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Article

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Administrative Sciences

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Suggested Citation: Panagiotidou, Evangelia; Chountalas, Panos T.; Magoutas, Anastasios I.; Georgakellos, Dimitrios A.; Lagodimos, Athanasios G. (2025) : Systematic identification and validation of critical success factors for ISO/IEC 17025 implementation, *Administrative Sciences*, ISSN 2076-3387, MDPI, Basel, Vol. 15, Iss. 2, pp. 1-30, <https://doi.org/10.3390/admsci15020060>

This Version is available at:

<https://hdl.handle.net/10419/321204>

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Article

Systematic Identification and Validation of Critical Success Factors for ISO/IEC 17025 Implementation

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Abstract: In the broader context of quality management, testing and calibration laboratories are increasingly adopting ISO/IEC 17025 accreditation as a key benchmark for achieving operational excellence. This management system standard outlines the essential requirements laboratories must meet to demonstrate their technical competence and produce accurate, reliable results. This study aims to identify and validate the Critical Success Factors (CSFs) for effective ISO/IEC 17025 implementation. It begins with a systematic literature review focusing primarily on ISO/IEC 17025, supplemented by insights from other established standards such as ISO 9001 and ISO 14001 to enrich the findings. This study employed an interview-based qualitative approach to validate and refine the identified CSFs. This entailed conducting 34 semi-structured interviews with a diverse group of industry professionals—including technical managers, quality managers, auditors, and clients—from calibration, chemical, and civil engineering testing laboratories. The findings led to the establishment of 16 CSFs, including leadership and strategic commitment, motivation for accreditation, allocation of financial and organizational resources, and the provision of technical infrastructure. Also crucial are the management of human resources—competency, training, and engagement—and key quality management elements such as effective system design, method verification, measurement traceability, quality assurance, control, and performance improvement. Additional factors include fostering a quality-oriented culture, ensuring operational integrity and impartiality, managing supplier relationships, focusing on customer needs, and adhering to regulatory compliance. Recognizing these CSFs enables organizations to focus on pivotal areas, streamline monitoring processes, and align with strategic objectives. This study represents the first in-depth exploration into the CSFs for ISO/IEC 17025 implementation within testing and calibration laboratories, thereby contributing directly to enhancing their quality and operational performance.



Received: 29 October 2024

Revised: 15 January 2025

Accepted: 8 February 2025

Published: 13 February 2025

Citation: Panagiotidou, E., Chountalas, P. T., Magoutas, A. I., Georgakellos, D. A., & Lagodimos, A. G. (2025). Systematic Identification and Validation of Critical Success Factors for ISO/IEC 17025 Implementation. *Administrative Sciences*, 15(2), 60. <https://doi.org/10.3390/admsci15020060>

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Keywords: ISO/IEC 17025; accreditation; critical success factors; calibration laboratories; testing laboratories; civil engineering laboratories; chemical laboratories; technical competence; quality assurance; operational integrity

1. Introduction

Success in competitive markets is influenced by various factors, including product quality, market speed, and competitor capabilities (Soh & Markus, 1995). To ensure high-quality services or products, organizations increasingly prioritize comprehensive quality

management systems (Chountalas et al., 2020; Rodriguez-Arnaldo & Martínez-Lorente, 2021). By adhering to quality standards, they aim to achieve goals such as improving product or service quality, streamlining internal structures, enhancing productivity, and increasing customer satisfaction (Abdel-Fatah, 2010; Zgirkas et al., 2021; Zhang & Xia, 2013). Consequently, many organizations seek certifications based on internationally recognized quality standards (Abdel-Fatah, 2010; Bernardo et al., 2012; Chountalas & Lagodimos, 2019). According to Powell (1995), quality management is a crucial strategic force in the modern industrial economy. Additionally, quality management systems promote continuous improvement and provide essential qualifications for survival in competitive environments (Antunes et al., 2017; Martínez-Costa & Martínez-Lorente, 2008; Shafiq et al., 2019).

Within the field of quality management, testing and calibration laboratories are increasingly seeking ISO/IEC 17025 (ISO/IEC, 2017) accreditation as an essential standard for operational excellence (Krismastuti & Habibie, 2022; Mandal et al., 2021; Panagiotidou et al., 2024; Sari & Nurcahyo, 2018). These laboratories play a critical role in quality control and assurance of material performance by testing raw materials and finished products, and society is impacted by potential non-conformances that may arise (Ayub et al., 2021). Furthermore, Ayub et al. (2021) noted that inadequate verification of materials can lead to non-conformances during operation or result in health and safety issues. If final products are not verified, customer dissatisfaction may occur. ISO/IEC 17025 specifies the essential criteria that laboratories must meet to demonstrate their technical competence in performing accurate and repeatable measurements (Halevy, 2003; Hemraj & Dhondee, 2006).

In recent years, accreditation has become a legal requirement for laboratories to gain market acceptance for their measurements. International agreements on mutual recognition of accreditation have increased its application in regulated sectors like construction, hazardous materials, medical devices, and testing services, facilitating global quality control. By committing to quality, laboratories can improve their technical capabilities, enhance measurement accuracy, and seek global recognition (Karthiyayini & Rajendran, 2017). Testing and calibration laboratories that provide specialized services must validate their technical staff's credentials, typically through ISO/IEC 17025 accreditation (Cortez, 1999; Khodabocus & Balgobin, 2011). To demonstrate impartiality, independence, and technical adequacy, they must also be accredited under ISO/IEC 17025 (Papadakis et al., 2017). Furthermore, in a competitive environment, ISO/IEC 17025 has shifted from a voluntary standard to a competitive necessity, and in certain fields, such as calibration laboratories, it is a prerequisite for business sustainability (Barradas & Sampaio, 2017; Grochau & ten Caten, 2012).

Several technical and managerial factors are crucial for the successful implementation of ISO/IEC 17025. While previous research has intermittently and selectively identified certain factors associated with the ISO/IEC 17025 standard (Al-mijrab et al., 2019; Ilieva et al., 2022; Karthiyayini & Rajendran, 2017; Khodabocus & Balgobin, 2011; Mahdi et al., 2021; Martínez-Perales et al., 2021), these studies often focus narrowly on isolated aspects without capturing the full range of factors necessary for successful implementation. This fragmented approach differs significantly from the systematic methodologies employed in studies of more widely adopted standards like ISO 9001 (ISO, 2015a) and ISO 14001 (ISO, 2015b), which tend to offer a holistic view of CSFs. Consequently, there exists a significant gap in the literature regarding a full and systematic identification of all relevant factors critical for the effective implementation of ISO/IEC 17025. This gap underscores the need for comprehensive research, as also highlighted by Al-mijrab et al. (2019), to better understand what drives successful ISO/IEC 17025 implementation.

The primary objective of this study is to address the existing gap by identifying the CSFs essential for the effective implementation of ISO/IEC 17025 in testing and calibration laboratories, ultimately leading to sustained high-quality performance. This research marks a novel effort to conduct a thorough and systematic exploration of both generic and ISO/IEC 17025-specific CSFs, distinguishing it as the first comprehensive study focused explicitly on this standard. By outlining these factors, the study aims to address the existing gap and contribute significantly to the literature on management system standards.

The study begins with a systematic literature review to identify the CSFs that facilitate the optimal implementation of Management System Standards. To compensate for the limited comprehensive research on ISO/IEC 17025, where most studies have focused on individual factors influencing its implementation, the current review also includes insights from other established standards such as ISO 9001 and ISO 14001. Additionally, this study employs a qualitative methodology to validate the identified CSFs, utilizing data gathered through semi-structured interviews with subject matter experts across three laboratory sectors: calibration, chemical, and civil engineering testing laboratories. To provide a holistic understanding, this investigation includes perspectives from a diverse range of stakeholders within each sector, including technical managers, quality managers, auditors, and clients.

The remainder of this paper is organized as follows. Section 2 provides a comprehensive review of the existing literature, analyzing the CSFs for the prominent implementation of Management System Standards ISO/IEC 17025, ISO 9001, and ISO 14001. Section 3 outlines the qualitative research methodology employed, with an emphasis on data collection and analysis techniques. Section 4 details the findings obtained from the qualitative analysis, and Section 5 presents the conclusions drawn from the gathered evidence, emphasizing the study's research contributions and broader implications.

2. Literature Review

This section provides a comprehensive synthesis of the existing literature on the CSFs for the effective implementation of ISO/IEC 17025 in testing and calibration laboratories. Due to the limited number of systematic studies focused on identifying the CSFs for this standard, this literature review also includes CSFs related to ISO 9001 and ISO 14001 to enrich and support the findings.

The literature review methodology employed a three-step process. Initially, articles were sourced from the Scopus database using keyword combinations such as "ISO/IEC 17025" OR "ISO 9001" OR "ISO 14001" alongside "Critical Success Factors" in the titles, abstracts, or keywords of the articles. The second step involved a qualitative evaluation to eliminate articles that were not pertinent to the research topic. Finally, forward and backward citation tracking, as suggested by [Webster and Watson \(2002\)](#), was utilized to enrich the dataset.

