



**SIM  
METROLOGY  
SCHOOL**

# Quality Management Systems within the framework of the CIPM - MRA

**SPEAKER**

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**Bogotá, Colombia | August 2024**

# Presentation





# CIPM - MRA Requirements






## CIPM MRA-P-11

### Overview and implementation of the CIPM MRA

- This policy document (CIPM MRA-P-11) provides a quick reference guide to the current implementation of the CIPM MRA and is supported by other more detailed policy and guidance documents.


Let's review!

- The CIPM MRA was drawn up with the following objectives:
    - a) to establish the degree of equivalence of national measurement standards maintained by NMIs;
    - b) to provide for the mutual recognition of calibration and measurement certificates issued by NMIs; and
    - c) to provide governments and other parties with a secure technical foundation for wider agreements related to international trade, commerce and regulatory affairs.
- 



## CIPM MRA-P-11

### The main mechanisms through which the CIPM MRA achieves these objectives are:

- international comparisons of measurements, known as key comparisons;
  - regional comparisons of measurements, known as regional key comparisons;
  - supplementary comparisons;
  - open peer review of the participants' calibration and measurement capabilities, based mainly on the results of comparisons;
  - **reviewed implementation of the participants' quality management systems and demonstration of competence.**
- 



# CIPM MRA-P-11

## Quality Management Systems

The CIPM MRA requires that participating institutes establish and maintain a quality management system.

The CIPM MRA does not explicitly specify how its participants review, gain confidence and accept each other's quality management systems.

Note: It is understood that a QMS is required to ensure that an NMI or DI can provide reliable services consistent with their stated CMCs

The quality management systems established and operated by the institutes shall meet the requirements of

- ISO/IEC 17025 for calibration and measurement services, and
- ISO 17034 for certified reference materials.





# CIPM MRA-P-11


## Quality Management Systems

To confirm, the **RMO** shall peer review the quality management system either:

- with the support of an accreditation body fulfilling the requirements of ISO/IEC 17011 (\*), and following the ILAC-CIPM guidance on the accreditation of NMIs; or
- directly, without third-party involvement.

In both cases the responsibility for the review lies with the individual **RMOs** under the auspices of their respective **quality system working groups**.

(\* ) **ISO/IEC 17011:2017** - Conformity assessment — Requirements for accreditation bodies accrediting conformity assessment bodies






# CIPM MRA-P-11

## Quality Management Systems (QMS)

- The QMS of the institutes shall cover all their declared CMCs.
- The QMS shall undergo a full review with a period not longer than five years.
- This review includes examination of evidence for the continued validity and vitality of published CMCs.
  - Demonstration of competence and capability may require visits and examination of procedures by peers selected by the local RMO.

The RMOs provide annual summary reports on the status of the QMS of the institutes participating in the CIPM MRA in their region as part of the regular reports to the JCRB.

### CIPM MRA-G-12:

- Recommendations for on-site visits by peers and selection criteria for on-site visit peer and reviewers.
  - The guidelines for RMOs concerning the monitoring and reporting of the operation of quality management systems.
- 





# CIPM MRA-G-12

## Introduction

The CIPM MRA requires that:

- a) participating institutes establish and maintain a quality management system;
- b) RMOs review and monitor the quality management systems of their participating institutes;
- c) each RMO reports to the JCRB on its processes and the outcomes of its reviews

So...

**An approved quality management system is a prerequisite for the submission of CMCs.**





## CIPM MRA-G-12

### Requirements for establishing confidence

Let's remember!

To confirm the establishment of suitable quality management systems, the RMO shall peer review each quality management system either:

- with the support of an accreditation body; or
- directly, without third-party involvement.

In both cases, the responsibility for the review lies with the individual RMOs under the auspices of their respective **technical committees/working groups**.

