# ISO 9001 and ISO 17025 standards in a metrology laboratory

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## ABSTRACT

In the last decade, the number of companies with quality certification has increased 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 certified QMS.

Finally, there are companies that have an ISO 9001 QMS and also a metrology laboratory accredited by ISO 17025 standard. In this case the metrology laboratory must comply with the requirements of both standards.

With this research project we intend to analyze the importance level of ISO 9001 and ISO 17025 standards for a metrology laboratory in order to reach the organizational excellence.

**Keywords:** ISO 9000; ISO 17025; certification; accreditation; quality management systems; metrology laboratory.

## INTRODUCTION

According to the last available ISO survey, the number of ISO 9001 companies is still increasing in worldwide.

According to Peña (2002), the ISO 9001 registration is a guarantee that all the measuring and control equipment is calibrated or verified, or both. In doing so, the companies can ensure with accuracy and quality its measurement and use an reliable data to monitor the quality of its products and its improvement (Barradas and Sampaio, 2011), and these calibrations are performed by metrology laboratories.

According to the ISO 17000 standard, certification (management systems, products, and people) is a conformity assessment activity. On the other hand, accreditation is the recognition of technical competence to carry out conformity assessment activities.

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).

Currently there are certified or accredited laboratories according to ISO 9001 and ISO 17025 standards and also laboratories which have implemented both standards. Therefore the aim of this study is to analyze the importance level of ISO 9001 and ISO 17025 standards for a metrology laboratory.

## REVIEW

### ISO 9001 certification

The word certification is many times misused because a lot of people do not know the real meaning of it. According to the ISO 17000 standard, certification is a *"third party attestation for products, processes, systems or persons".* In other words, the certification (management systems, products, people) is one of the activities of conformity assessment (certification, inspection , testing, calibration).

### ISO 17025 accreditation

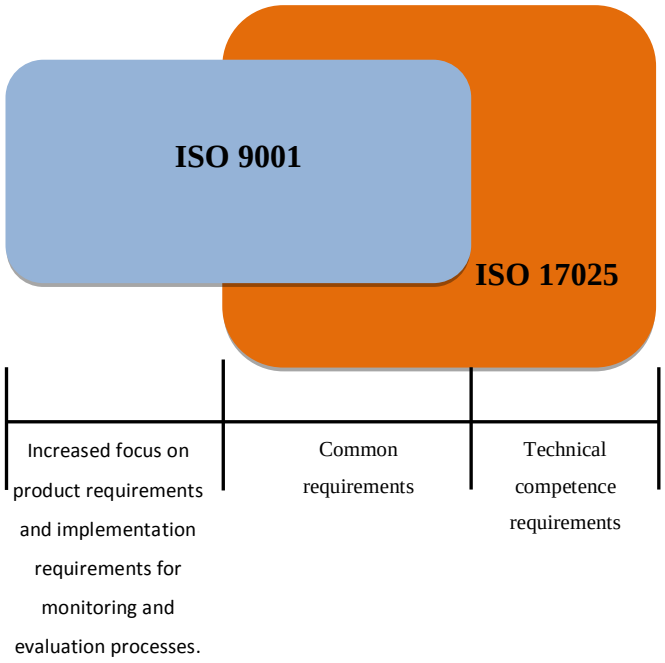
The definition of accreditation according to the ISO 17000 standard is the *"third party attestation, related to a conformity assessment body, which is a formal recognition of their competence to perform specific activities of conformity assessment."*, ie, the accreditation is a recognition of the technical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

**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.

A laboratory who is inserted in an organization that has its entire organizational structure certified according to the ISO 9001 standard, does not guarantee that it has adequate technical competence to assess conformity of certain equipment, products or services and people. Furthermore, a laboratory accredited according to the ISO 17025 standard is not a guarantee that it complies with all ISO 9001 requirements, mainly the product requirements and the requirements for monitoring and evaluation of processes (Barradas e Sampaio, 2011). Figure 1 illustrates the interaction between ISO 9001 and ISO 17025.

