ISO 15189:2012 Technical Requirements for Cytopathology Laboratory Information Systems

Abraham Poulakis, Department of Cytopathology, University of Athens, “ATTIKON” University Hospital, Athens, Greece

Niki Margari, Department of Cytopathology, University of Athens, “ATTIKON” University Hospital, Athens, Greece

Aris Spathis, Department of Cytopathology, University of Athens, Faculty of Medicine, “ATTIKON” University Hospital, Athens, Greece

Christine Kottaridi, Department of Cytopathology, University of Athens, Faculty of Medicine, “ATTIKON” University Hospital, Athens, Greece

Marilena Stamouli, Department of Biochemistry, Naval and Veterans Hospital, Athens, Greece

Antonia Mourtzikou, Department of Biochemistry, “Asclepeion” Voulas Hospital, Athens, Greece & Department of Cytopathology, University of Athens, Faculty of Medicine, “ATTIKON” University Hospital, Athens, Greece

Stavros Archondakis, Cytopathology Department 401 Military Hospital, Athens, Greece

Efrossyni Karakitsou, Biomedical Engineering Laboratory, National Technical University of Athens, Athens, Greece

Elena Athanasiadi, Department of Cytopathology, University of Athens “ATTIKON” University Hospital, Athens, Greece

Petros Karakitsos, Department of Cytopathology, University of Athens, “ATTIKON” University Hospital, Athens, Greece

ABSTRACT

Medical laboratories are complex systems composed of specialized personnel and medical modalities. Despite complexity, they are well-organized systems with standardized workflow. Especially for cytopathology laboratories the human factor is extremely important, because examination of glass slides is the majority of the workflow from experts (cytopathologists). Recently there is an increasing need to ensure the quality of medical laboratories by applying quality standards, such as ISO 15189:2012 which is proposed by many organizations and in many countries is enforced by law. ISO 15189 does not oblige the application of Laboratory Information Systems (LISs); however, nowadays, it is extremely difficult for a laboratory to routinely operate without it. In this paper we present the design and requirements of an enhanced LIS (eLIS), adapted to support not only the standard routine of a cytopathology laboratory (and other laboratory types) but to facilitate the support of technical requirements posed by ISO 15189.

Keywords: Accreditation, Cytology, Cytopathology, Enhanced LIS (eLIS), ISO 15189, Laboratory Information Systems, Quality, Quality Assurance, Quality Control

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INTRODUCTION

Clinical laboratory examinations are vital for patient management and treatment. Laboratory examinations influence directly the care and handling of a patient by a percentage as high as 70%.

The last decade in developed and developing countries, is required (by regulatory bodies, and in several countries enforced by law) that clinical laboratories implement measures to ensure the accuracy of their results (Mourtzikou et al., 2013). 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, 2014a) and additionally to obtain accreditation by an organization regulated by the government. In several countries medical laboratories can be accredited by ISO/IEC 17025:2005, entitled: General requirements for the competence of testing and calibration laboratories (ISO, 2014b), and in some countries it is allowable to choose between these two standards.

ISO 15189 is designed for medical laboratories handling 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.

ISO 15189 is composed of 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 adapted to medical laboratories. The requirements and the design of the LIS to address the management requirements are already presented (Pouliakis et al., 2014b). The second part of the standard (chapter 5) focuses on technical requirements. In this paper we analyze the consequences of ISO 15189 technical requirements in Laboratory Information Systems (LISs) and propose an enhanced LIS (eLIS) that is capable not only to facilitate the everyday routine of examination, but additionally can support ISO 15189 technical requirements and ensure that these are continuously fulfilled.

CYTOPATHOLOGY LABORATORY WORKFLOW

A modern cytopathology laboratory, especially when there are research and training activities, nowadays is composed of many branches (Figure 1). The laboratory director performs the management and quality control, and assurance procedures; assisted by the quality manager and in several cases by an assigned technical manager. The core of the laboratory subsequently is composed of units and smaller branches, each one responsible for performing specific examinations. The number of examination types performed is in the range of a few hundred due to the addition of molecular examinations. In cytopathology laboratories, usually most of the work volume is related to test Papanicolaou, for cervical cancer screening.

THE CYTOPATHOLOGY LABORATORY CYCLE AND THE LABORATORY INFORMATION SYSTEMS

The modern cytopathology laboratory follows a typical cycle for the daily workflow (Figure 2). The physician (usually a doctor from a clinic or another person, for example, a midwife) requests specific examinations and dispatches (unless it is already dispatched) a biological sample to the laboratory. Subsequently the sample is received, checked and marked (a unique identifier is assigned) in order to be traceable during the subsequent process. The creation of a worksheet that assigns examination (and additionally pre and post examination) tasks to persons or medical analyzers follows. Usually, many samples requiring the same examination are grouped together; the examinations are handled as a batch or in parallel from cytopathologists or
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