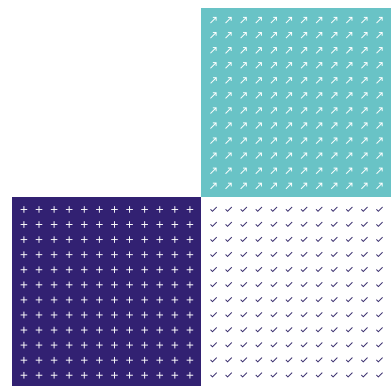


TPS 73

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UKAS Policy on Accreditation and Conformity Assessment During the COVID-19 Pandemic



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Changes since last edition

Section 4 updated to reflect additional FAQs published by IAF. Term “outbreak” replaced with “pandemic”.

1. Introduction

- 1.1 Every organisation is continuously exposed to opportunities, challenges, and risks in a normal business environment. However, extraordinary events or circumstances beyond the control of the organisation happen. At present, the world is facing the challenge of the pandemic and continued spread of coronavirus (COVID-19). UKAS is continuing to monitor Government and external advice in order to assess risks and undertake contingency planning.
- 1.2 It is important during this period that end-users and the wider community can continue to rely on the services of accredited conformity assessment bodies (CABs) and therefore that UKAS and the bodies it accredits continue to work together to ensure that the principles of accreditation are maintained. Although some of the traditional practices employed by UKAS to assess CABs may not be appropriate due to current restrictions, it remains a priority that the technical validity of its service and of the services of the CABs is maintained. Therefore, UKAS and its accredited organisations need to be able to demonstrate reasonable due diligence, mutual understanding and trust and to establish an appropriate course of action in response to this extraordinary event.
- 1.3 The aim of this document is to outline the requirements and provide guidance to UKAS accredited and applicant CABs on the appropriate course of action. During the COVID-19 pandemic, this document shall take precedence over existing UKAS publications where conflicts in requirements are identified.
- 1.4 The guidance and requirements included within this publication are consistent with the advice published by the European cooperation for Accreditation ([EA](#)) – see [Annex 2](#), the International Accreditation Forum ([IAF](#)) and the International Laboratory Accreditation Cooperation ([ILAC](#)).

2. Scope

- 2.1 The requirements and guidance contained in this document apply to all types of Conformity Assessment Bodies (CABs), including laboratories, certification bodies, verification bodies, inspection bodies, reference material producers, proficiency testing providers and providers of healthcare, scientific and diagnostic services.

3. Impact of the COVID-19 Pandemic on the Generic Operation of the CAB

- 3.1 It is recognised that the current pandemic may temporarily affect the ability of the CAB to conduct its activities and/or maintain compliance with the requirements for accreditation. Operations may be affected in a number of ways such as site closure, staff shortage, restricted access to supplies and services, sample delivery, additional workloads, reduced demand for services etc. The CAB shall deploy its risk management procedures taking into account the following:
- 3.1.1 Suspension of service: if the CAB is required to stop work for a short period of time that does not affect the delivery of its service to any great extent (e.g. no or minimal impact on service delivery time) then there is no need to inform UKAS. Records of any incident or outcome need to be retained and the CAB's customers kept informed. If the service has to be suspended for more than 2 weeks, then the CAB's UKAS Assessment Manager shall be informed.
- 3.1.2 Where the CAB can continue to provide a service but may have to deviate from its usual processes, a review of the situation and risks shall be conducted and shall include, at least, an evaluation of the CAB's current and expected future situation. Where this review identifies a significant risk to maintaining UKAS accreditation the CAB shall notify UKAS. At least the following information should be provided by the CAB:
- 3.1.2.1 Scope and extent of the effect on the CAB's services, business areas and locations, and the status of current activities;
- 3.1.2.2 Details of any alternative or mitigating actions in place or planned to address the impact;
- 3.1.2.3 Where relevant, the CAB's justified action plan to address any temporary deviation from accreditation requirements and/or its procedures;
- 3.1.2.4 Any request to modify the CAB's scope of accreditation to address the deviation;
- 3.1.2.5 Where necessary any request to voluntarily suspend part of/all accreditation.
- 3.2 Where required, UKAS will evaluate the proposed actions and seek to review the temporary deviation(s) to confirm maintenance of accreditation at the earliest opportunity. However, considering the impact that the pandemic may have on UKAS's ability to respond promptly, CABs can decide to progress with temporary deviations prior to UKAS's review where urgency is required. By doing so the CAB shall acknowledge that should a subsequent UKAS review identify deficiencies in the deviations then it may be required to implement corrective actions.
- 3.3 UKAS fully appreciates that CABs will have to re-evaluate priorities during this rapidly changing situation; it is important that the ongoing evaluation and decisions that are made are justified and details of deviations are recorded on an ongoing basis.

