Multicriteria conceptual framework for maturity assessment of testing and calibration laboratories based on the ISO/IEC 17025: 2017 standard

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Abstract. This paper proposes a multicriteria conceptual framework for assessing the maturity of testing and calibration laboratories based on the structure of the ISO/IEC 17025:2017 standard. The methodology consisted of the following steps: (i) conducting a literature review and documentary analysis on the central research theme; (ii) defining the analytical structure aligned with the requirements for the competence, impartiality, and consistent operation of testing and calibration laboratories; (iii) developing a multicriteria conceptual framework, combining two decision-making methods; (iv) applying the proposed framework with senior managers from one of the Brazilian Army Evaluation Center (CAEx)'s Laboratories to determine its maturity level concerning each requirement of the ISO/IEC 17025:2017 standard; and (v) adopting the Importance-Performance Analysis (IPA) method to identify critical issues and elaborate an action plan to prepare the Laboratory for holding accreditation. The main outcome of this research is an innovative conceptual framework for assessing the maturity of testing and calibration laboratories, representing a substantial contribution to the state-of-the-art compared to previous studies published from 2010 to 2023.

1. Introduction

Technological services constitute a strategic segment of national innovation systems [1], encompassing metrology, testing, calibration, inspection, certification, and accreditation services. Organizations that require these services can either perform them in-house or seek assistance from external suppliers, such as laboratories that operate independently from their activities.

According to the ISO/IEC 17025:2017 standard [2], a laboratory is an entity that conducts testing, calibration, or sampling, followed by subsequent testing or calibration.

Based on the following assumptions: (i) the ISO/IEC 17025:2017 standard serves as the international reference for laboratories providing testing or calibration services worldwide; (ii) the effectiveness of these laboratories' operations depends on both their competence in conducting tests and calibrations and their ability to manage operations consistently; (iii) the application of a multicriteria conceptual framework for maturity assessment based on the referred standard may help these laboratories in evaluating their readiness to hold accreditation, identify critical issues, and uncover opportunities for improvement to accomplish this goal; (iv) gaps have been identified in the literature regarding assessment models for testing and calibration laboratories based on the ISO/IEC 17025:2017 standard, this paper addresses the following main research questions:

i. How to assess the maturity level of test and calibration laboratories that aim to hold accreditation based on ISO/IEC 17025:2017 requirements?
ii. What key and specific elements should be considered in a conceptual framework for assessing the maturity level of testing and calibration laboratories to hold accreditation?
iii. What decision-making methods should be integrated into a conceptual framework to assess the maturity level of test and calibration laboratories aiming to hold accreditation?
iv. What are the critical issues and opportunities for improvement concerning their competence, impartiality, and operational consistency to accomplish this goal?

This work aims to bridge these research gaps by creating and applying a multicriteria conceptual framework for assessing the maturity of testing and calibration laboratories based on the ISO/IEC 17025:2017 standard. An empirical study was conducted at one of the testing and calibration laboratories within the Brazilian Army Evaluation Center (CAEx), focusing on ballistic testing.

The paper is divided into six sections, including this introduction. Section 2 provides a synthesis of the literature review, encompassing previous works published between 2010 and 2023 that focused on the ISO/IEC 17025:2017 standard. In Section 3, the research design and methodology are briefly presented. Section 4 introduces a multicriteria conceptual framework for assessing the maturity of testing and calibration laboratories based on the ISO/IEC 17025:2017 standard. Section 5 discusses the potential contributions of combining two decision-making methods to enhance self-assessments' efficiency by laboratories seeking accreditation. Lastly, Section 6 summarizes the concluding remarks and outlines future research developments.

2. Literature review

The literature review covered 15 previous works published between 2010 and 2023 by researchers from different contexts and countries, including Brazil [3-17]. In addition to searching in international scientific databases (Scopus, Web of Science, Science Direct, and Google Scholar), a backward search was conducted by analyzing the references cited in the most relevant articles.

The comparative analysis of the selected empirical studies included the following aspects: (i) the objective of the study; (ii) the region and sector(s) of application; (iii) the dimensions/variables considered; (iv) the methodological approaches and methods adopted. Due to space limitations, the detailed comparative analysis will not be presented here, but it can be found in [18].

Despite the importance of the results achieved so far in advancing knowledge in the focused research field, the analysis of these studies revealed that none of them adopted a network-based multicriteria approach capable of analyzing cause-and-effect relationships and feedback between the standard clauses at the first level, and between the requirements subordinated to each clause at the second level.

