Example of Implementation of QMS: TÜBİTAK UME

Enver SADIKOĞLU
Quality Manager

EURAMET Webinar on changes to ISO/IEC 17025
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Contents

- Roadmap on the way of transition
- Planned actions and their implementation
- Lessons learned

Main changes in the standard

The main changes compared to the previous edition are as follows:

- 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 (see 3.6).

See “Foreword” of the ISO/IEC 17025 standard

Some specific requirements

4.1.4 The laboratory shall identify risks to its impartiality on an on-going basis.

6.2.5 The laboratory shall have procedure(s) and retain records for:

….

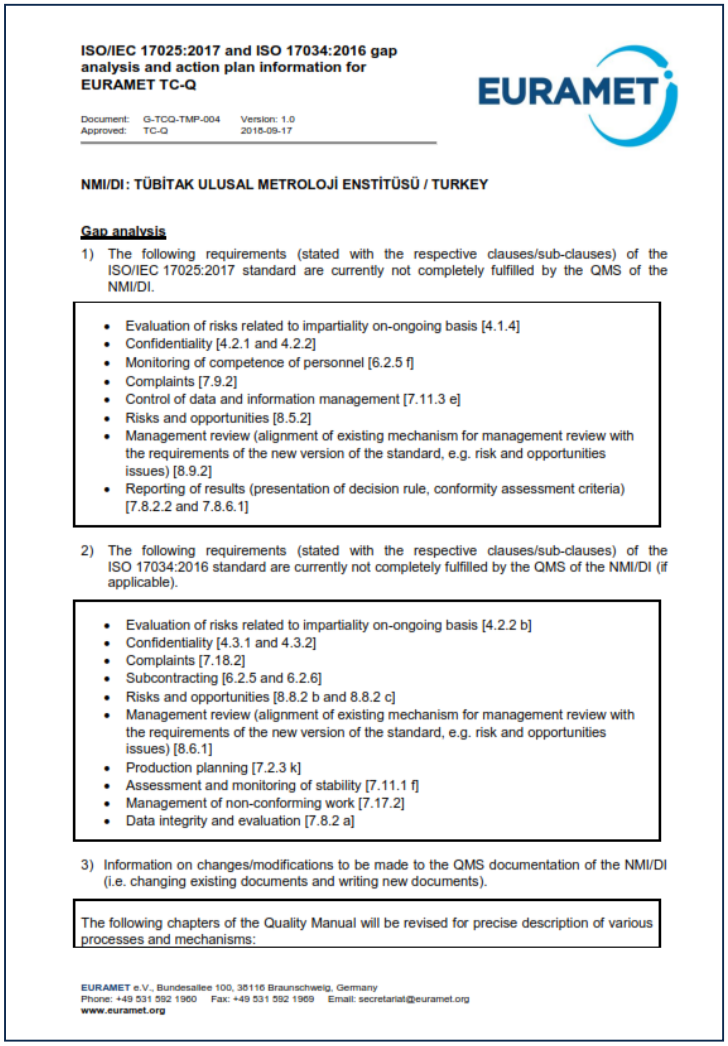
f) monitoring competence of personnel.

6.2.6 The laboratory shall authorize personnel to perform specific laboratory activities, including but not limited to, the following:

a) development, modification, verification and validation of methods;

Information presented in EUROLAB Cookbooks is very helpful…

First step – Gap Analysis



ISO/IEC 17025:2017 and ISO 17034:2016 gap analysis and action plan information for EURAMET TC-Q

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NMI/DI: TÜBİTAK ULUSAL METROLOJİ ENSTİTÜSÜ / TURKEY

Gap analysis

1) The following requirements (stated with the respective clauses/sub-clauses) of the ISO/IEC 17025:2017 standard are currently not completely fulfilled by the QMS of the NMI/DI.

- Evaluation of risks related to impartiality on-ongoing basis [4.1.4]
- Confidentiality [4.2.1 and 4.2.2]
- Monitoring of competence of personnel [6.2.5 f]
- Complaints [7.9.2]
- Control of data and information management [7.11.3 e]
- Risks and opportunities [8.5.2]
- Management review (alignment of existing mechanism for management review with the requirements of the new version of the standard, e.g. risk and opportunities issues) [8.9.2]
- Reporting of results (presentation of decision rule, conformity assessment criteria) [7.8.2.2 and 7.8.6.1]

2) The following requirements (stated with the respective clauses/sub-clauses) of the ISO 17034:2016 standard are currently not completely fulfilled by the QMS of the NMI/DI (if applicable).

- Evaluation of risks related to impartiality on-ongoing basis [4.2.2 b]
- Confidentiality [4.3.1 and 4.3.2]
- Complaints [7.18.2]
- Subcontracting [6.2.5 and 6.2.6]
- Risks and opportunities [8.8.2 b and 8.8.2 c]
- Management review (alignment of existing mechanism for management review with the requirements of the new version of the standard, e.g. risk and opportunities issues) [8.6.1]
- Production planning [7.2.3 k]
- Assessment and monitoring of stability [7.11.1 f]
- Management of non-conforming work [7.17.2]
- Data integrity and evaluation [7.8.2 a]

3) Information on changes/modifications to be made to the QMS documentation of the NMI/DI (i.e. changing existing documents and writing new documents).

