

ISO 9001 OR ISO 17025: WHAT IS MORE IMPORTANT FOR THE METROLOGY LABORATORY

ISO 9001 ILI ISO 17025: KOJA JE VAŽNIJA ZA MJERNE LABORATORIJE

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ABSTRACT

In the last decade, the number of Portuguese companies with quality certification has increased, as is the case in most countries. According to the ISO 9001 standard all the certified companies should calibrate their measuring equipment. By doing so, companies can guarantee, with rigor and quality, its measurement and use reliable data for monitoring the quality of its products and its improvement. However, a metrology laboratory is not required to hold an ISO 9001 certification or ISO 17025 accreditation. In this moment, there are companies that have metrology laboratories to conduct an internal check of their measuring equipment. These companies have their quality management systems (QMS) certified according to the ISO 9001 standard and so all its departments and sub-departments must also comply with the requirements of this standard. On the other hand there are companies with ISO 17025 accredited laboratories. Usually these companies are independent and his metrology laboratory is essentially to perform the calibration service to national companies who use their services to make the calibration of its measuring devices. These labs can be inserted into a company which does not have their QMS certified by any national or international standard. Finally,

there are companies that have their QMS certified to ISO 9001 and also its metrology laboratory accredited by ISO 17025. In this case the metrology lab must comply with the requirements of both standards. Thus, the aim of the research project is to analyze, in Portugal, the importance level of ISO 9001 and ISO 17025 standards for a metrology laboratory to reach the quality.

Key words: ISO 9001, ISO 17025, certification, accreditation, Quality Management Systems, metrology.

1. INTRODUCTION

The ISO 9001 management systems certification is one of the most important issues for the success of the Portuguese companies in the globalized market. According to Santos (1992), the ISO 9001 is a guarantee that the certified firms have the capacity to comply with some requirements recognized at a worldwide level. Furthermore this certification demonstrates more easily the validity of its Quality Management System (QMS) for his own customers, getting in the front line in possible contracts for the provision of services or products. According to Peña (2002), ISO 9001 registration is a guarantee that all the measuring and control equipment is calibrated or verified, or both, at specified intervals in metrology laboratories, whose measurement standards used are traceable to international measurement standards or national, according to section 7.6 of the standard ISO 9001. Thus ensuring, with rigor and quality, their measurements and the use of reliable data for monitoring the quality of their services or products and their improvement (Karnes and Kanet, 1994), and in many cases, provide considerable savings with services or non-compliant products. Concerning the Portuguese reality, the majority of the laboratories are accredited by the Portuguese Institute for Accreditation (IPAC), according to the ISO 17025 standard.

The management systems certification and accreditation differ with respect to the aim and standard. According to the ISO 17000 standard, certification (management systems, products, and people) is one of conformity assessment activities. On the other hand, accreditation is the recognition of technical competence to carry out conformity assessment activities, according to the same standard.

According to Prado Filho (2010), if a laboratory has been certified according to the ISO 9001 standard there is a guarantee that calibration or tests are conducted in accordance with written procedures and grounds to ensure the requirements of the standard concerned. By the other side, the accreditation according to the ISO 17025 standard goes beyond the execution of calibration according to a written procedure and required for a confirmation of technical competence of who performs the proper calibration (Duarte, 2007).

However, a metrology laboratory is not required to have a ISO 9001 certification or ISO 17025 accreditation. According to Noronha and Magalhães (2006) these recognitions are essential requirements for the laboratory differentiation in the market.

Main research question of this project is to analyse what it is the most important standard for a metrology laboratory, if only one of the standards (ISO 9001 or ISO 17025) or if both.

2. LITERATURE REVIEW

According to the ISO 17000 standard, certification is a “*third party attestation for products, processes, systems or persons*”. Guerreiro (2001) stated that a certified company is required to work with rigorous and specific standards.