***Each RMO should make their guidance documents on quality management system review openly available on their websites.***






## CIPM MRA-G-12

### Peer review with the support of an accreditation body

Institutes that select this option should follow the guidelines outlined in the ILAC-CIPM guidance on the accreditation of NMIs, noting that:

- Generally, the scope (range and measurement uncertainty) should be the same as that published in the KCDB.
  - The accreditation body shall operate according to ISO/IEC 17011 and the accreditation body shall be covered by the ILAC MRA or by Regional Arrangements recognized by ILAC.
  - the accreditation body should use technical assessors/technical experts who can also be accepted as peer reviewers by the RMO.
- 




## CIPM MRA-G-12

### Peer review without third-party involvement

Each RMO shall establish appropriate processes to ensure that the quality management systems of their member institutes comply with:

- ISO/IEC 17025 for calibration and measurement services, and,
- where applicable, ISO 17034 for institutes producing reference materials.


The requirement is applicable for all fields of metrology where the institute declares or intends to declare CMCs.



### Review, approval and monitoring guidelines

Each RMO shall develop and maintain an open process for reviewing, approval and monitoring the quality management systems of their member institutes.

The institute shall provide the RMO with necessary information from the quality management system, covering CMCs and, where applicable, reference materials production.






## CIPM MRA-G-12

### **On-site visits by peers during the review of quality management systems**

The CIPM MRA foresees on-site visits by peer reviewers as a possible way to assist the review process of quality management systems.

Such visits may be requested by the institute itself or the local RMO to establish the required level of confidence in the quality management systems.

Some RMOs only use on-site peer reviews when regular procedures instituted by their TC/WGs are unable to verify satisfactory performance of the quality management system under review.





# SIM Requirements





## SIM 09 - SIM Quality System Task Force: Rules of Order

### SIM Resolution CR04/05:

The SIM General Assembly established the **SIM Quality System Task Force** (QSTF) to meet the requirement that SIM review all member quality systems by passing the following Council Resolution in 2005:

- ✓ A task force will be set up to review QS implementations in SIM members for the purpose of the CIPM MRA, which will be formed by CIPM-MRA signatories.
- ✓ The chairperson of the QSTF will be appointed by the Council

*<https://sim-metrologia.org/about-us/structure/quality-system-task-force-qstf/>*








## **SIM 09 - SIM Quality System Task Force: Rules of Order**


### **SIM Bylaws state the responsibilities and membership of the SIM QSTF.**

- The meetings are open to all SIM members and observers, and provide an opportunity for discussion and comments
  - SIM QSTF decisions are made by the representatives of the SIM signatories to the CIPM MRA.
  - The QSTF assesses whether or not the QMS conforms with the requirements of the CIPM MRA.
    - ISO/IEC 17025 (Calibrations and testing services)
    - and/or ISO 17034 (Certified reference material production)
  - SIM QSTF approval is required prior to submission of the CMC claims to JCRB.
- 



## **SIM 09 - SIM Quality System Task Force: Rules of Order**


### **SIM QSTF Reports to the JCRB**

- ✓ All RMOs are required to report on their quality management system review process and the status of such reviews annually to the JCRB.
  - ✓ The SIM report provide information on the status of QSTF approval of the quality management system for each NMI and DI (including CMCs covered).
  - ✓ The summary will highlight any changes affecting the delivery of CMCs.
  - ✓ The Chair of the QSTF is responsible for reporting the approval status of the quality systems supporting existing and proposed CMCs to the Executive Secretary of the JCRB and the SIM Technical Committee Chair.
  - ✓ The Chair of the QSTF serves as one of the SIM delegates to the JCRB.
- 



# SIM 09 - SIM Quality System Task Force: Rules of Order


## Rules of Procedure

- ✓ The SIM QSTF is composed of one voting delegate from each SIM member NMI, which is also a signatory to the CIPM MRA.
  - ✓ Each delegate represents his/her NMI as well as any designated institutes associated with the NMI
    - Note: quality management systems of designated institutes must be presented to the QSTF by the designated institute.
  - ✓ Under circumstances where a country does not have a formal NMI, the organization responsible for the country's metrology system may appoint that country's official representative to the QSTF.
- 



