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GENERAL PAPER

System proposal for implementation of risk management in the context of ISO/IEC 17025

Fabiane Rodrigues da Silva[1] · **Inês Hexsel Grochau**[1,2] · **Hugo Marcelo Veit**[1]

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Abstract

Many higher education institutions in the world have testing laboratories linked, or not, to their teaching and/or research programs. However, only a small proportion of these laboratories have accreditation in accordance with the ISO/IEC 17025 standard. The ISO/IEC 17025 establishes the management and technical requirements necessary for the implementation and maintenance of a quality management system (QMS) in laboratories that perform testing, calibration and/or sampling activities, being used by them to demonstrate their competence in carrying out their activities. One of the requirements of the current version of the standard is the need to carry out risk management (RM), introduced with the demand for risk-based thinking. The objective of this research was to propose a system for the implementation of RM in laboratories, through mapping, identification, classification, critical analysis, and treatment of risks. The research considered the history of actions taken, the risks verified by the laboratory team, the evaluation of their impacts and the probabilities of their occurrence, their classification and the identification of actions necessary to accept, mitigate or eliminate these risks. The system proposed was applied in a testing laboratory at a university in southern Brazil, enabling the maintenance of its accreditation.

Keywords Risk management · Testing laboratory · ISO/IEC 17025 · ISO 31000 · Higher education institutions

Introduction

Universities have always played a fundamental role in the technological context of countries, especially those in development, such as Brazil. Although they are basically teaching and research institutions focused on the qualification of human resources and the production of knowledge, universities also respond to society's demands, interacting with other institutions and companies [1]. To meet these demands, several laboratories of Higher Education Institutions (HEIs) have quality management system (QMS) implemented and accredited in accordance with the ISO/IEC 17025 standard [2]. Accreditation has a positive impact on teaching and research activities, evidenced by the increase in the reliability of results and the qualification of personnel [3]. In addition, it was observed that HEI laboratories may be meeting demands not met by commercial laboratories [4] and that the number of accredited laboratories has a positive correlation with the country's GDP [4–6], directly influencing the socioeconomic conditions of the countries.

The ISO/IEC 17025 standard establishes the necessary requirements for the operation of a QMS in laboratories that perform testing, calibration and/or sampling activities. Their management system requirements, based on ISO 9001 [7], are complemented with specific technical requirements. Thus, for a laboratory to have ISO/IEC 17025 accreditation, it must have an established management system, be able to generate technically valid results, have been evaluated by an accrediting body and have been considered technically competent.

Likewise ISO 9001, ISO/IEC 17025 has been revised over time. The current version, launched in 2017, incorporated the risk-based thinking included in the 2015 version of ISO 9001 [8, 9], resulting in the need to carry out risk management (RM). The RM includes support strategies, methods and tools to identify and control risk at an acceptable level. Its main objective is to recognise all possible risks within a project, company or associated with a process. To be effective, it is necessary that the RM is considered as an

✉ Fabiane Rodrigues da Silva
fabianerviana@gmail.com

[1] PPGE3M, Federal University of Rio Grande Do Sul, Porto Alegre, RS, Brazil

[2] PPGEP, Federal University of Rio Grande Do Sul, Porto Alegre, RS, Brazil

integral part of the QMS [10]. Regardless of the objective, through the identification and techniques for risk management it is possible to implement internal controls more effectively, aiming to accept, mitigate or eliminate the main risks, identify opportunities for improvements and add value to a project [11]. In a survey conducted with 222 companies in Portugal, Romania, Switzerland, and Turkey, despite being considered the best benefit obtained, the adoption of risk-based thinking was identified as the greatest difficulty to be overcome during the ISO 9001 certification process [12].