In addition, reference works on organizational maturity models [19-21] were also analyzed to support the definition of a maturity five-point scale to be integrated into the conceptual framework, as described in Section 4 (Item 4.5).

3. Research design and methodology

This section describes the research methods to address the research questions posed in Table 1. As shown in this table, the research design comprises three phases and six stages, following a procedural model based on Rocha et al. [22] to establish a clear structure and approved course of action for this research. The research phases are: (i) motivation, (ii) development, and (iii) validation.

Table 1. Research design

Phase	Stage	Research questions [Section]
Motivation	Problem definition and the rationale for the research.	Why should we develop a multicriteria conceptual framework for assessing the maturity of testing and calibration laboratories based on the ISO/IEC 17025:2017 standard? [Section 1]
Development (What and How?)	State of research on central themes and identification of research gaps and unsolved problems.	What are the significant gaps in existing knowledge regarding the maturity assessment of testing and calibration laboratories based on the ISO/IEC 17025:2017 standard? [Section 2]
	Definition of the research methodology.	How can we assess the maturity level of testing and calibration laboratories based on the ISO/IEC 17025:2017 standard? Which decision-making methods should be integrated into a conceptual framework to assist laboratories aiming to hold accreditation? [Section 3]
	Development of a multicriteria conceptual framework for maturity assessment of testing and calibration laboratories based on the ISO/IEC 17025: 2017 standard.	What assessment factors should be considered in the analytical structure to evaluate the maturity level of testing and calibration laboratories aiming to hold accreditation? [Section 4] How can we identify critical issues and opportunities for improvement concerning the competence, impartiality, and operational consistency of a specific testing and calibration laboratory in its pursuit to hold accreditation? [Section 4]
Validation (How to demonstrate the applicability of the conceptual framework?	Application of the multicriteria conceptual framework at one of the testing and calibration laboratories within the Brazilian Army Evaluation Center (CAEx), focusing on ballistic testing.	Is it feasible to demonstrate the applicability of the proposed framework through an empirical study conducted at the Ballistic Testing Laboratory (LEB) of the Brazilian Army Evaluation Center (CAEx)? [Section 5] What is the current maturity level of the Ballistic Testing Laboratory (LEB)? [Section 5]. What are the main challenges faced by the Laboratory, and what recommendations should be provided to the LEB's senior leadership to enhance outcomes and impacts derived from accreditation? [Section 5]
	Discussion of the empirical results and implications of the adoption of the model in other testing and calibration laboratories.	Can the results of the empirical study conducted at the LEB of CAEx effectively demonstrate the applicability of the proposed framework? [Section 5] What are the primary differentiating factors of the proposed model compared to the methodological approaches covered in the literature review in Section 2? What are the managerial implications of this research? [Section 5]

The phases ‘motivation’ and ‘development’ are supported by the first four stages described in Table 1. The initial stage involves defining the problem and justifying the research. In contrast, the second stage encompasses a comprehensive review of existing research on the central themes, identifying research gaps and unresolved issues in the focused field. The third stage defines the research methodology, and the fourth stage refers to developing the conceptual model based on the ISO/IEC 17025:2017 standard.

A literature review of scientific articles and documentary analysis documents published between 2010 and 2023 [2, 3-17] was conducted during the initial two stages. This review highlighted the importance of developing a multicriteria conceptual framework for assessing the maturity level of testing and calibration laboratories based on the ISO/IEC 17025:2017 standard. It provided a more precise identification of research gaps. The third stage involved defining and detailing the research methodology.

From the literature review and documentary analysis, the ISO/IEC 17025:2017 structure was selected [2], along with two decision-making methods: the Analytical Network Process (ANP) [23] and Importance-Performance Analysis (IPA) methods [24]. The incorporation of these methods during the development phase constitutes a substantial contribution to the state-of-the-art compared to previous evaluation models reviewed in the second phase of this research.

The focus on unaddressed research gaps led to the selection of the ANP method among several multicriteria methods, mainly because the ISO/IEC 17025:2017 structure consists of five standard clauses (network clusters) and 28 assessment factors (network elements) that can be interconnected in various ways. A network formed by these elements can incorporate feedback and interdependent relationships within and between clusters. So, network elements' influence on other elements in that network can be represented in a supermatrix [23]. This new concept is a two-dimensional matrix of elements by elements that adjusts the relative importance weights in individual pairwise comparison matrices to form a new overall supermatrix with the eigenvectors of the adjusted relative importance weights.

