

# Chapter 8

## Quality Management and Quality Assurance in Medical Laboratories

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### ABSTRACT

*This chapter deals with issues of quality management and quality assurance in medical laboratories. Basic terms and their role in quality assurance in laboratory examinations are analyzed and discussed. Clarifications on certification and accreditation are given with a comprehensive analysis of the procedures they refer to and their implementation for particular tasks. The implementation of the international standard ISO 15189 is presented with reference to some recent developments. The chapter has been prepared to help medical laboratories in an introductory understanding of quality assurance issues and encourage them to proceed with the implementation of the standard ISO 15189 and not as a detailed guide. Some practical considerations rising from the experience of a small country such as Cyprus are also discussed.*

### INTRODUCTION

Quality can be defined as the degree to which the characteristics of a product, a service or a procedure satisfy set requirements and expectations. Legal and other requirements, reflecting the specific needs in each area, create the framework within which relevant activities are planned, implemented, monitored, controlled and assessed. Is there “good” and “bad” quality? Would it not

be better if we referred to “adequate” or “non-adequate” quality instead? In any case, we need to describe the criteria for this consideration.

All services, regardless of their nature, need to be organized in an appropriate way using appropriate and documented procedures, properly trained and competent personnel, properly maintained and calibrated equipment, and to be operated with clear quality tasks.

DOI: 10.4018/978-1-4666-6320-6.ch008

Medical (or, clinical) laboratories represent an important infrastructure in every society. The services they provide are of decisive importance for the health of people and the quality of life, thus constituting an important and illustrative indicator of the level of development in society. As a result, provision of reliable services by medical laboratories is of high priority.

Quality management and quality assurance can be evaluated by accreditation or certification, depending on the nature of the particular activity. For many activities certification is adequate; however, the key element which needs to be ensured in medical laboratories is their technical competence and accreditation is the only tool to apply. Basic aspects of quality management and quality assurance in medical laboratories are presented and discussed in this chapter.

To this end the requirements of the international standard ISO 15189 which is the main document for quality management and technical competence in medical laboratories are analyzed.

## **BACKGROUND**

In most economic activities quality and productivity issues are usually discussed in figures reflecting economic and quality indicators. A lot of aspects may be of a similar or an analogous relevance in all sectors. However, in the medical sector as well as in cases related to health and safety, the quality of services provided has quite a different significance.

There is very often a discussion on the cost of quality; the higher cost of high quality is considered as a disadvantage; however, what about the high cost of non-quality? Experience clearly illustrates that this cost is much higher even when corrective actions are possible, realistic and adequately efficient. To this end, a simplified approach “high quality or low cost?” seems to be the wrong question which may lead to a wrong answer, especially in times of economic recession. The

cost of failure and lack of reliability in medical laboratories cannot be estimated in figures and statistics. Although the economic aspects play their important and decisive role in the medical sector as well, the reliability of the results from medical laboratories is a must and a task for which no compromise can be allowed.

Laboratories in general represent the most widely known institution in the quality infrastructure in a country; other bodies, namely certification and inspection bodies are also important parts of the quality infrastructure. They all come under the title of “conformity assessment bodies” since they all contribute to the named task. Laboratories focus on two main activities, testing and calibration, the latter being an activity of high importance to all conformity assessment bodies since it contributes to the documentation of the metrological traceability, thus providing the basis for the “common measuring language” required in all measuring applications.

Measurements are carried out by laboratories. In almost all cases, measurements of various parameters and other factors are necessary. You can neither make an assessment nor an evaluation of compliance to set criteria without carrying out appropriate measurements. In the case of measurements, the meaning of quality includes reliability:

- What about the reliability of the measurement?
- What about the cost of non-reliable measurements?

In Europe, the European cooperation for Accreditation (EA) is the network of national accreditation bodies, one in each member state. All national accreditation bodies operate in compliance with both the ISO 17011 and the Regulation (EC) No 765/2008 of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 [2008] OJ L 218/30.

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