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Updates from APMP TCQS

(Asia Pacific Metrology Programme)

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Overview of APMP's practices for QMS

- How APMP makes "Review", "Approval", "Monitoring" on QMS
  - APMP TCQS has 17 active economies out of 27 full member economies
  - APMP has **3 pathways** according to **APMP-MRA-G05** (Guidelines for accepting a quality management system)

> **2.1. APMP PATHWAYS**
>
> Compliance can be demonstrated by following one of the three pathways:
>
> (a) Third party accreditation, using approved technical peers, or
>
> (b) Certification to ISO 9001 and attestation by technical peers, or
>
> (c) Attestation by a Review Team consisting of QMS experts and technical peers. This may be organised by the NMI/DI or by another recognised body, such as an accreditation body or APAC.

  - QMS annual reports are collected/presented during General Assembly every year
- APMP TCQS has 2 working groups to run and manage the QMS activities
  - WG 1 : Strategy and Policy (10 people) / WG 2 : QS review for CMC submission (20

[APMP]'s "Review"

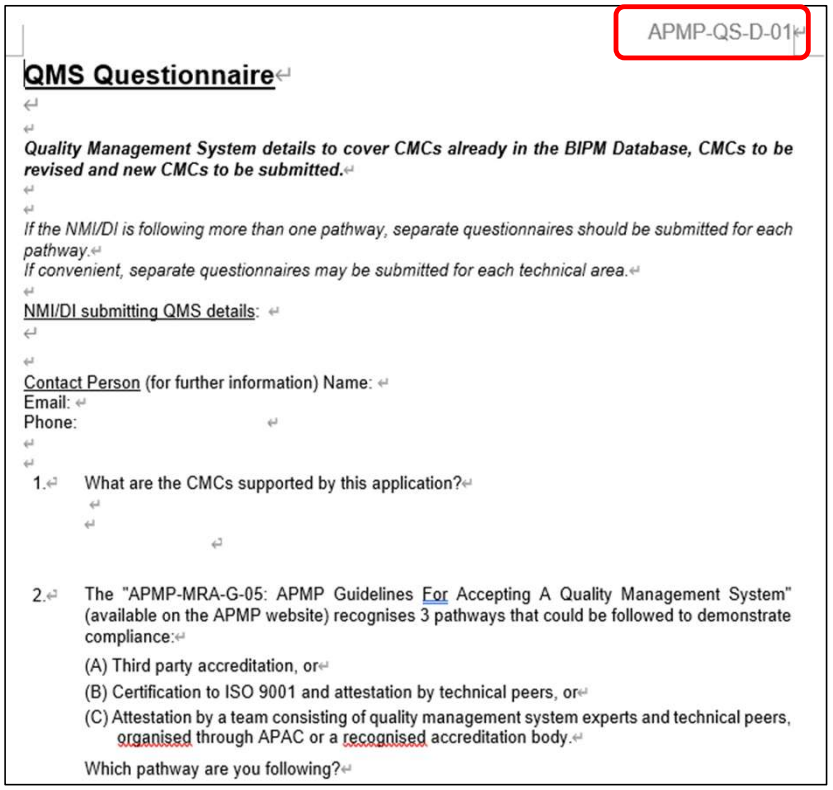
- According to APMP-MRA-G05, to accept the new CMC entries:

Technical Committee for Quality System (TCQS) working group 2 (WG2) conducts the review of the quality management system for a new CMC entry as follows:

1. The NMI/DI seeking a new CMC submits the required evidence to the TCQS Chair for review.
2. The TCQS Chair appoints a coordinator within WG2.
3. The coordinator appoints two other WG2 members to conduct the review of the documents submitted by the NMI/DI as per the requirements detailed in this chapter.

The two reviewers conduct independent reviews and write their report in the form APMP-QS-D-03 and provide to the coordinator.

4. The coordinator and the TCQS Chair check the reports and compiles the information into a report in the form APMP-QS-D-07. When the quality management system is deemed to be approved, the completed APMP-QS-D-07 form along with the APMP-QS-D-03 forms as its basis will be sent by the TCQS Chair to the relevant TC Chair and the submitting NMI/DI.
5. The TC Chair will compile the technical review and the QMS review to complete the intra-RMO review.



