

OEF-42: Guidance for Remote Assessment of CABs because of Extraordinary Circumstances (COVID-19) affecting ESYD Accredited Bodies and their Customers

Issued by: Quality Manager

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1. Introduction

The definition and conditions under which ESYD can choose the remote assessment procedure are described in paragraph 4 of OEF-41.

2. Scope

Provided that the conditions/cases of paragraph 4 of OEF-41 are met, the remote assessment may be used in accordance with the scope described in the table below.

SCOPE OF REMOTE ASSESSMENT FOR BODIES ACCREDITATION PROCEDURES

No.	<u>Accreditation Procedure</u>	<u>Application / Conduct</u>	<u>Methodology</u>
1	Initial Accreditation	<p>ESYD, during the COVID-19 pandemic conditions, will not accept applications for initial accreditation, as well as submission of studies for initial recognition of certification schemes, according to ISO/IEC 17024.</p> <p>In addition, during the same period, no initial assessments will be carried out on already submitted applications, for which the accreditation process is ongoing.</p>	
2	Extension	<p>Applications for extension of accreditation to be submitted during the crisis will be managed in accordance with the following:</p> <p>1. If the requested accreditation extension falls within the scope of §12.4 of ESYD Accreditation Procedures (ESYD PA), the provisions of the aforementioned paragraph of ESYD PA will be followed.</p> <p>2. In any other case, part of the Conformity Assessment Body (CAB) assessment may be carried out through remote access.</p> <p>In order for ESYD to examine the fulfillment of the necessary conditions to conduct part of the assessment through remote access, a request</p>	<p>Within four months from the removal of the conditions that required the assessment at the CAB's head offices through remote access, supplementary assessment shall be carried out with the physical presence of the assessment team at the CAB's head offices, if necessary, on the basis of the results of the risk assessment or/and experience gained from implementing remote assessment.</p> <p>The witnessed assessments are carried out in accordance with ESYD procedures.</p>

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should be made by the CAB for remote assessment. The request should be accompanied by procedures / instructions and any relevant documentation, including at least description of the necessary infrastructure and all the relevant information, justifying its adequacy.

3. It should be noted that remote assessment concerns only the assessment at the head offices of the CAB (i.e., the review of documents and records and interviews with the personnel of the CAB involved) and only if the required conditions/ technical infrastructures / prerequisites are ensured (see IAF MD4) and approved by ESYD, on the basis of a risk assessment and following a review, among others, of the relevant procedures of each CAB. In preparing the risk assessment by ESYD, it will be evaluated whether, due to the nature, object and specificities of the requested scope of accreditation extension, it is possible to apply the assessment at the head offices of the CAB through remote access and the extent of the provision will be determined.

(Taking into account the results of the risk assessment, it may be decided to carry out only part of the assessment at the CAB's head offices through remote access).

In the frame of the review of the procedures of each CAB, regarding the availability of the related infrastructure and its intended use, based on the provisions of IAF MD4, appropriate tests shall be carried out to verify the proper functioning of the equipment available to ensure the smooth performance of the assessment through remote access. In order to carry out the assessment effectively through remote access, appropriate adjustment of the initially planned assessment time is required (i.e., the estimated assessment time

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		with physical presence at the head offices of the CAB).	
3	Surveillance	<p>The CAB Surveillance may be transferred for an additional 6-month period, after CAB request and ESYD decision. In any case, merging of surveillances will be avoided. During the additional 6-month period, head office and witnessed assessments will be carried out.</p> <p><i>Regarding implementation of remote assessments see above (cl. 2).</i></p> <p>The witnessed assessments are carried out in accordance with ESYD procedures.</p>	
4	Reassessment	<p>In the case of CAB reassessment, ESYD intends to provide an additional maximum 6-month extension (plus to initial 6 months), if the crisis continues for the next 3 months (starting from March 2020 and until the end of the year), after CAB request and ESYD decision.</p> <p><i>Regarding implementation of remote assessments see above (cl. 2).</i></p> <p>The witnessed assessments are carried out in accordance with ESYD procedures.</p>	<p>The total extension period is 12 months under conditions.</p> <p>In any case, the 5-year certificate validity period shall not be exceeded. (e.g. accreditation certificates which, after a 6-month extension, expire between March 2020 and December 2020, may be extended for a further 6 month-period under conditions. In any case, the 5-year certificate validity period shall not be exceeded.)</p>
5	Transitions	<p><i>Regarding implementation of remote assessments see above (cl. 2).</i></p> <p>The witnessed assessments are carried out in accordance with ESYD procedures.</p>	

