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Evolution of the ISO 15189 Standard: A Comparative Analysis of the 2012 and 2022 Versions and Their Implications for Medical Biology Laboratories

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ABSTRACT: The reliability of medical laboratory test results is a key determinant of healthcare quality and patient safety. ISO 15189 is the international reference standard for the accreditation of medical biology laboratories, and its 2022 revision reflects technological advances, organizational changes, and increasing requirements related to performance and risk management.
The aim of this study is to conduct a comparative analysis of the major developments introduced in ISO 15189: 2022 compared with the 2012 version, in order to identify conceptual, structural, and operational changes, assess their organizational and technical implications for medical biology laboratories, and highlight the challenges related to patient safety and process performance.
This study adopts a qualitative, descriptive, and comparative approach based on a systematic, clause-by-clause analysis of ISO 15189: 2012 and ISO 15189: 2022. This analysis is complemented by a targeted review of the international scientific literature and by an examination of recommendations issued by recognized organizations in the fields of medical biology and quality management.
The results reveal major developments, including the reorganization of the standard's structure in alignment with ISO/IEC 17025: 2017, the explicit and cross-cutting integration of risk management across all laboratory processes, the expansion of the scope to include decentralized medical biology examinations and point-of-care testing, and a stronger focus on patient safety, governance, and the clinical relevance of results. The 2022 version also introduces greater flexibility in demonstrating conformity.
In conclusion, ISO 15189: 2022 represents a major conceptual shift, moving from a primarily document-based compliance approach toward a performance-oriented model that emphasizes proactive risk management and patient safety, thereby serving as a strategic lever for continuous improvement in medical biology laboratories.

KEYWORDS: ISO 15189, medical biology laboratories, quality management, risk management, patient safety, accreditation, process performance, point-of-care testing (POCT).

1 INTRODUCTION

Medical biology laboratories occupy a strategic position within healthcare systems, as approximately 60–70% of clinical decisions rely on laboratory test results (Lippi & Plebani, 2020). The reliability, accuracy, and traceability of these results are therefore critical for patient safety and quality of care. In this context, ISO 15189 has progressively become the international benchmark for ensuring the quality and competence of medical biology laboratories, providing a framework that covers all

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processes from the pre-analytical to the post-analytical phase (Takahashi, 2025). However, rapid advances in medical technologies, the growing digitalization of information systems, and increasing demands for risk management have made a revision of this standard necessary.

In response, the International Organization for Standardization published the revised ISO 15189: 2022, introducing a more integrated approach to quality management focused on patient safety, laboratory governance, and proactive risk control (Linko et al., 2025). This new version aligns with prior work emphasizing the importance of continuous improvement in laboratory practices and systematic management of error sources, particularly in the pre- and post-analytical phases, which are recognized as the most vulnerable parts of the analytical process (Alsharari, 2024).

Scientific literature has extensively documented the benefits of implementing ISO 15189: 2012, including standardized procedures, strengthened internal and external quality controls, and increased clinician confidence in results provided by accredited laboratories (Ali et al., 2024; Westgard & Westgard, 2016). Several studies have also shown a positive association between ISO 15189 accreditation and reduced analytical errors, thereby enhancing overall laboratory performance and patient safety (Lippi & Plebani, 2020). Yet, despite the recent publication of ISO 15189: 2022, comparative scientific analyses examining the conceptual and operational differences between the 2012 and 2022 versions remain limited.

In particular, the real-world impact of the new 2022 requirements—especially regarding risk management, data and information system governance, and increased accountability of laboratory leadership—has not been sufficiently documented in the scientific literature. This gap is particularly pronounced in hospital settings and in resource-limited countries, where the normative transition can represent a major organizational and human challenge (Edayan et al., 2024). There is thus a disconnect between the normative evolution proposed by ISO 15189: 2022 and the available knowledge on its effective implementation and tangible impact on the quality of medical laboratory services.

Against this backdrop, the present study aims to conduct a comparative analysis of the main developments introduced in ISO 15189: 2022 compared with the 2012 version, with the goals of identifying key changes, assessing their organizational and technical implications for medical biology laboratories, and proposing adaptation strategies to facilitate the transition to this new standard, ultimately supporting continuous quality improvement and patient safety.

2 METHODOLOGY

This study adopts a qualitative, descriptive, and comparative approach, based on an in-depth analysis of ISO 15189: 2012 and ISO 15189: 2022, which the authors systematically reviewed and compared. The aim of this approach is to identify the conceptual, structural, and operational changes introduced in the 2022 version and to analyze their implications for medical biology laboratories.

