TIC Council

Horizontal Task Force on Remote Activities

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Remote Activities of Conformity Assessment

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TIC COUNCIL

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1. INTRODUCTION

TIC Council is a global association representing over 90 international independent third-party testing, inspection, certification and verification organizations. Testing, Inspection and Certification (TIC) companies represent an estimated one million employees across the world, cater to a diverse range of industry sectors on the bases of a variety of standards and legislation and regulations. The members of the TIC Council stand for the competence and integrity of their personnel and contribute with their TIC activities to safe and high-quality products. At the same time, they are open to use and adopt new technologies for their worldwide conformity assessment activities, such as remote activities, which is facilitated by the increasing digitalization and its broader acceptance.

2. OBJECTIVE and SCOPE

This document represents the position of the TIC industry and provides guidance on the use of remote conformity assessment activities by considering the related possibilities and limitations, and it aims to strengthen confidence in their use, as appropriate.

With this document the TIC Council contributes to a better understanding, consistent application and higher acceptance and trust in the use of remote techniques in conformity assessment activities among customers, regulators, scheme owners, industry and employees for appropriate use of remote activities. It is addressed to all TIC stakeholders, including conformity assessment bodies, industry, customers, accreditors, regulators, scheme owners, sectors, employees and insurers.

This document covers the application of remote activities for all types of conformity assessment based on relevant procedures, standards and/or regulations. Remote activities may be applied to certification of products, management systems, processes, services and persons, as well as testing, inspection, validation and verification.

3. BACKGROUND

The use of remote activities in conformity assessment is not new. Many industries have utilized them for decades, and they will continue to be used in the future since current practice is showing the value that remote activities bring to the conformity assessment process.

The COVID-19 pandemic resulted in some necessary deviations from the established conformity assessment practices in many sectors. Where traditional onsite activities could not be performed, they were sometimes replaced, on a temporary basis, by remote activities. Based on the accumulated experience during the pandemic, the stakeholders in the global conformity assessment community and trade are now evaluating the potential for further extending the use of remote conformity assessment activities. While the TIC sector has continued to incorporate new techniques, the pandemic has significantly accelerated the adoption of remote activities and acted as a booster.

The need for and the usefulness of remote activities is also evident in other unforeseeable situations, such as natural disasters, unrest or conflicts which prevent the usual onsite activities, and of course, other circumstances that demand remote approaches will continue to arise.

Conformity assessment using remote techniques has provided evidence that, in most cases, it is the most effective solution to maintaining worldwide trade in compliance with the quality, health, safety and environmental restrictions imposed by the pandemic while, at the same time, ensuring the integrity of products and services, enhancing sustainability, and achieving a measure of CO2 reduction.

The use of remote activities is not intended to completely replace onsite conformity assessments. It is another option that can be used in certain cases or as a supplement to established procedures. Remote activities have clearly demonstrated their value in critical situations. Therefore, there is now a renewed emphasis in their routine incorporation in conformity assessment.

The undertaking of remote activities has not posed any acceptance problem where it already forms part of the usual conformity assessment such as the inspection of wind turbines with unmanned drones. In some other cases, customers may be reluctant to accommodate remote activities, e.g., in non-familiar situations. Nevertheless, it has been shown that remote activities, in certain scenarios, allow for a deeper and better verification, e.g., review of imaging, documents and recordings.

4. KEY PARAMETERS AND LIMITATIONS REGARDING THE USE OF REMOTE TECHNIQUES

The key parameters in decisions to use remote activities are:

- Integrity, efficiency and effectiveness of the process, including impartiality, quality of work and validity of results,
- The risk level related to the conformity assessment process,
- The safety of people involved in the conformity assessment activities,
- The ability to fully assess the compliance with the relevant requirements for safety, impartiality, reliability and integrity, and to ensure equivalency to onsite assessments,
- The level of confidence in the conformity assessment process from the perspective of the conformity assessment provider, the customer and other stakeholders, such as regulators,
- The protection of confidential and proprietary data and information, so as not to compromise the integrity of the process, and
- Circumstances where environmental, health and safety and security requirements make conformity assessment using remote techniques the only feasible solution or an unacceptable solution.

