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PRACTITIONER'S REPORT

A process approach to ISO/IEC 17025 in the implementation of a quality management system in testing laboratories

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Abstract The introduction of quality management systems (QMS) and the accreditation of laboratories according to ISO/IEC 17025 standard are not easy tasks, mainly for those laboratories located at teaching and research institutions. During the implementation of QMS at two testing laboratories of the Federal University of Rio Grande do Sul in Brazil, new solutions to overcome some of the difficulties inherent to this type of environment have been found. The knowledge acquired through this work has led to the proposition of some general steps incorporating a process approach presented in this article, which could be of use to laboratories in their pursuit for accreditation. This proposal suggests the use of strategic planning information, links the QMS objectives to the corresponding processes and sets a few indicators to monitor both performance of and improvements to the system.

Keywords Quality management system · Testing laboratories · Accreditation · ISO/IEC 17025 · Process approach · Teaching and research institutions

Introduction

In recent decades since the opening of national borders to international trade, the global exchange of products and services has intensified. Multilateral trade agreements have been signed indicating acceptance to follow internationally defined quality standards, thereby achieving the expression "tested once, accepted everywhere" [1, 2]. In this context, the accreditation of laboratories according to ISO/IEC 17025 has evolved from being a voluntary act at the beginning to becoming and remaining a competitive factor for some time, reaching the stage of being considered a requirement for survival [3].

Accreditation bodies [4, 5], private companies [6] and other institutions around the world [7] provide guidance through publications to help laboratories meet the 17025 requirements. Even then, the process of implementing a QMS often requires the use of external consultancy services.

However, accreditation of laboratories is even more difficult to accomplish in the case of teaching and research institutions. Some difficulties arise out of the peculiar characteristics of these environments, including the unclear definitions of the functions and responsibilities and the presence of temporary staff. The motivation for implementing a QMS at these places may not be very clear and it is also difficult to measure the impact of accreditation of such laboratories on the quality of human resources education, their innovation capacity, the results of their research, and the quality and quantity of their publications. Thus, the authors conclude that the greatest motivation for the implementation of a quality management system (QMS) and accreditation of laboratories in teaching and research institutions is the external pressure, which often comes from an external customer or from regulatory agencies, such as the International Atomic Energy Agency [8]. In Brazil, the release of funds from government agencies to teaching and research institutions is observed to spur the qualification of the country's laboratory infrastructure [9], which contributes to the decision of seeking accreditation to ISO/IEC 17025 [10].

During the implementation of a QMS at two testing laboratories of the Federal University of Rio Grande do Sul

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(UFRGS) in Brazil, some new solutions have been developed to overcome the arising problems [11]. The lack of customer focus of a broader understanding of the laboratory's role within the institution and of an institutional strategic planning hampers the definition of the policy and objectives of the QMS. Several other difficulties and the absence of a comprehensive methodology contribute, even today, to discourage and prevent the implementation of QMS and accreditation of laboratories at teaching and research institutions. However, the knowledge acquired through the experience at UFRGS has led to the proposition of some general steps for the implementation of QMS in laboratories.

The aim of this article was to present some steps for QMS implementation according to ISO/IEC 17025 standard, incorporating a process approach as employed in business administration [12, 13] and in the ISO 9001 standard [14]. The proposal links the QMS objectives to the corresponding processes and sets some indicators to monitor both performance of and improvements to the system.

Each proposed step is commented in the text. A set of processes involved in the laboratory's provision of testing services, the activities related to these processes and their correspondence with the items in ISO/IEC 17025, in addition to a few examples of indicators for monitoring the adherence to the quality objectives, are presented. Some suggestions to teaching and research institutions are also provided.