Figure 1 - Interaction between ISO 9001 and ISO 17025 standards.



## RESEARCH METHODOLOGY

The methodology used in order to gather date was the semi-structured interview. 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 Eisenhardt (1989), the case studies can involve single or multiple cases, and several levels of analysis.

In our investigation, we conducted nine case studies divided in three groups. Laboratories with ISO 9001 certification (group ISO 9001), laboratories with ISO 17025 accreditation (group ISO 17025) and laboratories with both of them (group ISO 9001 & 17025). The interviews were performed with the person responsible for the laboratory management system.

The companies analyzed activity sectors were: training centers, civil construction company, ceramics industry, gas equipment industry, technological centers and automotive industry.

Furthermore the companies were also from different geographic areas. We studied laboratories, located in central and northern Portugal and also one laboratory in Spain, located in the region of Galicia.

## MAIN RESULTS

After collecting and analyzing the voices of the interviews, we reached some important findings, that are listed in the following sections.

### Difficulties during the implementation process

The most importante difficulies pointed out by the companies related to the implementation process were the development of processes and procedures, the definition of acceptance criterias for the equipment, the lack of training in the area of metrology and the implementation of new ways of work, diferente than the ones used in the past by the companies.

The difficulties related to the management of equipment and the calculations of the uncertainties were only presented in groups ISO 17025 and ISO 9001 & 17025.

**Why certification and / or accreditation?**

The reasons that lead laboratories to apply for certification, accreditation or both are different.

In the case of the group ISO 9001, the main reason that lead the laboratories to implemente the ISO 9001 standard is the fact that they belong to a company that has its quality management system implemented according to the ISO 9001 standard. Companies that want to improve their internal working methods and focus on product quality or customer service, are more propense to have a metrology laboratory to make internal calibrations to their measuring equipment. The activity sector requirement, such as the automotive industry, is another reason to have a certification according to ISO 9001 standard in a metrology laboratory.

In the case of accreditation, the main reason why some laboratories use only this recognition was the market requirement. On the other hand, there are laboratories that have applied to ISO 17025 accreditation in order to perform calibrations, to their external customers.

Concerning those laboratories that are both certified and accreditated, the main reasons for certification/accreditaion were to standardize all the areas of the laboratory and to improve the recognition of the metrology services in any country signatory to the MRA (Mutual Recognition Agreement) of the EA (European Co-operation for Accreditation) and ILAC (International Laboratory Accreditation Cooperation).

**Certification and accreditation benefits.**

For the group ISO 9001 the certification of the laboratory brought greater systematization of all the information and activities. The people become more involved and more proactive. There was also a better training and information for people.

The requirement to calibrate / check the measuring equipment is another great benefit to laboratories, as they carry out in-house services, because the measuring equipments are crucial in evaluation the quality of products. As one of the interviewed said *"with the*

*calibration / verification of measuring equipments, we learn that the equipments are in proper working order"*, because you can not have quality products if the equipments used to control them do not have the minimum of rigor.

In the case of the laboratories only accredited by the ISO 17025 standard, the organizational benefits are the possibility of traceability of all the work and all the equipment, and also the operational definition of the laboratory, which means that the results are reliable and credible. In this case, there is an important benefit that is the higher training level for people who is working in the laboratory. The training for this group is considered an investment, since the technicians know what to do to be able to do it well. Another major benefit that accreditation brought was the increased number of customers and the workload for the laboratories, because the customers require accredited calibrations.

Concerning the third studied group, certified and accredited laboratories, the opinions are not consensual in relation to the benefits of having both recognitions.
Initially, the interviewed mentioned the benefits of each standard separately. The differences emerged after questioned about the benefits of having both standards. Some of them said that ISO 9001 is not useful for a laboratory that has the management system accredited by ISO 17025 standard. By the other side, others argued that the combination of the two standards is useful for the laboratory, since one of the benefits achieved was the increase in equipment life, because the technicians had more specific training in the areas of metrology and quality and so they are always updated with the equipments best practices. Another major benefit of joining the ISO 9001 and ISO 17025 is the improvement of customers perception of the quality of the service provided by the laboratory. This perception due to the fact that a considerable part do not knowing the real difference between certification and accreditation.