RM has been successfully carried out for a long time by private companies in different scenarios, in the analysis of threats and possible vulnerabilities. In the public area, the need to establish adequate and implemented risk management structures, processes and culture corroborates the achievement of good performance in an organisation. However, since the publication of the new version of the ISO 9001 standard, few studies have addressed aspects related to its implementation. Research found refer mainly to risks to the environment, occupational and financial health, and does not contribute to the implementation of RM in HEI testing laboratories. Peculiar factors of these environments as lack of financial resources, staff turnover and simultaneous involvement in testing, teaching and research activities [1, 3, 13], can contribute to the failure to achieve the objectives, adding to the difficulties that the HEI laboratories already encounter in the implementation of a QMS, and in the incorporation of the RM to the ISO/IEC 17025:2017 standard. The only work found in HEI was a survey conducted in 2011 by Sedrez and Fernandes [14], indicating that 69.2 % of HEIs in the State of Santa Catarina (Southern Brazil) did not adopt any RM system, although several managers had expressed concern about the subject. The risks considered most important in the strategic, financial, legal, operational, and image categories were identified, by the authors, through questionnaires sent to HEIs. However, HEI testing laboratories were not considered.

According to Wen et al. [15], it is worth mentioning that the focus of research in the field of quality management has gradually shifted to the "quality culture," with a significant increase in research on quality and innovation, risk management, management supply chain and sustainability. However, in preparing this manuscript, the authors detected a gap in scientific work in the area, which is still perceived today in relation to public institutions in general [16] and to HEIs specifically. That is, of the 45 bibliographic references used, only one article and the ISO/IEC 17025 standard address the peculiarities involved in the RM of testing and calibration laboratories. None of the others addressed specific risks related to HEI laboratories, only financial risks, lack of maintenance and motivation, bureaucracy, information security and society/university/market relationships. In this context, a research gap is observed mainly in relation to the RM both for the implementation of ISO 9001 [17] and for ISO/IEC 17025. The novelty and purpose of this article is to fill this gap in the literature and propose a systematic approach to RM in an HEI testing laboratory, through the identification, classification and treatment of risks, adapting its QMS to the new requirement of ISO/IEC 17025:2017, in the quest to maintain its accreditation.

Methodology

This research was carried out during the period of adaptation to the new version of the ISO/IEC 17025 standard, in a testing laboratory linked to the Materials Engineering Department at Federal University of Rio Grande do Sul (UFRGS), Brazil. This laboratory was recognised for its competence in meeting ISO/IEC 17025 by a regional body in 2007, 5 years after the start of the implementation of its QMS [1], and has been accredited since 2016 by the National Institute of Metrology, Standardisation and Industrial Quality (INMETRO), the body responsible for laboratory accreditation in Brazil.

Bibliographic survey and identification of stages and RM tools

The accomplishment of this work included research in scientific articles, magazines, and academic works, as well as with experts involved in the activities of the testing laboratory, and the identification of standards and technical reports related to the requirements introduced in the new version of the ISO/IEC 17025 standard, regarding the RM issue. For the identification of stages and tools for risk analysis and their specificities, the ISO 31000 family of standards [18, 19] was fundamental, this being the ISO/IEC 31010 [20] standard most used for the choice of applied tools.

Proposed system for RM

Based on the bibliographic survey, the identification of the stages of RM and the main tools to be used, a process flowchart was elaborated to represent the proposal of the system for the RM, providing for the identification of the need for treatment of each risk, as well as additional actions and activities related to each stage.

Application of the RM system

The flowchart proposed in the previous step was applied, using the brainstorming technique, the concept of semi-structured interviews and a multidisciplinary team formed by professionals working in the laboratory (Table 1), all with knowledge of ISO/IEC 17025:2017 and active in the QMS.

