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AN AUDIT APPROACH TO ASSESS AND IMPROVE THE QUALITY MANAGEMENT SYSTEMS OF ENVIRONMENTAL LABORATORIES

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Abstract

Environmental laboratories could use a quality management system (QMS) to organize their management activities in order to promote the standardization and reliability of the results generated. This research aimed to construct and apply a diagnostic model to identify the implementation of the best quality management practices based on the ISO 17025 standard in an environmental laboratory at the State University of Maringá, Brazil. The implementation of management practices was conducted over a period of ten months and two internal audits were performed using the developed model. The results of this study showed that the laboratory initially had 22.7% of compliance with the standard requirements and, after the corrective actions implemented, the system achieved 76.0% of compliance. Therefore, the practices adopted were important to solve problems encountered and to elaborate proposals for improvement actions for the consolidation of a QMS. The development of this work emphasizes the importance of organizational culture and employee training for the evolution of the QMS.

Keywords: environmental analysis, good laboratory practices, ISO 17025, test laboratory

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1. Introduction

In recent years, with the constant change in the world economy, the idea of management has passed by significant changes. Companies are increasingly competitive and globalized. Competitiveness a few years ago was just a factor of differentiation: today it is a survival factor. Therefore, there is no longer the idea of managing with focus on departments and sector efficiencies, but managing with focus on processes, material flows and information, aiming at the interests of all stakeholders, as well as promoting the preservation of natural resources (Stevens et al., 2012; Wastowski, 2011).

According to Poltronieri et al. (2018), Yamada et al. (2013) and Zhu et al. (2013), a quality management system (QMS) seeks the continuous improvement of organizations through a structure that manages specific issues, coordinating their different interrelated areas to achieve a specific goal. In this way, it is necessary to adopt actions that bring consistent responses to the management processes, as well as to build an efficient management of available resources and inputs. In addition, it should also enable the minimization of waste generated by operational processes. Unlike any other type of organization, the environmental laboratories also search for to consolidate their management systems.

Environmental laboratories play an important role in society since their activities are directly linked to the public health. The issuance of a result or report depends on the level of scientific knowledge and

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implies sanitary responsibility. Whatever the result or report, it will always be the expression of the health conditions of an individual and of the community itself. Since the lack of quality management implemented and consolidated in laboratories, there are the issuance of analyses with uncertainties and dubious results (Vital et al., 2009).

To aid the QMS implementation process, maturity models have become an essential tool for assessing organizations current capabilities and helping them implement changes and improvements in a structured manner (Jia et al., 2011). These models enable organizations to be evaluated against best management practices adopted, including the formulation of organizational strategies and policies, as well as the operational management and organizational capabilities of human resources and the organization. They also propose specific roadmaps through evolutionary scales for capacity improvement, i.e. guidelines on where an organization's resources should be allocated to improve its ability to perform its activities. However, the models must be accompanied by methodologies that standardize their applications, so that their measurements and evaluations are rigorous and replicable, and the models must also be accompanied by validation methodologies, representing assertiveness in meeting their objectives (Valdés et al., 2011). Khoshgoftar and Osman (2009) stated that maturity models help identify strengths and weaknesses from a specific point of view, helping to improve organizational performance. This view may be related to quality, product development, or any other functional area that you wish to improve. At higher maturity levels, companies are expected to be better managed, and therefore any activity they conduct will be less risky and more likely to deliver a quality product that meets budget and schedule. For this to happen, an assessment of the current status of the organization is needed to identify improvement goals. Although, there are problems for the development, implementation and maintenance of management systems, ranging from the low involvement of the management of organizations to difficulties in interpreting written procedures, especially those related to human resources (Neves et al., 2017; Oliveira and Pinheiro, 2009). In addition, there are difficulties to find tools (or guides) that assist in the diagnosis, implementation and/or maintenance of a QMS.

