REFLECTIONS OF A QUALITY MANAGER PT.I

Mairiead MacLennan looks back over the changes in diagnostic laboratory accreditation that have come into force over recent years.

Information on quality management and accreditation is available from a variety of sources. However, there are still misunderstandings and gaps in knowledge when it comes to setting up, maintaining and continually improving systems in our diagnostic laboratories. UKAS is also continually improving its processes for accrediting laboratories, so it's little wonder it can feel like the goal posts are always moving.

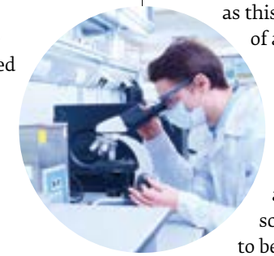
The transition project from CPA standards to ISO 15189 was a mammoth undertaking by UKAS, with ongoing recruitment and training of Assessment Managers as the project grew. UKAS also trained self-employed Technical Assessors and "volunteer" Technical Assessors, released on paid absence by their NHS employers, to perform assessments. They are paid their travel and subsistence, but no fees. In return the rate paid by NHS customers is reduced and many laboratories appear to be unaware of this.

Experiencing difficulties

For many, the step up to ISO 15189 has been a much larger undertaking than anticipated, complicated by structural and political developments in the delivery of health care services. Rising costs and new diagnostic developments, coupled with patient awareness and expectation have contributed to difficulties experienced by laboratories in meeting accreditation requirements . Even after the UKAS road shows, some laboratory staff felt like "rabbits in headlights" during and after initial assessments. There were stories of 'over a hundred findings' at initial assessments. Some staff with 40 years experience called it a day, a little sooner than they might have. A number of experienced staff who had adjusted to the introduction of computers onto the work bench, were lost due to perceptions about the requirements – for example, calibration of measuring devices for simple laboratory tasks. Of course some of the stories were exaggerated and the others were pure myth, but much sound, useful information was shared in laboratory networks. Now, with many laboratories through to their fourth assessments and a few preparing for their second major assessment, where are we? How much have we learned, what has been gained and where do gaps in knowledge and understanding remain?

Evolution

Scotland is extremely lucky in having the IBMS-affiliated Scottish Quality Management Discussion Group (SQMDG), formed by biomedical scientists in 2005 for those working or interested in laboratory quality management.



The SQMDG established a model offering biannual meetings and these have been a fertile learning ground. The opportunity to network and discuss our challenges has proved to be a significant support to us all. Most notably, this has supported a consistent approach within Scotland.

Regarding my own development in quality management, with experience of ISO 17025 and 15189, from discussions with colleagues, questions asked at SQMDG meetings as well as from performing Technical Assessments for UKAS, our ability to understand the concepts, the implications and the impact of the requirements is still evolving. I believe that is something to celebrate as this is the whole point of accreditation.

Reinvent the wheel?

It can be stressful and frustrating to face four days of assessment by a team of assessors. It can be just as scary for assessors, who want to be encouraging, put staff at ease, do the best job they can and not cause too much of a disruption. No one wants to feel they aren't getting it right. We are proud, conscientious professionals trained to work to HCPC standards of proficiency. We all believe we are doing the very best we can with the resources available, so it can be shocking, to have an improvement action report with many findings. However it is worth remembering, we are all in it together, and can help each other – just ask. I'm a firm believer in not reinventing the wheel. Technical assessors performing work for UKAS must not, however, cross the line into providing consultancy. Independence and objectivity is essential and nigh on impossible when reviewing your own work, ideas or thought processes. So it can appear unhelpful when assessors are vague or wary of answering queries put to them.

"There have been significant improvements in laboratory services delivery across the UK"

Inconsistent

Another criticism that some have is that assessors are inconsistent. Of course it happens, and is to some extent unavoidable. Some inconsistencies arise because assessors come from different backgrounds, have different key skills, experience and knowledge. They have different personalities and values, some are more pragmatic than others, some emphatic about detail, some precise and process driven others with a broader helicopter view.

There can be communication failings between assessor and staff being observed. Findings raised in one laboratory may not be in another when circumstances appear similar, however one had been able to justify their approach whereas the other could not. If you believe a finding is not justified or appropriate, calmly explain why. It is the responsibility of the assessor to demonstrate clearly to the laboratory where the nonconformity with the ISO 15189 clause and/or Technical Policy Statements (TPSs), or other associated document, arises. Many laboratories are unaware of the full extent of TPSs and that these must followed. It is the laboratory's responsibility to describe actions to close any non conformity.

Significant improvement

UK laboratories are through the major part of this massive undertaking, which is no mean feat. UKAS has done a good job in this achievement. The laboratories have performed exceptionally well, from what I hear on the networks with which I'm involved.

Whatever we all think as individuals, I have no doubt that there have been significant improvements in laboratory services delivery across the UK. Evidence of training and competence is more robust. Even if the only difference for some is that their documentation is immediately to hand if HCPC makes a request for CPD audit.

A major concern for all is, at what cost, to date and in the future? There is a balance of compliance, level of detail and pragmatism. UKAS must address the matter of consistency and be transparent in the process. Compliance does not come cheap. If, however, the benefits are measurable, in demonstrating improved quality and performance and service to the patient, then we will ensure we meet requirements. If "box ticking" creeps in and we do anything simply to keep UKAS "happy" then there is no added value and only resource wastage. That must always be our benchmark. IBMS

Mairiead MacLennan is Professional Manager (Quality and Training) at the Department of Medical Microbiology and Infection Control, Victoria Hospital in Kirkcaldy. She is also a technical Assessor for UKAS.