Transition of CPA accredited medical laboratories to ISO 15189 accreditation by UKAS

Since 2010, discussions have been taking place concerning the transfer of CPA accredited laboratories to ISO 15189 accreditation by UKAS. A mechanism for the transfer has been developed and a steering group formed. Information about the steering group and the strategic considerations which underpin the transition has been outlined in previous issues of the Newsletter. Here, recently-appointed manager of the Transition Project, Delia Geary, provides an update on how the project is progressing and clarifies the anticipated timelines and structures.

It was back in 2010 that a project plan for the transition was first drafted. More recently, the identification of seven project subgroups has helped to ensure that the many different aspects of the transition to BS EN ISO 15189:2012 are addressed efficiently and effectively to meet the overall requirements of the project. It is the responsibility of the project manager to ensure that the project is keeping to its key milestones.

Two of the subgroups have been identifying the differences between the two standards (ISO 15189 and CPA) and between the CPA and UKAS assessment processes. One of the reasons for comparing the assessment processes is that UKAS is required to demonstrate that it works to the international standard for accreditation bodies —ISO/IEC 17011—as well as requirements specified in the Accreditation Regulations 2009. This comparison work has been an important part of the early stages of the transition in order that we can highlight those areas that laboratories will need to focus on and which may need further guidance from CPA and UKAS.

Aware that ISO 15189 was under revision, UKAS and CPA made the early decision to carry out transition assessments against the most up-to-date version of ISO 15189 rather than the 2007 version. Timescales for these assessments have had to be adjusted because the revision of ISO 15189 overlapped but did not exactly align with our original project plan. In October 2012 the Final Draft International Standard (FDIS) ISO 15189 was approved and we felt confident therefore that there would be no further significant changes to the document and that any gap analyses done against this would be relevant to the final published version.

The final published version is now available from ISO (http://www.iso.org/iso/home/standards.htm) or BSI (http://www.bsigroup.com/standards). UKAS has negotiated a discounted price for laboratories with BSI, the details of which will be published on the CPA (www.cpa-uk.co.uk) and UKAS websites (www.ukas.com).

A small group of laboratories whose regular assessment visits were due, have agreed to participate in a pilot process. This will involve their assessment against both the CPA standard and ISO 15189 in order to help underpin confidence in the adopted transition procedures, including the effectiveness of training in UKAS assessment procedures. The eligibility criteria for the pilot process included, amongst other things, the timeframe for the next routine CPA visit, the size of the laboratory/user base, the type of organisation of which the laboratory is a part and the range of the accredited activities.

Peer assessors whose knowledge and expertise align with the scope of the laboratories’ activities have agreed to participate in the pilot process, along with a small number of CPA Regional Assessors. Formal training courses in ISO 15189 and UKAS assessment procedures will take place in January 2013. It is anticipated that the pilot assessments will run from the end of January to the end of March. These assessments will cover all aspects of the CPA standards as well as the additional ISO 15189 requirements in order to confirm continued conformity with CPA standards and to maintain CPA accreditation during the transition process. The pilot stage will be followed by a review period to determine whether the objectives of the pilot were achieved and that the approach adopted for the assessments was satisfactory or whether we need to modify the process.

The roll-out of the transition assessment process to CPA accredited laboratories is expected to start in October 2013 with the initial grants of accreditation occurring in July 2014. The phasing of laboratories into this roll-out will coincide with the planned timeframe for laboratories’ next CPA visit.

Between the end of the pilot assessments and the initial roll-out assessments, a series of road shows will be organised to inform laboratories of the differences identified between the CPA and UKAS processes for accreditation as well as the differences between the CPA standard and ISO 15189.

Delia Geary: Transition Project Manager
Validation and verification

The CPA standards for accreditation require laboratories to demonstrate and provide evidence that examination procedures, equipment and materials are fit for purpose and meet the needs of their users. Here we aim to highlight the CPA’s position on some issues specific to validation and verification.

There are three key CPA requirements related to validation and verification.

- **Procurement and management of equipment** (CPA D1) The proper procurement and management of equipment ensures that the laboratory can meet the needs and requirements of users.
- **Management of materials** (CPA D3) It is essential to have proper management of all materials used in the provision of the service.
- **Validation** (CPA F1.1) Examination procedures, including those for sampling, shall meet the needs and requirements of users and shall be validated by the manufacturer/method developer for their intended use.

In addressing these requirements applicant and accredited laboratories are expected to fulfil the following responsibilities.

- Define a clear specification of performance requirements for procedures, equipment and materials.
- Ensure the competence of staff involved in validating and verifying procedures, equipment and materials.
- Critically evaluate, where necessary with expert independent advice, any validation information provided to establish that the procedures, equipment and materials meet performance requirements and that confidence can be placed in the validation that has been carried out.