Therefore, this paper presents the development of a management system diagnostic model based on ISO 17025 standard for laboratories in the environmental area, with the purpose of being used as a facilitator of the internal audit process. Furthermore, the development of this diagnostic model represents the initial steps for the construction of a management system maturity model specific to environmental laboratories, since the determination of the maturity level is performed using assessment methods. Through the proposed diagnostic model, it is possible to evaluate the progress of the QMS and indicate improvement actions based on the requirements of ISO 17025.

2. Literature review

2.1. Quality management systems (QMS)

Organizations face intense pressure to continually stand out and improve their performance, which has led to the emergence of quality management. The concept of quality and its applications has been changing throughout the social and financial market evolution, through the improvement of production processes and its relationship with its stakeholders, also providing strategic benefits and showing a strong correlation between quality and productivity (Mokhtar et al., 2013; Movahedi et al., 2013).

According to the authors Gerolamo et al. (2014), a management system comprises a set of variables, such as resources and processes, which is used to achieve a specific objective. The latter can be tangible, intangible, or even a combination of both, in the form of a product or service. In addition, the authors Robles Junior and Bonelli (2016) reiterate that a management system provides guidelines for developing, implementing, achieving, critically analysing, as well as maintaining policy for a given dimension of interest (e.g. quality, environment, occupational safety and health, among others) through the development of the organizational structure, planning activities, responsibilities, practices, methods and criteria, processes and resources available in the organization.

Thus, the QMS aims to create management activities that permeate all organizational sectors, aiming not only to avoid the occurrence of cases of non-compliance with customer requirements, but also waste in production processes. When permeating all activities involved in product development or service delivery, great planning effort and review of progress is required. Therefore, the implementation of a QMS is only completed by establishing a virtuous cycle of measurement, analysis of results and development of improvement action plans (Gambi et al., 2015).

Quality audits help organizations and those requesting them to monitor and ensure that a QMS is up and running effectively. For some organizations, quality audits are a mandatory activity that needs to be performed to meet the requirements of their customers, suppliers, partners, employees or industry and even to comply with government regulations. With this audit process, products or services are expected to meet or exceed established quality standards. That is, a good quality management system will not work without proper audits and analysis (Garza-Reyes, 2018).

2.2. ISO 17025

In order to assist in the management implementation process, there are standards and

regulations that normalize and optimize methods and processes, thus promoting an efficient management system, such as ISO 17025 (ISO 17025, 2017). The standard describes test and calibration procedures applicable to laboratories carrying out all types of tests and/or calibrations. Environmental laboratories, for conducting analyses on samples of water, effluent and other components of the environment, fit as test laboratories. The standard can be used to regulate a management system and technical and administrative operations, since it has the necessary requirements for laboratories to produce technically valid results. Laboratories can use the standard for a variety of purposes, either to serve as a benchmark in building a work system, to reach the scope of the standard completely, or to be recognized or accredited by third party bodies (ISO 17025, 2017; Sadikoglu and Temur, 2012). The ISO 17025 establishes the criteria for laboratories that wish to demonstrate their technical competence have an effective quality system and are able to produce technically valid results. The most recent revision of the standard encompasses technical changes in the incorporation of electronic information management and risk management (Tranchard, 2017).

An organization whose services are accredited according to ISO 17025 demonstrates the formal recognition of its technical competence. This recognition enables organizations to add value to their activities and help customers identify companies that offer confidence in their services (ISO 17025, 2017). In addition, another benefit of ISO 17025 is to promote cooperation between laboratories and other organizations by collaborating in the exchange of information and experience and in the harmonization and standardization of procedures and standards. Accreditation of a laboratory further enhances the organization's performance through better control of laboratory processes, enhancing its potential and increasing the reliability of its activities (Barradas and Sampaio, 2017).

2.3. Maturity models

In general, maturity means that something is fully developed or perfected. To explain this, templates were created that indicate the resources (specific competency that must exist in an organization to perform project management processes and provide project and product management services) of an organization.