The comparative analysis was conducted through a critical, exhaustive reading of both standards, using a clause-by-clause comparison of managerial and technical requirements. This method allows for the identification of newly introduced requirements, those that have been strengthened or reformulated, as well as elements that have been maintained or clarified in the revised version, in accordance with recommended approaches for analyzing quality management standards (ISO 15189, 2012, 2022).

In addition to this direct normative analysis, a targeted review of the scientific literature was conducted to contextualize the ISO 15189 requirements within the broader field of quality and safety in medical biology. The PubMed, Scopus, and Web of Science databases were consulted to identify peer-reviewed articles addressing laboratory accreditation, risk management, analytical quality, and continuous improvement. The selected publications enabled a comparison of normative requirements with evidence-based findings from the scientific literature (Linko et al., 2025; Takahashi, 2025).

Moreover, the results of the comparison between the two versions of the standard were examined in light of recommendations from leading international organizations, including the World Health Organization and the Clinical and Laboratory Standards Institute, to assess the consistency of the 2022 revisions with recognized best practices in medical laboratory operations (Schuetz et al., 2025). This methodological triangulation strengthens the validity of the analysis and highlights areas of convergence and divergence between the normative requirements and international standards.

Finally, an interpretative analysis was performed to evaluate the practical implications of ISO 15189: 2022 for laboratory organization, human resource management, process control, and overall performance. This analysis aligns with a continuous improvement framework based on the PDCA cycle and a proactive risk management approach, both of which are well documented in the scientific literature on laboratory medicine.

3 RESULTS

The comparative analysis of ISO 15189: 2012 and ISO 15189: 2022 reveals significant structural, conceptual, and operational changes, impacting all activities of medical biology laboratories.

3.1 STRUCTURAL AND ORGANIZATIONAL CHANGES

The 2012 version consisted of 15 chapters, separating technical and managerial requirements, with a strong emphasis on documentation and procedure standardization. While comprehensive, this structure sometimes made it difficult to integrate managerial processes with day-to-day technical practices. The 2022 version reduces the number of chapters to 8 and organizes requirements more coherently, aligned with ISO/IEC 17025: 2017. This reorganization provides a more integrated view of the quality system, facilitating understanding and application in multi-standard and international laboratories (Datta et al., 2026; Ilinca et al., 2023).

3.2 RISK MANAGEMENT

Risk management is a central conceptual change. While implicit in the 2012 version, the 2022 revision makes it a cross-cutting requirement across all processes: pre-analytical, analytical, and post-analytical. Laboratories must identify risks affecting result quality and patient safety, plan corrective and preventive actions, and regularly evaluate their effectiveness. This systematic approach enhances laboratories' ability to anticipate and control incidents, reducing clinical errors and strengthening patient safety (Datta et al., 2026; Thomas et al., 2025).

3.3 EXPANDED SCOPE

The 2022 version now includes decentralized medical biology examinations and point-of-care testing (POCT), previously governed by ISO 22870. This expansion ensures uniform quality and safety practices across all laboratory activities, whether performed in a central lab or on site, reflecting modern clinical practices characterized by rapid diagnostics and test decentralization (Thomas et al., 2025).

3.4 PATIENT-CENTERED FOCUS AND SAFETY

ISO 15189: 2022 strengthens the focus on patient safety and outcome reliability. While the 2012 version emphasized document compliance, the 2022 revision prioritizes process performance and minimization of clinical risk. Laboratories are expected to demonstrate that their practices ensure not only analytical accuracy but also the safety and reliability of results provided to clinicians, supporting better patient care (Lippi & Plebani, 2020).

3.5 FLEXIBILITY IN IMPLEMENTATION

The new version allows laboratories to demonstrate compliance through multiple means: performance indicators, internal audits, and contextual assessments. This flexibility reduces documentation burdens while maintaining core requirements for competence and traceability (Vermeersch et al., 2021).