Table 1 Qualification of the laboratory's risk management team

Participant	Academic training	Position/ function in the laboratory	Time of experience in the function (years)
P1	PhD in Electrochemistry	Full Professor, Coordinator	37
P2	PhD in Engineering	Full Professor, Technical Manager	10
P3	PhD in Engineering and QMS	Quality Manager	18
P4	High school	Laboratory Technician	35
P5	Master student in engineering	Researcher	2

Following the risk assessment script based on the experience of those involved and based also on the history of occurrences in the laboratory since its accreditation, semi-structured interviews were carried out. Then, the reports of risks identified by the laboratory professionals were considered, opening space for reflection and discussion, always considering relevant issues in a deep and comprehensive way. Risks associated with each requirement of the ISO/IEC 17025 standard were also identified, taking into account the requirements established in item 8.5 of the same, which details the actions to address risks and opportunities. Based on the risk assessment carried out, the existing actions were individually analysed, many of them required by the previous version of the standard or from previous corrective and preventive actions, and extrapolated, excluded, added, and adapted to the needs of the laboratory. In addition, a scale for probability and consequence was used, as observed in the Risk Matrix in Fig. 1.

For the probability estimation of the risk, historical data were used, such as corrective and preventive actions of past occurrences. The experts' expertise in the analysed area was also considered, as they tend to recognise the specific limitations of the organisation, the projects and the historical data, and have the ability to formulate appropriate questions that help in estimating the probabilities [17, 21]. The need for additional actions was assessed, based on the re-evaluation of the risk classification made by the testing laboratory team, leading to the decision to accept, mitigate or eliminate the risks. For the identification of the probable root cause of the risks that were identified as not tolerable, the five Whys methodology was applied, and to identify the possible causes of occurrence and consequences of these risks, the Ishikawa Diagram was applied. In addition, an Action Plan (5W1H) was prepared to define actions and responsibilities regarding the risks associated with the new requirements of the standard that necessitate additional actions and treatment. As a final step of the RM system proposal, actions related to monitoring were defined with the laboratory's quality management.

Results and discussion

The proposed system was based on a bibliographic survey with subsequent identification of the various stages of the RM, the main tools to be used and related activities. Thus, as the proposed system for the RM, the elaboration of a process flowchart was chosen in order to contemplate all the activities involved in the RM, from the initial survey to the monitoring of these risks. The steps described in the flowchart identify the need to address each risk, as well as additional actions and the planning of these actions. Initially, risk survey, analysis, assessment, and validation stages were proposed. Subsequently, the verification steps were added, concluding the TR and risk monitoring process, and making the laboratory's RM effective. This system makes explicit the analysis of the root cause and the critical analysis of each risk, contributing to the

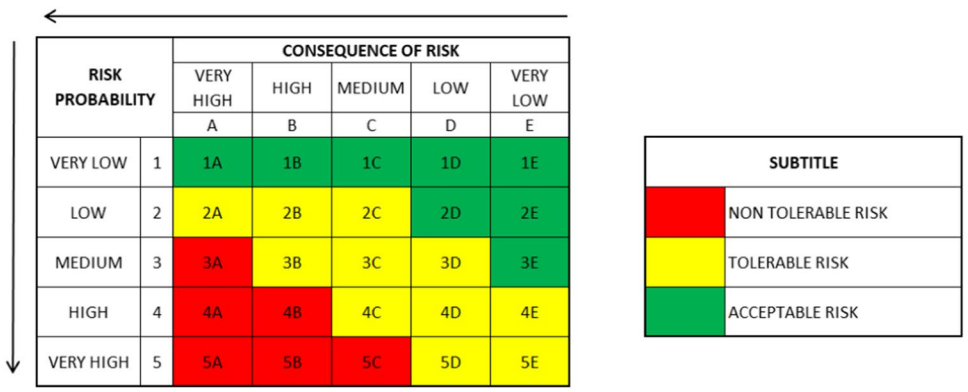

Fig. 1 Risk matrix. Source: Adapted from [21]

decision-making on whether to maintain, mitigate, or eliminate the risk. The flowchart of the process and its related activities are given in Fig. 2.

Through the activities proposed in the flowchart, it was possible to identify, allocate, analyse and classify the risks in the Probability/Consequence Matrix tool, as partially shown in Fig. 3, according to their defined levels of probability and occurrence. Risks related to the QMS itself were identified, as well as those related to technical competence, always considering the expertise and experience of the team involved in the laboratory's activities. By crossing the values assigned to each risk in relation to the probability and the consequence of it, the risk classification was obtained, which defined the decision making in relation to the treatment of maintaining, mitigating or eliminating the risk.

