

# Accreditation or certification – implications for the laboratory

Despite introduction of the revised laboratory accreditation standard ISO/IEC 17025:2005 nearly 18 months ago, confusion remains about the differences between accreditation and certification. Here, Graham Talbot seeks to dispel any misunderstanding.

When it comes to implementing a quality management system, the majority of biomedical laboratories are faced with a straight choice between accreditation and certification. However, not knowing the difference between an accredited laboratory and a certified laboratory is an all too common occurrence.

The United Kingdom Accreditation Service (UKAS) is the sole national

accreditation body recognised by government and has over 120 certification bodies and 1500 laboratories among its customers. This puts UKAS in an ideal position to be able to witness the sort of problems that can arise from the confusion about accreditation versus certification.

Despite this confusion, the distinctions between the two different types of laboratory recognition can be explained easily.

*Certification* represents a written assurance by a third party of the conformity of a product, process or service to specified requirements. *Accreditation*, on the other hand, is the formal recognition by an authoritative body (eg Clinical Pathology Accreditation [UK]) of competence to work to specified standards.

A key point to appreciate when considering the relative merits of a laboratory accredited to the International Organization for Standardization's standard ISO/IEC 17025:2005<sup>1</sup> or one certified to ISO 9001:2000,<sup>2</sup> is that there are differences between the emphasis and the processes used to determine compliance with the standards for each.

## CERTIFICATION

The ISO series of standards is recognised worldwide. ISO 9001:2000 certification is a generic standard for quality management systems. It is applicable to any organisation, irrespective of type, size or product, service provided or industry sector, including laboratories.

The ISO 9001:2000 assessment team consists of auditors with the technical expertise to enable them to apply the generic requirements of the standard to operations of laboratory services. However, emphasis is on establishing an organisation's compliance with requirements for a quality



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management system. This relates to what the organisation does to fulfil the customer's quality requirements and applicable regulatory requirements. It aims to enhance customer satisfaction and to achieve continual improvement of its performance in pursuit of these objectives.

Unlike the ISO/IEC 17025:2005 accreditation standard, ISO 9001:2000 certification does not contain technical requirements for laboratory personnel and operations. As such, certification against ISO 9001:2000 should not be interpreted to mean that a laboratory has demonstrated the technical competence to produce valid data and results.

### ACCREDITATION

ISO/IEC 17025:2005 is the accreditation standard applicable to all laboratories, including those in biomedical science. While management requirements form part of ISO/IEC 17025:2005, the emphasis of this standard is to establish the technical competence of a laboratory for a defined set of tests, measurements or calibrations.

The management requirements of ISO/IEC 17025:2005 meet the principles of ISO 9001:2000, but are written in language relevant to laboratory operations. The assessment team for laboratories comprises relevant technical experts and assessors able to evaluate compliance with these management requirements.

The accreditation team's major emphasis is on establishing that the laboratory being assessed meets the specific technical requirements. To achieve this, the team must determine the specific technical competence of personnel and the availability of all the technical resources needed to produce reliable data and results for specific test methods.

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### BENEFITS OF CERTIFICATION

A certified ISO 9001:2000 management system can offer a laboratory a number of benefits. The most obvious of these is increased customer satisfaction levels through improved product, process and service quality. As processes are made more efficient, there are internal benefits of productivity improvements and less waste. For laboratories operating in some industrial sectors, such certification remains a contractual obligation or expectation.

### BENEFITS OF ACCREDITATION

An increasing number of customers are stipulating the use of accredited services, whether as a legal requirement or as a preferred solution. Achieving UKAS accreditation will put laboratories in a better position to win business, particularly government tenders. As UKAS accreditation test certificates are recognised internationally, the potential customer base can be increased further by providing access to overseas business.

All laboratories want to distinguish themselves from their competitors, especially with new customers where it is often difficult to establish a proven track record. While effective marketing will undoubtedly help, it is accreditation that provides customers with a formal recognition of the competence, impartiality performance and capability of a particular laboratory.

Gaining accreditation to an internationally recognised standard such as ISO/IEC 17025:2005 provides a laboratory with access to the impartial technical expertise of assessors. The benefits of this experience can, in turn, be passed on to a laboratory's customers.

Customers of laboratories accredited to ISO/IEC 17025:2005 also benefit from the reliable accuracy of measurements and tests carried out by the laboratory in compliance with best practice. However, should a problem

arise which results in legal action, it is also worth bearing in mind that the use of an accredited body to carry out independent evaluations can help to demonstrate due diligence.

### APPROPRIATE SCOPE

There are differences between the purpose, criteria and emphasis of the ISO 9001:2000 quality system standards and those of the accreditation standard ISO/IEC 17025:2005. For laboratories concerned with demonstrating technical competence underpinned by a quality system, ISO/IEC 17025:2005 is the appropriate standard. Similarly, those seeking competent testing facilities should ensure that facilities are accredited to ISO/IEC 17025:2005, with a scope of accreditation (eg CPA) appropriate for the testing or calibration required.

Perhaps the most important consideration for any biomedical laboratory must be that the services in question should give accurate and reliable results. Achieving independent laboratory accreditation signifies that a laboratory is competent, well managed and that its users can rely on the results of any analysis undertaken.

A laboratory accredited by UKAS can prove its competence, impartiality and sustainable performance. This ensures that everyone can have confidence in the quality of goods and in the provision of services throughout the supply chain. Once laboratories and their customers understand the differences between the processes of laboratory accreditation and certification, they will begin to appreciate the real benefits that accreditation can bring. ■

### REFERENCES

- 1 ISO/IEC 17025:2005. *General requirements for competence of testing and calibration laboratories*. [www.iso.org](http://www.iso.org)
- 2 ISO 9001:2000. *Quality management systems – requirements*. [www.iso.org](http://www.iso.org)

Graham Talbot is UKAS technical and external affairs director. Information on how to become accredited or on the search for an accredited supplier can be found at the UKAS website ([www.ukas.com](http://www.ukas.com)). Information on Clinical Pathology Accreditation (UK) can be found at the CPA website ([www.cpa-uk.co.uk](http://www.cpa-uk.co.uk)).