

	COOMET Recommendation	COOMET R/AQ/9:2019 Number of pages: 4 Version: 28.03.2019
	Recommendations on the evaluation of quality management systems of National metrology institutes/Designated institutes	
	Document of COOMET Quality Forum Document code: QSF-doc_002e	
<i>Updated and agreed at the 26th meeting of the Technical Committee of the COOMET Quality Forum (Chisinau, Moldova, 27.03.2019)</i> <i>Approved at the 29th meeting of the COOMET Committee (Dresden, Germany, 3-4.04.2019)</i>		

1. SCOPE

This Recommendation establishes the requirements and procedure for evaluation (peer review) of quality management systems of National metrology institutes and Designated institutes in terms of their calibrations and measurements, the results of which shall be recognized in accordance with the Agreement on mutual recognition of national standards and certificates of calibration and measurements issued by national Metrology institutes/Designated institutes (hereinafter the Agreement).

The recommendations relate to the activities of the state metrology institutions - COOMET members, on behalf of which the CIPM MRA was signed. The recommendations meet the requirements of ISO/IEC 17025 and ISO 17034.

2. NORMATIVE REFERENCES

These Recommendations refer to the following documents:

Mutual recognition Agreement of national standards, calibration and measurement certificates of CIPM MRA.

ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories.

ISO 17034 General requirements for the competence of reference material producers

ISO 19011, Guidelines for auditing management systems.

ISO/IEC Guide 98-3 Uncertainty of measurement - Part 3: Guide to the expression of uncertainty in measurement (GUM:1995).

CIPM MRA-D-04 Calibration and Measurement Capabilities in the context of the CIPM MRA.

ISO/IEC Guide 99 International vocabulary of metrology - Basic and general concepts and associated terms (VIM).

CIPM/2007-25 Recommendations for on-site visits by peers and selection criteria for on-site visit peer reviewers.

3. TERMS AND DEFINITIONS

These recommendations apply the terms and definitions regulated in the documents, which are given in the section normative references, as well as:

National metrology institutes/Designated institutes (NMI/DI) – organisations (institutions) which keep, maintain and improve National measurement standards of the highest precision in a given country, provide for their inter-comparisons and transfer of unit to measuring instruments of calibration and measurement laboratories including that of other countries.

4. GENERAL

4.1 Based on the criteria approved (see Annex 1 to the Recommendation COOMET R/AQ/9:2019, document code QSF-doc_002e_anx1) a peer review of quality management systems of NMI/DI is carried out by COOMET experts and auditors commission, appointed by TC 3.1 "Quality Forum Technical Committee" (hereinafter - TC 3.1). Experts and auditors from other RMO can be included in this commission based on agreement with host party.

4.2 Qualification requirements for experts and auditors should be in accordance with the requirements of Joint Committee of RMO and BIPM (JCRB) and CIPM/2007-25 "Recommendations for on-site visits by peers and selection criteria for on-site visit peer reviewers" as well as ISO 19011.

5. PEER REVIEW PROCEDURE OF QUALITY MANAGEMENT SYSTEM

5.1. For a peer review of the quality management system of NMI/DI submit for the consideration of the Commission (point 4.1):

- documents regulating the organizational structure and activities of this organization within the framework of the quality management system (QMS) and confirming the compliance of the QMS with the requirements of ISO/IEC 17025, ISO 17034 (only for reference materials) and these recommendations.

The Commission may be provided with additional materials related to the peer review of the NMI/DI QMS, such as feedback from experts and auditors outside the Commission (including from other RMO).

When conducting a peer review of the quality management system of NMI/DI Commission (point. 4.1) checks functioning of the QMS. The steps and procedure for conducting a peer review of the NMI/DI QMS are set out in the COOMET Recommendation R/AQ/13:2019 "Rules and Procedure for the evaluation the quality management systems of national metrology institutes / designated institutes (NMI/DI)" (document code QSF-doc_003e).

5.2. NMI/DI QMS peer review is carried out in the main areas:

- general requirements;
- structural requirements;
- resource requirements;
- process requirements;
- management system requirements.

5.2.1. General requirements include:

- impartiality;
- confidentiality;

5.2.2. Structure requirements include:

- management responsibility;
- area of activity;
- organizational structure;
- authorized personnel.

5.2.3. Resource requirements include:

- personnel;
- facilities and environmental conditions;
- equipment;
- metrological traceability;
- externally provided products and services.

5.2.4. Process requirements include:

- review of requests, tenders and contracts;
- selection, verification and validation of methods;
- sampling;
- handling of test or calibration items;
- technical records;
- evaluation of measurement uncertainty;
- ensuring the validity of results;
- reporting on results;
- complaints;
- nonconforming work;
- control of data and information management.

5.2.5. Management system requirements include:

- management system documentation;
- control of management system documents;
- control of records;
- actions to address risks and opportunities;
- improvement;
- corrective actions;
- internal audits;
- management reviews.

5.2.6. In conducting a peer review of the NMI/DI QMS manufacturers of reference materials further verify compliance with the technical and production requirements of ISO 17034.

5.2.7 Peer review includes validation of the:

- implementation of the Guide to uncertainty of measurement, as well as the rules and regulations of JCRB;
- confirmation of all data about the measurement and calibration capabilities of NMIs/DIs, the results of comparisons of measurement standards;
- metrological traceability of measurement results to standards recognized by BIPM (in case of calibration of standards in other NMI/DI).

