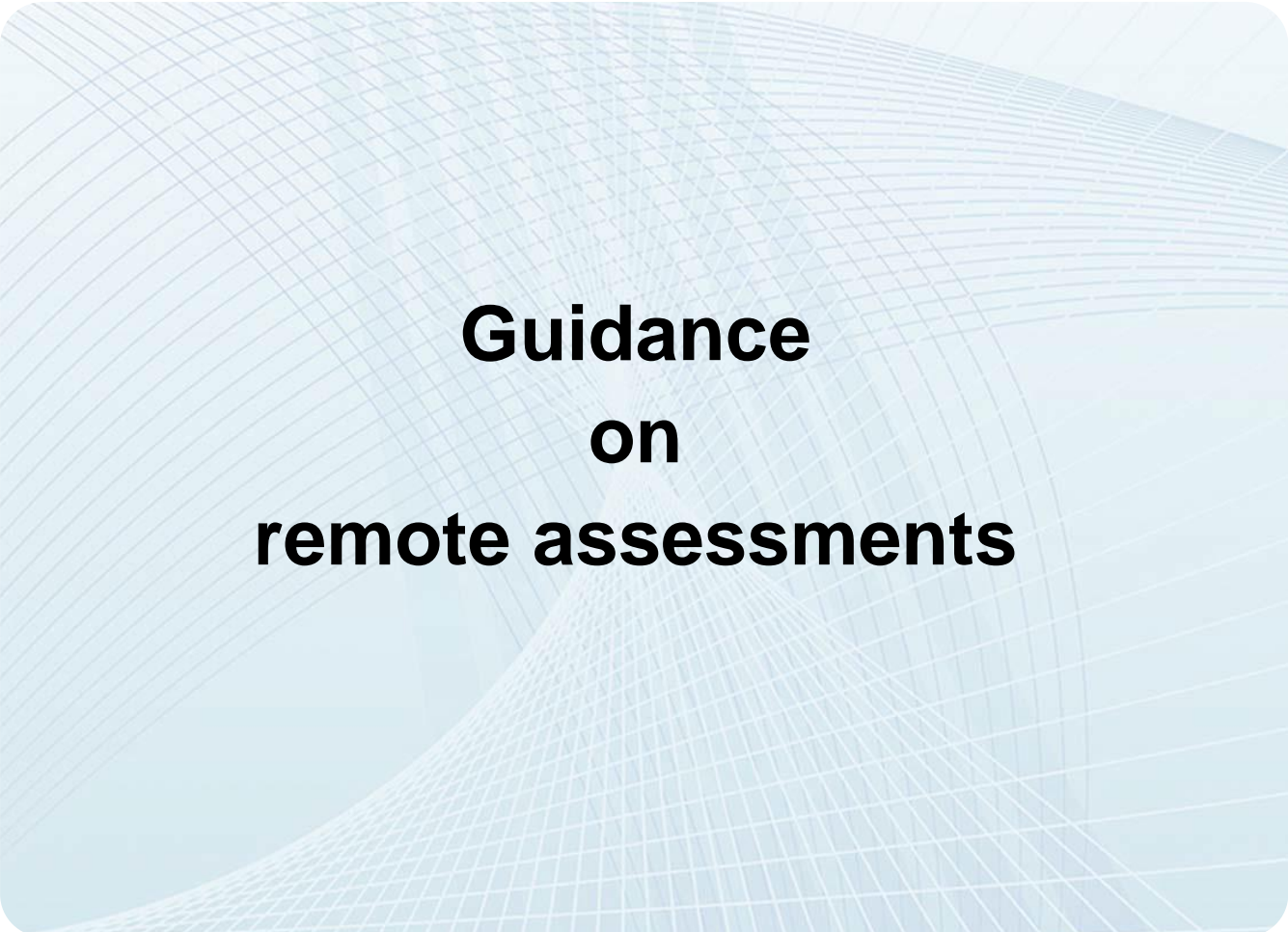




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Guidance on remote assessments

PURPOSE

The main purpose of this document is to give guidance on the use of remote assessment techniques by National Accreditation Bodies (NABs).

Authorship

This document has been written by the Horizontal Harmonisation Committee.

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The publication may be translated into other languages as required. The English language version remains the definitive version.

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INTRODUCTION

In September 2019, EA HHC held a first workshop on remote assessments. Since the beginning of 2020, the COVID-19 outbreak imposed severe restrictions on travelling and social interaction which limited the possibility of on-site assessments of Conformity Assessment Bodies (CABs). This led National Accreditation Bodies (NABs) to quickly adapt their practices by developing remote assessment techniques to maintain confidence in accredited conformity assessment activities.

