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Integrated Quality Management in Biomedical and Forensic Sciences: The Synergy Between ISO 21043 and Sectoral Standards

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Abstract: This study examines the interdisciplinary interaction and strategic integration between the ISO 21043 series, which provides holistic standardization in the field of forensic sciences, and quality management standards such as ISO 9001, ISO 13485, and ISO 15189, which form the foundation of the biomedical ecosystem. In this article, the common philosophical ground shared by forensic processes—ranging from crime scene management to analytical validation, and from probabilistic interpretation models to reporting phases—with risk management, biological safety, and traceability (UDI) protocols used in biomedical engineering is analyzed through a comparative perspective. Particular emphasis is placed on the critical role of the Likelihood Ratio (LR)-based rational framework highlighted within ISO 21043-4 and Linear Sequential Unmasking (LSU) protocols, which minimize cognitive biases, in preserving the integrity of substantive truth. The review indicates that integrating standards through the "Harmonized Structure" (Annex SL) not only enhances operational efficiency but also represents an ethical and legal commitment that reinforces public trust in the justice system.

Keywords: Core Standards, Forensic Science Concepts, Biomedical & Laboratory Integration, Quality & Risk Management.

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Adli Bilimler ve Suç Araştırmaları Dergisi

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Biyomedikal ve Adli Bilimlerde Entegre Kalite Yönetimi: ISO 21043 ve Sektörel Standartlar Arasındaki Sinerji

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Öz: Bu çalışma, adli bilimler alanında bütüncül standardizasyon sağlayan ISO 21043 serisi ile biyomedikal ekosistemin temelini oluşturan ISO 9001, ISO 13485 ve ISO 15189 gibi kalite yönetim standartları arasındaki disiplinlerarası etkileşimi ve stratejik entegrasyonu incelemektedir. Bu makalede, olay yeri yönetiminden analitik validasyona, olasılıksal yorumlama modellerinden raporlama aşamalarına kadar adli süreçlerin paylaştığı ortak felsefi zemin; biyomedikal mühendislikte kullanılan risk yönetimi, biyolojik güvenlik ve izlenebilirlik (UDI) protokolleri ile karşılaştırmalı bir perspektif üzerinden analiz edilmiştir. ISO 21043-4 kapsamında vurgulanan Olabilirlik Oranı (LR) tabanlı rasyonel çerçevenin ve bilişsel önyargıları en aza indiren Doğrusal Ardışık Maskeleme (LSU) protokollerinin maddi gerçeğin bütünlüğünü korumadaki kritik rolü üzerinde özellikle durulmuştur. İnceleme, standartların "Uyumlaştırılmış Yapı" (Annex SL) üzerinden entegre edilmesinin yalnızca operasyonel verimliliği artırmakla kalmayıp, aynı zamanda adalet sistemine yönelik kamu güvenini pekiştiren etik ve yasal bir taahhüt olduğunu göstermektedir.

Anahtar Kelimeler: Temel Standartlar, Adli Bilim Kavramları, Biyomedikal ve Laboratuvar Entegrasyonu, Kalite ve Risk Yönetimi.

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Introduction

Global standardization processes in the field of forensic sciences have reached a strategic turning point with the holistic publication of the ISO 21043 series (Berger, 2025). When examined from a historical perspective, it is observed that forensi∑c service providers have operated under a heterogeneous regulatory infrastructure that has generally been insufficient in managing the legally complex workflows ranging from crime scene investigations to expert testimony in court proceedings (Berger, 2025). This structure consisted of a fragmented combination of basic laboratory requirements, medical diagnostic standards, and local-level protocols (Berger, 2025). General Quality Management Systems (QMS) such as ISO 9001 (International Organization for Standardization [ISO], 2015), and specialized standards like ISO 13485 (ISO, 2016)—specific to the biomedical field—provide a framework for institutional quality assurance and product safety (Doyle, 2020). In contrast, these normative frameworks frequently fall short of fully encompassing the specific dynamics and sensitivities inherent to forensic processes, which are essential for protecting the integrity of forensic evidence against cognitive biases and violations of scientific validity (Neuteboom et al., 2024).

The principal aim of this review is to provide a comprehensive comparison of the ISO 21043 series and established biomedical quality management standards, specifically ISO 9001 (ISO, 2015), ISO 13485 (ISO, 2016), and ISO 15189 (ISO, 2022). By exploring their conceptual intersections, this study seeks to elucidate how shared principles—such as risk management, traceability, and biological safety—can be integrated to enhance the reliability of forensic processes. Furthermore, this review specifically evaluates the critical role of analytical validation, probabilistic interpretation models (such as the Likelihood Ratio), and cognitive bias mitigation strategies in preserving the integrity of forensic evidence and reinforcing public trust in the justice system.