These features are presented in a grouped manner and generally describe the degree of consistency, visibility, and control within the organization. Models move from a low level, also known as “ad hoc” or “reactive,” to a high level, where feedback and continuous improvement processes are incorporated. Continuous improvement is often achieved by creating review or auditing processes use on the day to day processes to evaluate their effectiveness, identify improvements, and implement them. Maturity models help the company see where it is and how long it will take to achieve best practice (Domingues et al., 2014; Domingues et al., 2016; Moumen and Elaoufir, 2018; Tahri and Drissi-Kaitouni, 2015).

According to Kluth et al. (2014), maturity models can be used to analyse and evaluate skills and levels of product or process development across different maturity levels. The authors further state that these models include not only methods for assessing levels, but also provide incentives and measures to increase the stage at which an organization or process is. Models can be classified in several ways; however, a common way is the classification proposed by Domingues et al. (2015), which classifies the models according to the field of application.

Accordingly, models can be classified as minimum requirements, when comparing the stage of the organization studied and its capabilities at a given moment with certain pre-established criteria; design requirements by descriptive models, classification used to identify certain desirable levels of maturity and provide information on possible improvement actions; and design requirements by prescriptive models, which enable internal or external comparisons.

Crosby’s Quality Management Maturity Grid is considered the first known maturity model. The Capability Maturity Model (CMM) is a maturity model developed by the Carnegie Mellon University Institute of Software Engineering (SEI), which served as the basis for the preparation of several other models. One of the most popular CMM models is Capability Maturity Model Integration (CMMI). There is also a maturity model for assessing Quality Management Systems, which was introduced in ISO 9004 (Poltronieri et al., 2019).

In addition, the authors Kluth et al. (2014) reiterate that maturity models can be used for different purposes. Maturity models may be limited to a competency measurement or may be part of a skill analysis. In addition, they may provide information on the causes of maturity deficits or may propose instructions for solutions to improve maturity. Different existing maturity models have been established in different fields of application as maturity models in the fields of project and process management, models based on quality management and tools from the field of development, maturity analysis models to check status of business processes, among others.

3. Case study

3.1. Research features

Can a diagnostic model be used as a tool to facilitate the adoption of standard ISO 17025 by the collaborators at environmental laboratories? This research goals to answer part of this question by having the opportunity to apply in a laboratory, however this could be an interest topic to be applied by the scientific community to run to another laboratory.

3.2. Research development

The application of the proposed diagnosis model was carried out in an environmental laboratory (Fig. 1) at State University of Maringá, Brazil. This laboratory performs academic research and analysis to customers in the following areas: physicochemical and bacteriological analyses of drinking water samples and physicochemical analyses of domestic and industrial wastewater samples.

The implementation of a plan of action to mitigate the possible problems and to adapt the system of quality management is conditioned to the correct obtaining of information on the current state of the laboratory system and detection of the possible critical points of improvement.

The new diagnostic model consists of a robust checklist, built based on the requirements of ISO 17025, to be used as a facilitator for the internal audit process. Each requirement of the standard comprises an item to be checked in the laboratory. The verification was performed on-site and in all sectors of the laboratory. It was sought to identify evidence (i.e. scripts, documents, procedures, records, posters, operational routine, and others) that represented the achievement and/or implementation of the item. The strategy used for the verification was to make observations in each sector of the laboratory evaluating the conformities and nonconformities in relation to the requirements of the standard. Nonconformity is understood to be items that are not met as per the norm. The evaluated requirements were assigned scores on a scale from 0 (zero) to 5 (five), according to the evidences found on the state of the management system according to the norm. The scale was constructed in order to cover all the possible steps of implementation of the items of the standard, through an adaptation in the methodology proposed by the authors Putri et al. (2019). This scale is also present in the works of García et al. (2014). The values follow the classification presented in Table 1.