Given the specific focus of this study, priority was given to articles on ISO/IEC 17025; as a result, every relevant article identified (totaling 25) was included in our dataset. Considering the extensive literature on ISO 9001 and ISO 14001, a selective approach was employed, incorporating only significant works (17 articles) until additional articles no longer provided new insights, thereby reaching the point of saturation. This selection approach, resulting in a final dataset of 42 articles, enhanced the depth and relevance of the analysis while maintaining a manageable review scope.

2.1. Critical Success Factors for the Implementation of ISO/IEC 17025

The research conducted by [Karthiyayini and Rajendran \(2017\)](#) on testing and calibration laboratories across various sectors in India highlighted the significant impact of six

CSFs on the reliability and validity of their measurements. The study identified essential factors influencing laboratory reputation, service quality, and client loyalty, including top management's commitment to quality policy, customer focus, an adequate technical system, quality-oriented process management, a monitoring system for continuous improvement, and the competence of personnel. Notably, the commitment of top management is strongly correlated with laboratory performance. The findings indicate that top management plays a crucial role in overseeing the entire quality system and addressing customer issues, a perspective corroborated by researchers such as [Al-mijrab et al. \(2019\)](#), [Gharibi and Abdullah \(2017\)](#), [Panhwar et al. \(2020\)](#), and [Khodabocus and Balgobin \(2011\)](#). [Karthiyayini and Rajendran \(2017\)](#) further emphasize that while top management is mandated by ISO/IEC 17025, the level of managerial commitment must be continuously evaluated due to its influence on overall processes. Additionally, increased customer focus is associated with attracting new clients. These findings align with the research by [Sadikoglu and Temur \(2012\)](#) across various testing laboratories, which underscored the importance of top management in enhancing employee satisfaction, measurement reliability, quality performance, and customer satisfaction. Top management's commitment to quality is essential for providing adequate resources and motivating employee engagement in quality initiatives. Furthermore, training can enhance awareness and commitment to delivering high-quality services. A shared understanding of accreditation is critical for maximizing its benefits. Similarly, studies by [Khodabocus and Balgobin \(2011\)](#) and [Grochau and ten Caten \(2012\)](#) indicate that individual commitment is a key factor for successfully implementing a quality management system based on ISO/IEC 17025. This perspective is also supported by [Martínez-Perales et al. \(2021\)](#), in the context of testing research laboratories.

[Al-mijrab et al. \(2019\)](#) argued that identifying CSFs enables laboratories to concentrate on primary issues, facilitates monitoring, and serves strategic planning methodologies. They emphasized the necessity of ongoing training for all personnel at every level, as achieving a comprehensive understanding of quality processes among all teams can lead to full compliance with quality standards, a view supported by [Panhwar et al. \(2020\)](#) and [Gerônimo et al. \(2020\)](#). [Panhwar et al. \(2020\)](#) proposed that to enhance the quality system's effectiveness, an evaluation mechanism should be implemented based on key criteria such as documentation and equipment. Additionally, understanding standard requirements and applying indicators and quality indexes to assess laboratory performance is recognized as a significant tool for continuous improvement ([Catiní et al., 2015](#); [Manickam & Ankanagari, 2015](#)).

[Gharibi and Abdullah \(2017\)](#) emphasized the necessity of cultivating a quality culture within organizations, which significantly influences the operational performance of laboratories. They also noted the critical role of department heads in selecting appropriate personnel for specific tasks. In line with these findings, [Gerônimo et al. \(2020\)](#) conducted a study in an environmental laboratory at the State University of Maringá, Brazil, and found that the organizational culture was crucial for the effective implementation of quality systems; without the awareness and engagement of all staff, the adoption of standards is impractical. Further supporting this, [Piton et al. \(2021\)](#) conducted quantitative analysis in Indonesian testing laboratories, identifying human resources as a key factor in maintaining compliance with ISO/IEC 17025 requirements. Additionally, [de Jesus et al. \(2023\)](#) and [Sari and Nurcahyo \(2018\)](#) highlighted the necessity of both technical and managerial skills for the successful implementation of quality systems. The integration of both managerial and technical competencies is essential for laboratories to effectively achieve their operational goals.

[Mahdi et al. \(2021\)](#) expanded on previous findings related to the construction laboratories sector, identifying key factors for implementing ISO/IEC 17025. These factors

include financial support from top management, training, equipment calibration and repair, consulting, implementation, and review processes. Additionally, the commitment of top management and staff involvement were highlighted as essential for success. Examining various sectors of accredited laboratories in Israel, [Halevy \(2003\)](#) identified several parameters critical to the successful implementation of quality systems, such as failure investigations, fostering a positive laboratory atmosphere, effective internal communication, customer focus, measurement validation, calibration, and participation in proficiency testing. [Ghernaout et al. \(2018\)](#) provided a unique perspective on the potential of Big Data Analysis for managing laboratory accreditation activities. Lastly, significant health and safety factors were emphasized in the research conducted by [Ratseou and Ramphal \(2014\)](#), [Piton et al. \(2021\)](#), and [Abreu et al. \(2018\)](#).

Another important aspect discussed in the literature is the role of human involvement in understanding and meeting the requirements for effective standards implementation. Identifying the key factors that are most responsive is essential, especially when positive outcomes are hindered by a lack of impartiality and independence in a laboratory. [Gordon and Fomin \(2019\)](#) argue that standardization and ethics are interconnected; ethics cannot exist without standards, and standardization cannot occur without ethics. In this context, [Sadikoglu and Temur \(2012\)](#) noted that improper motivations for accreditation can result in negative outcomes, such as questionable and unsatisfactory measurements. They recommend that accreditation bodies and laboratories focus on ethics, quality, and improvement initiatives to enhance the impartiality and quality of audits, thereby increasing the reliability and accuracy of laboratory measurements.

[Doyle \(2024\)](#) emphasizes that maintaining scientific integrity is a critical factor in laboratory operations. ISO/IEC 17025 highlights the importance of ensuring the validity and verification of results. However, the effectiveness of these requirements depends on the integrity and competence of laboratory personnel. While integrity is primarily an individual attribute, it also reflects the values of the organization. ISO/IEC 17025 focuses on organizational standards and provides limited guidance on individual behavior, stressing the need for staff to demonstrate impartiality and competence. Consequently, it is the organization's responsibility to define the expectations for honesty and ethical behavior within staff competency criteria and to implement effective monitoring systems to ensure compliance. In their research, [Dror and Pierce \(2020\)](#) found that even with appropriate management actions to control risks relating to impartiality, barriers may impede their implementation. Forensic service providers often face challenges due to their close relationships with stakeholders, which can complicate decision-making, particularly when political factors influence agency sustainability. Despite these challenges, it is essential to take proactive measures to comply with relevant ISO standards. Furthermore, in the context of food safety management systems, [Samoilichenko et al. \(2022\)](#) argue that international standards and guidelines do not explicitly require documentation of impartiality, leading to ambiguity and inconsistency in evidence between conformity assessment bodies and their supervisors. This lack of impartiality can potentially undermine the entire quality management framework. Ethics and impartiality are interconnected within a quality system; without ethical considerations, the benefits of a well-implemented quality system may be diminished, even if it adheres to its CSFs.

2.2. Critical Success Factors for the Implementation of ISO 9001 and ISO 14001

Previous research on ISO 9001 indicates that several factors are essential for the effective implementation and maintenance of a quality management system. These factors include commitment and support from top management and the active participation of employees in the implementation process ([Ingason, 2015](#)). These findings align with the

conclusions of [Zwane et al. \(2021\)](#), [de Guzman Santos \(2022\)](#), and [Carneiro et al. \(2021\)](#). Furthermore, [Ingason \(2015\)](#) conducted a qualitative study involving 21 organizations across various business sectors in Iceland, highlighting thorough preparation and clear goal setting as crucial for success. Additionally, [Carneiro et al. \(2021\)](#) emphasized the importance of customer satisfaction and supplier selection in enhancing the performance of Brazilian firms following ISO 9001 certification.

The study by [Boiral \(2011\)](#) examined various sectors of certified organizations, including those complying with ISO 9001 standards in both industrial and service contexts, as well as industrial organizations accredited under ISO 14001. The research identified four critical factors. The first factor is the motivation behind ISO certification; the findings indicate that pursuing commercial certification often exacerbates issues identified after the certification process, aligning with the findings of [Sadikoglu and Temur \(2012\)](#) regarding ISO/IEC 17025 accredited laboratories, suggesting that inadequate motivation for accreditation can lead to negative outcomes such as unreliable and unsatisfactory measurements. Other significant factors identified by [Boiral \(2011\)](#) include the adaptation of standards to the organization's internal structures and practices, employee involvement, and the firm's commitment to the principle of continual improvement. These findings are also consistent with the research of [Kim et al. \(2011\)](#), which emphasized the importance of organizations tailoring ISO 9001 requirements to align with their objectives and strategies for effective implementation of the standard. Organizations that do not customize these requirements may face employee resistance and find them incompatible with their existing systems.

[Ab Wahid and Corner \(2009\)](#) identified that managerial commitment and employee involvement as the primary CSFs for maintaining ISO 9001 certification. This finding aligns with the research conducted by [Heras-Saizarbitoria \(2011\)](#). Additionally, [Ab Wahid and Corner \(2009\)](#) emphasized the importance of teamwork, reward systems, communication, performance measurement, and understanding of the standard. These points are further supported by the findings of [de Guzman Santos \(2022\)](#). Ultimately, they concluded that the continuous improvement of processes, personnel, and systems is essential for sustaining quality management systems, allowing organizations to progress, grow, and remain competitive. This assertion is further validated by the study conducted by [Zwane et al. \(2021\)](#).

