

Technical Bulletin – Managing the impact of the coronavirus outbreak – Laboratories, Inspection Bodies & Healthcare Services

30 March 2020 - Version 2

Introduction

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 the present time the world is facing the challenge of the outbreak 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.

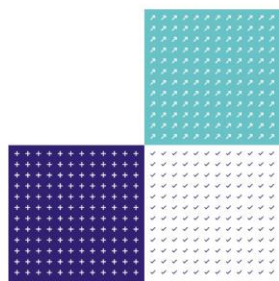
It is important that UKAS and its accredited organisations are able to demonstrate reasonable due diligence, mutual understanding and trust and to establish an appropriate course of action in response to this extraordinary event. For certification bodies, guidance is available in a separate [Technical Bulletin](#) and [TPS 62](#). For all other types of Conformity Assessment Bodies (CABs), including laboratories, inspection bodies, reference material producers, proficiency testing providers and providers of healthcare, scientific and diagnostic services, the requirements and guidance contained in this document apply. In the event of any doubt, CABs are advised to contact their Assessment Manager.

The aim of this document is to outline the requirements and provide guidance to UKAS accredited CABs on the appropriate course of action.

Impact of Coronavirus outbreak on the operation of the CAB

It is recognised that the current outbreak 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 staff shortage, restricted access to supplies and services, sample delivery, additional workloads etc. The CAB shall deploy its risk management procedures taking into account the following:

- 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 UKAS shall be informed.



- 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:
 - Scope and extent of the effect on the CAB's services, business areas and locations, and the status of current activities;
 - Details of any alternative or mitigating actions in place or planned to address the impact;
 - Where relevant, the CAB's justified action plan to address any temporary deviation from accreditation requirements and/or its procedures*;
 - Any request to modify the CAB's scope of accreditation to address the deviation;
 - Where necessary any request to voluntarily suspend part of/all accreditation

***Note:** 'Temporary deviation 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.

Where required, UKAS will evaluate the proposed actions and seek to agree the temporary deviation(s) to confirm maintenance of accreditation wherever possible. UKAS will seek to do this in the most efficient and effective way possible, considering the impact that any epidemic may have on UKAS resources.

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.

Routine assessment arrangements

As of 17th March 2020, UKAS stopped undertaking any on-site assessments as a result of government advice on travel/travel restrictions and social contact. Measures have been put in place to undertake scheduled assessments remotely wherever practicable, prioritising work to ensure trust and confidence can be maintained in existing accredited activities: further information on remote assessments can be found on the [UKAS website](#). UKAS may also modify the assessment visit programme should the need arise, taking into account the risk associated with a CAB's activities and circumstances.

This situation is being reviewed daily and any changes to UKAS policy, as well as further actions relating to the coronavirus pandemic, will be published on the [UKAS News](#) section of our website.