4. Guidance to Accredited Certification and Verification Bodies

- 4.1 Certification Bodies (CBs) offering accredited certification for Management Systems, Products, Processes and Services, and/or Persons, as well as Verification Bodies, are required to follow the requirements of UKAS Technical Policy Statement TPS 62, which sets out CB obligations when dealing with extraordinary situations such as pandemics. TPS 62 is based upon IAF Informative Document IAF ID 3 *Management of Extraordinary Events or Circumstances Affecting ABs, CABs and Certified Organizations*, and CBs should take this TPS into consideration when deciding on a strategy for maintaining certification in areas that cannot be accessed. CBs should also take note of the COVID 19 FAQs issued by the IAF and available on the IAF website (<https://iaffa.com/>).
- 4.2 In particular, information on the overall size of the problems facing a CB's UKAS accredited activities shall be provided to their UKAS Assessment Manager, with monthly updates of the status of their affected operations.
- 4.3 With respect to overseas certification activities, where the local accreditation body and/or authorities have issued instructions within their jurisdiction these requirements shall be taken into consideration when reviewing the acceptability of individual CB action plans.
- 4.4 When an application for initial certification or an extension to scope is received by a CB, the CB shall implement its risk management procedures to determine whether such work can be accepted during this period, and if so how this can be progressed: This shall be clearly documented during the contract review.
- 4.5 For initial management system certifications, at least part of the Stage 2 audit shall be completed on site, unless the CB can establish that all of the objectives and necessary activities can be robustly completed remotely, taking into account specific scheme requirements: This shall be reviewed by UKAS at the next assessment.
- 4.6 Management system recertification audits are normally expected to be completed and recertification decisions made prior to expiration to avoid loss of certification. IAF ID 3 allows for the extension of the certification for a period not normally exceeding 6 months beyond the original expiry date providing that sufficient evidence has been collected to provide confidence that the certified management system is effective. Given the unprecedented nature of the coronavirus pandemic, and the uncertainty over the potential impact this will have on the imposed time restrictions relating to travel and social contact, it is anticipated that 6 months may not provide sufficient opportunities for CBs to conclude recertification audits. As a consequence, UKAS policy for this pandemic is that the decision on recertification must be made within 3 months of the lifting of restrictions (e.g. travel) that were preventing the on-site or remote audit taking place. However, if this timeframe exceeds 12 months then the certificate should be reduced (if only part of the scope cannot be confirmed) or withdrawn, and a new initial audit will be required.
- 4.7 It is recognised that a delayed reassessment of up to 12 months (see above) will result in a shortened period to carry out required surveillance activities before the next reassessment. In order to maintain the certification cycle, the CB must ensure that the client audit programme for the full certification cycle is designed to cover all aspects of the certified client's scope and management system.
- 4.8 The certification of products, processes, services or persons would normally require the CB to undertake elements of the evaluation activity on site (e.g. manufacturing facility, assessment centre, etc): During the current pandemic this may not be possible. In these circumstances, the CB shall deploy its risk management procedures in accordance with 3.1 above.

- 4.9 Where the CB uses IT based systems as part of their audit process, this activity shall comply with IAF MD4.
- 4.10 Not all scheme owners recognise the validity of certification or recertification by remote assessments and therefore it is the responsibility of the CB to determine the acceptability of using remote techniques for recertification purposes for any scheme that it certifies to.