In their study of ISO 9001 certified Greek companies across various sectors, [Ismyrlis et al. \(2015\)](#) concluded that the key elements for effective quality implementation are management, training, resources, and customer focus. Similarly, [Khan et al. \(2021\)](#) highlighted the significance of training for employees and administrative staff. [Kafetzopoulos and Gotzamani \(2014\)](#) identified three critical factors for the success of ISO 9001: employee attributes, organizational attributes (including equipment, processes, and production technology), and internal motivation for certification. Additionally, [Psomas et al. \(2010\)](#) identified further essential factors such as sufficient financial resources, time management, and documentation management for system implementation, along with an awareness of external market conditions relevant to the company's operations. [Sweis et al. \(2022\)](#) specifically emphasized the importance of preventing non-conformance, as well as training and maintaining customer focus. [Briscoe et al. \(2005\)](#) argued that success is largely dependent on a quality-oriented approach, which includes fostering a culture of quality, minimizing behaviors that obstruct ISO 9001 adoption, conducting readiness assessments to tailor the standard's program to company needs, and leveraging a dynamic environment to enhance quality awareness.

2.3. Synthesis of Critical Success Factors Across ISO Management System Standards

This section synthesizes the CSFs identified for the efficient implementation of ISO management system standards, specifically ISO/IEC 17025, ISO 9001, and ISO 14001, as

explored in the preceding sections of this literature review. To facilitate deeper analysis, the individual factors identified from the literature are consolidated into sixteen overarching CSFs. Table 1 presents these CSFs and lists corresponding references from the literature on ISO/IEC 17025 alongside those on ISO 9001 and ISO 14001.

Table 1. Critical success factors across ISO management system standards.

Critical Success Factors	ISO/IEC 17025 Literature References	ISO 9001 and ISO 14001 Literature References
CSF 1: Leadership and strategic commitment	(Al-mijrab et al., 2019; de Jesus et al., 2023; Gerônimo et al., 2020; Gharibi & Abdullah, 2017; Grochau & ten Caten, 2012; Ilieva et al., 2022; Karthiyayini & Rajendran, 2017; Khodabocus & Balgobin, 2011; Mahdi et al., 2021; Martínez-Perales et al., 2021; Panhwar et al., 2020; Sadikoglu & Temur, 2012; Sari & Nurcahyo, 2018)	(Ab Wahid & Corner, 2009; Boiral, 2011; Carneiro et al., 2021; de Guzman Santos, 2022; Ingason, 2015; Ismyrlis et al., 2015; Ivanova et al., 2014; Khan et al., 2021; Kim et al., 2011; Magd, 2010; Psomas et al., 2010; Zwane et al., 2021)
CSF 2: Motivation for accreditation	(Sadikoglu & Temur, 2012)	(Psomas et al., 2010)
CSF 3: Financial and organizational resources	(Al-mijrab et al., 2019; Ilieva et al., 2022; Mahdi et al., 2021; Panhwar et al., 2020; Sadikoglu & Temur, 2012)	(Ismyrlis et al., 2015; Kim et al., 2011; Psomas et al., 2010; Zwane et al., 2021)
CSF 4: Technical resources and infrastructure	(Belezia & de Almeida, 2021; Grochau & ten Caten, 2012; Karthiyayini & Rajendran, 2017; Mahdi et al., 2021; Sari & Nurcahyo, 2018)	(Kafetzopoulos & Gotzamani, 2014; Psomas et al., 2010)
CSF 5: Human resources management and competency	(Belezia & de Almeida, 2021; de Jesus et al., 2023; Gharibi & Abdullah, 2017; Karthiyayini & Rajendran, 2017; Khodabocus & Balgobin, 2011; Martínez-Perales et al., 2021; Sari & Nurcahyo, 2018)	(Psomas et al., 2010)
CSF 6: Human resources training and development	(Al-mijrab et al., 2019; Catini et al., 2015; Gerônimo et al., 2020; Ilieva et al., 2022; Karthiyayini & Rajendran, 2017; Khodabocus & Balgobin, 2011; Mahdi et al., 2021; Manickam & Ankanagari, 2015; Martínez-Perales et al., 2021; Panhwar et al., 2020; Piton et al., 2021; Ratseou & Ramphal, 2014; Sadikoglu & Temur, 2012)	(Boiral, 2011; de Guzman Santos, 2022; Ismyrlis et al., 2015; Kafetzopoulos & Gotzamani, 2014; Khan et al., 2021; Kim et al., 2011; Magd, 2010; Psomas et al., 2010; Sweis et al., 2022; Zwane et al., 2021)
CSF 7: Human resources engagement	(Abdel-Fatah, 2010; Al-mijrab et al., 2019; de Jesus et al., 2023; Gerônimo et al., 2020; Grochau & ten Caten, 2012; Halevy, 2003; Ilieva et al., 2022; Khodabocus & Balgobin, 2011; Mahdi et al., 2021; Manickam & Ankanagari, 2015; Martínez-Perales et al., 2021; Panhwar et al., 2020)	(Ab Wahid & Corner, 2009; Boiral, 2011; Carneiro et al., 2021; de Guzman Santos, 2022; Heras-Saizarbitoria, 2011; Ingason, 2015; Ismyrlis et al., 2015; Ivanova et al., 2014; Kafetzopoulos & Gotzamani, 2014; Kim et al., 2011; Magd, 2010; Psomas et al., 2010; Zwane et al., 2021)

Table 1. *Cont.*

Critical Success Factors	ISO/IEC 17025 Literature References	ISO 9001 and ISO 14001 Literature References
CSF 8: Quality management system design	(Al-mijrab et al., 2019; de Jesus et al., 2023; Ghernaout et al., 2018; Halevy, 2003; Ilieva et al., 2022; Mahdi et al., 2021; Martínez-Perales et al., 2021; Sari & Nurcahyo, 2018)	(Boiral, 2011; Heras-Saizarbitoria, 2011)
CSF 9: Verification of methods and traceability of measurements	(Belezia & de Almeida, 2021; Grochau & ten Caten, 2012; Halevy, 2003; Khodabocus & Balgobin, 2011; Mahdi et al., 2021; Sari & Nurcahyo, 2018)	-
CSF 10: Quality assurance and control	(Catini et al., 2015; Halevy, 2003; Karthiyayini & Rajendran, 2017; Khodabocus & Balgobin, 2011; Mahdi et al., 2021; Panhwar et al., 2020; Sari & Nurcahyo, 2018)	(de Guzman Santos, 2022; Heras-Saizarbitoria, 2011; Kafetzopoulos & Gotzamani, 2014; Kim et al., 2011; Magd, 2010; Psomas et al., 2010; Sweis et al., 2022; Zwane et al., 2021)
CSF 11: Performance management and improvement	(Al-mijrab et al., 2019; Catini et al., 2015; Ghernaout et al., 2018; Ilieva et al., 2022; Manickam & Ankanagari, 2015; Panhwar et al., 2020)	(Ab Wahid & Corner, 2009; Ingason, 2015; Ismyrlis et al., 2015; Ivanova et al., 2014; Kafetzopoulos & Gotzamani, 2014; Magd, 2010; Psomas et al., 2010; Zwane et al., 2021)
CSF 12: Quality-oriented organizational culture and working environment	(Al-mijrab et al., 2019; de Jesus et al., 2023; Gerônimo et al., 2020; Gharibi & Abdullah, 2017; Ilieva et al., 2022; Manickam & Ankanagari, 2015; Martínez-Perales et al., 2021; Piton et al., 2021; Sadikoglu & Temur, 2012)	(Ab Wahid & Corner, 2009; Boiral, 2011; Briscoe et al., 2005; de Guzman Santos, 2022; Denton & Maatgi, 2016; Ismyrlis et al., 2015; Ivanova et al., 2014; Kafetzopoulos & Gotzamani, 2014; Khan et al., 2021; Kim et al., 2011; Magd, 2010; Psomas et al., 2010; Sweis et al., 2022; Zwane et al., 2021)
CSF 13: Operational integrity and impartiality	(Doyle, 2024; Dror & Pierce, 2020; Sadikoglu & Temur, 2012)	-
CSF 14: Supplier management	(Belezia & de Almeida, 2021)	(Ismyrlis et al., 2015)
CSF 15: Customer focus	(Catini et al., 2015; Gharibi & Abdullah, 2017; Halevy, 2003; Karthiyayini & Rajendran, 2017, 2021; Panhwar et al., 2020; Ratseou & Ramphal, 2014)	(Carneiro et al., 2021; Ismyrlis et al., 2015; Kim et al., 2011; Psomas et al., 2010; Sweis et al., 2022; Zwane et al., 2021)
CSF 16: Regulatory compliance and external factors	(Abreu et al., 2018; Al-mijrab et al., 2019; Ilieva et al., 2022; Piton et al., 2021; Ratseou & Ramphal, 2014)	(Sweis et al., 2022; Zwane et al., 2021)

This literature review indicates that the CSFs of the management systems ISO 9001, ISO 14001, and ISO/IEC 17025 share notable similarities, with no significant differences identified. Although these standards originate from different fields and have typically been studied by various researchers, their fundamental management principles and excellence mechanisms align closely. However, exceptions exist, such as the CSFs “operational integrity and impartiality” and “verification of methods and traceability of measurements”, which are absent from the literature concerning ISO 9001 and ISO 14001. This discrepancy

ancy can be attributed to the specific focus of ISO/IEC 17025 on laboratory environments, placing a higher emphasis on technical precision and unbiased results. In contrast, while focusing on broader quality and environmental management systems respectively, ISO 9001 and ISO 14001 do not specifically prioritize laboratory operational protocols or the technical specifics of testing and calibration processes.