2.1. ISO 9001 certification

The certification according to the ISO 9001 standard produces clear benefits for companies and for the society. For the society it ensures that the services or products that we buy respect some standards and thus it could be faced as deciding factor for the purchase. For companies, the implementation of ISO 9001 standard enables continuous improvement of their quality management systems and contributes to the increase of the customer satisfaction (Fonseca, 2002). The access to new markets is also an important ISO 9001 benefit, since certification is an international guarantee of the organizational management. According to Prieto (2008), for a metrology laboratory, the ISO 9001 standard promotes a better organization of the work and the motivation of all employees towards continuous improvement and even improves the communication between all levels of management and their own workers. According to Sampaio *et al.* (2009), the ISO 9001 benefits could be classified as internal and external ones. In Table 1 are listed the most common ISO 9001 benefits.

Table 1. ISO 9001 most common benefits (Sampaio *et al.* 2009)

| External benefits | Internal benefits |
|--|---|
| <ul style="list-style-type: none"> - Access to new markets. - Improving the company image. - Increased market share. - Marketing tool. - Improved customer relationship. - Increased customer satisfaction. - Improved communication with the customer. | <ul style="list-style-type: none"> - Productivity increases. - Decrease the percentage of non-conforming. - Greater awareness of the concept of quality. - Clarification of responsibilities and obligations. - Improvements in delivery times. - Improved internal organizational. - Reduction of non-conformities. - Decrease the number of complaints. - Improvements in internal communication. - Improvements in product quality. - Competitive Advantages. - Motivated employees. - Decreased levels of scrap. |

According to Dick *et al.* (2001), it appears that companies that have quality certification gives more importance to quality than the remaining ones and they recognize quality as an important contribution to business performance.

2.2. ISO 17025 accreditation

The definition of accreditation according to the ISO 17000 standard is the “*third party attestation, related to a conformity assessment body, which is a formal recognition of their competence to perform specific activities of conformity assessment.*”

One of the most important benefits of accreditation according to the ISO 17025 standard is to endorse the cooperation and partnership between laboratories and other institutions with the aim of exchanging information promoting the harmonization and standardization of procedures and standards. According to Ramjun (2009), a laboratory accreditation strengthens the organization performance through a better control of laboratory procedures and thereby increases their potential due to the increase customer satisfaction.

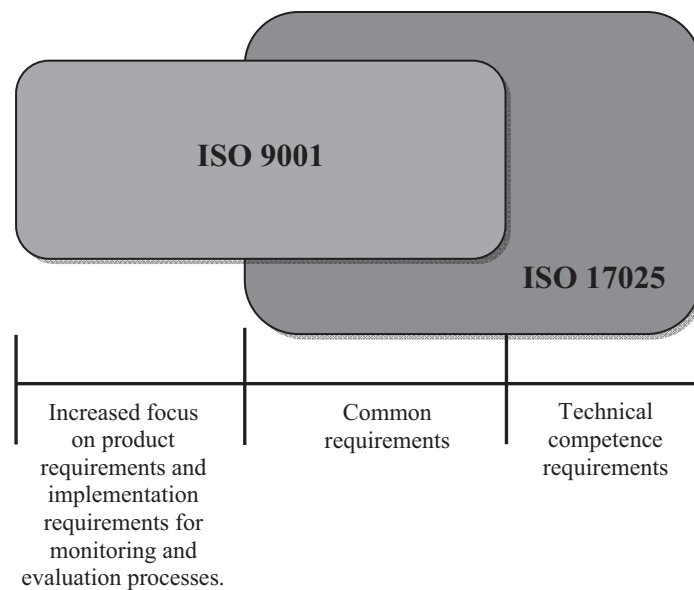
Accreditation is also an effective marketing tool for calibration or for testing, because it is a “passport” for companies and organizations that require reliable and independent laboratories. One of the most important ISO 17025 benefits is to reduce the number of audits and evaluations by customers, since it is periodically audited by an accreditation body. Additionally, according to Nara (2003) and Sousa (2008), one important accreditation benefit is that any test or calibration certificate issued by an accredited laboratory that is a signatory of the Mutual Recognition Agreement (MRA), is accepted in any country signatory of the Agreement.

