MAINTAIN AND EXTEND ACCREDITATION

John Ringrow and **Al Bryant** follow on from their December 2017 article on approaching UKAS assessments with a feature on maintaining and extending your scope of accreditation post-grant.

Accreditation by UKAS (whether to ISO 15189:2012, ISO 22870:2016, ISO 17025:2005/2017, 17043:2010, etc) involves annual assessments and has an expiry of four years from grant of accreditation. The first surveillance usually takes place six months after accreditation is granted, and assessments are annual from then on. There are three surveillance assessments, which cover a limited part of the accredited technical scope and quality management system, followed by a re-assessment that covers the full scope, using a combination of witnessing accredited activities and document review.

Findings that are deemed to be mandatory and a non-conformity against the standard assessed, may be raised at any/all of these assessments, with the evidence submission deadline to clear the non-conformity generally being set at one month post-assessment. When all mandatory findings are closed, the laboratory will receive notification that accreditation has been maintained (or renewed in the case of re-assessments), and so the annual cycle begins again.

It is imperative that UKAS is informed of any changes to the service, as these may require additional assessment to provide assurance that competence and conformity with the relevant standard has been maintained.

Some changes will require an extension to scope application to be submitted to UKAS, others may just be incorporated into the next UKAS assessment.

Extension to scope

Accreditation applies to the examinations and activities listed on the schedule of accreditation and the equipment referred to in the schedule. Changes to a laboratory's scope may require assessment and need to be discussed with your assessment manager to establish whether an extension to scope application is required. The following list is not exhaustive, but covers most of the changes a laboratory introduces:

- New examinations run on accredited platforms (e.g. new chemistry analyte, new immunohistochemistry antibody in cellular pathology)
- Upgraded platform running the same tests
- New platform running the same tests (e.g. managed service contract expires and the new contract is awarded to a different supplier)
- Completely new test e.g. introduction of molecular testing in micro or cellular pathology
- Additional site coming under the control of an accredited organisation (e.g. due to merger/move of service)
- New blood fridge in a new location
- Provision of point of care testing at a new location.

Information regarding how to apply for an extension to scope is available on the UKAS website.

Consider the timing of extension to scope applications. The assessment team will need to be assured that the new test/platform/etc is up and running, verified for fitness for purpose, and fully incorporated into the quality management system. It is worth contacting your UKAS assessment manager in advance of applying to discuss the laboratory's requirements and timescales. As mentioned in the last article, the sooner UKAS is informed of any planned changes, the easier it will be to work with you to organise any assessment processes. Planning a change is key and the further in advance you inform your assessment manager, the easier it is for UKAS to ensure accreditation is granted in line with your expected timescales.

When submitting an extension to scope application, ensure the scope of the application is clear, including whether the application covers additional tests, upgraded analysers, new sites, etc, and ensure any supporting documentation is clearly labelled and referenced.

Where practical UKAS will try to combine extension to scope assessments with surveillance assessments (e.g. by incorporating it into existing assessment time or adding extra time on site, where appropriate) to minimise the assessment burden on labs and to make the most effective use of UKAS' assessor resources.

We also consider the option of carrying out extension to scope assessments remotely by reviewing evidence including verification reports, internal quality control data, external quality assurance results, staff training records, test reports, and evidence that the extension activities have been integrated into the quality management system (e.g. audits, supplier assessments, non-conformities, etc).

Examples of extensions that may be considered for remote assessment include those where new tests are added to already accredited platforms using the same measurement principle, or where analysers are upgraded to a newer model from the same supplier, running the same tests and using the same measurement principle.

The assessment approach is planned by the assessment manager and approved by an independent decision-maker to enable consistency across the organisation. The lead time from application to assessment is generally at least three months. As for all assessments, findings may be raised, and any mandatory findings must be cleared before accreditation can be extended to cover the new activities. The evidence submission deadline is usually three months from the assessment. The application, findings, assessment report, and other relevant documents will be reviewed by an independent decision-maker before accreditation is extended and an updated schedule of accreditation published on the UKAS website. This timeline emphasises the need for effective communication prior to applying and with due consideration as to the needs of the laboratory with respect to reporting activities as accredited.

Other changes

The extension to scope process may not be applicable for the following changes but, as part of the UKAS agreement customers are required to inform UKAS as the changes may impact on the next assessment:

- New quality manager
- New laboratory manager/director
- New LIMS
- Providing services to new customers by incorporating additional test volume on accredited sites
- Exact like-for-like equipment replacement i.e. same make, model, software version, etc.