The decisions to use remote activities must take these essential parameters and elements into account.

As an additional technique in applying the TIC conformity assessment technique toolbox, remote activities may be used to demonstrate compliance when all of the above criteria are met. Moreover, they may provide more agility in situations where an additional, alternative or complementary conformity assessment activity is needed or where people's safety can be at risk.

In all contexts, it is essential to ensure that expected outcomes of remote conformity assessment activities are equivalent to those of the traditional onsite activities. In special situations where no in-person options exist, further considerations may be required. These expected outcomes should be considered in terms of the identified key parameters – confidence in the conformity assessment process and its objectives (e.g., product safety, reliability, etc.), people safety, and information security. The methods used to provide remote conformity assessment activities need not be the same, as long as the outcomes remain equivalent.

The specific criteria for judging equivalency and acceptability are to be determined by the scheme owner or regulator.

Customers' understanding of remote conformity assessment requirements and willingness to cooperate are also essential pre-requisites for remote conformity assessment activities.

All of the above principles apply also to "hybrid" conformity assessment activities which involve combined onsite and remote activities taking place usually at the same time. (Some accreditation bodies use the term "blended" for such activities.) A hybrid approach makes sense where a fully remote activity is not practical, e.g., when specialized expertise may be required or additional activities are necessary at different times.

Hybrid approaches could be used for, e.g.,

- Assessment of testing labs,
- Inspection of food production facilities,
- Complex product manufacturing facilities, and
- Inspection of hazardous products or facilities, e.g., involving potential explosion hazards or contaminants.

Remote conformity assessment is an established practice in difficult to access locations, such as:

- Underwater cables,
- Marine windfarms,
- Hazardous areas with restricted access, e.g., tests or inspections in areas with radiation or bio-hazards, and

- Pipeline inspections, etc.

Furthermore, remote conformity assessment activities have also been used widely in:

- Documentation audits, e.g. management system audits,
- Interviews of people,
- Remote witnessing of tests (with periodic onsite validation),
- Basic visual consignment inspections, and
- Remote diagnostic measurements (e.g., remote temperature measurement, remote thermal severity profile).

Although there is no doubt that remote activities are gaining more and more recognition and are thus used more frequently, there are nevertheless limiting factors, such as:

- Required use of some human senses that cannot be easily duplicated by today's technology – smell, hearing (low level, high frequency sounds), 3D vision, use of tactile senses (softness or hardness), visual assessment of general cleanliness of a facility,
- Legislative/regulatory provisions or schemes, which only accept onsite conformity assessment activities,
- Contentious situations where there is lack of collaboration or risk of conflict, and
- First-time new client or new product type.

These limiting factors must be considered when determining the extent and permissibility of remote activities.

The time spent in certain remote conformity assessment activities may also be a limiting factor due to the stress and fatigue resulting from the need for intensive concentration required for online work with various devices. Remote activities must be structured to take that factor into account.

5. RELEVANT CONFORMITY ASSESSMENT ACTIVITIES AND ASSESSMENT OF RISK

In general, the specified requirements, the object of conformity assessment and the resulting attestation of conformity assessment must be the same for onsite or remote situations.

Therefore, it is important to not refer to "remote conformity assessment", but rather to particular assessment activities which are conducted remotely instead of on site.

Specifically, the functions of selection (planning, preparation and sampling) and determination (testing, inspection, audit, validation, verification and assessment) are the same in onsite and remote situations. (See ISO/IEC 17000 for a description of the functional approach.)

The selection and determination activities can be carried out remotely depending on:

- The kind/type of specified requirements,
- The type, size, form and configuration of object of conformity assessment including test items, products, systems, installations or sites,
- The assessment method (including procedures, techniques and tools), and
- Qualifications of customer staff collecting the data.