2.3. ISO 9001 and ISO 17025: different or complementary?

According to Pizzolato *et al.* (2008), depending on the laboratory business, the laboratory could assess its QMS according to ISO 9001 or ISO 17015 standard.

According to the ISO 17025 standard, the conformity of the quality management system with the requirements of ISO 9001 does not prove, by itself, the competence of the laboratory to produce technically valid data and results. A laboratory that is accredited according to the ISO 17025 standard does not guarantee the fulfilment of all ISO 9001 requirements. By the other side, an ISO 9001 certified laboratory could not have enough technical competence to assess conformity of certain equipment, products or services or people. According to Dick *et al.* (2002), ISO 9001 standards is concerned mainly with what the laboratory does to ensure the compliance of their products or services according to customer requirements. In Figure 2 illustrates the interaction between ISO 9001 and ISO 17025.

Figure 1. Interaction between ISO 9001 and ISO 17025 standards



As is illustrated in Figure 2, there are some important differences between the two standards, because ISO 17025 does not meet all the ISO 9001 requirements, mainly those related to product requirements and implementation requirements for monitoring and evaluate processes.

Those laboratories that are interested in demonstrate technical competence should adopt the ISO 17025 standard. Moreover, those laboratories that are already accredited by the ISO 17025 standard and that are embedded in organizations that also carry out activities such as accounting, marketing, consulting, training and other, should evolve to an ISO 9001 quality management system.

2.4. Metrology

The word metrology can be divided into two parts: *metro* + *logy*. The word *meter* is related to measure something and the word *logy* is related to the science of something. Thus, Metrology is the science of measurement. The definition of metrology according to the International Vocabulary Metrology (2008) is the “*science of measurement and their applications.*”

Metrology is used by all. All comparisons between what we believe is hotter or colder, longer or shorter, etc. For example when we left to the street in the winter, we said: “*It is colder here than in the house.*” In this case we compare the temperature inside the house (our reference value) with the outside temperature (measured value), and so what we do is a calibration, but without its element of uncertainty. Now, it is really much colder? Is the difference so great? Metrology responds exactly to these issues and ensures, with a certain uncertainty, if what we are measuring is really correct.

As already mentioned by Bunday *et al.* (2007), when we measured something, the error and uncertainty is always present and can never be totally eliminated. That is the reason why we use weights and measures in order to minimize the error and its measurement uncertainty. The metrology laboratories and the calibration laboratories have that role.

The minimization of measurement errors and manufacturing defects are crucial to a company because it can make the difference between a high quality product and a product of low quality (Bunday *et al.*, 2007). Metrology was initially used to monitor the product.

Also in our day-to-day, metrology is important because we use many measuring equipment. Metrology is an important activity for business development and also for the society development (Martínez-Sánchez *et al.*, 2009 and Santos and Mainier, 2010).

3. RESEARCH METHODOLOGY

The research project here present in this paper will be supported in the case study methodology. According to MacNealy (1997), case studies are a qualitative tool and an asset to use for collecting information from a small sample and to increase understanding of a particular research issue. There are also some disadvantages in using this methodology, mainly the time that is needed to process each one of the case studies.

One of the methods for collecting data based on a case study methodology is the interview. In this research we will use a semi-structured interview in order to gather data. According to Pawson (1996), this type of interview allows more types of qualitative data through open questions. According to Pawson (1996)

and Houtkooper-Steenstra (1996), the interviewer with this type of method provides an “environment” more relaxed and also allows the interviewee to it, answer the questions in their own words and explain certain ideas and opinions. With this method we managed to gather facts, opinions, goals, plans and ideas that would be difficult to investigate and analyze by other methods such as filling out questionnaires (MacNealy, 1997). According to Voss *et al.* (2002), there are some disadvantages related to the interviews mainly in terms of the time that will be necessary to complete the collection of data.