Again, this is not an exhaustive list. If you are in any doubt as to whether UKAS needs to know about a change, contact your UKAS assessment manager.

If customers want to remove tests from their accredited scope (e.g. services have been centralised and a certain test is no longer offered on a particular site, or a test is now referred out to another provider due to low test volume), contact your UKAS assessment manager at the earliest opportunity, who will be able to arrange this.

Flexible scope

A key development we are expecting to see over the next few years is the implementation of flexible scopes of

KEY POINTS

- ✔ Discuss all planned or potential changes with your assessment manager as early as possible
- ✔ Accreditation applies to the tests listed on your schedule of accreditation and run on the equipment referred to. Any changes to this may require an extension to scope application
- ✔ Flexible scopes of accreditation may avoid the need for frequent extension to scope applications
- ✔ Flexible scope applications will usually not be considered until after at least the first successful surveillance assessment
- ✔ Ensure applications for extensions to scope and flexible scope are sufficiently detailed and clear.

accreditation for ISO 15189:2012 customers. Currently, all ISO 15189:2012 accredited customers have fixed scopes of accreditation, as defined on their schedule of accreditation. Flexible scopes of accreditation can allow a laboratory to undertake certain tests, and to report the results as accredited, even though they may not be explicitly stated on their accreditation schedule.

For example, a laboratory may be accredited for detection of specific antibodies and antigens in serum using an automated ELISA technique. Under a flexible scope of accreditation, that same laboratory may be accredited for detection of any similar antibody and antigen in serum using an automated ELISA technique, meaning they could introduce new antibodies/antigens into their scope and claim accreditation without having to apply for an extension to scope assessment.

However, a flexible scope does not mean a laboratory can then undertake any test that is requested by a user and claim it is accredited. The boundaries within which the scope is flexible must be clearly defined on the schedule of accreditation, with the laboratory demonstrating to UKAS that it has the knowledge, experience and competence to work within the full range of its flexible scope. These boundaries must be set, and specify the materials/products tested, the type of test (e.g. chemical, biological, etc), properties measured, and equipment/techniques used.

The key UKAS reference document for flexible scope accreditation is UKAS publication LAB 39 (currently under review). The assessment team will expect to see this document incorporated into the quality management system and evidence of its dissemination, review and implementation.

When a laboratory applies for a flexible scope, it must include a clear definition as to what it wants the flexible scope to cover (i.e. clear definition of the boundaries), as organisations will generally have schedules of accreditation where part of the scope is fixed and part is flexible. Applicants must demonstrate competence for the activities covered by the flexible scope e.g. method validation/verification, determination and application of measurement uncertainty, and other key aspects of ISO 15189:2012. They must have a documented procedure defining how the flexible scope will be managed, and will be required to document each time this procedure is activated and a new activity implemented. As part of the application for flexible scope, at least one worked example of when the procedure has been implemented is required to be submitted to UKAS.

Once accreditation is granted for a flexible scope, UKAS would need to see evidence of the first time the flexible scope procedure was implemented after accreditation. After this, the procedure would only be requested periodically or during assessments.

Although a flexible scope may seem like a great way to avoid the charges and assessment involved with extension to scope applications, flexible scopes may not necessarily be the best way forward for every lab. Flexible scopes involve additional assessment effort (and therefore cost) plus extra internal management of the flexible scope process, such as inclusion in the internal audit programme.

It is up to each laboratory to consider whether a flexible scope may suit its needs and the needs of users. If the test repertoire is stable with just occasional changes, it may be better to stay on a fixed scope and deal with changes via the extension to scope process. However, if there are regular changes to the service provided (e.g. genetics laboratories where new markers/mutations are being discovered regularly, or large reference centres), it may be worth considering a flexible scope.

To provide assurance to UKAS that laboratories can maintain competence and conformity with ISO 15189:2012, it is generally expected that CPA transition laboratories will have gone through at least their first surveillance assessment, and sometimes the second surveillance, before we consider discussing flexible scope applications. UKAS needs to be confident that the laboratory has the knowledge, resource and understanding to manage the process.

The key thing to remember, whether a laboratory is thinking about flexible scopes, extensions to scope, considering applying for point of care testing accreditation to ISO 22870:2016, or just generally has questions about the accreditation process, is to communicate with your UKAS assessment manager. We are here to help and all share the same goal of improving quality across medical laboratories. BMS

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