APMP-QS-D-01

QMS Questionnaire

Quality Management System details to cover CMCs already in the BIPM Database, CMCs to be revised and new CMCs to be submitted.

If the NMI/DI is following more than one pathway, separate questionnaires should be submitted for each pathway.
If convenient, separate questionnaires may be submitted for each technical area.

NMI/DI submitting QMS details:

Contact Person (for further information) Name:
Email:
Phone:

1. What are the CMCs supported by this application?

2. The "APMP-MRA-G-05: APMP Guidelines For Accepting A Quality Management System" (available on the APMP website) recognises 3 pathways that could be followed to demonstrate compliance:

   (A) Third party accreditation, or

   (B) Certification to ISO 9001 and attestation by technical peers, or

   (C) Attestation by a team consisting of quality management system experts and technical peers, organised through APAC or a recognised accreditation body.

   Which pathway are you following?

[APMP]'s "Review"

- 3.1 of APMP-MRA-G05 is exactly same as the 3.1 of CIPM MRA-G-12

3.1. Review and Approval

Review needs to include the following items specified in CIPM MRA- G-12 section 3.1

a) a diagram showing the organisational structure of the institute;

b) quality management system mechanisms;

c) detailed table of the contents of the quality management system documentation (e.g., of the quality manual when available);

d) list of administrative and technical procedures;

e) table of cross references between ISO/IEC 17025 and/or ISO 17034 and the quality management system documentation of the institute;

f) list of CMCs covered by the quality management system;

g) customer complaints – process employed and statistics;

h) nonconforming work – process employed and corrective actions;

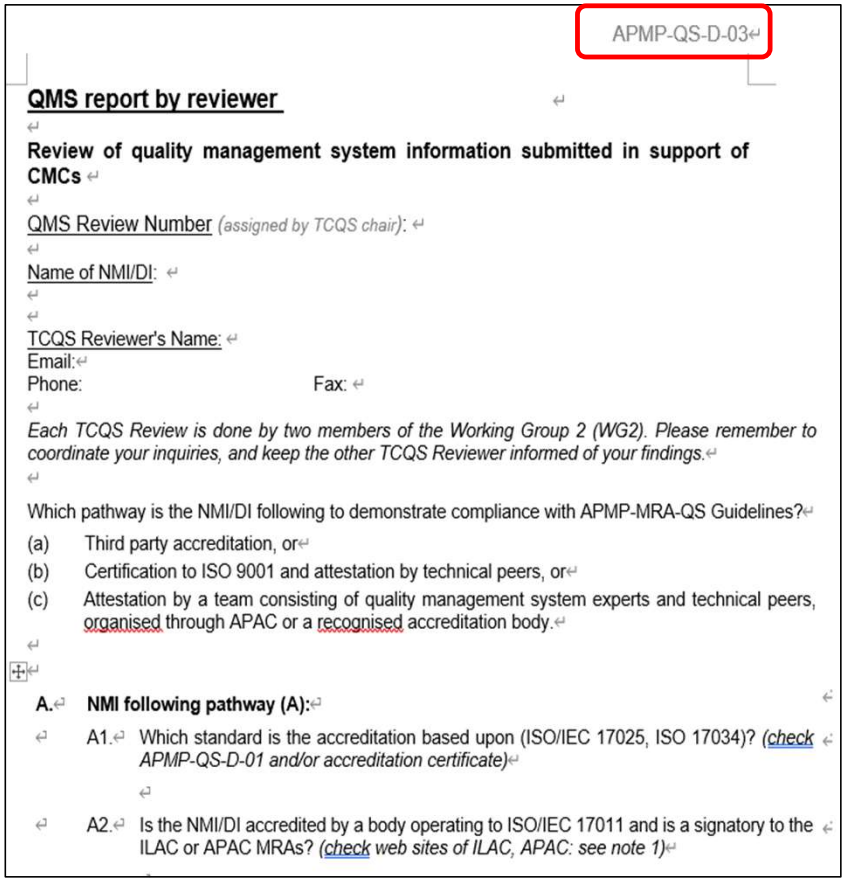
i) report on internal audits;

j) status of management reviews;

k) outcomes of peer-reviews where these have taken place;

l) plan and implement action to address major identified risks and opportunities.