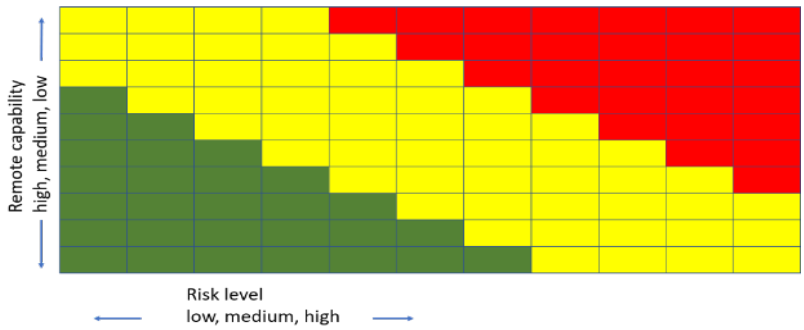
The decision to conduct remote activities, which traditionally have been conducted onsite, should follow a risk-based approach. The relevant risks to be considered are the risks related to the key parameters identified in Section 4 – integrity, ability, confidence, safety, and data security.

Specifically, the risk assessment should focus on:

- The additional risk of not detecting a non-conformity due to not having complete information in a remote activity, e.g., selecting a non-representative sample, limited camera view, or limited bandwidth, and
- Safety of people involved in conformity assessment activities.

The written justification of the decision should be included in the TIC service documentation and should be available to the customer, to the conformity assessment body's own employees as well as for the accreditation bodies, the regulatory authorities and scheme owners.

The decision criteria should be determined, for example, by utilizing the concept represented graphically in Figure 1.



In the diagram, red areas denote unacceptable risks and green areas are for acceptable risk.

- Define the boundaries of the red and green areas for each activity and object of assessment.

- For simplification, each CAB should develop two lists – a list of green (go) activities and a list of red (no go) activities.

- The activities that are not on either list should undergo additional risk assessment and decision on a case-by-case basis.

Annex 1 gives a more detailed description of how to proceed with the assessment of risk and provides some examples.

6. TECHNICAL AND PROCESS ISSUES

The conformity assessment body should provide a clear description of the remote activity process, including the preliminary requirements, the different steps of the process, a guidance on the technique to be used and the methodology adopted.

The scope of a proposed remote conformity assessment activity should be reviewed during the planning phase and confirmed as practical and achievable, and adapted if necessary.

Furthermore, the description should include:

- How the instructions are given,

- How the results are reported and submitted to the customer, and

- The terms of use for the data acquired during the assessment, including pictures and video recordings.

An accredited conformity assessment body must ensure that the relevant accreditation body accepts the planned arrangements for remote activities.

An essential prerequisite for successful remote activities is a well-functioning connection (for example internet, telephone) and reliable technical equipment. However, there is a risk that the time will be significantly longer due to unforeseen situations such as power outages or WiFi malfunction.

When performing remote activities, the customer and the conformity assessment body should ensure the onsite availability of the required equipment and services. See Annex 2 for details to be considered.

Additional training and qualifications may need to be carried out, covering the communication and information technology used, within the relevant scope, in order to fully qualify the people engaged in remote activities. Records of the persons qualified for remote activities should be maintained and updated as per the applicable procedures.

7. SUMMARY

Taking into account that conformity assessment activities span many different fields with established practices accepted by the regulators and the market, the recommendations of this paper are focused on potential future changes and enhancements to those practices, through appropriate use of remote conformity assessment activities.

For such remote activities:

- The objectives and the requirements of conformity assessment must remain the same and the expected outcomes of conducting onsite, remote, hybrid or mixed activities must remain equivalent.

- The decision to conduct activities remotely is to be taken with care, based on an assessment of feasibility, acceptability (including regulations or schemes rules) and risk.

- The risk assessment process should be transparent and should apply the general criteria outlined in this paper.

With the above qualifications, remote conformity assessment activities can serve to supplement physical onsite activities.

Remote activities thereby enhance the established procedures and provide added value, such as:

- Improve the availability of specialized expertise needed for specific tasks

- Saving of travel-related resources,

- Enhanced safety of personnel,

- Provide an acceptable alternative measure to maintain business continuity in cases of natural disasters, pandemic, social disruptions, etc.,

- Easier recording, securing and transmission of data, pictures and documents

- Subsequently verifiable, detailed close-up images, and

- Opportunities for process and accuracy improvements by facilitating the evaluation and gathering of evidence by remotely utilizing techniques such as high-resolution video analysis, etc.