For each item with a score lower than 5 (five) corrective actions were proposed and the execution time was established. The diagnostic model was designed with the intention of being easy to use and was applied in July 2018 and May 2019 with the aim of showing the improvements of the system through the adoption of best practices of quality management. After the second diagnosis, future improvement actions were proposed. An item is documented when you find a procedure, a record, a method, a manual, or another form of writing that determines how that item should be performed, understood, and/or verified. The dissemination concerns the accomplishment of the item by the employees, trainees and others involved in the activities of the laboratory through tacit knowledge. Dissemination represents the way the laboratory conducts activities, which is directly related to the organization's culture. The perception of the organizational culture in the laboratory was also an important tool in the concept of quality management. This analysis is of a subjective and qualitative nature, but fundamental for the evaluation of possible difficulties to execute the proposed objective. To illustrate the development of this case study, Fig. 2 shows the steps performed.

4. Results and discussion

In order to compose the diagnosis of the initial management system of the laboratory, the items of the standard ISO 17025 were inspected, and each score received the necessary measures for correction, in accordance with the current normative requirements.

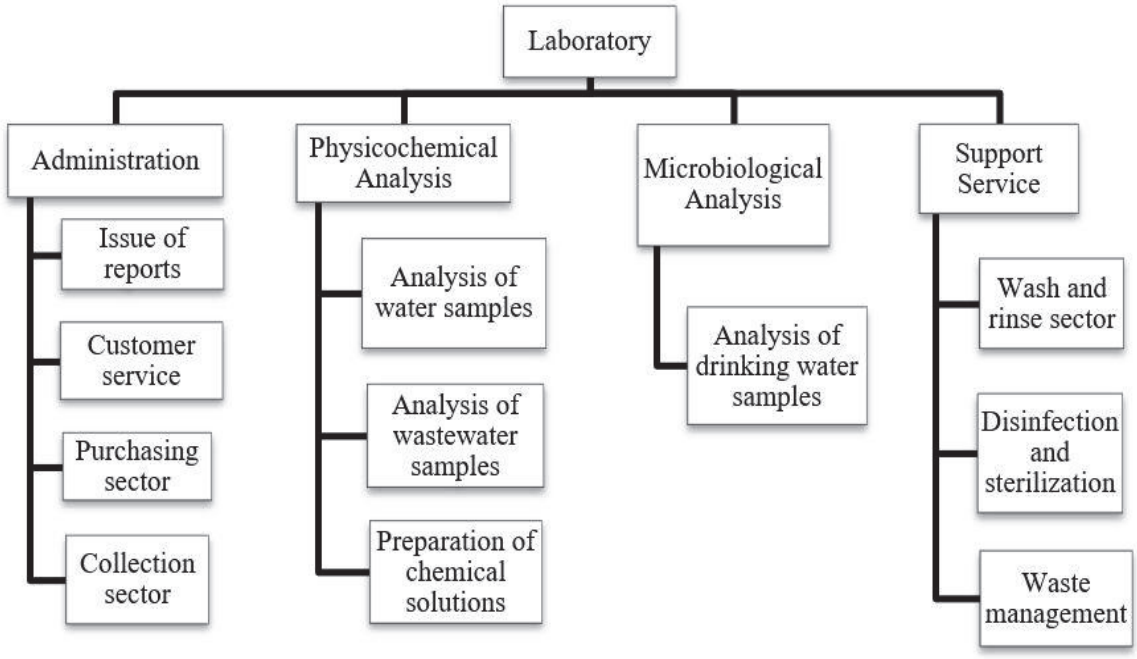

Fig. 1. Functional organization chart of the laboratory

Table 1. Scale of implementation of standard requirements

Score	*Classification*
0	There is no evidence of implementation of the requirement
1	It is not documented and is not disseminated in the areas of interest
2	It is not documented, but is disseminated by the areas of interest
3	It is documented, but it is not disseminated by the areas of interest
4	It is documented, but it is little disseminated by the areas of interest
5	It is implemented, documented and disseminated by the areas of interest

Fig. 2. Stages of research development

Table 2 presents the items of the standard, the score assigned to each item, the actions were taken to mitigate the problems and the time of implementation of these actions. In addition to the main requirements of the standard, there are some sub-items that have been considered due to their importance to the understanding and evaluation of the management system.

