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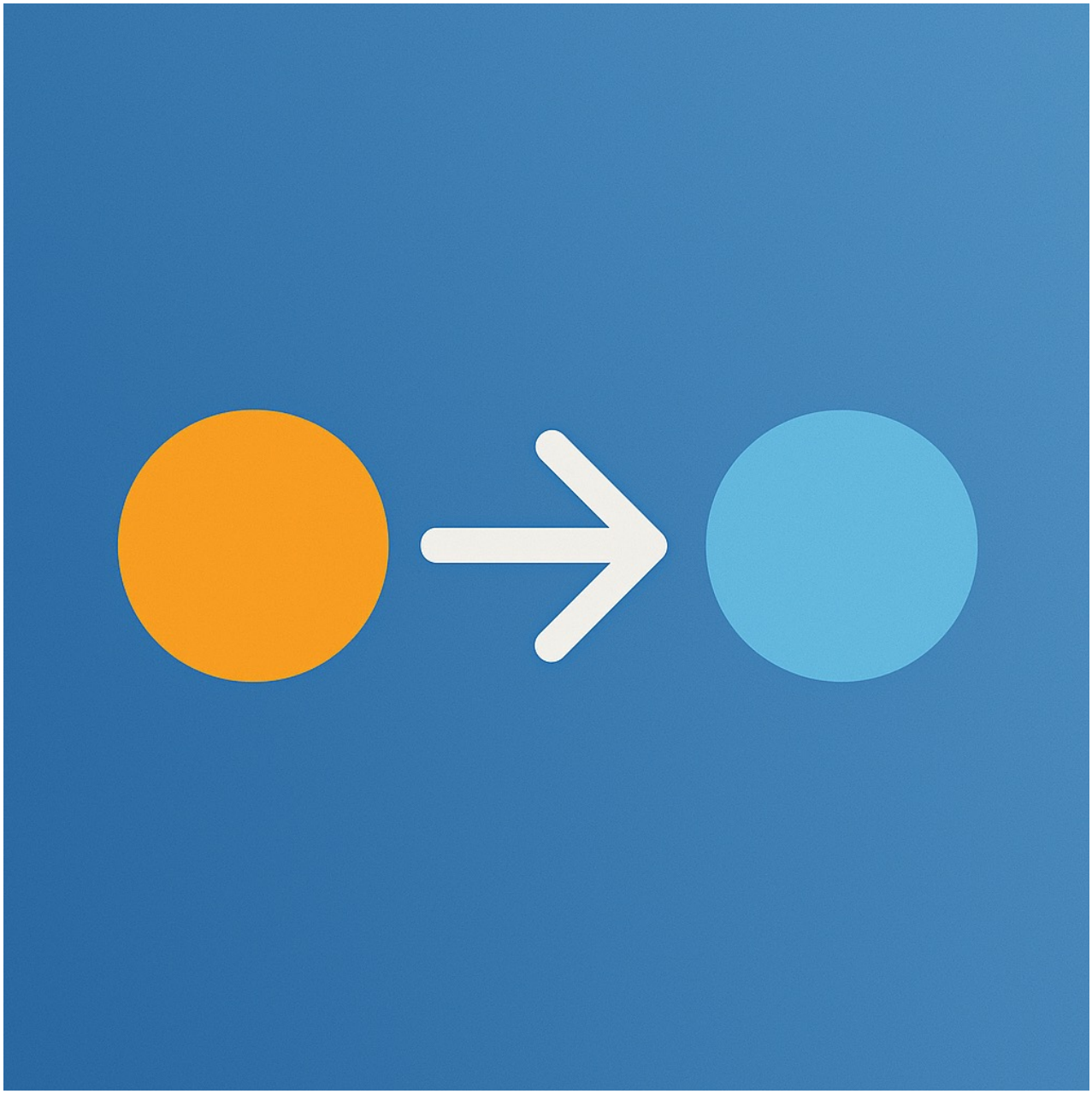

TRANSITION FROM ISO 15189:2012 TO ISO 15189:2022

ISO 15189 is an international standard that sets quality and competence requirements for medical laboratories. The 2022 revision introduces a modernized, process-based, and risk-aware framework that aligns with other key standards like ISO/IEC 17025 and ISO 9001. Unlike the more prescriptive 2012 edition, the 2022 version emphasizes flexibility, continuous improvement, patient safety, and clinical relevance.