The Normative Structure and Operational Scope of The ISO 21043 Series

The ISO 21043 series of standards, developed by the ISO/TC 272 Technical Committee, represents a transformative initiative aimed at integrating forensic sciences under an autonomous disciplinary umbrella (G. S. Morrison et al., 2025). Distinct from ISO/IEC 17025 (International Organization for Standardization & International Electrotechnical Commission [ISO/IEC], 2017), which primarily focuses on attesting the technical competence of testing and calibration laboratories, or ISO/IEC 17020 (ISO/IEC, 2012), which regulates the operational requirements of inspection bodies, ISO 21043 provides a holistic, five-stage

framework covering the entire lifecycle of the forensic process (G. S. Morrison et al., 2025). This series is not intended to substitute existing accreditation standards; rather, it is designed to work as a complement and in integration with them (Doyle, 2020). Accordingly, ISO 21043 aims to address methodological gaps in field-specific terminological standardization, evidence collection on-site, the rational interpretation of obtained findings, and the reporting of these findings to judicial authorities (Wilson-Wilde, 2018).

Forensic Terminology and Conceptual Foundations

ISO 21043-1 (ISO, 2018a) provides a standardized reference vocabulary that constitutes the conceptual infrastructure for all other standards within the series (G. S. Morrison et al., 2025). In forensic science practice, where fundamental concepts such as "material," "observation," and "analysis" can carry varying legal weights and interpretations across different jurisdictions, this first part establishes a binding and common ground for communication among practitioners, researchers, and legal stakeholders (Berger, 2025). This terminological standardization is of critical importance for the operability of the "forensic data science paradigm," which centers on process transparency, analytical reproducibility, and methodologies resilient to cognitive biases (G. S. Morrison et al., 2025).

Crime Scene Management: Integrity of Evidence and Field Protocols

ISO 21043-2 (ISO, 2018b) focuses on the initial stages of the forensic processes: detection, documentation, sampling (collection), transfer, and storage (G. S. Morrison et al., 2025). The standard emphasizes that the reliability of subsequent analytical stages and the integrity of evidence are directly dependent on the quality of the initial field collection processes (Berger, 2025). The primary objective of these normative requirements is to secure the obtained materials against risks of physical loss, degradation (structural deterioration), and contamination (Meuwly, 2024). This proactive approach to managing contamination risks presents a strong structural parallel with sterility requirements in biomedical quality systems (Kaur et al., 2021). However, the approach in question is specifically adapted to the uncontrolled and dynamic conditions of crime scenes, where the "ground truth" is often uncertain (Meuwly, 2024).

Analytical Rigor and Method Validation

The third part of the standard series (ISO 21043-3) (ISO, 2025a) defines the normative requirements for the "analysis" phase, which encompasses the process of obtaining empirical findings through the detection, measurement, or comparative evaluation of the characteristic properties of materials (G. S. Morrison et al., 2025). This part mandates that forensic service providers

implement methodologies validated for fitness for purpose and valid analytical procedures through competent (qualified) personnel (G. S. Morrison et al., 2025). In this context, specific criteria are established for analytical method validation, continuous monitoring of equipment performance, and the reporting of measurement uncertainty (G. S. Morrison et al., 2025). While ISO/IEC 17025 (ISO/IEC, 2017) offers a generic framework for standard laboratory quality management, ISO 21043-3 (ISO, 2025a) directly addresses methodological challenges inherent to forensic sciences, such as the qualitative comparison of trace findings and subjective evaluations based on expert perception (Berger, 2025).

Probabilistic Models in Forensic Interpretation: The Likelihood Ratio (*LR*)

The fourth part of the ISO 21043 series (ISO 21043-4) (ISO, 2025b), which regulates the normative requirements and guiding principles for the interpretation of forensic findings, constitutes the most innovative dimension of the series (Berger, 2025). This standard clause maintains a clear conceptual distinction between "investigative interpretation," intended to guide ongoing investigations, and "evaluative interpretation," which produces results based on the relative evidential strength of competing hypotheses (G. S. Morrison et al., 2025). Providing a rational infrastructure for interpretation methodology, this section adopts the "likelihood ratio" approach as the fundamental paradigm, specifically comparing the probability values of empirical evidence in the context of the prosecution's hypothesis () and the defense's hypothesis () (G. S. Morrison et al., 2025). Furthermore, the standard mandates the minimization of cognitive bias risks through the isolation (masking/blinding) of contextual information that is not directly related to the task and could compromise the professional judgment or analytical impartiality of experts (Berger, 2025). This holistic approach, which envisions the construction of interpretation processes on the psychological and logical foundations of science rather than mere technical procedures, creates a strategic distinction that sets the ISO 21043 series apart from traditional technical standards (Berger, 2025).

Reporting and the Justice System Interface

The fifth and final part of the ISO 21043 standard series (ISO 21043-5) (ISO, 2025c) regulates the reporting and subsequent expert-testimony phases, which constitute the final outputs of the forensic examination process (Berger, 2025). This section establishes strict normative criteria to ensure the principles of accuracy, transparency, data integrity (completeness), and analytical impartiality in the presentation of forensic findings (Meuwly, 2024). These requirements aim

to ensure that obtained forensic results are presented clearly and transparently to judicial authorities and with an argumentation that possesses defensible scientific validity (Meuwly, 2024). Accordingly, the standard mandates comprehensive case file reviews (peer review), where findings are subject to independent review, the controlled publication of reports in accordance with quality management principles, and structured training processes aimed at enhancing the in-court expert testimony competencies of forensic personnel (Meuwly, 2024).

