TC-Q Review Process

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EURAMET Information Day for INM Moldova
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Outline

- Introduction
- TC-Q processes for QMS review
- TC-Q documentation
- Initial evaluation of QMS
- Re-evaluation of QMS
- QMS Annual reporting

Introduction

- EURAMET database has records of 116 institutes
- 37 NMIs (members)
- 78 DIs (Associates)
- 1 International Organization – IAEA
- 1 Associated Candidate - INM

TC-Q granted confidence in QMS of 107 institutes

Introduction

- NMIs/DIs with non-approved QMS

  Cyprus MCIT
  Iceland NEST
  Luxembourg ILNAS, LGUL
  Malta MCCAA-SMI
  Norway NIVA
  Turkey MRC MI-UAL
  Moldavia INM

EURAMET TC-Q Review Criteria

- ISO/IEC 17025 to cover calibration and measurement activities under the CIPM MRA
- Production of Certified Reference Materials (CRMs) shall be covered by ISO/IEC 17034
- QMS meeting the requirements of ISO/IEC 17025 assessed by an accreditation body fulfilling the requirements of ISO/IEC 17011 and should be a signatory to the ILAC MRA
- QMS following ISO/IEC 17025 without third-party accreditation – considered as a self declaration

TC-Q processes

- Initial evaluation of QMS
- Re-evaluation of QMS – every 5 years
- QMS Monitoring through Annual Reporting
- On-site peer visits

CIPM MRA documents

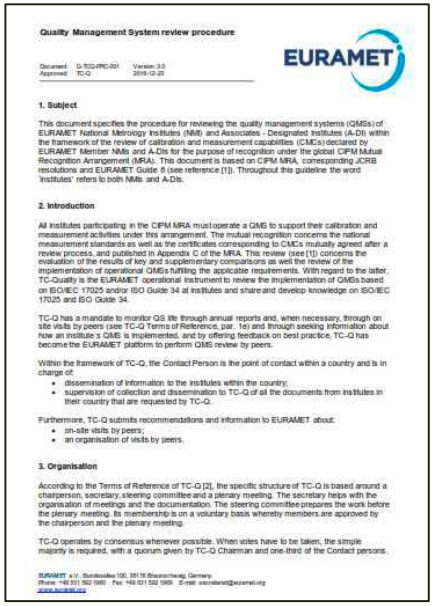
CIPM MRA-G-02 JCRB guidelines for the monitoring and reporting of the operation of quality systems by RMOs

CIPM MRA-G-03 Guidelines for the review of Quality Systems operated by IGO institutes and/or designated institutes, and the review of their calibration and measurement capabilities (CMCs)

TC-Q Documentation

- TC-Q documentation consist of:

- Quality Management System review procedure
- TC-Q Guidelines
- Templates
- Records (register)



Quality Management System review procedure

EURAMET

Document: D-TCQ-PRC-001 Version: 3.0
Approved: TC-Q 2018-12-20

1. Subject

This document specifies the procedure for reviewing the quality management systems (QMSs) of EURAMET National Metrology Institutes (NMI) and Associates - Designated Institutes (A-DI) within the framework of the review of calibration and measurement capabilities (CMCs) declared by EURAMET Member NMIs and A-DIs for the purpose of recognition under the global CIPM Mutual Recognition Arrangement (MRA). This document is based on CIPM MRA, corresponding JCRB resolutions and EURAMET Guide 8 (see reference [1]). Throughout this guideline the word 'institutes' refers to both NMIs and A-DIs.

2. Introduction

All institutes participating in the CIPM MRA must operate a QMS to support their calibration and measurement activities under this arrangement. The mutual recognition concerns the national measurement standards as well as the certificates corresponding to CMCs mutually agreed after a review process, and published in Appendix C of the MRA. This review (see [1]) concerns the evaluation of the results of key and supplementary comparisons as well the review of the implementation of operational QMSs fulfilling the applicable requirements. With regard to the latter, TC-Quality is the EURAMET operational instrument to review the implementation of QMSs based on ISO/IEC 17025 and/or ISO Guide 34 at institutes and share and develop knowledge on ISO/IEC 17025 and ISO Guide 34.