5. Guidance to Laboratories, Inspection Bodies and Other CABs Other than CBs

- 5.1 The restrictions imposed as a result of the pandemic may have serious implications on the provision of accredited services even though the operation of the CAB itself is not directly impacted, i.e. although the site may be open, some external (and in some circumstances internal) services and supplies may not be available. Under such circumstances the CAB will need to review the impact that such restrictions may have on its accredited service and identify what actions it can take to mitigate the risk associated with these. Any deviations from accreditation requirements and/or CAB procedures which pose a significant risk to maintaining UKAS accreditation must be notified to UKAS (see 3.1.2).
- 5.2 Temporary deviations from accreditation requirements and/or CAB procedures' could include, for example, delay in performing periodic calibration and intermediate checks of the measuring and test equipment, use of alternative supplies that could affect the validity of the conformity assessment activity, PT participation, outsourcing, internal quality control, internal audit and management review.
- 5.3 It is the responsibility of the CAB to ensure that any accredited service it continues to provide during this period remains technically valid and fit for its intended purpose. Therefore, for all justified deviations, it will be necessary to identify what alternatives are available and ensure that these meet appropriate requirements, e.g. identifying new suppliers and/or services. Where it is not possible to source appropriate supplies or services then the CAB should consider whether there are any alternative mechanisms that can be employed which will ensure the same goal is achieved. In circumstances where no reasonable alternatives can be found then the CAB will need to consider disclaiming accreditation for those services affected; in such instance the CAB is recommended to discuss this with its UKAS Assessment Manager.
- 5.4 It is possible that some site activities undertaken by a CAB, such as inspections, may be successfully achieved through the use of remote techniques. Where a CAB wishes to consider this, it shall first undertake a risk evaluation to ensure that the approach being proposed will not impact adversely on the technical validity of the service being provided. Further guidance on this can be found in the publications prepared for certification bodies, i.e. IAF MD 4, ID 3 and UKAS TPS 62. Any transition from site to remote activities shall first be discussed and agreed between the CAB and UKAS.

6. UKAS Assessments During the COVID-19 Pandemic

- 6.1 UKAS shall implement all measures necessary to protect the health and safety of its staff and assessment teams as well as the staff of the bodies that it accredits. Therefore, it will follow UK Government advice on travel restrictions and social contact, be this social distancing, self-isolation, or total lock-down. For overseas assessments UKAS shall also follow the advice of the local government of the country where an assessment is due to take place.
- 6.2 Where the advice restricts or forbids the possibility of undertaking assessments on-site then UKAS shall employ alternative mechanisms to ensure the technical validity of the services it accredits is maintained. This shall be achieved through the use of technologies that enable assessments to be conducted remotely, such as telephone or web-based meetings (e.g. Skype, Microsoft Teams,

- Zoom, etc), remote (electronic) access to CAB management systems, remote review of electronically submitted records, etc. For further information on remote assessments see [Annex 1](#).
- 6.3 The deployment of such techniques will focus on the essential elements to ensure that confidence can be maintained in accredited activities and UKAS will continue to monitor any necessary follow up activities once any travel restrictions are lifted. The key aim of using a remote assessment in these circumstances is for the UKAS assessment team to obtain sufficient confidence to continue to maintain accreditation.
- 6.4 It is recognised that the ability of a CAB to support remote assessment will vary depending on their capability to share information remotely and/or to partake in remote assessment activity. Their ability to support remote assessment will be established when the UKAS assessment team is developing an assessment plan.
- 6.5 It is strongly recommended that web-conferencing applications between UKAS and a CAB are trialled prior to starting the assessment to ensure that both parties can successfully use the selected platform / application. In the case that CABs have their own preferred web-conferencing application the CAB shall be requested to send a test link and UKAS will endeavour to access these systems.
- 6.6 Where, with justification, a CAB is unable to accept a remote assessment, either in full or in part, then this situation will need to be discussed with the CAB's Assessment Manager to determine an agreed approach. However, if a CAB that is able to accept a remote assessment (in full or part) but refuses to do so within an acceptable timeframe from its usual profile date, then UKAS will need to consider whether a sanction should be imposed.
- 6.7 UKAS will prioritise assessments to support surveillance and reassessment activity to enable existing accreditation to be maintained. Applications for extensions to scope and initial assessments will be progressed using remote assessment techniques where possible, recognising that it may not be possible to complete all aspects of the assessment remotely or by other means, which may delay the grant of accreditation. Each application will be evaluated, and the customer kept informed of how/whether the assessment can be conducted. Priority will be given to applications that are necessary as a result of the pandemic e.g. COVID-19.

