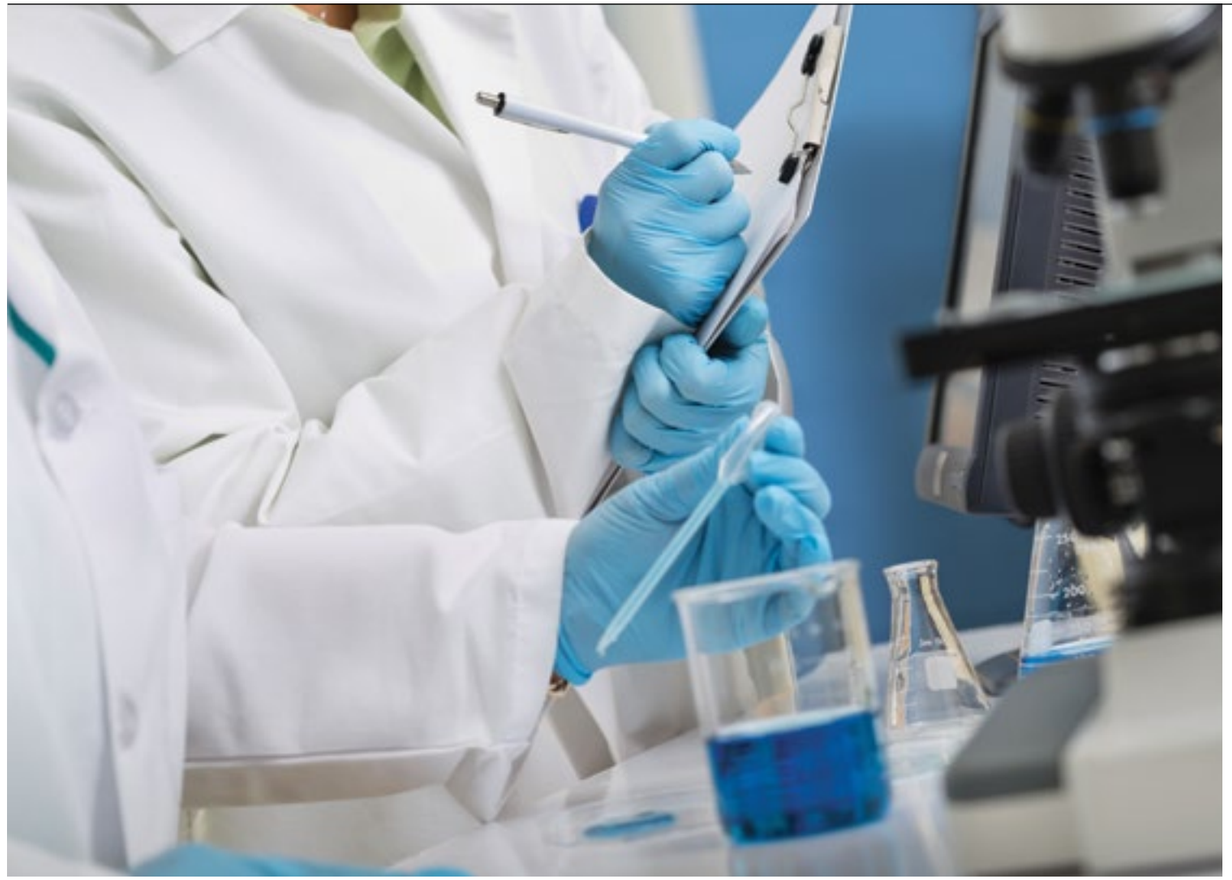

HOW TO...
APPROACH UKAS ASSESSMENT

John Ringrow and **Al Bryant**, Senior Assessment Managers at the United Kingdom Accreditation Service (UKAS), share some pointers on how to make the ISO15189:2012 assessment process smooth and enjoyable.

