

EFFECTS ON R&D AND TEACHING OF THE ISO 17025 ACCREDITATION IN A CALIBRATION UNIVERSITY LABORATORY

G. A. Ruiz¹, S. Padilla¹, J. Sanchez¹, R. Nava¹, B. Valera¹, F.M. Gutierrez²

¹Centro de Ciencias Aplicadas y Desarrollo Tecnológico, Universidad Nacional Autónoma de México, México, D.F., México, gerardo.ruiz@ccadet.unam.mx

²Coordinación de Gestión para la Calidad de la Investigación, Universidad Nacional Autónoma de México, México, D.F., México, fmg@unam.mx

Abstract – This work describes the process of implementing a quality management system (QMS) in a calibration laboratory at the National Autonomous University of Mexico (UNAM). Experiences since 30 years ago, from the accreditation of the laboratory with the former ISO 25 Guide until the most recent ISO 17025, are shown. The authors analyse how the accreditation impacts on R&D, teaching and customer satisfaction. The main benefits and challenges for ISO 17025 accredited laboratories are also described.

Keywords: quality management system, accreditation, ISO 17025, laboratory quality system, R&D

1. INTRODUCTION

The purpose of universities is the generation of knowledge and its transmission through teaching, in order to positively contribute to society. To be close to society and its problems, universities have to pursue a better and more direct collaboration with companies. Laboratories for testing and calibration have been drivers that enable universities to interact more closely with society, through supplying research and services that fulfil the needs of society for cutting edge knowledge and solutions to problems. [1]

One of the problems that companies frequently have is to assure the quality of their measurements. Testing and calibration laboratories have a very important role in providing calibration that provides confidence about the measurement given by equipment. But to be certain of this calibration, laboratories need to confirm their results and the best way to do this, is by implementing and maintaining a quality management system (QMS) based on the international standard ISO 17025.

The Metrology Laboratory (ML) of the Applied Science and Technology Development Centre (CCADET) of the UNAM was created in 1984 in order to provide calibrations and measurements in dimensional metrology for companies based in Mexico, public organisations and other research laboratories at the UNAM and other universities; develop research and innovation in dimensional calibration and measurement methods; and develop human resources specialised in dimensional metrology and quality management.

Through its history, the ML has been accredited on

various occasions with different international standards. Its first accreditation dated 1987 and was granted by the then Office for Commerce of the Mexican Government under the ISO 25 Guide, which is considered the first international standard for calibration laboratories. In fact, the laboratory was the second laboratory in the country to gain the accreditation and was the first in a university. In order to achieve this accreditation, it was necessary to develop an integrated QMS, which included not only technical but also management procedures and a quality manual. Later, when the ISO 17025 was published, repealing the ISO 25 Guide, the ML adapted its QMS to fulfil the requirements of the new standard and has been ISO 17025 accredited ever since.

In order to be granted ISO 17025 accreditation, laboratories have to develop and maintain a QMS focused on assuring the quality of measurements and calibrations they provide. A QMS based on ISO 17025 helps a laboratory to maintain its equipment in good condition; assures the environment and infrastructure that may interfere in testing or calibration results; updates technical procedures when science and techniques change; maintains personnel competence regarding new trends in the body of knowledge; and keeps all of the laboratory's processes on track and under control. Moreover, in the context of a university laboratory, an ISO 17025 QMS also enriches teaching and R&D activities by teaching cutting edge methods and best laboratory practices to students; and by assuring the quality of research results, which are submitted to peer review.

The implementation of an ISO 17025 QMS in a university laboratory is different than in other type of laboratories. As Robins *et al.* say [2], university laboratories are focused on research and teaching, which causes the provision of measurement and calibration services to third parties to be a difficult task because it has to be done in parallel with its main activities. This is when an ISO 17025 QMS becomes a very important management tool that enables the control of all the activities that are conducted in a laboratory and assure their quality.