1. The Risk Assessment intended for remote assessment shall also necessarily include the risk of impartiality and objectivity by the CAB that the exclusive use of information and telecommunications technologies may bring and the ways in which ESYD manages the risk involved. The Lead Assessor shall inform participating Assessors / Experts for these risks, in the preparation of the team.

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2. In any case of management of remote access technology, the following documents shall apply:
 - IAF ID 3:2011 - Extraordinary Events or Circumstances Affecting ABs, CABs and Certified Organizations
 - IAF MD 4:2018 - Use of ICT for Auditing /Assessment Purposes
 - IAF ID 12:2015 - Principle on Remote Assessment

Remote assessment equipment must be declared from the beginning by the CAB, in the initial phase of the process, as well as relevant platforms (e.g. Go To Meeting, Webex, Microsoft Lync, Skype Business, etc.) and a pilot implementation of good functioning by the CAB is required, prior to assessment, in order to avoid failures during assessment.

3. Documents – How to fill

The documents used for remote assessments are those used in assessments and referred to in ESYD procedures. The Lead Assessor / Assessor shall record the range of the use of information and telecommunications technologies and retain copies (screen shots or other) of the relevant conversations/exchanges of communication/ or a calendar recording thereof. **Lead Assessor should report to ESYD on the effectiveness of the use of information and telecommunications technologies during remote assessment.**

(The Lead Assessor / Assessor in his final report summarizes the circumstances / conditions of the teleconference and clearly expresses his judgement on its adequacy).

If communication or image transmission problems arise, the Lead Assessor / Assessor may discontinue or increase the time of the assessment.

Guidance for CABs – Principles for remote audits on Certification / Inspection / Verification Bodies clients due to extraordinary conditions (COVID-19)

1. General

The definition and conditions under which the CABs (Certification / Inspection / Verification Bodies) can choose remote audit because of COVID-19.

2. Scope of the audit

The exceptions mentioned in this document may apply in the following cases:

- **The certified/ controlled /verified company is located in an area (city, city or province in a country) with known cases of COVID-19 or**
- **The certified/ controlled /verified company is located in an area affected by state restrictions and/or official travel bans or**
- **The company's corporate policy temporarily prohibits visitors due to COVID-19 and does not allow inspectors to attend its premises or**
- **The certification body's corporate policy prohibits inspectors from travelling because of COVID-19**

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Where special conditions are met, remote audit may be used by CABs in accordance with the process described below:

SCOPE OF REMOTE AUDIT/ INSPECTION/ VERIFICATION FOR THE AUDITING PROCEDURES CARRIED OUT BY CERTIFICATION/ INSPECTION/ VERIFICATION BODIES

Initial Audits

Initial Certification can only be carried out when full control and evaluation of the Management System, data, installation, equipment and personnel of the client is possible.

In view of the current emergency circumstances, an initial audit may be carried out, using the remote audit technique and by reviewing data submitted by the auditee and completing the on-site audit once the conditions of the COVID-19 pandemic have been lifted and as soon as it is possible to move to restricted areas and businesses are in operation.