Table 1: Sectional distribution and legal impact matrix of the ISO 21043 series

ISO 21043 Part	Domain Focus	Primary Technical Requirement	Judicial Implication
Part 1	Vocabulary	Terminology consistency.	Reduced ambiguity in court.
Part 2	Field & Recovery	Protection from contamination.	Admissibility of evidence.
Part 3	Laboratory	Method validation & Uncertainty.	Reliable scientific observations.
Part 4	Interpretation	Likelihood ratio framework.	Minimized cognitive bias.
Part 5	Reporting	Transparent & Impartial testimony.	Enhanced trust in the justice system.

Source: (ISO, 2018a, 2018b, 2025a, 2025b, 2025c; Doyle, 2020; Meuwly, 2024; G. S. Morrison et al., 2025)

Comparative Quality Management: ISO 9001 and ISO 13485

The selection of a reference standard is of critical importance for forensic service providers that interact directly with the biomedical ecosystem through activities such as developing medical diagnostic kits (in vitro diagnostics - IVD) or conducting clinical/forensic toxicological analyses (Vanstapel et al., 2023). In this context, the choice between ISO 9001 (ISO, 2015), which offers a generic quality infrastructure, and ISO 13485 (ISO, 2016), which focuses on regulatory requirements specific to medical devices (such as MDR/IVDR compliance), is a strategic management decision that fundamentally shapes the institution's entire

Quality Management System (QMS) architecture and legal compliance strategy, rather than being a mere certification process (Sharma & Luthra, 2023a).

Universal Quality Versus Regulatory Rigidity

ISO 9001 (ISO, 2015) serves as a generic (horizontal) standard, offering a comprehensive quality management architecture applicable across all industries without sectoral restrictions (Doyle, 2020). This standard centers on a process-oriented "continual improvement" paradigm based on customer satisfaction, top management commitment (leadership), and the Plan-Do-Check-Act (PDCA) cycle (Doyle, 2020). In contrast, ISO 13485 (ISO, 2016) is a sectoral (vertical) standard specifically designed for the medical device industry and the biomedical ecosystem (Sharma & Luthra, 2023a). Although ISO 13485 (ISO, 2016) inherits the fundamental quality philosophy of ISO 9001 (ISO, 2015), it presents a much more prescriptive and uncompromising normative structure regarding strict regulatory compliance, integrated risk management, and the continuous maintenance of Quality Management System (QMS) effectiveness (Sharma & Luthra, 2023a).

Safety and Effectiveness in the Biomedical Context

In the biomedical ecosystem, the fundamental paradigm of the ISO 13485 (ISO, 2016) standard is the uncompromising establishment of patient safety and the clinical effectiveness of medical devices (Iqbal et al., 2025). In this context, the standard focuses on the control of design and development steps, the validation of production processes, and rigorous documentation management (Sharma & Luthra, 2023a). Unlike ISO 9001 (ISO, 2015), which allows management a relative degree of initiative and flexibility regarding the delegation of quality management responsibilities, ISO 13485 (ISO, 2016) explicitly mandates the appointment of specific authorized management representatives with clearly defined accountability for each major element of the Quality Management System (QMS) (Doyle, 2020).

However, the selection of a standard differs in the context of independent technical service providers that do not engage in manufacturing but solely provide maintenance, repair, and calibration services for medical devices (Sharma & Luthra, 2023a). The strict and prescriptive requirements of ISO 13485 (ISO, 2016) directed toward production may not fully align with the dynamics of pure field service operations (Iqbal et al., 2025). For this reason, the integration of ISO 9001 (ISO, 2015) for such independent service providers is generally considered a more rational and pragmatic strategic choice in terms of operational efficiency and field applicability (Francisco et al., 2024).

Table 2: Strategic comparison in quality management systems: ISO 9001 vs. ISO 13485

Feature	ISO 9001 (Universal)	ISO 13485 (Medical Device)
Industry Scope	Any industry.	Medical devices & related services.
Primary Goal	Customer satisfaction & Improvement.	Patient safety & Regulatory compliance.
Improvement Focus	Process-driven continual improvement.	Maintenance of QMS effectiveness.
Risk Management	Risk-based thinking (general).	Mandatory per ISO 14971.
Documentation	Flexible based on organization size.	Highly prescriptive & rigorous.

Source: (ISO, 2015, 2016, 2019; Francisco et al., 2024; Nunhes et al., 2021; Sharma & Luthra, 2023a)

Laboratory Competence and Clinical Responsibility: ISO 17025 and ISO 15189

Forensic laboratories, by virtue of their operational structures, are frequently positioned at the intersection of routine analytical testing procedures and clinical/medical diagnostic processes (Joseph et al., 2025). This multidisciplinary ecosystem necessitates an in-depth understanding of the structural dynamics and normative boundaries between the ISO/IEC 17025 (ISO/IEC, 2017) standard, which is based on the competence of testing and calibration laboratories, and the ISO 15189 (ISO, 2022) standard, which specifically regulates the quality and competence requirements of medical laboratories (Tsimillis & Michael, 2022).

