Self-assessment model for testing and calibration laboratories based on ISO/IEC 17025:2017 requirements

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Abstract. This paper aims to propose a self-assessment model for evaluating the competence, impartiality, and consistent operation of testing and calibration laboratories, based on ISO/IEC 17025:2017 requirements. During the research, an attempt was made to demonstrate the applicability of the proposed model through the development of a case study in one of the Brazilian Navy's Testing and Calibration Laboratories. The main outcome of this research is an innovative self-assessment model for testing and calibration laboratories, with a view to supporting decisions for achieving accreditation. Notably, the results of the empirical study demonstrate that it is feasible to determine the readiness level of the Navy's Laboratory in compliance with the requirements of the mentioned standard. Also, they allowed identifying opportunities for improvement of the current management system of the Laboratory.

Keywords. Metrology; testing and calibration laboratories; accreditation; ISO/IEC 17025:2017; self-assessment; decision-making methods.

1. Introduction
The mapping and evaluation of the research and development (R&D) infrastructure and technological services of a region are of fundamental importance for the formulation of public policies in Science, Technology, and Innovation (ST&I) and implementation of assertive strategies for the application of resources by public and private institutions and companies from various sectors of the economy. In particular, technological services constitute a strategic segment of national innovation systems [1] and comprise the services of metrology, testing, and calibration, inspection, certification, and accreditation. The productive sectors that demand these services can execute them themselves or request external suppliers, i.e., laboratories outside the scope of their activities.

According to ISO/IEC 17025: 2017 [2], the laboratory is a body that performs testing, calibration, or sampling, associated with subsequent testing or calibration. In Brazil, the infrastructure of accredited testing and calibration laboratories in the year 2018 comprises 1511 laboratories, 400 laboratories within the calibration modality, and 1111 test laboratories, as stated by the National Institute of Metrology, Standardization and Industrial Quality (Inmetro) [3].

Based on the assumptions that: (i) ISO/IEC 17025:2017 standard is the international reference for laboratories providing testing and calibration services around the world; (ii) the effectiveness of the operations of these laboratories depends on both their competency in conducting tests and calibrations, and their ability to manage their operations consistently; (iii) the application of a self-assessment model based on the referred standard may help these laboratories to evaluate their readiness to achieve
accreditation, and identify critical issues and opportunities for improvement to accomplish this goal; (iv) there are gaps identified in the literature regarding the central theme of this research, namely self-evaluation models for testing and calibration laboratories based on ISO/IEC 17025:2017 standard; the main questions addressed in this paper are:

i. How to assess the readiness of test and calibration laboratories readiness to achieve accreditation based on ISO/IEC 17025:2017 requirements? What are the critical issues and opportunities for improvement concerning their competence, impartiality, and operational consistency?

ii. What are the key and specific elements that should be considered in the hierarchical structure of a self-assessment model for testing and calibration laboratories?

iii. What multicriteria decision-making methods and management tools should be integrated into a model to assess the readiness of test and calibration laboratories to achieve accreditation?

This work aims to fill these research gaps by developing a self-assessment model for evaluating the competence, impartiality, and consistent operation of testing and calibration laboratories, based on ISO/IEC 17025:2017 requirements. During the research, an attempt was made to demonstrate the applicability of the proposed model through the development of a case study in one of the Brazilian Navy's Testing and Calibration Laboratories.

The paper is structured in six sections. Following this introduction, Section 2 briefly reviews the literature on the central themes of the research, covering the period of 1988-2018, with particular attention on process maturity models, decision-making methods, and tools applicable to the intended modeling. The literature review was complemented with documental analysis, focusing on ISO/IEC 17025:2017 standard, to construct the hierarchical structure of the proposed self-assessment model. In Section 3, we briefly present the research methodology. Section 4 introduces the self-assessment model for evaluating the competence, impartiality, and consistent operation of testing and calibration laboratories, based on ISO/IEC 17025:2017 requirements. Section 5 focuses on the applicability of the model through an empirical study carried out in one of the Brazilian Navy's Testing and Calibration Laboratories. Finally, Section 6 synthesizes the concluding remarks of this work.

