



#### **TC-Q Review Process**

#### Silvie Hoffmanova EURAMET, Quality Officer

**EURAMET Information Day for INM Moldova** INM, Chisinau, 7 - 8 November 2018



# Outline

- Introduction
- TC-Q processes for QMS review
- TC-Q documentation
- Initial evaluation of QMS
- Re-evaluation of QMS
- QMS Annual reporting

#### Introduction



- EURAMET database has records of 116 institutes
- 37 NMIs (members)
- 78 DIs (Associates)
- 1 International Organization IAEA
- 1 Associated Candidate INM

TC-Q granted confidence in QMS of 107 institutes

#### Introduction



NMIs/DIs with non-approved QMS

Cyprus MCIT Iceland NEST Luxembourg ILNAS, LGUL Malta MCCAA-SMI Norway NIVA Turkey MRC MI-UAL Moldavia INM

#### **EURAMET TC-Q Review Criteria**



- ISO/IEC 17025 to cover calibration and measurement activities under the CIPM MRA
- Production of Certified Reference Materials (CRMs) shall be covered by ISO/IEC 17034
- QMS meeting the requirements of ISO/IEC 17025 assessed by an accreditation body fulfilling the requirements of ISO/IEC 17011 and should be a signatory to the ILAC MRA
- QMS following ISO/IEC 17025 without third-party accreditation considered as a self declaration





- Initial evaluation of QMS
- Re-evaluation of QMS every 5 years
- QMS Monitoring through Annual Reporting
- On-site peer visits



**CIPM MRA-G-02** JCRB guidelines for the monitoring and reporting of the operation of quality systems by RMOs

**CIPM MRA-G-03** Guidelines for the review of Quality Systems operated by IGO institutes and/or designated institutes, and the review of their calibration and measurement capabilities (CMCs)

# **TC-Q** Documentation



- TC-Q documentation consist of:
- Quality Management System review
   procedure
- TC-Q Guidelines
- Templates
- Records (register)

			EURAMET
Distanced Approval	D-TOD-RMC-001 TD-Q	Varsie: 3.5 2016-12-20	EURITE
1. Subje	et		
ELIRAM the tram EURAM Recogni resolutio	ET National Met ework of the rev ET Member NM tion Arrangements and EURAM	rology Institutes (NMI) a tew of calibration and m is and A-Dis for the purp at (MRA). This document	sing the quality management systems (QMSs) of nd Associates – Designated thatbutes (A-Dh) with assumement capatitise (CRCs) declared by one of recognition under the glocal CPM Matual its barset on CPM MRA, consequenting JCM E barset on CPM MRA, consequenting JCM E (1). Throughout this guideline the word
2. introd	fuction		
measure review p evaluatio impleme TC-Qua on ISO/8	ment activities i ment standards rocess, and put in of the results intation of opera ity is the EURAI	ander this amangement, as well as the certificate lished in Appendix C of of key and supplementa tional OMSs fulfilling the MET operational instrum in ISO Guide 34 at institu	togenetic a GNE to support their catenation and The mutual recognition concernes the national es corresponding to CNEs mutually agreed after a the MRA. This review (ase (11) concerns the ry comparisons as well be review of the applicable requirements. With regard to the later ent to review the implementation of CNEs based dees and share and develop knowledge on SO/EEC
ste visit how an i	a by peers (see institute's OMS	TC-Q Terms of Reference	annual reports and, when necessary, through on is, par. Te) and through seeking information about offering feedback on best practice, TC-Q has 5 review by peers.
Within the		TC-Q, the Contact Pers	on is the point of contact within a country and is in
	issemination of upervision of co	information to the institu liection and disseminate are requested by TC-Q	on to TC-Q of all the documents from institutes in
	n-site visits by p		nd information to EURAMET about:
3. Orga	nisation		
charpen organisa the plens	tion of meetings any meetings its	teering committee and a and the documentation	I, the specific structure of TC-Q is based around a plenary meeting. The secretary helps with the The steering committee prepares the work before many basis whereby members are approved by
			. When votes have to be taken, the simple O Chairman and one-third of the Contact persons
HUNANET Pune *6	501 562 (940 Per	), 331 15 Grant schenig, Gernery +18 021 192 1969 - E-mill and	alaranganaran ay