Technical Competence Versus Patient-Centered Care

The ISO/IEC 17025 (ISO/IEC, 2017) standard defines the general (generic) requirements for the technical competence and operational quality of testing and calibration laboratories (Wilson-Wilde, 2018). In diverse operational ecosystems where independent test requests can be received from external stakeholders, this standard is widely referenced by forensic science service providers to certify analytical integrity, impartiality, and technical validation processes (Islek & Yukseloglu, 2018), as effectively demonstrated in the compliance frameworks of specialized DNA testing facilities (Doyle, 2024).

In contrast, the ISO 15189 (ISO, 2022) standard is specifically designed to meet the dynamics of medical laboratories that fulfill diagnostic analysis requests exclusively from clinical experts (physicians) (Wilson-Wilde, 2018). By demonstrating maximum sensitivity to medical personnel and patient-oriented ethical principles as well as patient safety, this standard ensures that obtained laboratory findings are transformed into clinically meaningful (high diagnostic value) data and directly support effective patient care processes (Tsimillis & Michael, 2024).

Pre-Analytical and Post-Analytical Nuances

The fundamental conceptual distinction between these two standards becomes evident in the structuring of laboratory workflows and operational phases (Tsimillis & Michael, 2022). ISO 15189 (ISO, 2022) defines specific terminology and strict normative requirements for the pre-analytical (patient identification, sample collection, and transfer) and post-analytical (clinical interpretation and consultation with physicians) phases, which are of vital importance for the reliability of clinical findings (Tsimillis & Michael, 2022).

In contrast, while ISO/IEC 17025 (ISO/IEC, 2017) contains basic operational requirements for the management of testing and calibration processes, it does not mandate the comprehensive "clinical consultation" service that lies at the heart of ISO 15189 (ISO, 2022) to the same extent (Vanstapel et al., 2023). When evaluated in the context of forensic medicine experts and clinical toxicologists; although the technical analytical procedures performed continue to be subject to the uncompromising metrological traceability principles of ISO/IEC 17025 (ISO/IEC, 2017), ISO 15189 (ISO, 2022) provides a holistic reference framework that aligns much more closely with the diagnostic nature of the activities carried out by these professionals (Tsimillis & Michael, 2024).

Table 3: Analysis of laboratory accreditation parameters: ISO/IEC 17025 and ISO 15189

Requirement	**ISO/IEC 17025**	**ISO 15189**
Environment	Testing/Calibration (General).	Medical/Clinical (Specific).
Requestor	General Public/Any entity.	Medical Professionals.
Calibration	Direct requirement for traceability.	Often relies on 17025-accredited labs.

Internal Audits	Focus on technical process control.	Focus on areas critical to patient care.
Safety Focus	Laboratory environment & personnel.	Patient, visitor, and staff safety.

Source: (ISO, 2022; ISO/IEC, 2017; Doyle, 2024; Linko et al., 2025; G. S. Morrison et al., 2025; Tsimillis & Michael, 2024; Wilson-Wilde, 2018)

The Duality of Risk: ISO 31000 and ISO 14971

Risk management is a fundamental cornerstone of the normative standards regulating both forensic sciences and biomedical disciplines (Smith & Horne, 2024). Conversely, the conceptual framework and methodological approach to the phenomenon of risk present a structural divergence between generic approaches aimed at operational continuity and corporate strategy, and sectoral regulations that center on patient/user health and technical product safety (such as the requirements of ISO 14971) (Yang, 2024).

The Universal Framework of ISO 31000

The ISO 31000 (ISO, 2018c) standard provides macro-level guiding principles for the systematic management of the phenomenon of risk across a broad industrial spectrum, ranging from the finance sector to forensic sciences (Wilson et al., 2020). This framework conceptualizes risk from a multidisciplinary perspective as the "effect of uncertainty on objectives"; accordingly, it treats risk not merely as a threat to be eliminated (negative risk), but also as a potential opportunity to be evaluated (positive risk) (Wilson et al., 2020). The primary objective of this normative framework is to transform the "risk-based thinking" paradigm into an organic part of the corporate culture and to structure risk management processes in a fully integrated manner aligned with the institution's general business strategy and Key Performance Indicators (KPIs) (Lizarzaburu et al., 2025).

The Technical Rigor of ISO 14971

In contrast, ISO 14971 (ISO, 2019) is a sector-specific (vertical) and technical normative standard developed exclusively for the medical device industry (Yang, 2024). Unlike generic approaches, this standard addresses the phenomenon of risk within a more specific and narrow framework, defining it as the "combination of the probability of occurrence of harm and the severity of that harm" (Tsimillis & Michael, 2024). In this analytical context, the concept of "harm" is grounded

directly on the axis of violations of patient and user safety (Yang, 2024). Full compliance with the ISO 14971 (ISO, 2019) standard serves as a regulatory and binding legal requirement for medical device manufacturers to demonstrate their risk management competencies with objective evidence throughout the entire product lifecycle, spanning from the design and development phase to the "Post-Market Surveillance" (PMS) stage (Yang, 2024).

