

INTERNAL AND EXTERNAL AUDITS ISO 9001:2015: A CRITICAL ANALYSIS ON COMPLIANCE AND STRATEGIC VALUE

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Abstract: This article presents an in-depth analysis of the role of quality management system (QMS) audits under the ISO 9001:2015 standard, investigating how these transcend the function of compliance verification to become a pillar of strategic value and corporate governance. The research, theoretical in nature and based on a systematic literature review, explores the dichotomy and synergy between internal and external audits, contextualizing them within the PDCA cycle and risk-based thinking. It analyzes the effectiveness of audits as drivers of continuous improvement and their impact on organizational performance, based on empirical evidence. Additionally, the study correlates the maturity of ISO 9001 certification with business excellence models, such as EFQM. The discussion delves into the auditor's competence as a critical factor and the alignment of audit programs with top management, proposing that audit results be used as business intelligence. It is concluded that the effective integration of audits into business strategy is a competitive differential, transforming a normative requirement into a driver of resilience and sustainable excellence.

Keywords: ISO 9001:2015, Quality Audit, Strategic Value, Corporate Governance, Continuous Improvement, Business Excellence.

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Introdução

The International Organization for Standardization (ISO) 9001 is, unquestionably, the most influential quality management system (QMS) standard on a global scale, serving as a reference for more than one million organizations in 189 countries (ISO, 2015). The transition to the 2015 version represented a paradigmatic inflection, moving away from a prescriptive approach to a more flexible and strategic framework, grounded in concepts such as risk-based thinking, in-depth analysis of the organizational context, and accountability of top leadership (ISO, 2015). In this ecosystem, audits (clause 9.2) emerge not only as a verification mechanism but as a vital sensor for the health and effectiveness of the QMS (ISO, 2015). Historically, the audit process has often been perceived as a bureaucratic exercise, focused on detecting deviations and maintaining a certificate. However, recent literature and advanced management practice suggest a latent and underutilized potential (LENNING; GREMYR, 2022). Audits, when properly planned and executed, can function as a powerful organizational diagnostic tool, providing insights that feed continuous improvement and strategic planning (ALIČ; RUSJAN, 2010). The objective of this article is, therefore, to critically dissect the ISO 9001:2015 audit process, going beyond the surface of compliance to explore its deep strategic implications. We will analyze the dynamics between internal and external audits, the role of the ISO 19011:2018 standard as a methodological guide (ISO, 2018), and how auditor competence and management support are decisive in transforming this process into a generator of sustainable value and a pillar of good corporate governance.

Literature Review

The literature on quality management systems and audits is vast, but can be categorized into thematic axes that underpin the present analysis.

Evolution and Impact of ISO 9001

ISO 9001 has undergone significant evolution since its creation, migrating from a model focused on quality assurance to a strategic management system (OCHIENG et al., 2015). Empirical studies have consistently sought to validate the relationship between ISO 9001 certification and organizational performance. Research such as that by Ochieng et al. (2015) and Gotzamani et al. (2007) demonstrate positive correlations, although the impact is moderated by factors such as motivation for certification and system maturity (OCHIENG et al., 2015; GOTZAMANI et al., 2007). The 2015 version, with its emphasis on organizational context and risk-based thinking, aims to strengthen this link, making the QMS more aligned with business strategy (ISO, 2015).

Internal Audit as an Improvement Tool

Despite its importance, internal auditing is frequently cited as one of the weakest elements in the practice of ISO 9001 (LENNING; GREMYR, 2022). A systematic review conducted by Lenning and Gremyr (2022) concluded that internal audits tend to focus excessively on compliance to the detriment of improvement, and that auditors lack the knowledge and skills for a process-oriented audit (LENNING; GREMYR, 2022). On the other hand, Alič and Rusjan (2010) argue that a well-structured internal audit contributes significantly to business performance, especially when its results are effectively used by management (ALIČ; RUSJAN, 2010). Therefore, the effectiveness of internal auditing depends on factors such as management support, auditor competence, and the ability to generate recommendations that add value.