[APMP]'s "Review"



APMP-QS-D-03

QMS report by reviewer

Review of quality management system information submitted in support of CMCs

QMS Review Number *(assigned by TCQS chair)*:

Name of NMI/DI:

TCQS Reviewer's Name:
Email:
Phone: Fax:

Each TCQS Review is done by two members of the Working Group 2 (WG2). Please remember to coordinate your inquiries, and keep the other TCQS Reviewer informed of your findings.

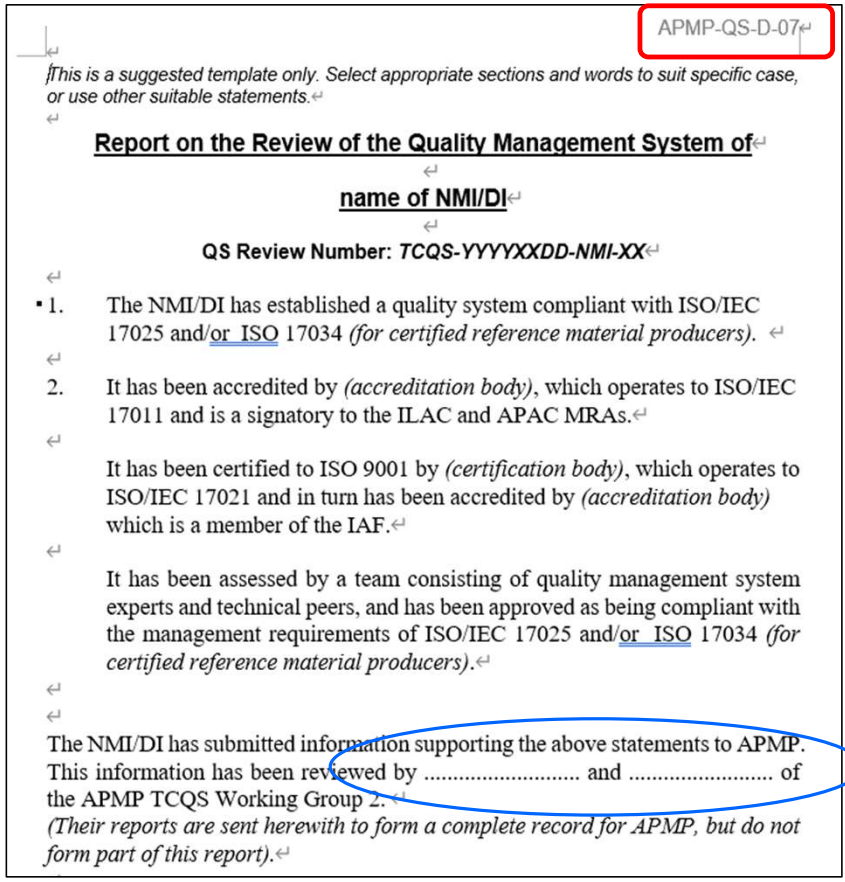
Which pathway is the NMI/DI following to demonstrate compliance with APMP-MRA-QS Guidelines?

(a) Third party accreditation, or
(b) Certification to ISO 9001 and attestation by technical peers, or
(c) Attestation by a team consisting of quality management system experts and technical peers, organised through APAC or a recognised accreditation body.

A. NMI following pathway (A):

A1. Which standard is the accreditation based upon (ISO/IEC 17025, ISO 17034)? *(check APMP-QS-D-01 and/or accreditation certificate)*

A2. Is the NMI/DI accredited by a body operating to ISO/IEC 17011 and is a signatory to the ILAC or APAC MRAs? *(check web sites of ILAC, APAC: see note 1)*



APMP-QS-D-07

This is a suggested template only. Select appropriate sections and words to suit specific case, or use other suitable statements.