TC-Q has a mandate to monitor QS life through annual reports and, when necessary, through on site visits by peers (see TC-Q Terms of Reference, par. 1e) and through seeking information about how an institute's QMS is implemented, and by offering feedback on best practice. TC-Q has become the EURAMET platform to perform QMS review by peers.

Within the framework of TC-Q, the Contact Person is the point of contact within a country and is in charge of:

- dissemination of information to the institutes within the country;
- supervision of collection and dissemination to TC-Q of all the documents from institutes in their country that are requested by TC-Q.

Furthermore, TC-Q submits recommendations and information to EURAMET about:

- on-site visits by peers;
- an organisation of visits by peers.

3. Organisation

According to the Terms of Reference of TC-Q [2], the specific structure of TC-Q is based around a chairperson, secretary, steering committee and a plenary meeting. The secretary helps with the organisation of meetings and the documentation. The steering committee prepares the work before the plenary meeting. Its membership is on a voluntary basis whereby members are approved by the chairperson and the plenary meeting.

TC-Q operates by consensus whenever possible. When votes have to be taken, the simple majority is required, with a quorum given by TC-Q Chairman and one-third of the Contact persons.

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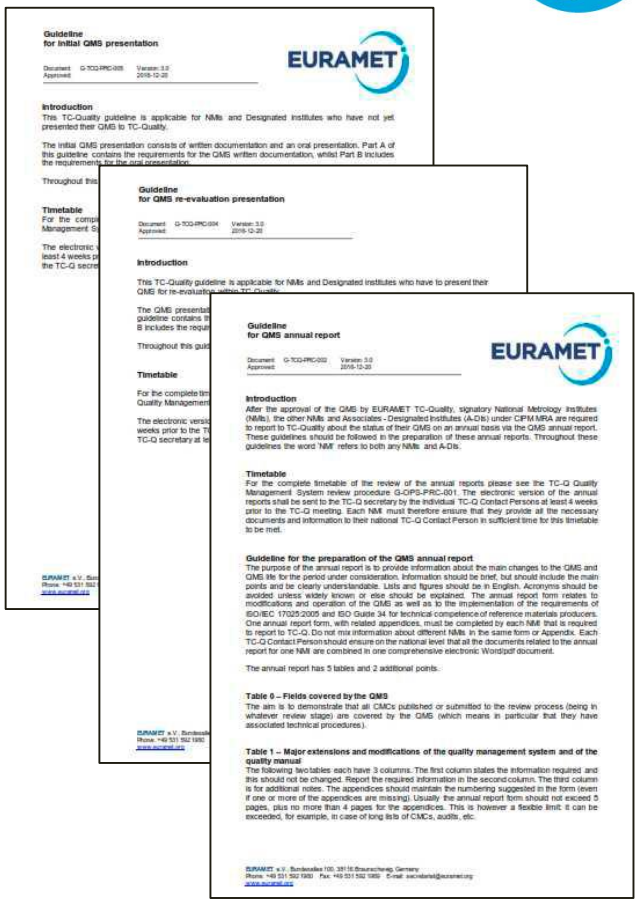
All these documents are publicly available on the EURAMET website.

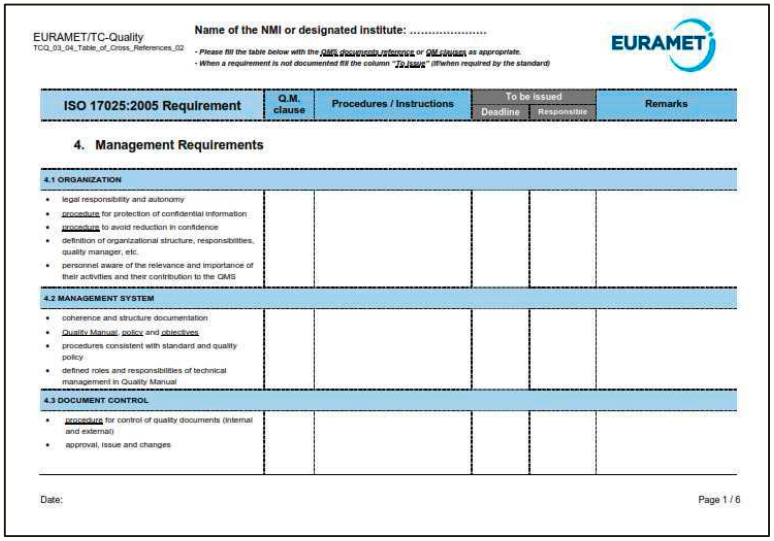
TC-Q Documentation: Guides

- Guideline for initial QMS presentation
- Guideline for QMS re-evaluation presentation
- Guideline for QMS Annual Report
- Guide for on site visits by peers



