Guideline
for QMS annual report

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1. Introduction

After the approval of the QMS by EURAMET TC-Quality, signatory National Metrology Institutes (NMIs) and Associates - Designated Institutes (A-DIs) under CIPM MRA are required to report to TC-Quality about the status of their QMS on an annual basis.

These guidelines should be followed in the preparation of these annual reports. Throughout these guidelines the word 'NMI' refers to both any NMIs and A-DIs.

2. Timetable

The complete timetable for the submission and review of the annual reports is presented in the "Quality Management System review procedure" (G-TCQ-PRC-001). The electronic version of the annual reports shall be sent to the TC-Q secretary by the individual TC-Q Contact Persons at least 4 weeks prior to the TC-Q meeting. Therefore, each NMI/DI must ensure that they provide all the necessary documents and information to their national TC-Q Contact Person in sufficient time for this timetable to be met.

3. Guideline for the preparation of the report

The purpose of the annual report is to provide information about the main changes to the QMS and QMS life for the period under consideration. Information should be brief but should include the main points and be clearly understandable. Lists and figures should be in English. Acronyms should be avoided unless widely known or else should be explained. The annual report form relates to modifications and operation of the QMS as well as to the implementation of the requirements of ISO/IEC 17025:2017 and ISO 17034 for technical competence of reference materials producers. One annual report form, with related appendices, must be completed by each NMI/DI that is required to report to TC-Q. Mixing of information about different NMIs/DIs in the same form or Appendix shall be avoided. Each TC-Q Contact Person should ensure on the national level that all the documents related to the annual report for one NMI/DI are combined in one comprehensive electronic Word/pdf document.

The annual report has 5 main sections as tables and 2 additional points.

Table 0 – Fields covered by the QMS

The aim is to demonstrate that all CMCs published or submitted for the review (being in whatever review stage) are covered by the QMS (which means in particular that they have associated technical procedures).

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

The following two tables each have 3 columns. The first column states the information required and this should not be changed. Report the required information in the second column. The third column is for additional notes. The appendices should maintain the numbering suggested in the form (even if one or more of the appendices are missing). The annual report form should not exceed 5 pages, plus no more than 4 pages for the appendices. This is however a flexible limit: it can be exceeded, for example, in case of long lists of CMCs, on-site peer visits, interlaboratory comparisons, etc.

Organogram – The organogram should be included in Appendix 1 even if there are no changes from the previous year (but a comment should be included that there are “no changes”). The organogram should include both the names of people and their functions, and the changes should be indicated. Additional comments (e.g., about changes in the internal organization of the NMI/DI) can be reported in column 2 or in Appendix 1 if more details are needed.

Quality management system – Report the main changes in the QMS steering mechanism, in the QMS processes and in the way the ISO/IEC 17025 and ISO 17034 requirements are implemented in column 2 or in Appendix 2 if there is not enough space in column 2. Also report about significant changes in administrative and general procedures and identify the related new or modified documents by their title and the date of approval.

Changes and validity of CMCs – Considering the CMCs published during the year, or submitted for the review process, indicate whether these are new CMCs, modified CMCs, deleted CMCs or greyed-out CMCs. For each of these four cases report the number of CMCs, the CMC categories involved, and for the new CMCs also provide the titles of the corresponding procedures and their effective dates.

It is assumed that all published CMCs represent services which are valid and available in line with the requirements described in the chapter 3.3 of the CIPM MRA-G-12 document.

RM technical procedures – NMIs/DIs being producers of reference materials (RM) and certifying reference materials (RM) should list the general and specific technical procedures related to the production and certification of RMs in column 2. Report any modifications to processes and documentation. If this information has already been provided to TC-Q, please indicate the document where it was reported.

Table 2 - Operation of the quality management system

Number of calibration and measurement certificates. This gives an idea of the extent of the NMI´s/DI’s calibration and measurement activities and helps to put the information about the number of certificates with the CIPM MRA logo that follows into scale/context. Please do not include any kind of verification certificates in the statistics.

Customer complaints – Report the number of complaints during the period under consideration and the areas concerned in column 2, using broad but descriptive categories. The column 3 or Appendix 5 should be used for reporting further information if needed.

Nonconformities – Report the total number of nonconformities from any sources (e.g. internal and external audits, peer reviews, management review, complaints, interlaboratory comparisons (ILCs), proficiency tests (PTs), etc.) during the period under consideration and the areas concerned by those non-conformities in column 2 using broad but descriptive categories. The column 3 or Appendix 5 should be used for reporting further information if needed.

Outcome of related corrective actions – Indicate in column 2 whether the treatment of the complaints and nonconformities reported above led to corrective actions and explain about the major improvements that were implemented. The column 3 or Appendix 5 should be used for reporting further information if needed. Corrective actions due to an unsatisfactory performance of NMI/DI in a key or supplementary comparison shall be reported in detail.

