



## FUNDAMENTAL PROBLEMS IN ISO 9001:2015 QUALITY MANAGEMENT SYSTEM CERTIFICATION PROCESSES: A STUDY IN İZMİR PROVINCE

### ISO 9001:2015 KALİTE YÖNETİM SİSTEMLERİ STANDARDI BELGELENDİRME SÜREÇLERİNE YÖNELİK TEMEL PROBLEMLER: İZMİR İLİNDE BİR ARAŞTIRMA

Ömer ÖZKAN<sup>1</sup>

#### Abstract

The aim of this study is to identify the fundamental problems encountered by enterprises during the ISO 9001:2015 Quality Management System certification process through a holistic approach based on the perceptions of individuals directly involved in this process. The significance of the study lies in its focus on the practical challenges experienced during the certification process itself, in contrast to the dominant body of ISO 9001 literature, which primarily emphasizes system outputs and performance outcomes.

The main contribution of this study to the literature is its problem-oriented examination of the ISO 9001:2015 certification process, addressing certification-related difficulties rather than post-certification results or performance indicators. The research was conducted using a quantitative methodology, and data were collected through a three-part questionnaire administered to 133 participants. The first section of the questionnaire gathered demographic and professional information about the respondents; the second section focused on problems encountered during the certification process and possible solution approaches; and the third section collected evaluations related to twelve statements concerning the certification process. The data were analyzed using the SPSS statistical software package.

The findings indicate that the primary problems encountered during the ISO 9001:2015 certification process are concentrated around deficiencies in top management approach and leadership, inadequate organizational and strategic preparedness, insufficient employee motivation and training, documentation and process management challenges, and financial and resource constraints. The results of the factor analysis demonstrate that these problems converge into a single, holistic dimension. Moreover, participants generally expressed a positive perception regarding the possibility of resolving these problems in a rapid and effective manner.

**Keywords:** ISO 9001:2015 Quality Management Systems standards, certification processes, fundamental problems

#### Özet

Bu araştırmanın amacı, ISO 9001:2015 Kalite Yönetim Sistemi belgelendirme sürecinde işletmelerin karşılaştığı temel problemleri, süreçte doğrudan dahil olan bireylerin algıları çerçevesinde bütüncül bir yaklaşımla ortaya koymaktır. Çalışmanın önemi, ISO 9001 literatüründe ağırlıklı olarak sistem çıktıları ve performans sonuçlarına odaklanan çalışmalarдан farklı olarak, belgelendirme sürecinin kendisinde yaşanan pratik zorlukları empirik olarak incelemesinden kaynaklanmaktadır. Bu çalışmanın literatüre temel katkısı, ISO 9001:2015 Kalite Yönetim Sistemi belgelendirme sürecini, sistemin çıktıları veya performans sonuçları yerine, doğrudan belgelendirme sürecinde yaşanan problemler üzerinden ele almasıdır. Araştırma niceł yöntemle yürütülmüş olup,

<sup>1</sup>Dr., [omerozkan2016@gmail.com](mailto:omerozkan2016@gmail.com), SOCAR TÜRKİYE, ORCHID iD: [0000-0002-0752-307X](http://0000-0002-0752-307X)

veri toplama aracı olarak 133 katılımcıya uygulanan üç bölümlü bir anket kullanılmıştır. Anketin ilk bölümünde katılımcıların demografik ve mesleki bilgileri; ikinci bölümde belgelendirme sürecinde karşılaşılan problemler ve çözüm önerileri; üçüncü bölümde ise 12 önermeye ilişkin değerlendirmeleri toplanmıştır. Veriler SPSS programı kullanılarak analiz edilmiştir. Araştırma bulguları, ISO 9001:2015 belgelendirme sürecinde karşılaşılan temel problemlerin; üst yönetim yaklaşımı ve liderlik eksiklikleri, organizasyonel ve stratejik hazırlık yetersizlikleri, çalışan motivasyonu ve eğitim eksiklikleri, dokümantasyon ve süreç yönetimi sorunları ile finansal ve kaynak kısıtları etrafında yoğunlaştığını göstermektedir. Faktör analizi sonuçları, bu problemlerin tek boyutlu ve bütüncül bir yapı altında toplandığını ortaya koymuştur. Katılımcılar ayrıca, söz konusu problemlerin hızlı ve etkili biçimde çözülebileceğine yönelik genel olarak olumlu bir algıya sahiptir. Bu çalışmada sektör ayrimı yapılmamış olup tüm katılımcılar genel kalite yönetim deneyimi olan kişilerden oluşmuştur. Sonuç olarak, çalışma ISO 9001:2015 belgelendirme sürecinin yalnızca teknik bir uygunluk değerlendirmesi değil, aynı zamanda yönetsel, kültürel ve stratejik boyutları olan karmaşık bir süreç olduğunu ortaya koymaktadır. Elde edilen bulguların, hem literatüre katkı sağlama hem de yöneticiler, kalite profesyonelleri ve belgelendirme kuruluşları için belgelendirme sürecinin etkinliğini ve sürdürilebilirliğini artırmaya yönelik yol gösterici nitelikte olması beklenmektedir. Bu çerçevede, gelecek araştırmalarda faaliyet alanına yönelik yöntem ve yaklaşım ayrıntılı olarak irdelenmesi önerilmiştir

**Anahtar kelimeler:** ISO 9001:2015 Kalite Yönetim Sistemleri standarı, belgelendirme süreçleri, temel problemler

## Introduction

Quality management systems (QMS) have become a critical component of organisational strategies worldwide. These systems provide structured methods to increase productivity, ensure customer satisfaction and ensure compliance with international standards. In this context, the ISO 9000 series play a central role by defining principles, terminology and best practices for quality management for organisations in a variety of sectors.

The ISO 9000 standard defines the basic principles and terminology of quality and management systems and provides a systematic framework for understanding and implementing quality management. The requirements of ISO 9001 are based on the quality management principles in ISO 9000 and are built on basic policies such as customer orientation, leadership, process approach, continuous improvement, evidence-based decision making and relationship management (Dönen, 2021: 9).

The scope of ISO 9001 is designed to be applicable to all businesses and organisations regardless of sector. This standard is successfully applied in many sectors such as manufacturing, service, health, food, automotive, education, IT, energy, construction and public administration. Organisations of all sizes, from small and medium-sized enterprises to large-scale organisations, can increase their productivity and customer satisfaction by adopting a quality management system (Kesici, 2022: 36). For example, it is seen that ISO 9001 is applied

in the automotive sector to ensure quality in supply chain management and in the health sector to increase patient safety. This wide applicability has made ISO 9001 one of the most widely adopted quality management standards worldwide.

### 1. Sectoral Analysis of ISO 9001

ISO 9001 has a wide range of applications. It is seen that the research in the literature generally focus on production, service and public sectors. In the production sector, the effectiveness of quality management systems in industries such as automotive, textile, food and pharmaceuticals have been analysed (Adıgüzel & Aydınlı, 2006:368). In the service sector, the applicability and effects of ISO 9001 have been analysed in fields such as education, health, tourism and finance. In studies on public authorities, the adoption process of ISO 9001 and its effects on the efficiency and quality of public services are evaluated (Şireci, 2006:226-228).

#### 1.1. Continuous Improvement and Total Quality Management of ISO 9001

The principle of continuous improvement, one of the main pillars of ISO 9001, is widely discussed in the literature. The studies address the compatibility of ISO 9001 with Total Quality Management (TQM) approaches and the integration of quality principles throughout organisational processes. It is also emphasised that internal and external audit mechanisms play a critical role in ensuring the sustainability of quality management systems. It is also found in the literature that the risk-based thinking approach, which came to the fore with the ISO 9001:2015 revision, contributes to proactive risk management and process optimisation.

#### 1.2. Impact of ISO 9001 on Business Performance

Research on the effects of ISO 9001 generally focuses on dimensions such as financial performance, operational efficiency, customer satisfaction and competitive advantage (Al-Refaie et al., 2012:45). For example, Benli (2019) analysed the transition process of an electronics company to ISO 9001:2015 and found that improvements were achieved in customer satisfaction, cost efficiency and production accuracy. Similarly, Şahoğlu (2010) found that the implementation of ISO 9001 significantly increased the level of customer orientation and satisfaction (Kerdige, 2021:19). These findings show that ISO 9001 contributes to measurable improvements in different operational dimensions.

#### 1.2. Relationship of ISO 9001 and Cultural - Regional Factors

Cultural and regional factors play an important role in the implementation of ISO 9001. Many studies have examined how quality management systems are adapted internationally. For example, (Özen & Berkman 2007) investigated the transfer of Total Quality Management from the USA to other countries and found that each country restructured its management systems according to its own contextual characteristics. In general, research on ISO 9001 quality management systems covers a wide range of topics such as business performance, sectoral differences, cultural and regional influences, and integration with other management systems.

