

A practical tool for assessment for evaluation of the information systems in medical laboratories in terms of quality assurance

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Abstract

The advent of information technology in the medical field has increased tremendously. This occurs especially in the case of medical laboratories where, with the exception of microbiology examination, most of the examination processes are automated. Besides this, almost any laboratory has implemented an information system which manages the flow of information from the sampling to the result validation. Standardization plays an important role since quality assurance is a requirement that has to be met in order to operate on the market. ISO 15189:2013 is the international standard of choice in the field. In Romania, any laboratory that aims at contracting public funding must provide, by means of accreditation against this standard technical competence. This standard contains special requirements that have to be met by the information system deployed in the laboratory. However, the requirements are not detailed such that the assessor would determine if the requirement is met or not. The present paper introduces a practical assessment tool for the assessor such that it would help decide if the specific requirements to the information systems of the ISO 15189:2013 are met. The tool can be used for any type of laboratory: hospital, individual, chain and so forth. Besides the assessment tool, the paper also discusses the main type of information systems deployed on the Romanian market of medical laboratories.

Keywords:

Quality Assurance; Medical Laboratory; Information Systems' ISO 15189:2013