

QUALITY FOR AFRICA



**GUIDELINES FOR
ACCREDITATION BODIES**

REMOTE ASSESSMENTS

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ABBREVIATIONS

AB	Accreditation Body
AFRAC	African Accreditation Cooperation
APAC	Asia Pacific Accreditation Cooperation
CAB	Conformity Assessment Body
EA	European co-operation for Accreditation
EU	European Union
IAF	International Accreditation Forum
ICT	Information and Communication Technology
ILAC	International Laboratory Accreditation System
ISO	International Standards Organisation
SANAS	South African National Accreditation System
SPS	Sanitary and Phytosanitary
TBT	Technical Barriers to Trade
WTO	World Trade Organisation

DEFINITIONS

Accreditation

Third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks.

Accreditation body

Authoritative body that performs accreditation.

Note 1 to entry: The authority of an accreditation body is generally derived from government.

Assessment plan

Description of the activities and arrangements for an assessment.

Conformity Assessment Body

body that performs conformity assessment activities and that can be the object of accreditation.

Conformity Assessment Activity

Activity conducted by a conformity assessment body when assessing conformity including, but are not limited to, testing, calibration, inspection, certification of management systems, persons, products, processes and services, provision of proficiency testing, production of reference materials, validation and verification. For simplicity, these are referred to as conformity assessment activities being performed by conformity assessment bodies.

Desktop review

The review of policies, procedures, files, records, etc. This assessment technique is used under circumstances of low risk or low residual risk, for example, where an extension of range is required to an existing method and equipment, a new test method is requested using an existing measurement platform, or the approval of personnel is supported by a registration or certification scheme.

Remote assessment

Assessment of the physical location or virtual site of a conformity assessment body (CAB) using electronic means.

Note 1 to entry: A virtual site is an online environment allowing persons to execute processes, e.g. in a cloud environment.

Residual risk

The risk remaining after inherent risks have been reduced by risk controls.

NOTE 1: Residual risk can contain unidentified risk.

NOTE 2: Residual risk can also be known as "retained risk". [ISO Guide 73]

Virtual site

An online environment allowing persons to execute processes, or services irrespective of physical locations, e.g. in a cloud environment.

NOTE 1: A virtual site cannot be considered where the processes must be executed in a physical environment, e.g., warehousing, manufacturing, physical testing laboratories, installation or repairs to physical products.

NOTE 2: A virtual site (e.g. company intranet) is considered a single site for the calculation of audit/assessment time.

Witnessing

Observation by the accreditation body (AB) of a conformity assessment body (CAB) carrying out conformity assessment activities within its scope of accreditation.

ACKNOWLEDGEMENT



The global onslaught of the COVID-19 pandemic has forced us to look at the world differently. Never again will our world be the same. A changed world requires new rules and guidance to navigate our way through the “new norm”. The recently revised ISO/IEC 17011:2017, and other conformity assessment standards such as ISO 9000:2015, opened the way for a new approach to the assessment and auditing of conformity assessment procedures through the introduction of remote assessments and remote audits. This guidance document sets out PAQI’s attempt to provide guidance to accreditation bodies and conformity assessment bodies embarking on the optimization of digital technology to augment their assessment and audit processes.

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Finally, I am grateful to the author of this publication, Dr Ron Josias, whose experience and contribution in the field of accreditation and quality infrastructure is reflected in this publication. I hope that this publication is the first PAQI document that will help to navigate us into the “new norm”.

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1 INTRODUCTION

Advances in information and communication technology has opened the path for cost effective and efficient processes. The advances not only challenge existing practices but also introduce various possibilities. Accreditation is not exempt from these developments. The recently revised international standard that lays down the requirements for accreditation bodies (AB's) accrediting conformity assessment bodies (CABs), ISO/IEC 17011:2017, introduced the utilisation of electronic means to conduct assessments, through the introduction of remote assessment. Remote assessment is defined as the assessment of the physical location or virtual site of a CAB using electronic means.