Report on the Review of the Quality Management System of

name of NMI/DI

QS Review Number: *TCQS-YYYYXXDD-NMI-XX*

1. The NMI/DI has established a quality system compliant with ISO/IEC 17025 and/or ISO 17034 *(for certified reference material producers)*.

2. It has been accredited by *(accreditation body)*, which operates to ISO/IEC 17011 and is a signatory to the ILAC and APAC MRAs.

   It has been certified to ISO 9001 by *(certification body)*, which operates to ISO/IEC 17021 and in turn has been accredited by *(accreditation body)* which is a member of the IAF.

   It has been assessed by a team consisting of quality management system experts and technical peers, and has been approved as being compliant with the management requirements of ISO/IEC 17025 and/or ISO 17034 *(for certified reference material producers)*.

The NMI/DI has submitted information supporting the above statements to APMP. This information has been reviewed by ..... and ..... of the APMP TCQS Working Group 2.
(Their reports are sent herewith to form a complete record for APMP, but do not form part of this report).

[APMP]'s "Approval"

- Approval according to 3 respective pathways

3.1.1 Pathway (A)

NMIs/DIs following pathway (A) must submit the following evidence to APMP[1]:

- Copies of accreditation certificate(s) or equivalent accreditation information
- Scope(s) of accreditation
- Names and affiliations of the technical assessors or technical peers
- Assessment report(s)/technical peer review report(s)
- Technical peer approval from related TC or EC

3.1.3 Pathway (C)

NMIs/DIs following pathway (C) must submit the following evidence to APMP[5]:

- A report by the Review Team of QMS experts and technical peers. This report must be prepared following the assessment review visits and shall report against the relevant [6] technical requirements of the appropriate standard / guide. The following are minimum reporting requirements[7]:
  - Scope of the review
  - Schedule of the review
  - Names and affiliations of the technical peers
  - Names, affiliations, qualifications, and experience of the QMS experts.
  - Findings of the review (especially the non-conformances)
  - Listing of the NMI/DI's capabilities
  - Any other comments
  - Attestation by the reviewers
  - Signatures and dates
- Final attestation by the reviewers, or at least by the leader of the Review Team, stating that all the non-conformances have been satisfactorily addressed
- Technical peer approval from related TC or EC
- QMS expert approval from TCQS

3.1.2 Pathway (B)

NMIs/DIs following pathway (B) must submit the following evidence to APMP[2]:

- ISO 9001 Quality Management System certificate(s), with details of the areas covered by each certificate, or a statement that the certification covers all technical areas of the NMI/DI.
- Report(s) from the technical peer review(s). This must be prepared following the assessment review visits and shall report against the relevant[3] technical requirements of the appropriate standard/guide. The following are minimum reporting requirements[4]:
  - Scope of the review
  - Schedule of the review
  - Names and affiliations of the technical peers
  - Findings of the Review Team (especially the non-conformances)
  - Listing of the NMI/DI's capabilities
  - Any other comments
  - Attestation by the technical peers
  - Signatures and dates
- A final attestation by the technical peers, or at least by the leader of the Review Team, stating that all the non-conformances have been satisfactorily addressed.
- Technical peer approval from related TC or EC

[APMP]'s "Monitoring"

- Monitoring and reapproval

3.2. Monitoring and Reapproval

3.2.1 On-Going Monitoring of QMS

- To provide evidence that APMP QMS is operating correctly, each institute shall submit an annual report[8] to the TCQS four weeks before the annual TCQS meeting.
- The quality manager, or representative, of the NMI/DI shall also submit the annual report and present the key issues as an abstract of their submitted annual report to the TCQS meeting. The submitted annual report will include a record of any recent assessments or review. Such record include technical

- The following is evidence that TCQS has reapproved the NMI/DI QMS:
  - The NMI/DI annual report provided to the TCQS Chair
  - The peer review reports written by peers who are approved by the relevant TC
  - Annual report presentation to TCQS

[APMP]’s “Monitoring”

QMS Annual Report Form

APMP-QS-D-02

QMS Annual Report to APMP

—Year 20… —

In order for the APMP to assure the continuous effectiveness of NMI/DI’s quality management system, it is required that the member economies to report any major changes in the QMS that might affect the NMI/DI capabilities of measurement and service to APMP. Please be advised that the information should be concise but clearly understandable as far as possible.