# All these documents are publicly available on the EURAMET website.

# **TC-Q** Documentation: Guides

- Guideline for initial QMS presentation
- Guideline for QMS re-evaluation presentation
- Guideline for QMS Annual Report
- Guide for on site visits by peers

uldeline or initial GMS pro	esentation	
nament G-ROQUINCO ground	05 Varana: 3.5 2018-10-25	EURAMET
troduction is TC-Quality gut esented their QMS	teline is applicable for NMs to TC-Quality.	and Designated Institutes who have not yet
e escitados contain	entation consists of written doc s the requirements for the GME the oral presentation	umentation and an oral presentation. Part A of 5 written documentation, whilst Part B includes
roughout this	Guideline for QMS re-evaluation	s presentation
r the comple inagement Sp	Decument G-100-PRO1004 Approval	Version 1.0 2016 (0.2)
e electronic v ist 4 weeks p e TC-Q secre	Introduction	
	This TC-Quality guideline QME for re-evaluation and	is applicable for NMs and Designated institutes who have to present their tes TC Cluster
	The QMS presentat guideline contains th B includes the regult	Guideline for GMS annual report
	Throughout this guid	Provent G-102-FRC-00 1276-132
	For the complete tim Quality Management	Introduction
	The electronic versic weeks prior to the TO TG-Q secretary at le	After the approval of the CMB by EURAMET TO-Couldy, sprandary National Metrology Institutes (MMb), the other NMB and Associates -Despirable Strafface (AAD) survey CPM MRA are required to report to TO-Couldy should be atitute of their QMB on an annual basis via the CMB annual report. There qualifies should be followed in the preparation of these annual reports. Throughout these guadelines the word NMF refers to both any NMB and A-Dis.
		Transistor for the constraints functiable of the involve of the annual inports plane are the TC-Q Quality Management System involves procedure G-QPE-PRC-Q11. The electronic version of the annual records table as and the B-TC-Q contractly for lenditistical. To Contract Persons after 4 electro- documents and information is there realised to CONTRACT Contract Persons after 4 electro- documents and information is their realised to CONTRACT Contract Persons after the two limitable table mini-
999 27 a.V. San ya 40 31 321 a acardi 42		Guideline for the preparation of the CMS annual report The trappet of the small report is to provide information about the main changes to the CML and the main changes of the small report is the context the main changes to the CML and porter and to context understanding. It is an diputer should be independent on the context models and the context understanding and the small should be main changes to the models within the context of the context and the context of the context and the models of the context of the context and the context of the small report the transfer of the small report form, with resided appendixes, main a context being and the context form and the context of the context and the context of the small the models that a context form and the main and context the the that all the accument. Such as the transfer the context and the completencies main and the context of the the main struct the context and the context of the context and the context of the context of the context.
		The annual report has 5 lables and 2 additional points.
	DANG SV. Sectors	Table 0 – Fields covered by the QMS The aim is to demonstrate that all CMCs published or submitted to the review process (being in whatever review stage) are accovered by the CMS (which means in particular that they have associated technical procedures).
L	EPANET N.V. Bendesik Pron 4031 Statistic pron. according	Table 1 – Major extensions and modifications of the quality management system and of the quality manual The following bioclables each have 3 ociumns. The first column states the information required and first adults of the charged. Report the resulted information in the second column. The time column is no adultant and the The approvides columnitation the manners' supported in the time intern is no adultant and the time internation in the second column. The time column pack, plan on more than 4 pages for the sportfaces. This is however a feedble kind it can be exceeded, if we supply, in case of tops that of CACs, adults, and the CACs.

#### **TC-Q Documents: Templates**



- Table of Cross References
- Template for QMS Annual Reporting
- Template of the final peer review record

JRAME I/IC-Quality 2_03_04_Table_of_Cross_References_02 - Please fill the tab	ie below with the	ignated institute:	appropriate.	EURAMET
ISO 17025:2005 Requirement	Q.M. clause	Procedures / Instructions	To be issued Deadline Responsible	Remarks
Management Requirement     storGANIZATION     Isolaresponsibility and autonomy     gracedure for projection of confidential information     monotone to avail reduction in confidence				
<ul> <li>definition of organizational structure, responsibilities, quality manager, etc.</li> <li>personnel aware of the relevance and importance of their activities and their contribution to the GMS</li> <li>AMANAGEMENT SYSTEM</li> </ul>				
<ul> <li>coherence and structure documentation</li> <li><u>Duality Manual</u>, policy and objectives procedures consistent with standard and quality policy</li> <li>defined rules and responsibilities of technical management in Quality Manual</li> </ul>				
4.3 DOCUMENT CONTROL	T 1	1		1
<u>procedure</u> for control of quality documents (internal and external)     approval, issue and changes				