Parameters that might be considered during validation include:

- selectivity and specificity;
- measurement range;
- calibration of measurements that have an impact on results;
- traceability of measurements;
- bias;
- linearity;
- limit of detection/limit of quantitation;
- ruggedness (ability to withstand small variations to procedure without the performance characteristics being affected);
- precision;
- rates of true and false negatives and positives.

- Procure equipment and, where applicable, materials with acceptable validated performance requirements that meet analytical and examination needs.

Having validated and verified the procedures and performance of equipment and materials, laboratories are also required to continue to:

- verify that the equipment, once installed, meets the laboratory’s required (and where necessary the manufacturer’s stated) performance characteristics and provide evidence of how this was done, prior to use.
- if procedures or equipment are used outside of the intended use, specify the required performance characteristics for the proposed use, fully validate the procedures and equipment against the performance characteristics for the proposed use, and then verify that these can meet the required performance characteristics.

Suppliers and manufacturers have an important role to play in helping laboratories to demonstrate that equipment and materials are fit for purpose. It is expected that reputable suppliers and manufacturers of such items should provide their customers with the following:

- clear statement on the recommended procedures and intervals for maintenance, cleaning, calibration and performance (system suitability) checks of equipment, as well as recommendations on suitable calibration standards or reference materials;
- validation information that demonstrates the equipment and materials meet the declared performance characteristics when used for the intended purpose including, for example, validation of any automated calculations performed by integral computer software;
- user guidance including, for example, environmental conditions for equipment and material location.

CPI will continue to seek evidence of satisfactory validation and verification of all procedures, equipment and materials as necessary. In addition, laboratories will be expected to demonstrate and provide evidence of on-going control of their procedures through the use of internal quality control and comparability with other laboratories through the demonstration of satisfactory performance in appropriate EQA schemes.

CPI does not endorse or exclude the use of any specific makes or models of equipment or materials. Any non-conformities raised during the course of CPI assessments will relate to the responsibilities of a laboratory in providing satisfactory evidence to demonstrate that procedures, equipment and materials are fit-for-purpose and that equipment is operated, maintained and, where applicable, calibrated in an acceptable manner.

**Jane Beaumont**, Business Development Director
New Assessment Managers/Regional Assessors

We are delighted to be able to welcome the following three new Assessment Managers/Regional Assessors.

Carol Moore
Carol spent much of her career as a BMS in Haematology and Blood Transfusion. For the past six years she has been Area Laboratory Quality Manager with Ayrshire and with Arran NHS Trusts. She has also been a CPA Peer Assessor for nearly three years. She is a Fellow of the Institute of Biomedical Science (FIBMS) and has a postgraduate diploma in Quality Management.

Julie Sims
Julie trained in multi-disciplinary Biomedical Science before specialising in Microbiology. Her varied career has included working as Laboratory Manager of an NHS Microbiology Laboratory and also of an international multi-disciplinary reference laboratory supporting the work of CAREC (Caribbean Regional Epidemiology Centre). After a stint developing microbiology laboratories in the Caribbean, she returned to the UK to work as a Microbiology Manager before taking up her post as an Assessment Manager/Regional Assessor. Julie is FIBMS, MSc, and has a diploma in Management.

Mark Prescott
Mark spent 19 years working in microbiology laboratories in Wigan and Dublin and, most recently, in Scarborough Hospital as Head BMS. He has been a CPA Peer Assessor (for microbiology) for the past two years and, prior to joining UKAS, completed an IRCA certified QMS Lead Auditors course. He has a BSc in Biological Sciences from the University of Wolverhampton, and an MSc in Biomedical Sciences and also in Healthcare Management.

Delia Geary: CPA Transition Project Manager

In September, Delia Geary was appointed Manager of the project to implement the transition of CPA laboratories from the CPA Standard to BS EN ISO 15189:2012.

Delia joined UKAS as an Assessment Manager in December 1998 before which she had been a BMS in the Public Health Laboratory Service and subsequently in the NHS at the Leicester Royal Infirmary (LRI). Whilst working at the LRI she was the Deputy Quality Manager in the food and environmental laboratory where she helped to develop the management system which resulted in their UKAS accreditation to ISO 17025.

Since joining UKAS, Delia has assessed and managed the accreditations of numerous organisations to a variety of International standards including ISO 17025, ISO 17043, ISO 15189 (and ISO 22870) and ISO 17020. She also has experience in assessments to ISO Guide 34 for reference material producers. She has contributed to the development and delivery of training to customers and to assessors in, amongst other things, the specific requirements of ISO 15189:2007. Delia is a Fellow of the Institute of Biomedical Science.

