

# Chapter 6

## ISO 15189:2007: Implementation in a Laboratory Information System

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### ABSTRACT

*ISO 15189:2007 constitutes an international certification standard, based upon ISO/IEC 17025 and ISO 9001, which can be used by medical laboratories wishing to improve their quality standards. The requirements of this standard form a group of general guidelines that will help laboratories establish and enhance their quality systems. Although direct references to the use of computer systems are made in only 7 cases, through the mandatory section of the ISO 15189:2007, many more clauses of the standard include indirect references to electronic medical records handling. The chapter analyzes the guidelines concerning the use of laboratory information systems for medical records storage and retrieval. Furthermore, the authors discuss challenging difficulties that may be detected during implementation of ISO 15189:2007 in the field of electronic laboratory medical records.*

### INTRODUCTION

During the last decades, medical data deriving from the analysis of patient samples was stored in medical laboratories and was provided to physicians manually (Brerider-Jr-McNai, 1996). Manual processing of medical information during

specimen collection, order entry, results entry and results reporting was presenting many significant problems with crucial impact to patient care. The absence of an integrated laboratory information system was making medical data transfer slow and possibly ineffective while results inquiry, quality control and results correction a time and money spending process (Kubono, 2004).

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Over the last years, informatics and computer sciences have changed dramatically the practice of clinical laboratory professionals. The wide implementation of laboratory information systems became a necessity dictated by the need of real-time results and the increasing role of laboratory medicine in therapeutic decisions (Georgiou & Westbrook, 2007).

Laboratory information systems have been implemented in many medical laboratories wishing to improve their quality standards. A laboratory information system (LIS) is a valuable tool for medical professionals in order to manage complex processes, ensure regulatory compliance, promote collaboration between departments of the same or different laboratories, deliver detailed reports, and develop the laboratory networking capabilities. The result is better data management and sharing between the laboratory and its clients (either laboratories or clinicians) (Brerider-Jr-McNai, 1996).

However, LIS implementation in the everyday laboratory workflow may present specific problems, concerning medical data storage, protection and retrieval, as well as improper use of hardware and software. Medical data stored in computer systems may be lost or changed by unauthorized personnel. Therefore, specific measures should be followed in order to protect the laboratory information system, and solve the problems that may be encountered (Brerider-Jr-McNai, 1996).

ISO 15189:2007 is a powerful tool for diminishing dramatically all unsuspected errors or problems that may be encountered during LIS use. ISO 15189:2007 requirements for laboratory information systems suggest the implementation of specific measures concerning environmental conditions, system security, data entry control, medical reports, data retrieval and storage, and finally system's hardware and software maintenance (Kubono, 2004).

The objective of the chapter is to emphasize on the necessity of adopting specific policies concerning electronic laboratory records storage and retrieval. Furthermore, we intend to discuss

all challenging difficulties that may be detected during implementation of ISO 15189:2007 in the field of electronic laboratory medical records. Finally, we give clear and comprehensive guidance to all members of the medical community, wishing to overcome bureaucratic or technical problems in this field.

## **BACKGROUND**

Laboratory automation has been propelled during the last 10 year by the advantages of greater productivity, lower cost and the capacity of integration with modern instrumental equipment, which connect to a laboratory intranet (Westbrook et al., 2008; Vacata et al., 2007). Laboratory information systems provide better functionality through automation in parts of the inspection procedures, permitting the lab to achieve maximum efficiency (Westbrook et al., 2008; Vacata et al., 2007). Laboratory information systems also improve service to physicians and other stakeholders and ultimately reduce the probability of human errors. It is widely accepted that error-prone activities can be substantially reduced, but not eliminated. However, information technology systems can provide reasonable, accurate, and reliable standardized procedures of quality control for the assessment procedure as well as sophisticated quality indices for all the control system of the medical laboratory (Westbrook et al., 2008; Vacata et al., 2007). Medical laboratory computers may be used in many ways. They may be used for preparing and administering the management handbook and standard operation procedures, for personnel training, for providing and archiving documents via intranet. The laboratory computers may also be used for creating customer databases, for evaluating test results, for connecting via the Internet with external sources of information and for contacting with customers, or as a typewriter. A computing system contains at least one computer, some peripheral devices and some

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