5.3. According to the results of a peer review of the NMIs/DIs QMS the following is drawn up:

- report on results of the peer review signed by all members of the Commission including reports of the auditor and technical experts on each type of measurements.

5.4. Report on 5.3 sent by the auditor (see 5.5) to the Secretariat of TC 3.1.

5.5. After the external audit, the auditor who performed the external audit of the NMI/DI QMS reports on its results at the meeting of TC 3.1.

5.6. The decision on the conformity of the NMI/DI QMS based on the results of the peer review is carried out at the next meeting of TC 3.1, or by closed electronic voting of TC members.

5.7. In case of a closed electronic voting the Secretariat of TC 3.1 forwards the information prepared by the auditor about external audit together with the form of the ballot for voting to TC members and posts on the closed part of the web portal www.coomet.net. The newsletter is filled with members of the TC and shall be sent within two weeks to the Secretariat of TC 3.1. The Secretariat of TC 3.1 shall count the votes on the provided ballots and draw up a Protocol. TC members have the right to request additional information from the auditor about the external audit.

5.8. The decision to recognize the NMI/DI QMS is taken by a majority of votes of full members of the TC 3.1 and Chairperson of the COOMET Quality Forum.

5.9. Based on the decision of TC 3.1 on the recognition of NMI/DI QMS (in English and Russian) Confirmations of Recognition indicating the metrological areas are issued signed by Chairperson of the COOMET Quality Forum.

The validity of the Confirmations should not be more than five years.

5.10. At the end of the period of validity of the Confirmations, a second peer review shall be carried out. Peer review can be carried out according to the reduced plan taking into account improvement of QMS, new CMC-lines, changes in structure, etc.

5.11. An oral presentation of the QMS at the COOMET Quality Forum is held before the peer review. Before the Quality Forum the NMI/DI shall submit a written presentation to the TC 3.1 Secretariat.

5.12 Written and oral presentations of the NMI/DI QMS are held in accordance with the schedule of the COOMET Quality Forum.

It is recommended to use the "Recommendations on giving an oral presentation to the COOMET Quality Forum of the quality management systems of National metrology institutes/Designated institutes (NMIs/DIs)" (Annex 2 (Annex A), document code QSF-doc_002r_003r_anxA) in preparation for the oral presentation of the NMI/DI QMS.

Not later than a month before the oral presentation NMI/DI, which presents its QMS to COOMET Quality Forum, sends a written presentation to the members of TC 3.1 through the Secretariat of TC 3.1. Secretariat of TC 3.1 shall post a written presentation of the NMI/DI on the web-portal www.coomet.net.

When preparing a written presentation, it is recommended to use the "Recommendations on giving a written presentation to the COOMET Quality Forum of quality management systems of National Metrology institutes//Designated institutes (NMIs/DIs)" (Annex 3 (Annex B) (document code QSF-doc_002r_003r_anxB).

In the absence of remarks from the TC 3.1 members on the submitted documentation, the Secretariat of TC 3.1 include in the agenda of COOMET Quality Forum oral presentation of NMI/DI QMS.

To conduct oral presentations NMI/DI, representing its quality management system on the COOMET Quality Forum, is preparing a handout for its oral presentation.

After the oral presentation, COOMET Quality Forum decides on the readiness of the NMI/DI to conduct a peer review of the NMI/DI QMS, which is recorded in the minutes of the meeting of the COOMET Quality Forum.

5.13. TC 3.1 conducts annual monitoring of the state of NMI/DI QMS through review of annual reports on NMI/DI QMS.

5.14. At least once every five years (during the validity of Confirmations of Recognition of the NMI/DI QMS) all CMC data, provided in the database of the BIPM, shall be checked. This check can be carried out in different ways (checking the status of QMS documentation, evaluation of comparison results, reports of COOMET TEs and other RMO).

Note: the audit does not include mandatory visits of Technical experts to the NMI/DI.

5.15. In the case of inconsistencies according to point 5.14. TC 3.1 can make a decision on conducting the extraordinary peer review of NMI/DI QMS. A peer review is carried out in the case of:

- revisions of CMC lines;
- inclusion in the database of BIPM of new CMC lines;
- ~~significant changes in the NMI/DI QMS.~~

6. ANNEXES

Annex 1

Criteria for the recognition of the quality management systems in COOMET NMIs/DIs (document code QSF-doc_002e_anx1).

Annex 2 (Annex A)

Recommendations on giving an oral presentation at the COOMET Quality Forum of the quality management systems of National metrology institutes/Designated institutes (NMI/DI QMS) (document code QSF-doc_002e_003e_anxA).

Annex 3 (Annex B)

Recommendations on preparing a written presentation at the COOMET Quality Forum of the quality management systems of National metrology institutes/ Designated institutes (NMI/DI QMS) (document code QSF-doc_002e_003e_anxB).

Annex 4

Regulation for auditors on a peer review of the quality management systems of National metrology institutes/Designated institutes (document code QSF-doc_002e_anx4).

Annex 5

Form of electronic voting ballots on the recognition of a quality management system (document code QSF-doc_002e_anx5).