According to Eisenhardt (1989), the case studies can involve single or multiple cases, and several levels of analysis. In the present investigation, will be conducted three case studies in laboratories, respectively with, ISO 9001 certification, ISO 17025 accreditation both of them. The selection of the target population is one of the most important aspects when the case study methodology is used. The concept of a target population is crucial, because the population defines the set of entities in which research and its samples are being delineated Eisenhardt (1989).

In this research project, the target population will be three metrology laboratories. Semi-structured interviews will be performed with the person responsible for the laboratory management system. According to Mintzberg (1979), cited in Eisenhardt (1989), there is no problem if we have a small sample, if we have tried to go into organizations with a well-defined focus to collect specific data systematically.

4. RESEARCH QUESTIONS

By the end of this research project, we intend to answer the following questions:

- Which are the main reasons for a metrology laboratory implement a quality management system according to the ISO 9001 standard or the ISO 17025 one or both?
- Which are the most evident organizational changes after the standard(s) implementation?
- Which are the main difficulties encountered in the implementation phase?
- What is the standard implementation impact on a organizational level, on a technical and on financial level?
- Are there substantial differences between an ISO 9001 and an ISO 17025 laboratory?
- Which is the most important standard for a metrology laboratory? ISO 9001, ISO 17025, both?

5. CONCLUSIONS AND FUTURE WORK

Based on the literature review carried out we were able to conclude that there are a considerable number of published papers related to the benefits of ISO 9001 and ISO 17025 standards. However, it is very common the paper analyzed the standards separately and not in an integrated perspective. ISO 9001 and ISO 17025 had been developed in order to be integrated and used together in a unique management system. Additionally, we also found out that there are few studies about the importance of metrology for the differentiation and quality improvement of the organizations.

Sažetak:

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Tijekom prošlog desetljeća porastao je broj organizacija u Portugalu, kao i u brojnim drugim zemljama, koje imaju certificiran sustav upravljanja kvalitetom. Sukladno zahtjevima ISO 9001 norme sve certificirane organizacije trebale bi vršiti umjeravanje svoje mjerne opreme. Na taj način organizacije mogu jamčiti pouzdanost i kvalitetu mjerenja i koristiti podatke za praćenje kvalitete proizvoda i njezino poboljšanje. Međutim, nije nužno da mjerni laboratorij bude certificiran po ISO 9001 ili ISO 17025. Trenutno mnoge organizacije imaju mjerne laboratorije u kojima vrše umjeravanje mjerne opreme za svoje potrebe. Te organizacije imaju certificiran sustav upravljanja kvalitetom sukladno sa zahtjevima ISO 9001 norme i sve njihove organizacijske jedinice također ispunjavaju zahtjeve ove norme. S druge strane, postoje organizacije s akreditiranim laboratorijima sukladno zahtjevima norme ISO 17025. Obično su to samostalne organizacije i njihovi mjerni laboratoriji u biti pružaju usluge umjeravanja mjerne opreme državnim kompanijama. Ti laboratoriji mogu biti sastavnice organizacija koje nemaju certificiran sustav upravljanja kvalitetom sukladno nacionalnoj ili međunarodnoj normi. Nadalje, postoje organizacije koje imaju certificiran sustav upravljanja sukladno sa zahtjevima norme ISO 9001, ali i akreditirane mjerne laboratorije sukladno sa zahtjevima norme ISO 17025. U tom slučaju mjerni laboratorij treba ispuniti zahtjeve obiju međunarodnih normi. Cilj ovo istraživanja i rada je analizirati, u Portugalu, razinu značaja ISO 9001 i ISO 17025 normi za postizanje kvalitete mjernih laboratorija.

Ključne riječi: ISO 9001, ISO 17025, certifikacija, akreditacija, sustav upravljanja kvalitetom, metrologija.

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