To highlight the contributions of each article to this analysis, Tables A1 and A2 in Appendix A present the specific CSFs identified in each study. A notable observation from this compilation is that only a limited number of studies on the CSFs for ISO/IEC 17025 encompass multiple CSFs. Even fewer examine the implications of impartiality, integrity, and independence within the laboratory, which are essential for maintaining the integrity of the quality system according to ISO/IEC 17025.

3. Methodology

The primary goal of this study is to identify and validate the CSFs that contribute to the successful implementation of ISO/IEC 17025 in testing and calibration laboratories, thereby directly improving the quality and reliability of laboratory measurements. The methodology builds upon the foundations established by the systematic literature review of CSFs, detailed in Section 2, and employs an interview-based qualitative approach to further validate these factors. Validation is essential for two main reasons. Previous research has not comprehensively identified the CSFs for ISO/IEC 17025, necessitating a validation process to ensure the completeness of the CSF list compiled from various individual studies. Additionally, as detailed in Section 2, the literature on ISO 9001 and ISO 14,001 was incorporated to augment the initial findings from the ISO/IEC 17025 literature. However, the applicability of CSFs from these standards to ISO/IEC 17025 is not assured. Therefore, further validation is crucial to confirm the relevance of all identified CSFs to the specific context of ISO/IEC 17025.

3.1. Data Collection

The qualitative approach in this study involved conducting 34 semi-structured interviews with subject matter experts from three laboratory sectors in Greece: civil engineering testing laboratories (including concrete, soil mechanics, and metallurgy), chemical laboratories (including environmental, fuel, microbiological, and analytical chemistry), and calibration laboratories. The sampling strategy was purposive, selecting participants based on their extensive involvement with ISO/IEC 17025 implementation. This ensured that individuals included in the study had deep operational knowledge and could provide insights on the CSFs for accreditation.

To ensure a comprehensive understanding, the sample included diverse stakeholders within each sector, as outlined in Table 2. Specifically, the interviews encompassed eleven technical or quality managers from civil engineering testing laboratories and five from chemical laboratories. The calibration sector was represented by five technical managers from accredited calibration laboratories. Additionally, one internal auditor with experience in inspecting the quality systems of all three laboratory sectors participated in the study. All technical and quality managers had over ten years of experience in their respective laboratories and in implementing ISO/IEC 17025. This depth of experience was instrumental in capturing the complex challenges and opportunities in meeting accreditation requirements. To incorporate the client's perspective, the sample included eight professionals from the civil engineering sector and four clients of calibration laboratories. Their inclusion was deliberate to gather feedback on specific CSFs, such as impartiality and client-imposed pressures, thereby broadening the understanding of client-laboratory interactions. Fifteen interviews were carried out face-to-face, two through web conferencing, and seventeen

over the phone. The duration of each interview ranged from 40 to 120 min. Detailed profiles of the participants are provided in Appendix A, Table A3.

Table 2. Participant profiles.

Number	Role	Professional Background
7	Technical Directors and/or Quality Managers in Accredited Testing Laboratories (T-Labs 1, 2, 3, 5, 9, 10, 11).	Permanent employees with over 12 years of experience, serving in four distinct civil engineering testing laboratories.
2	Technical Directors and/or Quality Managers in Accredited Testing Laboratories (T-Labs 7, 8), also serving as External Auditors.	Professionals with over 12 years of experience in civil engineering testing laboratories, also serving as external auditors.
1	Multifaceted Technical Supervisor and Quality Consultant in Accredited Testing Laboratory (T-Lab 6).	Specialist with over 25 years of experience, consulting across various sectors in civil engineering testing laboratories.
1	Technical Supervisor in Certified, Non-Accredited Testing Laboratory (T-Lab 4).	Permanent employee in soil mechanics, with over 20 years of industry experience.
5	Technical Supervisors/Directors and/or Quality Managers in Accredited Chemical Testing Laboratories (Chem-Lab 1, 2, 3, 4, 5).	Permanent employees with over 14 years of experience, across four distinct chemical testing laboratories.
5	Technical Supervisors/Directors and/or Quality Managers in Accredited Calibration Laboratories (C-Labs 1, 2, 3, 4, 5).	Permanent employees with over 12 years of experience across four distinct calibration laboratories.
1	Quality manager and experienced internal auditor in various sectors of laboratories—civil engineering, calibrations, and chemical laboratories (Int-Aud 1).	Permanent employee in an organization consisting of laboratories from various sectors.
6	Clients of Civil Engineering Testing Laboratories (T-Clients 1, 4, 5, 6, 7, 8).	Civil engineers engaged with testing and calibration laboratories for a minimum of 8 years.
2	Contractor Clients of Concrete Testing Laboratories (T-Clients 2, 3).	Contractors in concrete construction with a work history of at least 10 years in testing laboratories.
4	Clients of Calibration Laboratories (C-Clients 1, 2, 3, 4).	Quality managers from four different accredited testing laboratories, each with over 8 years of professional experience.

The interview protocol was formulated based on the findings from a comprehensive literature review, as outlined in Section 2. The questionnaire utilized for the semi-structured interviews with the laboratory professionals is presented in Appendix A, Table A4. Participants were encouraged to elaborate on key themes, thereby enhancing the dataset with deeper insights. In cases where interviewees encountered difficulty providing spontaneous responses, contextual information from the literature was offered to facilitate their responses. Detailed notes were recorded during each interview. Furthermore, at the conclusion of each interview, a summary of essential points was compiled and reviewed with the respondent to ensure accuracy and reliability.

3.2. Data Analysis

To analyze the data collected from the interviews, we employed Braun and Clarke's (Braun & Clarke, 2006) thematic analysis, a qualitative research method recognized for its adaptability and effectiveness in identifying, analyzing, and reporting patterns within data. This approach is particularly effective for examining the subjective experiences, perspectives, and emotions of interviewees, which are essential to our research on the implementation of ISO/IEC 17025. To support this analytical process, we utilized MAXQDA software, a specialized tool designed for computer-assisted qualitative data analysis.

In the initial familiarization phase, each transcript was thoroughly read multiple times to gain a comprehensive understanding of the content, which facilitated the initial identification of ideas and potential themes. This deep engagement with the data ensured a comprehensive grasp of its depth and complexity. During the coding stage, data extracts were systematically coded at a granular level without trying to fit it into a preexisting coding frame. This inductive approach allowed emergent codes to be identified purely from the data. Codes such as "leadership commitment to quality" and "balanced resource allocation" were carefully applied to relevant data segments. Following coding, we began searching for themes by collating all relevant coded data extracts and sorting them into potential themes. This involved a recursive process of refinement; themes were developed and reviewed, ensuring they related coherently to the coded extracts and formed a meaningful pattern. The themes were then reviewed on two levels: first, by checking whether they worked in relation to the coded extracts (internal homogeneity), and second, by ensuring clear distinctions between themes (external heterogeneity). This review process was critical in order to validate the accuracy of the themes. In the penultimate stage, themes were defined and named. This involved refining the specifics of each theme and the overall narrative they conveyed about the data. Themes were aligned with the identified CSFs to ensure a coherent narrative that accurately reflected the study's objectives. In the final stage, we examined the underlying reasons for the identified themes, integrating the analysis with the existing literature on ISO/IEC 17025 implementation. We ensured that the themes supported the CSFs and provided insights into their significance.

To assess the adequacy of our sample size, we applied the principle of "theoretical saturation" as defined by Guest et al. (2006). Saturation was achieved when additional interviews did not yield new themes or information. In our dataset, we identified a saturation point where new participant responses did not introduce any new elements within the CSF categories.

To ensure the validity of our findings, we employed several strategies. The coding process was iterative, involving multiple rounds of coding by different team members to cross-verify the application of codes and themes. This triangulation method reduced researcher bias and enhanced reliability. Additionally, we maintained a comprehensive audit trail that documented all decisions made during the research process, enhancing transparency and traceability, further reinforcing the validity of our results.

Figure 1 outlines the hierarchical arrangement of themes and codes, providing a visual representation of the study's thematic structure.