Many studies emphasise the positive effects of quality management systems on business performance. However, some critics argue that these systems are not universally applicable and that each society is restructured according to its own institutional context. For example, Whitley (1999) argues that organisational structures and management practices are not only dependent on technical environmental conditions but are also influenced by national theoretical contexts. On the other hand, Mueller (1994) states that businesses must adapt to both national and international systems. In this context, it is stated that organisational structures have evolved towards a US-centred, multidimensional management model, but no significant changes have been observed in business systems in France, Germany and the UK (Özen, 2002:50). From a quality management perspective, there is a widespread view that international standards cannot be applied in the same way in every sector and that practices are shaped according to the national context. For example, Frenkel (2005) reveals that the scientific management and human resources models transferred from the USA to Israel were harmonised with Israel's state structure and national policies. Therefore, it can be said that quality management systems do not offer a universal standard model and are adapted to the institutional context of the countries in which they are implemented (Aguilera, 2004:415).

Despite the widespread adoption of ISO 9001 and related standards, organisations may face various challenges in implementing these systems effectively. Overcoming these challenges (especially understanding in regional contexts and different sectors, developing certification processes) is important for the sustainable success of quality management practices and competition. As a matter of fact, factors such as competition, customer expectations, technology and legal reforms play an important role in the spread of quality management practices (Güçlü & Şehitoğlu, 2006:243-244). In a rapidly changing competitive environment, businesses need to focus on improvements and make their management models more flexible. To increase

management success in this transformation process and to support elements such as inter-organisational communication, employee commitment and innovative organisational structure, related standards focusing on specific aspects of quality management systems have been developed in addition to ISO 9001.

ISO 9003 focuses on quality management practices related to the inspection and testing of final products within the framework of assurance models. This standard is considered important for organisations that want to assess the conformity of final products to quality requirements rather than production processes (Başer, 2022: 65). On the other hand, ISO 9004 not only defines the requirements of a quality management system but also guides management approaches to achieve long-term sustainable success. In this context, it offers strategies for increasing organisational efficiency, optimising processes and improving the effectiveness of quality management systems. Regarding audit processes, ISO 19011 provides guidance for the evaluation of the effectiveness of management systems (Çakar & Serdar, 2002: 88). This standard provides a framework for conducting internal and external audits and serves a critical function in ensuring the continuous improvement of quality management systems (TS ISO 9004, 2011: 1).

All these standards are integrated with the risk-based thinking approach, continuous improvement and stakeholder-oriented management approach, which have become prominent especially with the revision of ISO 9001:2015. Thus, ISO 9001:2015 not only provides existing quality assurance but also aims to strengthen organisations' ability to adapt to changing environmental conditions and sustainable competitive advantage. However, it is stated that the literature specific to ISO 9001:2015 is limited, and in this context, more research, case studies and sectoral studies on the effects and applications of the revision are needed.

Despite the widespread adoption of ISO 9001:2015 Quality Management System certification, organizations continue to encounter various managerial, organizational, human-related, documentation, and resource-based challenges throughout the certification process. While the standard aims to promote customer satisfaction, process effectiveness, and continuous improvement, certification practices often remain formalistic and compliance-oriented, limiting their potential value creation for organizations.

The research problem of this study arises from the lack of empirical evidence that systematically identifies and evaluates the fundamental problems experienced during ISO 9001:2015

certification processes from the perspectives of individuals directly involved in these practices. In particular, there is limited research that holistically examines why these problems persist, why they are critical for the effectiveness and sustainability of quality management systems, and how they influence organizational outcomes.

Accordingly, the primary purpose of this study is to determine the fundamental problems encountered by organizations during the ISO 9001:2015 certification process within the framework of practitioners' perceptions. Specifically, the study aims to identify managerial and organizational deficiencies, employee-related challenges, documentation and process management problems, and resource-related constraints experienced throughout the certification process.

By empirically examining these problem dimensions, the study seeks to contribute to the existing literature by providing a structured and practice-oriented understanding of ISO 9001:2015 certification challenges. From a practical perspective, the findings are expected to support managers, quality professionals, and certification bodies by offering insights that may improve the effectiveness, sustainability, and value-adding capacity of ISO 9001:2015 certification practices.

## 2. Literature Review

In addition to academic sources, this study directly refers to the ISO 9001:2015 standard itself as the primary normative reference for the revised requirements (ISO, 2015).

To reflect the current global relevance and diffusion of ISO 9001 certification, the study also incorporates the most recent publicly available certification statistics from the ISO Survey / IAF CertSearch platform (ISO, n.d.; IAF CertSearch, n.d.).

Furthermore, recent studies examining ISO 9001:2015 implementation outcomes and challenges—including risk-based thinking, leadership engagement, and operational effectiveness—have been integrated into the literature review (Rathilall, 2024; Hernawan et al., 2025; Maswanganye, 2024).

ISO 9001:2015 represents a substantial shift from earlier versions of the standard, particularly ISO 9001:2008, by adopting a more strategic, risk-oriented, and performance-based approach

to quality management systems. With this revision, the standard moves beyond a predominantly procedure- and documentation-driven framework and emphasizes organizational context, strategic direction, and sustainable performance.

One of the most significant innovations introduced in ISO 9001:2015 is risk-based thinking. Unlike previous versions, where preventive action was addressed as a separate requirement, the 2015 revision integrates risk consideration throughout the quality management system. Organizations are encouraged to identify uncertainties, prioritize risks and opportunities, and embed risk awareness into planning, operational control, and decision-making processes.

Another major advancement concerns the explicit focus on organizational context and the needs and expectations of interested parties (Clause 4). ISO 9001:2015 requires organizations to analyze internal and external issues relevant to their purpose and strategic direction, thereby strengthening the linkage between quality management and strategic management.

The 2015 revision also places a stronger emphasis on leadership (Clause 5). Top management is expected to demonstrate accountability for the effectiveness of the quality management system, integrate quality objectives into business processes, and actively promote a process-based and risk-aware culture.

In addition, ISO 9001:2015 introduces organizational knowledge management as a formal requirement (Clause 7.1.6). Organizations are required to determine, maintain, and make available the knowledge necessary for the operation of their processes and for achieving conformity of products and services, highlighting the role of learning and knowledge continuity.

These innovations form the conceptual basis for many of the challenges encountered during ISO 9001:2015 certification processes, including difficulties related to effective risk integration, organizational context analysis, leadership involvement, and knowledge management practices.

The ISO 9001:2015 certification process should be conceptualized as a multi-stage and integrated management process consisting of preparation, implementation, internal audit, certification, and surveillance phases. This process is directly aligned with the Plan–Do–Check–Act (PDCA) cycle, which constitutes a fundamental reference framework in the quality management literature. Disruptions or deficiencies occurring at any stage of the certification

process may affect subsequent stages, thereby generating cumulative and systemic problems throughout the quality management system.

Within the scope of this study, management-related, organizational, employee-related, documentation/process-related, and resource-based problems are not treated as isolated or independent issues; rather, they are conceptualized as systemic weaknesses that collectively influence the certification process as a whole. This perspective is consistent with Systems Theory, which emphasizes the interdependence and interaction of organizational subsystems within the quality management literature.

The risk-based thinking approach and the analysis of organizational context—key elements that distinguish ISO 9001:2015 from its previous versions—play a central role in the theoretical explanation of the problems encountered during the certification process. Inadequate identification of risks and superficial context analysis may result in insufficient preparation, unsustainable structuring of resources, and recurring nonconformities during audits. Accordingly, the problems measured in this study are interpreted as empirical manifestations of the insufficient internalization of the strategic and risk-oriented philosophy embedded in ISO 9001:2015 within organizational practices.

## **2.1. ISO 9001:2015 Revision: Key Innovations Compared to Previous Versions**

ISO 9001:2015 introduced a set of substantive changes compared to earlier versions (e.g., ISO 9001:2008), shifting the standard from a predominantly procedure- and documentation-driven perspective toward a more strategic, risk-aware, and performance-oriented management system approach.

Risk-based thinking (RBT) represents one of the most critical innovations of the 2015 revision. Rather than treating preventive action as a standalone requirement, ISO 9001:2015 embeds risk consideration throughout planning and operational controls, encouraging organizations to anticipate uncertainties, prioritize controls, and integrate risk into decision-making processes.

Another major advancement is the explicit emphasis on organizational context (Clause 4) and the needs and expectations of interested parties. By requiring organizations to analyze internal and external issues, understand stakeholder expectations, and align the QMS with strategic direction, ISO 9001:2015 strengthens the linkage between quality management and strategic management.

The revision also reinforces leadership (Clause 5) by replacing the former “management responsibility” framing with a stronger accountability model. Top management is expected to take a more active role in integrating the QMS into business processes, promoting process thinking, and ensuring that quality objectives are aligned with organizational strategy.

Finally, ISO 9001:2015 introduces “organizational knowledge” (Clause 7.1.6) as a formal requirement, recognizing knowledge management as a determinant of process consistency and sustained performance. Organizations are expected to determine, maintain, and make available the knowledge necessary for process operation and conformity, which is particularly relevant for learning, competence development, and continuity under changing conditions.

Overall, these innovations provide the conceptual foundation for examining certification experiences under ISO 9001:2015, as many challenges observed in practice (e.g., effective risk integration, context analysis, leadership engagement, and knowledge capture) are directly linked to the revised requirements.

