UKAS PROCESSES AND MAINTAINING ACCREDITATION

Senior Assessment Managers **John Ringrow** and **Al Bryant** give an update with the latest from UKAS.

It has been some time now since the completion of the project to transition medical laboratories from CPA accreditation to ISO/IEC 15189:2012. Those laboratories that had initial assessments at the beginning of the transition are now preparing for (or have had) their reassessments to renew the accreditation for another four years. Other laboratories are in the first cycle of surveillance visits.

Alongside this, there are many changes and external pressures upon laboratories to maintain a service throughout immense change within the NHS, with new networks being formed, re-organisation and rationalisation of health boards in Scotland, modernising health and social care projects in Northern Ireland, centralisation of microbiology services across Wales and consolidation of key parts of pathology services, for example cervical cytology and human papillomavirus primary screening.

Such influences require mechanisms for maintaining accreditation and processes to accurately reflect a laboratory's schedule of tests.

As UKAS is appointed as the national accreditation body by Accreditation

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Regulations 2009 and EU Regulation 765/2008, it operates through a memorandum of understanding with the Government, through the Secretary of State for Department for Business, Energy and Industrial Strategy (BEIS). UKAS must assess to international standards and must also comply with ISO/IEC 17011:2017 – Conformity assessment – Requirements for accreditation bodies accrediting conformity assessment bodies.

It may be of interest then to briefly take a look at ISO/IEC 17011:2017, to understand why we at UKAS have to do what we do and why we follow certain processes.

ISO/IEC 17011:2017 specifies requirements for any accreditation body engaged in accrediting conformity assessment bodies (in this instance, medical laboratories) and as customers of UKAS, this gives confidence that the accreditation body is competent to perform such tasks. UKAS is peer-evaluated by other accreditation bodies within the European co-operation for accreditation (EA), not just to establish competence to assess to ISO15189:2012, but to all other ISO standards that UKAS assesses. This peer evaluation takes place every four years and the next time evaluation of UKAS' compliance with the requirements of ISO/IEC 17011:2017 will be in late 2020.

EA peer assessors attend on-site assessments and review UKAS documents and records. Findings may be raised, and UKAS is required to provide evidence to clear these, exactly as laboratories are required to after assessments.

Key areas of ISO/IEC 17011:2017 include the organisation and management of assessments and set out general requirements for accreditation agreements, use of accreditation symbols and claims of accreditation, impartiality, financing and liability, establishment of accreditation schemes and structural requirements for the accreditation body. These parts of the ISO/IEC 17011:2017 set out how UKAS function as an organisation. There are also requirements on how an accreditation body manages personnel and management processes to ensure that the right teams at the right time is able to competently assess a laboratory's scope.

ISO/IEC 17011:2017 also sets out requirements for an accreditation body to demonstrate that processes are in place for the administration of the assessment processes. That includes contract review (the process whereby UKAS plans which technical assessors will participate in each assessment, what they will assess, and which aspects of the quality management system will be assessed and for how long), preparation for assessment (visit plans – which will define exactly what is to be assessed and how), the assessment itself and how it is conducted, and then the post-assessment processes, which include reporting (the content of the assessment report and IAR) and mechanisms for clearing mandatory findings.

ISO/IEC 17011:2017 also defines how an assessment body manages the accreditation cycle, how accreditation is extended and limited (through suspensions and withdrawals). UKAS, as an assessment body, must also demonstrate that the information management processes and systems are in place.

Similarly, as there are management requirements for ISO15189:2012, UKAS has to demonstrate that it has a management system that includes document and record control, a process and procedures for nonconformities and corrective actions, improvement processes and

Working with your assessment manager will ensure smooth changes

internal audits and that we undertake management reviews.

The documentation in place and the processes that UKAS uses prior to, during and post-assessment are all peer reviewed and have been shown to demonstrate conformance with ISO/IEC 17011:2017 and are a requirement of remaining as a signatory to the EA.

Maintaining accreditation

There are many changes, with drivers for this coming from either internal trust and health boards, or external to medical laboratories. The latter would include formation of networks in the light of on-going changes proposed within the NHS across England, Northern Ireland, Scotland and Wales, consolidations and rationalisation across trusts and health boards and work on-going with specific service areas, as mentioned previously.

It is important through any changes that there is an overall awareness and consideration of the risk to the service and also the risk and impact upon the laboratory's accreditation. Therefore, very early involvement with your assessment manager is vital, so that UKAS can work with you through the change. Sometimes formation of networks will involve mergers of pathology services across trusts or health boards, and that may involve changes of legal entity. Appropriate documentation to demonstrate that a legal entity to whom accreditation is transferred is prepared to accept all contractual, legal, financial and other obligation, which relate to both the current and historic accredited activities, will be required. Working with your assessment manager well before any changes will ensure smooth transitions and minimise risk of any loss of accreditation.

During periods of change, regular review of a laboratory's current schedule of accreditation (which is visible in the public domain on the UKAS website) is important. Tests may need to be removed from scope from time to time, and that is all part of a laboratory's journey. For instance, tests may no longer be required by a user, new methods supersede previous assays, or tests may need to be removed from scope as a result of sanctions. The key message is to inform your assessment manager at the earliest opportunity of any change, however small that may seem, so that we can work with you and that there are no surprises when the team arrive on site for an assessment.

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Extensions to scope have been reviewed in earlier articles. However, it is always worth a reminder that all the information that a laboratory needs to apply for an extension is available on the UKAS website.

With reference to sanctions, it is important that laboratories understand what these are and why they are there. Sanctions can be imposed by UKAS and, as discussed earlier, ISO/IEC 17011:2017 states that accreditation bodies are required to have procedures for suspension, withdrawal or reduction of the accreditation scope – collectively what are known as "sanctions".

A sanction can be full, and that covers the entire scope of accredited activities, or partial, which may cover a specific location or technical discipline (or individual tests/groups of tests).

Imposed suspensions are applied when UKAS has identified that the laboratory is unable to continue to meet the requirements of the standard for which they hold accreditation. As a consequence, there is a significant probability of invalid work being performed.

Voluntary suspensions are applied if the laboratory has identified a temporary inability to meet the requirements of the standard, or if they lack the necessary competence for their activities. This might include the departure of key technical staff or a move of facilities.

Withdrawal of accreditation is generally applied when a suspended laboratory has failed to address the issues that resulted in suspension adequately or in a timely manner (e.g. failure to satisfactorily close out findings raised). It will also apply if there are failings in the integrity of the laboratory's senior management.

It is important for a laboratory that wishes to regain accreditation for part or all of the service where a sanction is applied, is aware that it is in their hands as to how long it might take to address any issues.

Again, information on sanctions is available on the UKAS website. BMS

UKAS will be at the IBMS Congress in September, where it is presenting at various sessions and also be delivering a specific laboratory accreditation programme on Monday 23 September. It also has a stand where staff from the UKAS office and assessment managers will be available to answer any questions.