Addressing the impact of the COVID-19 pandemic and the emergence of virtual sites, electronic document management systems and general application of Information and Communication Technology (ICT) in the workplace has hastened the need for the effective implementation of remote assessments to improve the effectiveness and efficiency of the accreditation assessment processes. However, most ICT projects fail due to a lack of proper understanding of what is required, poor planning, poor communication, use of the wrong technologies and the lack of buy-in from all stakeholders. The uptake of ICT based innovations can also introduce problems as many users

have privacy concerns and are wary of information security in web-based transactions. The new post COVID-19 "norm" will certainly be driven by the optimisation of ICT and thus ICT utilization cannot be avoided. Therefore, it is important to understand and evaluate the readiness of the AB and the CAB's to adapt and to optimize the advantages presented by ICT. As a minimum, careful consideration should be given to the readiness, risk, planning, communication, skills and change management prior to embarking on a digitalization strategy.

This informative document aims to support ABs in their quest to implement remote assessments in support of their accreditation assessment activities in compliance with ISO/IEC 17011:2017.

2 SCOPE

This informative document provides guidance for the application of remote assessment of CAB's records, documents, performance of proficiency testing and other inter-laboratory comparisons, as relevant, quality controls, staff evaluation including interviewing and witnessing of activities, through the optimization of ICT.

AB's who comply with or are working towards full compliance to ISO/IEC 17011:2017, should have a documented management system in place that addresses all the requirements of ISO/IEC 17011:2017. This document therefore will not repeat all of the ISO/IEC 17011:2017 requirements or the mandatory requirements of ILAC and IAF. Requirements relating to assessment will be limited to addressing the implementation and management of remote assessments, unless expansion of ISO/IEC 17011 requirements is necessary to assist in understanding the relevance of the requirements to remote assessments.

3 OBJECTIVE

The objective of this document is to support the management of the accreditation integrity and accreditation assessment process by providing guidance on the management and implementation of remote assessments, as permitted by the ISO/IEC 17011:2017 standard.

4 GENERAL REQUIREMENTS

General requirements include cross-cutting requirements that have an impact on the implementation and management of remote assessments. These requirements include information security, confidentiality of information, risk management, eligibility to qualify for remote assessments, structural requirements, resource requirements and where applicable, outsourcing of assessments.

4.1 Information security

The principles of information security are confidentiality, integrity and availability. These principles maintain the protection of data against the unauthorized disclosure of information, the protection against unauthorized modification of data (such as adding, deleting or changing), the protection of the functionality of the support systems and the availability of the data when required by the user.

Therefore, it is important that the AB provides the necessary assurance to its clients and other interested parties, such as the conformity assessment bodies and regulators that they comply with the information and security principles of the ICT protocols for remote assessments. The following guidelines are therefore provided:

- i. The AB should have a clear policy on information security, addressing the management of the key principles as identified above. The legally enforceable agreement between the AB and CAB to adapt to changes in the requirements for accreditation as required by ISO/IEC 17011 par. 4.2a, could address or support the use of ICT and other techniques of assessments.
- ii. To ensure acceptance of the AB's information security, the use of ICT and remote assessments should be mutually agreed upon between the AB and the CAB, prior to the assessment. Any conflicting issue should be resolved before the commencement of the remote assessment process.
- iii. In the case of non-fulfilment or non-agreement to information security measures, the AB should consider other methods to conduct the assessment, such as a face-to-face on-site assessment.

- iv. Should an on-site or face-to-face assessment not be possible, the AB should evaluate its risk and relationship with the CAB in line with its legally binding agreement and the ILAC/IAF requirements.

A clear remote assessment policy and associated procedure(s) suitable to the capabilities of the AB and its client will serve as a good governance tool that sets out the AB's expectations and aligns its staff, contractors and clients to the objective it aims to achieve through the utilization and optimization of ICT.

4.2 Risk management

The AB should identify, analyse, evaluate, treat, monitor and document the risks and opportunities from the use of ICT, its personnel and the associated assessment activities. Any residual risk should be reviewed by the AB to determine if it is within the level of acceptable risk to the AB. If the risk is unacceptable and cannot be mitigated to acceptable levels, then the AB should not embark on the remote assessments (ISO/IEC 17011:2017 par. 7.4.6). Consideration should be given to but not limited to, the following:

- i. The selection of the type of technologies to be used, and how they are managed.
- ii. Secure and reliable infrastructure to support the use of the ICT proposed by both the AB and the CAB.
- iii. The extent to which ICT will be used for assessment purposes while maintaining the integrity of the assessment process. Based on the risks and opportunities, the assessment plan should identify how ICT will be utilized.
- iv. Assessors and other involved persons (e.g. technical experts) competence and ability to understand and utilize the ICT employed to achieve the desired results of the assessment.
- v. The assessor's awareness of the risks and opportunities of the ICT that will be

deployed for remote assessment and the impact that the assessors may have on the validity and objectivity of the information gathered.