**Investment in the registration and renewal of the certification and/ or accreditation processes.**

The analysis of the investment with the registration and renewal of the certification and/ or accreditation process that an laboratory need to have, was another study section. Here too, were obtained different perspectives.

For the group of ISO 9001, all the investment related to the QMS implementation would not have been worthwhile if it was only for the laboratory, but as the laboratory is one of the links in the quality of the product or service, the company's investment was well done.
Furthermore, the companies pointed out indicated that the cost with the management of equipment is very high, but do not understand this cost as an expense but as an requirement for product quality and customer service.

The ISO 17025 laboratories pointed out that the investment they must have to fulfill the requirements for accreditation, such as the calibration of standards, interlaboratory comparisons, internal and external audits are very high compared to the cost they charge by the service to the customer. However, all the laboratories had stated that the balance of the investment in the accreditation is very positive, because the customer satisfaction also improves.

For those laboratories that have implemented both standards, one of the points also referred was the high accreditation costs with the registration and renewal processes.
The investment related to the implementation of both standards, increases workload and gives a greater credibility when compared to others laboratories. The costs regard certification according to the ISO 9001 standard are reduced when the laboratory is also acredited by ISO 17025 standard.

**The reasons for not implemente the ISO 17025 standard.**
The most common reasons for why the companies do not implemente the ISO 17025 standard in the laboratories were:
- High internal costs;
- Not intend to perform services abroad.

According to the analyzed companies, the internal costs related to the maintenance of the system are usually high. Additionally the accreditation would only make sense if the laboratories want to "sell" the calibration services to the outside and make money with that and this is not his main interest.

**The reasons for not implemente the ISO 9001 standard.**

The case studies for the group ISO 17025 said they do not have the certification according to the ISO 9001 standard because it is not an added value to the laboratory, and because the customers just require an accredited report/ certificate and not asked if the company or laboratory are certified. Another reason point out was that they had never pondered this option.

**The reasons for having the ISO 9001 certification and ISO 17025 accreditation.**

In this group the answers were more comprehensive. One of the reasons that lead the laboratories in this group to have both standards is the highest competence and a greater pride from the part of its technicians when performing a service. With the implementation of the two standards, the technicians have a higher perception of the impact that a nonconforming work has in the quality of products and services provided by its customers. The position of the laboratories in the market and the improvement in the standardization of procedures, processes and documents was a positive result of the two systems.

## CONCLUSIONS

After an analysis and reflection on the data obtained in the interviews, we verified that a metrology laboratory is ISO 9001 certified only when it is considered a department within a company that has its QMS certificate doing only internal calibrations or internal verifications.

For a metrology laboratory, the ISO 17025 accreditation allows the laboratories to perform external services as it is a requirement of the market and customers. For these laboratories, the ISO 9001 certification would not add any benefit to the customer service and would be an additional cost to the laboratory.

The laboratories that are simultaneously ISO 9001 certified and ISO 17025 acredited have more benefits. The main benefits pointed out were the fact of their technicians are properly updated and so the laboratories perform high quality services for external customers. In this way, they realize the impact of their service has on the final quality of products and services provided by its customers.

We can then conclude that the ISO 9001 certification, by itself, it is useful only to those laboratories which carry out internal calibration or internal checks.

The ISO 17025 accreditation is the most important recognition for metrology laboratories. However, if the laboratory work in accordance with ISO 9001 and ISO

17025, its technicians have a high sensitivity to customer servisse and also comunicate more effectively the quality of laboratory services to the customer. The impact on customer perception is significantly positive, if the laboratory refer that it is certified and accredited.

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