In this case certification could be granted under conditions and only if a documented risk analysis related with the relevant standard, business risk and scope of certification have been evaluated. The accredited CB/IB/VB shall:

- have a documented risk analysis procedure for these types of audits
- submit to ESYD a written request, prior to conducting remote audit/desk review, including all relevant information and documented risk analysis

It should be noted that even in the case that ESYD approves the conduct of the initial audit entirely remotely and through data review, with a documented risk analysis, this does not remove the obligation of the accredited CAB to carry out the on-site audit, due to exceptional circumstances, but it shall be shifted in time when the conditions of the pandemic allow.

Note: The Risk Analysis includes at least the requirements of the standard IAF ID3:2011

ESYD examines the accredited CAB's request for initial certification / inspection / verification and approves or rejects the request within 10 (ten) working days.

Therefore, the audit / inspection / verification due to exceptional pandemic conditions is carried out in two phases (the first phase with the remote audit/desk review and the second phase with the completion of the on-site audit as soon as pandemic conditions allow).

Surveillance Audits

Surveillance audits shall be completed as soon as possible (with on-site audit) once the conditions of the COVID-19 pandemic have been lifted and as soon as it is possible to move to restricted areas and businesses are in operation. The surveillance audit procedure (as a surveillance audit is defined as both the first and second annual surveillance of the three-year cycle) shall be completed no later than six months after the deadline for its implementation, on the basis of the initial three-year program and until the end of 2020, if the pandemic conditions allow.

Surveillance audits may be carried out if it is documented by the risk assessment (low risk), using the remote audit and review technique of data submitted by the auditee. On the basis of the data/evidence collected, the accredited CAB (CB/IB/VB) may take a decision to continue

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the validity of the certification and thus retain the validity of the certificate of conformity (in cases of low-risk companies).

Therefore, in cases of low risk scopes of certification and on the basis of the risk analysis and documentation process of each case by each accredited CAB, the surveillance audit may proceed on the basis of the data/evidence collected from the remote audit/desk review phase.

The obligation of the accredited CAB to implement the on-site audit is not waived due to the exceptional circumstances, but it shall shift in time when the pandemic conditions allow.

Note: The Risk Analysis includes at least the requirements of the standard IAF ID3:2011

In the case that, due to the interruption of the smooth operation of the certified customer (due to the pandemic), it is not possible to apply either the remote audit/desk review, the accredited CAB may grant a 6-month extension of the maintenance of the validity of the certificate.

During this period, the following shall have been implemented:

The application of remote audit/desk review as an audit procedure, on-site audits and other procedures leading to the issue of the certificate.

When the 6-month extension has expired and neither an on-site audit nor the other procedures leading to the issue of the certificate are possible, the certificate shall be withdrawn.

Re-certification Audits

Re-certification audits shall be completed as soon as possible (with on-site audit) once the conditions of the COVID-19 pandemic have been lifted and as soon as it is possible to move to restricted areas and businesses are in operation. The re-certification shall be completed no later than six months after the deadline for its implementation, on the basis of the initial three-year program and until the end of 2020, if the pandemic conditions allow.

Re-certification audits related with Low Risk Companies may be carried out if it is documented by the risk assessment (low risk), using the remote audit and review technique of data submitted by the auditee. On the basis of the data/evidence collected, the accredited CAB (CB/IB/VB) may take a decision to continue the validity of the certification and thus renew the validity of the certificate of conformity (in cases of low-risk companies).

It is noted that the audit due to exceptional pandemic conditions is implemented in two phases (the first phase with the remote audit/desk review and the second phase with the completion of the on-site audit as soon as pandemic conditions allow).

The obligation of the accredited CAB to implement the on-site audit is not waived due to the exceptional circumstances, but it shall shift in time when the pandemic conditions allow.

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In the case that, due to the interruption of the smooth operation of the certified customer (due to the pandemic), it is not possible to apply either the remote audit/desk review, the accredited CAB may grant a 6-month extension of the validity of the certificate.

During this period, the following shall have been implemented:

The application of remote audit/desk review as an audit procedure, on-site audits and other procedures leading to the issue of the certificate.