The following chapters of the Quality Manual will be revised for precise description of various processes and mechanisms:

EURAMET e.V., Bundesallee 100, 38116 Braunschweig, Germany
Phone: +49 531 592 1960 Fax: +49 531 592 1969 Email: secretariat@euramet.org
www.euramet.org

”Missing” or points requiring attention…

- Evaluation of risks related to impartiality on-ongoing basis [4.1.4]
- Confidentiality [4.2.1 and 4.2.2]
- Monitoring of competence of personnel [6.2.5 f]
- Complaints [7.9.2]
- Control of data and information management [7.11.3 e]
- Risks and opportunities [8.5.2]
- Management review [8.9.2]
- Reporting of results (presentation of decision rule, conformity assessment criteria) [7.8.2.2 and 7.8.6.1]

Planned actions

- Communication with all staff of the institute about changes in the ISO/IEC 17025 and ISO 17034 standards
- Development of missing and modification of existing mechanisms within Quality Management System to meet requirements of the standards
  - Mechanism for monitoring of competence of personnel
  - Evaluation of risks related to impartiality on-ongoing basis
  - Emphasize confidentiality issues in QMS documentation
  - Mechanism for evaluation of risks and opportunities
  - Availability of description of the handling process for complaints to any interested parties
- Implementation and testing of newly developed and revised mechanisms.

Planned actions

- Revision of Quality Management System documentation
- Training of all staff on the requirements of the ISO/IEC 17025:2017 and ISO 17034:2016 standards.
- Training of internal auditors on the requirements of the ISO/IEC 17025:2017 standard.
- Internal audit covering requirements of the ISO/IEC 17025:2017 standard.
- Management review with agenda fully aligned to requirements of the ISO/IEC 17025:2017 standard.

Training and awareness activities

- Training given by Turkish Accreditation Agency (TÜRKAK) in May 2018. Participants UME staff acting as assessors for TÜRKAK in accreditation assessments.

- Training given by Quality Manager to all UME staff (November and December 2019) with overall participation of 200 people out of 350.

- Regular meetings (at least weekly) of UME Quality Management Board discussing various mechanisms.

- Seminars/workshops on various subjects with participation of all UME staff (November 2018 – March 2019)

    - Decision rule
    - Validation of software and electronic worksheets
    - Control of data and information management

Confidentiality

- Confidentiality is one of the main principles of all institutional activities
- Issue about confidentiality is described in many QMS documents, and mainly in general procedure ”Procedure on authorities and responsibilities”.
- Obeying to principles of confidentiality is secured through individual “Employment Contracts” and signed “Code of Conduct”

However,

- “Procedure for review of requests, tenders and contracts” was revised and amended with explanations (e.g. use of information about customers on web-site and/or printed promotional documentation of UME).
- New clauses in full compliance of the requirement of the standard were added to “Terms for Service Contract”.

Complaints

New elements in the standard…

7.9.2 A description of the handling process for complaints shall be available to any interested party on request.

7.9.6 The outcomes to be communicated to the complainant shall be made by, or reviewed and approved by, individual(s) not involved in the original laboratory activities in question.

Implemented actions:

- "Procedure for handling of customer complaints" as well as related chapter of the Quality Manual was revised.
- Issue on communication with customer during the process was better described.
- "Procedure for handling of customer complaints" is publicly available on UME web-site.

Management review

- No need for modification of the mechanism.
- Agenda of management review meetings has to be amended with new items such as
  - status of actions from previous management reviews
  - personnel feedback
  - results of risk identification

- Outcomes of the meeting has to be recorded. Some mandatory elements to be appeared in the minutes

Implemented actions:

- Agenda was updated to include few new items required by the ISO/IEC 17025:2017 and ISO 17034
- General procedure and relevant chapter of the Quality Manual were revised accordingly.
- Management review with updated agenda took place in February 2019.

Note: In case of large scale NMI current agenda of the MR meeting could be heavy for the single meeting…

Summary

- TÜBİTAK UME started work on QMS transition in March 2018 and fully completed in February 2019.
- QMS was assessed by TÜRKAK against the requirements of the ISO/IEC 17025:2017 standard. Accreditation certificate was renewed in April 2019.
- QMS was assessed by TÜRKAK against the requirements of the ISO 17034 standard. Accreditation certificate was renewed in May 2019.
- QMS of TÜBİTAK UME passed sucesfully re-evaluation within EURAMET TC-Q in April 2019.

Lessons learned

- Transition to new requirements of the standard is not complicated task for NMIs/DIs, especially if NMI/DI is a governmental organisation.
- With appropriate planning transition to the new requirements of the standard could be completed in relatively short period (9 month – 1 year).
- Efficiency of the work strongly depends on broad participation of institute staff.
- Training and awareness activities are crucial elements on the way of transition.
- Requirement on risk based thinking (not risk assessment) is an element probably requiring more efforts.
- Although the requirement on decision rule is relatively clear, it is not well understood.

Thank you for your attention!

enver.sadikoglu@tubitak.gov.tr

enver.sadikoglu@euramet.org