To summarize these key differences and their implications, the main changes between ISO 15189: 2012 and ISO 15189: 2022 are presented in the following table:

Table 1. Summary of Key Differences:

Category	ISO 15189:2012	ISO 15189:2022	Implications / Notes
Structural & Organizational Changes	15 chapters; technical and managerial requirements separated; emphasis on documentation and standardization.	8 chapters; more coherent organization; aligned with ISO/IEC 17025:2017.	Facilitates integrated quality system, understanding, and application in multi-standard labs.
Risk Management	Implicit; not formally cross-cutting.	Explicit, cross-cutting requirement across all processes. Corrective/preventive actions required.	Enhances incident control, reduces errors, improves patient safety.
Scope	Central lab-focused; POCT/decentralized tests governed separately by ISO 22870.	Includes decentralized tests and POCT.	Ensures uniform quality and safety practices; reflects modern decentralized testing.
Patient-Centered Focus & Safety	Emphasis on document compliance.	Focus on process performance, clinical risk minimization, and outcome reliability.	Strengthens patient safety, reliability of results, and clinician confidence.
Flexibility in Implementation	Compliance mainly via documentation.	Compliance via performance metrics, audits, contextual assessments.	Reduces documentation burden while maintaining competence and traceability.

Source: authors

4 DISCUSSION

The revision from ISO 15189: 2012 to 2022 represents a strategic and conceptual shift, moving beyond technical adjustments. It reflects a paradigm change: from procedural compliance to a focus on performance, risk management, and patient safety.

4.1 CONCEPTUAL EVOLUTION: FROM COMPLIANCE TO PERFORMANCE

Historically, ISO 15189: 2012 ensured standardization and traceability, limiting errors in pre-analytical, analytical, and post-analytical phases (Vermeersch et al., 2021). However, this rigid approach restricted laboratories' ability to adapt to technological innovations and emerging healthcare needs (Westgard & Westgard, 2016).

The 2022 version, by integrating proactive risk management, allows laboratories to prioritize critical processes, reduce errors that could affect patient safety, and allocate resources to high-value activities. This performance-oriented approach aligns with current quality management recommendations, emphasizing process integration, continuous improvement, and focus on clinical outcomes (Thomas et al., 2025).

4.2 INTERNATIONAL HARMONIZATION AND MULTI-STANDARD INTEGRATION

Alignment with ISO/IEC 17025: 2017 and other management standards promotes coherence between frameworks, facilitating the integration of multi-standard systems. The simplified structure and reduced number of chapters improve clarity and harmonized application, enhancing organizational resilience and overall laboratory efficiency (Datta et al., 2026).

4.3 SCOPE EXTENSION AND PATIENT ORIENTATION

Incorporating decentralized tests and POCT reflects recent clinical transformations: speed, decentralization, and proximity to the patient. This systemic approach ensures the quality and safety of results at all stages of the diagnostic pathway while supporting continuity and coordination of care (Thomas et al., 2025).

4.4 ETHICAL DIMENSION AND DATA MANAGEMENT

The 2022 revision strengthens impartiality, confidentiality, and traceability of information. Consideration of computerized systems and data protection addresses the growing digitalization of laboratories (Datta et al., 2026; Edayan et al., 2024). Ethical aspects, such as patient autonomy, remain underdeveloped, representing a potential area for future revisions.

4.5 PRACTICAL IMPACTS AND IMPLEMENTATION CHALLENGES

Adopting the revised standard improves analytical accuracy, reduces errors, and enhances clinician and patient satisfaction (Beyanga et al., 2018; Takahashi, 2025). Implementation challenges include risk-based management training, adaptation of information systems, electronic documentation, and validation of new processes, especially in resource-limited laboratories (Attoh et al., 2022).

4.6 SCIENTIFIC PERSPECTIVES AND FUTURE IMPLICATIONS

ISO 15189: 2022 opens avenues for research and practice:

- Empirical evaluation of the new requirements' impact on patient safety and clinical performance.
- Development of tailored tools for decentralized laboratories and POCT.
- Exploration of patient participation and autonomy within the normative framework.

Thus, the standard serves both as a tool for standardization and a lever for innovation, guiding laboratories through the rapid transformations occurring in the healthcare sector.

The transition from ISO 15189: 2012 to 2022 goes beyond a simple technical update, representing a major conceptual shift: optimizing performance, implementing proactive risk management, integrating decentralized testing and POCT, achieving international harmonization, and strengthening the patient-centered focus.

These developments respond to the scientific, technological, and organizational transformations in the field of medical biology. They provide laboratories with a flexible, resilient framework oriented toward clinical outcomes, while maintaining the fundamental requirements for competence and quality.

Adopting the 2022 version also represents both a scientific and operational opportunity: the development of new risk management strategies, empirical evaluation of performance, and enhanced ethical and organizational integration of quality systems. ISO 15189: 2022 thus emerges as a strategic lever for achieving excellence in medical biology laboratories within an ever-evolving healthcare environment.

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