Key changes include the integration of risk-based thinking, a stronger focus on patient-centered care, and the inclusion of Point-of-Care Testing (POCT) under its scope. The revised standard also simplifies documentation, strengthens data integrity requirements, and shifts focus from initial qualifications to ongoing staff competence evaluations.

Transitioning to ISO 15189:2022 requires laboratories to understand the new requirements, conduct a gap analysis, revise their Quality Management System (QMS), train staff, and coordinate with accreditation bodies. This process not only ensures continued compliance but also improves operational efficiency and healthcare integration.

In summary, ISO 15189:2022 equips laboratories to be more adaptable, accountable, and aligned with modern clinical demands, ultimately enhancing the quality of patient care and laboratory services.

TRANSITION FROM ISO 15189:2012 TO 2022 EDITION

ISO 15189 is an internationally recognized standard developed by the International Organization for Standardization (ISO), specifically designed for medical laboratories. It outlines requirements for both technical competence and a robust quality management system (QMS), ensuring accurate, reliable, and timely test results for patients. Beyond technical reliability, ISO 15189 promotes continuous improvement, regulatory compliance, and ultimately, patient safety. Since its initial publication, ISO 15189 has become the benchmark for medical laboratory accreditation worldwide.

The previous edition, ISO 15189:2012, provided laboratories with clear expectations regarding documentation, competence, equipment, quality assurance, and other critical elements. However, it largely adhered to a prescriptive format, with less emphasis on flexibility, risk management, or process integration. Over time, it became evident that modern laboratories needed a more dynamic and risk-aware framework to meet the challenges of evolving healthcare systems and technological advancements. In response, ISO released ISO 15189:2022—a modernized version that addresses these gaps and aligns with other key international standards, such as ISO/IEC 17025 and ISO 9001.

The ISO 15189:2022 standard represents a significant transformation, not merely a revision. It introduces a process-based approach to quality management, emphasizing continuous

improvement, patient-centric care, and proactive risk management. Laboratories accredited under the 2012 version are now required to transition to the new version within the timelines stipulated by their accreditation bodies. This transition is not only about compliance—it is also an opportunity to enhance overall efficiency, ensure data integrity, and align better with the clinical demands of healthcare systems today.

KEY CHANGES IN ISO 15189:2022

The 2022 revision of ISO 15189 introduces several pivotal changes that reflect contemporary best practices in laboratory quality and clinical relevance. One of the most notable changes is the adoption of a **process-based and risk-based approach**, which aligns ISO 15189 more closely with ISO/IEC 17025 and ISO 9001. This approach enables laboratories to manage their operations more holistically, focusing on interactions between processes and anticipating potential risks and opportunities. Risk-based thinking is now integrated throughout the standard, encouraging labs to develop mechanisms for identifying, evaluating, and mitigating risks as part of routine operations.

Another major shift is the **increased focus on patient safety and clinical relevance**. The new standard encourages laboratories to align their services more closely with the needs of healthcare providers and the patients themselves. Communication between the laboratory, clinicians, and patients is emphasized, particularly in areas like result interpretation and turnaround times. This reinforces the idea that laboratories are not just service providers but critical contributors to patient outcomes.

Furthermore, ISO 15189:2022 has **expanded its scope** to explicitly include **Point-of-Care Testing (POCT)**. The standard now acknowledges that laboratory testing is increasingly being conducted outside of traditional laboratory settings, such as in clinics, emergency rooms, or even in patients' homes. With this inclusion, laboratories are required to establish appropriate oversight, training, and quality control mechanisms for POCT to ensure the same level of reliability and accuracy expected from centralized testing.