2. Theoretical background

The literature review and documentary analysis covering the period of 1998-2018 encompass the following themes: (i) accreditation of testing and calibration laboratories; (ii) process and capability maturity models adopted by organizations of various sectors, which seek to measure and evaluate the level of quality of their internal structures and thus improve the way routines are performed; and (iii) application of decision-making methods and managerial tools in the research context.

2.1. Accreditation of testing and calibration laboratories

The testing and calibration laboratory accreditation aims to assure the quality of services and the laboratory's competence. Conformity to ISO/IEC 17025: 2017 standard demonstrates internal skills, facilities, management system documentation, and procedures to produce reliable and traceable results based on measurable quantities. Most of the works related to the ISO/IEC 17025 accreditation of testing and calibration laboratories have confirmed the helpfulness of the system application but also identified many obstacles concerning the accreditation process [4-7].

The implementation of quality management systems (QMS) and accreditation of laboratories according to ISO/IEC 17025 standard are not easy tasks so that critical factors should be systematically monitored [4-7]. From this perspective, an approach for the implementation of a quality management system in compliance with ISO/IEC 17025 requirements was proposed for a Mauritian Laboratory [4].

In Brazil, a study conducted in two testing laboratories of the Federal University of Rio Grande do Sul (UFRGS) presents some steps for QMS implementation according to ISO/IEC 17025, combined with a process approach as defined in ISO 9001 standard [5]. Another study carried out in South Africa investigated the impact of ISO/IEC 17025 and Good Laboratory Practices (GLP) adoption on the operational performance of both commercial and non-commercial laboratories [6].
Several studies have been devoted to this subject, but the emphasis has been on the ISO/IEC 17025 implementation process and its impacts. Too little attention has been paid to self-assessment frameworks for testing and calibration laboratories that aim to achieve ISO/IEC 17025 accreditation.

2.2. Process and capability maturity models

A considerable amount of literature has been published on process maturity models developed for organizations of various sectors, which seek to measure and evaluate the level of quality of their internal structures and thus improve the way routines are performed [8-11].

A maturity model is a conceptual framework that comprises a categorization of discrete maturity levels for a class of processes in one or more contexts and represents an evolutionary trajectory for achieving the desired readiness level of these processes [10]. In turn, process assessment examines the strong, weak, and missing points in the process under analysis concerning a reference framework [14-17]. In summary, a maturity model acts as the reference framework against which the current status of a process is evaluated using an assessment model. The assessment provides an understanding of the current process situation and enables rating about process quality based on this understanding. For this research, we reviewed the following maturity models:

- Capability Maturity Model (CMM) [12];
- Capability Maturity Model Integration (CMMI) [13];
- Business Process Maturity Model (BPMM) [14];
- Business Process Orientation Maturity Model (BPOMM) [15];
- Process Management Maturity Model [16];
- Maturity Model for Knowledge-Intensive Business Processes [17];
- Knowledge Management Capability Assessment Model (KMCA) [18].

Together with the literature review and documental analysis on laboratory accreditation (item 2.1), understanding these models helped the development of the conceptual model of self-evaluation and also the elaboration of the instrument to be applied during the empirical study.

The expression ‘maturity level of a testing and calibration laboratory’ should be understood as the current readiness level that the laboratory is in relation to the international technical requirements established for its operations consistently and with the required technical competence.

The common characteristics of different maturity models reviewed in this item, associated with the scale defined in Annex A of ISO 9004:2010 [19], were used in the two first steps of modeling (section 4 – items 4.1 and 4.2).

2.3. Application of decision-making methods and managerial tools in the research context

Considering the specificities and challenges of testing and calibrating laboratories to self-assess their readiness to achieve accreditation and also the results from the literature review on decision-making methods and tools, we combined two of them for the conceptual modeling phase. They are: (i) Analytical Hierarchy Process (AHP) [20;21] for comparing the importance of the key and detailed elements within the proposed hierarchical structure of self-assessment; and (ii) Importance-Performance Analysis (IPA) [22;23] focusing on the results of self-assessment, particularly the critical issues and opportunities for improvement to be considered by the laboratory managers and team, with a view to future accreditation.