QMS Annual Report for the year YYYYby Desense: GTCD194-503 Venue: 16 2016-022				EUR/	MET	1
	n of IBO/IEC 17025 and IBO Gu rposes of CIPM MRA.	ide 34 rec	uirements ()	50 Guide 34 wh	ere applicable)	
	tions and operation of the QMS covered by the QMS:	(approx.	5 pages + Ap	pendices *).		
1000	d relevant EURAMET Technical	Field covered by the QMST (Y/N)	CMCs pubitshed? (Y/N)	CMCs in the review process? (19N)	CMCs in the raview process covered by CMS? (Y/N)	
TC-AUV	Acoustics, Ultrasound and Vibration					
TC-EM	Electricity and Magnetism	8	2			
TC-F	Flow	-				
TC-IR	Ionising Radiation	6	8	0	1	
TC-L	Length	-			2	
TC-M	Mass and Retaled Quantilles	0	8	0		
	Metrology in Chemistry				2	
TC-MC	Metrology in Chemistry (CRM)	5	2	8		
TC-PR	Photometry and Radiometry					
TC-T	Thermometry	2	<u> </u>			
TC-TF	Time and Frequency					
1 – Majo manual:	r extensions and modifications	201400100				
(showing names a organog reported unchang	Subject sogram of the NML key staff", their not their rolens, The ram should be in Aspendix 1, even if ed. Changes should ded in the commenta	Proportion	Information	Futt	ver commenta	
	es, when required, should be as what as					

of the final peer review record	EURAMET			
Approved 10-0 2018-12-3	8			
EURAMET Project			TC-Q	
Plat. No. 7 adartiset: SUbject	d Sabili T Quality	De On site paar revier	Participanta:	
PERIODICAL	EXTRAORDINA	RY PEER REVIE	WRECORD	
NMI or DI visited:				
Visit Start date:	8	Visit End date:		
Names and affiliations of the revi Name	ewer(s) Affiliation	3	Ignature	
1 MALLAN	condition (		geneliul U	{(i)}
Assigned responsible person of the visited NMI Name Position			ignature	
				ure
2844 S			en e	Identifiers).
Programme of the on-site visit (e		Os specified by inte	mai NMI Service	
Programme of the on-site visit (e		Specified by inte sobmittee (thck if YE)	mal NMI Service	e5 / approved at if YES)
Programme of the on-site visit (e Forwarded documentation		Cs specified by inte	mal NMI Service	ed / apprived
Programme of the on-site visit (e Forwarded documentation Quality monual		Specified by inte sobmittee (thck if YE)	mal NMI Service	e5 / approved at if YES)
Programme of the on-site visit (e Forwarded documentation Coality monual List of used procedures		Sobrefield by inte	mal NMI Service	ed / approved at if VES)
Programme of the on-site visit (e Forwarded documentation Quality manual List of completed comparisons	g. ranges of CMA	Submittee	mal NMI Service	ed / approved at if YES)
Name Programme of the on-site visit (e Forwarded documentation Quality manual List of used procedures List of ourspitted comparisons List of services included in the A Reference writes inductors	g. ranges of CMA	Submittee	mal NMI Service	ed / approved kit YES)

#### QMS review procedure - contents



- Code: G-TCQ-PRC-001
- Version: 3.0
- Date: 20/12/2016
- Volume: 6 pages

#### Contents:

- Subject •
- Introduction
- Organisation
- Review Criteria
- Review procedure and timetable
- References

Quality	Managemen	System review procedure	
Dicarneril Approval	5-100-840-60) 10-0	Varaine: 3.5 2016-(2-35	EURAMET
1. Subje	at		
EURAME the frame EURAME Recognit resolution	T National Met work of the rev T Member NM on Arrangements and EURAM	rology institutes (NMI) and Asso lew of calibration and measurem is and A-Dis for the purpose of n it (MRA). This document is base	quality management systems (QMSs) of cates - Designated institutes (A-DI) within end capabilities (CMCs) doctared by scopshon under the global CPM Mutual d on CPM MRA, corresponding JCRB hnoughout this guideline the word
2. Introd	uction		
measure	ment activities i	inder this arrangement. The mut	a GMS to support their calibration and ual recognition concerns the national sondho to CMCs mutually agreed after a