When the 6-month extension has expired and neither an on-site audit nor the other procedures leading to the issue of the certificate are possible, the certificate shall be withdrawn.

Example:

FSSC 22000 certificate valid from 18/03/2017 to 18/03/2020. Following a positive result on risk assessment and remote audit, the validity of the certificate may be extended by six months, so in this example the expiry date of the certificate is extended to 18/09/2020.

The on-site audit takes place in July 2020 with the certification decision dated on 05/09/2020.

The subsequent certificate is issued and aligned with the previous cycle, therefore with an expiry date of **18/03/2023**.

GENERAL INFORMATION

1. Conformity assessment activities carried out by the CABs, which relate to products covered by the New Approach Directives and require CE marking, i.e., products of the mandatory sector, industrial products covered by national legislation requiring audits/inspections (initial, periodic, exceptional, etc.), products of the agro-food sector (organic, etc.) and any other products requiring labelling, will in any case be carried out by on-site audit/inspection at the premises of the manufacturer/producer/user, etc. with the physical presence of the audit / inspection team.

Furthermore, the audit cannot be completed on the basis of the data/evidence collected from the remote audit/desk review phase for the following standards: ISO 22000, ISO 45001/OHSAS 18001 (medium & high-risk activities), ISO 14001 (medium & high-risk activities), ISO 22716, ISO 50001, ISO/IEC 27001, ELOT EN 15224, ISO 13485 (medium & high-risk activities).

In any case, ESYD will be informed in writing.

Classification in high/medium risk activities is based on IAF documents as well as Guidelines issued by ESYD (where available by standard).

Audits and/or inspections in production areas, warehouses, accounting departments, assembly areas and any other places outside the office, shall be carried out under normal audit / inspection conditions and in any case with the physical presence of the audit / inspection team.

Certification / Inspection / Verification Bodies shall, on a regular basis per month (on the last working day), inform ESYD on the number of audits / inspections / verifications carried out with

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remote access (especially if combined with verification services e.g. EU-ETS, where the competent state authorities must also be informed).

2. Persons Certification Bodies, activating in the standard ELOT EN ISO/IEC 17024 and planning to conduct remote examinations, should apply relevant **tele-proctoring procedures**.

These procedures will be assessed by ESYD and accreditation for this scope will be granted in accordance with ESYD procedures and criteria. Certification, if it also requires practical examinations, will be carried out as normal before the crisis.

Those CBs wishing to implement the relevant **tele-proctoring procedures** will submit application for extension to ESYD and the relevant ESYD procedures will be followed (i.e., application for specific scope, assessment, etc).

3. During remote audit to a company to be certified / audited / verified and depending on the findings, the CAB will decide to extend the validity of the certificate of the company which it certifies.

Supervision and control by ESYD

For as long as the COVID-19 pandemic conditions last and with regard to the specific rules and conditions of certification, ESYD systematically supervises the relevant special procedures developed by the accredited CABs, CBs/IBs/VBs. In this frame, the accredited CBs/IBs/VBs are obliged to:

- i. Submit the procedure(s) specially prepared for pandemic conditions (COVID-19) to ESYD in accordance with the above.
- ii. Send to ESYD per month (on the last working day) a list of customers, having been audited and continuing to be certified under the special conditions' procedure of the COVID-19 pandemic.
- iii. All customers of accredited CBs/IBs/VBs to be audited / inspected based on these procedures under the pandemic conditions (COVID-19) will be assessed in regular assessments or short notice / unannounced assessments, if required. In any case and upon request from ESYD assessors, CABs are obliged to show tickets, toll receipts, petrol invoices and any other necessary documentation, in order to demonstrate the on-site audits / inspections required by this document.
- iv. ESYD, at the end of the crisis, will review this process, with the purpose of improving it and applying it to a more general framework, for the implementation of procedures for extraordinary circumstances.