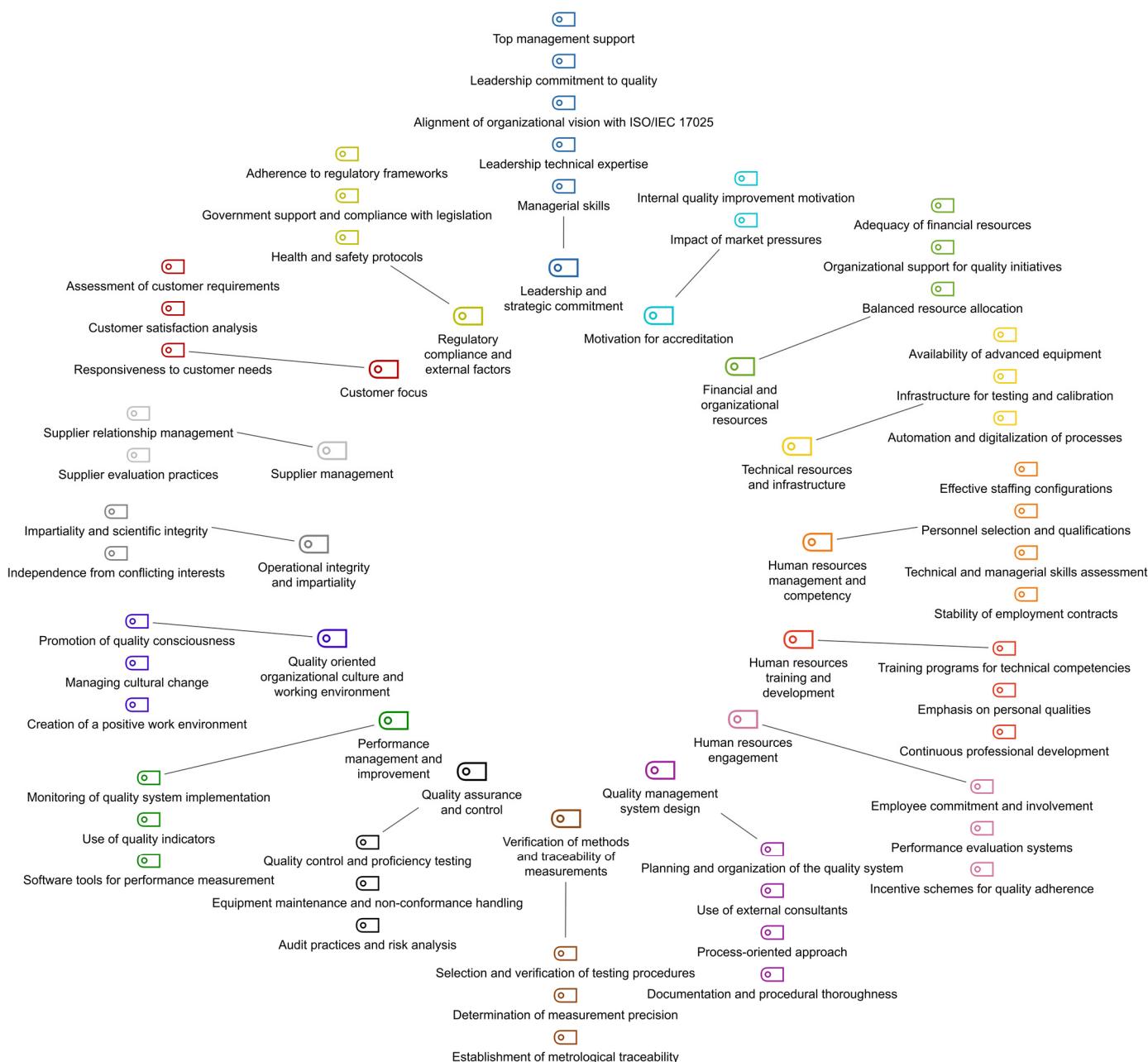


Figure 1. Hierarchical themes—codes framework.

4. Results

In this section, we present the findings from thematic analysis. For enhanced readability and interpretive clarity, participants in the thematic analysis are organized into six groups:

- Testing Laboratories (11 participants): Designated as “T-Labs”;
- Chemical Testing Laboratories (5 participants): Designated as “Chem-Labs”;
- Calibration Laboratories (5 participants): Designated as “C-Labs”;
- Internal auditor (1 participant): Designated as “Int-Aud”;
- Clients of Testing Laboratories (8 participants)—Designated as “T-Clients”;
- Clients of Calibration Laboratories (4 participants)—Designated as “C-Clients”.

A consensus among respondents from accredited testing and calibration laboratories highlighted the importance of support and commitment from top management to ensure the successful implementation of ISO/IEC 17025. The Quality Manager of Chem-Lab 1 noted,

"The effectiveness of the quality system and accreditation process relies on management support, which fosters a commitment that extends to all laboratory staff; the alignment of vision between the laboratory and top management is crucial". Similarly, the Technical Director of T-Lab 7 emphasized that "top management's dedication to quality is vital; without it, the entire quality system risks failure. It is essential for top management to not only endorse the quality system but also allocate necessary resources to enable the Quality Manager and technicians to fulfill their roles effectively".

During interviews, another significant theme that emerged was the impact of aligning the organization's vision and mission with the rigorous requirements of the quality system, alongside the leadership styles of the directors that reflect their unique characteristics and aspirations. The Head Director of T-Lab 11 pointed out that "when the organization's mission changes, employees must comply with new directives, even if they conflict with previous quality-focused practices. If the organization shifts its primary objective to profit maximization, the emphasis on quality culture may diminish". Supporting this view, the Technical Supervisor of T-Lab 5 recounted a transition in the laboratory's focus towards profit under the new director's vision, "resulting in insufficient allocation of resources, including time and personnel, which adversely affects compliance with quality system requirements". As a result, the integrity of measurements and accuracy of reporting are increasingly at risk when top management does not appreciate and support the implementation of quality processes. This situation places significant pressure on the technical supervisor, who faces the difficult choice of either concealing laboratory errors or yielding to client demands, both of which threaten the credibility of the results.

Most participants highlighted the crucial role of internal quality control measures implemented by laboratories, including participation in proficiency testing, internal quality testing, and the use of certified reference materials, in enhancing the repeatability, accuracy, and consistency of measurements. These quality control procedures provide rigorous quality assurance and ensure the repeatability of measurements. Effective quality control requires comprehensive quality assurance, which aids in error detection and performance improvement. In this context, the Technical Supervisor of T-Lab 5 stated, "Proficiency testing and internal checks are the pillars of our capability improvement". This view was also supported by the Technical Supervisor of Chem-Lab 3, who emphasized "the essential nature of certified reference materials, proficiency testing, standard reference materials, and internal quality control in the functioning of chemical laboratories". Within the quality management system CSFs, participants noted significant issues such as equipment calibration and maintenance, auditing, the existence of documented procedures, and effective organization. Participants' insights also revealed an issue not previously identified in the literature, namely, the frequency with which analysts perform specific types of tests. This issue highlights the significance of regular practice in the development and enhancement of technical competence.

Furthermore, participants universally highlighted the essential importance of utilizing appropriate equipment with the required accuracy to ensure the credibility of measurements. The Technical Supervisor of T-Lab 6 highlighted the need for "suitable (preferably modern) equipment, along with the availability of spare equipment, particularly for critical measurements". The Technical Supervisors of Chem-Lab 3 and Chem-Lab 4 agreed that possessing the latest or most expensive equipment is not always essential, as well-maintained equipment can perform just as effectively. In addition to suitable equipment, participants' insights identified a significant issue not previously noted in the literature, namely, the integration of automation in testing with simultaneous measurement recording. This issue was raised by most participants across various laboratory sectors, in relation to the aim of minimizing human error and thereby enhancing the impartiality of measurements. The

Technical Supervisor of T-Lab 6 elaborated that “the automation and recording of test results are critical for eliminating human influence. Mere accreditation does not ensure credibility; for example, in the case of concrete specimens of category C20/25, inadequate recording could lead to manipulated results. Only through a specific recording system can results be considered credible and immutable. Test results should be transmitted instantly to a central system to eliminate any potential for modification”. The Quality Manager of T-Lab 9 and the Technical Supervisor of T-Lab 10 stressed that digitalization and automatic recording of measurements, when applicable, save time, reduce error, and mitigate human factors such as mood, personality, fatigue, and workload. Supporting these views, the Quality Manager of C-Lab 1 noted, “automation and automatic recording of measurements are vital to prevent interference”. The Technical Supervisor of Chem-Lab 3, also backed by the Technical Supervisor of Chem-Lab 4, stated, “the automation of testing with fully automated equipment has been crucial in their chemical laboratory’s ability to withstand client pressure. The recording of results eliminates opportunities for manipulation, allowing the laboratory to maintain accuracy in its measurements despite external pressures”.

In relation to the impact of CSFs relating to human resources, most interviewees emphasized the importance of continuous training, employee incentives, commitment, awareness, and the recruitment of technically qualified personnel. Additionally, participants offered new insights that had not been previously documented in the literature, referring to the recruitment of experienced individuals who demonstrate essential character traits such as attentiveness, conscientiousness, and observational skills, which are deemed vital for technical laboratory staff. The Technical Supervisor of C-Lab-3 stated, “it is crucial to employ individuals who are organized, observant, and possess systematic thinking”. Another significant issue, not addressed in prior research, pertains to the retention of permanent staff. The Internal Auditor and Quality Manager Int-Aud-1 noted, “it is particularly challenging for a laboratory to frequently change technicians. Experience and technical expertise develop over time and require a specific duration to achieve proficiency. Moreover, professional uncertainty can render staff more vulnerable to internal or external pressures, thereby undermining impartiality and integrity”. Concerning employee incentives, he remarked, “often, only financial incentives are provided. While bonuses or salary increases are significant when offered under fair conditions, recognition through honorable mentions is equally important. Acknowledging and appreciating those who contribute to the organization’s objectives and overcome challenges to support the company’s growth and profitability is essential. The company should employ specific, objective criteria to recognize and reward the efforts of its staff”.

