

LABORATORY FOR LENGTH MEASUREMENT-STANDARD ISO 17025:2005 – ORIENTATION TO SUCCESS

Almira Softic
University of Sarajevo, Mechanical Engineering Faculty in Sarajevo
Sarajevo
Bosnia and Herzegovina

ABSTRACT

Effective implementation of quality management system as per the requirements of ISO 17025:2005, either on its own or in conjunction with requirements of ISO 9001:2000, is a key requisite for laboratories who provide testing and calibration services commercially, or as an internal department providing the service within larger organization. ISO 17025:2005 covers every aspect of laboratory management. It involves everyone in the laboratory, including the laboratory manager, assistant laboratory manager, or quality manager. The standard also involves all laboratory staff whose functions relate to the quality of laboratory data generated. A laboratory's fulfillment of the requirements of ISO 17025:2005 means that the laboratory meets both the technical competence requirements and management system requirements that are necessary for it to consistently deliver technically valid test results and calibrations. Laboratory accreditation for calibration and testing: Being accredited to perform the specific work you are buying offers strong assurances that the answer will be correct and traceable.

Keywords: accreditation, laboratory, ISO/IEC 17025:2005

1. INTRODUCTION

ISO 17025:2005 is the evolution of the ISO/IEC Guide 25, a joint partnership between the International Organization for Standardization and the International Electrotechnical Commission, called the General Requirements for the Competence of Calibration and Testing Laboratories. This standard was developed specifically to give guidance to lab managers on both quality management and the technical requirements for the proper operation of a laboratory. Thus, ISO 17025:2005 can be thought of as the technical compliment to ISO 9000. As a matter of fact, any organization who meets the requirements for ISO 17025 automatically is ISO 9000 compliant (but the converse is not true).

ISO 17025:2005 is to provide a third-party demonstration to customers that the laboratory has the technical and managerial capabilities to perform specific tests, measurements, or calibrations, to stated standards or to customized procedures within their bounds of stated accuracies, chosen test methods & equipment.

ISO/IEC 17025:2005 contains all of the requirements that testing and calibration laboratories need to meet to demonstrate to customers and regulators that they operate a sound management system which puts them in full control of their processes, are technically competent, and are able to generate technically valid results. Accreditation bodies that recognize the competence of testing and calibration laboratories use the standard as the basis for their accreditation.

2. THE COMPARATIVE ADVANTAGE OF ISO 17025:2005

While the ISO 9000 requirements are generic and can be used by any type of organization, the ISO 17025:2005 requirements are specific to laboratory functions. This standard addresses issues such as: the technical competence of personnel, ethical behavior of staff, use of well-defined test & calibration

procedures, participation in proficiency testing (i.e.: interlaboratory comparisons and/or reference materials), and provide guidance on the contents of test reports & certificates generated. One function of the ISO 17025:2005 standard is to demonstrate the lab's abilities to carry out specific tests and/or calibrations. The accreditation certificate will state the tests, equipment used and the degree of accuracies obtained.

ISO 17025:2005 also promotes cooperation between laboratories and other bodies to exchange information and experience and the harmonization of standards and procedural goals. ISO 17025:2005 covers every aspect of laboratory management. It involves everyone in the lab, including the laboratory manager, assistant laboratory manager, or quality manager. The standard also involves all laboratory staff whose functions relate to the quality of laboratory data generated. A laboratory's fulfillment of the requirements of ISO/IEC 17025:2005 means that the laboratory meets both the technical competence requirements and management system requirements that are necessary for it to consistently deliver technically valid test results and calibrations.

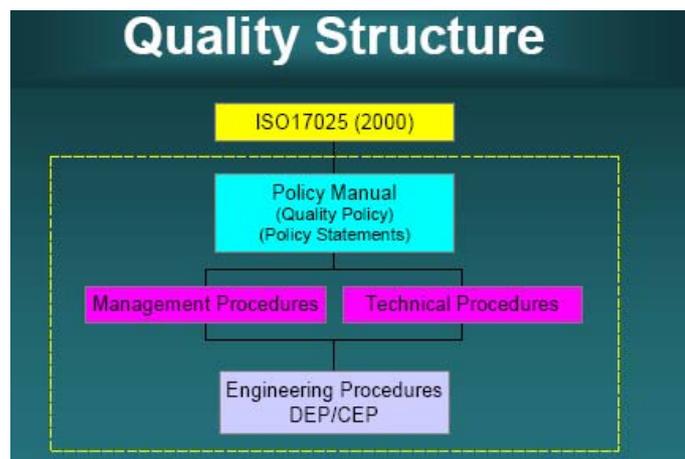


Figure 1. Documentation of quality management system according to ISO/IEC 17025:2005