Methodologies for implementation of QMS in laboratories

The difficulties and limitations in the implementation of QMS in teaching and research institutions and the advantages of accreditation for testing laboratories are widely described in the literature [11, 15–21]. Some of the difficulties and limitations encountered are: (1) the provision of testing services is not a priority; (2) the temporary staff has a high turnover; (3) the laboratories are shared with the research and teaching activities; (4) the staff's functions and responsibilities are varied and diffuse; and (5) the staff's performance is commonly measured based on their teaching activities and publications. The main advantages of accreditation were: (1) increased customer satisfaction; (2) increased reliability of results and staff's qualification; (3) decreased damage to or malfunction problems of equipment; (4) increased number of tests and bills; and (5) receipt of government funds. In the case of UFRGS laboratories [11], in contrast to the results reported by Abdel-Fatah [22], an increase in the number of tests for external clients (of approximately 85 %) in the period 2005–2009 was observed, also due to the better organization afforded by the QMS.

During the implementation of QMS in a test laboratory according to the European Norms EN 45001 standard, the precursor of ISO/IEC 17025, Benoliel [23] identified the following phases: planning, management responsibility, quality training, preparation of documentation, validation of analytical methods, implementation of the analytical quality control system and internal audits. Ferguson et al. [24] presented the following steps for implementation of QMS according to ISO 9001 at an R&D and routine-analysis laboratory: choice of a standard and of a certifying agency, identification of government standards and protocols that would impact on the system, clear definition of clients and scope, appraisal and adaptation of methods and procedures employed in the laboratory, system implementation, preaudit and full audit conduction.

The 2005 version of the ISO/IEC 17025 standard has incorporated all those requirements of ISO 9001 relevant to the scope of testing and calibration services and covered by the laboratory's QMS. Although the management system requirements in ISO/IEC 17025:2005 have been expressed in a language relevant to laboratory operations and aligned to ISO 9001:2008 pertinent requirements [25], the approach to process management in the ISO/IEC 17025 has not yet been fully adopted, especially with respect to the technical requirements. Based on the difficulties encountered during its implementation at the UFRGS laboratories [11], the process management approach can help because it (1) highlights the client's focus; (2) favors a view of all activities and their interrelationships; (3) contributes to fixing of responsibilities; (4) allows process optimization and elimination of unnecessary activities; and (5) generates elements needed for evaluating and obtaining continuous improvement of the QMS.

Rauret and Compañó [26] used the process approach during the implementation of ISO 9001 QMS for the activities related to practical classes at university teaching laboratories. They also established a set of indicators associated with the proposed objectives for each of the identified processes. Moreover, based on the ISO 9001, Robins et al. [27] identified seven key processes for the whole spectrum of research (fundamental, strategic and applied) in a research institute and indicated the need to establish controls for each of these processes according to their goals. Burnett [28] reorganized the ISO 15189 requirements to propose a process- and outcome-based QMS model to be used in accreditation for medical laboratory services.

According to Harrington [29], performance evaluation systems are used to assess the processes, to establish goals for improvement and to better understand what is important to the organization. Additionally, Müller [30] indicates the

need to integrate strategies with the institution's processes in the pursuit of organizational alignment to support the institution in the long term. He considers that this link is established by the performance appraisal system, in which the objectives are unfolded to the processes. Then, the performance derived is evaluated and compared with the prediction by setting and monitoring indicators and targets.

In spite of these reports, the use of process management in the implementation of QMS based on ISO/IEC 17025 is not seen in literature. The authors believe this to be a probable evolution trend of the standard.

General steps for implementing a QMS

The implementation of a QMS in any organization could result out of internal desire, external pressure [11] or even institutional strategic planning [31]. This decision should consider (1) the organization's culture; (2) the actual need for pursuing accreditation; (3) the time and the resources available; (4) the staff's knowledge and previous experience in quality; and (5) the current conditions of the laboratory with reference to compliance with the standard. Regardless of these issues, the top management must be committed and must communicate the importance and reasons of the implementation of a QMS to all staff before starting the process. The QMS should be developed internally, respecting the peculiarities of the laboratory and of its personnel, even with the help from external consultants.

The time required to conclude the implementation of a QMS according to ISO/IEC 17025 can vary and is related to the factors mentioned in the previous paragraph. Some testing laboratories of teaching and research institutions reported a time requirement of: about 1 year when the implementation was derived from a strategic decision of the top management [31] with the university rector involvement [19, 31]; 18 months, not counting the previous experience [20]; up to about 3 years, due to other tasks as teaching and research activities [11].