Accreditation for medical reference measurement laboratories

The specific requirements for reference measurement laboratories in the field of laboratory medicine are set out in an international standard, BS EN ISO 15195: 2003 Laboratory medicine. Requirements for reference measurement laboratories. Under this standard, laboratories are regarded as providing a calibration service and, in order to become accredited, medical reference measurement laboratories must meet the requirements of BS EN ISO 15195 in conjunction with the requirements of ISO/IEC 17025: 2005 General requirements for the competence of testing and calibration laboratories.

Reference measurement laboratories in the UK can apply to UKAS for accreditation for ISO/IEC 17025 and BS EN ISO 15195. Details of how to apply can be found at http://www.ukas.com/about-accreditation/apply-for-accreditation/Apply_for_Accreditation.asp

BS EN ISO 15195: 2003 is not applicable to routine medical laboratories. Within the UK the majority of routine medical laboratories are currently accredited by CPA against the requirements of the CPA standards.
Have you got what it takes to be a CPA peer assessor?

We are recruiting new peer assessors from many branches of laboratory medicine. There are particular shortages of medical staff in cytopathology, histopathology, haematology and andrology, but we encourage applicants from any discipline.

Why be a peer assessor?

CPA accreditation is widely recognised throughout the UK and is fully supported by all the main professional bodies, in particular the Royal College of Pathologists (RCP), Association of Clinical Pathologists (ACP), Association of Clinical Biochemists (ACB), and the Institute of Biomedical Science (IBMS).

Being a peer assessor enables laboratory practitioners to gain a deeper understanding of the CPA standards and to share best practice through visits to laboratories similar to their own.

What does a peer assessor do?

The role of the CPA Peer Assessor is to provide specific medical laboratory expertise for the assessment of applicant and accredited laboratories. The CPA Assessment Teams are normally composed of a full-time CPA Regional Assessor acting as Lead Assessor, supported by peer assessor(s) who will assess the validity of systems, appropriateness of equipment, facilities and resources, competence of staff, internal quality control, external quality assessment and patient needs and requirements.

What are the criteria for peer assessors?

A peer assessor must be employed at a senior professional level within their own institution and/or must be able to demonstrate maintenance of up-to-date knowledge and skills. In addition peer assessors must:

- be a member of a relevant professional body and endorsed as such;
- be supported by the Chief Executive and the Head of Department of their own institution, where relevant;
- be committed to accreditation and quality improvement;
- be able to commit to at least 3 assessment visits per annum, for a minimum of 3 consecutive years;
- be able to undertake all the necessary training and to attend the update sessions;
- maintain competence to assess a medical laboratory;
- be organised and well presented;
- have good interpersonal skills;
- be able to communicate with staff and management at all levels;
- be able to give empathetic feedback;
- be able to report accurately and concisely, both orally and in writing;
- have a wide knowledge of the functioning of a medical laboratory;
- have an open-minded approach to assessment;
- have the ability to work within a team;
- adhere to the policy on confidentiality.

Approaching retirement?
The increased availability of recently retired peer assessors has been invaluable to CPA and we would encourage you, if possible, to apply to us and train before you retire.

How to apply

If you are interested please complete the application form available from www.cpa-uk.co.uk/files/pa.doc

For further information, please call the CPA Office in the first instance on 020 8917 8400 or email office@cpa-uk.co.uk

Why not encourage your colleagues to apply as well?

IQIPS Programme

Independent assessment and accreditation is a key part of the Royal College of Physicians (RCP) IQIPS Programme (Improving Quality in Physiological diagnostics Service) which covers the range of physiological diagnostic specialisms including audiology, cardiac-physiology, gastro-intestinal physiology, neurophysiology, ophthalmic and vision science, respiratory and sleep physiology, urodynamics, and vascular science.

UKAS has been contracted to deliver the national assessment and accreditation service for all eight of these physiological diagnostic specialisms. Assessments for accreditation will be against the IQIPS Standard which is owned by the RCP and is based on the imaging services ISAS model. UKAS is working closely with the RCP on a plan for the staged roll out of accreditation to each specialism. The first phase was launched in June 2012 when applications were invited from adult hearing services. The next stages will cover vascular science, respiratory and sleep physiology, and cardiac physiology.

The NHS Any Qualified Provider (AQP) programme, under the auspices of the Department of Health’s Chief Scientific Officer, Professor Sue Hill, has specified the achievement of accreditation as one of the criteria for organisations wishing to be placed on their register to provide adult hearing services.