The brainstorming technique, the semi-structured interview concept and the Probability/Consequence Matrix tool were considered adequate and were included in the testing laboratory's QMS for the management of its risks, as they allow the identification and execution of future actions necessary to mitigate or eliminate risks, in compliance with requirement 8.5 of ISO/IEC 17025:2017. It was also possible to identify and justify the maintenance of some risks considered acceptable. An inconvenience identified in the Probability/Consequence Matrix tool is its form of interpretation, which, due to its strong subjectivity, may lead to a greater or lesser probability or consequence, due to the ambiguity of its scales. This can cause a significant variation in the risk classification, according to the interpretation of the individual carrying out this analysis, who might

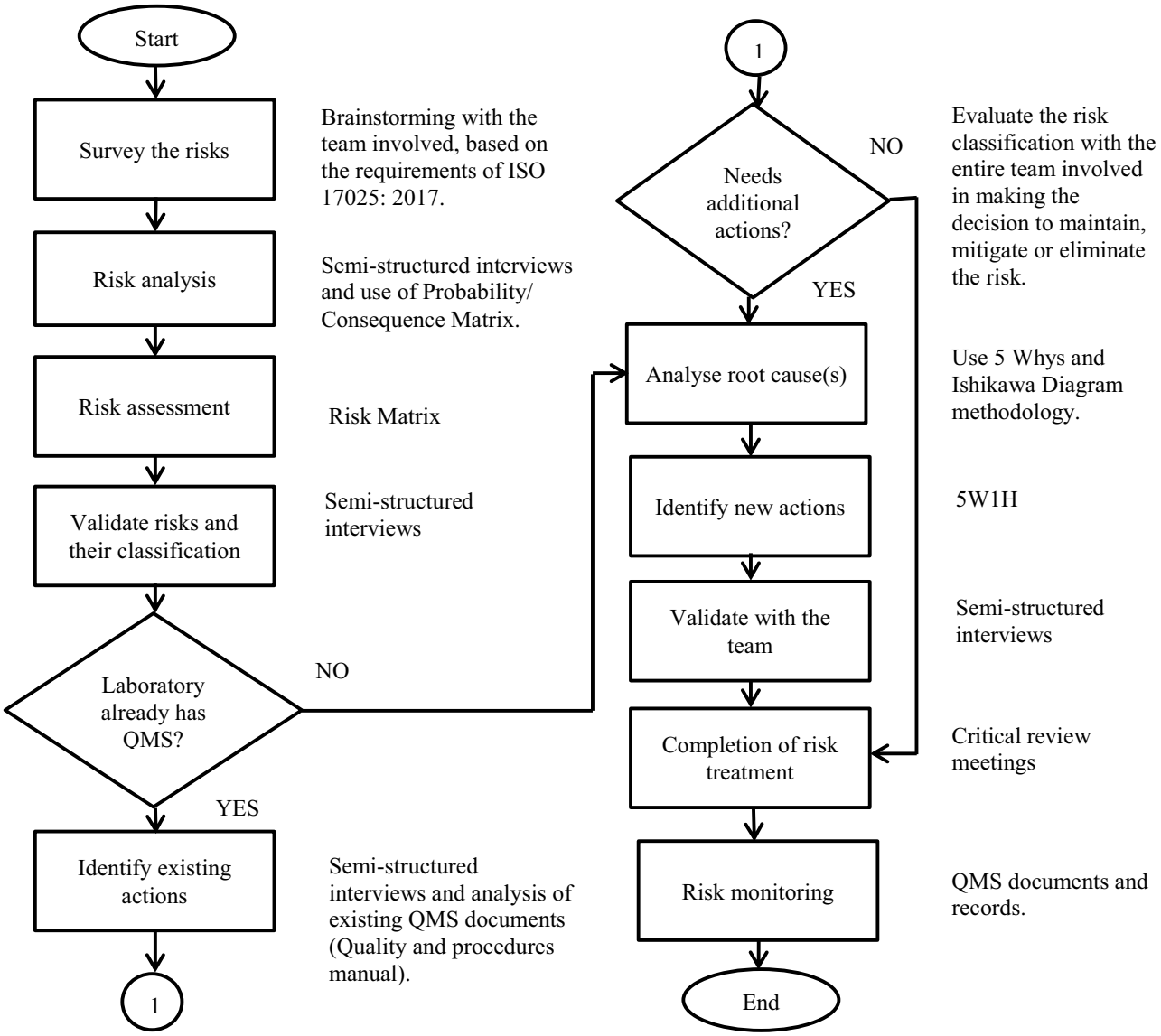

Fig. 2 Flowchart of the RM process

RISK MATRIX OF THE TESTING LABORATORY			CLASSIFICATION OF THE RISKS OF THE TESTING LABORATORY										
REQUIREMENTS / RISKS	EXISTING ACTIONS - planned (and executed) in the laboratory's QMS before the new version of the standard	ADDITIONAL ACTIONS / NEW ACTIONS	PROBABILITY					CONSEQUENCE					RISK
			VERY LOW	LOW	MEDIUM	HIGH	VERY HIGH	VERY HIGH	HIGH	MEDIUM	LOW	VERY LOW	
			1	2	3	4	5	A	B	C	D	E	
5.0 Structural requirements													
Changes to technical management	Appointment of competent technical manager by the coordinator	Not needed		X							X		2D
Lack of top management commitment related to ISO/IEC 17025 requirements	None, current top management is committed	Not needed	X						X				1A