In the context of quality culture within accredited laboratories, participants predominantly emphasized its critical significance. They recognized that a robust quality culture is vital for ensuring the reliability, consistency, and credibility of laboratory operations, in compliance with ISO/IEC 17025. This culture is foundational to all laboratory activities, including sampling, analysis, reporting, and customer interactions, thereby contributing to the laboratory’s overall success. The Quality Manager of Chem-Lab 1 stated, “quality culture instills a habit of adhering to basic principles of quality standards in everyday tasks, which is essential for maintaining these standards”. Similarly, Technical Supervisors from Chem-Lab 2 and Chem-Lab 4 noted that the successful implementation of ISO standards hinges on a pervasive quality culture within the organization. They emphasized the necessity of conducting all processes consistently and in accordance with established standards, on a daily basis. The Technical Director of C-Lab 4 further affirmed that “active engagement with quality principles is crucial for achieving and maintaining accreditation. By embedding quality practices into routine laboratory operations, personnel can effectively support the quality system and ensure that tasks are executed accurately and efficiently”.

Beyond establishing a quality culture, several other issues were mentioned, including the involvement of all personnel, a common understanding of ISO/IEC 17025, impartiality, and cultural change. The Internal Auditor Int-Aud-1 remarked, “impartiality, objectivity, and confidentiality are essential in testing, as violating standard principles can lead to severe consequences, including inaccurate results that may cause significant harm or fatalities”. Reflecting on this, the Technical Supervisor of T-Lab 5 questioned the value of the quality system “if measurements are not accurate, impartial, and credible”.

At this stage, it is crucial to further investigate the perspectives of laboratory clients, particularly concerning the pressures they may exert on laboratories and the potential impact on the laboratories’ integrity. Over half of the clients surveyed in this study were aware of laboratories willing to compromise measurement accuracy to meet clients’ demands. Several clients admitted that they have on multiple occasions pressured their partner laboratories to deliver favorable results in cases where the tested materials did not comply with regulatory or project-specific standards. T-Client 7 commented, “in major projects, strict timelines and costly delay clauses create significant pressure. When test results deviate from required specifications, it can create major challenges, leading clients to expect laboratories to adjust results to keep projects and partnerships on track. Similarly, T-Client 2 and C-Client 3 shared that they have worked with many laboratories willing to modify results to satisfy client needs and maintain business stability.

Furthermore, regarding the management of cultural change, the Technical Supervisor of T-Lab 10 emphasized the importance of addressing this issue, particularly for older staff, to mitigate resistance to the changes necessary for implementing the quality system. The Internal Auditor Int-Aud-1 added that “cultural change is crucial for the effective application of the quality system within the organization. Older employees often believe their practices are correct, while younger employees may mistakenly view their innovations as inherently beneficial. It is essential for the company to develop processes that manage reactions and resistance to quality system requirements, focusing on enhancing service and product quality while simultaneously increasing productivity without compromising the quality system”.

Customer focus also emerged as a significant factor during the interviews with Technical Supervisors across various laboratory sectors. The Internal Auditor Int-Aud-1 highlighted the growing importance of customer focus, indicating that “ISO/IEC 17025 has transitioned into a customer-centered standard”. Supporting this perspective, the Technical Supervisor of T-Lab 6 emphasized the necessity of addressing customer needs, which “not only builds positive relationships but also enhances trust; for instance, in calibration laboratories, offering consulting services to clients not only meets their requirements but also strengthens their confidence in the laboratory’s capabilities”.

Furthermore, the participants underscored the beneficial impact of continuous monitoring and evaluation through quality indices, laboratory information systems, systematic statistical data analysis, and risk analysis, which are essential for achieving ongoing improvement. The Technical Supervisor of T-Lab 10 noted the importance of quality indices in evaluating laboratory performance and identifying emerging trends. Furthermore, the maintenance of statistical data was recognized as critical for this assessment.

A consensus among respondents from accredited testing laboratories highlighted the significance of organizational standardization, including well-defined written procedures that enhance the efficiency and effectiveness of laboratory operations. The Technical Supervisor of T-Lab 5 remarked, “the lab adheres to specific rules, streamlining our processes”. The Technical Director of T-Lab 7 added, “accreditation facilitates effective process categorization”, while the Technical Supervisor of T-Lab 1 noted that “technicians operate with greater awareness and reduced guesswork”.

The interview-based qualitative approach employed in this study provided insights from subject matter experts that confirmed, refined, or enhanced the findings from the systematic literature review detailed in Section 2. Table 3 outlines the validated CSFs essential for the effective implementation of ISO/IEC 17025, with experts' insights not previously noted in the literature underlined in each description.

Table 3. Validated critical success factors for ISO/IEC 17025 implementation.

CSFs	Description
CSF 1: Leadership and strategic commitment	Effective leadership involves top management's support, commitment, and active engagement in the quality system, along with strong leadership qualities that encompass technical expertise and managerial skills. The organization's vision and mission should align with the requirements of ISO/IEC 17025.
CSF 2: Motivation for accreditation	Motivation for adopting ISO/IEC 17025 should primarily involve internal factors aimed at enhancing measurement accuracy and quality management, ahead of external factors driven by market pressures.
CSF 3: Financial and organizational resources	There should be adequate and <u>balanced allocation</u> of financial and organizational resources.
CSF 4: Technical resources and infrastructure	Relevant technical resources and infrastructure must be provided, including equipment, facilities, and <u>automation of testing, digitalization, and measurement recording</u> .
CSF 5: Human resources management and competency	Human resource management involves effective staffing configurations, selection of personnel, and ensuring workforce qualifications including education, scientific competence, technical and managerial skills, and personality attributes. It also considers the number of employees and <u>the stability of employment contracts</u> .
CSF 6: Human resources training and development	Continuous training for personnel at all levels is essential in order to maintain and enhance technical competence, <u>emphasizing qualities such as attentiveness, conscientiousness, and observational skills</u> .
CSF 7: Human resources engagement	Employee engagement includes commitment, awareness, and involvement. It also involves mechanisms for evaluating staff performance, assessing satisfaction, and providing incentives to improve productivity and ensure adherence to quality procedures critical for accurate results.
CSF 8: Quality management system design	The implementation of the quality system should be efficiently planned and organized, potentially involving external consultants. A process-oriented approach is essential, covering planning, organization, control, and review. The chosen design of the quality system, whether stringent or flexible, should align with the organization's <u>strategic objectives</u> . This design must be thoroughly documented, with procedures established for all activities.
CSF 9: Verification of methods and Traceability of measurements	This involves selecting appropriate testing procedures and verifying test methods to ensure they meet the required performance standards. It includes determining measurement precision and evaluating measurement uncertainty, as well as establishing metrological traceability through a documented, <u>uninterrupted chain of calibrations</u> .

Table 3. *Cont.*

CSFs	Description
CSF 10: Quality assurance and control	Quality control procedures must adhere to ISO/IEC 17025 standards. These include conducting quality control tests, proficiency testing, internal equipment checks and maintenance, monitoring and addressing non-conformance, implementing corrective actions, investigating failures, auditing, conducting management reviews, performing risk analysis, and ensuring a minimum quota of tests for each category.
CSF 11: Performance management and improvement	This involves monitoring and evaluating the implementation of the quality system to ensure continuous improvement, utilizing quality indicators and employing software tools for performance measurement.
CSF 12: Quality oriented organizational culture and working environment	Establishing a quality-oriented culture involves promoting consciousness of quality among all stakeholders and creating an environment conducive to continuous improvement. It also includes managing cultural change and recognizing its importance for adaptation. A positive working environment is essential, characterized by effective communication, a pleasant atmosphere, balanced workloads, and teamwork.
CSF 13: Operational integrity and impartiality	This emphasizes the importance of impartiality, honesty, scientific integrity, and independence from conflicting interests, for both the organization and its employees.
CSF 14: Supplier management	Effective management of supplier relationships is crucial for ensuring cooperation and quality.
CSF 15: Customer focus	A customer-centric approach involves assessing and analyzing customer requirements and satisfaction while being responsive to their changing needs.
CSF 16: Regulatory compliance and external factors	This includes the type of regulatory framework governing the laboratory's operations, encompassing government support for accreditation, differentiating between certified and accredited laboratories, mandatory licensing for technicians, compliance with legislation affecting laboratory operations and health and safety protocols, and establishing mechanisms for arbitration.

5. Conclusions

This study carried out an in-depth investigation of the CSFs essential for the effective implementation of ISO/IEC 17025 and the establishment of a robust quality system in accredited testing and calibration laboratories. Identifying these CSFs is beneficial as it enables organizations to focus on relevant issues for the successful implementation of the ISO/IEC 17025 quality system, align their strategic planning with the standard's requirements, and promote continuous improvement towards excellence.