Table 3 - Interlaboratory comparisons/proficiency testing

The aim is to list here all types of interlaboratory comparisons or proficiency testing (key or supplementary comparisons and pilot studies under CIPM MRA):

- for which NMI/DI has registered during the reported period;
- that NMI/DI participated in (measurements within comparison have been made) during the reported year;
- the results of which NMI/DI received during the reported year (either Draft A or Draft B, as well as a final report)

made to underpin the published or submitted CMCs under CIPM MRA (it would be useless to give ILCs/PTs not having a direct relation to these CMCs – the nomenclature is given in the CIPM document no. CIPM MRA-G-11):

- key/supplementary comparisons of national standards under CIPM MRA: these are comparisons where the reference value of the comparison is derived from results of NMIs/DIs mainly with primary realisations of the corresponding unit, but every such comparison has a pilot providing the artefact (together with associated measurements of its stability etc.). The result of the comparison can be reported as CMCs supported, or CMCs not supported.
- pilot studies (ILCs in physical metrology): usually used by (secondary) calibration laboratories where there is a pilot laboratory with superior metrological performance (e.g. a NMI) which provides the reference value for such a comparison or the reference value is given by a key/supplementary comparison with which the pilot study is associated. These comparisons can be multilateral or bilateral ones.
- pilot studies (proficiency tests in chemical metrology): traditionally, comparisons without a pre-defined reference value prevailed here, the reference value was established on the basis of the participants´ results by various statistical methods: z -score, median, weighted average, ANOVA method (Analysis of Variance). Presently, also piloted comparisons where the reference value is established by NMIs/DIs in this area and evaluated by means of En – criteria are more abundant (e.g., IMEP program).

Pilot studies of any kind must be registered with the EURAMET project database, and they are not given in the KCDB database as clearly stated in the CIPM MRA-G-11 document. The detailed information on piloted comparisons/PTs is given in the international standard ISO/IEC 17043.

Table 4 – On – site visits by peers of any kind as defined by EURAMET TC-Q

Report about any external audits including peer review visits and internal audits with external auditors from other NMIs/DIs. Provide dates of audits, areas audited, name and function and affiliation of the auditors, whether the audits were done on site or remotely and a summary of the outcomes. “Affiliation” means the information about the employer of the given person (e.g., legal body to which he/she is attached). The outputs from these actions should be a subject of review during the visits aimed at the management system (what has happened with findings in technical areas etc.). The following terms being in line with *the Joint ILAC – CIPM Communication regarding the Accreditation of Calibration and Measurement Services of National Metrology Institutes* should be used here:

> ***Technical expert (TE):*** *A person assigned by a national accreditation body to provide specific knowledge or expertise within the scope of accreditation. Technical experts do not necessarily*

have the relevant assessor qualifications to be a technical assessor (TA) as approved by the accreditation body.

***Technical assessor (TA):** A person who conducts the assessment of the technical competence of the laboratory or inspection body for specific area(s) of the desired scope of accreditation. It is expected that such assessors meet the requirements stipulated in ILAC Guide 11 - ILAC Guidelines on Qualifications and Competence of Assessors and Technical Experts.*

***Peer reviewer:** A person participating in a peer review assessment of a NMI´s/DI's technical competence who is recognised by the RMOs or CIPM. Peer reviewers may not necessarily have assessor qualifications.*

The table in the template gives some examples of possible entries – the first one is e.g., for VSL the Netherlands, an accredited NMI, the second one is for a self-declared DI from Czech Republic. In case of lead assessors and TAs in accreditation, it is enough to give what is written in the table in the template – their qualifications are guaranteed by the corresponding NABs (NAB: national accreditation body as per EU Regulation no. 765/2008).

Provide brief information about periodicity and systematics of onsite visits by peers and/or accreditation assessments, including planning for the next year. Refer to relevant EURAMET TC-Q projects if applicable.

This requirement is also valid for accredited NMIs/DIs. That is why an information about periodicity of accreditation assessments should be specified, as this could vary from one NAB to another.

Please confirm that all technical assessors used in peer review or accreditation meet the criteria given in EURAMET Guide for on-site visits by peers in the framework of CIPM MRA - G-TCQ-PRC-006 and meet the requirements of Appendix 3 - Criteria for the selection of visiting peer reviewers of CIPM MRA-G12 document. If some of the technical assessors do not fully meet the criteria, please specify the area, or add a comment. TC-Q can prescribe that those areas be covered by internal audit with external auditors that comply with the said requirements within certain period.

Point 5 - Significant risks and opportunities and changes encountered.

Please report under this heading the most significant risks and/or opportunities in the QMS activity identified during the year. If important changes occurred in the metrology structure of your country or in the role of your NMI/DI please report them under this heading. It could be expected that most NMIs/DIs would have something to report here.

Point 6 – Declaration

The NMI/DI hereby declares that all CMCs published in the KCDB of BIPM are valid. and that the requirements of the relevant QMS standards have been duly fulfilled during the year (the reported period), e.g., internal audits, management reviews etc. The detailed information about the requirements on the validity and vitality of CMCs is presented in chapter 3.3 of the CIPM MRA-G-12 document). These elements are to be reviewed in detail during actions of external auditing on the spot.

Related Documents

G-TCQ-PRC-001	Quality Management System review procedure
G-TCQ-TMP-003	Template for QMS Annual Report
G-TCQ-PRC-006	Guide for on-site visits by peers in the framework of CIPM MRA
CIPM MRA-G-11	Measurement comparisons in the CIPM MRA: Guidelines for organizing, participating, and reporting
CIPM MRA-G-12	Quality management systems in the CIPM MRA: Guidelines for monitoring and reporting
	Joint ILAC-CIPM communication regarding the accreditation of calibration and measurement services of national metrology institutes