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Editor's Note About TIC Council

TIC Council is the global trade federation representing the independent third-party Testing, Inspection and Certification (TIC) industry which brings together more than 90-member companies and organizations from around the world to speak with one voice. Its members provide services across a wide range of sectors: consumer products, medical devices, petroleum, mining and metals, food, and agriculture among others. Through provision of these services, TIC Council members assure that not only regulatory requirements are met, but also that reliability, economic value, and sustainability are enhanced. TIC Council's members are present in more than 160 countries and employ more than 300,000 people across the globe.

The Value of TIC Report

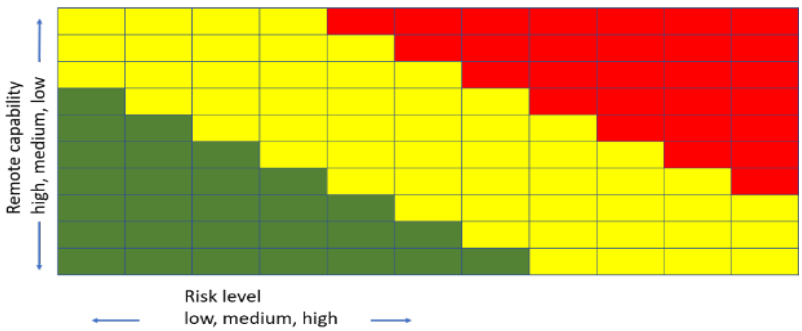
To learn more about TIC Council and its member's activities, the landmark report on the Value of the TIC sector, developed jointly by the international law firm Steptoe and the London-based consultancy Europe Economics is now available to read. This report illustrates, by using data and case studies, how the TIC sector benefits a variety of stakeholders and industries around the world. You can find the study here, and we welcome you to share it with anyone who might be interested.

ANNEX 1

Annex 1 provides additional guidance on the risk assessment process outlined in Section 5 with some examples of how it can apply in auditing, type examination, inspection, etc.

It is important to note that the same products or systems bear different risks depending on the type of remote activity used, as well as on the applied requirements.

The following examples refer to the illustration in Section 5.



Graphical illustration of defined acceptance criteria for remote activities - red areas for high risks, green areas for suitable application, and yellow areas for applications that require case-by case risk analysis and decision.

Example 1: Examination of a highly regulated product (e.g., Lift, under the EU Lift Directive)

- The product "Lift" can appear in the "Green List" area for remote activities, when associated with conformity assessment activities such as:
  - Assessment of amendments to an already existing "EU type examination certificate" (modifications) or
  - "Conformity to type" with random checking for safety components for lifts (factory checks)
- The same product ("Lift") must appear in the "Red List" for remote activities, when assessed as:
  - New EU type examination (new product, new customer) or
  - Periodic third-party Inspection (recurrent inspections with complex inspection activities)

Example 2: Auditing of a Quality Management System

- People interviews and document review are well suited to be audited remotely. Companies without physical production (data processing, programming, etc.) can be on the green list and can be audited 100% remotely.

- Physical production facilities or warehouses are on the red list and parts can be audited remotely up to some specified maximum level.

- Remote activities can also be useful for companies with several locations: one manufacturing location (e.g., Germany), two sales offices (e.g., France and Netherlands) - sales offices can be audited 100% remotely.

The lists described in Section 5 should be structured to take into account both the product or system and the activity to be carried out.

Particular attention should be paid to the yellow areas in the diagram where risk-based decisions are needed in the wide range of cases and applications in the TIC sector.

As outlined in Sections 4 and 5, the risks must be analyzed in terms of the key parameters, i.e., integrity, ability, confidence, safety, data security, and decisions must be made on how to perform the required conformity assessment – onsite, fully remotely, or using the hybrid approach.

The "ability" should be analyzed by reviewing the existing conditions and situations, the availability and qualifications of the personnel involved, as well as the required facilities and equipment.

From the point of view of integrity (including independence and reliability) of the results, as well as the related confidence, the hybrid approach, with a data collection person onsite, comes closest to onsite conformity assessment, so this alternative should always be considered first.