TC-Q Documents: Templates

- Table of Cross References
- Template for QMS Annual Reporting
- Template of the final peer review record



EURAMET/TC-Quality
TCQ_03_04_Table_of_Cross_References_02

Name of the NMI or designated institute: .....

- *Please fill the table below with the QMS documents references or QM clauses as appropriate.*
- *When a requirement is not documented fill the column "To issue" (if/when required by the standard)*

ISO 17025:2005 Requirement	Q.M. clause	Procedures / Instructions	To be issued: Deadline	To be issued: Responsible	Remarks
4. Management Requirements					
4.1 ORGANIZATION					
• legal responsibility and autonomy • procedure for protection of confidential information • procedure to avoid reduction in confidence • definition of organizational structure, responsibilities, quality manager, etc. • personnel aware of the relevance and importance of their activities and their contribution to the QMS					
4.2 MANAGEMENT SYSTEM					
• coherence and structure documentation • Quality Manual, policy and objectives • procedures consistent with standard and quality policy • defined roles and responsibilities of technical management in Quality Manual					
4.3 DOCUMENT CONTROL					
• procedure for control of quality documents (internal and external) • approval, issue and changes					

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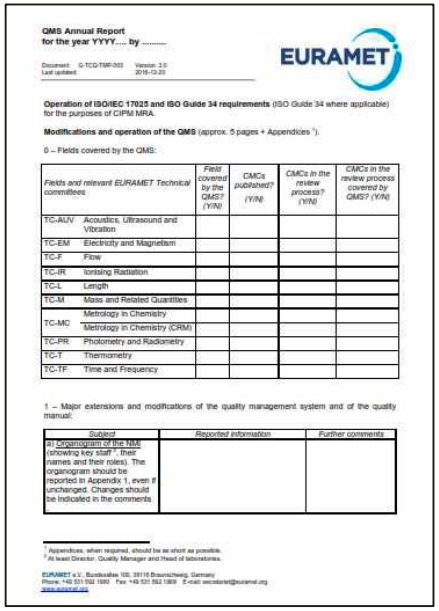


QMS Annual Report for the year YYYY.... by .....

Operation of ISO/IEC 17025 and ISO Guide 34 requirements (ISO Guide 34 where applicable) for the purposes of CIPM MRA.

Modifications and operation of the QMS (approx. 5 pages + Appendices [1]).

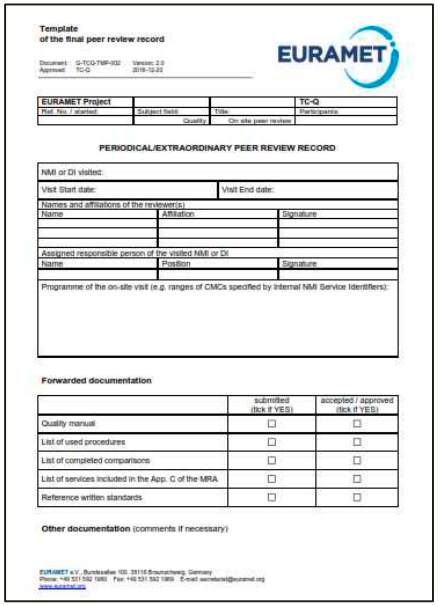
0 – Fields covered by the QMS:

Fields and relevant EURAMET Technical committees		*Field covered by the QMS? (Y/N)*	*CMCs published? (Y/N)*	*CMCs in the review process? (Y/N)*	*CMCs in the review process covered by QMS? (Y/N)*
TC-AUV	Acoustics, Ultrasound and Vibration				
TC-EM	Electricity and Magnetism				
TC-F	Flow				
TC-IR	Ionising Radiation				
TC-L	Length				
TC-M	Mass and Related Quantities				
TC-MC	Metrology in Chemistry Metrology in Chemistry (CRM)				
TC-PR	Photometry and Radiometry				
TC-T	Thermometry				
TC-TF	Time and Frequency				