ISO 9001:2015 standard aims to increase customer satisfaction in organisations, ensure continuous improvement and manage processes effectively. With the 2015 revision, the standard encourages a risk-based approach and aims to achieve sustainable results (Kesici, 2022: 24-25). It has a wide scope and is applicable to all kinds of organisations regardless of scale or sector. In this context, managing processes, identifying risks, evaluating opportunities and carrying out continuous improvement activities are among the basic requirements of the standard. When considered together with other standards of the ISO 9000 series, ISO 9001:2015 provides a comprehensive and systematic framework to increase the global competitiveness of organisations (Benli, 2019: 32). Recent empirical evidence continues to associate ISO 9001-based QMS implementation with improved operational performance and organizational sustainability outcomes (Bakhtiar, 2023; Jacob, 2025).

In addition, effective risk management encourages organisations to seize opportunities and continuously improve processes. For example, through a risk-based approach, organisations can manage potential delays or quality problems that may arise in the supply chain through preventive measures. This approach increases efficiency and contributes to the development of more effective management strategies (Güldoğan, 2022: 48).

Another important innovation of ISO 9001:2015 is the emphasis on relationships with suppliers and other stakeholders in addition to customer satisfaction. The revised structure enables

organisations to improve not only their internal processes but also their interactions with the supply chain and external stakeholders. This contributes to the creation of a sustainable business model by encouraging the establishment of strong relationships with a wide network of stakeholders (Benli, 2019: 46). Therefore, it is not only limited to improving internal processes; it also offers a comprehensive and systematic approach to increasing competitiveness on a global scale. The standard provides organisations with significant advantages in increasing efficiency, ensuring customer satisfaction, strengthening credibility and reputation, and supporting long-term sustainability (Karakas & Savaş, 2019: 3519-3524).

The ISO 9001:2015 certification process is a multi-stage procedure for verifying and auditing the compliance of organisations' quality management systems with international standards. The ISO 9001:2015 certification process is a structured, multi-stage procedure for assessing the conformity of an organization's quality management system with international requirements (ISO, 2015; Hoyle, 2017). The process typically starts with a preparatory phase, including gap analysis, documentation development, and system planning, followed by internal audits and management reviews to evaluate readiness and leadership involvement (ISO, 2015; Sampaio et al., 2009). The certification audit, conducted by an accredited certification body, generally consists of Stage 1 (documentation review) and Stage 2 (on-site assessment), focusing on effective implementation and operational control (Bravi et al., 2019). Throughout the process, multiple actors—including top management, employees, consultants, certification bodies, and auditors—play distinct roles in system implementation and conformity assessment (Heras-Saizarbitoria & Boiral, 2013). From a practical perspective, certification requires considerable time, financial, and human resources, and shortcomings in early stages may lead to delays, increased costs, and repeated nonconformities in later audits (Gopal & Attri, 2017). Therefore, understanding the certification process as an interconnected and cumulative system is essential for analyzing the challenges addressed in this study.

This process ensures the effective implementation of the standard, contributes to the identification of problems and the institutionalisation of a culture of continuous improvement.

## 2.2. Preliminary and Planning

The ISO 9001:2015 certification process begins with a comprehensive evaluation of an organization's existing quality management system and the development of a detailed improvement plan (TS ISO 9001:2015 Md.0.3.2). During this initial stage, organizations

systematically assess current processes, identify gaps, and establish a roadmap to ensure full compliance with the standard's requirements. This stage is critical as it sets the foundation for all subsequent quality management activities and defines quality policies, objectives, and procedures (Kerdige, 2021:14).

For successful certification, the quality management system must adhere to core principles, including customer orientation, process approach, continuous improvement, and productivity. Additionally, organizations are expected to implement training and awareness programs to foster a quality-conscious culture across all levels of staff. Each component of the quality management system should be supported by proper documentation, with responsibilities clearly delineated to ensure active participation by all employees (Keşkek, 2006:25). Risk-based thinking and the identification of potential opportunities should also be integrated into the planning process to enhance proactive quality management. In accordance with ISO 9001:2015 (Clauses 4–10), organizations are expected to establish the context, leadership commitment, planning, support, operation, performance evaluation, and improvement mechanisms as an integrated system (ISO, 2015).

### 2.3. Internal Audit and Management Review

Following the planning stage, organizations conduct internal audits to evaluate the extent to which their quality management system conforms to ISO 9001:2015 requirements (Hoyle, 2000:507). Internal audits serve as a mechanism to verify the system's effectiveness, identify deficiencies early, and ensure corrective actions are implemented as needed. During audits, auditors examine manuals, procedures, work instructions, and related documentation, while assessing operational performance and identifying potential process inefficiencies (Kesici, 2022:69–72). This aligns with the internal audit requirements of ISO 9001:2015 (Clause 9.2) and the management review requirements (Clause 9.3) (ISO, 2015).

Subsequently, management review meetings are convened, allowing senior management to appraise the overall status of the quality management system. These reviews include evaluation of organizational performance, customer feedback, internal audit results, corrective actions, and system effectiveness. The outcomes of these meetings provide a structured roadmap for continuous improvement and support informed decisions regarding future strategic initiatives and process enhancements (Bilgin, 2019:41).

### 2.4. Certification Audit Process

The certification audit is typically conducted in two stages:

**Step 1 (Documentation Audit):** This stage involves a thorough examination of all documents related to the quality management system. Auditors evaluate quality manuals, procedures, work instructions, and other relevant records to verify conformity with ISO 9001:2015 requirements. The primary goal is to ensure consistency between the documented system and its practical implementation. Organizations are generally provided an opportunity to address any identified deficiencies prior to the next stage (ISO, 2015).

**Step 2 (On-site Audit):** The second stage assesses the implementation and effectiveness of the quality management system within the operational environment. Auditors observe processes, interview employees, and evaluate the practical application of documented methods. This stage provides a comprehensive assessment of system performance, ensuring alignment between procedures and actual operations. Upon completion, the certification body prepares a detailed audit report and determines whether the organization meets the ISO 9001:2015 requirements.

## 2.5. Certification and Surveillance Audits

The ISO 9001:2015 certification process formally verifies that an organization's quality management system conforms to international standards. The issuance of the certificate confirms that the system is designed to prioritize customer satisfaction, operational efficiency, and productivity. Following certification, surveillance audits are conducted at regular intervals to ensure the continued compliance and effectiveness of the organization's quality management system (ISO, 2015).

Surveillance audits are intended to maintain the sustainability of the quality management system and promote ongoing improvement. These audits verify that nonconformities identified in previous assessments have been appropriately addressed. Furthermore, they evaluate continuous customer satisfaction and the outcomes of internal audits. By systematically conducting surveillance audits, organizations can monitor and enhance their quality management processes, ensuring that improvements are sustained over time (ASQ, 2025; ISO, 2015).

In summary, the ISO 9001:2015 certification process follows a structured, evidence-based approach to enhance organizational quality management systems. Through internal audits, management reviews, certification procedures, and surveillance audits, organizations are

enabled to optimize operations, strengthen reliability, and achieve competitive advantages. The process reinforces customer orientation, continuous improvement, and adherence to high-quality standards across all organizational activities.

## 2.6. Fundamental Challenges in ISO 9001:2015 Certification

Compliance with ISO 9001:2015 requires organizations to meet standards designed to enhance the efficiency and effectiveness of quality management systems. However, organizations frequently encounter managerial, operational, and financial challenges that may impede both the implementation and sustainability of the system. These challenges can be categorized into five main areas: management and organizational issues, employee resistance and training deficiencies, documentation and process management difficulties, audit-related challenges, and financial constraints.

Compliance with ISO 9001:2015 requires organizations to establish, implement, maintain, and continually improve a quality management system that is aligned with their strategic direction and operational context (ISO, 2015). The standard defines a set of core requirements, including leadership commitment, risk-based thinking, process management, performance evaluation, and continual improvement, which guide organizations in systematically managing quality-related activities (Hoyle, 2017).

In this framework, efficiency refers to the ability to achieve intended outputs with optimal use of resources through well-defined and controlled processes, while effectiveness relates to the extent to which quality objectives, customer requirements, and regulatory expectations are consistently fulfilled (ISO, 2015; Psomas & Antony, 2015). These concepts are operationalized through process performance indicators, internal audit results, management review outcomes, and corrective action effectiveness.

Empirical studies indicate that effective ISO 9001:2015 compliance can lead to tangible organizational benefits such as improved process consistency, reduced nonconformities, enhanced customer satisfaction, and stronger managerial control, provided that the system is implemented beyond formal documentation requirements (Bravi et al., 2019; Heras-Saizarbitoria & Boiral, 2013). Accordingly, ISO 9001:2015 compliance represents not merely

procedural conformity but a structured managerial approach that enables organizations to translate quality requirements into measurable performance improvements.

#### Management and Organizational Issues

Active support from senior management is critical for successful certification. In some organizations, however, management engagement is limited, and quality management systems are implemented solely to obtain certification. This approach jeopardizes the sustainability of the system and undermines the principle of continuous improvement (Güldoğan, 2022:53). Organizational changes, such as mergers, internal restructuring, or the introduction of new managerial policies, can further impede effective implementation. Additionally, insufficient financial and human resources may prevent organizations from fully executing the necessary processes (KarakAŞ & Savaş, 2019:3525-3528).

