

Technical Bulletin: Guidance for ISO 15189:2022 accredited medical laboratories on changes to their accredited scope

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The UKAS schedule of accreditation is the official statement for each customer of those activities for which accreditation has been granted.

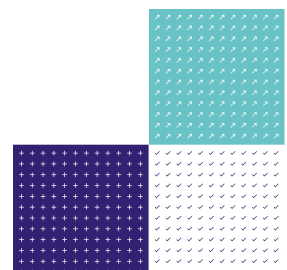
The vast majority of ISO 15189:2022 UKAS accredited medical laboratories have a fixed scope of accreditation, which is the clearly defined description of activities in their schedule published on www.ukas.com. Customers with a fixed scope that want to add to or change their range of accredited activities must usually apply for an [extension to scope](#).

An increasing number of accredited medical laboratories are opting to have part of their scope accredited flexibly, where frequent changes are made within the boundaries of the laboratory's accredited technical competence. Information about flexible scope can be found in [GEN 4 UKAS policy and general guidance for the implementation and management of flexible scopes of accreditation](#) and [LAB 60 UKAS policy on accreditation of medical laboratories performing genomic tests](#).

This bulletin is intended to provide general guidance to accredited medical laboratories on when an extension to scope application is required when changes are made within a fixed scope of accreditation.

Where a medical laboratory is planning to implement a brand-new test or technique, add a new sample type or install new equipment, beyond the current accredited scope of competence, this will usually require an extension to scope application. Where changes are made within the current accredited scope of competence, these may be able to be assessed without a formal extension to scope application. This may be via assessment of the change at the next planned visit, or via an interim 'extra' assessment, and additional effort will be required to carry out this assessment. Accreditation cannot be claimed or inferred until UKAS has evaluated the risks of the change, assessed the change as required and, where necessary, published an updated Schedule incorporating the changes.

The ability to make changes to a fixed scope without a formal extension to scope application does not mean the medical laboratory has a flexible scope of accreditation. A flexible scope requires additional, specific processes and competencies to be implemented by the laboratory, and these shall be assessed by UKAS (see UKAS publication [GEN 4](#)). Schedules of accreditation for flexible scopes also differ in that the boundaries and specific testing to which the flexibility is applicable to is clearly presented.



The lists below are not intended to be exhaustive and, in all instances, where changes are planned to be made to an accredited scope it is essential that the UKAS Assessment Manager is informed *before* changes are implemented, including any new activities/locations, any amended activities/locations, and any accredited activities/locations which will need to be removed from the accredited scope. This is a requirement of the [UKAS Customer Agreement](#) and enables UKAS to evaluate the change(s) and determine the assessment required, taking a risk-based approach.

Changes below are examples which normally require an extension to scope application:

- Additional laboratory locations
- New or replacement analysers/equipment of a different type and/or from a different manufacturer and/or with different measurement principles/technologies
- New or changed test kit of a different type and/or from a different manufacturer and/or with different measurement principles/methodologies
- Additional sample types for already-accredited tests
- Additional analytes, targets, staining methods, probes, antibodies or measurement principles using existing analysers/equipment
- Change of reference/validated method (e.g. type of PCR, antimicrobial susceptibility testing method)
- Automation of manual examination processes (e.g. automated ELISA, blood grouping, staining, microtomy, or semen analysis), or vice versa
- Implementation of a new bioinformatics pipeline, whether commercially sourced or developed in-house
- Blood storage fridges being brought under accreditation at new locations (i.e. hospital sites, clinics, community sites, etc. with no current blood storage fridges accredited)
- Additional “Kiosks” for remote issue of blood, whether located at a new location or a new clinical area within an already accredited site

Changes below are examples which would not normally require a *formal* extension to scope application but are still likely to require assessment by UKAS:

- Movement of accredited equipment/testing from one area to another within a currently accredited location
- Changes to peripheral equipment such as pipettes, balances, incubators, centrifuges
- Changes/upgrades to Laboratory Information Management Systems (LIMS), bioinformatics pipelines and other key software
- Test kit formulation changes
- Changes to consumables used in manual testing (e.g. culture media)
- Like-for-like equipment replacement or addition (same make, same model)
- Blood storage fridges being brought under accreditation in new clinical areas at locations where there is existing blood fridge accreditation (e.g. accredited fridges are in Wards 1,2, and 3 in a hospital, then additional fridges are added to Wards 4 and 5 in the same hospital)

Changes below are examples which will be reviewed on a case-by-case basis by UKAS

- Additional, replacement or upgraded analyser/equipment of the same type from the same manufacturer using the same measurement principle. *The extent and risk of the change will be taken into account by UKAS when determining the assessment approach and any requirement for an extension to scope application. For example, the risk of an analyser upgrade in a single-site laboratory with a single analyser delivering testing for a stable, local population is different to that of a large, multi-site reference laboratory delivering testing UK-wide.*
- Additional point-of-care testing (POCT) delivery points within an established cluster *The extent and risk of the change will be taken into account by UKAS when determining the assessment approach and any requirement for an extension to scope application. For example, the risks associated with the addition of one or two delivery points may be different to the risks associated with the addition of 20+ delivery points.*

Guidance on how to apply for an [extension to scope](#) and relevant [UKAS publications](#) can be found at www.ukas.com. Please note the normal lead time for extension to scope assessments is approximately three months. It is therefore important to submit extension to scope applications as soon as possible.