Guidance for performing and conducting remote assessments at National Metrology Institutes and Designated Institutes within the SIM Regional Metrology Organization

1. Background

Review of Quality Management Systems (QMS) at National Metrology Institutes (NMI) and Designated Institutes (DI) within the SIM region when international or domestic travel is not possible, as experienced with the COVID-19 pandemic, highlights the need to define assessment means other than on-site assessments. Furthermore, other restrictions (e.g., quarantine requirements) would continue to make on-site reviews impractical or impossible to perform.

CIPM MRA establishes that QMS supporting Institute's CMC's shall undergo a review at least every 5 years. Situations such as the COVID-19 pandemic give rise to the need to undergo such QMS reviews in a remote/internet environment. Besides these reviews, internal audits in NMI or DI could also be done in similar circumstances, if conditions warranted.

2. Objective

This is not a policy document, instead it provides guidance for performing and conducting remote assessments of QMSs supporting measurement capabilities delivered by NMIs/DIs within the SIM region.

3. Scope

These guidelines apply to QMS remote (external) peer reviews or internal audits under the responsibility of the NMI or DI organizing it. If an Institute uses the accreditation route by an ILAC MRA signatory, it should ensure that they follow their Accreditation Body's remote assessment guidance in meeting the international laboratory accreditation requirements/guidance.

4. Terminology

- For this document, the term *assessment* is used to refer to internal or external peer reviews and internal audits. Sometimes internal peer review can be referred to as internal assessment.
- National Metrology Institutes and Designated Institutes are both referred to as Institutes.
- The term *measurement service* includes calibrations, tests, production of reference materials, and/or Proficiency Testing.

5. Recommendations

General Assessment/Audit international documents criteria (e.g. ISO 17011, ISO 19011) should be considered. In that follows, specific recommendations for remote assessments are listed.

6. Assessment

6.1 Preparation for assessment

The objective of the preparation step is to verify that the institute has the resources, and general capabilities to participate in a remote assessment.

The Institute should consider the following:

- Examine the risks and opportunities of the remote assessment in comparison to an on-site assessment.
- In preparation of a remote assessment, give serious consideration to:

  ✓ The previous knowledge of the QMS to be assessed is advantageous: the assessment of a new QMS may be more challenging using remote means.
  ✓ Past peer review reports, past internal audit records, including dates, scopes, findings, conclusions, and corrective actions.
  ✓ The availability of the Institute's technical capabilities and ready access to their documentation and records.
  ✓ When the assessment has not been performed in the last 5-year cycle.
  ✓ When the QMS was on-site reviewed in the last 5 years, but it was frequently internal audited in the meantime, a remote peer review may be feasible.

Note 1: A Risk Analysis should be documented by the Institute to document the departure from the normal assessment activity and if the risk is to an acceptable level and how/if this will/can be mitigated if not.

- Consider that a remote assessment will make it more challenging to obtain information when compared to that of a direct, on-site observation. As an example, it will be hard to assess the appropriate sticking of gauge blocks or the wide-angle sight seeking the presence of adverse influences on the laboratory activities unless pre-recorded videos are used and provided to assessors. When some aspect could not be assessed, it is recommended that the reviewer mentions it in the section "Scope" of the report.

- Organization and plans for the review activity in many aspects would be the same as the in-person efforts.

- Verify that QMS documents, including if records are in digital versions and are available to the assessors for the preparation step. If the QMS is digitalized, verify if the reviewer/assessor/auditor can receive the documents or access the system where they are located.

- A series of documents and information should to be available to the reviewer / assessor / auditor at least 2 weeks before the assessment. This may include:

  ✓ QMS procedures
  ✓ related records
  ✓ spreadsheets, software
  ✓ videos showing how procedures are implemented (not edited)
  ✓ staff bios

- ✓ plans of the laboratories and records of environmental conditions
- ✓ lists of equipment/standards and calibration plans
- ✓ internal audits reports
- ✓ complaints, non-conformities, corrective actions, customer feedback
- ✓ management reviews reports
- ✓ recordings, pre-recorded videos uploaded on a secured Cloud (If the institute has the necessary resources,) to demonstrate critical technical steps

Note 2: It is noted that, for on-site assessments, several of these records, are generally assessed during the visit. For remote assessments it is recommended that the reviewer request and receive this information in advance.

- Check that the rules for information confidentiality and the cyber protection policies of the assessed institutes allow a remote assessment.

- Select Peer Reviewers/Assessors based on the matching of expertise with the measurement capability and/or QMS as much as possible.

- Daily schedules and the duration of the assessment may need to be paced and may take longer for remote reviews. They could be recorded if recording is allowed by the IT policy of the institute and with the permissions of all involved.

- Determine the web-based meeting application(s) available for the Institute; and make sure that those IT applications are available/acceptable to the assessors.

- Plan 2-hour maximum duration for a specific review activity is recommended for one time period, based on feedback on experiences from the Conformity Assessment community. The medium of being on-line can be more stressful, can become tiring, so if the activity takes more than 2-hours, take a break, and follow-up at another time slot.

- Check that use of web cameras or recording devices are allowed, if needed. Some web meeting tools are available as apps, so smart phones or lap tops and other portable devices could be used to allow mobility and flexibility of locations.