Lack of resources for system maintenance	Involvement in public and private projects	Centralised QMS for resource optimisation				X			X				4B
Scope not adequately defined according to the standard	Scope defined in the Test List	Not needed		X						X			2C
Failing to meet the requirements of the accrediting authority	Control documents related to accreditation	Not needed		X					X				2B
Do not guarantee the integrity of the system when its transition occurs	None	Plan transition and review all documents			X				X				3B
6.2 Personnel													
Deficiency in the training of the technical staff	Training	Training monitoring	X					X					1A
Significant change in the technical framework. Retirement of teachers and technicians. Student turnover	Proper selection and training	Not needed		X				X					2A
Not following QMS procedures	Training	Not needed	X						X				1B
Lack of competency monitoring	Informal monitoring	Define and formalize monitoring (intralaboratory comparisons,e.g.) (*)		X						X			2C
6.4 Equipment													
Acquisition or use of reagents unsuitable or out of specification	Specify on acquisition and inspect upon receipt, described in a procedure. Check conditions and validity before each use, team training.	Not needed		X					X				2B
Failure to comply with the calibration plan	Calibration control sheet on the rehearsal room wall	Reinforce the need for team attention		X					X				2B
Failure to perform and/or not record proper equipment check	Written instructions and team training	Not needed		X						X			2C