The revised standard also introduces **greater flexibility in documentation requirements**, removing many of the overly prescriptive elements from the previous edition. Laboratories now have more freedom to design documentation systems that are efficient and practical, provided they meet the overall objectives of the standard. Additionally, there is now a **stronger focus on information management and data integrity**, including detailed requirements for electronic systems, data security, and confidentiality. With growing reliance on Laboratory Information Systems (LIS) and electronic health records, this area has become increasingly critical.

Lastly, the 2022 edition updates expectations regarding **personnel competence**. Whereas the 2012 version focused largely on initial qualifications, the new standard emphasizes **ongoing evaluation** of staff competence through continual training, performance monitoring, and

development. This shift reflects a deeper understanding of how continuous learning and adaptability contribute to laboratory quality and safety.

Clause (2022)	Requirement Summary	What's New or Changed	Actions Needed
4.1	Impartiality	Clear expectations on maintaining impartiality, avoiding conflicts of interest	Review policies for impartiality; conduct conflict of interest declarations annually.
4.2	Confidentiality	Stronger controls on data confidentiality and patient information security	Update confidentiality policy; ensure data access is role-based and logged.
5.1	Legal entity and management responsibility	Clarifies legal identity and leadership accountability in lab operations	Document legal status; define leadership responsibilities clearly in QMS.
5.2	Laboratory activities and organizational structure	Focus on documented roles, responsibilities, and reporting lines	Revise organizational chart; define roles in job descriptions and procedures.
5.3	Laboratory management and support services	Emphasis on integration and oversight of management support services	Review agreements with support services; define responsibilities and KPIs.
6.1	General personnel requirements	Requirement for appropriate number of competent personnel	Assess staffing levels; ensure adequate coverage for all lab activities.
6.2	Competence and ongoing evaluation	Ongoing competence evaluation; not just qualifications	Implement a structured ongoing competency evaluation system.
6.3	Facilities and environmental conditions	Facility conditions must ensure test validity and safety	Inspect facility conditions; address environmental controls and safety gaps.
6.4	Laboratory equipment and calibration	Risk-based approach to equipment selection, use, and maintenance	Create or update equipment maintenance and calibration schedules.
6.5	Metrological traceability	Greater emphasis on metrological traceability of results	Ensure traceability through certified calibration providers.
6.6	External services and supplies	Evaluation and monitoring of suppliers and outsourced services	Review supplier evaluation criteria and create supplier performance logs.
7.1	Review of requests and contract review	Processes for reviewing and accepting test requests clarified	Develop SOP for request review and acceptance, including rejection criteria.

7.2	Patient preparation and identification	Stronger emphasis on accurate patient identification	Standardize patient ID verification process across all points of entry.
7.3	Pre-examination processes	Detailed requirements for sample handling before analysis	Update specimen collection and transport procedures; include time limits.
7.4	Examination procedures and validation	Validation/verification requirements for examination methods reinforced	Validate all in-house and non-standard examination procedures.
7.5	Ensuring quality of examination results	More detailed approach to internal quality control	Enhance internal quality control program with documented review processes.
7.6	Post-examination processes	Clarified post-examination review and sample storage	Review post-exam procedures; ensure proper sample retention and disposal.
7.7	Reporting of results	Greater clarity on report content and interpretation	Standardize report format and ensure clinical interpretation is accurate.
7.8	Release of results and confidentiality	Secure and controlled result release processes	Verify access rights to results; implement audit trail in LIS.
7.9	Laboratory information management	Expanded focus on electronic data, access, and cybersecurity	Strengthen cybersecurity; enforce password policies and backups.
7.1	Point-of-care testing (POCT)	Full inclusion of POCT with oversight and staff competence	Define responsibilities, training, and oversight for POCT operations.
8.1	Management system documentation and scope	No longer requires a quality manual; documentation still essential	Replace quality manual with process-based documentation where needed.
8.2	Control of documents and records	Document control simplified; more flexible formats allowed	Simplify document control procedure to fit new flexibility in format.
8.3	Actions to address risks and opportunities	Preventive action clause removed; risk-based thinking applied instead	Adopt risk assessment templates; integrate with all core processes.
8.4	Internal audits	Audit scope to address risks, opportunities, and process effectiveness	Update internal audit program to include risk and performance focus.
8.5	Management review	Management review must include risk, resources, and improvement	Revise management review agenda and inputs to align with new requirements.