## **SIM 09 - SIM Quality System Task Force: Rules of Order**

### **Chair and Attendees**

- ✓ The Chair of the SIM QSTF is recommended by the members of the QSTF and officially approved by the SIM Council.
  - ✓ The Chair is responsible for the operation of the SIM QSTF and is a non-voting member except in the rare instance where the breaking of a tie vote is required.
  - ✓ The QSTF meetings are generally open to observers from all SIM members, representatives from other RMOs, and representatives from other metrology related organizations.
  - ✓ On occasion, the QSTF Chair may declare part of the meeting closed allowing QSTF delegates to discuss internal QSTF matters and formulate policy.
- 



# QSTF

## MEMBERS

- ✓ The SIM QSTF is composed of 16 voting members (from the eight (8) Member States and the eight (8) Associates of the CGPM).
- ✓ Voting members to the SIM QSTF are nominated by an NMI that is both a SIM member and a signatory to the CIPM MRA.

## Contacts

[Sally Bruce](#), Chair, QSTF

[Isabelle Amen](#), Deputy Chair, QSTF

[Andrew Conn](#), Secretariat, QSTF

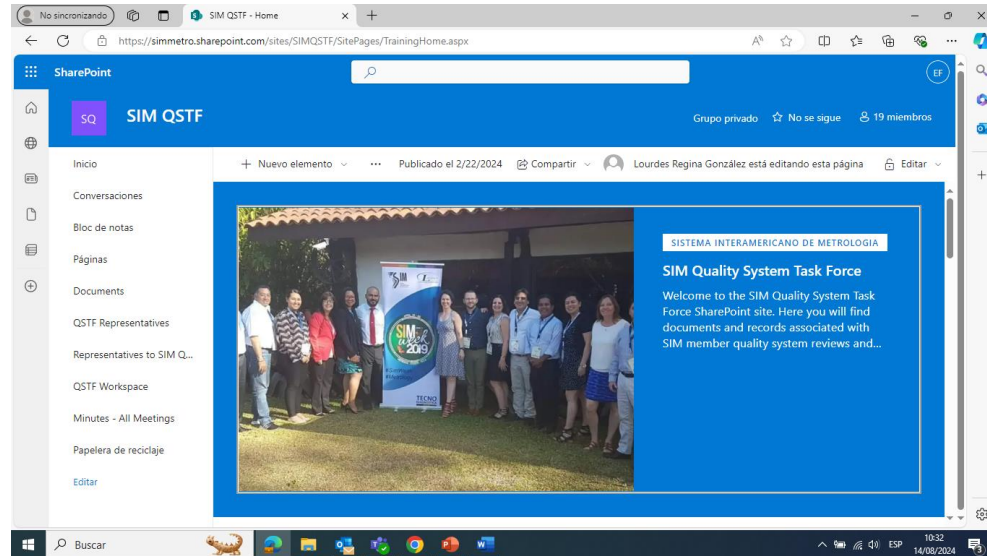


# SIM 09 - SIM Quality System Task Force: Rules of Order

## Confidentiality

Information distributed to the QSTF members in support of QMS reviews is considered confidential.


All information is managed through the QSTF Share Point site with restricted access for QSTF members.





## SIM 09 - SIM Quality System Task Force: Rules of Order

### Resolutions

- ✓ A quorum of 50% of the QSTF members is required to conduct business.
  - ✓ Resolutions are made by a simple majority of the members voting either for or against a resolution.
  - ✓ All QSTF members in attendance can vote on all motions *excluding the member representing a country or economy seeking approval*.
  - ✓ The minutes of the QSTF are official records of the approval and will be made available to the representatives of SIM in a timely fashion and archived for at least ten years following approval.
- 



# SIM 09 - SIM Quality System Task Force: Rules of Order

## Updating SIM 09

- This document is regularly reviewed and periodically updated by the QSTF members to reflect the changing requirements on the SIM QSTF because of SIM Council resolutions, JCRB decisions and other factors.
- Changes are approved by the SIM Council and presented to the General Assembly.



