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Transition to ISO 15189 : 2012 for Cytopathology Laboratories Part 1: General and Management Requirements

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ABSTRACT

Nowadays, due to the latest advances in Laboratory Medicine, diagnostic medical laboratories with their highly qualified personnel and state-of-the-art analytical equipment, have completely changed the way modern healthcare is offered. In order to maintain or even increase the already high quality level of the provided testing services, diagnostic laboratories including the cytopathology ones, need to design and apply a Quality Management System (QMS) in agreement with the requirements of the ISO 15189 International Standard. The authors present their experience on the implementation of such a QMS in cytopathology laboratories and highlight the most important general and management parameters that should be taken into consideration when moving from ISO 15189:2007 to the latest ISO 15189:2012. In addition, useful recommendations and suggestions that could make the transition to the latest Standard easier are included. Finally, possible issues and potential adverse events associated with the laboratory's implementation of the ISO 15189:2012 are also described.

KEYWORDS

Accreditation, Internal Auditing, ISO 15189, Management Requirements, Management Review, Quality Control & Assurance, Quality Management System, Referral Laboratories

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INTRODUCTION

Over the last decades, all the latest advances and innovations in the modern Sciences and Technologies have completely transformed the field of Medical Cytopathology. More specifically, cytopathology has already gone a long way from the point when the cancer screening based solely on the detection of abnormal cells on smeared slides was adequate enough for the doctors to make a definite diagnosis especially with the introduction of liquid-based cytology (LBC) methodology (Longatto Filho et al, 2005). The implementation of state-of-the-art tools and techniques of Laboratory Medicine and Diagnostics into the so far conventional cytology laboratories led to the appearance of modern cytopathology laboratories where highly-specialized personnel and diagnostic methods from many fields including conventional cytology, molecular biology, analytical chemistry and others compose a complex system whose organized and structured workflow provide excellent testing and diagnostic services (Joste & Gober-Wilcox, 2013).

The clinical significance of the diagnostic evaluations that cytopathology laboratories carry out implies the need for providing laboratory services of high quality and credibility to patients and clinicians. 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).

However, the most efficient and permanent way to ensure that a diagnostic laboratory will maintain or even increase the quality levels of its testing procedures and overall performance is through the design and implementation of a well-organized and well-structured Quality System and successful achievement of official accreditation status (Archondakis, Vavoulidis & Nasioutziki, 2016). Accreditation process involves an in-depth laboratory evaluation procedure that is performed by a certified state agency or body in order to ensure that this specific laboratory operates according to determined and established standards that are associated with its purpose, scope and spectrum of activities. Accreditation basically means that a diagnostic medical laboratory has been evaluated and assessed according to international standards to demonstrate its competence, impartiality, credibility and professional capabilities (Guzel & Guner, 2009).

In Europe, every country owns one unique accreditation organization that is responsible for monitoring the application of these standards and estimating the implementation level of this applied standards inside accredited medical laboratories that carry out diagnostic examinations (Huisman et al., 2007; Braithwaite et al., 2011). For example, in Greece the "Hellenic Accreditation System (ESYD)" has been appointed as the National Accreditation Body of Greece according to the requirements of Article 4 of the Regulation (EC) No 765/2008 according to which each Member State shall appoint a single national accreditation body (ESYD, 2016).

In order to obtain accreditation status, according to these standards, the laboratory needs to design and apply well-designed and well-implemented Quality Control (QC) and Quality Assurance (QA) processes and standard operating procedures (SOPs) in terms of an established Quality Management System (QMS) covering all the stages of laboratory activity including every single pre-analytic, analytic and post-analytic step. QC defines service's quality, imparting to it the credibility needed for its intended purpose, while QA activities measure the degree to which desired outcomes are successful (Archondakis, 2015). QC and QA can be either internal when the corresponding processes are intra-laboratory or external in cases where the required procedures involve inter-laboratory interaction and co-operation with external collaborators. Both internal and external QC and QA are equally important for a laboratory since they 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).

Cytopathology laboratories, along with all the other medical diagnostic ones, need to meet the requirements that are dictated by a specific pre-defined standard that is proposed and recommended