3. Methodology

The research methodology comprised: (i) a systematic search on articles and documents published between 1998 and 2018 about the central research themes and selection of most relevant works; (ii) development of a self-assessment model for evaluating the competence, impartiality, and operational consistency of testing and calibration laboratories, including the construction of the analytical hierarchical structure; application of the analytical hierarchy process (AHP) method to assign weights to the core and specific elements, with the participation of invited experts; and (iv) demonstration of
the applicability of the self-assessment model through an empirical study carried out in one of the Brazilian Navy’s Testing and Calibration Laboratories.

4. Description of the developed self-assessment model for testing and calibration laboratories

Based on the theoretical background that founded this work and considering the institutional profiles and external conditions for the operation and management of testing and calibration laboratories, a self-assessment model was developed to help these laboratories to evaluate their readiness level to achieve accreditation and identify critical issues and opportunities for improvement to accomplish this target.

The common characteristics of different maturity models reviewed in item 2.2, associated with the scale defined in Annex A of ISO 9004:2010, were used in the two first steps of modeling. Besides, AHP method [20;21] and IPA tool [22;23] were integrated into the conceptual model for running step 3 towards. As a result, the self-assessment model proposed for testing and calibration laboratories comprises seven stages, as follows:

• Step 1: Definition of the hierarchical structure of self-assessment: core and specific elements;
• Step 2: Definition of a five-point maturity scale designed for testing and calibration laboratories;
• Step 3: Pairwise comparisons of core and specific elements by invited experts;
• Step 4: Calculation of the weights of core and specific elements;
• Step 5: Elaboration and pre-test of the self-assessment instrument and further application with managers of a Testing and Calibration Laboratory under analysis;
• Step 6: Analysis of the results of self-assessment by using the IPA tool; and
• Step 7: Elaboration of the self-assessment report of the Testing and Calibration Laboratory, including the indication of critical issues and opportunities for improvement to be considered by its managers, with a view to future accreditation.

4.1. Step 1: Definition of the hierarchical structure of self-assessment

Figure 1 shows the hierarchical structure of self-assessment proposed for laboratories of testing and calibration. The structure based on the ISO/IEC 17025:2017 requirements [2] consists of five core elements and 28 (specific) linked to these core elements.

Figure 1. The hierarchical structure of self-assessment proposed for laboratories of testing and calibration
4.2. Step 2: Definition of a five-point maturity scale designed for testing and calibration laboratories

A five-point maturity scale should be specially designed for testing and calibration laboratories based on the common characteristics of different maturity models reviewed in item 2.2, associated with the scale defined in Annex A of ISO 9004:2010 [19].

4.3. Step 3: Pairwise comparisons of core and specific elements by invited experts

In this step, the AHP method [20;21] should be adopted by invited experts to perform the pairwise comparisons of the core and specific elements. In total, six comparative tables should be completed, being the first concerning the core elements. The other comparative tables refer to the specific elements of each core element, according to the hierarchical structure of self-assessment (Fig.1).

4.4. Step 4: Calculation of the weights of core and specific elements resulting from the pairwise comparison matrices

To calculate the weights of core and specific elements resulting from the pairwise comparison matrices, the computational system IPÊ (version 1.0) can be used [24]. The whole procedure and formulas concerning this step are detailed in [25].

4.5. Step 5: Elaboration and pre-test of the self-assessment instrument and further application with managers of a Testing and Calibration Laboratory under analysis

The application of the self-assessment instrument should be carried out with the managers and team of the Testing and Calibration Laboratory. This step should include the following tasks: (i) conducting a meeting for the presentation of the self-assessment instrument for the testing and calibration laboratory managers; and (ii) completion of the self-assessment form by the managers and collaborators.

Radar-type charts should be generated for the five core elements, as recommended by ISO 9004:2010 standard [19]. So, the maturity level of a given core element can be calculated by adding up the percentage of the chart area corresponding to the maturity level (1 to 5) assigned to each of the specific elements of this core element and dividing the total found by the number of specific elements. For maturity level 1, 20% of maturity is considered; for level 2, 40%; for level 3, 60%; for level 4, 80%; and for level 5, 100%. Figure 2 shows an illustrative radar-type chart generated for the core element ‘Resource requirements’.