The mitigating actions originated documents, standard operating procedures (SOPs), which have a detailed step-by-step description for the execution of tasks, records and other controls that have been incorporated into the routine of the laboratory; in Table 2 the main actions are listed.

After the 10-month period, the same diagnosis was applied in the same laboratory through the internal audit process and the scores were awarded, as well as the proposed improvement actions can be visualized in Table 3. For the items that received scores lower than five, future improvement actions have been proposed for the implementation of nonconforming or missing items in accordance with ISO 17025. The other items in which score five were attributed did not propose improvement actions.

Table 2. Initial diagnosis and corrective actions

Item of the standard	*Score*	*Corrective improvement action*	*Deployment time*
4. General Requirements			
4.1 Impartiality	2	Creation of a confidentiality and impartiality term; creation of a record of recognition of signatures and headings; updated list of employees	Seven days
4.2 Confidentiality	2		
5. Structure Requirements			
5.1 to 5.4 Responsibilities	2	Elaboration of the Quality Manual	Ten months
5.5 to 5. 7 Organizational structure	2	Definition of the organization chart of the laboratory; definition of the matrix of responsibilities in relation to the management system; elaboration of the Quality Manual	
6. Resource Requirements			
6.1 Generality	5	Not applicable	Not applicable
6.2 Staff	1	Conducting internal training on management system	Five trainings were carried out in the studied period of four hours each
6.3 Facilities and environmental conditions	1	Preparation of the Biosafety Manual; acquisition of air conditioning and temperature monitoring through SOP for temperature and humidity control of the environments; creation of SOPs for laboratory cleaning	Three months
6.4 Equipment's	1	Elaboration of calibration control and maintenance of equipment; insertion of calibration curves in equipment; creation of SOP for critical analysis of calibration certificate; creation of SOP for equipment use control and SOP for temperature control of equipment's	One month for the creation of controls and procedures and seven months for the insertion of calibration curves.
6.5 Metrological traceability	1	Creation of SOPs for traceability and use of reagent standards; creation of SOPs for quality control of culture medium	Eight months for the acquisition of all the standards
6.6 Products and services provided externally	1	Creation of the SOP for procurement of services and supplies, SOP for qualification of suppliers, SOP for receiving materials; implementation of purchase order forms and calibrations	Two months

7. Process Requirements			
7.1 Critical analysis of requests, proposals and contracts	0	Elaboration of procedures for analysis of customer requests	One month
7.2 Selecting, checking methods	2	Elaboration of the SOPs of each analytical method; creation of the SOP for Proficiency Testing Program	Five months
7.2.2 Validation of methods	0	Elaboration of the Manual of Validation of Analytical Methods	Two months
7.3 Sampling	-	Not part of the scope of the laboratory studied	
7.4 Handling of test items	1	Definition of time to discard samples; definition of storage location of samples	Ten days
7.5 Technical Records	5	Not applicable	Not applicable
7.6 Measurement uncertainty assessment	0	Elaboration of procedure for critical analysis and control of uncertainties resulting from measurements	In progress
7.7 Guarantee of the validity of the results	2	Use of reference materials; creation of letter-process control	Ten months
7.8 Results Report	4	Adequacy of information on the methods used in the reports issued	Five days
7.8.3 Specific requirements for test reports	0	Study of measurement uncertainties	In progress
7.9 Complaints	0	Elaboration of procedure for customer service	Two months
7.10 Nonconforming work	0	Elaboration of procedures for analysis and treatment of nonconformities	Three months
7.11 Data and information management	1	Elaboration of procedures for data control; Elaboration of the Quality Manual	Ten months
8. Management System Requirements			
8.2 Management System Documentation	0	Elaboration of the Quality Manual; Creation of SOP for Control of Documented Information	Ten months
8.3 Documents control	0		
8.4 Records control	0		
8.5 Actions to address risks and opportunities	0	Study on risks and opportunities in laboratories	Ten months
8.6 Improvement	0	Preparation of a continuous improvement plan for operational procedures and processes	Ten months
8.7 Corrective actions	0	Elaboration of procedure for corrective actions	Two months
8.8 Internal audits	0	Elaboration of SOP for Audit Plan, SOP for Internal Audit Selection, Internal Audit Program, Internal Audit Report	Two months
8.9 Traveler rating	1	Elaboration of the action plan for the critical analyses and documentation of the analyses carried out	Four months