- vi. The testing of the effectiveness of the ICT tools before commencing the remote assessment by both parties to the assessment i.e. the assessor and the CAB.

4.3 Eligibility

The possibility exists that not all conformity assessment bodies might qualify for remotely assessment. To ensure eligibility of a CAB as candidate for remote assessment, certain conditions need to be met to protect the integrity of the accreditation and process. These conditions include, but are not limited to the following:

- i. Access by the CAB to the Internet through a fast, reliable internet connection, (E.g. Fibre or 4G/5G).
- ii. Suitable video conferencing or communication software (e.g. Microsoft Teams, Zoom, wearable technology e.g. augmented glasses, or a combination of these technologies, etc.), and associated computer network to enable communication with the CAB as necessary, including opening and closing meetings, and a visual tour of the premises, if needed.
- iii. Confirmation of confidentiality of information that will be accessed via the internet should be obtained before the remote assessment may be scheduled.
- iv. Team members must always have access to CAB documents/records, contact personal and the relevant staff, for interview and/or remote witnessing purposes.
- v. The eligibility of the CAB for remote assessment (i.e., the facility may be contractually obligated, or the scheme or regulator may require CABs to be assessed on-site).
- vi. whether there is a conflict of interest with the parties being assessed remotely.

vii. Whether the CAB permits and accommodates remote assessment activity (i.e., availability of records in electronic format or document reader).

viii. Whether the AB has the capability to conduct the remote assessment in the chosen medium/platform of the remote assessment.

ix. Whether the CAB can share all necessary information to conduct the assessment via the electronic media.

x. Whether a list of activities to be covered by the remote assessment and the personnel involved is available.

4.4 Structural requirements

Structural requirements relate to the ability of both the AB and CAB to accommodate remote assessments. These includes, but is not limited to, ICT infrastructure, hardware, software and internet connectivity. Currently there is no prescribed mode of ICT utilization. Each AB should decide on what works best for them and their clients if the objective of the assessment is to be achieved and the integrity of the accreditation remains sound.

Accreditation requires the review of the management system as well as the verification of technical competence through witnessing. However, challenges with witnessing remains problematic due to a 'third eye view' required by the assessor on the work being observed and the need for the use of both hands by the person being witnessed. The optimization of the ICT currently in use, such as WebEx, Microsoft Teams, Zoom, handheld cameras etc. does not accommodate the challenge of witnessing without major disruptions to the process. Developments within augmented reality space such as wearable technology (data glasses, interactive cameras etc.) are emerging as possible good practice to address the challenges currently experienced with remote witnessing.

The optimisation of ICT for remote assessment can be both positive and negative. These include:

I. Positive aspects

- Ease of scheduling and reduced costs and time (no travel, accommodation, courier cost).
- Personnel safety.
- Assessor monitoring simplified through online monitoring.
- Effective to maintain confidentiality and data integrity.
- Minimization of “assessor burn out” due to long-distance travel prior to an assessment.
- Increased assessor utilization due to elimination of travel time.
- Integrity based assessment due to recording/transcription.
- Value adding to CABs.
- Improved transparency and control.
- Solution for remote locations.
- Allows for longer assessment time.

II. Negative aspects

- Missing non-verbal clues.
- Struggling with internet connectivity.
- Struggling with evidence gathering/ access to information – slow access or non-availability of electronic information (only hard copies).
- Health concerns (e.g. Screen fatigue, dizziness, etc.).
- CAB staff commitment and unease with technology.
- Pre-recorded “staged” demonstrations versus real time witnessing.
- Non-availability of representatives for each assessor due to one shared connection by the CAB.
- Unauthorised participants with access to information.