NABs have noted the benefits, but also the limitations, of such remote assessment techniques. These experiences, the fact that remote assessments have been generally accepted (part of the new “normal”) and are now a reality and the outcome from the HHC workshop identified the need to define a general framework for the use of such techniques. This would also help in providing guidance and improving harmonization among the NABs.

In addition, the publication of EN ISO/IEC17011:2017, has introduced the following:

- Clause 7.4.4 - “The accreditation body shall establish documented procedures to assess the competence of a conformity assessment body to perform all activities in its scope of accreditation irrespective of where these activities are performed. These procedures shall describe the manner in which the scope of an applicant or an accredited conformity assessment body is covered through the use of a combination of on-site assessments and other assessment techniques sufficient to provide confidence in the conformity with the relevant accreditation criteria”
- Clause 7.9.3 - “The assessment programme shall ensure that the requirements of the international standards and other normative documents containing requirements for conformity assessment bodies and the scope of accreditation shall be assessed taking risk into consideration. A sample of the scope of accreditation shall be assessed at least every two years. The time between consecutive on-site assessments shall not exceed two years. However, if the accreditation body determines that an on-site assessment is not applicable it shall use another assessment technique to achieve the same objective as the on-site assessment being replaced and justify the use of such techniques e.g. remote assessment”

The last sentence of clause 7.9.3 refers to ‘not applicable’. This is understood to mean where an on-site assessment cannot be undertaken. It refers for instance to the assessment of virtual sites and to situations where the physical presence of the assessment team in some locations is not possible (e.g. due to force majeure event, health or security crisis, etc).

Remote assessment is one of the assessment techniques¹ that is available to NABs. Like the rest of the assessment techniques, it is the sole responsibility of the NABs to design the most appropriate assessment process taking into account the phase of the accreditation cycle, the objective of the assessment and the relevant risk factors, and ensure that the same objectives and outcome have been achieved. If the assessment is for initial accreditation, then the assessment will, under normal circumstances, have to include on-site elements.

¹ see clause 3.24 of ISO/IEC 17011

1 SCOPE

This document gives guidance on the use of remote assessment techniques by NABs.

Remark 1: This document may also be applicable in other contexts. (e.g. for conformity assessment activities.)

Remark 2: Although the document frequently refers to “assessments on-site” and “remote assessments”. It should be understood that many assessments in practise are blended assessments where some activities are performed on-site and others remotely.

2 DEFINITIONS

Remote assessment² - assessment of the physical location or virtual site of a CAB, using ICT

Blended assessment – a combination of assessment techniques including remote and on-site (this can be also referred as “hybrid assessment”)

Information & Communication Technology (ICT) – Technology that serves gathering, storing, retrieving, processing, analysing, and transmitting information. It includes software and hardware such as smart phones, PDAs, laptops, desktop computers, drones, video cameras, transmission technology, artificial intelligence devices, etc.

3 CONSIDERATIONS FOR USING REMOTE ASSESSMENT TECHNIQUES

The assessment may be carried out remotely when the information to be reviewed is mainly based on the review of documents, records and interviews. The on-site assessment will generally be chosen, when the requirements to be evaluated include reviewing the adequacy of facilities, equipment or witnessing of the conformity assessment activities.

Witnessing of the activity can be carried out remotely provided the witness audit objectives are met. Decision upon usage of remote assessment for witnessing of activity should be based on in-advance risk analysis.

Within risk analysis the NAB should consider:

- Time period since the previous onsite assessment;
- The availability of appropriate ICT equipment and the ability to use it efficiently (both for the CAB and assessment team);
- The time difference between the respective locations of the CAB and the assessment team members (including interpreters);

² see clause 3.26 of ISO/IEC 17011

- The nature of requirements to be covered during the assessment;
- The nature of findings to be followed up and types of evidence expected;
- The nature of complaints and other matters that need to be investigated;
- The level of digitalization of the information to be made available to the assessors;
- Safety and security constraints within the CAB;
- The stability of the CAB's resources and management system;
- The history of the CAB, especially performance, transparency, and collaboration;
- The size of the assessment team and the assessment duration;
- The training and experience of assessors in the use of remote assessment techniques and tools.

The CAB is informed in advance about the use of remote assessment techniques. The framework for the use of remote assessment techniques is defined and accepted by the CAB and the assessors (may need to be clarified in contracts/agreements/terms and conditions/application forms). Remote assessment techniques and the whole process shall be compliant to data protection legislations (e.g. GDPR).