Auditing, Governance and Excellence Models

The discussion about quality audits is intrinsically connected to corporate governance. The

audit committee, a key governance body, is responsible for overseeing the integrity of processes, which includes the effectiveness of the QMS. Quality audits provide the committee and top management with independent assurance about the effectiveness of internal controls related to quality.

Moreover, ISO 9001 is often seen as an initial step in the journey toward business excellence. Models such as the European Foundation for Quality Management (EFQM) and the Malcolm Baldrige National Quality Award (MBNQA) offer a more holistic framework (EFQM; MBNQA). Comparative studies indicate that, while ISO 9001 focuses on the consistency and compliance of processes (ensuring that “we do things right”), excellence models focus on results and stakeholder satisfaction (ensuring that “we do the right things”). Maturity in ISO 9001 certification has been positively correlated with better results in the EFQM model criteria, suggesting a trajectory of evolution.

Methodology

The present research is characterized as a theoretical study, developed through a systematic literature review. The methodology was designed to ensure a comprehensive and critical analysis of the subject, following a structured approach for data collection, analysis, and synthesis.

The review process was conducted in three main stages:

Review Planning: The initial phase involved defining the scope and central research questions:

(i) How do internal and external audits of ISO 9001:2015 differ and complement each other? (ii) In what way can the audit process be leveraged to generate strategic value beyond compliance? (iii) What is the role of auditor competence and corporate governance in the effectiveness of quality audits?

Data Collection: The search for sources was carried out in renowned academic databases, such as Scopus, Web of Science, Emerald Insight, and Taylor & Francis Online, as well as standards repositories like that of ISO itself. The keywords used, in English and Portuguese, included “ISO 9001 audit,” “quality audit effectiveness,” “strategic value,” “corporate governance,” “business excellence,”

“ISO 19011,” and their combinations. Peer-reviewed journal articles, books, theses, and the technical standards themselves were selected, focusing on publications from 2010 onwards to ensure relevance, but including seminal works prior when necessary.

Data Analysis and Synthesis: The selected documents were subjected to a thematic content analysis. Information was extracted, categorized, and organized according to the thematic axes defined in the literature review: the impact of ISO 9001, the effectiveness of internal audit, and the relationship with governance and excellence models. The synthesis of data aimed not only to summarize the findings but also to identify synergies, contradictions, and gaps in the literature, allowing the construction of a critical and in-depth argument that constitutes the body of this article.

This methodological approach allows a robust and multifaceted analysis, integrating theoretical perspectives, empirical evidence, and normative guidelines to offer a holistic view of the strategic role of ISO 9001:2015 audits.

Analysis and Discussion

From the reviewed literature and applicable standards, a multifaceted analysis of the audit process emerges, which can be broken down into four central axes of discussion.

The Functional Dichotomy: Internal Audit as a Proactive Tool and External as Reactive Validation

The distinction between internal and external audits goes far beyond who performs them. They represent two sides of the same quality coin, with distinct but synergistic functions. The following table deepens the comparative analysis:

Dimension	Internal Audit (First Party)	External Audit (Third Party)
Strategic Purpose	Proactive and Formative: Identify improvement opportunities, optimize processes, mitigate risks before they materialize, and train the organization.	Reactive and Summative: Validate compliance with an external standard, provide market credibility, and assure stakeholders.
Main Focus	Efficiency and effectiveness of processes. Search for waste, bottlenecks, and misalignments with strategic objectives.	Compliance with the ISO 9001 standard requirements. Adherence to what was documented.
Depth	High. Can dive deep into specific processes, conducting thematic or “deep dive” audits.	Medium. Sampling by nature, seeks evidence of compliance in a representative sample of the QMS.
Mindset	“How can we do better?” - Focus on performance and innovation.	“Are we doing what we said we would?” - Focus on consistency and control.
Relationship with the Audited	Collaborative. The internal auditor acts as a consultant and partner in improvement.	Formal and distant. Independence is crucial for the credibility of the evaluation.

While the external audit provides the seal of approval that is often a market requirement, the internal audit is the true engine of continuous improvement. Organizations that treat the internal audit merely as a rehearsal for the external one waste its greatest potential: that of being a catalyst for change and an instrument of organizational learning (ALIČ; RUSJAN, 2010; LENNING; GREMYR, 2022).

