ISO/IEC 17043:2023

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Terms of Reference

- Incorporate CASCO common elements (PROC 33);
- Incorporate inspection and sampling;
- Align with other standards (e.g., 17025, 17034, 13528 and 35);
- Update structure and symbols for statistical calculations;
- Harmonize structure and management system requirements with ISO/IEC 17025 and ISO 17034;
- Bring consistency in requirements for 3rd party accreditation bodies.

Standardization of Terms

- Use ISO/IEC 17025:2017 wording when it applies;
- Use "Value" or "Assigned Value" rather than "Measurand";
- Use "Measurements and/or Tests" throughout;
- Use "Method" when referring to test or measurement procedure;
- Use "Customer" and "Participant" rather than Client*

Title

ISO/IEC 17043: 2010
- Conformity assessment — General requirements for proficiency testing

ISO/IEC 17043: 2023
- Conformity assessment — General requirements for the competence of proficiency testing providers

Structure Comparison

17043:2010 Structure

1. Scope
2. Normative References
3. Terms and Definitions
4. Technical Requirements
5. Management Requirements
6. Annex A
7. Annex B
8. Annex C

17043:2023 Structure

1. Scope
2. Normative References
3. Terms and Definitions
4. General Requirements
5. Structural Requirements
6. Resource Requirements
7. Process Requirements
8. Management System Requirements
9. Annex A
10. Annex B

Normative References

New normative references

- ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories* ;

- ISO 17034, *General requirements for the competence of reference material producers* ;

Terms and Definitions

Added

1. Consensus Value

Removed

1. Coordinator
2. Robust Statistical Method
3. Subcontractor
4. Metrological Traceability
5. Measurement Uncertainty

The decision was made not to include definitions that were included in ISO/IEC 17000 or ISO/IEC Guide 99.

Policies

ISO/IEC 17043:2010

- 4.2.6   Training
- 4.4.5.5   Release of assigned values
- 4.5.2   Comparison of methods
- 4.8.4   Use of reports
- 5.1.5 c)   Confidentiality
- 5.1.5 d)   Impartiality
- 5.4.1   Requests, tenders, proposals
- 5.5.1   Selection of services
- 5.8   Complaints and appeals
- 5.9.1   Nonconforming work
- 5.11.1   Corrective actions

ISO/IEC 17043:2023

- 7.2.3.5   Release of assigned values
- 7.4.3.4   Use of reports

Procedures

- ISO/IEC 17043:2023 has reduced the number of required procedures;
  - E.g., no requirement for procedures for document or record control.

4.1 Impartiality

- New clause to the standard;
- PROC 33;
- Much of it was covered in 5.1 Organization.

4.2 Confidentiality

Mostly PROC 33

4.2.1 The PT Provider needs **legally enforceable agreements** for management of information obtained or created during the performance of PT activities.

4.2.3 Information about a customer obtained from a third party must be kept confidential, even from the customer (17025).

Note: A PT provider can use PT data for academic articles provided participant ID is kept confidential.

5.0 Structural Requirements

- Adopted the wording from 17025;

- No longer a specific requirement for a Quality Manual, Quality Manager or Technical Management. Allows for different ways of conforming to the requirements in the standard.

6.0 Resource Requirements - General

- Requires that measurements or tests be conducted by a body conformant to relevant requirements of ISO/IEC 17025.

- Requires that where the PT item meets the definition of a reference material that it be produced by a body conformant to ISO 17034.

6.2 Personnel

- Some PROC 33 wording;
- Some 17025 wording;
- Reduced the number of specific tasks that require named authorizations.

6.3 Facilities and Environmental Services

- Reworded but most requirements remain the same;
- Adopted some wording from 17025.

6.4 Externally Provided Services

5.5 Subcontracted Services and 5.6 Purchasing Services and Supplies have been combined.

- 6.4.3 Inform participants about subcontracted services that impact validity of scheme;

- Require a procedure to ensure competence of service providers;

- Communicating requirements to service providers enhanced.

6.4 Externally Provided Services

- 2010: "5.5.4 The proficiency testing provider shall be responsible to the participants and other customers for the subcontractor's work, except in the case where a regulatory authority specifies which subcontractor is to be used."

- 2023: "6.4.6 The PT provider shall be responsible to the participants or customers for the externally provided products and services."

7.1.2 Scheme Communication

Some items that were required in planning have been added to required communication to customers:

- Objectives of the PT scheme;
- Criteria for determining assigned value and evaluation;
- Critical timelines.

7.2 Design and Planning of a PT Scheme

The documented plan has removed the following:

- Name and address of PT Provider;

- Name of coordinator.

The following has been added:

- Identify and manage risk when a significant change to the scheme has been made.

7.2.2 Statistical Design

Added:

- Whether participants report uncertainty and how it is used in evaluation of performance.

7.2.3 Determination of Assigned Values

- Added "where applicable" to 4.4.5.1 about taking traceability and uncertainty into account when determining the assigned value.

Removed:

- If consensus value is used as assigned value, the PTP must document the reason for using it.

7.3 Production and Distribution of PT Items

- Moved the requirement to have PT items match the matrix of typical samples to a note.

Removed:

- Note about producing sufficient PT items for re-shipping;

- Requirement to obtain PT items in accordance with regulatory and ethical requirements.

7.3.2 Homogeneity and Stability Assessment of PT Items

Removed:

- Requirement to use a statistically randomly selection of PT items for homogeneity assessment;

- Requirement to perform homogeneity assessment before shipping;

- When assessments aren't feasible, PTP shall demonstrate production is suitable for scheme.

7.3.2 Homogeneity and Stability Assessment of PT Items

Added:

- Use appropriate methods for homogeneity and stability assessment if experimental evidence is used.

7.3.5 Instructions to Participants

Added:

- Participants must provide method details if a method isn't specified by the scheme.

Changed:

- If participant reports uncertainty it must report coverage factor AND coverage probability. "Whenever practicable" was removed.

7.4.1 Data Analysis

Added:

- Procedures for handling results from different methods.

7.4.3 PT Reports

Added for revised reports:

- Identification of what was revised;
- When a revised report is issued, the impact on other participants must be investigated.

7.5.3 Surveillance of the Process

New

- Monitoring PT activities must be planned and recorded.

7.6 Handling of complaints

- Differs from 17025 in that the person relaying the outcome, or reviewed the outcome, need not be made by independent individual if resources do not allow.

7.7 Handling of Appeals

- Note added stating that schemes using statistically derived evaluations do not handle appeals;
  - They are more often handled as complaints.

8.3 Control of Management System Documentation

Removed:

- Requirement for a document control procedure;
- Requirement for a master document list;
- Softened requirement to identify altered text;
- List of what "Uniquely Identified" includes (e.g., rev #, date, page numbers, etc.).

8.5 Actions to Address Risks and Opportunities

- Partially replaces Preventive Actions;
- Consistent with the risk-based approach;
- Actions to address risk are to be proportional to potential impact on PT.

8.9 Management Review

Additions to items to be included in review:

- Fulfilment of objectives;
- Status of actions from previous reviews;
- Effectiveness of improvements;
- Adequacy of resources;
- Risk identification;
- Outcome of surveillance.