IMAGES: ISTOCK

The transition of laboratories from the CPA Standards for the Medical laboratory 2010 to BS EN ISO 15189:2012 – Medical laboratories – Requirements for quality and competence, started in 2013 with pilot assessments. We are now entering the final phases of the transition. Some laboratories are still to have their initial assessments. However, it is always useful to run through what we have learned throughout the transition, and how laboratories preparing for any assessment can focus their resources to achieve successful outcomes.

Communication

A visit from an external assessment team can be an intimidating experience. However, communication and preparation are vital.

There are some key phases of any assessment, whether that may be Initial Assessment, Surveillance, Extension to Scope, Additional Visit or Re-assessment.

All phases require inputs from both the laboratory as a customer and from UKAS.

Even though most laboratories will have submitted their applications for transition to ISO15189:2012 by now, there will be times when a laboratory has to submit an application for Extensions to Scope, or a laboratory which has not been accredited may decide to apply. The key to this is ensuring that you have followed the guidance on the application form and the UKAS website and have attached the relevant documents. This is the first way that UKAS and your Assessment Manager will find out more about you.

Review of the application will generate questions from the Assessment Manager. Being prompt and complete in response helps to then make decisions on the expertise and time required to assess the given scope. We consider things like repertoire, locations, other activities, CPA history, size of the laboratory operation.

For Initial Assessments, and if the laboratory is already CPA accredited, there is an expectation that they will undertake a comprehensive gap analysis. This helps a laboratory greatly, and if they have identified the gaps through extensive audit – and addressed the gaps – then it makes the assessment much less onerous, both for the laboratory and the assessment team.

Visit details

After information gathering, we can then prepare a visit plan that details the team, the dates when individuals will be on sites, what they are going to be witnessing and the supporting elements of the standard that they will be also assessing. This document is a good guide for the laboratory to put together a documentation package that will be given to the team prior to the visit. It is important to submit in a timely way, to allow the team to prepare for the visit. Also, the laboratory can think about availability of specimens for tests, staff who will be involved with the technical teams and considering to make the assessment go smoothly for the team.

There may be circumstances where technical assessors require further documents, if the provided literature needs supplementary information.

Communication with the Liaison Team at UKAS offices will be prolific during the final stages leading up to an assessment, so prompt response is useful to help the visit to run smoothly.

The assessment team arrive on site. They are also human, so Maslow's Hierarchy of Needs do apply, and so work with your team. The assessment will be consistent in approach, but might not be uniform, and sometimes we may need to deviate from the visit plan to adapt to evolving situations or circumstances. However, we do have a prescriptive approach to the coverage.

Your approach

Each team member has a different role – the Assessment Manager or Lead Assessor does just that but, in addition, will be focusing on the quality management system and supporting activities, whereas the Technical Assessors will be witnessing activities and processes across the scope applied for. They will use a variety of approaches to assessment. However, the main emphasis is seeing objective evidence that the laboratory meets requirements of ISO15189:2012. It is useful for the laboratory to think about the purpose of the assessment and what accreditation is expected to deliver – that is to provide confidence that a body can provide reliable, reproducible results that are fit for purpose. There will be a holistic approach to the assessment, rather than a clause-by-clause checklist system.

In your gap analysis and preparations for assessment, you will have already realised that many parts of the 15189 standard are intrinsically linked and that ensuring conformity with one clause has direct impacts and consequences on other clauses, hence the holistic approach.

During the assessment, the team may objectively record any potential non-

IN SUMMARY

- ✔ Read the Standard
- ✔ Audit your Quality Management
- ✔ Perform a gap analysis
- ✔ Provide documentation when asked
- ✔ Respond to communications
- ✔ Provide clearance evidence by the dates requested
- ✔ Talk and share good practice
- ✔ Keep UKAS informed
- ✔ Utilise the information, publications and resources on the UKAS website
- ✔ Enjoy the experience.

conformities or opportunities for improvement and these will be discussed with the laboratory in real time as they arise. Findings are either "M": mandatory, where an action is needed or "R": recommendation. The discussions between the assessors and laboratory staff are a very important and beneficial part of the assessment. It helps to understand why there is a finding and to start the process of how to start and evidence any improvement actions. Communication is key here too, and many laboratories have found that this is one of the most useful parts of the assessment. However, it only works if the discussion is not defensive and there is not resistance to change.

