Supplement requirements for remote assessment

1. Purpose

This document describes the criteria and process for conducting remote assessment.

2. Application

It is applicable to initial assessment, re-assessment, surveillance and extend scope of the accreditation when an onsite assessment is not applicable.

3. References

3.1 IAF MD 4:2018. Mandatory Document for The use of Information and Communication Technology (ICT) for Auditing/Assessment Purposes. Issue 2, Issued 4 July 2018.

3.2 IAF ID 12:2015. Informative Document for Principles on Remote Assessment. Issue 1, Issued 23 December 2015.

3.3 ISO/ IEC 17011: 2017. Conformity assessment- General requirements for accreditation bodies accrediting conformity assessment bodies.

3.4 APAC TEC0-001. Guidance on Remote Assessments by Accreditation Bodies. Issue no.1.0, Issue Date 20 October 2020

3.5 IAF-ILAC Statement on Replacement of Assessments During the COVID-19 Pandemic (05 March 2021)

3.6 APAC MRA-009:2020. Performing Remote Evaluations-Requirements and Guidance.

4. Definition and Abbreviation

4.1 Force Majeure

An occurrence beyond the control of the organization such as war, protest, strike, political instability, geopolitical tension, terrorism, crime, pandemic, flooding, earthquakes, fire, malicious computer hacking , and other natural or man-made disasters.

4.2 Document Review

Assessments of documents and records of accredited laboratory.

4.3 Remote Assessment

Remote assessment of the physical location or virtual site of a conformity assessment body, using electronic means such as Video Call, Virtual Site, Teleconferences, Microsoft Teams, Zoom Meeting, Google Hangouts, Line group, E-mail, Fax, Telephone ,Clip VDO, etc.

4.4 Information and Communication Technology (ICT)

Technology for gathering, storing, retrieving, processing, analysing, and transmitting the information. It includes software and hardware such as smartphones, handheld devices, laptop computers, desktop computers, drones, video cameras, wearable technology, artificial intelligence, and others.

4.5 Case officer

Accreditation body personnel who review the application form and coordinate with other divisions for laboratory and reference material producer accreditation.

4.6 BLQS is mean the Bureau of Laboratory Quality Standards.

5. Associated Documents

5.1 G 07 15 001 : Guidelines for laboratory assessment.

5.2 G 07 15 025 : Guidelines for a medical and health laboratory on management of force majeure affecting accreditation.

5.3 R 07 15 001 : Policies, requirements and conditions for laboratory accreditation.

5.4 R 07 15 004 : Policy, Requirements and Conditions for Reference Material Producer Accreditation.

5.5 N 07 15 030 : Requirement for Management of Impartiality.

6. Procedures

6.1 Remote Assessment Considerations

6.1.1 Travel to a laboratory or specific location is not reasonable/feasible or the risk level of the assessment is deemed high with assessor.

☞ 6.1.2 There are force majeure events that do not allow for on-site assessments or travelling.

☞ 6.1.3 An activity or activities planned for the on-site assessment could not be completed and extending the on-site assessment is not the best solution.

☞ 6.1.4 BLQS shall use remote assessment to replace the on-site assessment for surveillance and re-assessment when an on-site assessment is not applicable.

☞ 6.1.5 The assessment is for an extension scope of accreditation and the laboratory has the same or similar competency on its accredited scope.

☞ 6.1.6 In the case of initial assessment or extension of scope where the competency is new to the laboratory , BLQS shall consider case by case basis taking the level of risk into account. On-site surveillance shall be carried out within 12 months after the initial assessment.

☞ 6.1.7 The use of remote assessment will be evaluated on a case by case basis. BLQS will make the ultimate decision as to when and how a remote assessment can be utilized.