The following requirements should therefore be considered for an effective and efficient remote assessment:

- i. Access to the Internet through a fast, reliable internet connection, (e.g. Fibre or 4G/5G) by all the team members as well as the CAB.
- ii. To familiarize the assessors with the CAB’s environment, a walkthrough using ICT or other visual communication tools should be used to enable a virtual walk-through of the space relevant to the assessment.

iii. In-advance notification of the documents / records / information required prior to and during an assessment is necessary to avoid struggling with evidence gathering and review. Furthermore, confirmation of confidentiality of information that will be accessed via the internet shall be obtained before the remote assessment may be scheduled.

iv. To avoid the possibility of screen fatigue regular breaks should be agreed on and forms part of the assessment plan.

- v. Team members must always have access to CAB contact personal, and the rest of the staff to be available, as needed.
- vi. Change management programs and open communication to manage probable resistance to the new technologies should be considered for both the AB personnel and assessors as well as and the CAB's personnel.
- vii. Remote witnessing to be in real time, not pre-recorded or staged.
- viii. Arrangements to be made to cater for each assessor's needs with a CAB representative

The AB shall ensure data security and confidentiality (i.e. no unauthorised third party is privy to the assessment and information being shared, e.g. use of own laptop, email, no external views on CAB's information).

4.5 Avoidance of ICT project failure

Failure of ICT project and tools especially as it relates to remote assessment could lead to financial loss, business reputational harm, and the loss of customers loss of staff /assessor morale and deterioration of stakeholder relations. In addition to the requirements noted under 4.4, the following, non-exhaustive requirements should be considered when developing, rolling out and managing the ICT infrastructure:

- i. Ensure alignment of the ICT technology to the capabilities of the AB and the CAB.
- ii. Availability of competent ICT support staff who can immediately respond to any ICT related challenges experienced as well as support the ICT training needs of the users.
- iii. Establish a clear line of authority, responsibility and communication amongst the assessment team members, staff of the CAB and relevant managers.
- iv. Develop and roll-out a suitable mechanism to gather, evaluate and monitor feedback.

4.6 Change management and resource requirements

Remote assessment introduces a new way of work for most AB staff and ABs customers. It is generally accepted that most ICT programs fail due poor communication, underestimating or ignoring the impact of change, lack of leadership and resistance to the use of the new technology. Change management, therefore, becomes particularly important. Change management may include approaches to prepare, support and help staff, assessors, the ABs and relevant stakeholders. The extent of the interventions should be determined by each AB. However, at least the following could be considered:

- i. Provide personal counselling, if required, to alleviate any change related fears.
- ii. Develop and implement effective education, training and skill upgrade schemes for the AB.
- iii. Develop and implement a clear verbal and written communication strategy.
- iv. Act swiftly on feedback received from users.

The AB should review its ability to carry out the remote assessment of the CAB, in terms of its own policy and procedures, its competence in performing remote assessments and the availability of suitably qualified and competent personnel for the assessment activities and decision-making.

4.7 Outsourcing (ISO/IEC 17011:2017 par. 6.4.5b)

Although outsourcing of the accreditation activities is not preferred, some instances exist that might require outsourcing. However, the AB cannot outsource its decision-making and the AB shall remain responsible for all activities outsourced. Should the AB decide to outsource its remote assessment function or part thereof, it should ensure that:

- i. It has enforceable arrangements in place covering the outsourcing arrangement which should include information security (see 4.1), confidentiality and conflict of interest.
- ii. The AB should ensure that the body that provides the remote assessment outsourced services, and the individuals they use, conform to requirements of the AB and also to the applicable provisions of the ISO/IEC 17011:2017, including competence, impartiality and confidentiality.
- iii. The AB should approve and monitor the body to which it has or plans to outsource remote assessment activities.
- iv. The AB should obtain the consent of the CAB to use a particular provider of any outsourced scope.
- v. The outsourced body shall also have the ICT capabilities required for a successful remote assessment.

5 PLANNING THE REMOTE ASSESSMENT

Planning is the pillar for a successful remote assessment as it will guide the conduct of the assessment proceedings. The plan defines the scope, resources and execution of the remote assessment processes. It is therefore important that the AB develops an assessment plan which should include the planned duration and time-frame for the remote assessment, a list of activities, sample of the locations, the personnel to be witnessed and the ICT medium through which the remote assessment will be conducted. It should specify which part shall be conducted virtually and which are to be performed via other assessment techniques, as applicable, as well as the personnel and scope to be assessed and witnessed remotely. Additional time may be needed to facilitate remote assessments.