Al institutes participat measurement activitie measurement standar measurement sundards as well as the certificates corresponding to CACs mutually agreed after a measurement of the results of key and supplementary consumptions as well her needed of the exclusion of the results of key and supplementary consumptions as well her needed of the subscription of the results of key and supplementary consumptions as well her needed of the subscription of the results of key and supplementary consumptions as well her needed of the subscription of the results of key and supplementary consumptions as well her needed of the subscription of the results of key and supplementary of the supplementation of CASEs based on ECAEC 17025 and ECO CASEs and DECE 1705 a

-O has a mandate to monitor QS life twough annual reports and, when ne twists by peers (see TC-Q Terms of Reference, par. 1e) and through see how an institute s QMS is implemented, and by offering feedback on best practice, TC-Q has become the EUFUANET platform to perform QMS review by peers.

Within the framework of TC-D, the Contact Person is the point of contact within a country and is i

dissemination of information to the institutes within the co supervision of collection and dissemination to TC-Q of all the documents from institutes in their country that are requested by TC-Q.

Purthermore, TC-Q submits recommendations and information to EURAMET about nn-site visits by peers;
an organisation of visits by peers.

3 Organisation

According in the Terms of Reference of TC-Q [2], the specific structure of TC-Q is based around a charpetson, scorelary, steering committee and a plenary meeting. The societary heps with the organisation of meetings and the documentation. The steering committee prepares the work before the plenary meeting. Its membership to on a voluntary basis whereby members are appro the chairperson and the plenary meeting.

O operates by consensus whenever possible. When votes have to be taken, the simple only is required, with a quorum given by TC-O Chahman and one-third of the Contact personal operations of the contact personal sectors.

12534251 v.V. Duminisation 100, 33115 Discontinuing, Germany Name 146 531 562 (960 Perc 148 621 562 1965 Direct Amerikaning Automation

#### Implementation of the procedure



- Written report(s) has to be prepared carefully
- Reports has to be submitted in time
- TC-Q contact persons are responsible for collection of all reports from DIs
- TC-Q contact persons have to check contents of the collected reports
- Any unclear information could be triggering either major or minor questions
- Do not try to write fairy tale, present realities

# Specific guidelines for accredited NMIs/DIs



- The claimed CMCs are identical with CMCs assessed by the accreditation body and documented in the assessment report;
- Technical assessors shall come from a laboratory which is at least on the level as the assessed laboratory or meets requirements of CIPM 2007-25
- The names and qualifications of assessors must be made known to TC-Q;
- The relevant excerpts from assessment reports, especially those concerning findings, must be made available to TC-Q by way of annual reports.

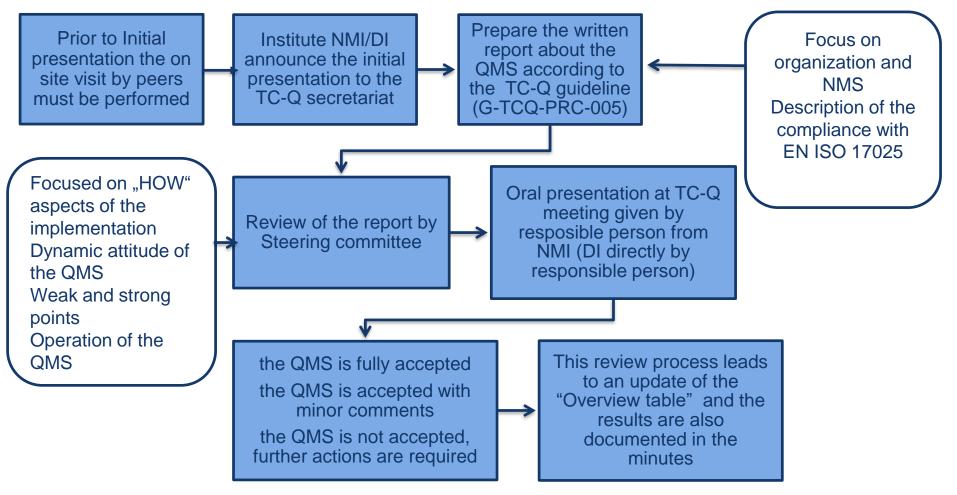
### Specific guidelines for selfdeclared NMIs/DIs



- The QMS should undergo an on-site peer review visit covering both the management and technical requirements of ISO/IEC 17025 and/or ISO/IEC 17034 (where applicable);
- Institutes are to arrange for on-site peer review visits by themselves in compliance with the provisions of EURAMET "Guide for on-site visits by peers in the frame work of CIPM MRA" usually using external reviewers;
- Institutes submitting their CMCs for the first time shall undergo an onsite peer review prior to their initial QMS presentation.

