HOW TO... MAINTAIN ACCREDITATION

Ben Courtney, UKAS Accreditation Manager, and **Delia Geary**, UKAS Technical Manager, give practical guidance for compliance with ISO 15189:2012 and maintaining accreditation.

The deadline for transitioning from CPA accreditation to ISO 15189:2012 accreditation by UKAS was set for the end of September 2018. Over 97% of previously CPA-accredited laboratories transitioned in time, with most of the handful of laboratories that were not able to meet the deadline having since progressed. This was a monumental effort by all involved and the laboratories deserve huge credit for their efforts.

As the vast majority of medical labs in the UK are now UKAS accredited, attention turns to how laboratories can ensure they successfully maintain accreditation, particularly in light of on-going changes proposed by NHS England and NHS Improvement. There are broad themes of non-conformity when maintaining/extending or making changes to accreditation; whilst there are still trends to technical issues, primarily the risk to a laboratory's accreditation is more around organisational issues, understanding of the accreditation process and extensions to scope (ETS).

Organisational issues

With sustainability and transformation plans come ETS and changes of legal entity. UKAS has published *Technical Bulletin - Medical Laboratories: Maintaining UKAS Accreditation During Periods of Change*, which is available to download from the UKAS website.

Advice from UKAS would be to inform their Assessment Manager of any change at the earliest opportunity. By doing so, UKAS can establish the impact and whether an assessment is required – whether this involves a change to the plan of the next surveillance visit or the need to apply for an extension to scope. Using changes to legal entity as an example, informing UKAS of the change well in advance means that UKAS can perform the assessment before the change is due to go live, providing the laboratory with time to clear any findings raised during the assessment with no break in accreditation. Critical to a change of legal entity is ensuring that the organisation to whom accreditation is being transferred is prepared to accept all contractual, legal, financial and other obligations which relate to both the current and historic accredited activities. Where this can be confirmed, UKAS will request that the relevant application form is submitted (available from the UKAS website) accompanied by the supporting evidence requested.

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Accreditation process

The objective of surveillance visits is for UKAS to ensure an accredited laboratory is meeting requirements for accreditation on an ongoing basis. UKAS is required to advise the laboratory when they are due for an assessment visit (called a laboratory's profile month). Assessments must take place in or before this month and only in exceptional circumstances can this be delayed. Although UKAS tries to find dates that are mutually acceptable, laboratory staff leave cannot be regarded as an exceptional circumstance. An objective of accreditation is to provide continued confidence in accredited laboratories and it makes sense that such confidence can be demonstrated to be maintained when laboratories are at a perceived weakness (i.e. low staff numbers). As such, staff being on leave or sick by itself would not be justification for postponing a visit.

The most effective surveillance visits are those where the assessment team is well informed prior to an assessment, which is why pre-visit documentation is requested. Providing information in a timely way ensures an appropriate assessment that is most likely to add value. It follows that any changes, however trivial they may seem, are made clear to the Assessment Manager at the earliest opportunity so that the assessment can be suitably planned. As part of the UKAS Agreement, laboratories are required to inform UKAS of such changes and a judgement can be made as to whether (at a minimum) the focus of the assessment needs to be changed, or whether an ETS is required.

Extensions to scope

A laboratory's schedule of accreditation is the official and detailed statement of activities for which the accredited body has accreditation. If a laboratory requires its schedule to be changed or updated, UKAS offers the ETS process.

To help clear up any confusion as to what is and what is not an ETS UKAS will shortly be issuing guidance (available from the UKAS website) as to what constitutes an ETS. Ultimately though, Assessment Managers are there to advise on matters such as this and it is worthwhile having this discussion regarding a change (however small) to ensure that accreditation is not put at risk.

Technical Issues

Whilst each organisation and UKAS assessment visit is different, there are identifiable themes in technical findings raised at assessments; in particular, measurement uncertainty, traceability and verification of assays have consistently been areas to improve on throughout the CPA to ISO 15189 transition process and beyond. Best advice for laboratories would be to regularly review each of these areas to evaluate if changes need to be made and to perform this review based on clinical risk.

For instance, whilst measurement uncertainty must be reviewed at regular intervals, it makes sense to conduct an additional review if there was a significant change that brought the validity of any assigned measurement uncertainty values into question, such as a change of skill mix in the laboratory.

Summary

Whilst it is sometimes useful to discuss with other laboratories the various approaches they take to meet accreditation requirements, it is understood that this can sometimes be commercially confidential information.

It's also worth bearing in mind that each organisation has its own unique set of circumstances, meaning that the 650 different UKAS ISO 15189 accredited laboratories could be satisfactorily meeting requirements in 650 different ways.

The key to maintaining accreditation is close liaison with the Assessment Manager and awareness of risk. Any change may risk the scope and indeed status of a laboratory's accreditation and it is always worthwhile seeking reassurance from UKAS as to what the boundaries are. BMS