As a minimum the planning phase should define and ensure the following for the remote assessment (APAC, 2020) (IAF, 2015) (SANAS, 2020):

- i. Agenda and the assessment plan, which covers the scope for review and witnessing during the remote assessment.
- ii. The documents, including records that need to be submitted prior to, and available during the remote assessment.
- iii. The availability of the relevant CAB personnel.
- iv. Appropriate remote access to the documents used by the client.
- v. Sufficient time for training on how to access and navigate any document management software and controls/permissions.
- vi. A plan on how to review the information that cannot be shared remotely (e.g. due to confidentiality or access issues). The AB should define or express how this will be dealt with (e.g. follow-up, issuance of a non-conformance, etc.).

5.1 Responsibilities of the AB

The AB should ensure that:

- i. The CAB meets the minimum eligibility requirements (see 4.3).

- ii. The CAB makes available a person(s) responsible for facilitating, managing and coordinating all arrangements to enable an effective and efficient remote assessment. This should include ICT support competencies.
- iii. The CAB provides all pre-selected documents/records/files within the timelines specified by the AB.
- iv. The CAB provides a summary of the key changes that has occurred since its last assessment (e.g. key personnel changes, organizational changes, equipment, accredited methods etc.).
- v. The CAB enabled AB and CAB security and/or profile access to persons involved in the assessment (e.g. assessors, relevant CAB staff).
- vi. The CAB tests the ICT compatibility between the assessor(s) and the CAB before the assessment by performing a trial run.
- vii. There is an agreement between the AB and CAB for the recording of remote activities, including discussions that take place, prior to the assessment. This includes arrangements for storage and disposal of recordings (Note: this could form part of the legally binding agreement).

5.2 Scheduling considerations

Scheduling requires the following to be carefully considered:

- i. Time zone acknowledgement and management to coordinate reasonable and mutually agreeable convening times.
- ii. A trial meeting using the same media platforms agreed upon should be conducted to ensure the scheduled assessment will perform as planned.
- iii. Proper security measures should be taken, when applicable, to protect confidential information.

6 EXECUTION

The execution phase of the remote assessment process involves the implementation of the assessment plan and the review of the CAB documents. Remote assessments shall follow as closely as possible the usual assessment process established in ISO/IEC 17011:2017. The execution phase normally covers a preliminary preparatory meeting between the team members, the opening meeting, the assessment, a private meeting between the assessors to consolidate their feedback and possible findings and the closing meeting. The normal assessment process aligned to the requirements of ISO/IEC 17011:2017 should be followed, however, for the execution of the remote assessment, the following should be considered:

- i. As far as possible, the meetings and assessment should be facilitated in quiet and secure environments to avoid interference and background noise and ensure information security.
- ii. The most effective ICT for the specific activity should be chosen. Multiple types of ICT may be considered during the same assessment e.g. Microsoft Teams, Zoom, WebEx etc. for the meetings and staff interview, and cameras, phones, wearable technology e.g. augmented reality for technical witnessing.
- iii. In the event of ICT failure or experiencing internet connection challenges, the AB should at least attempt to use a cellphone or other means to continue the assessment.

6.1 Management system review

A desk review may be conducted on documents requested by the AB prior to the assessment to minimize the online session. This information may include:

- i. Results of a self-assessment conducted (where applicable).
- ii. Evidence of an internal audit conducted, and the clearance of any findings raised during the internal audit.
- iii. Management Review minutes/records.
- iv. List of appeals and complaints and the resolution thereof.

6.2 Technical witnessing

In preparation for the witnessing and to reduce time spent online, the following documents / records may be requested and reviewed prior to the assessment:

- i. Results of Proficiency Testing (PT) and PT plan, Inter-laboratory comparison participation and actions taken where needed.
- ii. A list and description of Certificates or Reports issued since the last assessment, to enable the selection of several certificates and or reports to conduct an assessment(s).

