Point-of-care testing: why is accreditation of this service needed?

Point-of-care (POC) testing is now ubiquitous in all healthcare environments and at every stage, from the commencement of emergency care with paramedics to specialist treatment in acute and critical care units. In the wider community, many GPs offer some form of POC testing via their clinics or surgeries. Accreditation of POC testing providers, whether publicly or privately owned, presents a wide range of challenges, particularly for multisite organisations operating the hub and spoke model.

Since the transition to ISO 15189:2012 commenced in October 2013, UKAS has been talking on a case by case basis to organisations accredited to CPA standards for POC testing about the process of transitioning to ISO 22870 when their next ISO 15189 assessment became due. Any new applicants for POC testing accreditation may only apply for ISO 15189/ISO 22870 accreditation. Both ISO 15189 and ISO 22870 are internationally recognised standards and, as a full member of the International Laboratory Accreditation Cooperation (ILAC), UKAS is a signatory to multilateral Mutual Recognition Arrangements. As a result, any organisation achieving UKAS accreditation to that standard is able to demonstrate its competence in over 80 global economies. This ‘tested once, accepted everywhere’ philosophy could be very useful for global multisite international POC testing providers, as it reduces the need for individual accreditation in each country, thus saving the provider time and money.

Accreditation of POC testing services

The introduction of ISO 22870:2006 (Point of Care Testing – particular requirements for quality and competence), applied in conjunction with ISO 15189:2012 (Medical Laboratories – particular requirements for quality and competence), provides a platform for using international standards in the accreditation of organisations that provide POC testing. ISO 22870:2006 is directly applicable to POC testing conducted in hospitals and ambulatory care. While patient self-testing in the home (or a community setting) is excluded from the standard, elements of ISO 22870:2006 can still be applied. However, as ISO 22870 is not a standalone standard, it needs to be used in conjunction with ISO 15189. This means that the POC testing provider must also be accredited to ISO 15189.
Hub and spoke model

Long established in the private sector, the hub and spoke model is now common practice in the public sector. In the majority of models, the location that coordinates the management system is considered to be the hub, and is generally the head office or main testing laboratory. Part of the accreditation process includes identification and assessment of the entity that takes legal responsibility for the results. As each accreditation is only granted to one legal entity under a single accreditation number, this will usually reside with the hub.

The spokes in this model are where the POC testing services are delivered, typically wards, clinics or surgeries. These spokes are not always under the direct line management of the POC testing service provider. In order for accreditation to be granted, POC testing at the spokes must be demonstrably under the control and responsibility of the accredited provider. This is usually achieved through a contractual arrangement between the accredited entity and the legal entity where the delivery point is based. As the detail within that contractual arrangement forms an integral part of the accreditation process, it is subject to rigorous assessment.

The assessment process will distinguish between those POC testing providers that offer the management of POC testing, rather than the provision of POC testing services. This is an important issue as potentially there are significant differences between the two, particularly with regard to responsibility for results.

Management system

To comply with ISO 15189/22870, overall control of the management system must be under the responsibility of a quality manager who has appropriate competence, authority and resources. Part of the responsibilities of the quality manager must be effective planning of the audit programme, which can also be used in a proactive manner to identify preventive actions (ie to prevent the occurrence of non-conformities) and potential improvements.

Competence

Clear procedures must be in place and implemented to ensure that only authorised operators who can demonstrate continued competence can undertake testing. There must be evidence to show that performance in appropriate external quality assessment (EQA) and internal quality control programmes (and participation) is satisfactory and reviewed regularly, with any anomalies in performance investigated and the potential impact on patients results evaluated.
Role of accreditation within healthcare

Under EU legislation, every Member State has a single National Accreditation Body (NAB) and for the UK this is the United Kingdom Accreditation Service. Appointed by, but independent of, government, UKAS’s role is to assess the competence of organisations providing conformity assessment services (testing, calibration, inspection and certification). In other words, accreditation is there to check the checkers.

Clinical Pathology Accreditation (CPA) has a proven track record of delivering pathology accreditation to over 1250 laboratories across the world. In 2009 CPA became a wholly owned subsidiary of UKAS as part of a strategy to contribute to the modernisation and development of pathology services in the UK.

