ISO 15189:2012 Management Requirements for Cytopathology Laboratory Information Systems

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ABSTRACT

During the last decade, there is an increasing need for quality improvement of medical laboratories via the use of quality-related standards. Recently regulatory bodies suggest and sometimes enforce the application of ISO 15189, which is designed especially for medical laboratories. Despite the standard does oblige the application of Laboratory Information Systems (LISs), it is evident that without a LIS it is difficult for laboratories to operate efficiently. Modern cytopathology laboratories form complex systems composed of a multidisciplinary human team coupled with medical modalities and capabilities. Hopefully, such laboratories have well-standardized and defined workflow. The adoption of the standard, creates numerous management requirements, introduces new functions and associated overhead. In this paper, we present design and implementation issues of an enhanced LIS to support ISO 15189 in a cytopathology laboratory. The LIS designed around ISO 15189 management requirements can improve, enhance and facilitate the standard application and adoption.

Keywords: Accreditation, Cytology, Cytopathology, Distributed Computing, E-Health, E-Learning, Laboratory Information Systems, Quality Assurance, Quality Control, Telecytology, Telediagnosis

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INTRODUCTION

ISO 15189:2012 Becomes Obligatory

In many developed and developing countries, there is a requirement posed by regulatory bodies, and in several countries enforced by law, for the implementation of measures that ensure the confidence of medical laboratories results, due to the fact that laboratory examinations are vital for patient management and treatment. In the majority of the countries this requirement forces medical laboratories to apply ISO 15189:2012, an international standard entitled: “Medical laboratories — Particular requirements for quality and competence” (ISO, 2014b) and additionally to obtain accreditation by an organization regulated by the government. In several countries medical laboratories can be accredited instead of ISO 15189:2012, by ISO/IEC 17025:2005, entitled: General requirements for the competence of testing and calibration laboratories (ISO, 2014d), and in some cases it is allowable to choose between the two standards. Currently, every European country has a single accreditation organization that controls the application of these standards and certify that a medical laboratory has applied the standard correctly and therefore produces accurate examination results.

The standard targets medical laboratories that handle human biological material irrelevant of their legal status (private or public), their size or geographical distribution, the number of employees and the number or types of examinations performed. This becomes more important as laboratory examinations on the patient, directly influence the care and handling by a percentage as high as 70%. The primary target of the standard is the patient and how to ensure the best patient care; thus the cytopathology laboratory should minimize errors. Errors in medical laboratories can occur in the pre-analytical, analytical or post-analytical phase, the vast percentage (about 70%) is in the pre-analytical phase while smaller percentages are in the analytical (20%) and post-analytical (10%) (Abdollahi et al., 2014). Standardization systems such as ISO 15189 improve this picture by reducing them (Mourtzikou et al., 2013); in addition, set the guidelines for their handling, often being a difficult task to communicate (Dintzis et al., 2011).

ISO 15189 Brief History

ISO 15189, one of the fastest growing international quality standards in the world, was created by the International Organization for Standardization (ISO) (ISO, 2014a). The first version of the standard was issued in 2003, following a second revision in 2007. Nowadays the most recent, and applicable, version of this standard is ISO 15189:2012.

The standard was influenced by ISO 9000 (ISO, 2009), today ISO 15189 supersedes ISO 9001 (IAF et al., September 2009); additionally, it was influenced by ISO 17025 (ISO, 2014d) that was originally known as ISO/IEC Guide 25 controlled by ILAC (International Laboratory Accreditation Cooperation) (ILAC, 2014) and finally from checklists of the College of American Pathologists (CAP) and the Clinical and Laboratory Standards Institute (CLSI) (CLSI, 2014) Quality Systems Essentials (QSEs). ISO standards are revised every five years; therefore, the next revision of ISO 15189 is expected in 2017.

The typical process of a quality system (Deming, 1982) is an endless cycle (Figure 1); there are “Clients” that pose requirements, the implementation of a product or service (note that ISO 15189 addresses products and services via the same manner) and the delivery of product or service to the client. Within this stage there is a continuous cycle that measures the quality of the product, analyses the results, concludes to actions for improvement and subsequently plans according to resource availability, the well known PCDA (Plan-Do-Check-Act cycle).

ISO 15189 is composed by two parts: chapter 4 describes the management requirements, this chapter has as basis the ISO 9001:2008 as well as family 9000 standards (Deming, 1982; ISO, 2009). However, it is generalized to ad-
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