A laboratory must document a quality management system. A documented quality manual is a basic requirement on the road to laboratory accreditation. In addition, quality management procedures must be established for how the system is maintained. Once the system is documented it must be implemented in the laboratory as it shown on Figure 1.

The standard was revised in 2005, the purpose of which was to align it with ISO 9001:2000. Unlike before, the two standards are now considered to be compatible. The revision makes it clear that meeting the requirements of ISO/IEC 17025:2005 does not automatically mean that the requirements of ISO 9001:2000 are met. The standard does however recognize that, by being accredited to ISO/IEC17025:2005, a laboratory will meet the principles of ISO 9001:2000.

Consequently, laboratories may choose to be accredited to ISO/IEC 17025:2005, or be certified to ISO 9001:2000, or both, but the processes of accreditation and certification would be two separate actions.

Accreditation according to ISO/IEC 17025:2005 is not a substitute for certification according to the ISO 9001:2000. There are differences between the purpose, criteria and emphasis of the ISO 9001:2000 quality system standard, and those of the accreditation standard ISO/IEC 17025:2005. For laboratories concerned with demonstrating technical competence underpinned by sound quality system elements, ISO/IEC 17025:2005 is the appropriate standard.

3. WHAT ARE BENEFITS OF ACCREDITATION?

In the EU, it is almost an unwritten rule that companies within their economic community have accreditation according to ISO/IEC 17025:2005 to freely market their product or service. This standard can be implemented for anyone who performs testing, measuring, or calibrating. As with any well constructed standard, ISO/IEC 17025:2005 is not to be considered as an unnecessary imposition on your time and efforts. It is designed to be help you improve, and then maintain, your quality and standards. By following the procedures and methods specified, everyone can be assured of the

accuracy and integrity of your laboratory. However, you will have to continually monitor your quality processes to ensure that they continue to meet the guidelines of this standard. This is a good thing for everyone: rigorous quality processes equate to fewer failures and errors.

It is also important to remember that as more calibration laboratories become accredited, correlation between these accredited laboratories' measurements will improve, thereby improving the general quality of the measurement process everywhere.

Benefits of accreditation in short can be stated as:

- Provides valid test data that the customer (whether internal or external) can trust;
- Strong quality control, qualified processes and demonstrations of staff competence provide a greater degree of data defensibility;
- Provide excellent third-party recognition to your customers;
- Should lead to fewer re-analysis of samples;
- Clear definition of roles, responsibilities, and authority, provide for greater efficiency in operation of the laboratory;
- Audit and assessment activity by laboratory customers can be reduced through third party recognition;
- Increased efficiency will lead to a reduction in operating costs;
- Increased efficiency will result in less re-analysis of samples. This too, effects the cost of operations in a positive way;
- Increased efficiency and reduction of re-analysis will decrease customer complaints and should contribute to decreased turnaround time for analyses; and
- Increased efficiency should also free up capacity to increase throughput and provide for increased business.

4. CONCLUSION

One function of the standard ISO/IEC 17025:2005 is to demonstrate the lab's abilities to carry out specific tests and/or calibrations. The accreditation certificate will state the tests, equipment used and the degree of accuracies obtained. Second function of the ISO/IEC 17025:2005 standard is to harmonize laboratory accreditation and acceptance of test data throughout the world.

Accreditation bodies encourage laboratories to endorse test reports in the name of the accreditation body to make public statement that particular test data has been produced by a laboratory which has demonstrated to a third party that it is competent to perform such tests. Therefore, both users of laboratories practice and laboratory itself, should be concerned with the potential for performing a quality job (quality system) and technical competence (ability to achieve a technical result). The best available method of achieving these two objectives is through laboratory accreditation bodies, operating themselves to best international practice, requiring laboratories to adopt best practices and through constant application of ISO/IEC 17025:2005 to assure the necessary confidence in the data's validity.

5. REFERENCES

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