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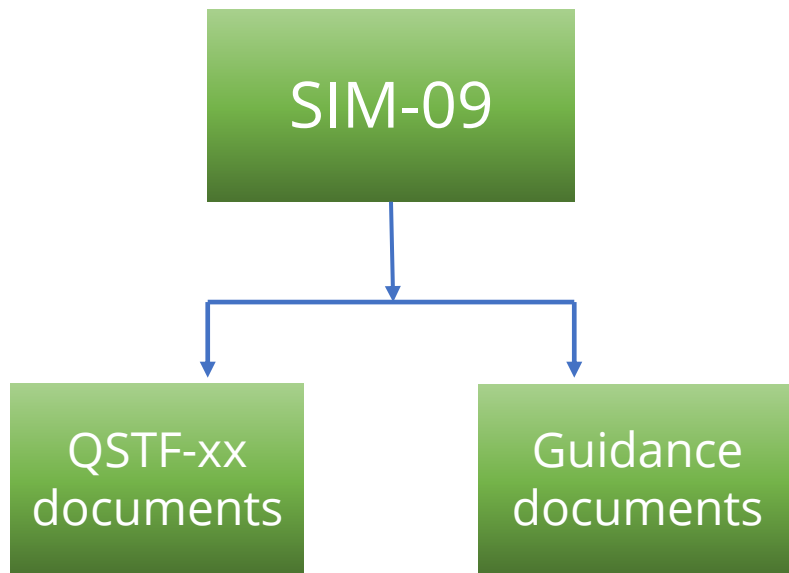


# QSTF Documentation



# SIM QSTF Documentation

## SIM QSTF Documentation Structure



# SIM QSTF Documentation

## Where do we find the QSTF documents?

SIM website:

<https://sim-metrologia.org/>

'About SIM' / 'STRUCTURE' / 'QUALITY SYSTEM TASK FORCE (QSTF)'

<https://sim-metrologia.org/about-us/structure/quality-system-task-force-qstf/>

The controlled approved version of all the SIM QSTF documents is published on the SIM website

Any other electronic copies are uncontrolled

The screenshot shows a web browser window displaying the SIM website. The address bar shows the URL: [sim-metrologia.org/about-us/structure/quality-system-task-force-qstf/](https://sim-metrologia.org/about-us/structure/quality-system-task-force-qstf/). The page content includes the SIM logo, a navigation menu, and a main heading: **QUALITY SYSTEM TASK FORCE (QSTF)**. Below the heading, there is a paragraph: "Ensuring efficient and effective review of the quality systems of SIM NMIs to ensure conformance with the expectations of the CIPM MRA and to serve other quality system approval needs of SIM NMIs." This is followed by a sub-section titled **Quality System Review Guidelines**. The text under this section reads: "The SIM QSTF must satisfy itself that, through its review process, the quality management system operated by the NMI or DI is effective and conforms with the requirements of the CIPM MRA, including the applicable requirements of ISO IEC 17025, ISO 17034, etc." Another paragraph states: "The SIM QSTF requires on-site peer reviews and may request additional review to be undertaken, in order that the NMI or DI may demonstrate confidence in their ability to deliver their claimed CMCs." A final paragraph notes: "Quality systems that have been approved must be fully re-evaluated and re-approved within five years." On the right side of the page, there are two sections: "Next Events" and "Recent Events". The "Recent Events" section lists two events: "SIM WEEK - 6-10 November INTN, Paraguay" and "SIM-NCISLI EARLY CAREER METROLOGISTS AWARD". The browser's taskbar at the bottom shows the Windows logo, a search bar, and various application icons, with the system tray displaying the time as 11:30 and the date as 14/08/2024.