Table 3. Diagnosis and proposed actions for future improvements

Item of the standard	*Score*	*Proposed improvement action*
4. General requirements		
4.1 Impartiality	5	Not applicable
4.2 Confidentiality	5	Not applicable
5. Structure Requirements		
5.1 to 5.4 Responsibilities	5	Not applicable
5.5 to 5.7 Organizational structure	5	Not applicable
6. Resource Requirements		
6.1 Generality	5	Not applicable
6.2 Staff	4	Implementation of training plan
6.3 Facilities and environmental conditions	4	Deployment of cleaning plan of laboratory environments
6.4 Equipment	4	Implantation of preventive maintenance plan
6.5 Metrological traceability	5	Not applicable
6.6 Products and services provided externally	4	Implementation of procedure for Qualification of Suppliers
7. Process Requirements		
7.1 Critical analysis of requests, proposals and contracts	3	Implementation of procedures for analysis of customer requests
7.2 Selecting, checking methods	5	Not applicable
7.2.2 Validation of methods	4	Adequacy of plan for validation of analytical methods
7.3 Sampling	-	Not part of the scope of the laboratory studied
7.4 Handling of test items	4	Adequacy of storage conditions and sample disposal
7.5 Technical records	5	Not applicable

7.6 Measurement uncertainty assessment	1	Implementation of procedure for critical analysis and control of uncertainties resulting from measurements
7.7 Guarantee of the validity of the results	5	Not applicable
7.8 Results report	5	Not applicable
7.8.3 Specific requirements for test reports	1	Adequacy of the test report with the inclusion of measurement uncertainties
7.9 Complaints	3	Implementation of procedure for customer service
7.10 Nonconforming work	3	Implementation of procedures for analysis and treatment of nonconformities
7.11 Data and information management	4	Backup of data stored in computers and implementation of data control procedures
8. Management System Requirements		
8.2 Management system documentation	5	Not applicable
8.3 Documents control	5	Not applicable
8.4 Records control	5	Not applicable
8.5 Actions to address risks and opportunities	0	Formulation and implementation of risk and opportunity planning and management
8.6 Improvement	0	Implantation of a continuous improvement plan for operational procedures and processes
8.7 Corrective actions	3	Implementation of a procedure for corrective actions arising from critical analysis of procedures and processes
8.8 Internal audits	3	Conduct internal audit based on established plan
8.9 Traveler rating	4	Implementation of an action plan for the critical analysis and documentation of the analyzes carried out

Table 4. Percentage of compliance with the standard ISO 17025

Standard requirements	***Sum of scores***	***Initial score***	***Percentage of initial fulfillment***	***Score after corrective actions***	***Percentage of fulfillment after corrective actions***
General Requirements	10	4	4.0	10	100
Structure Requirements	10	4	4.0	10	100
Resource Requirements	30	10	33.3	26	86.7
Process Requirements	60	15	25.0	43	71.7
Management System Requirements	40	1	2.5	25	62.5
Total	**150**	**34**	**22.7**	**114**	**76.0**

Given the results obtained by applying the diagnostic model, it was possible to measure the degree of implementation of the standard in the laboratory studied. For this, the sum of the points that an item could have were calculated, besides the sum of the scores of each item and thus, the percentages of attendance of the standard. The values obtained can be visualized in Table 4.

In view of the percentages obtained, it was possible to notice that the implementation of best quality management practices related to laboratory processes promoted a significant increase in the degree of compliance with the requirements of ISO 17025. On the study period, the laboratory initially had 22.7% of meeting the requirements of the standard and, after the corrective actions implemented, the system reached 76.0% of attendance. This result shows that the QMS of the laboratory studied partially complies with the standard and it is therefore necessary to draw up a plan of action to fully meet the requirements.

