

Chapter 10

A Practical Approach for Implementing the Additional Requirements of the ISO 15189:2012 Revision

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ABSTRACT

Medical laboratory services have a critical role as an integral component of patient care. The accreditation standard of ISO 15189, a guidance document, provides validation that a laboratory is competent to deliver accurate and reliable test results. This international standard has been evolving since 2003. Following the second publication (2007), the standard was released as a revised and updated version in 2012 (Medical laboratories – Requirements for quality and competence). The text of ISO 15189:2012 has been approved as EN ISO15189:2012. European Union members and associate countries agreed to accord it the status of a national standard by May 2013. Any conflicting national standards need to be withdrawn by November 2015 at the latest. The purpose of this chapter is to mark the differences between the two versions of the standards and to highlight the changes and additions that have been incorporated into ISO 15189:2012. A practical approach will be helpful for laboratories to make a smooth transition to the updated standard when revising their quality and technical documentation to meet the new requirements.

INTRODUCTION

There is a need for diagnostic tests which can identify illness, isolate causes and subsequently check the effectiveness of treatment. In order to achieve reliability and consistency of results a comprehensive laboratory quality management system is called for (Peter T.F., 2010). The ac-

creditation standard of the International Organization for Standardization (ISO) 15189 provides for this. It promotes ‘best practice’ globally and makes for comprehensive harmonisation of lab practices in the field.

The standard of ISO 15189 has been implemented in over 140 countries, in most cases voluntarily although it is mandatory in some countries,

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Australia, the Canadian province of Ontario, Iran, and some European countries (e.g. France and Latvia) (Ford A., 2008; ENAC, 2011).

ISO first published its 15189 standard in 2003, “Medical laboratories— Particular requirements for quality and competence for clinical laboratory testing and in vitro diagnostic test systems”, for use in medical laboratories worldwide (2003). It was reformulated in 2007, which is to be superseded by a third- technically revised 2012 version (ISO, 2007 and 2012). Currently, it is closely aligned with the requirements for ‘testing and calibration laboratories’ (ISO 17025).

A cross-reference, including the itemizing of the clauses, between the second and third editions of this International Standard is provided as Annex B in the updated version (ISO, 2012). There have been several important changes to the content of ISO 15189:2012. The purpose of this chapter is to mark the differences between the two versions of the standards, and to highlight the changes and additions that have been incorporated into the ISO 15189:2012.

BACKGROUND

The text of ISO 15189:2012 has been approved by the European Committee for Standardization (CEN) as EN ISO 15189, as it stands on 31 October 2012 (Austrian Standards Institute, 2013). CEN members are legally required to observe the CEN/ CENELEC Internal Regulations, which imposes this as a basis for a common European standard. This has to be incorporated into national law as it stands, without modification. Accordingly, it had to be given the status of a national standard by issuing an identical text or by endorsement, by May 2013, and any conflicting national standards have to be withdrawn by November 2015 at the latest. By the CEN/CENELEC Internal Regulations, the national standards organisations of the European Union (EU) member and associate countries are bound to implement this European Standard.

The International Laboratory Accreditation Cooperation (ILAC) organisation has agreed a transition period of three years four months for the implementation of ISO 15189:2012 (ILAC, 2012). Henceforward, all accredited medical laboratories must demonstrate their conformity to the new standard and have up-dated accreditation certificates issued by March 2016.

Using the ISO 15189 standard the College of American Pathologists (CAP) now offers a new laboratory accreditation programme, ‘CAP 15189’, which is available for US-based medical laboratories. Laboratories applying for the accreditation to CAP 15189 must be CAP accredited by the CAP’s Laboratory Accreditation Program (CAP, 2012). ISO 15189 accreditation is voluntary in the United States.

In the UK, UKAS (United Kingdom Accreditation Service) is currently managing the transition of all CPA (Clinical Pathology Accreditation) accredited laboratories to the standard ISO 15189:2012. UKAS and CPA made an early decision to carry out transition assessments against the 2012 version of ISO 15189 rather than the 2007 version, with initial accreditation scheduled for July 2014 (CPA, 2012). They have provided summarised information regarding the new, additional, requirements of the updated version in their web pages (UKAS, ‘Potential’ and ‘Summary’).

Some national and regional accreditation organizations have prepared their transition plans and given detailed information for the main changes in practice to provide guidance and practical steps for managing the transition from ISO 15189:2007 to ISO 15189:2012. These are: The National Association of Testing Authorities (NATA)(2013), Irish National Accreditation Board (INAP)(2013), International Accreditation New Zealand (IANZ) (IANZ, n.d.), South African National Accreditation Services Accreditation Service (SANAS), The Southern African Development Community (SADCAS)(2013), Malaysian Accreditation Body (SAMM) (2013), Dutch Accreditation Council (RVA) (RVA, n.d.), Hong Kong Laboratory Ac-

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