The first four steps are presented as: (1) predetermine tests and personnel covered by the QMS; (2) check the current situation; (3) calculate the costs for QMS implementation; (4) draw schedule and fix responsibilities—corresponding to the planning of the implementation and critical to the success of the job. The process approach, included in step 5 through the mapping and analysis of all the processes involved in conducting tests in the laboratory, eases the adaptations needed for compliance to the ISO/IEC 17025 standard requirements mainly in the laboratories of teaching and research institutions. Steps 6 and 7 correspond to the phase of QMS implementation related to the establishment of management and technical requirements. Steps 8 and 9 are related to the internal assessment of the adequacy of the QMS and its compliance with the ISO/IEC 17025 requirements and step 10 suggests the application for the accreditation.

Our experience with the QMS implementation in the UFRGS laboratories, including the problems encountered and solutions identified, was described in a previous publication [11]. In this paper, we introduce some suggestions at each corresponding step.

Step 1: predetermine tests and personnel covered by the QMS

The preliminary scope of the activities, including the laboratory's physical area, tests, personnel and equipment involved, should be stated. If the organization has several laboratories or the laboratory performs too many tests, it should be established which laboratories and tests are to be covered by the QMS.

The choice of the tests to be included in the QMS is important and, based on the experience of the authors and according to literature [7, 22], should consider, among others, the following aspects: (1) external demand of tests; (2) accreditation requirement by the customer or the regulatory authority; (3) use of standard test methods already established and known well by the laboratory staff; and (4) condition of equipment used for tests, in addition to involving appropriate costs of maintenance and calibration.

If the organization intends to implement the QMS in more than one of its laboratories, their staffs must participate. It will also be important to appoint the persons who shall be responsible for the process, in addition to the management representative. The decision to hire an external consultant will depend on the availability of resources, previous experience of the staff in QMS and on the time provided for the implementation. However, the direct involvement and commitment of the users of QMS and the top management are essential for successful implementation.

Due to the proximity and similar activities carried out by the two UFRGS laboratories, a single QMS was created [11]. In this case, their technical differences were respected, and the top management was represented by the teachers of each laboratory. Because of the autonomy in managing their own resources, this structure favored communication within the staff and agility of the processes involved in providing testing services.

Step 2: check current situation

A survey of the laboratory's current situation and the needs to comply with the ISO/IEC 17025 standard requirements will be necessary to assess the resources to be allocated, to

estimate the time required for implementation and to formulate a strategy for further work.

Some important aspects to be checked are as follows: (1) proper functioning and calibration status of equipments; (2) the staff's knowledge and skill; (3) the use of clearly described and validated analytical methods; and (4) the adequacy of the facilities. All necessary changes requiring investment or financial inputs, as well as training demands and participation in proficiency testing or interlaboratory comparison programs, should be noted.

This diagnosis could be obtained through an external assessment; otherwise, the use of a checklist suggested by accreditation bodies or an internally created questionnaire is recommended. To perform this step, it may be necessary to provide some previous staff training in ISO/IEC 17025.

Step 3: calculate costs for the QMS implementation

The needs identified in the previous step should be budgeted, also considering the costs payable to the external consultant or the accreditation body as applicable.

The final definition of tests and personnel covered by the QMS should consider the values obtained and the investment capacity of the institution. It may be necessary to limit the number of tests for the first stage of the QMS implementation, expanding the scope later.

After staff consolidation, training in relation to the ISO/IEC 17025 standard should be provided to them.

Step 4: draw schedule and fix responsibilities

Based on the needs identified in step 2, the available resources and the desired time, a schedule is drawn listing the activities and the persons responsible and deadlines. If necessary, this schedule may be periodically reviewed, corrected and harmonized with the staff.

Step 5: map and analyze processes

Following the process approach mentioned previously, all the processes involved in conducting tests in the laboratory should be mapped, and their inputs, outputs, stakeholders and related activities defined. The interfaces, suppliers, customers and, if required, the areas or the physical spaces of each process should be clearly identified. Even if the laboratory has already mapped its processes, it should analyze them by comparing the current situation with the ISO/IEC 17025 requirements for making the necessary adjustments.