#### 2.7. Employee Resistance and Training Deficiencies

The successful adoption of ISO 9001:2015 depends on employees internalizing quality management principles. Employees may perceive quality management activities as additional workload, resulting in resistance or low engagement, which can hinder the achievement of organizational quality objectives (Al-Mijrab & Elwalda, 2020:7–8). Inadequate training and limited understanding of quality management procedures can lead to errors and nonconformities in documentation, further complicating compliance (Karakuş, 2021:8–15).

#### 2.8. Documentation and Process Management Challenges

ISO 9001:2015 emphasizes systematic documentation and process integration. Many organizations, particularly SMEs, perceive these requirements as burdensome, which may result in deficiencies in document management (Kapucugil & Dönən, 2023:121). Ineffective process management, including poorly defined or inadequately integrated procedures, can disrupt both documentation and operational performance.

#### 2.9. Audit-Related Challenges

Internal and external audits are essential for verifying compliance with ISO 9001:2015 requirements. Ineffective internal audits can increase the number of nonconformities discovered

during certification audits, causing delays and additional costs. External audits may also present challenges due to variations in auditors' interpretations and perceived subjectivity, which can undermine confidence in the certification process (ISO, 2015).

## 2.10. Financial Constraints

Certification incurs expenses, including fees for certification bodies, internal audits, and consultancy services. For SMEs, these costs can be substantial, complicating certification completion (Kapucugil & Dönem, 2023:100–101). Additional investments in equipment, software, or process improvements may also be necessary to meet ISO 9001:2015 requirements. Organizations with limited financial resources may struggle to implement these improvements, risking failure in certification (Bravi et al., 2019:67).

In conclusion, while ISO 9001:2015 certification is vital for aligning organizational quality management systems with international standards, effective management of managerial, operational, and financial challenges is essential. Systematic planning, active employee engagement, strong senior management support, optimized documentation, robust control mechanisms, and adequate financial resources are all crucial to achieving successful certification and sustaining a high-performing quality management system.

## 3. Method

The main purpose of this research is to determine the main problems faced by enterprises in the ISO 9001:2015 Quality Management System certification process within the framework of the perceptions of individuals involved in this process. The main purpose of this research is to empirically identify and analyze the fundamental problems encountered during the ISO 9001:2015 Quality Management System certification process, based on the perceptions of practitioners directly involved in implementation and certification activities. Although ISO 9001 has been extensively studied in terms of performance outcomes and post-certification benefits, prior research has devoted relatively limited attention to the certification process itself and the practical challenges experienced during this critical phase (Sampaio et al., 2009; Gopal & Attri, 2017; Bravi et al., 2019) The significance of this study lies in addressing this gap by focusing on managerial, organizational, employee-related, documentation/process-related, and

resource-based problems, which have been identified in the literature as recurring barriers to effective certification but are rarely examined within a unified empirical framework (Heras-Saizarbitoria & Boiral, 2013; Psomas & Antony, 2015). By structuring these problem dimensions, the study contributes to a more systematic understanding of certification-related difficulties. The perceptions of quality managers, process owners, internal auditors, and other practitioners actively involved in ISO 9001:2015 certification processes are particularly important, as these individuals directly experience the operational and managerial implications of compliance requirements and audit practices (Sousa-Poza et al., 2009; Kerdige, 2021). Accordingly, the study is guided by clearly defined research questions and hypotheses that examine the relationships between these problem dimensions and the perceived effectiveness of the ISO 9001:2015 certification process. The research aims to reveal the managerial, organisational, employee-related, documentation and financial problems experienced by the participants during the process. Therefore, it aims to guide both academic literature and practitioner managers by identifying problem areas in the ISO 9001: 2015 certification process, evaluating the intensity of the problems and revealing the solutions.

### 3.1. Data Collection Tools

In this research, the survey method was used to determine the main problems experienced in the ISO 9001: 2015 Quality Management System certification process. The questionnaire consists of three main parts. In the first section, information on the demographic and professional profiles of the participants was collected, including age, gender, educational level, job position and length of professional experience. The second section is aimed at evaluating the level of problems encountered by the participants in the certification process and the level of providing fast and effective solutions to these problems. The questions in this section were evaluated using a 5-point Likert scale ranging from 1 (Strongly Disagree) to 5 (Strongly Agree). The questions were prepared by the author.

Overall, this structured scale development and validation process enhances the scientific rigor of the measurement tool and supports the reliability and interpretability of the empirical findings derived from the study.

The development of the measurement tool used in the third part (Part 3) was based on ISO 9000 standard series and the ISO 9001:2015 Quality Management Systems Standard. Within

this context, the writers' studies about quality like Gill (2002), Kavi (2005), Robert (2004), etc. take place in literature. and is intended to evaluate the main obstacles encountered in the implementation of the ISO 9000 quality management system. In the literature, the main obstacles encountered in ISO 9001 implementation include top management commitment, employee resistance, difficulty in implementing internal audits, lack of financial resources, insufficient human resources, inadequate employee training and lack of knowledge about quality programmes (Gopal & Attri, 2017). Hesham and Magd (2007) stated that one of the main obstacles is that top management usually does not fully understand the requirements of the ISO 9000 quality system and is not sufficiently involved in the process. Sousa-Poza et al. (2009) listed the difficulties faced by small and medium-sized enterprises in the process of implementing ISO 9001 standards as lack of financial and human resources, lack of technical knowledge on quality management, lack of knowledge about formalised systems and lack of internal audit experience. Accordingly, the research was conducted with a total of 133 participants working in different sectors. The reliability of the 5-point Likert scale (1 - Strongly Disagree, 5 - Strongly Agree) was tested with Cronbach's Alpha and a high reliability value was obtained. This data collection tool also enables the evaluation of the obstacles in ISO 9001:2015 implementation processes.

#### Proposed Research Hypotheses

H1: The fundamental problems perceived during the ISO 9001:2015 Quality Management System certification process—namely management-related, organizational, employee-related, documentation/process-related, and resource-based problems—have a statistically significant effect on the perceived effectiveness of the certification process.

### **3.2. Data Collection and Analysis**

The data collection process was carried out between January-February 2025, and a total of 133 participants were reached. The selection of the participants was made by purposive sampling method and only the personnel experienced in the ISO 9001:2015 process was included in the survey. The participants were selected using a purposive sampling method, which is particularly appropriate for studies aiming to obtain in-depth insights from individuals with specific knowledge and experience related to the research phenomenon (Creswell, 2014; Etikan et al., 2016). Given that the objective of this study is to examine problems encountered during the

ISO 9001:2015 certification process, purposive sampling enables the inclusion of respondents who are directly involved in and knowledgeable about certification-related activities, thereby enhancing the relevance and quality of the collected data. The questionnaire was delivered directly to the participants via e-mail, telephone and in-house managers. The inclusion criteria were that the participants were directly involved in quality management processes and were familiar with the ISO 9001:2015 certification process. In addition, no sectoral distinction was made and participants from different sectors were evaluated together. During data collection, the purpose of the study and confidentiality policies were explained to the participants, and their consent was obtained.

Written informed consent was obtained from all participants that they agreed to participate in the study. Participants were clearly informed that the information they provided would be used only within the scope of this research and would not be shared with third parties. Data were collected anonymously, personal information was separated and stored in accordance with confidentiality principles. The research was conducted in accordance with participant rights and ethical rules.

The data obtained were analysed using SPSS statistical package programme v.27. In the analysis process, firstly, descriptive statistics and demographic distributions and proposition levels were analysed. Then, factor analysis was applied to determine the structural dimensions of the 12 propositions, and the suitability of the data set was checked by Kaiser-Meyer-Olkin (KMO) test and Bartlett's sphericity test. Proposition reliability was assessed with Cronbach's alpha coefficient and factor loadings and variance explained were reported. In addition, a one-sample t-test was conducted.

In this study, the 12 items used to measure the perceived problems related to the ISO 9001:2015 certification process were initially designed to represent distinct problem domains discussed in the literature, including management-related, organizational, employee-related, documentation/process-related, and resource-based factors. However, during the analytical stage, these items were not treated as separate independent variables; instead, they were evaluated as measurement indicators representing a single, holistic construct.

The results of the exploratory factor analysis revealed that all items loaded onto a single factor, indicating that the problems encountered during the ISO 9001:2015 certification process are perceived by participants as a unified and comprehensive problem structure rather than as

independent dimensions. Based on this finding, the hypothesis structure and analytical framework of the study were revised accordingly. Problem domains that are treated as distinct categories in the literature were thus operationalized as a single latent variable—referred to as the Fundamental Problems Factor—in the analyses.

Given that the primary purpose of the factor analysis was to assess the structural integrity of the measurement scale, the Principal Component Analysis (PCA) method was employed. As a single-factor solution was obtained, rotation methods were deemed unnecessary, as they would not have produced meaningful changes in the factor structure. Furthermore, normality tests indicated that the Likert-type perceptual variables did not satisfy the assumption of normal distribution. Consequently, non-parametric statistical tests were applied, and all statistical analyses were conducted based on valid responses obtained from  $N = 133$  participants included in the final analysis.

#### 4. Research And Findings

In this section, the findings of the analysis are presented.