6.2 Qualification of the laboratory for use of document review and remote assessment.

6.2.1 Have the appropriate resources to facilitate the level of remote assessment that is being used during the assessment process. That is, have appropriate stable internet access and bandwidth, have capabilities for remote access of their data processing and management system, have the appropriate computers, audio/visual, and other equipment to facilitate the process, etc. This includes all the logistical and technical considerations necessary to ensure that the appropriate staff and resources are available at the times requested by the assessors.

☞ 6.2.2 Have the appropriate devices with cameras and allow these devices in to the laboratory in order to facilitate appropriate witnessing of equipment and process

6.2.3 Have available to facilitate the remote assessment process such as Microsoft Teams, Zoom Meeting, Google Hangouts, online video/audio services, remote access to organization’s data processing and management systems, database, etc.

6.2.4 Identify a member of staff who is responsible for facilitating the remote assessment process.

6.2.5 The laboratory must participate in a pre-assessment meeting and validate process prior to the remote assessment to ensure that the appropriate resource and system capabilities are in place to conduct assessment.

6.2.6 Assessor must have full access to the organization’s electronic systems, review documents and records sufficient to assess conformance to the accreditation requirements.

6.2.7 The laboratory is responsible for any additional expenses associated with the remote assessment process such as fees for application software.

6.3 Assessment Preparation

6.3.1 All details of the quality management system and the implementation document, which are fulfill the requirements of the BLQS, shall be submitted with a current copy and electronic file as follow as :

- Application form No.1, No.2, No.3, No.4, No.8, and No.10 (relevant standards);
- Quality manaul (other name);
- Quality management system procedures;
- Technical management procedures;
- Test methods for each accredited tests;
- Standard operating procedure;
- Work instruction;
- Reference methods for each accredited tests;
- Method verification report/ Method validation report;
- Measurement uncertainty report;
- Plan and result of the current PT/ Interlaboratory comparison;
- Plan and result of the internal audit;
- Plan and result of the management review;
- Plan and result of the calibrate equpment;
- Risk of management (for ISO/IEC 17025);
- Decision rule (for ISO/IEC 17025);
- Impartiality (for ISO/IEC 17025);
- Technical records such as training record;
- Competence of analyst;
- Production planning (for ISO 17034);
- Homogeneity/Stability data (for ISO 17034);
- Other data relevant standards.

6.3.2 BLQS shall appoint assessor who has already familiar with the laboratory management system and practices, if possible.

☞ 6.3.3 Case officer shall schedule a test call with the laboratory and assessors prior the assessment to verify the selected software and network connections are suitable and the assessment can be performed as planned.

☞ 6.3.4 Case officer identify and document the risks that may impact effectiveness for each use of ICT including the ICT considerations such as software, hardware, connectivity, security (data acquisition, transit, storage and deletion), test, and activities unable to be evaluated with ICT. The risk assessment is to be recorded using remote evaluation checklist and risk assessment (F 07 15 179). If the assessment activity is high level, the remote assessment cannot be utilized. Any recording of remote activities, including audio and video, should be collected evidence to support conformity to the remote assessment.

6.4 Remote Assessment

6.4.1 Top management, Laboratory management, Quality management, Technical management, Laboratory supervisor, Staff of laboratory and related personal shall attend the opening meeting and closing meeting.

☞ 6.4.2 All participants shall be identifiable with their full name. BLQS recommends the use of webcams, camera, etc. throughout assessment.

☞ 6.4.3 The laboratory shall confirm who is present during the assessment. The assessor team shall add these name to the attendance sheet for records F 07 15 140.

6.4.4 The assessor team shall assess for remote assessment refer to guidelines for laboratory assessment (G 07 15 001).

6.4.5 The assessor team can be a combination of any of the following assessment techniques:

- File/records review;
- Document review;
- Sampling the test report;
- Interviewing;

- Remote witnessing such as live video streaming, video demonstrate, and smartphone conference, etc.

The duration and timeframe for conducting the remote assessment has difference on-site assessment. Thus, additional time may be needed to facilitate remote assessments.