Based on the ISO/IEC 17025 requirements, the authors identified 16 processes (Table 1). Subsequently, these processes were grouped into the following macro processes: (1) product realization; (2) system management; (3) resource management, (4) effectiveness of QMS and its improvement; and (5) quality assurance of tests. For each of these processes, the main related activities and the corresponding items of ISO/IEC 17025 are listed.

Step 6: establish the management requirements

If the laboratory largely meets the technical requirements, a more formal "top-down" approach could be used. In this case, one should start with the definition of the policy and the objectives of the QMS along with the writing of the quality manual and other general procedures. On the other hand, if many of the technical requirements are still not complied with, adopting a "bottom-up" approach, starting from the more specific issues to the more general and changing the order of the steps 6 and 7, may be appropriate. The proposal in this paper uses a flexible and mixed approach; thus, the several activities of these steps could be conducted simultaneously or in any desired order.

The complete list of management requirements is presented as 15 items in the ISO/IEC 17025 standard [10], some of which are commented upon here.

Organization requirements

It is important to determine the organizational chart of the laboratory (or of each laboratory) and identify its place in the main organization. In the case of teaching and research institutions, the functions of technical and quality managers, as are usually carried out by teachers or researchers, need to be conciliated with other activities performed by them.

To ensure the protection of confidential information and proprietary rights of customers, considering the frequent presence of researchers and students, the following resources may be used: (1) signing of a nondisclosure agreement by all personnel involved with the tests; (2) maintaining the documentation containing customer information in a secure and controlled access area; and (3) removing client identification from the test items.

Management system

The policy statement regarding quality should be issued under the authority of the top management and shall include the commitment to good professional practice, to the quality of its testing in servicing its customers, to its compliance to the ISO/IEC 17025 standard and to continuous improvement [10]. If the institution or the laboratory has an established strategic plan, the objectives associated with quality should be reviewed from the perspective of ISO/IEC 17025. If there is no strategic plan or their objectives are not related to the QMS, it will be necessary

Table 1 Activities related to a laboratory's processes and the corresponding items of the ISO/IEC 17025 standard

Macro process	Process	Activity	Standard item
Product realization	Review of requests, tenders and contracts	Contact client; specify requirements; establish agreement on method, price and deadline; formalize the contract	4.4
	Testing	Collect, receive, identify, handle, protect and store test items	4.5, 5.1 5.7, 5.8
		Carry out or subcontract the test	
	Reporting the results	Analyze test data; write, protect and send the test report; charge the customer	5.10
System management	Management responsibility	Meet organizational requirements	4.1
		Establish QMS policy and objectives	4.2
		Plan, execute and record management review meetings	4.10, 4.15
	Information management	Issue, approve, distribute, and manage QMS documents	4.3, 4.13, 5.4, 5.10
		Identify, collect, index, store, maintain and dispose records regarding quality and technical details	
Resource management	Purchase	Evaluate suppliers, maintain list of those approved, specify requirements for purchase, accomplish purchase and check compliance with specifications	4.6
	Personnel	Hire, train, evaluate and authorize staff	4.1, 5.1, 5.2
		Describe personnel functions and responsibilities	
	Infrastructure	Monitor, control and record environmental conditions	5.1, 5.3
		Adapt laboratory facilities; control the access to and the use of areas	
	Methods	Acquire, create, validate, implement and use testing methods and related procedures; estimate measurement uncertainties	5.1, 5.4
	Equipment	Acquire, identify, monitor, maintain and calibrate equipment and instruments	5.1, 5.5
		Elaborate procedures for safe handling, transport, storage, use and planned maintenance of measuring equipment	
Effectiveness of QMS and its improvement	Customer service	Provide reasonable access to laboratory; provide a guide to the preparation, packaging and dispatch of test items; maintain communication throughout the process; seek feedback through customer satisfaction surveys	4.7
	Complaints	Record and solve complaints	4.8
	Nonconformities, corrective and preventive actions	Record and analyze nonconformities; plan and execute corrections; ensure corrective and preventive actions	4.9, 4.10, 4.11, 4.12
	Audits	Plan, conduct and record internal audits	4.10, 4.14
Quality assurance of tests	External QC	Establish program and procedure for the calibration of equipment and acquisition of standards	5.1, 5.6, 5.9
		Participate in interlaboratory comparison or proficiency testing programs and analyze the laboratory performance	
	Internal QC	Provide intermediate checks to maintain confidence in the calibration status of equipment and reference standards	5.5, 5.6, 5.9
		Develop intralaboratory comparisons	
		Establish quality control procedures as regular use of certified reference materials, replicate testing or retesting of retained items, among others	
		Analyze obtained data	