**Table 1. Demographic Findings**

N=133, Missing=0	Mean	Median	Std. Deviation	Variance	Minimum	Maximum
Gender	1,5489	2	0,49949	0,249	1	2
Education	3,3985	3	0,60227	0,363	1	4
Position	1,4211	1	0,49559	0,246	1	2
Age	47,2256	48	9,50647	90,373	22	74
	2,9925	3,0000	0,80242	0,644		
Experience Duration	23,2782	24	9,7424	94,914	0	50
	2,6842	3,0000	0,97986	0,960		

Table 1 shows the data of 133 participants (no missing data). The mean age of the participants was  $47.22 \pm 9.50$  years (min=22, max=74) and the median value was 48. The mean duration of professional experience was  $23.27 \pm 9.74$  years (min=0, max=50). The mean value for the gender variable was 1.54 (1=Female, 2=Male), and this finding shows that approximately half of the participants were female and half were male. The mean value of educational level is 3,39

(1=High School, 4=Graduate), which indicates that the majority of the participants have undergraduate and graduate level education. In the position variable, the mean value is 1.42 (1=Manager, 2=Other), indicating that the rate of participants in managerial positions is higher. These findings reveal that the group participating in the research consists of a middle-aged sample with long years of experience, a high level of education and a predominance of managers.

**Table 1. Participants' Perceptions of Certification Processes**

N=133, Missing=0	Mean	Median	Std. Deviation	Variance	Minimum	Maximum
How would you define the level of problems experienced during the ISO 9001:2015 Quality Management System certification process?	3,8496	4	0,97309	0,947	1	5
What is the level of speed and effectiveness in resolving the problems experienced during the ISO 9001:2015 Quality Management System certification process?	4,0226	4	0,95716	0,916	1	5

The 133 participants in the study evaluated the level of problems experienced in the ISO 9001:2015 Quality Management System standard certification processes and the level of fast and effective solutions to these problems. The mean of the participants' perception of the problem level is  $3.85 \pm 0.97$ . This finding shows that most of the participants think that the problems encountered in the certification processes are at medium-high level. In the perception of problem solution, the mean was found to be  $4.02 \pm 0.96$ . This shows that the participants think that fast and effective methods are applied to solve the problems experienced. In general, although the participants acknowledge the existence of problems in the certification processes, they state that the solution mechanisms for these problems are largely functional. These findings reveal that both problem awareness and solution-oriented approach are high in ISO 9001:2015 standard applications.

**Table 3. Scale Level Findings**

N=133, Missing=0	Mean	Median	Std. Deviation	Variance	Min.	Max.
1. Problems related to top management's approach (leadership, commitment, ownership, perception, collaboration, etc.)	4,391	4	0,7265	0,528	1	5
2. Insufficient organizational readiness within a strategic framework	4,2256	4	0,79407	0,631	1	5
3. Inadequate alignment of organizational culture	4,2857	4	0,77432	0,6	1	5
4. Problems arising from insufficient or ineffective organizational policies	4,203	4	0,70452	0,496	1	5
5. Lack of a sufficient and effective preparation process	4,2406	4	0,687	0,472	1	5
6. Failure to implement effective training and learning processes	4,2556	4	0,8317	0,692	1	5
7. Deficiencies in the participative management approach	4,3609	4	0,73173	0,535	1	5
8. Documentation-related problems in system development (project management, methodology, methods, communication, clarity, transparency, etc.)	4,2707	4	0,83601	0,699	1	5
9. Inability to effectively resolve issues identified during pilot implementation	4,1203	4	0,85314	0,728	1	5
10. Problems arising during the certification application phase that are not effectively resolved	4,0226	4	0,82081	0,674	1	5
11. Insufficient employee motivation	4,0977	4	0,76737	0,589	1	5
12. Inability to structure resources and capabilities in an adequate and sustainable manner	4,3383	4	0,75766	0,574	1	5

The participants evaluated their views on the main problems encountered in the ISO 9001: 2015 Quality Management System standard certification processes with a 5-point Likert scale. When the table is analysed, the mean values of all items vary between 4,02 and 4,39 and the median values are mostly determined as 4,00. Standard deviations were in the range of 0,687-0,853 and variances varied between 0,472-0,728. The highest mean value ( $4,391 \pm 0,726$ ) is seen in the problems experienced within the scope of the approach of senior management (leadership, determination, adoption, perception, co-operation, etc.). This is followed by inadequate and sustainable structuring of resources and facilities ( $4,338 \pm 0,758$ ) and inadequacies in participatory management approach ( $4,361 \pm 0,732$ ). The lowest mean was observed for the problems that arise in the certification application and cannot be solved effectively ( $4,023 \pm$

0,821). In general, all items had a mean value around 4, indicating that the respondents considered the problems experienced in the ISO 9001:2015 certification process to be of high importance. These findings reveal that management support, resource and documentation processes are critical in the certification process and that employee motivation and strategic preparation directly affect the effectiveness of the process.

**Table 2. Demographic Findings and Participant Perceptions Frequency Distribution**

Part 1		n	%	Part 2		n	%
Gender	Woman	60	45,1	Problem Level	Very low	1	0,8
	Male	73	54,9		Low	10	7,5
Education	High School	2	1,5		Centre	38	28,6
	Associate Degree	2	1,5		High	43	32,3
	Lisan	70	52,6		Very High	41	30,8
	Postgraduate	59	44,4	Solution Level	Very low	2	1,5
	Administrator	77	57,9		Low	5	3,8
Position	Other	56	42,1		Centre	32	24,1
	18-29 years	4	3,0		High	43	32,3
Age	30-41 years	27	20,3		Very High	51	38,3
	42-53 years	72	54,1				
	54-65 years	26	19,5				
	66-75 years	4	3,0				
	0-10 years	16	12,0				
Experience	11-20 years	37	27,8				
	21-30 years	59	44,4				
	31-40 years	15	11,3				
	41-50 years	6	4,5				

Among the 133 participants, the proportion of women was 45.1% (n=60) and the proportion of men was 54.9% (n=73). In terms of educational level, bachelor's degree graduates constitute the majority with 52.6% (n=70) and postgraduate graduates with 44.4% (n=59); high school and associate degree graduates are 1.5% (n=2) each. In terms of position, 57.9 per cent of the participants are managers, while 42.1 per cent work in other positions. In terms of age distribution, the highest group is 42-53 years old (54.1%, n=72), while the lowest groups are 18-29 years old (3.0%, n=4) and 66-75 years old (3.0%, n=4). In terms of professional

experience, 44.4% of the participants have 21-30 years of experience, while 12.0% have 0-10 years of experience.

When the participants evaluated the level of problems experienced in ISO 9001:2015 quality management system certification processes, 32.3% answered as high and 30.8% answered as very high; a total of 63.1% perceived the process as high problem level. This finding shows that certification processes are considered by the participants as a challenging process that needs to be handled with care. On the other hand, when asked about the level of fast and effective solutions to the problems experienced, 32.3% of the participants answered high and 38.3% answered very high; this reveals that the participants have a positive perception of problem-solving capacity.

**Table 3. Scale Level Frequency Distribution**

		n	%
1. Problems related to top management's approach (leadership, commitment, ownership, perception, collaboration, etc.)	Strongly disagree	1	0,8
	Disagree	3	2,3
	No opinion	4	3,0
	I agree	60	45,1
	Absolutely agree	65	48,9
2. Insufficient organizational readiness within a strategic framework	Strongly disagree	1	0,8
	Disagree	6	4,5
	No opinion	6	4,5
	I agree	69	51,9
	Absolutely agree	51	38,3
3. Inadequate level of organizational culture alignment	Strongly disagree	1	0,8
	Disagree	2	1,5
	No opinion	14	10,5
	I agree	57	42,9
	Absolutely agree	59	44,4
4. Problems arising from inadequate organizational policies	Strongly disagree	2	1,5
	Disagree	2	1,5
	No opinion	4	3,0
	I agree	84	63,2
	Absolutely agree	41	30,8
5. Lack of a sufficient and effective preparation process	Strongly disagree	1	0,8
	Disagree	2	1,5
	No opinion	7	5,3
	I agree	77	57,9
	Absolutely agree	46	34,6
6. Failure to implement effective training and learning processes	Strongly disagree	1	0,8
	Disagree	5	3,8
	No opinion	12	9,0

	I agree	56	42,1
	Absolutely agree	59	44,4
	Strongly disagree	1	0,8
	Disagree	3	2,3
	No opinion	5	3,8
7. Deficiencies in the participative management approach	I agree	62	46,6
	Absolutely agree	62	46,6
	Strongly disagree	1	0,8
8. Documentation-related problems in system development (project management, methodology, methods, communication, clarity, transparency, etc.)	Disagree	8	6,0
	No opinion	3	2,3
	I agree	63	47,4
	Absolutely agree	58	43,6
	Strongly disagree	1	0,8
9. Inability to effectively resolve issues identified during the system's pilot implementation	Disagree	9	6,8
	No opinion	8	6,0
	I agree	70	52,6
	Absolutely agree	45	33,8
10. Problems arising during the certification application stage that are not effectively resolved	Strongly disagree	1	0,8
	Disagree	7	5,3
	No opinion	16	12,0
	I agree	73	54,9
	Absolutely agree	36	27,1
	Strongly disagree	1	0,8
11. Insufficient employee motivation	Disagree	6	4,5
	No opinion	9	6,8
	I agree	80	60,2
	Absolutely agree	37	27,8
	Strongly disagree	1	0,8
12. Inability to structure resources and capabilities in an adequate and sustainable manner	Disagree	5	3,8
	No opinion	2	1,5
	I agree	65	48,9
	Absolutely agree	60	45,1

