

	<b>COOMET Recommendation</b>	<b>COOMET R/AQ/13:2019</b>  Number of pages: 5 Version: 28.03.2019
	<b>Rules and Procedure for the evaluation of the quality management systems of National metrology institutes/Designated institutes</b>	
	Document of COOMET Quality Forum Document code: <b>QSF-doc_003e</b>	
<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>		

This Recommendation defines the Rules and Procedures for evaluation (peer review) of the quality management systems (QMS) of National metrology institutes and Designated institutes (NMIs/DIs) of COOMET member countries for the implementation of the Agreement on the mutual recognition of national standards and calibration and measurement certificates issued by the NMI/DI (CIPM MRA).

Before a peer review of a QMS, the NMI/DI submits to the TC 3.1 "Quality Forum Technical Committee" of the COOMET (hereinafter - TC 3.1) a written and oral presentation of the NMI/NI QMS, after which TC 3.1 decides whether the NMI/DI is ready for a peer review.

### **Written and oral presentation**

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 "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 A, document code QSF-doc\_002e\_003e\_anxA).

Before conducting an oral presentation, the NMI/DI, presenting its QMS at COOMET Quality Forum, sends a written presentation through the TC 3.1 Secretariat, to the members of TC 3.1, a month before the presentation. It is recommended when preparing a written presentation to use "Recommendations on giving a written presentation to the COOMET Quality Forum of quality management systems of National metrology institutes/ Designated institutes (NMI/DI)" (Annex B, document code QSF-doc\_002e\_003e\_anxB).

In case the TC 3.1 members have no comments on the submitted written presentation, the TC 3.1 Secretariat includes on the agenda of the COOMET Quality Forum a presentation of the oral presentation of the stated NMI/DI QMS.

For an oral presentation, the NMI/DI, presenting its QMS at COOMET Quality Forum, prepares handouts on its oral presentation for each TC 3.1 member.

After an oral presentation, the TC 3.1 decides about the readiness of the NMI/DI to conduct a peer review of the NMI/DI QMS, which is recorded in the minutes of the TC 3.1 meeting and COOMET Quality Forum.

### **Peer review of the NMI/DI quality management system by auditors and technical experts of the COOMET Quality Forum**

The NMI/DI QMS is reviewed after a written and oral presentation is carried out directly at the NMI/DI on the basis of an NMI/DI application for a peer review (Annex 1, document code

QSF-doc\_003e\_anx1) and in accordance with the schedule approved by TC 3.1 (Annex 2, document code QSF-doc\_003e\_anx2).

A peer review of QMS is carried out by the commission, which includes auditors and technical experts of the COOMET Quality Forum (COOMET QF). Auditors and technical experts for the peer review of the QMS of a specific NMI/DI are appointed by the Chairperson of the TC 3.1.

When selecting auditors and technical experts, it should be borne in mind that they shall be from a different country than the NMI/DI that is being reviewed.

When selecting technical experts for a peer review of the QMS, NMI/DI is recommended to be guided by the field of activity of the given NMI/DI, the declared CMC tables and the technical competence of the expert, as well as economic aspects. In justified cases, the Chairperson of TC 3.1 may appoint experts from other RMOs (in the absence of COOMET experts in the declared area or inability of the expert to participate in COOMET in a peer review within the appointed time).

When choosing technical experts, it is recommended to use the COOMET list of technical experts.

The Chairperson of TC 3.1 informs the NMI/DI of the peer review and the composition of the group of technical experts of the Commission.

The Auditors and technical experts in their peer review should be guided by the Recommendation COOMET R/AQ/9:2019 "Recommendations for the evaluation of quality management systems of National metrology institutes/Designated institutes" (document code QSF-doc 002e).

The NMIs/DIs, no less than two months before the planned peer review date, submits to TC 3.1 the following documents:

- application for a peer review of the QMS (Annex 1, document code QSF-doc\_003e\_anx1),
- quality guide,
- analysis of the effectiveness of the QMS from the management over the last year,
- calibration procedures (calibration methods) with an indication of the calculation of the uncertainty budget for all the expected lines of the SMS tables. In the case of single-type documents (for example, for different measurement ranges), 1-2 documents may be submitted at the applicant's choice — these documents are confidential.

Documents submitted must be in Russian or in English.

The NMIs/DIs, which represents the QMS for peer review, must provide full information at the site of the peer review about the NMI/DI QMS, as well as a complete set of documents providing the NMI/DI QMS. The internal documents of the NMI/DI QMS can be in the language of the applicant country (in this case, the NMI/DI provides interpretation in Russian or English).

Technical experts when conducting a peer review have the right to require a specific metrological procedure from the NMI/DI providing evidence of traceability of measurement results to SI units.

The payment for a peer review is made by the applicant. The time of the peer review should not exceed three days, not counting the time spent on travel. The payment for work includes: travel back and forth, accommodation, daily allowance. The size of daily allowance is determined by the size of the daily allowance of the country from which the expert or auditor comes.

The peer review carried out in accordance with the Plan of a peer review (Annex 4, document code QSF-doc\_003e\_anx4).

All discrepancies that will be identified by the Commission during the peer review of the QMS are recorded in separate protocols (Annex 5, document code QSF-doc\_003e\_anx5).

These protocols should indicate specific nonconformities with an indication of the clause of ISO / IEC 17025 and ISO 34 ISO 17034 (in the case of reference materials), and corrective actions and / or proposals by the applicant to remedy this nonconformity.

When conducting a peer review, the auditor and technical experts may use the recommended questionnaires.

According to the results of the peer review, each technical expert compiles a report that is submitted to the auditor during the peer review for the preparation of a general report. The auditor makes a report. Report forms are given in Annex 6 (document code QSF-doc\_003e\_anx6).