The assessment team want the laboratory to succeed and to be recommended for offer of accreditation, not to just look for faults. So, open, two-way, learned and in-depth discussion helps gain the most from any findings. One caveat though – the team cannot advise, consult or tell you what to do – the improvement actions must work for you in your own laboratory.

Any assessment is formally opened by the Assessment Manager/Lead Assessor and closed again by a formal meeting. The team will ensure that the laboratory is clear about the assessment outcome, and by the closing meeting, all the findings will have already been agreed. A summary of the visit and a recommendation will be delivered, and a full explanation of what happens next will be given.

The assessment team leaves and the laboratory can relax – well, not quite yet

Providing evidence

The assessment team leaves and the laboratory can relax – well, not quite yet. There is a timeframe by which you need to provide evidence to show that you have addressed findings raised. It is important that these timescales are adhered to, as there may be occasions where the assessor wishes to see further data or documentation to provide assurance that a finding has been cleared. Also, it is important to follow any instructions that your Assessment Manager has given at the closing meeting about submission of evidence (for example, separate response forms for each assessor), identifying which finding the evidence relates to. It is useful to copy your Assessment Manager into emails when submitting evidence.

The Assessment Manager will provide a full report that includes both the managerial and technical aspects of the standard. They will also initiate the next stage in the process – that is submitting all the documents relevant to the assessment for scrutiny by an independent decision-maker.

There may be some situations where, for some reason, an offer of accreditation for any or part of the scope cannot be made at assessment, or if a transition assessment, where maintenance of CPA accreditation cannot be continued.

Such instances will be dealt with on a case-by-case basis and the Assessment Manager will discuss next steps fully with the laboratory.

Correspondence

Decision-making processes go on behind the scenes and may involve questions to the Assessment Manager, if necessary. For Initial Assessments, eventually a package of correspondence that includes a formal offer of accreditation will be sent out by the decision-maker. This is in the form of a letter that requires the laboratory to sign and return, if they agree then to the terms of the accreditation.

Usually a laboratory is delighted at this stage to receive this and returns the signed agreement quickly. However, sometimes there can be surprising delays in returning the document, which delays the Final Decision stage.

If the laboratory wants to progress to the grant of accreditation, it is in their interests to ensure that they return the signed agreements promptly.

Grant of accreditation (for Initial Assessments) is done by the Accreditation Manager/Section Lead within UKAS.

For surveillance visits, accreditation is maintained following assessment, providing that any caveats stated are met (usually clearance of findings – but in a shorter timescale). This process is dealt with by the Assessment Manager.

Schedules of Accreditation – this is important in that it is the public domain document that states what tests the laboratory is accredited for, so it makes sense to work with your Assessment Manager at Initial Assessment to ensure that the detail is correct.

Surveillance

Finally, you are granted accreditation – well, the pressure is still not quite off yet, as at six months post-grant, we will conduct your first surveillance visit, and thereafter yearly including re-assessment.

During this time, it is imperative that UKAS is informed of any changes, new tests, new equipment, new premises, mergers or closures, as any of these will in some way affect the accreditation status (and this is part of the agreement between the laboratory and UKAS).

For such changes, and whenever you are wanting to add tests to a schedule, we will then work with you to first establish that this is an extension to scope and if it will require on-site or remote assessment. Either way, some form of assessment activity is always required, which may be on-site or remote.

Communication is the key here – so many times, a team will arrive for a surveillance visit to discover that a laboratory has introduced new tests or equipment without the knowledge of UKAS. It might be that we do not have the resource or time to accommodate assessment of that new test and a further visit may be required.

Carefully consider your accreditation cycle when you are introducing changes and then we can work with you to mutually establish how this can be managed to maintain accreditation and add to the scope (including consideration of adding Point of Care Testing assessment to ISO22870:2016). BMS

IMAGE: ISTOCK