

P119 - Policy on Remote Assessment

Publication Date:

02/23/22

Scope and Field of Application

The intent of this document is to outline how A2LA will utilize remote assessment techniques in our accreditation processes to provide the best assessment experience for our accredited organizations while, most importantly, maintaining the integrity and the confirmation of technical competence that comes along with A2LA accreditation.

This policy details the different approaches and techniques that can be utilized in remote assessments and in what instances remote assessment techniques could be applied as part of the A2LA assessment process. This document also contains the A2LA requirements pertaining to the use of remote assessment techniques in the assessment process. Even in cases where remote assessment could apply, it is acknowledged that some organizations may still seek a more "traditional" assessment approach with no use of remote assessment techniques, which is acceptable to the extent possible. The acceptability and the extent of remote assessment techniques, will vary from field to field, program to program, and organization to organization and will depend on circumstances such as level of technology available to the organization, the organization's assessment preference, resources, etc.

Definition of Terms:

The following definitions are taken from ISO/IEC 17011:2017: *Requirements for accreditation bodies accrediting conformity assessment bodies*.

Remote Assessment - *assessment* of the physical location or virtual site of a *conformity assessment body*, using electronic means

<u>NOTE 1</u>: Examples of remote assessment include: webinars/web meetings, teleconferences, online video/audio services, remote access to organization's data processing and management systems, databases, etc.

<u>NOTE 2</u>: to entry: A virtual site is an online environment allowing persons to execute processes, e.g. in a cloud environment.

Qualifications for Use of Remote Assessment

The extent of remote assessment technique used will vary, depending on the structure of the organization and other considerations such as the organization's standing with A2LA and the type of assessment being performed (e.g. initial, surveillance, renewal, expansion of scope of accreditation, etc.).

Surveillance assessments, which take place approximately a year after the initial assessment, may be conducted remotely (usually by a member of A2LA staff); however, an onsite surveillance assessment may be required depending on the outcome of the initial assessment and other considerations such as the relocation of the organization, request to add to the scope of accreditation, complaints received against the organization, etc. A2LA will present the option when it is determined appropriate.

The use of remote assessment will be evaluated on a case-by-case basis. A2LA management will make the ultimate decision as to when and how a remote assessment can be utilized. Remote assessments will not be considered under the following circumstances:

- Initial assessments
- Back to Back renewal assessments/cycles
- When prohibited by regulatory authorities for specific programs (e.g. FCC, ISED, FDA, DoD, etc.)
- Accreditation Council recommendations against remote assessment for next renewal; and
- For Cause assessments

If an organization performs: testing (unless in a virtual environment); calibration; product certification; inspection; production of reference materials and/or proficiency testing samples, and/or biobanking or similar activities, then these activities may require an onsite assessment, (this will be determined by A2LA on a case-by-case basis). This will be evaluated by A2LA staff and final considerations will be made by A2LA Management. Medical testing laboratories currently accredited under the A2LA CLIA program will only be considered for remote assessments when a public health emergency has been declared and CMS has approved the use of remote assessments. Please note that live streaming is a requirement unless A2LA has approved other methods such as video recordings.

In most cases, remote assessments are not the primary approach for conducting an assessment. However, full remote assessments may be necessary when outside events occur that are out of A2LA's control. Please note that when a remote assessment is used to assess conformity for activities during an accreditation cycle those activities will likely need to be observed onsite during the next accreditation cycle. As such, it should not be expected that, once approved for a remote assessment, those activities will be assessed remotely on a routine basis and will not be assessed remotely in successive renewal cycles.

Specific Requirements

The following requirements shall be met for remote assessment:

(*C1*) The organization shall 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(s), have the appropriate computers, audio/visual, and other equipment to facilitate the process, etc. The organization must identify a member(s) of staff who is responsible for facilitating the remote assessment process. 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 assessor(s).

(C2) The organization is responsible for any additional expenses associated with the remote assessment process such as fees for teleconference, webinar, audio/visual, etc.

(C3) Remote assessments shall be capable of facilitating the conformity assessment process to the same level as an onsite assessment.

(C4) Upon request from A2LA, the organization shall provide information/evidence to validate their ability to perform the requested remote assessment with A2LA staff and the assessor prior to the remote assessment. This validation process may include verification of internet bandwidth, availability of acceptable technology, access to information management systems, access to web conferencing tools, etc. Final considerations will be made by A2LA Management.

(C5) The organization must grant the appropriate security and profile access to the assessor(s) to allow for remote collection of objective evidence to support conformity to the assessment criteria. This does not mean the assessor must have full access to the organization's electronic systems, but they must have the ability to review documents and records sufficient to assess conformance to the accreditation requirements. If records must be shared with the assessor to review on their own device, the CAB shall utilize the A2LA CAB portal to upload documents. Any records shared with the assessor outside of the CAB portal are at the discretion of the CAB, and A2LA will not be held responsible for any security or confidentiality breaches that may occur through use of outside platforms (i.e. email, Dropbox, Skype, Zoom, etc.).

(*C6*) Upon request by A2LA, the organization must participate in a meeting and validation process prior to the remote assessment to ensure that the appropriate resources and system capabilities/compatibilities are in place to conduct the remote assessment.

(*C7*) Requests for records of compliance may occur prior to the remote assessment videoconferencing sessions to allow for a more effective remote assessment. The CAB must provide the requested records in advance of the remote videoconferencing assessment sessions or the remote assessment may be delayed or cancelled until the requested records are received.

Please note that remote assessment videoconferencing sessions may be limited to shorter sessions that span more days than an on-site assessment to prevent "videoconference fatigue". Additionally, please note that with remote assessments, the assessor(s) and organization will likely be in different time zones and both parties must take this into consideration during planning. In consideration of time zone differences, the assessor is authorized to bill additional international differential time to compensate for disruptions to normal sleep schedules.

At any time during the assessment process, if the organization cannot support the remote assessment or if it is determined that the assessor(s) cannot perform the assessment sufficiently using remote techniques then the organization must have an onsite assessment for those functions that could not be assessed during the remote assessment.

DOCUMENT REVISION HISTORY

Date	Description
12/14/20	> Revised document to include ISO/IEC 17011:2017 terminology and reflect the
	current approach to remote assessment. Requirements remain
	fundamentally the same but removed the annex associated with requesting
	remote assessment.
02/23/22	 Editorial revisions throughout
	Added criteria for when remote assessments cannot be performed in the
	"Qualifications" section
	 Added reference to billing international differential time in paragraph
	following section C7