Transition to ISO 15189: 2012 for Cytopathology Laboratories Part 2: Technical Requirements

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ABSTRACT

Modern diagnostic medical laboratories personnel should be an ideal combination of highly qualified scientists and technologists who use innovative analytical equipment to provide high quality diagnostic services to mankind. A well-designed and a well-implemented Quality Management System (QMS) according to the ISO 15189 requirements is regarded as a prerequisite that will ensure that a cytopathology laboratory is capable enough to provide precise and credible results. The authors present their knowledge on the implementation of such a QMS in cytopathology laboratories and emphasize the most crucial technical parameters that should be considered when advancing from ISO 15189:2007 to the latest ISO 15189:2012. Furthermore, helpful advice and pointers that could accommodate relative transition are included. Finally, potential issues related to the laboratory’s implementation of ISO 15189:2012 and a mobile technology application for better personnel management are also depicted.

KEYWORDS

INTRODUCTION

Modern cytopathology has made many important front steps during the last decades. Due to the latest scientific and technological advances, cytopathology of today bears little resemblance to that of the past. Analytical chemistry, molecular biology, computer algorithm and software programming along with other innovative and promising scientific fields and technological sectors have greatly reshaped the practice of conventional cytology into a modern cytopathology approach that includes, among others, liquid-based cytology, thin-layer slide preparations and HPV DNA testing (Arbyn et
It is obvious that, nowadays, the personnel in cytopathology laboratories is not consisted exclusively by clinical cytologists and pathologists but also by from chemists, molecular biologists, data-analysts, laboratory technologists and computer programmers. The proper co-operation and efficient interaction among all these scientists, that possess different theoretical background, expertise and technical skills, is a necessary prerequisite for a cytopathology laboratory in order to provide excellent and superb diagnostic results to doctors and patients. The testing examinations and analytical evaluations that are performed by the personnel of cytopathology laboratories are of crucial and vital importance for modern healthcare. As a result, there is an indisputable need for outstanding laboratory results and credible final reports. Laboratory Medicine has defined high quality standards in modern cytopathology laboratories by introducing, among others, the concepts of the quality monitoring, patient’s rights, standard operation procedures and standards of health care quality in the everyday workflow of a laboratory (Zima, 2010).

As mentioned in the previous article, ISO 15189 gives prominence to a well-designed and well-implemented Quality Management System (QMS) ensuring that the entire spectrum of laboratory activities is capable enough to provide superior results satisfying the pre-defined quality standards that the laboratory has established for its intended use. In particular, ISO 15189 provides a series of instructions, pointers and recommendations that will assist the laboratory in its effort to design and apply a suitable and efficient QMS according to its purposes and goals (International Organization for Standardization, 2012).

The ISO 15189 requirements are divided into two categories: a) the management ones and b) the technical ones. The significance of management requirements has already been described in detail in the previous article. The main role of these requirements is to constantly monitor the functionality, the effectiveness and the suitability of the QMS that has been established within the laboratory. A well-organized document control system, scheduled management reviews, a systematic auditing plan and suitable management of applied measures and potential risks are the most representative management requirements whose fulfillment will play a deciding role in maintaining the elevated quality levels of laboratory performance and results (International Organization for Standardization, 2012).

However important management requirements are only the one side of the coin. The other side are the technical requirements that address the performance of the laboratory personnel, the competence of testing methodologies and the quality of diagnostic results and their following reporting and release to the laboratory clients. More specifically, the technical requirements are based on the fact that the credibility and reliability of a diagnostic evaluation can be affected by numerous factors and parameters related with any pre-analytical, analytical and post-analytical process within the laboratory and aim to ensure that all these different result-impacting factors are properly managed and constantly monitored and evaluated by the laboratory personnel that in modern laboratories is consisted of scientists with different background, skills and expertise including molecular biologists, cytopathologists, cytotechnologists, laboratory technicians, secretaries, computer and data analysts that have to interact efficiently under the continuous supervision of the Laboratory Director and Laboratory Quality Manager.

The simultaneous fulfillment of management and technical requirements is essential for a modern cytopathology laboratory in order to achieve optimal performance and provide excellent testing results. The laboratory should consider both the management and technical requirements as equally important since both may lead to significant increase in the overall performance, accuracy, efficiency, and remarkable decrease in the occurrence of errors, hazards and failures that may affect the laboratory activity (Mourtzikou, Stamouli, & Athanasiadi, 2013).
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