1 – Major extensions and modifications of the quality management system and of the quality manual:

Subject	*Reported information*	*Further comments*
a) Organogram of the NMI (showing key staff [2], their names and their roles). The organogram should be reported in Appendix 1, even if unchanged. Changes should be indicated in the comments		

[1] Appendices, when required, should be as short as possible.
[2] At least Director, Quality Manager and Head of laboratories.



Template of the final peer review record

EURAMET Project			TC-Q
Ref. No. / started:	Subject field:	Title:	Participants:
	Quality	On site peer review	

PERIODICAL/EXTRAORDINARY PEER REVIEW RECORD

NMI or DI visited:

Visit Start date: | Visit End date:

Names and affiliations of the reviewer(s)

Name	Affiliation	Signature

Assigned responsible person of the visited NMI or DI

Name	Position	Signature

Programme of the on-site visit (e.g. ranges of CMCs specified by Internal NMI Service Identifiers):

Forwarded documentation

	submitted (tick if YES)	accepted / approved (tick if YES)
Quality manual	☐	☐
List of used procedures	☐	☐
List of completed comparisons	☐	☐
List of services included in the App. C of the MRA	☐	☐
Reference written standards	☐	☐

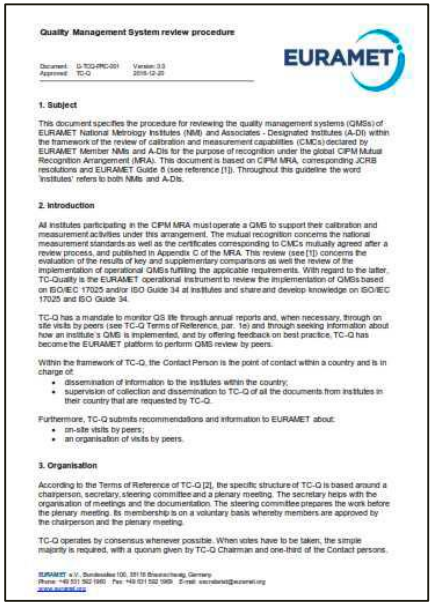
Other documentation (comments if necessary)

QMS review procedure - contents

- Code: G-TCQ-PRC-001
- Version: 3.0
- Date: 20/12/2016
- Volume: 6 pages

Contents:

- Subject
- Introduction
- Organisation
- Review Criteria
- Review procedure and timetable
- References



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Implementation of the procedure

- Written report(s) has to be prepared carefully
- Reports has to be submitted in time
- TC-Q contact persons are responsible for collection of all reports from DIs
- TC-Q contact persons have to check contents of the collected reports
- Any unclear information could be triggering either major or minor questions
- Do not try to write fairy tale, present realities