to establish them. Both the policy and the objectives of the QMS should be communicated and fully understood by the staff.

The institution (UFRGS) reported in this paper had no strategic planning at the time of QMS implementation. The following QMS objectives were then fixed: (1) meet

customer needs by ensuring the quality of services with reliability; (2) assure human and technical improvement of the staff; (3) assure adherence of the QMS to ISO/IEC 17025; and (4) assure sustainability of the laboratory.

Document control

The documentation should be structured as recommended by ISO/IEC 17025, maintaining utmost clarity and simplicity while avoiding redundancy. As stated by Vermaercke [32], "write what you do, do what you have written". The ISO/TR 10013 standard [33] could also be used as it "will aid in establishing a documented system as required by the applicable quality management system standard".

The policies and the procedures for attending each of the ISO/IEC 17025 management requirements should be based on survey, analysis, and adequacy of the processes and activities previously identified, in addition to respecting the routines already consolidated and implementing adjustments where necessary. To avoid excessive documentation, simple procedures can be described only in the quality manual. If possible, an electronic document control could be established.

Review of requests, tenders and contracts

To ensure complete understanding and subsequent meeting of customer requirements, in addition to properly maintaining records, this process should be as simple and complete as possible and well understood by all the staff involved.

In teaching and research institutions, the request for testing is often routed through teachers or researchers. Sometimes, the nature of the research work performed by them may preclude that the requirements are completely known before the performance of the tests. Therefore, for the tests covered by the QMS, any differences between request and contract shall be resolved before the beginning of the tests and each contract shall be acceptable both to the laboratory and the customer.

At the UFRGS laboratories, the review of requests, tenders and contracts is registered in a single document. To maintain the agility of the process, the customer contact may be accomplished by phone, through mail or in person. In these laboratories, external customers are those outside the university, such as businesses and other institutions in general, who hire and pay for services performed. Internal customers are UFRGS teachers, researchers and students who use the test results for learning or research and often do not pay for the tests. In these situations, the review of request could be performed in a simplified way, as allowed by the ISO/IEC 17025 standard, since the number of samples, the need for changes in test parameters or even the lack of knowledge of how long it will take to perform the tests may not be known in the beginning.

Step 7: establish the technical requirements

The technical requirements are arranged in the form of ten items in the ISO/IEC 17025 standard. Some of the technical requirements are commented upon here.

Personnel requirements

The staff should be trained regarding the various quality-related aspects (ISO/IEC 17025 standard, estimation of measurement uncertainties, and internal audits) and, when necessary, in the associated technical issues to qualify for their jobs. Especially for teaching and research institutions, where the presence of temporary staff may be considered a problem, training [11, 20, 21] and supervision [11, 19, 21] are fundamental. The effectiveness of training could be monitored through regular intra-laboratory trials. Postgraduate students should receive training to conduct their tests, be formally authorized by the laboratory manager and should sign nondisclosure agreements.

Accommodation and environmental conditions

Laboratory facilities must be adequate for testing and other related activities and in accordance with the test methods and equipment manuals. When necessary, procedures to control the environmental conditions, in addition to those related to the use of and access to different of areas, should be established.

At the UFRGS laboratories, the areas covered by the QMS have restricted access and entry of students, researchers or others is only allowed when accompanied by a staff member or with formal authorization by the manager.