Among all audited items, the item "Management System Requirements" has the lowest percentage of attendance, i.e., there are fewer evidence of implementation in the laboratory. Belonging to this same requirement, two stand out, which received the score 0 (zero): the item "Actions to approach risks and opportunities" and "Improvement". The first refers to the risks and opportunities associated with laboratory activities in order to ensure that the management system achieves its objectives and to prevent or reduce undesirable impacts and possible failures in laboratory activities. The second item refers to the identification and selection of opportunities for improvement of the management system, which come from critical analyses of audits and operational procedures, from customer suggestions and criticisms, from analysis of the results of proficiency tests, risk assessment, and others. When they received 0 (zero), this implies that no action was taken to implement these items. Therefore, the next step in the consolidation of the laboratory management system is the development of a strategic plan that addresses these two issues, in order to promote the cycle of continuous improvement of the QMS.

Regarding human resources management, which is one of the key success factors of the management system implementation strategies in any organization (Cunha et al., 2011; Neves et al., 2017; Outaki and Kerak, 2018; Salgueiro, 2012), the results showed that there is a difficulty to mobilize them for the benefit of the laboratory's objectives, since several items are documented, but are not disseminated or are partially disseminated in the areas of interest. There

are several factors that may contribute to the lack of practical application of the requirements of the standard. One is the detachment of top management from the operational processes required for implementation. And this fact occurs because one of the characteristics of the laboratory coordinators of Brazilian universities is, that in most cases, they perform other functions within the university; they are teachers, course coordinators, department heads, council members, and therefore, the hours of dealing with laboratory problems are smaller when compared, for example, in laboratories of private institutions. Other known factors are varied and diffuse technical functions and responsibilities, low level of employee knowledge about concepts and tools related to quality management, lack of financial and material resources, and others.

But as a way of reversing this scenario and also to improve the skills of the employees, it is recommended a training schedule, which should be performed with all laboratory team (e.g. trainees, technicians and the top managers) and should include management requirements based on the standard and which are related to the sector of action of each employee. These actions can increase the level of implementation of best quality management practices in the research laboratory.

5. Conclusions

The implementation of the requirements of ISO 17025 allows better management of the operational processes of environmental laboratories in general. In addition, the effective implementation of these requirements, together with the constant monitoring and improvement of the management system, encourages the competitiveness of the laboratory, satisfies the needs of the customers and enables an increase in the quality of the services provided.

The construction of the diagnostic model assisted the internal audit process and enable transferring the ISO 17025 concepts in an easier way for the collaboration team which resulted in positive change at working environment. Besides, when applying the diagnostic model developed in the studied laboratory, it was possible to observe that the organizational culture has an important role in the implementation of items of the standard, since without the awareness and involvement of all employees, the implantation of the norm completely becomes unfeasible. Then, in addition to a plan of action for the implementation of the missing items of the standard, it is also necessary to develop a training plan focusing on the importance of the QMS. So, for future work it is recommended the development of a training program on quality management for environmental laboratories. Training should be conducted with all laboratory employee, including top management, and should address the standard-based quality management requirements that are related to each employee's work sector. Training can be conducted both internally and externally by trained personnel, addressing both quality tools such as the Ishikawa Diagram and the PDCA cycle, as well as standard-specific issues such as validation of analytical methods, handling of test items and calibration, among others. These actions can increase the level of implementation of good quality management practices in the research laboratory. The caveat is that top management plays a key role in encouraging and assisting in the process of implementing a QMS.

It is believed that, with the evaluation model for internal audits presented in this research, it is possible to quantify the level of QMS implementation based on ISO 17025, as well as to identify nonconformities, and consequently, opportunities for improvement.

However, a limitation of this work is that this diagnosis only reports the percentage of the degree of implementation of the items in general, based on observations made in each sector of the laboratory. It is necessary to deepen each item for a better evaluation, since the best implementation actions depend on the characteristics of the laboratories.

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