# SIM QSTF Documentation

## What type of documents can we find?

- ✓ Documents
- ✓ Templates and checklist
  - Mandatory
  - Optional
- ✓ Guidelines

gia.org/about-us/structure/quality-system-task-force-qstf/



Home News About SIM Official Documents Projects Capacity Building Publications Only Members Contact

Quality systems that have been approved must be fully re-evaluated and re-approved within five years.

#### QSTF Documents:

[QSTF-00](#) (Procedure for Review and Approval Quality Management Systems) / *Version 1.3; Approved on 23 February 2024*

[QSTF-01](#) (Submission Template) [required] / *Version 2.1; Approved on 11 September 2020 (editorial changes completed on 5 March 2024)*

[QSTF-02](#) (Presentation Template) [optional] / *Version 2.0; Approved on 07 May 2024*

[QSTF-03](#) (Checklist for QMS Submission) [required] / *Version 3.1; Approved on 11 September 2020 (editorial changes completed on 29 February 2024)*

[QSTF-04](#) (Findings Template) [optional] / *Version 2.0; Approved on 07 May 2024*

[QSTF-05](#) (New CMC for existing QMS) [optional] / *Version 2.1; Approved on 2 April 2014 (editorial changes completed on 15 February 2024)*

[QSTF-06](#) (SIM QSTF Transition Policy and Plan – ISO/IEC 17025:2017 and ISO 17034:2016) / *Version 2.0; Approved on 7 August 2020 [RETIRED]*

[QSTF-07](#) (SIM QSTF Electronic Ballots) / *Version 1.0; Approved on 11 July 2019*

[SIM-09](#) – Procedure for Review of the Quality Management System of National Metrology Institutes and Designated Institutes / *Version 11.0; Approved by the SIM Council on 4 April 2017*

#### Guidance Documents:

[Guidelines for the Submission of Information to the SIM QSTF for the Review of Quality Management Systems](#)

[Guidance for Performing and Conducting Remote Assessments](#)

#### AWARD



First PAQI and QICA Exchange Meeting



SIM WEEK – INM, Colombia – May 23-26 2023



OPEN EVENTS SIM WEEK-COLOMBIA: CELEBRATION OF WORLD METROLOGY DAY- 24th May 2023






# SIM QSTF Documentation

## Documents

[QSTF-00](#) (Procedure for Review and Approval Quality Management Systems)  
*/ Version 1.3; Approved on 23 February 2024.*

[QSTF-05](#) (New CMC for existing QMS) [optional] / *Version 2.1; Approved on 2 April 2014 (editorial changes completed on 15 February 2024)*

[QSTF-07](#) (SIM QSTF Electronic Ballots) / *Version 1.0; Approved on 11 July 2019*





# SIM QSTF Documentation

## Mandatory Templates and checklist


[QSTF-01](#) (Submission Template) **[required]** / *Version 2.1; Approved on 11 September 2020 (editorial changes completed on 5 March 2024)*

[QSTF-03](#) (Checklist for QMS Submission) **[required]** / *Version 3.1; Approved on 11 September 2020 (editorial changes completed on 29 February 2024)*

## Optional Templates and checklist

[QSTF-02](#) (Presentation Template) [optional] / *Version 2.0; Approved on 07 May 2024*

[QSTF-04](#) (Findings Template) [optional] / *Version 2.0; Approved on 07 May 2024*





# SIM QSTF Documentation

## Guidelines

[Guidelines for the Submission of Information to the SIM QSTF for the Review of Quality Management Systems](#)

[Guidance for Performing and Conducting Remote Assessments](#)

QSTF-xx series of Documents are periodically reviewed and approved by the 16 delegates of the SIM QSTF, either during a QSTF meeting or by electronic vote.