RISK MATRIX OF THE TESTING LABORATORY			CLASSIFICATION OF THE RISKS OF THE TESTING LABORATORY										
REQUIREMENTS / RISKS	EXISTING ACTIONS - planned (and executed) in the laboratory's QMS before the new version of the standard	ADDITIONAL ACTIONS / NEW ACTIONS	PROBABILITY					CONSEQUENCE					RISK
			VERY LOW	LOW	MEDIUM	HIGH	VERY HIGH	VERY HIGH	HIGH	MEDIUM	LOW	VERY LOW	
			1	2	3	4	5	A	B	C	D	E	
Use of defective equipment or outside of specified requirements	Identification of disused equipment or removal from the testing area, team training	Not needed		X							X		2D
7.1 Review of requests, tenders and contracts													
Not identify the customer's real need	Procedure and form for recording the review, personnel training	Not needed		X					X				2B
Oversize laboratory capacity (large items)	Procedure and form for recording the review, team training	Specify in the budget the maximum size supported by the test chamber. Request photos of items/ parts		X					X				2B
7.2 Selection, verification and validation of methods													
Failure to confirm the performance of the method as performed by the laboratory	Team training, equipment checking, method confirmation registration form	Not needed		X					X				2B
Use of outdated standards	Periodic control of external documents	Not needed		X					X				2B
7.4 Handling of test items													
Damage to samples due to improper transportation	Test Item Handling Procedure, customer notification, record on the Test Request form	Not needed			X				X				3B
Improper storage of samples before testing	Test Item Handling Procedure, team training	Include guidance on large samples in the procedure (customer must not deliver too much in advance)		X						X			2C
7.5 Technical records													
Erasures and unreadable records	Team training	Not needed		X					X				2B
Lack of information in records to ensure traceability	Forms with adequate fields for records, team training	Not needed	X					X					1A
7.7 Ensuring the validity of results													
Failure to monitor the validity of test results	List of Testing Quality Assurance Procedures	Revise for adaptation to the new version of the standard (*)			X				X				3B
Do not participate in interlaboratory activities and / or in adequate frequency	Plan for participation in interlaboratory activities	Not needed		X							X		2D

* Additional item, due to the new version of the standard.

Fig. 3 Probability/consequence Matrix of the testing laboratory

minimise the severity of a risk and disregard the need for its treatment. One solution for this was to include a step to validate the analysis with the other individuals involved in the processes related to each risk, avoiding mistakes and seeking impartiality in the assessment. In this way, everyone reviewed all the classifications performed and agreed on the classification levels of each risk. After completing this stage, the team met again and validated the results, critically analysing each of the risks found in relation to each level of probability and occurrence. During this evaluation, there was an opportunity to consider actions already taken that altered the classification of some risks that were deemed acceptable and inherent to the process or tolerable, provided that the appropriate controls are in place, or that are not tolerable, reinforcing risk-based thinking, as required by the standard.

After tabulation of the data, it was possible to quantify the risks identified in the testing laboratory, in each requirement of the standard and according to their classification. The actions already existing in the laboratory and the additional actions proposed for each risk were also counted. As shown in Table 2, of the 97 risks found, 21 required additional actions, 14 of which are new risks identified by the new demands of the ISO/IEC 17025:2017 standard. The risks identified in the laboratory were classified with the help of the team and it was possible to see that most of them were considered tolerable and only a small fraction was not tolerable. Additionally, it was identified that about 80 % of the identified risks already had related control actions, coming from previous corrective and preventive actions, due to the fact that the testing laboratory is already accredited and is adequate for the previous version of the standard. Risks related to sampling and the decision rule have not been identified, since the laboratory does not carry out this activity and does not make a declaration of conformity. However, in the case of sampling, it was considered that there was a need to guide customers as to the adequacy of the quantity, size and transport of samples. The risk assessment was carried out on a preliminary basis and these aspects will be monitored and critically analysed at least once a year. The risk data mapped in each requirement of the standard was gathered according to its classification, in addition to the number of actions already existing in the laboratory and the additional actions proposed for each risk. This information was incorporated into the Probability/Consequence Matrix, including the existing actions and the need for additional actions and/or new TR actions.

Additionally, for the risks considered not tolerable, the five Whys techniques (Table 3) and the Ishikawa Diagram were used, in search of their root cause. In this way, it was possible to identify possible solutions for each of the risks. For the most critical risk of the laboratory, related to the lack of resources for maintaining the QMS, the suggestion of creating a centralised QMS covering more UFRGS laboratories would also allow the standardisation of actions in relation to the quality of the laboratories involved, in addition to the optimisation of resources for the maintenance of accreditation. For the risks of "not meeting the new version of the standard" and of "not updating risks and opportunities," the treatment was eventually made possible with this research.