Risk in the Forensic Process: Integrity and the Fallacy of Justice

The ISO 21043 standard series, while not explicitly mandating the generic risk management standard ISO 31000 (ISO, 2018c) or the medical device-specific ISO 14971 (ISO, 2019) as a normative prerequisite, organically integrates risk management principles into its own architecture to eliminate hazards inherent in the forensic science discipline (G. S. Morrison et al., 2025). This integration manifests as specific risk control mechanisms across different parts of the standard (Meuwly, 2024):

- **Part 2 (Sample Collection and Transfer):** Minimizes the risks of contamination and degradation (structural deterioration) of physical evidence through strict custody and transfer protocols (ISO, 2018b; Meuwly, 2024).
- **Part 3 (Analytical Processes):** Reduces the risk of generating erroneous or deviated empirical results to a minimum through analytical method validation and the accounting of measurement uncertainty (ISO, 2025a; G. S. Morrison et al., 2025).
- **Part 4 (Interpretation of Findings):** Targets errors based on subjective human judgment and cognitive bias risks through a rationally grounded "likelihood ratio" framework (ISO, 2025b; G. S. Morrison et al., 2025).
- **Part 5 (Reporting and Presentation):** Eliminates the risks of faulty expert testimony that could mislead judicial authorities, thanks to process transparency and comprehensive peer review (case file examination) mechanisms (ISO, 2025c).

The concept of "severity of harm," which forms the basis of risk analysis in the forensic science ecosystem, ontologically differs from the direct physical or clinical patient harm defined in ISO 14971 (ISO, 2019; Yang, 2024). In this field, the phenomenon of harm is generally equated with a "miscarriage of justice" (Wilson et al., 2020). This fallacy manifests as "false positive" (Type I error) analytical outputs leading to the wrongful conviction of an innocent individual, or "false negative" (Type II error) outputs resulting in the actual perpetrator remaining unpunished (Wilson et al., 2020).

Table 4: Definitional and regulatory taxonomy of risk management standards

Standard	Risk Definition	Domain	Regulatory Status
ISO 31000	Effect of uncertainty on objectives.	Universal/ Strategic.	Voluntary guideline.
ISO 14971	Probability & severity of harm.	Medical Device Safety.	Mandatory for marketing.
ISO 21043	Process integrity & reliability.	Forensic Evidence.	Voluntary but recommended.

Source: (Leitch, 2010; Lizarzaburu et al., 2025; Sharma & Luthra, 2023a; Yang, 2024)

THE INTERSECTION OF BIOLOGICAL EVALUATION AND TOXICOLOGICAL SAFETY

The analytical evaluation processes of biological materials (or findings of biological origin) necessitate the synergistic integration of the ISO 10993 (ISO, 2025d) standard series, which regulates the biological evaluation and toxicological risk management of medical devices, with the ISO 21043 normative framework, which ensures the preservation of evidential integrity (Bernard et al., 2018).

ISO 10993: Biocompatibility and Biological Safety

The ISO 10993-1 standard establishes the fundamental normative framework that integrates the biological evaluation processes of medical devices within a comprehensive risk management (e.g., ISO 14971) architecture (Sharma & Luthra, 2023b). In biomedical literature, "biocompatibility" is defined as the capacity of a biomaterial to perform its intended therapeutic or diagnostic function in a specific clinical application with an "appropriate host response," without causing unwanted or adverse reactions in the host tissue (Bernard et al., 2018). Biological evaluation procedures in this context involve the analytical detection of potential biological hazards such as cytotoxicity (lethal effect at the cellular level), genotoxicity (damage to genetic material/DNA), sensitization (immunological allergic response), and systemic toxicity (Sharma & Luthra, 2023b).

Recent revisions to the ISO 10993-1 standard have shifted the methodological focus toward a proactive and risk-based paradigm that positions chemical characterization (ISO 10993-18) and toxicological risk assessment (ISO 10993-17) steps at much earlier stages of the product development (R&D) cycle (ISO, 2025d). This innovative strategy allows manufacturers to scientifically optimize (or minimize) the projected burden of costly and time-consuming biological testing (in vivo / in vitro), provided they can prove with analytical data that exposure levels to potential toxic components (extractables/leachables) remain below specific acceptable toxicological threshold values (Bernard et al., 2018).

DNA Integrity in the Forensic Context

From a forensic science perspective, biological evaluation processes primarily focus on the stages of detection, field collection, and laboratory analysis of biological materials such as blood, saliva, and tissue to identify individuals through DNA profiling (J. Morrison et al., 2018). The conceptual and operational intersection of this specific field with the ISO 10993 (ISO, 2025d) standard series emerges in the necessity to analytically verify that the inventory used for forensic sampling—or during the process of obtaining forensic evidence directly from a medical device—does not contain contaminants capable of inhibiting subsequent biological analyses.

