# Technical Bulletin – Guidance on Extension to Scope for ISO 15189:2012 Accredited Medical Laboratories

21 November 2019 – *Revised 19/12/2019*

A UKAS Schedule of Accreditation is the official and detailed statement of the scope of activities for which an accredited body (medical laboratory) is granted accreditation. UKAS offers an extension to scope service for customers who wish to add to or change their range of accredited activities.

The vast majority of ISO 15189:2012 UKAS accredited medical laboratories have a fixed scope of accreditation, which is the clearly defined description of conformity assessment activities in their Schedule published on www.ukas.com. However, fixed scopes can incorporate a degree of flexibility depending on the risk associated with the accredited testing. The level of inherent flexibility within the fixed scope must be agreed between UKAS and the accredited laboratory.

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

The list below is not intended to be exhaustive and, in all instances, where changes such as these are going to be made to an accredited scope it is essential that your UKAS Assessment Manager is informed before changes are implemented. This is a requirement under the terms and conditions of your UKAS Agreement and enables UKAS to evaluate the change(s). Following this, UKAS can provide guidance on what information the laboratory must provide before accreditation can be maintained or granted. This may include assessment of the change at the next planned visit, and additional effort may be required to carry out this assessment. Accreditation cannot be claimed or inferred until UKAS has evaluated the information, assessed the change as required and, where necessary, published an updated Schedule incorporating the changes. In some cases, extra assessment before the next planned visit may also be required.

Changes below would not normally require a formal extension to scope application:

- Movement of equipment/testing from one area to another within an accredited location
- Additional locations for supporting activities (e.g. blood fridges, sample collection sites)
- Additional, replacement or upgraded analyser/equipment of the same type from the same manufacturer using the same measurement principle
- Changes to peripheral equipment (e.g. pipettes, balances, incubators) or equipment used in pre-examination processes (e.g. tissue processors, centrifuges, sample transfer equipment/robotics)
- Changes/upgrades to Laboratory Information Management Systems (LIMS)
- Change of components/consumables within analysers/equipment (e.g. HPLC column)
- Test kit formulation changes
- Changes to consumables used in manual testing (e.g. culture media)
- Changed or expanded panels (e.g. for organism identification/susceptibility testing, genetic mutations/gene sequences, autoantibodies/specific IgE)
- Additional point-of-care testing (POCT) delivery points within an established cluster (for ISO 22870:2016 accreditation)

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 need to 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.

Following evaluation of risk on a case-by-case basis, UKAS may still require an extension to scope application for any of the changes listed above. Other changes are more clearly identifiable as being outside any inherent flexibility within a fixed scope of accreditation. For the examples below an extension to scope application should be submitted. Again, this list is not intended to be exhaustive.

Changes below would normally require a formal extension to scope application:

- New laboratory locations
- New or replacement analysers/equipment of a different type and/or from a different manufacturer
- New or changed test kit
- New sample types
- New 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 or semen analysis), or *vice versa*

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 of three months. It is therefore important to submit extension to scope applications as soon as possible.

It is also essential that you inform your UKAS Assessment Manager of any accredited tests that have ceased being carried out. These can then be removed from your published Schedule of Accreditation.

**Revision note 19/12/2019:**
Reference to the UKAS Flexible Scope publication updated as GEN 4 has replaced LAB 39 and TPS 59.