

	COOMET Recommendation COOMET Quality Forum document	COOMET R/AQ/13:2013 Pages: 5 Version: 15.3.2010
	The Rules and Procedure for the Evaluation of Quality Management Systems In National Metrology Institutes	
	Code of the document: QSF-doc_003e	
<i>Approval on the 11th COOMET Quality Forum Technical Committee Meeting (Chisinau, 4.12.2009)</i> <i>Approved at the 20th COOMET Committee Meeting (Astana, Kazakhstan, on April 21–22, 2010)</i> <i>Updated and amended at the 23rd COOMET Committee Meeting (Nizhny Novgorod, Russia, on June 5–6, 2013)</i>		

The present Recommendation determines the procedure for the evaluation of quality management systems in National Metrology Institutes (NMI) of COOMET Member states for the purpose of realizing the Agreement of Mutual Recognition of National Measurement Standards and Certificates of Calibration and Measurement issued by National Metrology Institutes (CIPM MRA).

The Quality Management System (QMS) evaluation is made by auditors and technical experts of the COOMET Quality Forum.

Before realization of quality management systems evaluation by auditors and technical experts the NMI represents written and oral presentations of QMS NMI to the Technical Committee of the COOMET Quality Forum which will be followed by the decision of the Technical Committee of COOMET QF regarding the readiness of the NMI to undergo the peer-evaluation.

Written and oral presentation

Written and oral presentations of the NMI QMS are carried out in accordance with the time schedule of the COOMET Quality Forum.

It is recommended to use a methodical material of COOMET

“Recommendations on carrying out an oral presentation at the COOMET Quality Forum of Quality Management System of National Metrology Institutes (QMS NMI)” (Annex A) while preparing for the oral presentation of QMS NMI.

One month before the oral presentation, the NMI presenting its Quality Management System to the COOMET Quality Forum submits a written presentation to members of Technical Committee of COOMET Quality Forum. It is recommended, in order to prepare the written presentation to use the procedural document of COOMET: “Recommendations on carrying out a written presentation of Quality Management System of National Metrology Institutes (QMS NMI)” (Annex B).

In case the Technical Committee members have no comments on the submitted document, the Secretariat of the COOMET Quality Forum includes the oral presentation of QMS NMI of the applicant NMI in the Agenda of the COOMET Quality Forum.

In order to carry out the oral presentation the NMI that submits its QMS to the COOMET Quality Forum prepares hand-outs on its oral presentation for each Technical Committee member.

After realization of oral presentation the Technical Committee of the COOMET Quality Forum makes a decision regarding the readiness of the NMI to undergo the peer-evaluation of NMI QMS which is written down in the protocol of TC QF COOMET meeting.

NMI Quality Measurement System Evaluation by auditors and technical experts of the COOMET Quality Forum

The NMI Quality Management System evaluation is carried out directly in National Metrology Institute after realization of written and oral presentations, on the basis of the application of the NMI to conduct peer evaluation (Annex 1) and in accordance with a schedule approved by Technical Committee of the COOMET Quality Forum (Annex 2). Conduction of peer evaluation is carried out no later than 4 month from the moment the NMI request is received.

The evaluation is made by auditors and technical experts approved by the COOMET Quality Forum.

Auditors and technical experts that are to carry out QMS evaluation of a specific NMI are appointed by the Chairman of the Technical Committee of the COOMET Quality Forum.

While appointing the auditors and technical experts it should be considered that they must not be from the same country as the NMI that is subject to evaluation is from.

When choosing technical experts for the NMI QMS evaluation it is recommended to take as a guide the field of activity of the given NMI, CMC tables submitted thereof and technical competence of the expert, as well as economic aspects. In cases reasonable the Chairman of the Technical Committee may appoint technical experts from other RMO (in case of absence of COOMET technical experts in the field declared or in case it is impossible for the COOMET technical expert's to take part in the peer evaluation in the period given).