#### Initial QMS Evaluation





## Information required for review



Information on national metrology system

- Quality policy (Including quality objectives).
- Structure of NMI (Including organogram showing key staff, their names and their roles).
- QMS structure
- Table of contents of the quality manual
- List of general and administrative procedures
- List of technical procedures
- QMS and calibration measurement capabilities covered by QMS

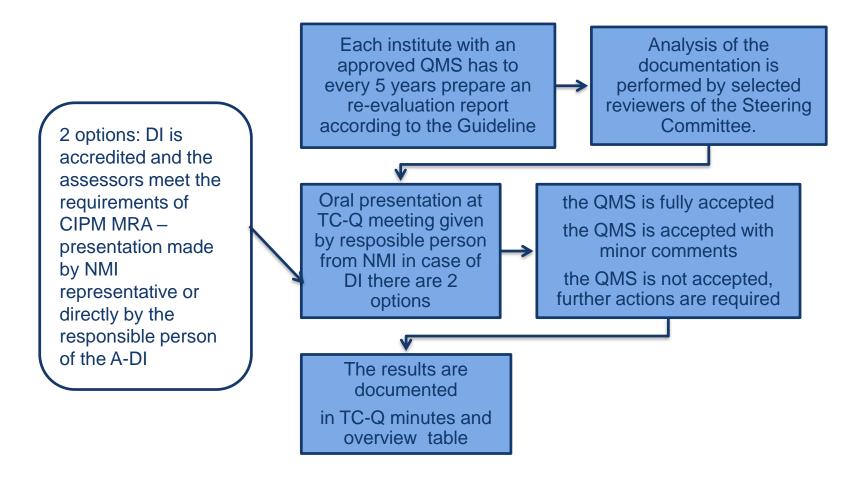
### Information required for review

EURAMET

- Information about QMS Life
- Continuous improvement
- Service to the customer
- Complaints
- Non-conforming work
- Internal audits
- Management reviews
- Results of on-site visits or accrediation
- Further information on ISO/IEC 17034 implementation for reference materials (CRMs)
- From the 2019 TC-Q meeting onwards all initial presentations of NMIs/DIs shall be in accordance with the requirements of the ISO/IEC 17025:2017 standard.

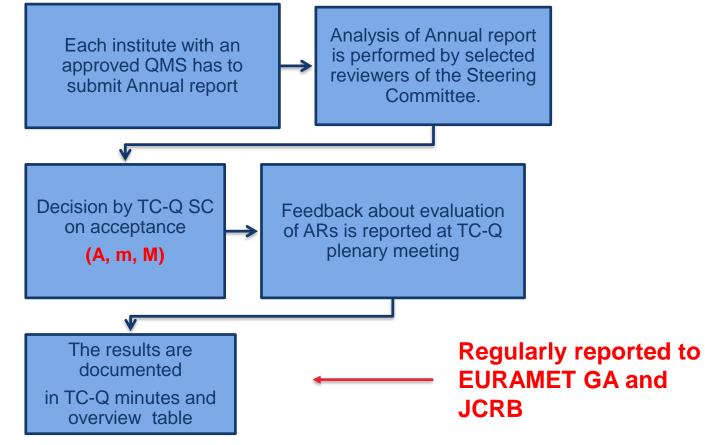
#### **QMS** Re-evaluation





## **QMS** Annual reporting





- A the QMS is fully accepted
- m the QMS is accepted with minor comments
- M the QMS is not accepted, further actions are required

EURAMET Information Day for INM Moldova, INM, Chisinau, 7 - 8 November 2018

#### Thank you for your attention!



#### silvie.hoffmanova@euramet.org

EURAMET Information Day for INM Moldova, INM, Chisinau, 7 - 8 November 2018