When the perceptions of the participants regarding the problems experienced in the ISO 9001:2015 quality management system certification process were analysed, the majority of the participants answered "Agree" or "Strongly Agree" for all 12 items. For example, 45.1% of the participants agreed and 48.9% of the participants strongly agreed on the item of problems within the scope of top management's approach. In the item that the organisation is not prepared in the strategic framework, 51.9% of the respondents agreed and 38.3% strongly agreed. Similarly, a high perception was observed on the item of insufficient level of adaptability of the organisation's culture, with 42.9% agreement and 44.4% definite agreement. Other items similarly reflect a high perception of problems: inadequate policies (63.2% agreement, 30.8%

definite agreement), lack of adequate preparation process (57.9% agreement, 34.6% definite agreement), failure to realise effective training and learning processes (42.1% agreement, 44.4% definite agreement), inadequacies in participatory management approach (46.6% agreement and 46.6% definite agreement) and problems in documentation processes (47.4% agreement, 43.6% definite agreement). Most of the participants (between 50% and 60%) also stated that they found the process problematic in items such as problems in the pilot implementation and application phase, employee motivation and the lack of sustainable structuring of resources/opportunities. These results show that the participants encountered multidimensional and comprehensive problems in the ISO 9001:2015 certification process and emphasised the importance of effective management of the process.

#### 4.1. Validity and Reliability Tests

**Table 6. Testing Normal Distribution**

	N	Skewness		Kurtosis		Kolmogorov-Smirnov <sup>a</sup>		Shapiro-Wilk	
		Statistic	SE	Statistic	SE	Statistic	Sig.	Statistic	Sig.
Gender	133	-,199	,210	-1,991	,417	0,366	0,000	0,633	0,000
Education	133	-,868	,210	1,952	,417	0,302	0,000	0,699	0,000
Position	133	,323	,210	-1,925	,417	0,381	0,000	0,627	0,000
Age	133	-,025	,210	,029	,417	0,058	,200*	0,994	0,826
Age Group	133	,014	,210	,392	,417	0,271	0,000	0,864	0,000
Experience Duration	133	,081	,210	-,138	,417	0,087	0,015	0,991	0,563
Experience Duration Group	133	,182	,210	-,017	,417	0,228	0,000	0,893	0,000
Problem Level	133	-,394	,210	-,641	,417	0,193	0,000	0,867	0,000
Solution Level	133	-,730	,210	,068	,417	0,230	0,000	0,836	0,000

\*. This is a lower bound of the true significance. a. Lilliefors Significance Correction

For the demographic variables of the participants and the items related to the ISO 9001:2015 certification process, normal distribution analysis was performed with Kolmogorov-Smirnov and Shapiro-Wilk tests. Since the Shapiro-Wilk test  $p>0.05$  (0.826 and 0.563 respectively) for age and experience duration variables, the assumption of normal distribution is met. Since  $p<0.05$  for gender, education, position and other Likert items, the assumption of normal

distribution is not met. This result shows that nonparametric tests would be appropriate for demographic categorical variables and perceptual items. In addition, when the skewness and kurtosis values are analysed, it is seen that the distributions for most items are slightly skewed to the left and some items (1, 4, 12) show high leptokurtic characteristics. This situation indicates that there are extreme values and concentrations in the data set. In line with these findings, non-parametric tests (Mann-Whitney U, Kruskal-Wallis) or median/percentile based descriptions were preferred for Likert scale items and categorical variables.

**Table 4. Validity and Reliability Findings-1**

Component Matrix <sup>a</sup>		Total Variance Explained					
	Component	Initial Eigenvalues			Extraction Sums of Squared Loadings		
		1	Total	% of Variance	Cumulative %	Total	% of Variance
1 Proposition	0,706	6,596	54,963	54,963	6,596	54,963	54,963
2 Proposition	0,750	0,881	7,341	62,304			
3 Proposition	0,714	0,796	6,632	68,937			
4 Proposition	0,797	0,725	6,042	74,979			
5 Proposition	0,800	0,585	4,874	79,853			
6 Proposition	0,742	0,532	4,431	84,284			
7 Proposition	0,728	0,455	3,788	88,072			
8 Proposition	0,766	0,373	3,111	91,183			
9 Proposition	0,738	0,358	2,979	94,163			
10 Proposition	0,740	0,269	2,242	96,405			
11 Proposition	0,639	0,256	2,131	98,536			
12 Proposition	0,763	0,176	1,464	100,000			

## Proposition Extraction Method: Principal Component Analysis

### *Extraction Method. Principle*

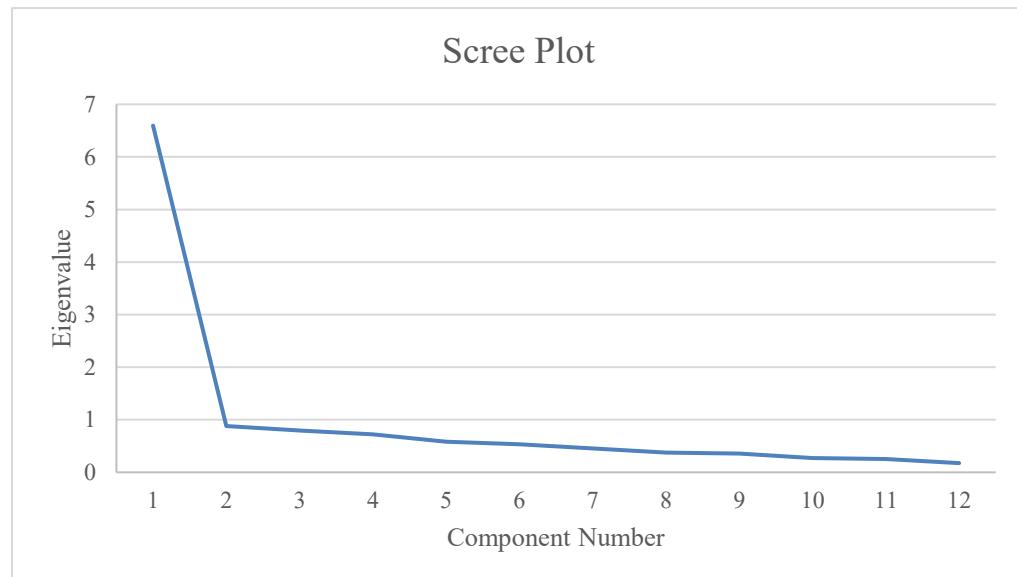
### KMO and Bartlett's Test

KMO and Bartlett's Test		
Kaiser-Meyer-Olkin Measure of Sampling Adequacy.		0,899
Bartlett's Test of Sphericity	Approx. Chi-Square	912,526
	df	66
	Sig.	0,000

In the study, exploratory factor analysis (EFA) was applied to test the construct validity of the 12-item scale for measuring the problems experienced in the ISO 9001:2015 certification process. Firstly, Kaiser-Meyer-Olkin (KMO) value for sampling adequacy was found as 0.899. This value indicates "excellent" level of suitability for factor analysis. As a result of Bartlett's

Test of Sphericity,  $\chi^2(66) = 912,526$ ,  $p < 0.001$  was obtained. This result reveals that there are significant relationships between the variables suitable for factor analysis.

**Figure 1 . Scree Plot**



As a result of the factor analysis, it is seen that the scale has a unidimensional structure. The new factor is named as "Fundamental Problems Factor" in accordance with the propositions it includes. The single factor explains 54.96% of the total variance. Considering that the variance explained above 40% is acceptable in social sciences, this ratio indicates a very strong structure. The factor loadings of the items vary between 0.639 and 0.800. The item with the highest factor loading was "not having sufficient and effective preparation process" (0,800), while the lowest loading value was observed in the item "employees not having sufficient motivation" (0,639). The common variances ranged between 0.409 and 0.640 and it was seen that the items adequately represented the factor. These findings indicate that the scale has a high level of validity and can reliably measure the problems experienced in the ISO 9001:2015 certification process under a single factor.

**Table 5. Validity and Reliability Findings-2**

Reliability Statistics						
Cronbach's Alpha	Cronbach's Alpha Based on Standardized Items		N of Items	Mean	Variance	Std. Deviation
0,924	0,925		12	50,8120	47,199	6,87017
Item Statistics						
	Mean	Std. Deviation	Corrected Item-Total Correlation		Cronbach's Alpha if Item Deleted	
1	4,3910	0,72650	0,642		0,919	
2	4,2256	0,79407	0,691		0,917	
3	4,2857	0,77432	0,651		0,919	
4	4,2030	0,70452	0,745		0,915	
5	4,2406	0,68700	0,749		0,915	
6	4,2556	0,83170	0,681		0,918	
7	4,3609	0,73173	0,668		0,918	
8	4,2707	0,83601	0,713		0,916	
9	4,1203	0,85314	0,684		0,918	
10	4,0226	0,82081	0,684		0,918	
11	4,0977	0,76737	0,575		0,922	
12	4,3383	0,75766	0,706		0,917	

When the internal consistency of the 12-proposition scale used to measure the problems experienced in the ISO 9001:2015 certification process was examined, Cronbach's Alpha coefficient was found to be 0.924. This value shows that the scale is highly reliable. When evaluated on item basis, the corrected item-total correlations ranged between 0.575 and 0.749, and it was observed that all items made a significant contribution to the scale. In addition, when any item was removed from the scale, the Cronbach's Alpha value remained in the range of 0.915-0.922, indicating that no item negatively affected the overall reliability of the scale. These results show that the scale has high reliability both holistically and at item level.