According to Saaty [23], the ANP method comprises the following main steps: (i) determination of the network structure; (ii) determination of network-element and cluster importance weights; and (iii) calculation of the limit matrix and resulting weighting of network elements and clusters. The first step involves representing the decision problem using a network structure, requiring a deep understanding of the situation decision-makers face. Tasks needed for constructing the network model include determining the network elements, logical groups of elements (clusters), and the influence network by constructing a zero-one interfactorial dominance matrix concerning the network elements.

A zero-one interfactorial dominance matrix is used to determine the influence network, with network elements taking the value 1 or 0 depending on whether there is or is not some influence of an element on another one [23]. Accurate identification of these influences by decision-makers is essential to successfully transfer the real-world case study's complexity to the model.

In the second step of the ANP method, pairwise comparisons of the elements are conducted based on Saaty's nine-point scale (Table 2).

Table 2. Saaty's nine-point scale [23]

Scale	Linguistic scale
1	Equally important
2	Equally to moderately more important
3	Moderately more important
4	Moderately to strongly important
5	Strongly important
6	Strongly to very strongly more important
7	Very strongly more important
8	Very strongly more important to absolutely important
9	Absolutely important

After consolidating judgments and preferences from decision-makers or experts, a comparison matrix of multiple valuation criteria is constructed. Decision-makers or experts who provided judgments or preferences must undergo the consistency test during the adoption of the ANP method based on the pairwise comparison matrices' consistency ratios (C.R.). The C.R. of a pairwise comparison matrix is the consistency index's ratio to the corresponding random value.

The third step of constructing the ANP model involves calculating the limit matrix and the resulting prioritization of network elements. The limit matrix is obtained by raising the weighted supermatrix to successive powers. In this work, the network elements correspond to 28 assessment factors associated with the five clauses of the ISO/IEC 17025:2017 standard [2]. These 28 factors were logically grouped into five clusters corresponding to the mentioned clauses (see Figure 1 in the next Section). The weights of the 28 items were calculated using the Super Decisions® software (https://www.superdecisions.com/manuals/) [25].

Additionally, assessment data should be obtained from decision-makers' or experts' judgments within the Laboratory and then synthesized to obtain the final results concerning the maturity level concerning each assessment factor. Besides using this multicriteria approach described so far, another decision-making method was employed in the last phase of the proposed framework, namely the IPA method [24]. This method assists a given testing and calibration laboratory in efficiently allocating resources to demonstrate that they operate competently and can generate valid results, as described in section 4 - item 4.8.

4. Multicriteria conceptual framework for maturity assessment of testing and calibration laboratories based on the ISO/IEC 17025: 2017 standard

Following the methodology described in the third Section, the proposed conceptual framework comprises nine stages, as presented in the following items.

4.1. Stage 1: Determination of the analytical structure based on the ISO/IEC 17025:2017 clauses and requirements

The analytical structure for maturity assessment is defined based on the ISO/IEC 17025:2017 standard. The clauses correspond to the assessment dimensions and the requirements for assessment factors, as shown in Table 3 and Figure 3.

Table 3. Analytical structure based on the ISO/IEC 17025:2017 standard

Control layer		**Network layer**
Target	**Assessment dimensions**	**Assessment factors**
Maturity assessment (A) based on the ISO/IEC 17025:2017 clauses (R)	General requirements [R1]	Impartiality (R11)
		Confidentiality (R12)
	Structural requirements [R2]	Defined legal entity (R21)
		Laboratory scope, capabilities, and responsibilities of staff (R22)
	Resource requirements [R3]	Personnel (R31)
		Facilities and environmental conditions (R32)
		Equipment (R33)
		Metrological traceability (R34)
		Externally provided products and services (R35)
	Process requirements [R4]	Review of requests, tenders and contracts (R41)
		Selection, verification and validation of methods (R42)
		Sampling (R43)
		Handling of test or calibration items (R44)
		Technical records (R45)
		Evaluation of measurement uncertainty (R46)
		Ensuring the validity of results (R47)
		Reporting of results (R48)
		Complaints (R49)
		Nonconforming work (R410)
		Control of data and information management (R411)
	Management system requirements [R5]	Management system documentation (R51)
		Control of management system documents (R52)
		Control of records (R53)
		Actions to address risks and opportunities (R54)
		Improvement (R55)
		Corrective actions (R56)
		Internal audits (R57)
		Management reviews (R58)
One target	**Five clauses**	**28 requirements**