While choosing technical experts it is recommended to use the document of The Joint Committee of Regional Metrology Organizations and BIPM (JCRB): **CIPM/2007-25** "Recommendations for on-site visits by peer and selection criteria for on-site visit peer reviewers" (Annex 3).

The Chairman of the Technical Committee of the COOMET Quality Forum informs the NMI about the peer evaluation to be carried out and about the composition of the technical experts group. In justified cases the NMI has a right to decline the nominated auditors and technical experts.

During the evaluation, the auditors and technical experts must follow the COOMET document "Recommendations on the Evaluation of Quality Management System of National Metrology Institutes". Auditors and technical experts should also maintain confidentiality concerning the data of the NMI subject to evaluation.

The NMI that is to undergo the evaluation should submit to the Technical Committee of the COOMET Quality Forum the following documents one month prior to the date scheduled:

- Application for the peer evaluation of the QMS (Annex 3);
- Quality Manual;
- management review of the effectiveness of the QMS from the last year;
- Calibration Procedures (calibration methods) with the demonstration of the uncertainty budget calculation regarding the all prospective entries of CMC-tables. In case of the same type of documents (for example, on various ranges of measurements) submission of 1-2 documents is admitted at the applicant's choice – these documents are confidential.

The documents are presented in English and/or Russian.

The National Metrology Institute that presents its QMS for the evaluation should provide complete information on-site of evaluation of QMS NMI, as well as a complete list of documents providing the QMS NMI. Internal QMS NMI documents may be in language of the applicant's country (in this case NMI provides oral translation to the expert's language).

While performing the evaluation technical experts have a right to request from the NMI a conduction of a specific metrological procedure ensuring evidence of the measurement traceability up to the SI units or to standards recognized by BIPM.

The work related to the evaluation is carried out at applicant's expenses. The duration of the evaluation must not exceed three days not including the time necessary for experts' journey. The expenses of works include: two-way trip, accommodation, daily allowance. The daily allowance is defined by the daily allowance measures of country where the expert or auditor comes from.

The evaluation is made in accordance with evaluation schedule (see Annex 4).

All nonconformities that will be disclosed by auditors or technical experts during the QMS evaluation are recorded in separate protocols (Annex 5). Specific nonconformities with references on the corresponding point of the ISO/IEC 17025 Standard and ISO Guide 34 (in case of reference materials) as well as applicant's proposals on removal of the given nonconformity must be recorded in these Protocols.

While evaluation the technical experts and auditors apply the recommended "Questionnaire on evaluation of QMS NMI" (Annex 13) and "Questionnaire on evaluation of QMS NMI on conformity with the ISO/IEC 17025 requirements" (Annex 14) to their work. If the NMI produces or tests the reference materials, then a technical expert performing the evaluation of this field should apply recommended "Questionnaire of a Technical Expert on evaluation of QMS NMI on conformity with ISO guide 34 requirements" (Annex 15).

Based on the results of the evaluation each technical expert draws up a report (of ISO/IEC 17025, chapter 5), that he/she submits to the auditor during the evaluation process in order to draw up the final report. The auditor draws up a report (ISO/IEC 17025, chapter). The forms of the report are given in Annex 6.

The report must contain the following points in details:

- Compliance with which points of the Standard ISO/IEC 17025 and ISO Guide 34 (in case of reference materials) was evaluated by the given expert.
- Subdivisions of which NMI he has evaluated.
- If any metrological procedures were carried out they are to be indicated along with the results of measurements and uncertainty calculation.
- What non-conformities were disclosed and proposals for elimination thereof.
- Proposals regarding the possibility to recognize the NMI QMS.

In addition, the technical expert may draw up written recommendations for improvement of the NMI QMS.

The auditor on the basis of the technical experts' reports draws up a report on the realization of peer evaluation (Annex 7) and submits it to the NMI subject to evaluation and to the Technical Committee of the COOMET Quality Forum. The reports of technical experts mentioned above are to be attached to the final report.

The NMI submits its action plan regarding the removal of non-conformities to the TC of the COOMET Quality Forum within one month after the report is received (Annex 8).