Figure 2. Illustrative radar-type chart generated for the core element ‘Resource requirements’

Step 6: Analysis of the results of self-assessment by using the IPA tool

This step refers to the analysis of the results of self-assessment from step 5. Here, the use of the importance-performance analysis (IPA) tool is recommended, as described in [22; 23].

For each core element, a two-dimensional space is generated – importance (horizontal axis), and performance (vertical axis). The importance-performance matrices allow the managers of testing and calibration laboratories to map four decision zones to establish targets and action plans to achieve the desired accreditation, as shown in Figure 3.
Figure 3. Illustrative importance-performance matrix for the core element ‘Resource requirements’

Step 7: Elaboration of the self-assessment report of the Testing and Calibration laboratory
This is the last step of the conceptual model, in which a self-assessment report should be prepared to contain: (i) diagnosis of the level of maturity of the testing and calibration laboratory under analysis, containing radial graphs that indicate the current readiness stage of the laboratory concerning the specific elements of each core element; (ii) indication of critical issues and opportunities for improvement, according to decision zones of the respective importance-dependence matrices of each core element, as illustrated in Figure 3; and (iii) definition of goals to increase the maturity levels for those specific elements, which showed lower levels (Figure 4).

Figure 4. Illustrative radar-type chart with targets for the core element ‘Resource requirements’

It is important to emphasize that the proposed self-assessment model can be descriptive, prescriptive, and potentially comparative in nature, according to the classification suggested by [8]. As a descriptive model, it can be used for assessing the current readiness level of the laboratory in view of ISO/IEC 17025:2017 accreditation. Besides evaluating the current readiness level, the model may be prescriptive, provided that the managerial information generated in the IPA matrices can be used as a basis for establishing targets and action plans to achieve the accreditation or even for continuous improvement. In addition to identifying the readiness level to achieve ISO/IEC 17025:2017 accreditation and also opportunities for strategic and operational improvement, the results of the
application of the proposed self-assessment model in real laboratory contexts can be useful to stimulate benchmarking initiatives between laboratories of a given network, provided that the final weights of the key and specific elements are maintained.

5. Demonstration of the applicability of the self-assessment model: an empirical study in one of the Brazilian Navy's Test and Calibration Laboratories

During the period from November 2018 to March 2019 an empirical study was carried out in two stages: (i) from step 1 to 4, through meetings with seven invited experts from PUC-Rio, National Institute of Metrology, Standardization and Industrial Quality (Inmetro), and National Institute of Technology (INT); and (ii) application of the self-assessment instrument with the manager and team of one of the Brazilian Navy's Test and Calibration Laboratories (from step 5 to 7).

Due to space limitations, the results of the empirical study are not presented in this section. Nevertheless, the detailed description of the conceptual model and all results of the empirical study are published in the first author’s MSc. Dissertation, on which this paper was based [25].

6. Final remarks

In this paper, an attempt was made to demonstrate the applicability of a conceptual model developed for assessing the readiness of test and calibration laboratories to achieve ISO/IEC 17025:2017 accreditation. From November 2018 to March 2019, through an empirical study carried out in one of the Brazilian Navy's Testing and Calibration Laboratories the applicability of the model could be confirmed a real laboratory context.

The empirical results demonstrated an affirmative acceptance of the proposed self-assessment instrument in the Lab in terms of usefulness and feasibility. However, there still may be limitations concerning the generality of its findings because only one Lab of the Brazilian Navy's Test and Calibration Laboratories was considered. Nevertheless, the material developed for this study is suitable for later implementation in other laboratories of the Brazilian Navy's Test and Calibration Network and also in similar laboratories.

The conceptual model and the empirical results of this work may contribute to the improvement of self-assessment tools used by testing and calibration laboratories in view of future accreditation. These contributions refer to the creation of a five-point maturity scale specially designed for these laboratories, and the use of a multicriteria decision-making method (AHP) combined with a managerial tool (IPA) for identifying the importance and urgency of actions required to achieve ISO/IEC 17025:2017 accreditation’s targets.

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