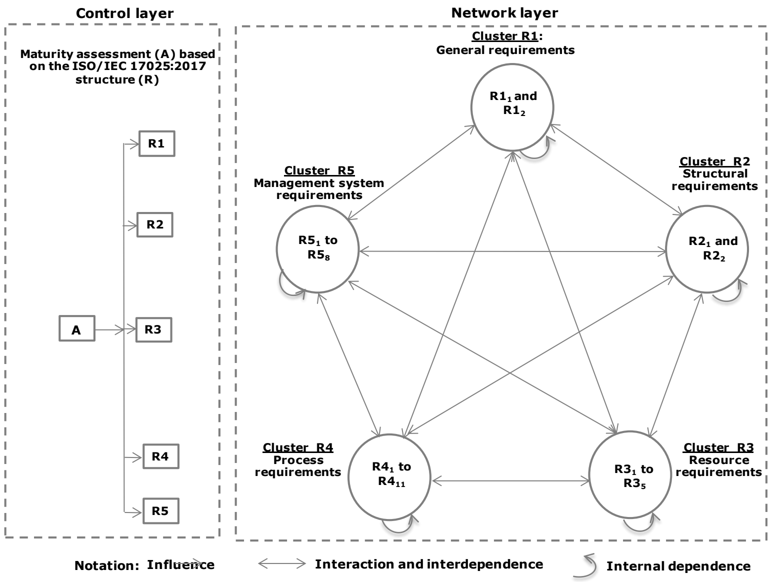

Figure 1. The network analytical structure based on the ISO/IEC 17025:2017 standard

To determine the influences between the assessment factors, a zero-one interfactorial dominance matrix is built, with elements taking the value 1 or 0, representing the presence or absence of influence between factors. The matrix is organized with the 28 assessment factors grouped into five clusters.

4.2. Stage 2: Designing the questionnaire for pairwise comparisons of assessment factors and dimensions

In this stage, a questionnaire for pairwise comparisons of the 28 assessment factors and five clusters is designed and pretested to assess (i) clarity, (ii) suitability to respondents, (iii) time required to answer questions, and (iv) possible obstacles during application. The pairwise comparisons should be conducted using Saaty's nine-point scale (Table 2) by managers and collaborators involved in preparing the Laboratory for accreditation.

4.3. Stage 3: Determination of weights of assessment factors and dimensions

Consolidating judgments and preferences and testing consistency ratios (C.R.), the corresponding pairwise comparison matrices are generated to obtain eigenvectors [23]. A supermatrix is constructed, listing all sub-matrices comprising the five clusters (assessment dimensions) and 28 assessment factors. The weighted supermatrix is obtained by combining the unweighted supermatrix and the control hierarchy matrix, derived from pairwise comparisons using Saaty's scale from Table 2. Finally, the weights of the 28 assessment factors are calculated using the Super Decisions® software [25], as mentioned in section 3.

4.4. Stage 4: Calculation of the limit supermatrix and resulting weights of assessment factors

The limit supermatrix is calculated by performing power operations on the weighted supermatrix, with its weighted value approaching stability. This process gradually consolidates the interdependency and relative importance weights. Ultimately, the weights of the 28 assessment factors are determined, aided by the Super Decisions® software [25].

4.5. Stage 5: Designing the maturity five-point scale for assessing test and calibration laboratories

A specific maturity five-point scale is designed for evaluating test and calibration laboratories based on common characteristics observed in different maturity models reviewed during the exploratory phase of this research [19-21]. The proposed five-point maturity scale is shown in Table 4.

Table 4. Maturity scale to evaluate the competence, impartiality and consistent operation of testing and calibration laboratories

Maturity Level	Description
1. Nothing, informal or ad hoc	The capability is not established or established in an informal or ad hoc manner. It is not defined or managed.
2. Managed at the basic level	The capability is established at a basic level. It is, to some extent, but not entirely managed.
3. Defined and managed	The capability is defined and established. It is managed in a proactive manner.
4. Systematically managed	The capability is defined, established, and aligned. It is systematically and dynamically managed.
5. Optimized	The capability is continuously improved and optimized. It is managed based on active monitoring, feedback, and learning.

Source: Based on [19-21].

4.6. Stage 6: Designing the questionnaire for assessment data collection

In this stage, a second questionnaire is designed, considering the 28 network assessment factors, five clusters (assessment dimensions), and the maturity scale proposed in stage 5 (Table 4). After pretesting, the questionnaire is ready to be applied to the managers and collaborators involved in preparing the Laboratory for accreditation. If multiple experts are involved in this evaluation, consensus can be achieved in a consensual meeting, or fuzzy logic can be used to compute collective weightings [23].