The role of accreditation within the health and social care sector has been formally recognised in a joint policy agreement released by the Department of Health and Department of Business Innovation and Skills. The agreement highlights that “Accreditation increases trust in conformity assessment services and thus reinforces the mutual recognition of products, processes, services, persons and bodies across the EU”. Supporting this approach, a key deliverable of the NHS England business plan for 2014–15 to 2016–17 is to “ensure that more than 70% of all scientific and diagnostic services are part of accreditation programmes and demonstrate robust quality assurance measures”.

Further formal recognition of the value of accreditation within the healthcare sector comes from the Care Quality Commission, which states “CQC recognises the potential value of clinical service accreditation and peer-review schemes as information sources to support its inspections. Such schemes have the potential to provide useful intelligence and provide independent assurance that accredited services meet standards”. Clinical Pathology Accreditation is one of the three UKAS-accredited schemes that have been approved as an official information source.

The Pathology Quality Assurance Review, chaired by Dr Ian Barnes, recommended that commissioners should follow Medicines and Healthcare products Regulatory Agency (MHRA) published guidelines (Management and Use of IVD Point of Care Test Devices, December 2013) when commissioning POC testing.

Accreditation also receives support from NHS England and Chief Scientific Officer Professor Sue Hill: “…accreditation schemes are so important. Independent assessment provides an objective view of what is being delivered and the standards and approach of the process itself do an enormous amount to embed a quality culture”.

Information technology

The generation of results and subsequent review for possible urgent communication to clinical staff is a critical element of the POC testing service. Effective interfacing of IT systems is essential, as it allows clinicians to make appropriate commentary in a clinically suitable timeframe. In those instances where the delivery points may be at different sites with potentially different IT systems, the impact of the various systems has to be established and the impact on the service considered.

Summary

Accreditation allows providers of POC testing to demonstrate that they comply with defined standards and best practice. It provides authoritative assurance of the technical competence of the provider to undertake specific analyses or measurements according to validated methods. It encourages the sharing of best practice and prevents unnecessary duplication of performance information gathering for Care Quality Commission (CQC) registration. By bringing together all quality assessments into a single package, accreditation reduces risks and controls costs, giving accredited organisations a competitive edge. It also stimulates innovation and can be used as an effective lever for change or service improvement.

Accreditation to ISO 15189 and ISO 22870 gives confidence in the quality of the testing service offered at the point of care, to commissioners, providers and most importantly patients. The accreditation process includes an assessment of the overall competence of the entity seeking accreditation through an evaluation of the effectiveness of the management system and the mechanisms implemented to establish and maintain competence of all relevant personnel.

The organisation of POC testing and identification of associated responsibilities are essential in establishing confidence in the results and the overall service delivery. Key control points such as audits, EQA and internal quality control measures across all POC testing services and delivery points offered by a particular organisation are intrinsic to the assessment for accreditation to ISO 15189/22870.

About the author

Delia Geary has worked with medical laboratories for almost 40 years. Her career began at the Public Health Laboratory Service, where she started as a medical laboratory technician in microbiology, ultimately gaining over 20 years of practical experience. Delia’s first involvement with accreditation came in 1992 while working as a deputy quality manager in the food and water laboratory, where she played a part in the task of achieving laboratory accreditation with NAMAS, the predecessor to UKAS. It wasn’t until 1998 that Delia’s career in accreditation took off, when she joined UKAS as an assessment manager. After almost 20 years in accreditation, Delia now has extensive knowledge and experience of assessing and managing the accreditation of organisations to various standards, including ISO/IEC 17025; ISO 15189; ISO Guide 34; ISO/IEC 17043; ISO/IEC 17020; and ISO 22870. In 2012, Delia became the CPA transition project manager with specific responsibility for managing the transition of CPA-accredited laboratories and EQA providers to ISO 15189 and ISO/IEC 17043, respectively.

Further information on UKAS and accreditation can be found online (www.ukas.com) or general enquiries can be submitted by email (communications@ukas.com).