The evaluation of risks related to confidence, safety and data security in remote activities can include an analysis of the differences between remote and onsite activities. Existing ISO standards can be used as a basis for such analysis. For example, for product certification:

- ISO 12100: 2010 – Safety of Machinery – General principles for design – Risk assessment and risk reduction

- ISO 14798:2009 – Lifts (elevators), escalators and moving walks – Risk assessment and reduction methodology

- ISO 14971:2019 – Medical devices – Application of risk management to medical devices

Opportunities to mitigate the identified risks through some further alternative solutions should be considered and should be documented.

Generally accepted risk assessment methods, such as the rating of a combination of “frequency” and “severity” of any identified risk (related to our key parameters) can be used to quantify and compare the residual risks associated with the proposed remote activity and the traditional, accepted method. The newly determined risk class (combination of “severity” and “frequency”) should be smaller than or equal to the risk class of the conventional method.

To properly document this process, it is advisable to utilize a procedure used in international standards, i.e., preparing a table with the expected risks arising from the use of remote assessment. (“List of significant hazards”, based on the key parameters listed in Sections 4 and 5).

When preparing a risk assessment for complex situations, this table could be used to identify various scenarios, including hazardous situations, harmful events (cause and effect), on a case-by-case basis, if needed, and could be incorporated into a risk assessment according to the attached flowchart.

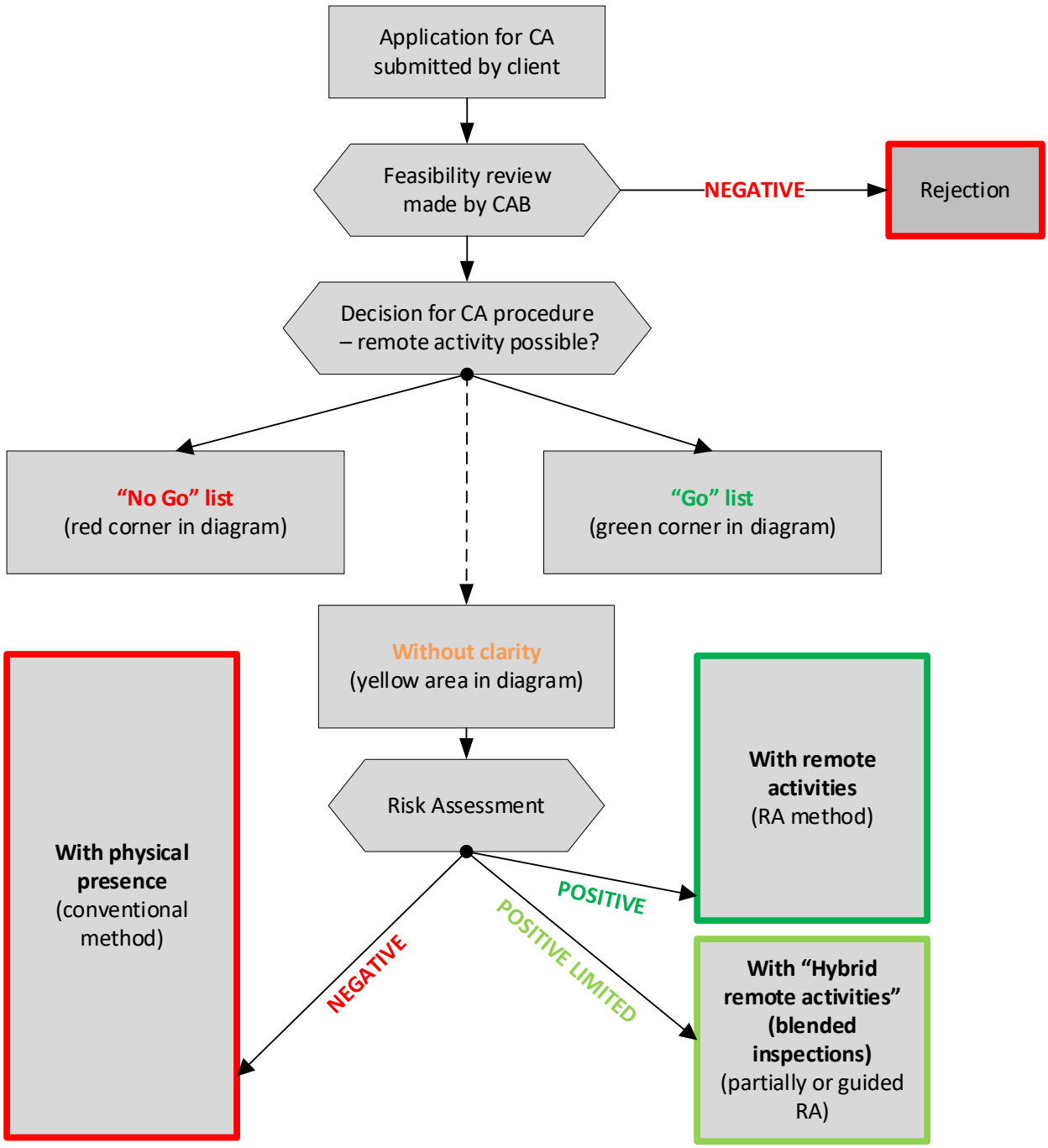
The risk related to activities and situations that have not been clearly categorized in a “Go” or “No Go” list, should not be underestimated.