5.1. Key Findings

This study offers a multidimensional perspective on CSFs, which distinguishes it from typical single-source research that has mostly relied on individual case studies. It begins with a literature review that identifies the CSFs essential for the effective implementation of ISO/IEC 17025, while also incorporating insights from ISO 9001 and ISO 14001 standards to enhance these findings. The review identifies 16 distinct CSFs; these were further confirmed, refined, and enhanced through qualitative analysis based on interviews.

The 16 validated CSFs are essential for the adoption and maintenance of ISO/IEC 17025, encompassing managerial, human resource, and technical domains. Within the managerial domain, leadership and strategic commitment are highlighted as particularly significant, necessitating robust support and active engagement in the quality system. This includes leadership qualities that integrate technical expertise with managerial skills to ensure alignment between the organization's vision and ISO/IEC 17025 requirements. Motivation for accreditation is another critical factor, reflecting the organization's ambition

and incentives to achieve ISO/IEC 17025 accreditation. The availability of financial and organizational resources is also vital for laboratory operations, as are technical infrastructure and equipment. Performance management and improvement are addressed through the monitoring and evaluation of the quality system's implementation to ensure continuous improvement, supported by quality indicators and performance measurement tools. Additionally, promoting a quality-oriented organizational culture and a supportive working environment focusing on effective communication and teamwork are crucial for successful accreditation. Managing cultural change and developing a supportive workplace are also important. Furthermore, the research underscores the importance of operational integrity and impartiality, highlighting the necessity for honesty, scientific integrity, and independence from conflicts of interest at both organizational and individual levels. Effective supplier management and a strong customer focus are recognized as key CSFs. Finally, regulatory compliance, which includes the legislative and regulatory framework governing each laboratory sector and governmental support for accreditation, is identified as a critical component for success.

The second domain encompasses human resource factors, beginning with human resources management and competence, including staffing configuration, personnel selection, and workforce qualifications. Furthermore, human resources engagement—reflecting employees' commitment, awareness, and active participation in the quality system, and training and development are regarded as vital components. Collectively, these elements underscore the significant impact of human competency on the laboratory's overall performance.

The third domain addresses the technical requirements of ISO/IEC 17025, which refer to the design of the quality management system, verification of test methods, and measurement traceability. Quality assurance and control entail strict quality control procedures as required by the standard, such as quality control tests, proficiency testing, equipment inspections, corrective actions, audits, management reviews, and risk analysis.

This comprehensive overview of 16 validated CSFs for the effective implementation of ISO/IEC 17025 offers a more integrated view than previously available in fragmented studies. By synthesizing insights from ISO 9001 and ISO 14001 then refining and confirming them through qualitative interviews, this research provides the first systematic exploration of both generic and ISO/IEC 17025-specific CSFs. In doing so, it directly addresses the literature gap highlighted by earlier studies (2019), bridging managerial, human resource, and technical dimensions under one robust framework. Consequently, the findings inform practitioners and accrediting bodies about the multifaceted nature of successful ISO/IEC 17025 implementation and set the foundation for future research to examine these factors in different organizational and industrial contexts.

5.2. Managerial and Societal Implications

The findings of this study offer important insights for the accredited laboratory sector, providing recommendations to enhance the quality and operational performance of laboratories. Identifying CSFs for the effective implementation of ISO/IEC 17025 enables organizations to prioritize key areas and align their strategic planning accordingly. It is crucial for top management to recognize the significance of accreditation at all organizational levels. Strategic planning must integrate accreditation requirements and promote awareness of the benefits associated with adopting ISO/IEC 17025. Additionally, the study emphasizes the influence of the regulatory framework on laboratory operations, highlighting its impact across various regulatory domains. This insight is particularly relevant for policymakers and regulatory bodies in sectors where accreditation is not mandatory, suggesting a potential need for similar requirements to enhance public safety and trust. Increasing customer awareness of the importance of accreditation can motivate them to

select accredited laboratories, thereby providing financial incentives for these laboratories to establish and maintain robust quality systems.

Furthermore, this study points out significant societal implications, emphasizing the essential role of accreditation in promoting public safety. By ensuring compliance with safety standards for food, water, fuel, building materials, and other tested products, accreditation plays a vital role in reducing risks to public safety across multiple sectors. However, this study indicates that accreditation alone does not guarantee the reliability of measurements, as technical requirements must be supported by equally important managerial and human resource factors for the successful implementation of ISO/IEC 17025.

5.3. Limitations and Future Research Directions

Despite its valuable contributions, this study has certain limitations that should be considered. The research was conducted with a relatively small sample size of 34 participants, all located in Greece and representing three sectors: civil engineering testing laboratories, chemical laboratories, and calibration laboratories. This limited scope may restrict the generalizability of the findings. Future research should seek to broaden the study both geographically and across a wider range of testing sectors. Incorporating diverse laboratory types from various countries would allow more comprehensive comparison of CSFs across different testing activities and regions. Given the interrelated nature of independent CSFs, employing a multi-criteria decision-making method would be advantageous for exploring the complex relationships among them. This approach would prioritize the significance of these factors and establish causal links. The results of such research could aid stakeholders and decision-makers in comprehensively understanding the structure of the problem, highlighting how actions in one area impact others. This would facilitate informed and strategic decision-making, identifying key areas for laboratories to focus on to enhance excellence in their testing and calibration services.

5.4. Concluding Remarks

In conclusion, this research enhances the theoretical understanding of the factors that contribute to the successful implementation of the ISO/IEC 17025 quality system. The findings indicate that an integrated approach to managerial factors, particularly in relation to leadership, strategic management, motivation, training, and operational integrity, can significantly improve the application of ISO/IEC 17025 in accredited laboratories, thus increasing the reliability of measurements. This improvement fosters public trust, as accreditation assures the community of the safety and reliability of public infrastructure and other products.

Author Contributions: Conceptualization, E.P., P.T.C. and A.I.M.; methodology, E.P. and P.T.C.; software, E.P. and P.T.C.; validation, A.I.M. and D.A.G.; formal analysis, E.P., P.T.C. and A.I.M.; investigation, E.P. and P.T.C.; resources, E.P.; data curation, P.T.C. and A.I.M.; writing—original draft preparation, E.P., P.T.C., A.I.M., D.A.G. and A.G.L.; writing—review and editing, E.P., P.T.C., A.I.M., D.A.G. and A.G.L.; visualization, E.P. and P.T.C.; supervision, D.A.G. and A.G.L.; project administration, D.A.G. and A.G.L.; funding acquisition, P.T.C. All authors have read and agreed to the published version of the manuscript.

Funding: The publication of this paper has been partly supported by the University of Piraeus Research Center.

Institutional Review Board Statement: Not applicable.

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: Data are contained within the article.

Conflicts of Interest: The authors declare no conflicts of interest.

Appendix A

Table A1. Distribution of selected articles addressing the critical success factors for ISO/IEC 17025 implementation.

Table A1. *Cont.*

References	Critical Success Factors for ISO/IEC 17025 Implementation														
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
(Doyle, 2024)														✓	
(Dror & Pierce, 2020)													✓		
(Belezia & de Almeida, 2021)			✓		✓				✓					✓	
(Karthiyayini & Rajendran, 2021)															✓

Table A2. Distribution of selected articles addressing the critical success factors for ISO 9001 and ISO 14001 implementation.

References	Critical Success Factors for ISO 9001 and ISO14001 Implementation														
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
(Ingason, 2015)	✓						✓				✓				
(Zwane et al., 2021)	✓		✓			✓	✓			✓	✓	✓		✓	✓
(de Guzman Santos, 2022)	✓					✓	✓			✓		✓			
(Carneiro et al., 2021)	✓						✓								✓
(Boiral, 2011)	✓					✓	✓	✓				✓			
(Kim et al., 2011)	✓		✓			✓	✓			✓		✓			✓
(Ab Wahid & Corner, 2009)	✓						✓				✓	✓			
(Heras-Saizarbitoria, 2011)							✓	✓			✓				
(Ismyrlis et al., 2015)	✓		✓			✓	✓				✓	✓		✓	✓
(Khan et al., 2021)	✓					✓						✓			
(Kafetzopoulos & Gotzamani, 2014)				✓		✓	✓			✓	✓	✓			
(Psomas et al., 2010)	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓			✓
(Sweis et al., 2022)						✓				✓		✓		✓	✓
(Briscoe et al., 2005)												✓			
(Ivanova et al., 2014)	✓						✓				✓	✓			
(Magd, 2010)	✓					✓	✓			✓	✓	✓			
(Denton & Maatgi, 2016)												✓			

Table A3. Detailed participant profiles.