EXECUTION STAGES	GUIDELINES
Team preliminary meeting	<p>a. Can be conducted using remote meeting enabling technology such as Zoom, WebEx, MS Teams etc. the Team may decide on the technology to be used;</p>
Opening meeting	<p>a. Can be conducted using remote meeting enabling technology such as Zoom, WebEx, MS Teams etc. with the CAB representatives.</p> <p>b. The Team and CAB may decide on the technology to be used.</p>
Management System assessment and interviews	<p>a. Can be conducted utilizing remote meeting enabling technology such as Zoom, WebEx, Microsoft Teams etc. with the CAB representatives.</p> <p>b. The Team and CAB may decide on the technology to be used.</p>
Technical witnessing and interviews	<p>a. A combination of technologies might be used such as a combination of Zoom, or WebEx, or Microsoft Teams and augmented reality glasses, or a combination of Zoom, WebEx, Microsoft Teams and video camera(s).</p> <p>b. The type of technology used might be dictated by the scheme (Certification, Inspection, testing etc.) being assessed.</p> <p>c. The optimum technology will allow for a “third eye” view of the activity and person being assessed as well as freeing the person to perform the function without restricting or obstructing the normal performance of the persons work.</p> <p>d. In such cases where a witnessing/observation is not possible, an assessment of work completed, a recording of the work performed and/or a review of key documents may support the witnessing objective. However, the acceptability of these alternative arrangements must be verified with the relevant Regional Cooperation and the ILAC and IAF.</p>
Assessment team meeting	<p>a. Can be conducted using remote meeting enabling technology such as Zoom, WebEx, Ms Teams etc. the Team may decide the technology to be used.</p>
Closing meeting	<p>a. Can be conducted using remote meeting enabling technology such as Zoom, WebEx, MS Teams etc. with the CAB representatives.</p> <p>b. The Team and CAB may decide on the technology to be used.</p>

7 REPORTING

The reporting phase deals with the compilation of assessment evidence, reports, records and lessons learnt to aid the decision-making structure in making the accreditation decision as well as assisting the AB to fine-tune and improve its remote assessment strategy. The following should be considered (APAC, 2020):

- i. The assessment reports and related records should indicate whether the assessment was conducted on-site or remotely, the extent to which ICT has been used in carrying out assessment and the effectiveness of ICT in achieving the assessment objectives.
- ii. If virtual sites are included within the scope, the accreditation documentation (e.g. assessment report) should note that virtual sites are included, and the activities performed at the virtual sites should be identified.
- iii. The assessment report should include the details of the records reviewed and any findings. Both parties should make their best efforts to confirm what was heard, stated, and read throughout the assessment.
- iv. Assessment findings (Nonconformities, opportunities for improvement, etc.) should be drafted by assessment team members and provided to the CAB in writing promptly after the assessment for review and acknowledgment. The normal AB procedures should be followed.
- v. The CAB should respond to all assessment findings per the normal AB procedures.
- vi. The AB should consider its process for obtaining official signature or acknowledgment requirements for remote assessment documentation. Measures should be taken to assure the integrity of the final documentation.
- vii. Communication between the assessor(s) and the CAB for sending documents or clarification on issues and corrective action management should be pre-defined and communicated.
- viii. The assessor should confirm the deletion of any confidential documents, images, recordings, etc. per prior arrangements.
- ix. The closure of remote assessment nonconformities, review of assessment deliverables, and accreditation decision-making process (granting, renewal, extension, suspension, reducing, withdrawal) should follow the same processes that are used for on-site assessments.

8 EXTENDING ACCREDITATION (COVID -19)

Where a scheduled on-site or remote assessment cannot be performed by the AB or through subcontracting to an IAF MLA/ILAC MRA signatory, as a result of the ongoing COVID-19 pandemic, the assessment may be replaced with an off-site review of documentation to provide assurance of the CAB's on-going competence. The concession for the review of documentation should only be considered if the justifications for not being able to conduct the on-site or remote assessment are traced back to the exceptional situation due to COVID-19.

After the review of documentation, if neither a remote assessment or an on-site assessment has been conducted within 12 months from the date of the document review, for reasons not attributable to the AB, the AB shall normally initiate the process for suspension or withdrawal of the CAB's accreditation status.

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