General test methods and method validation

As stated at ISO/IEC 17025 [10], "methods published in international, regional or national standards shall preferably be used". Often in teaching and research institutions, self-developed testing methods are used, but the demand for using consolidated and published methods may occur due to external customers or even to support research. Then, the use of standard methods is suggested whenever possible. Otherwise, the method should be properly validated to confirm that it is fit for the intended use.

Equipment requirements

In teaching and research institutions, equipment used for tests covered by QMS should not be allowed to be manipulated by students; those used for teaching purposes should stay in other laboratories. The availability of complete instructions regarding the use and maintenance of equipments, as required by the ISO/IEC 17025 standard, and the implementation of intense training and supervision will minimize the effects of the presence of temporary staff. At the UFRGS laboratories, damages or malfunction problems caused by inadequate operations were diminished by restricting their use to trained, qualified and authorized staff.

Assuring the quality of test results

The quality assurance of test results is related to internal and external processes, as shown in Table 1. It may include, but not limited to, the use of control charts, certified reference materials, replicate testing or retesting of retained items and frequent participation in intra- and interlaboratory programs. These are especially important in case of the presence of temporary staff.

Step 8: fix and track the indicators

In a QMS, indicators constitute a fundamental tool in the assessment of the degree of attainment of the proposed objectives, and their proper definition will lead to a more realistic formulation of the objectives [26].

In this step, indicators related to each process linked to the respective objectives of the QMS should be established. The format presented in Table 2 facilitates the establishment and monitoring of targets and the implementation of corresponding actions in the case of noncompliance. It also allows visualization and understanding by everyone as well as ensuring the optimization of resource allocation. For example, monitoring the number of tests and the income for each type of test enables the allocation of resources for higher-demand tests or even the discontinuation of a test that does not show enough demand to justify its cost. The monitoring of the global revenue could be used to evaluate the self-sustainability, especially when the laboratory is responsible for generating its own funds for its activities.

Step 9: assess the QMS

The first formal internal audit covering all the QMS elements should be conducted by trained and qualified personnel, preferably with previous experience in audits according to ISO/IEC 17025 and technical knowledge regarding the scope of the laboratory. Checklists, internal questionnaires or even the standard itself could be used. If the laboratory staff is inexperienced in auditing, the hiring of external auditors is suggested. It may be convenient to operate the laboratory under the QMS for some time before such assessment.

Furthermore, the first review of QMS with respect to ISO/IEC 17025 must be conducted by the top management "to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements" [10]. Anastasakis and Theodorou [34] present a checklist for use in this process. The findings of the review and the actions that arise should be fully communicated to and understood by all staff.

The internal audit results and the management review findings will point out the necessary corrections and adjustments, allowing the process of handling nonconformities. This process gets completed after evaluation of the proposed actions' effectiveness to prevent the recurrence of nonconformities.

Step 10: apply for accreditation

The laboratory should demonstrate its technical competence to perform the tests of the intended scope, providing reliable and accurate test results, and its compliance with all the requirements of ISO/IEC 17025 to conquer accreditation. Thus, there is always a gap between the full implementation of the QMS and the request for accreditation. This time may be necessary for the staff to get used to working under the QMS and to generate objective evidence of the relevance and effectiveness of the QMS. For example, records of interlaboratory programs and results of internal audits and of customer satisfaction surveys will be gathered during this period. This may take about 1 year [11, 19, 20] or even more.