Participant Code	Stakeholder Type	Gender	Age Group	Highest Academic Qualification	Professional Role	Laboratory Experience (Years)	Accreditation Experience (Years)	Construction Industry Experience (Years)	Interview Date	Interview Duration (min)	Interview Mode
TLab-1	Civil Engineering Testing Laboratory Professional	Male	55–65	University Degree	Technical Supervisor, Accredited Testing Laboratory	28	22	-	16/02/2024	90	Face-to-face
TLab-2	Civil Engineering Testing Laboratory Professional	Female	55–65	University Degree	Quality Manager, Accredited Testing Laboratory	34	21	-	19/02/2024	60	Face-to-face
TLab-3	Civil Engineering Testing Laboratory Professional	Male	45–54	Technical School	Technical Supervisor, Accredited Testing Laboratory Division	22	20	-	20/02/2024	50	Face-to-face
TLab-4	Civil Engineering Testing Laboratory Professional	Female	55–65	University Degree	Technical Supervisor, Certified Testing Laboratory	24	24	-	28/02/2024	60	Face-to-face
TLab-5	Civil Engineering Testing Laboratory Professional	Female	35–44	MEng, Msc, MBA, PhD Candidate	Technical Supervisor and Quality Manager, Accredited Testing Laboratory	14	14	-	28/02/2024	90	Face-to-face
TLab-6	Civil Engineering Testing Laboratory Professional	Male	55–65	PhD	Multifaceted Technical Supervisor and Quality Consultant, Accredited Testing Laboratories	27	18	-	12/03/2024	120	Web conference

Table A3. Cont.

Participant Code	Stakeholder Type	Gender	Age Group	Highest Academic Qualification	Professional Role	Laboratory Experience (Years)	Accreditation Experience (Years)	Construction Industry Experience (Years)	Interview Date	Interview Duration (min)	Interview Mode
TLab-7	Civil Engineering Testing Laboratory Professional	Female	45–54	Msc	Technical Director, Accredited Testing Laboratories	25	22	-	12/03/2024	100	Web conference
TLab-8	Civil Engineering Testing Laboratory Professional	Female	35–44	MEng, Msc	Quality Manager, Accredited Testing Laboratory	16	16	-	13/03/2024	50	Face-to-face
TLab-9	Civil Engineering Testing Laboratory Professional	Female	35–44	University Degree	Quality Manager, Accredited Testing Laboratory	17	17	-	29/03/2024	50	Face-to-face
TLab-10	Civil Engineering Testing Laboratory Professional	Male	45–54	University Degree	Technical Supervisor, Accredited Testing Laboratory Division	30	20	-	01/04/2024	45	Phone
TLab-11	Civil Engineering Testing Laboratory Professional	Male	45–54	MEng, MBA	Head Director, Accredited Testing Laboratories	30	21	-	08/04/2024	40	Face-to-face
C-Lab-1	Calibration Laboratory Professional	Male	45–54	University Degree	Quality Manager, Accredited Calibration Laboratory	20	20	-	12/02/2024	80	Phone
C-Lab-2	Calibration Laboratory Professional	Male	45–54	MEng, MBA	Technical Director, Accredited Calibration Laboratory	16	16	-	22/02/2024	80	Phone

Table A3. Cont.

Participant Code	Stakeholder Type	Gender	Age Group	Highest Academic Qualification	Professional Role	Laboratory Experience (Years)	Accreditation Experience (Years)	Construction Industry Experience (Years)	Interview Date	Interview Duration (min)	Interview Mode
C-Lab-3	Calibration Laboratory Professional	Male	35–44	University Degree	Technical Supervisor, Accredited Calibration Laboratory	12	8	-	23/02/2024	40	Face-to-face
C-Lab-4	Calibration Laboratory Professional	Male	35–44	University Degree	Technical Director, Accredited Calibration Laboratory	16	16	-	11/03/2024	50	Phone
C-Lab-5	Calibration Laboratory Professional	Male	45–54	PhD	Quality Manager, Accredited Calibration Laboratory	10	10	-	29/03/2024	90	Phone
Chem-Lab-1	Chemical Laboratory Professional	Female	45–54	Msc	Quality Manager, Accredited Chemical and Microbiological Laboratory	20	5	-	20/02/2024	45	Phone
Chem-Lab-2	Chemical Laboratory Professional	Female	55–65	Technical School	Technical Supervisor, Accredited Chemical Laboratory Division	15	5	-	04/03/2024	40	Phone
Chem-Lab-3	Chemical Laboratory Professional	Female	45–54	PhD	Technical Supervisor, Accredited Chemical Laboratory Division	20	15	-	05/03/2024	60	Phone

Table A3. Cont.

Participant Code	Stakeholder Type	Gender	Age Group	Highest Academic Qualification	Professional Role	Laboratory Experience (Years)	Accreditation Experience (Years)	Construction Industry Experience (Years)	Interview Date	Interview Duration (min)	Interview Mode
Chem-Lab-4	Chemical Laboratory Professional	Female	45–54	PhD	Technical Supervisor, Accredited Chemical Laboratory Division	14	4	-	08/03/2024	90	Phone
Chem-Lab-5	Chemical Laboratory Professional	Female	35–44	University Degree	Technical Supervisor, Accredited Chemical Laboratory Division	15	15	-	08/04/2024	60	Phone
Int Aud-1	Internal Auditor of Laboratory Professional	Male	55–65	University Degree	Quality Manager, Accredited Testing Laboratory	20	20	-	12/04/2024	60	Phone
T-Client 1	Client of Civil Engineering Testing Laboratory	Male	55–65	MEng	Civil Engineer	-	-	25	19/02/2024	50	Phone
T-Client 2	Client of Civil Engineering Testing Laboratory	Male	45–54	High School	Concrete Construction Contractor	-	-	20	18/03/2024	40	Face-to-face
T-Client 3	Client of Civil Engineering Testing Laboratory	Male	35–44	High School	Concrete Construction Contractor	-	-	15	19/03/2024	40	Phone
T-Client 4	Client of Civil Engineering Testing Laboratory	Male	45–54	PhD	Civil Engineer	-	-	9	20/03/2024	40	Phone

Table A3. Cont.

Participant Code	Stakeholder Type	Gender	Age Group	Highest Academic Qualification	Professional Role	Laboratory Experience (Years)	Accreditation Experience (Years)	Construction Industry Experience (Years)	Interview Date	Interview Duration (min)	Interview Mode
T-Client 5	Client of Civil Engineering Testing Laboratory	Male	35–44	MEng	Civil Engineer, Concrete Construction Contractor	-	-	10	26/03/2024	40	Phone
T-Client 6	Client of Civil Engineering Testing Laboratory	Male	45–54	MEng	Civil Engineer	-	-	10	28/03/2024	40	Face-to-face
T-Client 7	Client of Civil Engineering Testing Laboratory	Male	45–54	MEng	Civil Engineer, Concrete Construction Contractor	-	-	15	04/04/2024	50	Face-to-face
T-Client 8	Client of Civil Engineering Testing Laboratory	Female	45–54	MEng, Msc	Civil Engineer	-	-	20	09/04/2024	60	Phone
C-Client 1	Client of Calibration Laboratory	Female	45–54	Msc	Quality Manager, Accredited Testing Laboratory	8	8	-	14/02/2024	60	Face-to-face
C-Client 2	Client of Calibration Laboratory	Female	35–44	MEng-PhD Canditate	Quality Manager, Accredited Testing Laboratory	10	10	-	27/02/2024	50	Phone
C-Client 3	Client of Calibration Laboratory	Female	35–44	MEng, Msc	Quality Manager, Accredited Testing Laboratory	14	14	-	04/04/2024	50	Face-to-face
C-Client 4	Client of Calibration Laboratory	Male	55–65	BEng	Quality Manager, Accredited Testing Laboratory	20	18	-	09/04/2024	60	Face-to-face

Table A4. Indicative Questionnaires for the Semi-Structured Interviews.

Questionnaire for Laboratory Professionals (T-Labs, Chem-Labs, and C-Labs)	
1.	What do you consider the most significant factors that contribute to the successful application of ISO/IEC 17025 and improved quality performance in your laboratory?
Questionnaire for Clients of Laboratories (T-Clients and C-Clients)	
2.	How critical is top management's commitment to the successful implementation of ISO/IEC 17025 quality requirements in your laboratory?
3.	Does your laboratory's top management demonstrate a strong commitment to achieving accreditation and maintaining quality standards? Could you provide specific examples?
4.	What factors do you believe are essential for assessing and demonstrating the actual technical competence of a laboratory?
5.	Given that laboratories often depend on client fees, how does competitive market pressure affect your operations? Could you share your personal experiences?
6.	What challenges does your laboratory face in maintaining impartiality under client pressures, and how are these challenges managed?
7.	In what ways do you embed a "quality-oriented culture" in day-to-day activities, and how do you handle potential resistance to changes required by the quality system?
8.	How does your laboratory ensure that adequate financial and organizational resources are allocated for accreditation, and what challenges do you face in maintaining these resources?
9.	How do your laboratory's internal quality control procedures, such as proficiency testing or use of certified reference materials, enhance the reliability and repeatability of your measurements?
10.	Could you elaborate on the importance of staff training and development programs in ensuring compliance with ISO/IEC 17025 standards?
11.	In your view, how important is it to offer incentives (financial or otherwise) that acknowledge and reward quality-focused practices among laboratory personnel?
12.	How does your laboratory's governance structure support the implementation and continuous improvement of the quality management system?
13.	How do you manage supplier relationships (e.g., vendors, equipment providers) to ensure consistency in the quality of inputs and services critical to laboratory operations?
14.	What role does automation and digitalization play in improving the accuracy and impartiality of your laboratory's test results?

Note: The above questions are indicative of the types of inquiries posed during the semi-structured interviews. Depending on the interviewee's role, experience, and the flow of conversation, additional or follow-up questions may have been asked to examine more thoroughly particular areas of interest.

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