#### 4.2. Comparisons Based on Demographic Variables

**Table 9. Differences According to Gender**

Cinsiyet (1,5489 ± 0,49949)		N	Mean Rank	Sum of Ranks	Mean	Std. Deviation	Mann-Whitney U	Wilcoxon W	Z	Asymp. Sig. (2-tailed)
Problem Level	Woman	60	68,13	4087,50	3,8496	0,97309	2122,500	4823,500	-0,319	0,749
	Male	73	66,08	4823,50						
Solution Level	Woman	60	67,00	4020,00	4,0226	0,95716	2190,000	4891,000	0,000	1,000
	Male	73	67,00	4891,00						
	Male	73	63,19	4613,00						

\*Mann-Whitney U Testi

According to the Mann-Whitney U test results, the problem and solution level related to ISO 9001:2015 processes did not differ significantly in terms of gender. However, a significant difference was observed between male and female participants in "Culture" ( $p = 0,020$ ), "Process" ( $p = 0,014$ ) and "Training" ( $p = 0,016$ ) items. Female participants made higher evaluations in the related problem types than male participants.

**Table 10. Differences by Position**

Position (1,4211 ± 0,49559)		N	Mean Rank	Sum of Ranks	Mean	Std. Deviation	Mann-Whitney U	Wilcoxon W	Z	Asymp. Sig. (2-tailed)
Problem Level	Administrator	77	65,73	5061,00	3,8496	0,97309	2058,000	5061,000	-0,467	0,640
	Other	56	68,75	3850,00						
Solution Level	Administrator	77	64,75	4985,50	4,0226	0,95716	1982,500	4985,500	-0,835	0,404
	Other	56	70,10	3925,50						

According to the Mann-Whitney U test results, the level of problems and solutions related to ISO 9001:2015 processes did not show a significant difference in terms of position. In addition, no significant difference was found between the positions of the participants (Manager and Other) and the perceptions of the participants in problem types. These findings show that the

positions of the employees do not generally affect their evaluations of ISO 9000 processes. In other words, both managers and other employees evaluated the problems, solution suggestions, training and process management in a similar way.

**Table 11. Differences According to Education Level**

Education (3,3985 ± 0,6023)		N	Mean Rank	Mean	Std. Deviation	Kruskal-Wallis H	Asymp. Sig.	p
Problem Level	High School <sup>a</sup>	2	30,50	3,8496	0,97309	7,019	0,071	
	Associate degree <sup>b</sup>	2	38,75					
	Bachelor's degree <sup>c</sup>	70	73,79					
	Graduate degree <sup>d</sup>	59	61,14					
Solution Level	High School <sup>a</sup>	2	42,25	4,0226	0,95716	5,648	0,130	
	Associate degree <sup>b</sup>	2	61,00					
	Bachelor's degree <sup>c</sup>	70	73,84					
	Graduate degree <sup>d</sup>	59	59,93					

According to the Kruskal-Wallis test results, the problem and solution level related to ISO 9001:2015 processes did not show a significant difference in terms of education level. However, significant differences were found between educational levels in the problem types "documentation" ( $H = 9,208$ ,  $p = 0,027$ ) and "pilot implementation" ( $H = 8,385$ ,  $p = 0,039$ ). This finding indicates that there may be differences between undergraduate and graduate level participants especially in the perception of documentation and piloting processes.

**Table 6. Differences by Age Group**

Age (2,9925 0,80242)		N	Mean Rank	Mean	Std. Deviation	Kruskal-Wallis H	Asymp. Sig.	
Problem Level	18–29 <sup>a</sup>	4	92,00	3,8496	0,97309	6,231	0,183	
	30–41 <sup>b</sup>	27	77,56					
	42–53 <sup>c</sup>	72	65,44					
	54–65 <sup>d</sup>	26	56,69					
	66–75 <sup>e</sup>	4	65,75					
Solution Level	18–29 <sup>a</sup>	4	108,00	4,0226	0,95716	10,092	<b>0,039</b>	a>b a>c a>d a>e
	30–41 <sup>b</sup>	27	75,30					
	42–53 <sup>c</sup>	72	66,88					
	54–65 <sup>d</sup>	26	53,83					
	66–75 <sup>e</sup>	4	57,88					
	30–41 <sup>b</sup>	27	65,09					
	42–53 <sup>c</sup>	72	69,38					
	54–65 <sup>d</sup>	26	62,19					
	66–75 <sup>e</sup>	4	31,75					

According to the results of Kruskal-Wallis H test, the problem level related to ISO 9001:2015 processes did not differ significantly in terms of age group. The solution level ( $H = 10,092, p = 0,039$ ) differed depending on age. In addition, a significant difference was observed in the proposition Resources ( $H = 9,705, p = 0,046$ ) among the problem types. This result shows that especially the 18-29 age group evaluates the solution process more positively than other age groups. However, although the differences are not significant in some variables (e.g. documentation, piloting), trends can be observed between young and middle age groups. In general, the solution-oriented approach of young participants seems to be more positive compared to other age groups. It can be said that age has a limited effect on participant perception.

**Table 7. Differences According to Duration of Experience**

Experience (2,6842 ± 0,97986)		N	Mean Rank	Mean	Std. Deviation	Kruskal-Wallis H	Asymp. Sig.
Problem Level	0-10 <sup>a</sup>	16	69,88	3,8496	0,97309	0,960	0,916
	11-20 <sup>b</sup>	37	68,65				
	21-30 <sup>c</sup>	59	66,48				
	31-40 <sup>d</sup>	15	67,20				
	41-50 <sup>e</sup>	6	53,75				
Solution Level	0-10 <sup>a</sup>	16	83,34	4,0226	0,95716	4,989	0,288
	11-20 <sup>b</sup>	37	68,66				
	21-30 <sup>c</sup>	59	63,54				
	31-40 <sup>d</sup>	15	65,43				
	41-50 <sup>e</sup>	6	51,08				
	41-50 <sup>e</sup>	6	34,83				

According to the results of the Kruskal-Wallis test, the problem and solution level related to ISO 9001:2015 processes did not show a significant difference in terms of length of experience. However, a significant difference was found in the proposition "documentation" ( $H = 9, 568$ ,  $p = 0, 048$ ) among the problem types. In particular, it was determined that participants with 41-50 years of experience evaluated the issue of documentation more negatively than other experience groups. According to the results of Tukey HSD test, the scores of this group were statistically significantly lower than the groups with 0-10 years, 11-20 years, 21-30 years and 31-40 years of experience ( $p < 0.05$ ). This finding suggests that individuals with a high level of professional experience are able to see the documentation deficiencies in the processes more clearly and develop a more critical view of current practices.

**Table 14. Spearman's rho Correlation Analysis**

Solution Level		Problem Level		Experience		Age		Position		Education		Gender								
N	p	r	N	p	r	N	p	r	N	p	r	N	p	r						
133	1,000	0,000	133	0,751	-0,028	133	0,013	,214*	133	0,031	,187*	133	0,043	-,176*	133	0,077	-0,154	133	1	Gender
133	0,082	-0,151	133	0,221	-0,107	133	0,824	0,019	133	0,914	0,010	133	0,010	-,221*	133	1,000				Education
133	0,406	0,073	133	0,642	0,041	133	0,071	-0,157	133	0,091	-0,147	133	1,000						Position	
133	0,005	-,242**	133	0,021	-,200*	133	0,000	,831**	133	1,000									Age	
133	0,067	-0,159	133	0,516	-0,057	133	1,000												Experience	
133	0,000	,489**	133	1,000															Problem Level	
133		1,000																	Solution Level	

The correlation coefficients presented in the table illustrate the relationships between the Fundamental Problems Factor derived from the exploratory factor analysis and participants'

demographic variables, including gender, education level, position, age, and length of work experience. Given the unidimensional structure of the measurement scale, item-level correlation analyses were not conducted; instead, all analyses were performed exclusively at the factor-score level.

Correlation coefficients were calculated using Spearman's rho method, and all analyses were based on data obtained from  $N = 133$  participants included in the study.

Spearman's rho correlation analysis revealed significant relationships between some demographic variables and problem, solution and factors. Significant relationships were found between gender variable and position ( $r=-,176$ ;  $p<0,05$ ), age ( $r=,187$ ;  $p<0,05$ ), experience ( $r=,214$ ;  $p<0,05$ ), A significant relationship was observed between education level and position ( $r=-,221$ ;  $p<0,01$ ). Significant relationships were found between age and experience ( $r=,831$ ;  $p<0,01$ ), problem level ( $r=-,200$ ;  $p<0,05$ ) and solution level ( $r=-,242$ ;  $p<0,01$ ) Significant relationships were also found between experience and gender ( $r=,214$ ;  $p<0,05$ ) and age ( $r=,831$ ;  $p<0,01$ ) variables.