4.7. Stage 7: Calculation of the overall maturity level of a given testing and calibration laboratory
In stage 7, the importance weights of the assessment factors (resulting from stage 4) and the rating scores (based on the scale presented in Table 4) are synthesized to obtain the overall maturity level of a given testing and calibration laboratory. Composite indicators can express the maturity level for each of the five assessment dimensions (i.e., the standard clauses), and radar-type charts can be generated to visualize the respective assessment results (Figure 2).

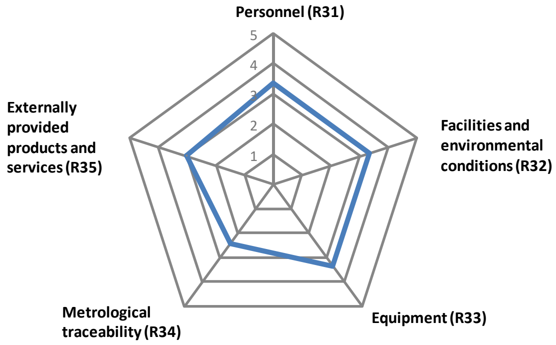

Figure 2. An illustrative example of a radar-type chart for the 'Resource requirements' dimension

4.8. Stage 8: Mapping decision-making zones for establishing targets and action plans
The objective in this stage is to map decision-making zones, allowing the establishment of targets and action plans to improve the maturity level of a given laboratory by using the Importance-Performance Analysis (IPA) method [24] for each assessment dimension. Figure 3 shows an illustrative example of an IPA matrix for the assessment dimension 'Resource requirements'.

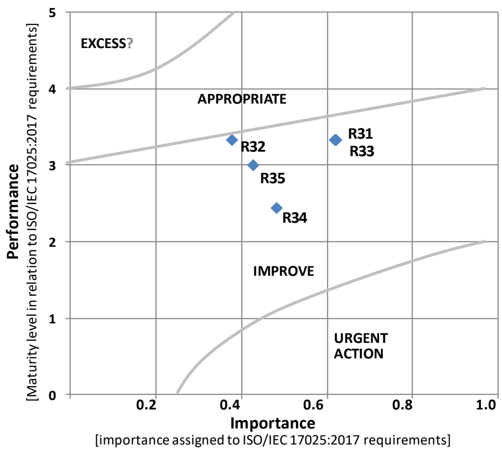

Figure 3. An illustrative example of an IPA matrix for the 'Resource requirements' dimension

4.9. Stage 9: Preparing the self-assessment report of the testing and calibration laboratory in focus
The final stage is dedicated to preparing a comprehensive report, encompassing all the results of the self-assessment of the focused Laboratory, along with action plans associated with targets to enhance the maturity level to hold accreditation.

5. Application in the Ballistic Testing Laboratory (LEB) of the Brazilian Army Evaluation Center (CAEx)
To demonstrate the effectiveness of the proposed framework, we conducted an empirical study in the Ballistic Testing Laboratory (LEB) of the Brazilian Army Evaluation Center (CAEx), which allowed us to demonstrate the applicability of the multicriteria framework in a real laboratory context [26].

The central questions of this empirical study were: 'What is the current maturity level of the LEB regarding its competence, impartiality and consistent operation?' and 'What are the main challenges to be managed by this Laboratory and what recommendations should be forwarded to the institution's senior leadership to improve outcomes and impacts from the value generated by a future accreditation?'.

5.1. Data collection

For data collection in stages 2 and 3, we conducted three consensual meetings with three senior leadership representatives at the LEB. Initially, we obtained the hierarchical control matrix (5 clauses x 5 clauses), presented in Table 5.

Afterwards, the interfactorial dominance matrix (28 x 28 assessment factors) was built. During judgments, when one element in the row influenced some element in the column, the number 1 was inserted in the respective cell of the interfactorial dominance matrix and 0 otherwise.