- A short Risk Analysis should be documented by the Institute to document the departure from the normal in-person assessment activity and if the risk is to an acceptable level and how/if this will/can be mitigated if not. An example is provided in Annex 2.

- Test the connections the day before the review activities to make sure everything is working properly – audio and video. Make sure to have back-up means to communicate in case web connections are not possible.

- An assessment plan/schedule shall be prepared, including which activities are to be performed. For instance:

- ✓ IT tools used for each slot in the schedule,
- ✓ detailed schedules,
- ✓ remote reviews of documents, including spreadsheets or calculation software
- ✓ remote review of records,
- ✓ list of interviews*
- ✓ remote initial and closing meetings, etc.

Note 1: If the Institute's staff are in telework status, that is the location that they should remain for these remote assessment activities. These remote assessments are not a means to force anyone back before their normal times as agreed by the Institutes' management and safety personnel.

6.2 During the assessment

- Be sure to have an opening meeting and a closing meeting, also allow time each day for the reviewers to meet with each other to debrief as to their progress and their observations.

- Make sure that connectivity exists in the laboratories, and in all locations that normally would be needed to perform interviews of staff and management, and for demonstration of processes.
- Pacing is important to make the experience less stressful for all.

- Request permission of the assessed to make recordings in devices, including photo cameras, audio recorders, and the like., either for recording specific items, parts of the assessment or of whole interviews.

- Seek to conduct the assessment in a quiet atmosphere, far from no high noises or abrupt interruptions. Avoid the use of your cell phone as much as possible during the interviews.

- Exchange information within the assessors' team, as frequently as needed, seeking feedback to avoid the risks of gaps in the assessment scope, or contradictions in the findings.

- Share the findings with the assessed once they are confirmed within the assessor team, preferably.

6.3 After the assessment

- Include in the assessment report the risks and opportunities associated with the remote assessment.
- Specify the timeframe for delivering items requested along the assessment, and the consequences of incompliance.
- Deliver the assessment report in the terms and within the deadlines agreed with the assessed.
- A description of the performed activities (mentioned in the above plan or others) must be mentioned in the peer review report or in a separate document. It will give to the QSTF an idea about the depth of the assessment.
- Include which activities or processes that could not be assessed remotely.

Annex 1 Example of Checklist for a remote assessment

A. Audit plan preparation (include the list of the Information and Communications tools which are available)

1. Has the assessed institute had previous assessments?
2. Have the assessors and assessed institute had experience on remote assessments?
3. At what extent the assessment is feasibly to be performed remotely?
4. How are the risks of the remote assessment taken into account?
5. Are the assessment objective and scope compatible with the remote assessment risks?
6. Has been taken the measures to ensure an appropriate and fluent oral communication, especially when the native languages of the assessed and assessors are different?
7. Does the digital platform selected ensure sufficient expertise of the assessors and the assessed for using it fluently?
8. Does the schedule for the interviews consider working time blocks of a maximum duration of 2 h?
9. Does the schedule allow short stops to use as needed?
10. What are the measures to address items considered non-feasible to assess remotely?
11. What are the risks involved for the remote assessing?
12. Are all the assessed confirmed to participate in the assessment according to the schedule?
13. Have the connections tested to ensure appropriate audio and video?

B. Performing the assessment

1. What are the provisions to exchange information among the assessors during the assessment?
2. Are there means to check the authenticity of the information, records, documents, person identification and other items provided by the assessed?

C. Post-assessment

1. Have the findings reached the assessment team consensus either in wording as on the level of concern?
2. Have been ensured the understanding and acceptance of the assessment findings by the assessed? Is there any disagreement been documented?

Annex 2 Example of a short Risk Analysis prior and after the assessment

Remote Assessment Feasibility - Risk Assessment Checklist	DATE			
Institute:				
Risk	Probability (1-4)	Impact (1-4)	Total (1-16)	Comments
Personnel (turnover, availability, management)			0	
Facilities (moving location, moving the laboratory within the facility)			0	
Equipment (changes to equipment)			0	
Methods (changes to methods)			0	
Scope/CMCs (Extensions, recent additions)			0	
QMS (overall impression of how robust the QMS is)			0	
Operations (Is the institute open)			0	
IT infrastructure for remote assessment (is equipment available)			0	
QMS infrastructure for remote assessment			0	

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Risk	Probability (1-4)	Impact (1-4)	Total (1-16)	Comments
Assessor familiarity with institute (remote assessment easier if assessor knows the institute but not necessary)			0	
Confidentiality risk			0	
Overall Risk (before the assessment)			0	
Overall residual risk (**After the assessment):** indicate if things went well, better than expected or severe difficulty occurred that makes the assessment results acceptable.				
Evaluate Risk (probability and impact) using scales:				
	Probability scale (for this particular remote assessment):			
	1	Low probability it will happen		
	2	Medium probability it will happen		
	3	High probability it will happen		
	4	Will happen		
Impact scale (for this particular remote assessment):				
	1	Minimal impact		
	2	Impact to internal processes only		
	3	Significant impact on a limited number of requirements/technical areas		
	4	Significant impact on the feasibility of being able to conduct an effective assessment		