Eurachem

A Focus for Analytical Chemistry in Europe

10th PT/EQA Workshop - Windsor 2023

Report from WG1A

Revision of ISO/IEC 17043

- Convenors:
  - Monika Horsky (IAEA, Austria)
  - Brian Brookman (LGC, UK)

WG1A Members

- PT Providers - 25
- Participants - 12
- Accreditation Bodies - 8
- Others – none

- *No PT provider has implemented the revised standard at this stage.*
- *Large majority had read the revised standard*

Q1 Appropriateness of revised content

- Based on your experience as a PT/EQA provider / participant / accreditation body:

  a. Do you think the revised content of ISO/IEC 17043 appropriately addresses current practice?

  b. What changes have been most welcome, and which have been less welcome?

  c. Have the changes addressed the issues of concern in the 2010 version of ISO/IEC 17043?

Q1 Appropriateness of revised content

a. Do you think the revised content of ISO/IEC 17043 appropriately addresses current practice?

Yes

- No examples were provided where it doesn't

Q1 Appropriateness of revised content

b. What changes have been most welcome, and which have been less welcome?

- normative references to ISO/IEC 17025 and ISO 17034
  - Harmonization of what are “relevant requirements” likely to be an issue
  - Use of non-accredited service providers – how to prove competence?
  - Wish for clear definition/distinction of RM vs fit-for-purpose PT item – PT providers to justify
  - Debate about suitability/relevance of certain ISO 17034 requirements – e.g. of uncertainty contributors (homogeneity, stability…), long-term stability
  - Will the mandatory use of ISO/IEC 17025 enforce more requirements, e.g. method validation?
    - E.g. homogeneity: only repeatability precision of relevance, not all validation parameters (e.g. measurement uncertainty)

Q1 Appropriateness of revised content

c. Have the changes addressed the issues of concern in the 2010 version of ISO/IEC 17043?

- Alignment in structure to other ISO 17000 series standards
- Risk-based approach

- Clarity about homogeneity assessment not necessarily by experimentation

Q2 Implementation

a. As a PT/EQA provider, which new or changed requirements of ISO/IEC 17043 do you feel will be most difficult to implement?

b. As a PT/EQA participant, which new or changed requirements of ISO/IEC 17043 are most difficult to “understand”?

c. As an accreditation body, which new or changed requirements of ISO/IEC 17043 do you feel will be most difficult to assess?

Q2 Implementation

a. As a PT/EQA provider, which new or changed requirements of ISO/IEC 17043 do you feel will be most difficult to implement?

- Surveillance requirement – interpretation of requirement?
  - E.g., change of relative SD over time, failure rates…
  - Lessons learned from each scheme
  - How to implement it for single-round schemes?
  - Note in standards gives examples – includes e.g. report submission
  - Monitoring performance of participants' performance vs. PT provider performance
  - Most important to monitor areas with highest risk
  - Happens within management system 'automatically' – question on adequate proof
  - Case example: how to monitor shipment process – in case of high risk

- Requirement to instruct participants to provide method information

Q2 Implementation

b. As a PT/EQA participant, which new or changed requirements of ISO/IEC 17043 are most difficult to “understand”?

- Terminology: client vs. customer vs. participant
  - Definitions are included
- 5.4 Structural requirements – meet requirements of [….] and customers, regulators, …
- 7.4.3.7 Certificates ”shall not be misleading”
  - certificates should be “of participation” not “of performance”
- 7.3.5 Instructions to participants
  - fitness for purpose – depends on scheme objective.
- Confidentiality – of all information created during PT, possibly misleading wording
  - Advance notice to customers is required when making information public.

Q2 Implementation

c. As an accreditation body, which new or changed requirements of ISO/IEC 17043 do you feel will be most difficult to assess?

- see question 2.a – surveillance requirement

Q3 Harmonization of implementation

- Based on your experience as a PT/EQA provider / participant / accreditation body:

  a. Is the implementation of ISO/IEC 17043 harmonized and will the revised version improve the situation?

  b. Which specific requirements of ISO/IEC 17043 are likely to need specific attention to achieve harmonized implementation/assessment?

Q3 Harmonization of implementation

a. Is the implementation of ISO/IEC 17043 harmonized and will the revised version improve the situation?

- Acceptance of suppliers (of test results) who are not accredited?
  - It is not a requirement. Other proof of competence is possible.
  - Accreditation bodies can add policies, theoretically
- If PT provider does testing in-house – assessment of ISO/IEC 17025 requirements is required → define relevant requirements

- Revised standard provides more flexibility – risk for lower degree of harmonisation

Q3 Harmonization of implementation

b. Which specific requirements of ISO/IEC 17043 are likely to need specific attention to achieve harmonized implementation/assessment?

- Addition of two normative references

- Thank you to all working group participants