Table 5. Hierarchy control matrix based on the ISO/IEC 17025:2017 clauses

Hierarchy control matrix	**R1**	**R2**	**R3**	**R4**	**R5**
General requirements **[R1]**	0	1	1	1	1
Structural requirements **[R2]**	1	0	1	1	1
Resource requirements **[R3]**	1	1	0	1	1
Process requirements **[R4]**	1	1	1	0	1
Management system requirements **[R5]**	0	0	1	1	0

5.2. Final weights of the assessment factors that integrate the proposed framework

After completing all the paired comparisons during the consensus meetings, the Super Decisions® software was utilized to calculate the weights of the 28 assessment factors. The steps outlined in its manual [25] were followed, leading to the generation of three super matrices: (i) the original weightless supermatrix, obtained from pairwise comparisons between the 28 factors, resulting in priority vectors organized in columns; (ii) the weighted supermatrix, created by multiplying the weights of the clusters (representing the five clauses of the standard) with their respective counterparts in the unweighted supermatrix; (iii) the stochastic limiting supermatrix, generated by iteratively raising the power-weighted supermatrix until convergence, which allowed for the final calculation of the weights assigned to the 28 items of the standard, forming the assessment framework.

Due to space constraints, this paper does not present these supermatrices. However, they are accessible and can be referred to in [18].

5.3. Overall maturity of the LEB

Following the determination of the final weights for the 28 items, the participants in the empirical study were individually asked to assess the Laboratory of Experimental Biology (LEB) on the level of maturity for each assessment factor. They assigned a grade from 1 to 5, using the maturity scale presented in Table 4. A subsequent consensus meeting was conducted to establish the overall maturity level of the LEB for each assessment factor presented in Table 3. The overall maturity was rated at 3.0. Additionally, radar-type charts were employed to visually represent the maturity levels based on the assessment factors for each standard clause (see illustrative example in Figure 2).

Furthermore, the final weights of the assessment factors and the current maturity levels were used to create five Importance-Performance Analysis (IPA) matrices, as illustrated in Figure 3. Each standard clause was represented in a two-dimensional space, with the horizontal axis denoting importance (weights calculated for each assessment factor), and the vertical axis representing performance (maturity level). The matrices were divided into four decision zones: (i) appropriate, (ii) improve, (iii) urgent action, and (iv) excess [24]. Through the IPA matrices, the LEB's managers were able to identify the situation of the associated factors in each assessment dimension regarding the four decision zones. The visual matrices facilitated a comprehensive understanding of areas that require focus and improvement and those where the LEB is performing well.

6. Discussion

The proposed framework can be descriptive, prescriptive, and potentially comparative, as per the classification suggested by De Bruin et al. [20]. As a descriptive model, it can be used to assess the current maturity level of a given laboratory according to the requirements of the ISO/IEC 17025:2017 standard. Additionally, the model can be prescriptive, as the managerial information generated in the IPA matrices can be employed to establish targets and action plans, preparing the Laboratory for accreditation or continuous improvement (see illustrative example in Figure 3).

As discussed in Section 2, several empirical studies on adopting the ISO/IEC 17025:2017 standard in different countries, published from 2010 to 2023, were reviewed [3-17]. However, the model proposed here is original, as no previous study on this subject has developed a multicriteria framework to assess the maturity of testing and calibration laboratories, integrating two decision-making methods: (i) the Analytic Network Process (ANP) [23], and (ii) the Importance-Performance Analysis (IPA) [24].

Despite the results obtained, three limitations can be identified in this research, namely: (i) the application of the conceptual framework was conducted in a single laboratory; (ii) the consensual meetings during the empirical study were limited to three senior leadership representatives; (iii) the use of fuzzy logic could have been applied during the meetings to avoid bias in judgments.

For future studies, as a natural extension of the present research and to further explore its results, we suggest: (i) conducting multiple case studies involving other laboratories in the country to compare the results of self-assessment processes and identify opportunities for improving the proposed framework; (ii) using fuzzy logic in stages 3 and 6 to avoid bias in judgments (see items 4.3 and 4.6); (iii) continuously improving practices related to the five clauses of the standard integrated into the analytical network-structure of the framework, and disseminating best laboratory practices at local, national, or international meetings; and (iv) developing a computational tool based on the proposed framework, to facilitate future replication in other testing and calibration laboratories interested in obtaining accreditation.

7. Final remarks

This paper aims to propose a multicriteria conceptual framework based on the ISO/IEC 17025:2017 standard for assessing the maturity of testing and calibration laboratories, integrating the Analytic Network Process (ANP) and the Importance-Performance Analysis (IPA) methods. The combined use of these methods can help laboratories define action plans to enhance their competence and improve impartiality and consistent operation, aligning with the introductory contents of the referred standard [2]. The present work has successfully achieved its objectives and establishes a foundation for more comprehensive future research, given that the proposed framework was initially applied in a single laboratory in Brazil. Following this initial demonstration, we intend to continue using the proposed model in other testing and calibration laboratories to compare the results.

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