7. Expiring UKAS Certificates of Accreditation

- 7.1 UKAS accreditation is granted for a period of 4 years, with reassessments planned every 4th visit to automatically renew for a further 4 years subject to demonstration of conformity with the applicable standard(s). All accreditations have an expiry date, as detailed with the UKAS e-Certificates, which is generally scheduled for 6 months after the due date of the reassessment visit.
- 7.2 With the changes to the timing and completion of reassessments during the pandemic it is possible that the expiry date of an accreditation certificate is reached without the full reassessment being completed and the associated decision made to renew accreditation.
- 7.3 UKAS has the ability, with justification, to extend the validity of its accreditation certificates by up to a maximum of 12 months. Such an extension would still comply with the requirements on accreditation cycles laid down in ISO/IEC 17011: 2017 *Conformity assessment - Requirements for accreditation bodies accrediting conformity assessment bodies*. Where a delay in a CABs reassessment is due to circumstances outside of the CABs control then UKAS will instigate the extension of the current certificates' validity as appropriate. The decision to extend certificate validity will be reviewed at regular intervals, e.g. every 3 months up to the maximum of 12 months. If a CAB holds a certificate that has been extended by 12 months and yet has still not completed its reassessment then the accreditation shall expire, and the CAB will need to reapply for accreditation once it is in a position to do so.

8. Further Information

- 8.1 For up to date information on UKAS policy and actions relating to the coronavirus pandemic please refer to the article in the UKAS News section of our website.
- 8.2 In the event of any doubt, CABs are advised to contact their Assessment Manager.
- 8.3 The following publications can also be a useful source of information:
 - 8.3.1 TPS 62 - Management of Extraordinary Events or Circumstances Affecting UKAS Accredited Certification Bodies and their Certified Organisations
 - 8.3.2 IAF MD 4: 2018 - IAF Mandatory Document for the Use of Information and Communication Technology (ICT) for Auditing/Assessment Purposes
 - 8.3.3 IAF ID 3: 2011 - Informative Document for Management of Extraordinary Events or Circumstances Affecting ABs, CABs and Certified Organizations
 - 8.3.4 IAF ID 12: 2015 - Principles on Remote Assessment

Annex 1: What to expect from a UKAS remote assessment

What is a remote assessment?

A remote assessment is one that is conducted off site either in whole or in part. Remote assessments generally make use of technology, such as Skype, Microsoft Teams, Zoom Meeting or GoTo Meeting, to support the Assessment team when a site visit is not possible / appropriate.

The assessment may include everything that is usually covered during a site visit, but it is likely that some activities, particularly our witnessing of staff conducting their technical functions will not be able to be covered. These technical aspects may need to be assessed at a later date, but this will be discussed and agreed during the remote assessment.

What should customers expect?

The structure of the visit will be quite familiar; we will conduct opening and closing meetings and review information with you to ensure ongoing competence although there will clearly be some changes as to how we achieve these reviews. The duration of a remote assessment may differ to that of your on-site assessment, depending on what aspects are planned to be covered. In addition, it is also likely that the assessment may be fragmented with individual activities happening over the course of a longer period. Therefore, you will not necessarily need to be available at all times when the assessment is occurring, but a schedule of planned web-conferencing will be agreed with you.

When assessments are conducted via web-conference technology it is recommended that both parties use screen sharing and web-cam functionality. This reduces the amount of data and information that has to be transferred between your organisation and UKAS. However, it is also likely that the assessors will ask for documentation to be submitted for them to review offline because this is often done more efficiently with large amounts of information. You may be asked to email documents or use file sharing sites to provide the documentation to the Assessor. Please be assured that the information you send us will be securely managed in accordance with our existing confidentiality and data privacy policies.

What do customers need to do to make sure they are ready?

Remote assessment is heavily reliant on technology, so we recommend taking the following actions to ensure you are ready;

- Check your IT systems will allow to access one of the following web-conferencing solutions Skype, Microsoft Teams, Zoom Meeting, GoTo Meeting. Confirm with your Assessment Manager which of these applications works for you.
- NOTE: You do not need to have a licence for these applications as UKAS will initiate the meeting request.
- If you cannot access these applications and wish to use your own web-conferencing solution, contact your Assessment Manager so that UKAS can check whether it is accessible to us.
- If online connectivity is not possible, then the assessment will be carried out using telephone conferencing and the emailing/file sharing of documentation;

As well as checking access please ensure you are familiar with the technology, particularly the management of your audio and screen sharing prior to your assessment to avoid unnecessary delays.