To be more specific, a forensic scientist conducting analytical processes must be methodologically aware of risks associated with “extractables” that could be released from polymeric consumables under laboratory conditions and function as Polymerase Chain Reaction (PCR) inhibitors or degrade the target DNA integrity (Kaur et al., 2021). While the ISO 10993-3 standard specifically evaluates the genotoxic potential of medical device materials to ensure patient safety, forensic science service providers utilize similar toxicological risk management principles to prevent materials used for evidence collection (e.g., swabs, sample tubes, and reagents) from manipulating the “ground truth” of the biological sample (Bernard et al., 2018).

Identification, Labeling, and Traceability

Ensuring end-to-end traceability of a material or product throughout its entire lifecycle constitutes one of the fundamental normative requirements where both ISO 13485 (ISO, 2016) and ISO 21043 standards converge, even though the operational mechanisms applied and the ultimate goals achieved differ contextually (Iqbal et al., 2025; G. S. Morrison et al., 2025).

ISO 15223: Universal Symbols for Biomedical Safety

The ISO 15223-1 (ISO, 2021) standard provides a directory of standardized symbols to be used in labeling processes to ensure that critical safety and usage information regarding medical devices is communicated clearly on a global scale, without being hindered by language barriers. The integration of universal symbols such as "Manufacturer," "Caution," "Biological Risk," and "Do Not Reuse" into the system enhances user safety by eliminating the risk of misinterpretation (use-errors) arising from different languages and minimizes the legal and operational risk profile of manufacturing firms (Sharma & Luthra, 2023a).

Although the use of these symbols is technically voluntary, since the relevant norm holds the status of a harmonized standard, it constitutes a legal "presumption of conformity" for the essential safety and performance requirements sought in major regulatory frameworks such as the European Union Medical Device Regulation (EU MDR 2017/745) (Sharma & Luthra, 2023a). Therefore, the implementation of this standard is a strategic necessity strongly encouraged by sector professionals in the processes of placement on the international market (Sharma & Luthra, 2023b).

Unique Device Identification (UDI)

The "Unique Device Identification" (UDI) system constitutes the most critical and technological cornerstone of end-to-end traceability within the biomedical ecosystem (Bianchini et al., 2019). In the regulatory architecture, a UDI structure primarily consists of the integration of two major components:

- **Device Identifier (UDI-DI):** A static reference code registered in databases (such as EUDAMED or GUDID) that makes the specific model, version, and legal manufacturer of the medical device globally unique (Bianchini et al., 2019).
- **Production Identifier (UDI-PI):** A variable containing specific and dynamic production data such as lot/batch numbers, serial numbers, manufacturing date, and expiration date pertaining to the production of the device (Valdes et al., 2025).

This systemic infrastructure establishes the "closed-loop traceability" essential for the flawless execution of urgent field withdrawal/recall operations and regulatory audits in the event of potential adverse incidents, spanning from the manufacturing line to the supply chain and ultimately to the point-of-care (Bianchini et al., 2019). The ISO 13485 (ISO, 2016) standard stipulates as a definitive normative requirement that manufacturing firms document such rigorous traceability procedures within their Quality Management System (QMS) to ensure medical device safety (Iqbal et al., 2025).

Forensic Chain of Custody and Labeling

From a forensic science perspective, the ISO 21043-2 (ISO, 2018b) standard establishes definitive normative requirements for the identification and labeling of potential forensic evidence to preserve the legal and scientific integrity of the "chain of custody" (Meuwly, 2024). The forensic labeling procedure must identify each material with a unique reference from the very first moment it is detected at the scene and must uninterruptedly document the entire chronological history of the material, covering the phases of transfer, storage, and laboratory analysis (Alketbi, 2023).

While medical device labeling focuses primarily on the safety of clinical outcomes, standardization of use, and monitoring of patient health, the forensic labeling paradigm is based on the principle of "legal admissibility" and the obligation to prove with concrete data that the finding has not been subjected to any tampering (manipulation) or unauthorized intervention (Alketbi, 2023). In this context, a forensic scientist is obliged to record the physical displacement of samples or devices with the same metrological and documentation rigor found in the logic of a biomedical Production Identifier (UDI-PI); because in forensic processes, the ultimate "end-user" is not a patient, but the judicial authorities (the court) themselves (Wilson-Wilde, 2018).

Proficiency Testing: A Tool for Performance Evaluation

Proficiency Testing (PT) functions as a critical external quality assurance mechanism in both forensic science and biomedical laboratory practices for the objective measurement of analytical performance and the periodic verification of practitioner competence (Mejia et al., 2020).

ISO/IEC 17043: General Requirements for Proficiency Testing Providers

The ISO/IEC 17043 (ISO/IEC, 2023) standard defines the general normative requirements for the technical competence, operational impartiality, and consistent functioning of Proficiency Testing (PT) provider organizations (Tsimillis & Michael, 2022). Proficiency testing is the process of objectively evaluating the analytical performance of participant laboratories against pre-randomized and validated criteria through "interlaboratory comparisons" (Badrick et al., 2022). This mechanism serves strategic purposes within Quality Management Systems (Bezerra et al., 2025):

- **Certification of Analytical Performance:** Verification of the laboratory's measurement capability and technical performance specific to certain test methods and parameters (Mejia et al., 2020).