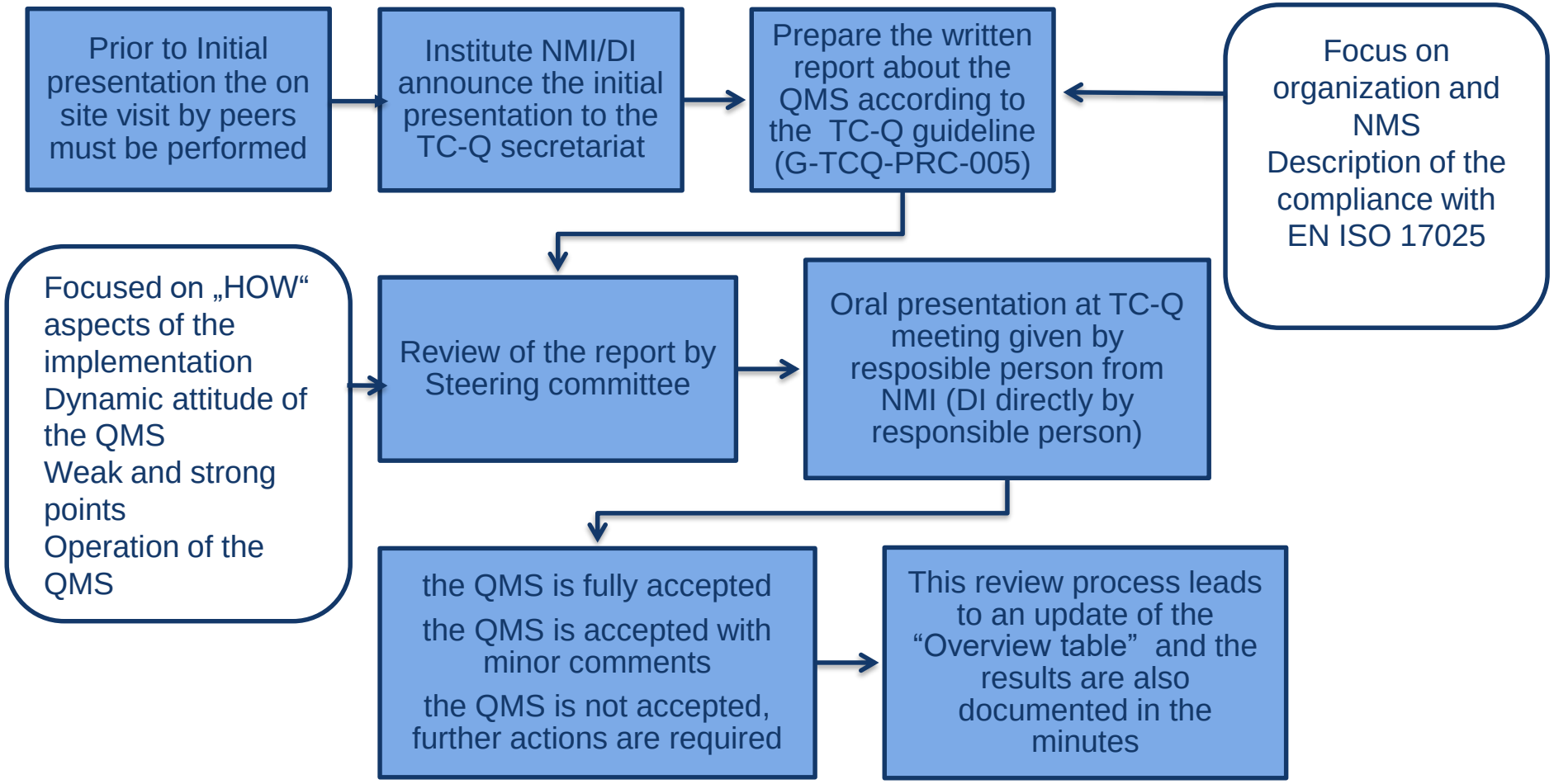
Specific guidelines for accredited NMIs/DIs

- The claimed CMCs are identical with CMCs assessed by the accreditation body and documented in the assessment report;
- Technical assessors shall come from a laboratory which is at least on the level as the assessed laboratory or meets requirements of CIPM 2007-25
- The names and qualifications of assessors must be made known to TC-Q;
- The relevant excerpts from assessment reports, especially those concerning findings, must be made available to TC-Q by way of annual reports.

Specific guidelines for self-declared NMIs/DIs

- The QMS should undergo an on-site peer review visit covering both the management and technical requirements of ISO/IEC 17025 and/or ISO/IEC 17034 (where applicable);
- Institutes are to arrange for on-site peer review visits by themselves in compliance with the provisions of EURAMET “Guide for on-site visits by peers in the frame work of CIPM MRA” usually using external reviewers;
- Institutes submitting their CMCs for the first time shall undergo an onsite peer review prior to their initial QMS presentation.

Initial QMS Evaluation



Information required for review

Information on national metrology system

Quality policy (Including quality objectives).

Structure of NMI (Including organogram showing key staff, their names and their roles).