What do customers need to make available for the remote assessment?

- Personnel
 - Key personnel who normally support the on-site UKAS assessment need to be available for web-conferences and answering ad-hoc queries from the assessment team as the assessment progresses;
 - Personnel with specific technical or administrative responsibilities will need to be available for their relevant parts of the assessment;
 - Top management and members of the leadership team will need to be available for relevant parts of the assessment as well as the opening and closing meetings.
- Documentation
 - We will review as much of the management system as possible remotely. This can be done via screen share or by sending the information to your Assessor via email/file sharing;
 - Your assessment team may well request documentation to be sent in advance of the assessment so they can review beforehand.
 - Typical documents your assessment team may request are:
 - Internal audit programme and supporting records or reports
 - Minutes of management system review
 - Reports of complaints and nonconforming work
 - Case/job files
 - Training records of new staff
 - Details of changes affecting your organisation
 - Proficiency testing data (where relevant)
 - Quality control data (where relevant)
- Witnessing of technical activities
 - This is the most challenging part of any remote assessment, but it can be achieved by a mix of live streaming, recordings, post audit reviews or technical interviews;
 - For live streaming, check you can live stream visual and have two-way audio at the location the activity is performed. This often requires use of mobile networks or wi-fi so check connectivity at the location;
 - For recordings, these need to be agreed with the assessment team in advance. Make sure that the recording is of suitable clarity for both visual and audio. Also, the personnel conducting the activity should narrate what they are doing and why. It is also likely that the technical personnel will need to be available for discussions with the assessor to explain elements of the recording when it is assessed;
 - For post audit reviews the UKAS team will select job files which will then be reviewed with the individual(s) who conducted the technical activity. Therefore, the individual(s) involved need to be available to interact with the UKAS team;
 - Technical interviews involve a UKAS assessor talking through key aspects of the technical activity with a member of your staff who is authorised for that activity. They are used when it is not possible to live stream or record the activity or to conduct a post audit review.

What happens if connectivity fails during the assessment?

The assessment team will try to continue with the assessment wherever possible. If the issues cannot be corrected quickly, then the assessment team will revert to conducting the assessment by telephone conference.

Annex 2: EA communication about the impact of the COVID-19 outbreak

Published: 23rd March 2020

Due to the outbreak of the coronavirus disease 2019 (COVID-19) and the subsequent travel restrictions established by national governments in the vast majority of countries both conformity assessment and accreditation activities have been seriously affected in different ways. In particular, conformity assessment bodies (CABs) and national accreditation bodies (NABs) are being forced to cancel or postpone most of their “in situ” activities such as on-site assessments, audits, witnessing visits and inspections and they will have to face the situation of only being able to provide their services with a workforce that that is now mostly working remotely. This will affect the service provided and also lead to a possible temporary lack of access to certain supplies or services normally subcontracted by the CABs.

Under these circumstances although not all the applicable standards foresee the use of remote assessment techniques, including document reviews, and recognizing that these assessment techniques may not always enable exactly the same objective to be achieved as on-site assessments, EA suggests the use of these techniques whenever needed to substitute or complement on-site assessments.

Nevertheless EA recognises that, in certain circumstances, accredited CABs and NABs will have to take difficult decisions that could include stopping the provision of certain services or temporarily deviating, in order to be able to provide the services, from certain requirements included in the standards or in the accreditation rules.

When facing these situations, both EA members and accredited CABs are required to act responsibly, to analyse the risk of providing services with deviations from the requirements and not to provide them if such deviations jeopardize the technical validity of that specific activity. EA also expects EA NABs and accredited CABs to act with full transparency, informing affected clients of any change in the procedures and keeping records justifying the decisions taken.

Accreditation is an international activity so we recommend both NABs and accredited CABs to visit the ILAC and IAF websites where they can find useful information regarding aspects of global impact. This information also contains valuable information regarding required transition periods like the transition of laboratories to ISO/IEC 17025:2017.

For activities performed in the regulatory field or under a specific scheme CABs must seek information from scheme owners or relevant competent authorities on how they expect related conformity assessment activities should be handled under these circumstances.

As the situation is constantly changing and different countries are establishing different measures to adapt to it, accredited CABs should contact their NAB for further details or questions.

EA will closely follow the development of the coronavirus crisis in order to take any further action when needed and will publish more specific advice and relevant information.