Remote assessment techniques can be used when they will achieve the same objectives of the on-site assessment being replaced and justified. The decision on the use of remote assessment techniques rests with the NAB.

3.1 General considerations

- When on-site assessment cannot be performed (e.g. health, climatic events, political instability, risks to safety of assessment team members, etc.).
- When the physical presence of assessors negatively influences the outcome of the witnessed conformity assessment activities (e.g. contamination, lack of space).
- When due to the nature of the accredited activity and the manner of the accredited CAB's operation on-site assessment would not make sense (e.g. for activities controlled in the virtual environment).

3.2 Basic requirements for remote assessments

- The use of remote assessment is compatible with the requirements applicable to the NAB for the concerned accreditation scope.
- The period between on-site assessment is consistent with EN ISO/IEC 17011/2017 § 7.9.3.

- The CAB's security rules allow to grant remote access to information related to its resources, its procedures and the results of its activities.
- The CAB is adequately equipped, having at least
 - ✓ A computer workstation for the interlocutors of the same assessor in case of simultaneous interventions of team members;
 - ✓ A video-conferencing system to ensure audio and video contact and to allow screen sharing;
 - ✓ A stable internet connection enabling smooth exchanges with the assessment team.
- The assessors have adequate equipment and environment to intervene remotely.
- The level of digitalization of the CAB's information available for review by the assessors for the assessment is sufficient for the scope of the assessment.
- The use of electronic devices does not create risks such as contamination and safety (e.g., explosible atmospheres).
- The use of electronic devices does not create privacy issues (e.g. filming people who were not directly involved in the assessment), unless there has been prior agreement.

3.3 Preparation for the remote assessment

- Check if the general considerations are followed and if all basic requirements are met (technical, security and confidentiality issues).
- Agree on ICT tool to be used, if applicable.
- Consider performing a trial session to check that the chosen ICT system works for all parties to prevent wasting time during the remote assessment. During this session, check that all parties are familiar with the technology, particularly in the management of the audio and screen sharing.
- Prepare an assessment plan detailing whether all or part of the activities will be done remotely, and which member of the team will be working on-site and which remotely (full, remote, or blended assessment). Allow for time for intermediate/frequent internal briefings of the assessment team (to be performed on a private team connection).
- More information and documents may be needed from the CAB prior to the assessment when compared with on-site assessments. Request such additional information sufficiently in advance.
- Create a private communication channel for discussions between the team members.
- Plan the availability of the CAB's key staff members to be assessed at pre-arranged times to improve assessment efficiency.

- Foresee the need to redo/complete some assessment activities in case there are problems with the connection or the outcome of the assessment is ineffective.

3.4 Conducting the remote assessments

- Confirm confidentiality matters.
- Agree on the possibility of screenshots and videos (useful for completion of the assessment report).
- If possible, use more than 1 screen (for simultaneous consultation of document + interaction with CAB).
- It is recommended to take more frequent breaks than for on-site assessments.
- Be flexible on the assessment times, provided that the total assessment duration is not reduced.
- Keep attentive to communication. There is a need to compensate for reduced or lack of visible body language.
- Be ready to cope with scenarios different from the trial session (for e.g., in case a change of ICT is needed), as far as the conditions which were verified during the trial are still met.

3.5 Reporting

- No specific changes to the assessment report templates are needed for remote assessments.
- Specify if there were any limitations.

4 CIRCUMSTANCES WHERE THE USE OF REMOTE TECHNIQUES MAY NOT BE APPROPRIATE

- When it is not possible to meet the specific requirements of some schemes (e.g. on-site assessments are specified).
- When the assessment is planned for initial applications for accreditation and, where relevant, on the basis of a risk analysis, also for extension into new areas and technical fields. It is expected that initial assessments and extensions in new areas or technical fields will be carried out on-site. Nevertheless, there could be exceptions (e.g. for virtual conformity assessment activities) where it is possible for such assessments to be carried out remotely.
- When there is inadequate connectivity for live-streaming.

- When limitations of equipment (e.g. microscopes) may need specialist cameras to be fitted.
- When privacy and security concerns exist in some areas (e.g. healthcare, forensics).
- When some sectors and situations are restricted by the sensory limits of remote techniques (need to hear, smell, feel, have a not limited view), for instance in some situations of witnessing of activities.
- When NAB have not at disposal assessors who have sufficient experience with the use of remote assessment techniques and tools. (need to train assessors to the use of remote techniques).
- When the risk analysis during the planning of an assessment shows that the CAB's accreditation history showed failures in transparency and efficient collaboration (availability of staff during the assessments, ability to provide adequate information and evidences in a timely manner, etc.).