NMI/DI:

.....

Pathway option:

- ☐ A- third party accreditation
- ☐ B- ISO 9001 certification and attestation by technical peers
- ☐ C- attestation by QMS experts and technical peers

Review/assessment visit conducted during the year:

Technical Area Reviewed	Dates of Review	Names & Affiliations of Peers (for each area)	Accreditation or Certification Body (if relevant)	Quality Management System Expert (if Pathway C review)

Annual Report **Presentations** during TCQS meeting

➢ **Improvement**

Any Improvement during implementation.

3) Examples from the use of digital tools:

A) EQA data transcription automation using UiPath

CML conducts an annual EQA programme in Clinical Chemistry for local clinical laboratories. This programme comprises two cycles per year, with each cycle requiring the issuance of an interim report detailing the participating laboratory's performance and results. Traditionally, about 1,600 results from 40 laboratories had to be manually transcribed into 19 separate analyte-specific spreadsheets for statistical analysis. To enhance efficiency and accuracy, a UiPath automation script was developed to automate the data transfer. This validated tool now enables the transfer of participating laboratories' results with a single click, reducing the data processing time from 48 h to just 2 h per year, resulting in a significant 24-fold time saving and significantly minimising transcription errors. The automation saves approximately 46 man-hours annually.

Manual method	UiPath automation script
Total manpower time (h)	Total manpower time (h)
48	2

The project has streamlined the EQA interim reporting process, reduced manpower demands, improved data accuracy, and allowed scientists to focus on higher-value tasks. It demonstrates how digitalisation can drive operational excellence and strengthen service

[APMP]'s publication on QMS

- APMP TCQS makes the QS review result public in APMP website:

Status of APMP NMIs quality systems

Economy	NMI/DI	Management System Implementation				Pathway		
		17025	17034	9001	17043	(a)	(b)	(c)
Australia	NMIA	Y	Y	N	Y	Y	N	N
Australia	ARPANSA	Y	N	N	Y	Y	N	N
Australia	ANSTO	N	N	Y	N	N	N	Y
Bangladesh	BRiCM	Y	N	Y	N	Y	N	N
Bangladesh	NML-BSTI	Y	N	N	N	Y	N	N
China	NIM	Y	Y	N	Y	Y	N	Y
Chinese Taipei	CMS/ITRI	Y	Y	Y	N	Y	N	N
Chinese Taipei	INER	Y	N	Y	N	Y	N	N
Chinese Taipei	TL	Y	N	N	Y	Y	N	N
Hong Kong, China	SCL	Y	N	N	Y	Y	N	N
Hong Kong, China	GL	Y	Y	N	Y	N	N	Y
India	NPLI	Y	Y	N	N	N	N	Y

APMP quality system review and monitor database

QS review documents

Economy

NMIs

Year

Search

No.	Economy	NMI/DI	Year
TCQS-20201125-NMC-AUV	Singapore	NMC A STAR	19 Mar 2021
TCQS 20210804-NIM-AUV	China	NIM	17 Aug 2021
TCQS-20221219-NIMT-QM-Bio	Thailand	NIMT	13 Jan 2023
TCQS-20221219-NIMT-QM	Thailand	NIMT	13 Jan 2023
TCQS-20221219-HSA-QM	Singapore	HSA	4 Jan 2023
TCQS-20221122-NMIJ-QM	Japan	NMIJ	13 Jan 2023
TCQS-20221108-KRISS-QM	Korea	KRISS	6 Mar 2023
TCQS 20220113-NIMT-QM	Thailand	NIMT	15 Apr 2022
TCQS 20211214-NMIJ-QM	Japan	NMIJ	26 Jan 2022
TCQS 20211209-HSA-QM	Singapore	HSA	26 Jan 2022

[APMP]’s activities in TCQS

- TCQS annual workshop during General Assembly 2025

Thank you for your attention!