The Strategic Role of ISO 19011:2018: Risk, Evidence, and Competence

ISO 19011:2018 is not just a procedural manual; it is a strategic guide to conducting audits that add value. The emphasis on the “risk-based approach” is particularly transformative. It guides auditors to focus their time and effort on areas presenting higher risk to achieving quality and business objectives (ISO, 2018). This transforms the audit from a generic checklist to a targeted and intelligent investigation.

A risk-based audit considers, for example:

- Critical processes for customer satisfaction.
- Areas with a history of nonconformities.
- Recent changes in processes, technology, or personnel.
- Risks and opportunities identified by the organization itself (clause 6.1 of ISO 9001).

Additionally, the principle of “evidence-based approach” requires that audit conclusions be based on verifiable facts, not assumptions or impressions (ISO, 2018). This provides rigor and objectivity to the process, making audit reports defensible and reliable documents for decision-making.

From Nonconformities to Business Intelligence: Maximizing Strategic Value

The most visible outcome of an audit is often the nonconformity report. However, the strategic value lies in the aggregated analysis and interpretation of these data. A single nonconformity is an isolated problem; a pattern of recurring nonconformities in the same process or department is a symptom of a systemic weakness that requires deeper root cause analysis.

Mature organizations treat audit data (internal and external) as a source of business intelligence. Trend analysis of audit findings over time can:

- **Reveal Emerging Risks:** Identify areas where controls are deteriorating before a significant failure occurs.
- **Point Out Efficiency Opportunities:** Highlight processes that are consistently sources of waste, rework, or bureaucracy.
- **Validate the Effectiveness of Corrective Actions:** Verify whether solutions implemented in the past were, in fact, effective in eliminating the root causes of problems.
- **Inform Strategic Planning:** Provide senior management with a realistic overview of

the organization's operational capacity, supporting investment, expansion, or change decisions.

This approach transforms the auditor from an “inspector” to a “business analyst,” and the audit report from a “problem list” to a “strategic diagnosis.”

Quality Governance: Aligning Audit, Senior Management, and Business Excellence

The effectiveness of the entire audit process ultimately depends on its alignment with corporate governance. Senior management involvement cannot be passive. Clause 9.3, “Management review,” requires that the audit results be a fundamental input for this review (ISO, 2015). It is in this forum that audit findings should be discussed, contextualized, and transformed into strategic actions.

The relationship between ISO 9001 and excellence models such as EFQM illustrates this connection. ISO 9001 establishes the foundation of controlled and consistent processes. Excellence models build upon this foundation, driving the organization towards superior results for all stakeholders (EFQM). Quality audits, in this context, serve as the bridge, assessing not only the conformity of the foundation but also the effectiveness with which it supports the organization's excellence objectives.

An audit program aligned with governance ensures that:

- The objectives of the audit program are aligned with the business's strategic objectives.
- Adequate resources (including competent auditors) are allocated.
- Results are communicated clearly and actionably to senior management.
- There is rigorous follow-up on the implementation and effectiveness of actions resulting from audits.

Conclusions and Implications

This in-depth study of ISO 9001:2015 audits reveals that their role goes far beyond traditional compliance verification. The critical analysis of the literature and standards shows that audits, when strategically designed and executed, are an indispensable tool for continuous improvement, corporate governance, and the pursuit of business excellence.

The main conclusions are:

- **Functional Synergy:** Internal and external audits are not redundant but complementary. The internal audit should be the proactive tool for improvement and learning, while the external audit serves as independent validation and compliance reference. Underutilizing internal audit as merely preparation for the external audit wastes its strategic potential.
- **Strategic Intelligence:** The true value of audits is not in the counting of nonconformities, but in the analysis of trends and identification of systemic weaknesses. Audit data, when treated as business intelligence, offer senior management valuable insights for decision making, risk management, and resource allocation.
- **Competence as a Pillar:** The effectiveness of an audit is directly proportional to the auditor's competence. Auditors who combine technical knowledge of the standard with a deep understanding of the business and communication skills are able to identify not only failures but also opportunities, turning the audit into a high-value consultancy.

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