Significant relationships were observed between the problem level dimension and age ( $r=-,200$ ;  $p<0,05$ ). The solution level dimension showed a positive and strong significant relationship with the problem level ( $r=,489$ ;  $p<0,01$ ). In addition, there were significant relationships between solution level and problem level ( $r=,489$ ;  $p<0,01$ ).

### **Research Model Description**

The research model is based on a problem-oriented certification process framework, in which perceived certification problems constitute the dependent construct, while management-related, organizational, employee-related, documentation/process-related, and resource-related factors represent the independent constructs. This structure is consistent with prior empirical ISO 9001 research adopting survey-based explanatory models (Sousa-Poza et al., 2009; Gopal & Attri, 2017; Benli, 2019).

The selected model is appropriate for the objectives of this study because it allows the aggregation of practitioner perceptions and the empirical testing of certification process challenges within a unified factor structure. The use of a unidimensional problem factor is further justified by the exploratory factor analysis results, which confirm the theoretical coherence of the model

## 5. Conclusion

This study aims analysing basic steps towards certification process of ISO 9001:2015 quality management system, advantages it provides for organizations and fundamental difficulties encountered. Reviews performed within the scope of research reveal that quality management systems have a critical role in terms of institutional productivity and sustainability. Considering the 133 participants, the sample can be considered as a middle-aged and experienced group. The gender distribution of the participants is balanced and the level of education is generally undergraduate and graduate level. In addition, the number of participants in managerial positions is higher than other positions. These demographic characteristics indicate that the findings of the study can be generalised to middle-aged, experienced and highly educated managers (Table 1).

The participants in the study evaluated their perceptions of the problems encountered in ISO 9001:2015 Quality Management System certification processes and the solution mechanisms for these problems. The findings show that the participants acknowledge that the process involves some difficulties, but they think that effective and fast methods are applied to solve these problems. This situation reveals that both problem awareness and solution-oriented approach are high in certification processes (Table 2).

Participants evaluated their views on the main problems encountered in ISO 9001:2015 Quality Management System certification processes. The findings show that all items were evaluated with high scores and the participants found the problems encountered in various dimensions of the process important. In particular, the perceived inadequacies related to the approach of senior management, the lack of sustainable structuring of resources and facilities, and participant management stand out. This situation reveals that the lack of leadership, strategic preparation and managerial support in the certification process plays a decisive role in the effectiveness of the process. The lowest scoring areas are the problems experienced in the application processes that have not been solved effectively, indicating that the respondents still observe some problems in the implementation stages of the process. In general, the high values of all items indicate that the participants recognise the problems in the certification processes and think that management support, resource planning and documentation processes are critical to solve these problems. These findings emphasise that not only the identification of problems in quality

management system applications, but also the solution-oriented approach and effective management of processes are vital for the success of the process (Table 3).

Participants perceive the problems encountered in certification processes at a high level. In particular, 63% of the respondents rated the process as "high problem level", indicating that ISO 9001:2015 applications are seen by the respondents as a challenging process that needs to be handled with care. This finding reveals that problem awareness is high in certification processes and the complexity of the system has an impact on users. On the other hand, the perception of the level of solution to the problems experienced was also found to be high. The fact that a significant portion of the participants find the solution mechanisms effective and fast shows that they think that the process is not only problematic but also solution-oriented. This situation reveals that the solution processes are functional as well as the identification of problems in quality management system implementations and is a positive indicator of the effectiveness of the system in practice (Table 4).

The construct validity of the 12-item scale for measuring the problems experienced in the ISO 9001:2015 certification process was tested by exploratory factor analysis. Sampling adequacy was confirmed by KMO value and Bartlett Sphericity Test results and it was shown that the scale was suitable for factor analysis. As a result of the analysis, the scale has a unidimensional structure and the single factor explains 54.96% of the total variance. The fact that the factor loadings of the items are high and the common variance values are at a sufficient level reveals that the scale has a strong structure. These findings show that the scale can reliably and validly measure the main problems experienced in the ISO 9001:2015 certification process. The Cronbach's Alpha coefficient of the 12-item scale used to measure the problems experienced in the ISO 9001:2015 certification process was found to be high. This coefficient of 0.924 indicates that the reliability of the scale is strong.

The normal distribution analyses for the demographic variables of the participants and the items related to the ISO 9001:2015 certification process revealed that most of the data did not show a normal distribution. The examination of skewness and kurtosis values showed that the data set was slightly left skewed and highly skewed in some items. These findings revealed that nonparametric tests (such as Mann-Whitney U, Kruskal-Wallis) and median/percentile-based descriptions were appropriate for demographic categorical variables and perceptual items.

Mann-Whitney U test results revealed that the general problem and solution levels regarding ISO 9001:2015 certification processes did not differ significantly in terms of gender. However, on the basis of problem types, significant differences were found between female and male participants in the items "Culture", "Process" and "Training", and it was observed that female participants made higher evaluations in these areas than male participants. In the analyses made in terms of position, no significant difference was found between the general problem and solution levels and problem types. These findings show that the positions of the participants do not affect their perceptions of ISO 9001:2015 processes; both managers and other employees evaluate the process and related problems similarly.

The research findings show that there are multidimensional and comprehensive problems in the ISO 9001:2015 quality management system certification process. Although the participants generally accepted that the process is problematic, they stated that the solution mechanisms for the problems are largely functional. When analysed in terms of demographic variables, while gender created different perceptions in some problem types (culture, process, education), the position did not affect the evaluations in general. Significant differences were observed in the perception of documentation and piloting processes depending on the level of education, and differences were found in the level of solution and some problem types (resources) in terms of age group. The length of experience was particularly effective in the perception of documentation, and participants with longer experience evaluated process deficiencies more critically.

Spearman correlation results revealed that problem and solution levels showed significant relationships with many factors. Positive relationships were found between the problem and solution levels and the factors, and the solution level was found to have a strong relationship with the problem level. The correlations between the factors show that the elements in the system are complementary and supportive structures, which reveals that the ISO 9001:2015 certification process requires a holistic and integrated approach.

From a theoretical perspective, this study contributes to the ISO 9001 literature by shifting the focus from outcome-oriented evaluations of quality management systems toward the certification process itself as a critical implementation phase. While prior studies have predominantly examined the performance impacts and benefits of ISO 9001 certification (e.g., Benner & Veloso, 2008; Psomas & Antony, 2015), this research empirically identifies and

structures the core problem dimensions experienced during certification. By doing so, it enriches the limited body of empirical research that explicitly addresses certification-related challenges under the ISO 9001:2015 framework, particularly in relation to leadership, risk-based thinking, and organizational context requirements (ISO, 2015; Fonseca, 2015).

From a practical perspective, the findings provide concrete recommendations for organizations aiming to enhance the effectiveness and sustainability of ISO 9001:2015 certification. First, the prominence of problems related to top management approach underscores the necessity of visible leadership commitment, strategic ownership of the quality management system, and active managerial involvement beyond symbolic compliance (Boiral, 2011; Heras-Saizarbitoria & Boiral, 2013). Certification efforts that lack genuine leadership engagement risk remaining formalistic and failing to generate long-term value.

In the direction of obtained findings, it is determined that organizations must adopt a systematic approach for completing ISO 9001:2015 certification process successfully. Especially active participation of senior management to the process, increasing awareness of employees towards quality management system and documenting the processes effectively influence the success of certification process directly. However, the factors like compliance problems encountered in internal and external audit processes, limited financial sources and compliance problems of employee feature as the main factors which difficultate practicability of the process (Güldoğan, 2022: 53-54). Organizations must discuss quality management systems not only for the purpose of certification but also within the frame of a sense of institutional management to be able to increase efficiency of ISO 9001:2015 certification process (Dönen, 2021:97). In this context, continuous improvement of quality management system, adopting risk-based approaches and developing customer orientation hcritical significance in terms of strengthening organizations' competitive advantages.

Consequently, for applying ISO 9001:2015 quality management systems in businesses victoriously, both technical and managerial processes must be dealed with a holistic approach. Examining sectoral differencies of quality management systems and improvement fields in implementation processes by future research more detailed will contribute literature and practitioners.

The results indicating that leadership commitment, organizational culture, documentation burden, and resource constraints constitute the most critical challenges are consistent with

findings reported in national studies conducted in Türkiye (Benli, 2019; Karakaş & Savaş, 2019; Kapucugil & Dönən, 2023). Similarly, international studies have emphasized the central role of top management involvement and employee engagement in determining certification success (Sousa-Poza et al., 2009; Bravi et al., 2019; Gopal & Attri, 2017).

However, unlike some international studies that report documentation issues as secondary barriers, the present study identifies documentation and process management problems as highly salient, reflecting contextual and institutional characteristics of the national setting. This divergence underscores the importance of considering country-specific organizational practices when evaluating ISO 9001:2015 certification experiences.

Overall, the comparative assessment confirms that while the core challenges of ISO 9001 certification exhibit structural similarities across contexts, their relative intensity and manifestations may vary between national and international settings.

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