

# Chapter 9

## Differences of ISO 15189:2012 and ISO 15189:2007

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### ABSTRACT

*The new version of the ISO 15189:2007 Standard was published in 2012, and it is called ISO 15189:2012. The new version is more specific to clinical laboratories as compared to the old one. The present chapter emphasizes in the most important changes between the two versions of the standard, especially in those that reveal the “spirit” of the new version. Some of these refer to ethics, quality management system, encouragement of the staff, risk management, evaluation of staff performance, purchase and withdraw of equipment, laboratory facilities, reagents and consumables, communication between the laboratory and its stakeholders, verification of the results by trained personnel, procedures of reporting the results, metrological procedures and traceability, function of laboratory information system, and responsibilities of laboratory director.*

### INTRODUCTION

The new version of the ISO 15189:2007 Standard isn't a copy of ISO 15189:2007 neither can be used as a substitute. The laboratories interested to apply for ISO 15189:2012 should procure a valid copy of the new version. The purpose of this chapter is to help laboratories to “transfer” their quality system from ISO 15189:2007 to the new ISO 15189:2012. For these laboratories, it wishes to be useful and comprehensible guideline serving actually as a manual.

The new version of the ISO 15189 will be presented a paragraph per paragraph summarizing

mostly in tables the differences and similarities with the version of 2007. The most important parts of the two documents are presented, which must always be considered during the writing process of the quality manual and its accompanying documents. It is underlined that the described paragraphs and sentences are only summaries of the original documents since the intention is to only present the correspondence. The readers are advised to procure the two versions, ISO 15189:2012 and ISO 15189:2007 for further reading and understanding.

This chapter is also addressed to the laboratory personnel who have in their possession either ISO

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ISO 15189:2012 either ISO 15189:2007. In order to satisfy both readers, we comprised in this chapter quite enough documents from ISO 15189:2012 in order to help laboratories with ISO 15189:2007 Standard to understand every pairing between paragraphs of both Standards. We comprise on purpose the minimum document of ISO 15189:2012 in order not to violate the copyright.

The chapter contains a lot of tables which pair the paragraphs between ISO 15189:2012 and ISO 15189:2007. The readers shall have in mind that these pairs have not always the same meaning, and many times are only informative. They should consider the authentic ISO 15189:2012 and ISO 15189:2007 for further information.

The old Standard for medical laboratories (ISO 15189:2007) was based upon the international Standards ISO/IEC 17025 and ISO 9001. The same is happening with the new Standard ISO 15189:2012. It is based on these two Standards and also on ISO 15189:2007. It has been written by the Technical Committee ISO/TC 212 with the collaboration of the International Electro-technical Commission (IEC) and the German Institute for Standardization (DIN).

Although the new Standard has the same number of chapters, and almost the same number of paragraphs it has many differences and new subparagraphs, thus it must be considered as a totally new Standard. It is true that the new Standard is much clearer and well written as compared to the old one. This conclusion is based on the following remarks:

- The annexes of ISO 15189:2007 have been included in the main body of the new Standard. Ethics and laboratory information security are now mandatory.
- Almost all the paragraphs of the Standard have become mandatory (the “should” has been replaced by “shall”).

- All paragraphs, new and old, their title and the general structure of the new Standard correspond much more to the actual structure of modern clinical laboratory.

The main differences between the two versions of the Standard (ISO 15189: 2007, ISO 15189: 2012) focus on chapters 4 and 5 and the appendixes at the end of the document. These two chapters, 4 and 5, include all the requirements of the Standard. The smallest chapters 1, 2 and 3 include the scope (chapter 1), the normative references (chapter 2) and a comprehensive vocabulary (chapter 3). At the end of the Standard 3 tables include the differences between ISO 9001, ISO 17025 as well as between ISO 15189:2007 and ISO 15189:2012.

## **BACKGROUND**

The new standard ISO 15189:2012 is more compatible with the real work in medical laboratories than the old one. The first ISO standard which was specific for the clinical laboratories was ISO 15189:2003 (eJFCC, 2004). It was based on the ISO 17025:1999 and ISO 9000: 2000. It was the first attempt to create a specific standard for the laboratories dealing with biological samples. At the beginning, the two standards were quite similar and for this reason the laboratories were free to choose which ISO Standard to follow.

The most important changes were based on the following:

- The ISO 15189 was specific to patient care in spite of the ISO 17025. For that reason, ISO 15189 has always special requirements for sampling, reports of results, ethics etc.
- The ISO 15189 had special requirements for the personnel. For example, the laboratory director should be a medical doctor or

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