In general, the decision to perform an assessment remotely or in the hybrid format, should be based on clearly specified “Go/No Go” lists.

In other cases, a comprehensive evaluation of the associated risks should be carried out.

New technologies and techniques for remote conformity assessment activities that fulfil the criteria of Section 4 should be included in the "Go" and "No Go" lists on an ongoing basis. However, the details of the related risk assessments must be clearly documented.

Figure 2: Illustrated example of a possible process flow



ANNEX 2

Annex 2 refers to section 6 and gives more details to be considered regarding performing remote activities. The customer and the conformity assessment body should ensure on site availability of certain equipment and services such as support services, IT services and others.

On site, the customer should provide:

- Internet connection of a quality suitable for the software/technology used to perform the remote activity, allowing the auditor or other assessing personnel and the customer to properly interact,
- A smart device with built in camera, compatible with the software/technology used,
- Skilled personnel to operate the smart device,
- Communication accessories like heavy duty headphones and microphone for noisy/industrial environment,
- Devices/accessories suitable for the hazardous area where the activity will be carried out.

The audio/video software or app used to perform the remote activity is to be checked and accepted by the CAB, if the CAB is nor providing them, in terms of:

- Quality of images and audio available to the auditor,
- Interoperability and compatibility of the technology, including formats,
- Consideration and fulfillment of cybersecurity requirements,
- Protection and confidentiality of the data transmitted, e.g., through encryption.

The CAB should verify or confirm and test for the proper working order of the equipment and services provided by the customer, in advance.

The software used to perform the remote activity may have technologies that support the auditor or other assessing personnel in the process of decision making like:

- Artificial Intelligence for the recognition and classification of defects,
- IoT for collecting parameters and evaluate acceptability/working condition of machineries, equipment or other devices,
- Other means considered acceptable by the CAB

Again, in such cases the software and technologies are to be accepted by the CAB prior to their use.

Proper preparation and planning of the remote activity is to be done in advance of the activity and should include a pre-meeting to ensure that:

- The audio/video software or app is working properly,
- Internet connection is satisfactory in respect to the audio/video software or app used and proper communication capabilities are provided,
- The onsite personnel operating the smart device are properly skilled in using the technology.

To perform the remote activity, one or more of the following are to be provided:

- Live-streaming video and audio,
- Recorded videos and/or audio provided by the customer,
- Photos provided by the customer,
- Other data and/or supporting documents acceptable to the CAB.

Authorization for collecting such evidence is to be obtained from the customer by the CAB.

When considered necessary and before starting the activity, the on-site personnel engaged in remote activities is to be trained and qualified as per standard procedures for the type of activity, and in accordance with the applicable scheme.

Files of all evidence, e.g., videos and/or photos should be retained at least for the period for which the issued attestation of conformity is valid plus a time period agreed by the conformity assessment body or other relevant entities.

The possibility for the conformity assessment body to retain evidence, videos, photos and audio recordings relevant to the object of the remote activity is to be considered an opportunity to avoid future potential risks for the CAB to be involved in complaints, disputes, proceedings or potential accreditation suspensions/withdrawals