- **Systemic Error Detection and Continual Improvement:** Diagnosis of operational bottlenecks or systematic analytical deviations (bias) and the proactive initiation of "Corrective Actions" accordingly (Miller et al., 2011).
- **Evidence of Accreditation:** Providing objective, third-party evidence to accreditation bodies (e.g., TÜRKAK) that the laboratory maintains its technical competence within its declared scope (Badrick et al., 2022).

Forensic Proficiency and Ground Truth

In the discipline of forensic science, the systematic implementation of standardized "Proficiency Testing" (PT) programs is an essential component for establishing institutional quality assurance (QA) (Mejia et al., 2020). Forensic proficiency testing programs differ from routine chemical analysis proficiency tests, as they must incorporate into their methodology the "ground truth" of complex sample matrices—such as heterogeneous DNA profiles (mixtures) or latent fingerprints—along with subjective human perception and interpretation during the analytical process (Mejia et al., 2020).

In this context, global providers such as Forensic Foundations International have adopted the ISO 21043 normative framework as a guide to ensure that proficiency testing exercises reflect entire real-life forensic case simulations, from the material collection phase to the final reporting stage (G. S. Morrison et al., 2025). This holistic approach allows laboratories to test not only instrument sensitivity but also the end-to-end methodological validity of the forensic process (Mejia et al., 2020).

Strategic Synthesis: Integrating Forensic and Biomedical QMS

The ultimate strategic goal for organizations operating in high-risk ecosystems is to establish an "Integrated Quality Management System" (IQMS) capable of meeting the rigorous requirements of heterogeneous standards (technical, sectoral, and regulatory) within a single system, while maintaining operational efficiency and dynamism (Smith & Horne, 2024). This approach aims to transform quality from being a series of independent operational burdens into a sustainable and auditable management architecture that blends risk-based thinking with corporate performance (Wilson et al., 2020).

High-Level Structure and Harmonized Approach

Modern standards, including ISO 9001 (ISO, 2015), ISO 13485 (ISO, 2016), ISO 15189 (ISO, 2022), and ISO/IEC 17025 (ISO/IEC, 2017), are based on the "Harmonized Structure" (HS; formerly known as High-Level Structure - HLS)

architecture, which optimizes the simultaneous and synergistic implementation of multiple management systems (Francisco et al., 2024). This common format, also defined as "Annex SL," facilitates terminological consistency, a common clause hierarchy, and the integration of core operational requirements across diverse management domains such as quality, environment, information security, and occupational health and safety (Nunhes et al., 2021). Such structural alignment enables organizations to construct an integrated and streamlined organizational governance framework instead of creating separate procedures for different standards (Nunhes et al., 2021).

The Role of Leadership and Continual Improvement

Both forensic science and biomedical standards emphasize that "leadership commitment" is an indispensable prerequisite for the sustainability of the system (Iqbal et al., 2025). Top management must assume a proactive role in the strategic formulation of the corporate quality policy, the determination of measurable quality objectives, and the integration of the Quality Management System (QMS) into the organization's routine business processes (Yang, 2024).

Furthermore, the "continual improvement" paradigm lies at the core of the ISO 9001 (ISO, 2015) standard. This paradigm is also reflected in the performance enhancement focus of medical laboratories under ISO 15189 (ISO, 2022; Alali et al., 2024). Together with the "maintenance of effectiveness" requirement of ISO 13485 (ISO, 2016), these principles ensure that the organization evolves with the flexibility to meet dynamic risks, regulatory changes, and technological innovations. This developmental approach transforms quality management from a static set of documents into a living corporate mechanism that consistently elevates performance (Wilson-Wilde, 2018).

Ethical Responsibility and Trust

Ultimately, these normative standards represent a moral and ethical commitment to all stakeholders, whether they be patients relying on a medical device for vital functions or the justice mechanism awaiting a verdict based on expert testimony (Smith & Horne, 2024). The ISO 21043 standard series enhances the reliability and scientific validity of expert opinions by providing a methodological framework specific to the discipline of forensic science, thereby reinforcing public trust in the justice system (Berger, 2025). Similarly, the ISO 13485 (ISO, 2016) and ISO 15189 (ISO, 2022) standards ensure that medical device manufacturers and clinical laboratories provide error-free services at high-quality standards that place human life and dignity at their core (Sharma & Luthra, 2023a).

Analytical Framework for Inference-Based Interpretation in ISO 21043

The most fundamental methodological distinction between the ISO 21043 standard series and general laboratory accreditation standards, such as ISO/IEC 17025 (ISO/IEC, 2017), is the requirement for a "formal logical framework" in the interpretation of findings, as explicitly defined under ISO 21043-4 (ISO, 2025b; Berger, 2025). While ISO/IEC 17025 (ISO/IEC, 2017) is primarily concerned with the technical accuracy, measurement uncertainty, and metrological traceability of analytical test and calibration results, ISO 21043-4 (ISO, 2025b) mandates the use of probabilistic and logical inference models, such as the "likelihood ratio," for the rational and transparent evaluation of technical findings within the forensic context (G. S. Morrison et al., 2025). This structured approach ensures that forensic opinions are stripped of subjective judgments and placed on a scientifically testable and defensible logical ground before the court (Doyle, 2020).