☞ 6.4.6 Lead assessor shall interview the approved signatories by using the form for interview Signatory (F 07 15 133 for ISO/IEC 17025, F 07 15 055 for ISO 15189 and F 07 15 070 for ISO 17034).

☞ 6.4.7 The assessor team are required to complete and sign the formal understanding for maintains confidentiality and impartiality. They shall dispose all documentation reviewed after assessment completed.

6.4.8 Lead assessor may terminate the assessment due to an inability to maintain satisfactory connections or conditions during the assessment. This shall be record in the form for data of changes/problems for on-site assessment report (F 07 15 048).

6.4.9 Lead assessor explain all nonconformity findings as shown in the report WS 07 15 001 /05.1 for ISO/IEC 17025 or reference material producer (RMP) on-site assessment report form (F 07 15 065) for ISO 17034 or WS 07 15 001/09.1 for ISO 15189, ISO 15190, ISO 22870. Nonconformity findings could be discussed or clarified by the laboratory or organization's staff if any. If at any time during the assessment process, the assessor cannot perform the assessment sufficiently using the remote assessment approach then the lead assessor shall record in the form for data of changes/problems for on-site assessment report (F 07 15 048). The laboratory must have an on-site assessment for those functions that could not be assessed using remote assessment.

6.4.10 Both lead assessor and laboratory or organization representative shall sign on the agreed assessment report including audio recording for accepting.

7. Data record and used document

7.1 F 07 15 048 : Form for data of changes/problems for on-site assessment report.

7.2 F 07 15 055 : Form for approved signatory.

7.3 F 07 15 065 : Reference Material Producer (RMP) On-site Assessment Report

Form.

7.4 F 07 15 070 : Form for Oral/Writing Examination of Candidate Signatory Approval for Reference Material Certificates, Statements, Analysis Reports or Information Sheets.

7.5 F 07 15 133 : Form for Interviewing Approved Signatory of Test Report ISO/IEC 17025:2017.

7.6 F 07 15 140 : Form for opening and closing meeting for laboratory accreditation.

7.7 F 07 15 179 : Remote Evaluation Checklist and Risk Assessment.

7.8 F 07 15 001 : Form for Interview Signatory.

7.9 WS 07 15 001/05.1: Worksheet for On-site Assessment Report.

7.10 WS 07 15 001/09.1: Worksheet for On-site Assessment Report for Medical Laboratory.

8. History of change

Revision No.	Documentation Changes	Prepared /Revised by	Date Issued
00	Initial Document	Saovanee Aromsook	24 June 2021

01	- Added detail initial assessment in clause 2 - Added the reference IAF-ILAC Statement on Replacement of Assessments During the COVID-19 Pandemic in clause 3.5 - Added the reference APAC MRA-009 in clause 3.6 - Added require and consider for remote assessment in clause 6.1.2-6.1.4 - Added require for extension scope in clause 6.1.5 - Added require for consideration in case by case of initial or extension scope in clause 6.1.6 - Added detail of evaluate on a case by case basis in clause 6.1.7 - Added detail of facilitate witnessing of equipment and process in clause 6.2.2	Saovanee Aromsook	
Revision No.	**Documentation Changes**	**Prepared /Revised by**	**Date Issued**

01	- Added detail of test call and verify software and network in clause 6.3.3 - Added record to remote evaluation checklist and risk assessment in clause 6.3.4 - Added identify and use the devices throughout assessment in clause 6.4.2 - Added detail of record F 07 15 140 in clause 6.4.3 - Added detail form of interview approved signatory in each standard in clause 6.4.6 - Added require confidentiality and impartiality in clause 6.4.7	Saovanee Aromsook	

Controlled copy list

1. Director of Bureau of Laboratory Quality Standards No. 07 00
2. Head of Laboratory Accreditation Section No. 07 03
3. Quality Manager of Laboratory Accreditation No. QM 07
4. Ms. Saovanee Aromsook