It is important to point out that even if accreditation is not a mandatory requirement for implementing the ISO 17025 standard, the assessment conducted by an accreditation body provides an external recognition of the technical competence of the laboratory for providing measurements and calibration services. Hence, accreditation

becomes an external guarantee for clients about the validity of laboratory results.

2. QMS AT THE UNAM

Quality management has occupied an important space in both leading journals and practitioner magazines in recent decades. But despite this body of knowledge being widely applied in different industries, it was only in the 1990's that quality concepts and techniques began to be applied in education [3].

Traditionally, education organisations started implementing quality models in education processes and services such as libraries and catering. But it was not until 2005 that quality models began to be used in research activities in order to assure the quality of research results [4]. ISO 9001, ISO 17025 and the OECD Good Laboratories Practices are the most implemented models in research processes.

The UNAM is one of the biggest universities in the world by number of students and since its foundation in 1551 has had a strong commitment to quality in both teaching and research activities. Its graduate and postgraduate programs are in high demand and currently have more than 330 000 students. The UNAM also has an important commitment to research; nowadays its academics produce more than 30% of Mexican scientific research.

In order to maintain this quality, the Scientific Research Coordination opened an office in 2002, the Coordination for Quality in Research (CGCI), devoted to help teaching and research laboratories implement quality management models and practices. Hence, the main objectives of the CGCI are: (1) disseminating quality culture through the UNAM's academics by teaching them about quality models, methods and techniques; (2) providing consultancy about how to implement QMS, from determining the needs of each laboratory until certification/accreditation is granted; and (3) managing the general internal audit process, which assures that QMS are well implemented and maintained.

During the last 13 years, more than 200 teaching and research laboratories in the UNAM have gained ISO 9001 certification and around 25 have been granted ISO 17025 accreditation. In addition, there are also some laboratories that are implementing ISO standards or other QMS without the expectation of obtaining a certificate, which is an indicator of quality culture dissemination within academics.

There are several reasons why the quality program at the UNAM has been successful, but maybe the most important one is its internal audit process. All of the existing QMS models require measuring the performance of the QMS by audits, management reviews and measuring customer satisfaction. Nevertheless, audits are recognised as the most important method of measuring QMS performance because they are used by both the organisation as a self-assessment tool and by accreditation bodies to grant the accreditation. Knowing this, the UNAM established a general internal audit process to guarantee the efficacy of the laboratories' QMS through internal audits. The process is run by the CGCI, as an independent office, which is in charge of organising internal audits for certified and accredited

laboratories with the participation of more than 120 academics trained as internal auditors in several disciplines. A key issue for the success of the internal audit process has been conducting audits with auditors that are not related to the QMS being assessed. This permits an independent evaluation by peers and provides credibility to the whole process. Training of internal auditors is also an important issue for the success and credibility of the internal audit process. The CGCI also runs an internal auditors qualification process (Fig. 1), which includes two training stages: (1) teaching academics about both quality and audit models, methods and techniques; and (2) training auditors in real audit conditions by letting them conduct key parts of the interrogatory during an audit under the supervision of senior auditors.



Fig. 1. Internal auditors training by international experts.

The implementation of ISO 9001 and ISO 17025 quality systems models has proved to be a very powerful tool for improving the operation of both teaching and research laboratories at the UNAM. The users of certified and accredited laboratories at the UNAM have declared that the services in these laboratories have improved, while the academics working in the laboratories comment that they are better organised and that the results they provide to third parties are perceived to be more valuable. As Dale (2007) [5] states, quality management models provide a reference framework to assure that every time a process is conducted, the same information, methods, tools and controls are used in a consistent matter.

3. THE QUALITY SYSTEM OF THE ML

The ML of CCADET was the first laboratory at the UNAM that was granted accreditation in 1987. Its QMS was designed to fulfil the requirements of the ISO 25 Guide [6] for testing and calibration laboratories, and ISO 9000 [7,8], the standard for QMS. Hence, the ML QMS was a first version of an integrated management system. Nevertheless, this caused the quality manual to be too long and complex.

When the ISO 17025 standard [9] was published, replacing the ISO 25 Guide, it was necessary to change the QMS documentation in order to fulfil the new requirements.