The Likelihood Ratio Framework

The Likelihood Ratio (LR) framework provides a logically consistent and mathematically valid methodology for quantifying the degree to which competing hypotheses are supported by the observed findings (see Equation 1) (G. S. Morrison, 2022). This evaluation is based on the ratio of the probabilities of observing the evidence (*E*) under each hypothesis through the "probability density function" (*f*) (G. S. Morrison, 2022):

Where:

- (Prosecution Hypothesis): The hypothesis proposing that the evidence (e.g., a biological sample) originates directly from the source in question (e.g., the suspect's genetic material) (Meuwly, 2024).
- (Defense Hypothesis): The hypothesis proposing that the evidence originates from an alternative and random source unrelated to the source in question (G. S. Morrison, 2022).
- (Background Information): The conditioning factor representing the technical background information and the case context surrounding the analysis (G. S. Morrison et al., 2025).

Measurement Uncertainty in Qualitative and Quantitative Observations

The ISO 21043-3 (ISO, 2025a) and ISO 21043-5 (ISO, 2025c) standards mandate that analytical estimates must be reported as numerical values supported by an expression of "measurement uncertainty" (G. S. Morrison et al., 2025). In the forensic ecosystem, the phenomenon of uncertainty primarily originates from three main sources (G. S. Morrison et al., 2025):

- **Measurement Variability:** Variations arising from the technical limitations of analytical instrumentation and measurement equipment (Meuwly, 2024).
- **Material (Finding) Quality:** The level of structural degradation or contamination to which the physical evidence has been subjected (G. S. Morrison et al., 2025).
- **Model Uncertainty:** Internal constraints and assumptions of the statistical model or the Likelihood Ratio (LR) framework itself (G. S. Morrison et al., 2025).

In cases where the quality of the finding is limited or controversial, the standard adopts a "conservative approach" regarding the evidential weight (G. S. Morrison et al., 2025). In this context, by allowing the reporting of a lower bound Likelihood Ratio closer to the "neutral value" of 1 which does not support either hypothesis, it minimizes the risk of erroneous inference arising from technical uncertainty in conviction or acquittal decisions (G. S. Morrison et al., 2025).

Resistance to Cognitive Bias

The ISO 21043-4 (ISO, 2025b) standard defines the minimization of cognitive biases, such as "circular reasoning" or "observer effects" that could undermine analytical integrity, as a normative requirement (Berger, 2025). In this context, forensic science service providers must implement structural protocols such as "Linear Sequential Unmasking" (LSU), in which the analyst independently interprets the finding obtained from the crime scene (the questioned evidence) before being exposed to the technical characteristics of the reference sample belonging to the suspect (Doyle, 2020).

This methodological approach reduces the risk of the expert's perception being "primed" by the suspect's known data and, consequently, the risk of "fitting" the evidence to the suspect (Dror & Pierce, 2020). This cognitive protection mechanism is a critical requirement specific to forensic sciences, which has no direct counterpart in general clinical diagnostic standards under ISO 15189 (ISO, 2022), where a patient's clinical history is explicitly shared to support the diagnostic process (Linko et al., 2025).

Conclusion

The ISO 21043 standard series provides a link between the technical rigor required by traditional laboratory quality management and the specific requirements of forensic processes (Berger, 2025). While this normative framework shares a common philosophical ground with biomedical standards such as ISO 9001 (ISO, 2015), ISO 13485 (ISO, 2016), and ISO 15189 (ISO, 2022) regarding risk management (ISO 31000 / ISO 14971), biological safety (ISO 10993), and

traceability; it also incorporates specific legal requirements aimed at preserving the “integrity of the material truth” against both physical contamination and cognitive biases (G. S. Morrison et al., 2025).

By integrating ISO 21043 into their existing accreditation portfolios, forensic service providers can guarantee that their scientific work possesses the resilience to withstand the most rigorous cross-examinations and scrutiny in the courtroom (G. S. Morrison et al., 2025). Similarly, biomedical organizations can project their technical competence into the forensic field with scientific and ethical confidence by leveraging this harmonized set of standards (Berger, 2025). Ultimately, the harmonization of these standards represents a global and steadfast commitment to analytical accuracy, individual safety, and the universal principles of justice (Berger, 2025).

ETHICAL DECLARATION

Research and publication ethics were strictly complied with in this study. Since this is a review article based on existing literature and standard frameworks, no data collection method requiring ethics committee approval was utilized.

CONFLICT OF INTEREST STATEMENT

The authors declare that there is no conflict of interest regarding the research, authorship, and/or publication of this article.

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AUTHOR CONTRIBUTIONS

Both authors contributed equally to the study conception and design, literature review, analysis and interpretation of the standards, and manuscript preparation. All authors read and approved the final manuscript.

DECLARATION OF AI USAGE

No artificial intelligence tools were used in the generation of the scientific content or conceptual framework of this study. AI-assisted technologies were solely utilized for minor language polishing and layout formatting purposes.

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