Guidance documents are developed as needed and are also approved by SIM QSTF delegates.





# SIM QSTF Documentation

## QSTF Documents – QSTF-00

While SIM-09 covers the mandate given to the QSTF by SIM, this document details how the QSTF operates. It covers, for example, the timeframes between each stage of the management systems approval process.

### Document SIM QSTF 00 - Version 1.3

#### **SIM QSTF Procedure for the Review and Approval of the Quality Management Systems**

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# SIM QSTF Documentation

## QSTF Documents – QSTF-00

### Introduction

Implementation of the CIPM MRA has delegated the responsibility to review the quality management systems (QMSs) to the Regional Metrology Organizations (RMOs). Thus, SIM is responsible to review and to approve the QMS operated by its member National Metrology Institutes (NMIs) and their Designated Institutes (DIs) and to report on their acceptance to the Joint Committee of the RMOs and the BIPM (JCRB). This responsibility has been assigned by SIM Council to the SIM Quality System Task Force (QSTF) [see SIM-09]. **QMS approval by SIM QSTF is required to support CMC claims, however since it is not limited to this purpose any NMI in the SIM region may present a QMS related to their measurement services for QSTF approval.**

any NMI/DI in the SIM region may present a QMS related to their services for QSTF approval.





# SIM QSTF Documentation

## QSTF Documents – QSTF-00. Relevant information about the process

### 2. Scope

This document applies to any NMI in the SIM region, even if it is not a signatory of the CIPM MRA. This document applies to all QMSs submitted by NMI/DIs. This document also applies to the review of a QMS submitted by the BIPM and an international intergovernmental organizations (IGO), or their DI, that is a signatory to the CIPM MRA and requests approval by SIM.

Measurement services include calibration and measurement capabilities, reference material and certified reference material production and proficiency testing activities.




# SIM QSTF Documentation

## QSTF Documents – QSTF-00. Relevant information about the process

- ✓ The QSTF requires that the QMS undergo an on-site peer review/assessment prior to and within 18 months of submission of the QMS to the QSTF.

## Meetings and Submission Requirements

- ✓ A meeting announcement, including deadlines for the submission of the documentation, will be sent by the QSTF Chair or Secretariat at least eight (8) weeks prior to the meeting.
  - ✓ For a QMS that has not previously been approved, NMI/DIs shall submit their documentation, in the format required by the QSTF templates, to the QSTF Secretariat at least six (6) weeks in advance of the meeting. In other cases, four (4) weeks in advance of the meeting
- 




# SIM QSTF Documentation

## QSTF Documents – QSTF-00. Relevant information about the process

### Meetings and Submission Requirements

- ✓ NMI/DIs must make their QMS documentation, in its original language, available to the SIM QSTF. They must submit, in full and in English, the Submission Template (QSTF-1), the Checklist for Submission of QMS for Review by QSTF (QSTF-3).

Note: to help the SIM QSTF review, the peer review/assessment report as well as the resolution of the findings should also be in English (or a translation in English)

- ✓ A summary of the submitted documentation will be presented at a QSTF meeting by a knowledgeable representative of the NMI/DI.
  - ✓ The SIM QSTF must satisfy itself that, through its review process, the QMS operated by the NMI/DI is effective and conforms to the applicable requirements
- 




# SIM QSTF Documentation

## QSTF Documents – QSTF-00. Relevant information about the process

### Meetings and Submission Requirements

In addition to the requirements regarding the QMS, the review process may also consider:


- ✓ knowledge of the NMI/DI's capabilities through active participation in SIM projects and activities;
  - ✓ other available knowledge and experience, such as scientific and quality related publications; and
  - ✓ participation in scientific and training activities, visits and consultation with technical and quality experts from other RMOs.
- 