According to ISO/IEC 17025, the acceptance of test results internationally could be facilitated if the accreditation body has established mutual recognition agreements with equivalent bodies in other countries. The National Institute of Metrology, Standardization and Industrial Quality (INMETRO) is the internationally recognized body responsible for laboratory accreditation in Brazil, besides other third-party regional agencies that recognize the technical competence of laboratories through assessment and verification of compliance with the requirements of ISO/IEC 17025. The advantage of these third-party agencies is its low cost and its proximity to several laboratories, but the recognition conferred by them is accepted only within the country, unlike the accreditation by INMETRO that is accepted internationally. For specific reasons and due to the demand from its customers, the two laboratories

Table 2 Examples of indicators linked to the objectives and processes of the QMS

Objective of the QMS	Macro process	Process	Indicator
Meet customer needs by ensuring the quality of services with reliability	Product realization	Review of requests, tenders and contracts	Percentage compliance with the requirements agreed with the customer (price, deadline, method)
	Effectiveness of QMS and its improvement	Customer service	Degree of customer satisfaction through surveys
	Effectiveness of QMS and its improvement	Complaints	Number of customer complaints
	Quality assurance of tests	Intercomparisons	Number of participations in interlaboratory comparisons or proficiency-testing programs and laboratory performance
Assure human and technical improvement of the staff	Resource management	Personnel	Hours of internal and external training
	Quality assurance of tests	Intercomparisons	Percentage of satisfactory results in intra- and interlaboratory comparisons
Assure adherence of the QMS to ISO/IEC 17025	Effectiveness of QMS and its improvement	Audits	Number of audits, number of nonconformities
	Effectiveness of QMS and its improvement	Nonconformities, corrective and preventive actions	Number of recurrent nonconformities, number of preventive actions
Assure the sustainability of the laboratory	Product realization	Review of requests, tenders and contracts	Number of new customers, laboratory income, number of tests per client, income per type of test
	Effectiveness of QMS and its improvement	Customer service	Percentage of customers who recommend the laboratory to others in the customer satisfaction survey

at UFRGS opted to first seek recognition by a third-party regional agency located in the south of Brazil (Metrological Network of Rio Grande do Sul).

Once the required documents for accreditation are filed with the accreditation body, it then schedules an assessment. The laboratory must provide all information, documents and records requested, as well as comply with the rules and regulations of the accreditation body. As in the internal audit, actions should be proposed to solve any identified nonconformities.

The work does not end with the accreditation of the laboratory. The laboratory shall periodically conduct internal audits and shall be subject to regular assessments by the accreditation body to ensure compliance with the ISO/IEC 17025 requirements. As required by the ISO/IEC 17025 standard, the laboratory shall also continually improve the effectiveness of its QMS. The maintenance of accreditation can be as difficult and challenging as obtaining it, especially in teaching and research institutions. The QMS should be self-sustaining and add value to the laboratory or institution. The costs of QMS maintenance at the two UFRGS laboratories have been supported in the last 4 years with funds obtained by increasing the billing amount and with government funds.

Conclusions

The aim of this article was to propose some general steps for implementing a QMS according to ISO/IEC 17025, in order to prepare laboratories for accreditation.

First, a literature review was conducted to identify proposals for systematizing QMS deployments and the use of process approach. Based on the findings and on researchers' experience with the implementation of a QMS in two testing laboratories at UFRGS, some suggestions in the ten-step format to meet the requirements of ISO/IEC 17025 are presented in this paper. The steps are relatively flexible to accommodate the differences between various institutions, laboratories and staffs. The first four steps—(1) predetermine tests and personnel covered by the QMS; (2) check current situation; (3) calculate costs for the QMS implementation; (4) draw schedule and fix responsibilities—are critical to the job's success. In some of the steps, solutions to overcome typical problems encountered in laboratories of teaching and research institutions are also suggested.

The process approach, along with the proposed suggestions, eases the adaptations needed for compliance to the ISO/IEC 17025 standard requirements, mainly in the laboratories of teaching and research institutions. It also

possesses the following advantages: (1) highlights the client focus; (2) favors the overview of all activities and their interrelationships; (3) contributes to fixing responsibilities; (4) allows process optimization and elimination of unnecessary activities; and (5) generates elements needed for evaluating and obtaining continuous improvement of the QMS.

The authors believe that these suggested steps should help test laboratories, especially those located at teaching and research institutions, to pursue accreditation according to the ISO/IEC 17025.

However, with all associated equipment and appropriate test procedures, it should be borne in mind that the key factor for the success of implementing a QMS, and the achievement and maintenance of accreditation, is the commitment of each individual involved.

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