Hence, a simplification of the documentation was conducted in parallel with the adaptation to ISO 17025. This documentation reengineering also included adding some requirements of ISO 9000 [10,11,12] and mandatory regulations [13] to the new QMS. As a result of these changes, the size of the documentation was considerably reduced, making it more accessible for the laboratory personnel and users.

Nowadays, the QMS documentation includes a quality manual, technical and managerial procedures, work instructions, policies and records. In order to make it easier to check and use, the QMS documentation is distributed in PDF format and individual passwords are given to all the members of the ML. This is particularly helpful when third party audits are conducted and auditors need to be able to easily search the documents to assess how the laboratory is complying with ISO 17025 requirements, the result being that audits are less stressful and more in depth.

A very important part of the ML QMS are procedures which are divided into two types: managerial and technical. The managerial procedures include: control of documents and records; customer satisfaction; corrective and preventive actions; review of contracts; internal auditing; and management review, amongst others. About 20 technical procedures have been accredited (Fig. 2), including between them calibration of gage blocks and length bars, surface plates, optical flats and parallels, optical comparators, angular scales, electronic and precision levels, optical polygons and CMM performance (Fig. 3).



Fig. 2. Instruments calibration and measurement main room.

Each technical procedure includes the reference standards for each calibration, the applicable work instructions and the procedures to estimate its uncertainty. All the documented methods for conducting calibration are standard and widely accepted in the body of knowledge.

4. MAIN BENEFITS AND CHALLENGES OF THE ISO 17025 ACCREDITATION

As stated above, the main objectives of university laboratories are conducting cutting edge research and teaching and this can be done perfectly without accreditation. Moreover, it can be argued that the

accreditation process is time consuming, expensive and stressful. Hence, why should a university laboratory pursue accreditation? In the last 30 years the authors have identified the following benefits of the accreditation:

- Updated traceability.
- Accuracy dissemination.
- Effective quality system assuring the measurement and calibration results with competitive uncertainty levels.
- Laboratory and personnel capacities and abilities assessed by external peers.
- Professional training based on experience on metrology and quality management.
- Connection with society.
- Earned incomes to attending LM needs.
- National and International recognition of the LM results and capacities through ILAC and MRA.

Particularly, additional benefits for a university laboratory are:

- Teaching of current metrological methods and techniques as well as quality management instruction based on knowledge and experience to graduate and postgraduate students.
- Assurance of R&D results.

Nevertheless, there are also some challenges that need to be addressed, such as:

- Produce of funds sufficient for supporting updated laboratory facilities and maintenance, as well as standards traceability.
- Keep the staff of the laboratory in the state of the art for developing new R&D lines and measurement techniques.
- Renovate the laboratory staff retaining some of the young new talents that could be being trained in metrology and quality systems, such as postgraduate students.
- Count with technical personnel devoted to support calibration and measurement services.



Fig. 3. 3D calibration and measurement room.

5. CONCLUSIONS

After implementing its ISO 17025 QMS, the ML became more effective and efficient. Having clearly documented how methods and procedures need to be conducted; who is responsible for executing activities; what has to be done in case of errors; which operations are critical to the quality of service; and what goals need to be achieved, are essential for the laboratory to be more productive and to incorporate new personnel easily.

Of course this also has a very positive impact on R&D and teaching activities. The ISO 17025 QMS provides a platform for better control of laboratory equipment; implementing new technical methods and procedures; assuring the quality of testing results; improving the activities conducted in the laboratory; and teaching cutting edge technology. On the whole, the authors believe that ISO 17025 QMS are an added value to university laboratories based on their own experience.

Nevertheless, implementing and maintaining this kind of QMS is a time and resource consuming activity. But the external recognition and visibility that is gained after the accreditation; the best practices that students get when working in an accredited laboratory; the continuing improvement in technical methods and procedures; as well as certainty of the quality of the results that the laboratory delivers to its customers, clearly overcome the challenges of the QMS.

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