# SIM QSTF Documentation

## QSTF Documents – QSTF-00. Relevant information about the process

### Monitoring of approved QMS


- ✓ NMIs/DIs must promptly notify the SIM QSTF Chair and Secretariat of any major changes that affect its approved measurement services.
  - ✓ Each NMI/DI having an approved QMS will submit an annual report to document significant changes that have occurred that might affect the continued delivery of those CMCs.
  - ✓ Upon notification of significant changes, the SIM QSTF Chair will take appropriate action.
- 



# SIM QSTF Documentation

## QSTF Documents – QSTF-00. Relevant information about the process

### Re-approval of QMS and Vitality of Published CMCs

- ✓ Approved quality management systems must be reviewed and reapproved within five (5) years by the QSTF.
  - ✓ Re-approvals of a QMS have the same requirement as original approvals.
  - ✓ In addition, re-approvals a QMS also require evidence accumulated over the last several years supporting the existence of a robust quality management system including:
    - ✓ regular internal audits,
    - ✓ management reviews,
    - ✓ customer feedback,
    - ✓ nonconformities and corrective actions, appropriate record keeping, action plans to address its.
- 



# MWVG 12

Quality Management Systems Metrology Working Group








## MWG 12

### Role of Quality Management Systems Working Group 12

- ✓ Working Group 12, Quality Management Systems, as part of the TC (technical committee), was created to support NMIs/DIs in their development needs in accordance with the quality management systems that they need to apply, implement and present internationally so that their measurement and calibration capabilities can be recognized by their peers.
  - ✓ This committee, in addition to working with its members (representatives in charge of quality), also works with technical committees of various magnitudes to better manage the understanding and implementation of quality systems.
  - ✓ Additionally, it works to support other committees such as the QSTF, to support NMIs and DIs with training, knowledge and compliance with the necessary requirements to achieve the approval of their quality systems within the CIPM MRA participations.
- 

### *The workshop includes two virtual workshops*

- **COURSE FOR DETERMINATION OF CALIBRATION INTERVALS**

Spanish 10/27/2020 and 10/29/2020. English 11/02/2020 and 11/04/2020.

**Instructor:**

I.Q. Claudia Santo, Expert

Capacity: 3 accesses by NMI / DI - in each course

- **MANAGEMENT RISK ACCORDING ISO/IEC 17025:2017**

Spanish and English interpretation 11/10/2020 and 11/12/2020

**Instructor:**

Ing. Pedro Sismondi, Expert

Capacity: 2 accesses by NMI / DI - in each course





## Guidelines for Performing and Conducting **Remote Assessments** within SIM Regional Metrology Organization

### QMSWG Webinar – 9 March 2021

The webinar will provide an opportunity to the SIM metrology community to better implement remote assessments, such as remote peer reviews, internal assessments, and internal audits. The SIM document in this regard will be discussed and the experience of two SIM NMIs will be shared.

# MWG 12



The poster features a dark blue background with a circular inset on the right showing a close-up of a hand holding a pair of tweezers over a small object. The background also contains faint, semi-transparent text including 'Melo Ambiental' and 'Sustentável'.

 INMETRO 50 anos

November, 13 and 14<sup>th</sup> 2023

## Workshop on ISO 17034:2016 Standard Requirements

Vanderléa de Souza, D.Sc.

[vsouza@inmetro.gov.br](mailto:vsouza@inmetro.gov.br)




# Guidelines for the characterization and evaluation of the homogeneity and stability of Reference Materials

Janaína Marques Rodrigues  
Chemical Metrology Division

2023:  
November, 16<sup>th</sup> and 23<sup>rd</sup>  
December, 01<sup>st</sup>





**Seminar:** A look at how  
the SIM Quality System  
Task Force (QSTF) works

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Elizabeth Ferreira  
SIM MWG 12 Chair  
2024-03-07

**SIM**

SISTEMA  
INTERAMERICANO  
DE METROLOGÍA



# Thanks!

Elizabeth Ferreira

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