QMS structure

Table of contents of the quality manual

List of general and administrative procedures

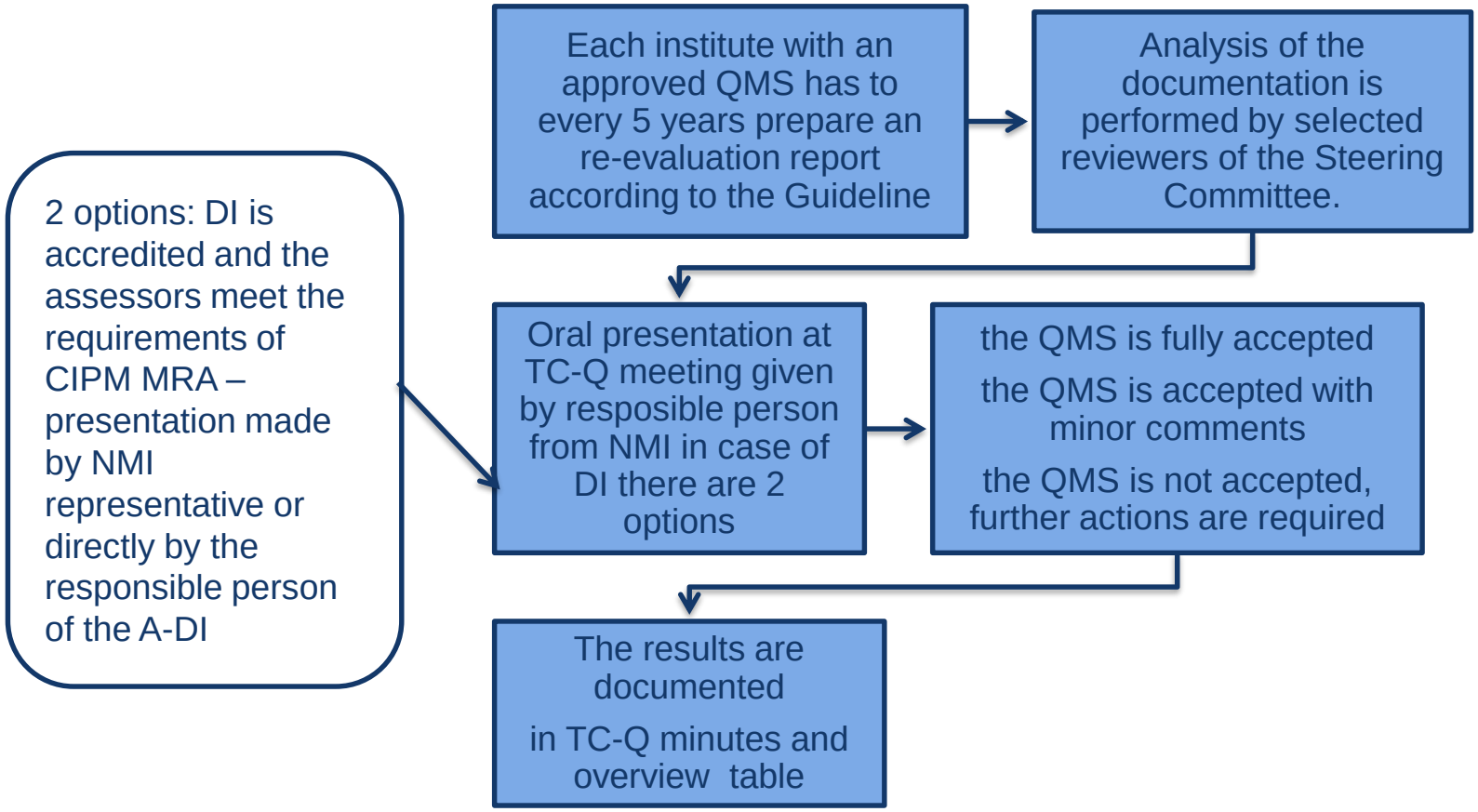
List of technical procedures

QMS and calibration measurement capabilities covered by QMS

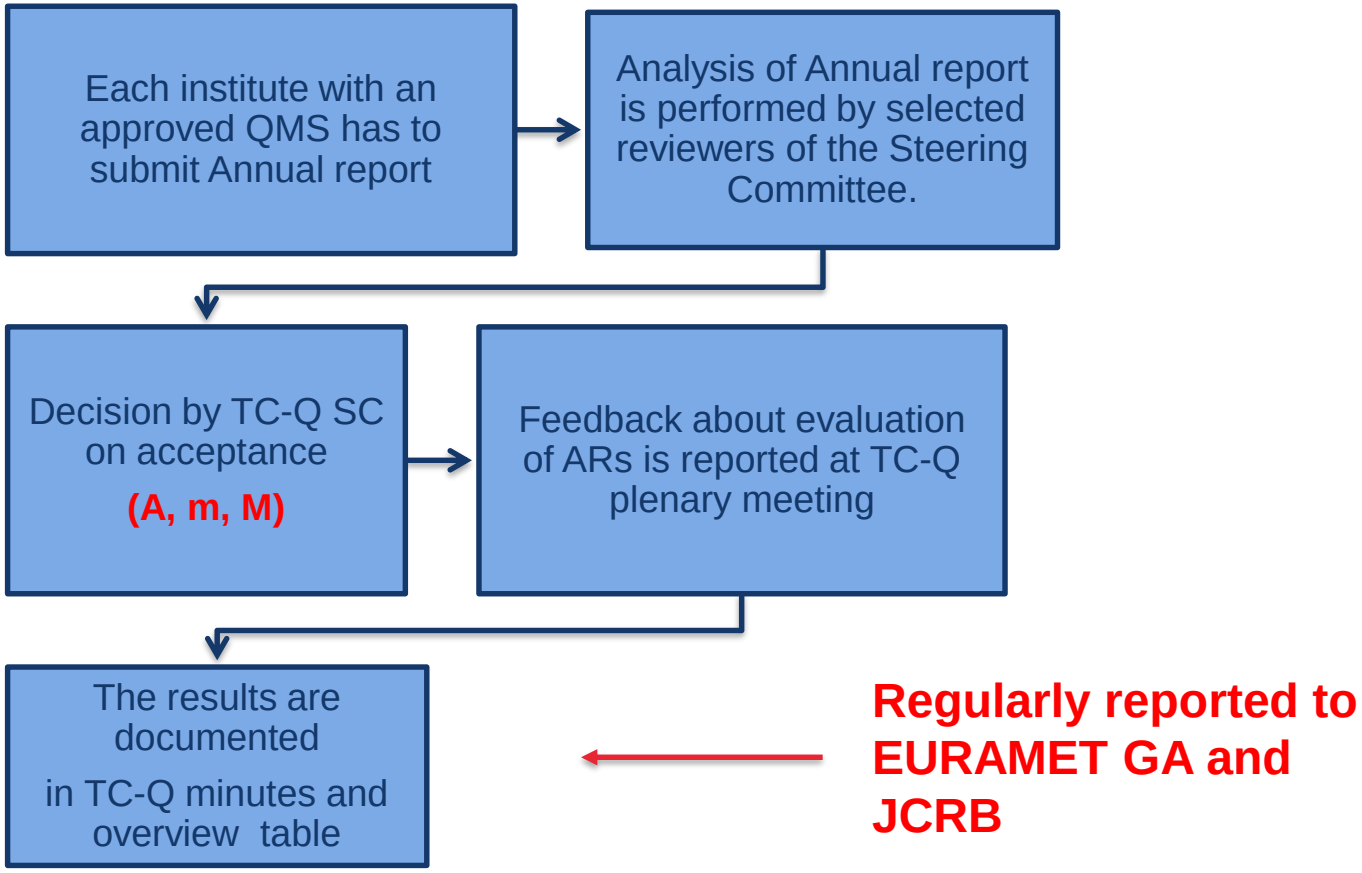
Information required for review

- Information about QMS Life
- Continuous improvement
- Service to the customer
- Complaints
- Non-conforming work
- Internal audits
- Management reviews
- Results of on-site visits or accrediation
- Further information on ISO/IEC 17034 implementation for reference materials (CRMs)
- From the 2019 TC-Q meeting onwards all initial presentations of NMIs/DIs shall be in accordance with the requirements of the ISO/IEC 17025:2017 standard.

QMS Re-evaluation



QMS Annual reporting



A - the QMS is fully accepted
m - the QMS is accepted with minor comments
M - the QMS is not accepted, further actions are required

Thank you for your attention!

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