An action plan was established to detail the necessary actions, those responsible for them, deadlines for implementing actions and status, new risks associated with new requirements of the standard, and for existing risks that required additional actions. In this way, the actions could be listed, prioritising new actions according to the classification assigned to each risk. The other proposed additional actions were considered opportunities for improvement, allowing the adequate and complete realisation of the RM in the testing laboratory.

The flowchart of the RM process, the form 5W1H and the techniques of analysis of causes (Probability/Consequence Matrix and five Whys) were considered adequate and incorporated in the laboratory's QMS for the management of its risks. Regarding risk monitoring, an additional field was added to the existing Nonconformity Treatment Form (NCTF), in order to identify new risks or new actions related to each occurrence, not already predicted in the risk matrix. Once a year, the risk matrix is completely reviewed and updated, if necessary, by the

Table 2 Number of risks and related actions for each requirement of ISO/IEC 17025:2017

Requirements ISO/IEC 17025:2017	Risks				New item*	Actions	
	Acceptable	Tolerable	Not tolerable	Total		Existing	Additional
4. General requirements	6	5	0	11	2	9	2
5. Structure requirements	2	3	1	6	1	4	2
6. Resource requirements	6	16	0	22	2	18	4
7. Process requirements	9	27	0	36	3	31	5
8. Management system requirements	1	19	2	22	6	14	8
Total	24	70	3	97	14	76	21

*Risks and actions related to the incorporation of new requirements in the 2017 version of the standard

Table 3 Five Whys tool applied to non-tolerable risks

Problem: risks identified and not tolerable						
Risk	1	2	3	4	5	Solution (s)
	Why?	Why?	Why?	Why?	Why?	
Lack of resources to maintain QMS	Federal government and university do not allocate resources to laboratories for their accreditation	This is an HEI test lab	Laboratories are mainly used for teaching and research	Lack of structure on the HEI to provide qualified services	–	Create a centralised QMS for multiple labs
Does not meet the new version of the standard	QMS complied with the previous version	No new version had been published	Lack of knowledge of the new version	–	–	Train staff in the new version and make adjustments to the QMS
Does not update risks and opportunities	There was no RM practice	There was no such requirement in the previous version of the standard	It was only necessary to address non-conformities and identify improvements	Lack of vision of the whole, with a preventive approach to risks	–	Train staff and monitor risks and opportunities. Include a field for the assessment of the need to update the non-conformity treatment form

laboratory team. Risks are assessed again as to their probability of occurrence, based on the records in the NCTF. The effectiveness of the actions proposed for each risk is also evaluated, considering the occurrence (or not) of events related to that risk in the period.

Conclusions

The objective of this work was to propose a system to carry out risk management in laboratories, in order to comply with the new version of ISO/IEC 17025. The proposed system, in the form of a flowchart, provides for the stages of analysis, evaluation, classification and validation of risks, their root cause(s), the identification of existing actions, the need for additional actions, and the treatment and monitoring of risks. The monitoring of risks and the verification of the effectiveness of the actions implemented must consider the time necessary for these measures to produce their effects and be an integral part of the management and decision-making process. It must also be effective and periodic, with the participation of all members of the work team, without placing too much burden on the process.

During the application of this system in the UFRGS laboratory, it was realised that many existing actions had been identified and implemented to meet the requirements of the previous version of the standard. Other actions resulted from the treatment of nonconformities identified over time, through internal findings, customer complaints and audits, or as a result of preventive actions or opportunities for improvement. In this way, it can be concluded that laboratories that meet the previous version of the standard already do an informal RM and that the new version did not incorporate very impactful requirements in relation to risks. This research made it possible to maintain the laboratory's accreditation, after auditing, without the occurrence of nonconformities related to the RM requirements.

This system can be used by other professionals and researchers from HEI laboratories or other types of institutions, in compliance with the demands of the ISO/IEC 17025:2017 standard, in laboratories that already have QMS implemented, or in those in the initial phase of implementation. However, each laboratory must carefully evaluate all its risks according to its own specificities.

Future research may identify other risks, or yet other approaches or tools to perform an effective MS.

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