The reports should indicate in detail:

- compliance with which clauses of ISO / IEC 17025 and ISO 17034 standards was carried out by a peer review by this expert;
- which units of the NMI/DI he checked;
- if any metrological procedures were carried out, they should be indicated with attachment of measurement results and calculation of uncertainty;
- what inconsistencies were identified and suggestions for eliminating them;
- proposals on the possibility of recognizing the NMI/DI QMS.

In addition, the auditor and technical expert can offer recommendations for improving the quality management system of the NMI/DI.

The auditor on the basis of the reports of technical experts compiles a general report on the conduct of a peer review (Annex 7, document code QSF-doc\_003e\_anx7). One copy of the report is transferred to the reviewed NMI/DI, and the second - to TC 3.1. The aforementioned reports of the auditor and technical experts are attached to the general report.

The NMI/DI, after receiving the report within one month, sends to TC 3.1 a plan of measures to eliminate nonconformities (Annex 8, document code QSF-doc\_003e\_anx8).

TC 3.1 decides on the results of the peer review of the NMI/DI QMS and presents them to COOMET Quality Forum. A vote on the results of peer review is carried out at the next meeting of TC 3.1 or by electronic voting.

TC 3.1, with positive results of a vote on the outcomes of a peer review of the NMI/NI QMS, sends to the NMI/DI a document (COOMET Confirmation of recognition of the QMS (Annex 9, document code QSF-doc\_003e\_anx9)). The Confirmation of recognition is issued for five years.

If the measures provided for by the Action Plan for the elimination of nonconformities are not fulfilled within the prescribed period, the Confirmation of recognition may be suspended. The decision on suspension is made at the meeting of TC 3.1, which is notified to the Head of the NMI/DI and the JCRB Secretariat. The validity of the Confirmation of recognition is resumed after submission and review in TC 3.1 of data on the elimination of nonconformities. In justified cases, TC 3.1 may decide to annul the Confirmation of recognition, which is also notified to the Head of the NMI/DI. In case of revocation of the Confirmation of recognition, the procedure of a peer review of the NMI/DI QMS is carried out in full.

The NMI/DI annually no later than March 15 sends to the Secretariat of TC 3.1 an annual report on the status of the QMS (Annex 10, document code QSF-doc\_003e\_anx10) in accordance with the Guidelines for compiling the annual report (Annex 11, document code QSF-doc\_003e\_anx11). In case of making changes to the QMS, the NMI/NI also sends a notification on making changes.

The Secretariat of TC 3.1 sends the annual report of the NMI/DI to two members of TC 3.1 for consideration. The TC 3.1 members review them for two weeks and send their opinion to the TC 3.1 Secretariat and NMI/DI. The Secretariat of TC 3.1 monitors the annual reports of the COOMET NMI/DI (Annex 12, document code QSF-doc\_003e\_anx12).

## **Peer review of the QMS**

A peer review of the NMI/DI QMS is carried out in all NMIs/DIs that have received recognition of TC 3.1.

Peer review can be scheduled (at least once every five years) and unscheduled.

A routine peer review is carried out in the form of a second peer review at the end of the validity period of the Confirmation of recognition.

An unscheduled peer review can be conducted in the following cases:

- revision of CMC tables;
- inclusion of new CMC tables in the BIPM database;
- significant changes in NMI/DI QMS.

The Secretariat of TC 3.1 prepares plans for peer reviews, taking into account the expiration of the Confirmation of recognition, and coordinates with NMIs/DIs the dates for their peer reviews.

In case of negative results during a peer review, TC 3.1 has the right to decide on the suspension or cancellation of the Confirmation of recognition.

## List of Annexes

- Annex A** Recommendations on giving an oral presentation at the COOMET Quality Forum of the quality management systems of National metrology institutes / Designated institutes (NMIs/DIs) (document code QSF-doc\_00e\_003e\_anxA)
- Annex B** Recommendations on preparing a written presentation at the COOMET Quality Forum of the quality management systems of National metrology institutes/Designated institutes (NMIs/DIs) (document code QSF-doc\_002e\_003e\_anxB)
- Annex 1** Application for a peer review of the NMI/DI quality management system (document code QSF-doc\_003e\_anx1)
- Annex 2** Schedule of the realization of peer reviews in the COOMET NMIs/DIs (form) (document code QSF-doc\_003e\_anx2)
- Annex 3** Recommendations for on-site visits by peers and selection criteria for on-site visit peer reviewers (document CIPM 2007-25, document code QSF-doc\_003e\_anx3)
- Annex 4** Plan for a peer review of the NMI/DI quality management systems (document code QSF-doc\_003e\_anx4)
- Annex 5** Nonconformance protocols (forms) (document code QSF-doc\_003e\_anx5)
- Annex 6** Reports of a technical expert and auditor for the peer review of the NMI/DI QMS (form) (document code QSF-doc\_003e\_anx6)
- Annex 7** General report on the peer review of the NMI/DI QMS (form) (document code QSF-doc\_003e\_anx7)
- Annex 8** Action plan to remove nonconformities (form) (document code QSF-doc\_003e\_anx8)
- Annex 9** COOMET Confirmation of recognition of the QMS (form) (document code QSF-doc\_003e\_anx9)
- Annex 10** Annual report on the NMI/DI QMS (form) (document code QSF-doc\_003e\_anx10)
- Annex 11** Recommendations for the preparation of an annual report on the NMI/DI QMS (document code QSF-doc\_003e\_anx11)
- Annex 12** Monitoring of annual reports of COOMET NMIs/DIs (form) (document code QSF-doc\_003e\_anx12)