The TC of the COOMET Quality Forum takes a decision about the NMI QMS evaluation results and submits it to the TC of the COOMET Quality Forum. Voting on the evaluation results is to be carried out at the next meeting of the TC of the COOMET Quality Forum.

The TC of the COOMET Quality Forum, upon the of positive results of the voting on NMI QMS evaluation, sends to the NMI a certificate of recognition of QMS COOMET (Annex 9). The Certificate is issued with a maximum validity period that does not exceed 5 years.

In case the measures specified in the action plan have not been taken in due time the validity of the Certificate of recognition may be suspended. The decision on suspension is taken at the meeting of the Technical Committee of the Quality Forum and the NMI director is notified in this regard. The validity of certificate is wakened after the data regarding the removal of non-conformities are submitted and considered by TC of the COOMET QF. In justified cases the TC of the COOMET QF can take a decision on cancellation of the certificate of recognition, and the NMI director is informed in this regard as well. In case of cancellation of the certificate of recognition a procedure of recognition is resumed thoroughly.

NMI submits annually no later than February to the Secretariat of TC QF COOMET Annual Report about the state of Quality Management System (Annex 10) in accordance with the Recommendations on a drawing-up an annual report (Annex 11). In case of amendments in the QMS the NMI also submits a notification on the changes introduced.

The TC Secretariat forwards an annual report to two members of the TC QF for consideration. The TC QF members consider the report during two weeks and submit their conclusion to the Secretariat of the TC QF and to the NMI. The Secretariat of the TC of the COOMET QF keeps monitoring of NMI COOMET annual reports (Annex 12).

The Surveillance

The surveillance is carried out over all the QMS of NMIs that received recognition from the TC of the COOMET QF.

The surveillance can be ordinary (at least once in five years) and extraordinary.

Ordinary surveillance is performed in terms of a re-evaluation upon the validity Certificate of Recognition is expired.

Extraordinary surveillance is performed if case of:

- Revision of the CMC tables;
- New CMC tables' enter into the BIPM database;
- Significant changes in QMS NMI.

The Secretariat of the TC of the COOMET QF develops the surveillance plan taking into consideration the expiry date of certificate of recognition validity and adjusts with the NMI the date of conduction thereof .

The surveillance is fulfilled by means of a written presentation of NMI, peer evaluation with a cut-down program approved by the Chairman of the TC of the COOMET QF (one presentation for all NMI of one COOMET member-country).

In case of negative results during the surveillance the Technical committee has the right to make a decision on suspension or cancellation of the validity of the certificate of recognition.

List of Annexes

- Annex A Recommendations on carrying out an oral presentation at the COOMET Quality Forum of Quality Management System of National Metrology Institutes (QMS NMI)
- Annex B Recommendations on carrying out a written presentation of Quality Management System of National Metrology Institutes (QMS NMI)
- Annex 1 Application of the NMI to conduct peer evaluation (Annex 1)
- Annex 2 Schedule of realization of QMS NMI peer evaluation
- Annex 3 CIPM/2007-25 “Recommendations for on-site visits by peer and selection criteria for on-site visit peer reviewers”
- Annex 4 Plan of realization QMS NMI evaluation
- Annex 5 Protocols of non-conformities
- Annex 6 Forms of technical expert and auditor reports on QMS NMI evaluation
- Annex 7 Form of a report on conduction of peer evaluation of QMS NMI
- Annex 8 Action plan for removing of non-conformities
- Annex 9 Certificate on recognition of QMS NMI
- Annex 10 Form of an annual report on the state of QMS NMI
- Annex 11 Recommendations on a drawing-up an annual report
- Annex 12 Form of annual report of QMS NMI monitoring
- Annex 13 A recommended questionnaire of a technical expert on evaluation of QMS NMI
- Annex 14 A recommended questionnaire of a technical expert on evaluation of QMS NMI on conformity thereof with requirements of ISO/IEC 17025
- Annex 15 A recommended questionnaire of a technical expert on evaluation of QMS NMI on conformity thereof with requirements of ISO guide 34