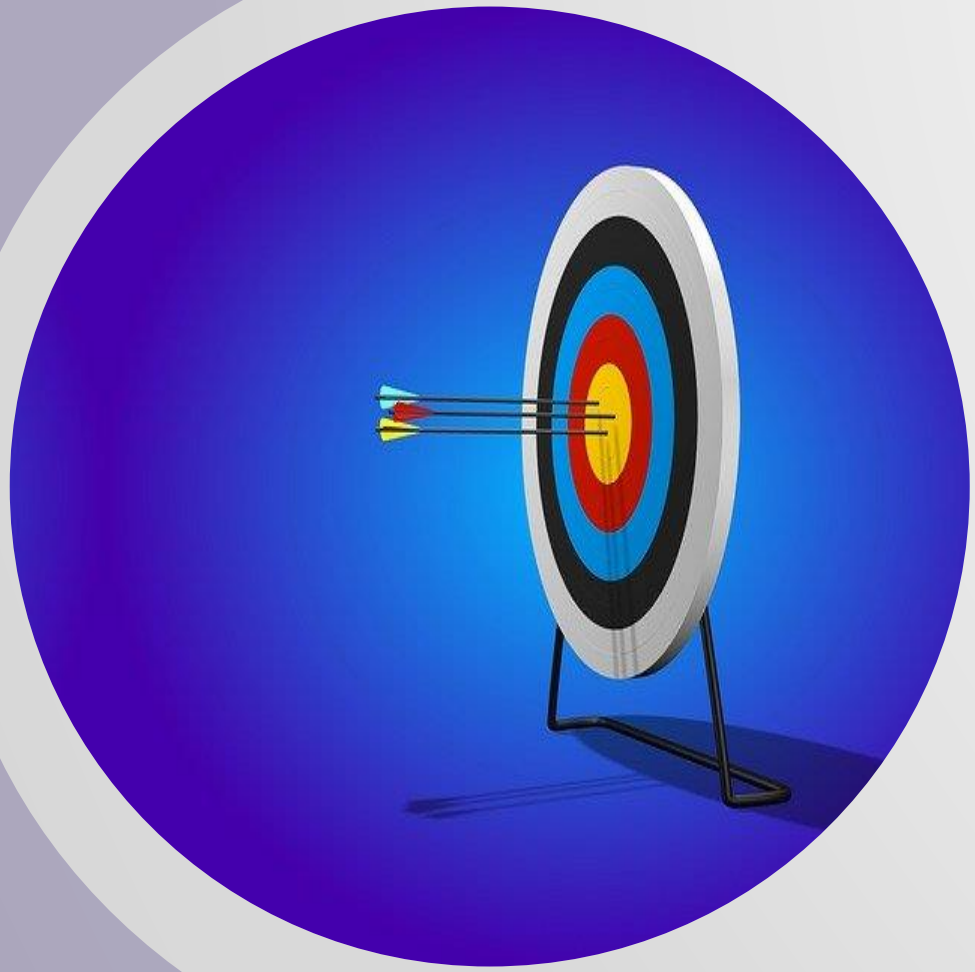
Aligned with ISO 9001:2015

- improvement (see 8.6)
- corrective action (see 8.7)
- internal audits (see 8.8)
- management review (see 8.9)

8 MANAGEMENT SYSTEM REQUIREMENTS

8.5 Actions to address risks and opportunities (Option A)

- Revision incorporates “risked-based thinking”
- Introduction and Note after 8.5.2 include two important points:
  - There is no requirement for formal methods for risk management or a documented risk management process
  - The laboratory is responsible for deciding which risks and opportunities need to be addressed



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