8.6	Identification and control of nonconformities	Focus on identifying, documenting, and correcting errors	Develop system for tracking and analyzing nonconformities.
8.7	Corrective actions	Root cause analysis and corrective action expectations clarified	Train staff on root cause analysis; link corrective actions to risks.
8.8	Continual improvement	Continual improvement integrated into risk and performance processes	Integrate improvement objectives with performance monitoring data.

TRANSITIONING FROM ISO 15189:2012 TO 2022: A STRATEGIC APPROACH

For laboratories currently accredited under ISO 15189:2012, transitioning to the 2022 version requires a structured, strategic approach. The first step involves gaining a **thorough understanding of the new standard**. Laboratory leadership, quality managers, and key personnel should be trained on the revised structure, new terminology, and changes in focus areas. Familiarity with the new process and risk-based framework is crucial for a successful transition.

The next key step is conducting a **comprehensive gap analysis**. This involves mapping current practices, policies, and documentation against the requirements of ISO 15189:2022 to identify areas of compliance, partial compliance, or non-compliance. Laboratories should focus on new or enhanced requirements such as risk management, process mapping, POCT oversight, patient-centered practices, and data integrity systems. A structured gap analysis table or checklist can help clarify action items, responsible personnel, and deadlines.

Following the gap analysis, laboratories must **revise and update their Quality Management Systems (QMS)**. This includes reviewing and rewriting standard operating procedures (SOPs), quality manuals, and related documentation to reflect the process-based approach. Processes should be clearly mapped, showing inputs, outputs, and interactions. Risk assessment and opportunity identification should be embedded into routine workflows. Additionally, labs must establish or update systems for ongoing personnel competence evaluation and define how they manage and monitor POCT services, if applicable.

Implementation of the revised QMS must be supported by **extensive staff training**. All personnel, from technicians to supervisors, should understand the revised roles and expectations under ISO 15189:2022. Training should cover risk management processes, changes in documentation practices, POCT responsibilities, patient-centered service approaches, and new protocols for data integrity. Continuous professional development should be emphasized as a strategic tool for competence assurance.

Once changes are implemented, the laboratory should conduct **internal audits and management reviews** to verify compliance with the 2022 standard. Internal audits must now reflect a broader focus, examining risk control, process performance, and patient impact in

addition to technical procedures. Management reviews should incorporate findings from internal audits, risk evaluations, and feedback from clinicians or patients, supporting an evidence-based approach to improvement.

Finally, laboratories must coordinate with their **accrediting bodies** (such as NABL, CAP, or UKAS) to plan for their **transition audit**. This could coincide with a routine surveillance visit or require a separate assessment. During the audit, the lab must demonstrate evidence of compliance with updated QMS documentation, risk management activities, process orientation, POCT oversight, and patient-focused policies. Proper preparation, documentation, and communication with assessors will be key to a successful audit outcome.

PLANNING AND TOOLS FOR A SUCCESSFUL TRANSITION

To effectively manage the transition, laboratories are encouraged to form a **dedicated transition team or task force**. This group can oversee the transition process, assign responsibilities, monitor progress, and provide support to different departments. Using structured tools like **Failure Mode and Effects Analysis (FMEA)** can help identify and mitigate operational risks that could affect quality or patient safety. Maintaining clear documentation of all actions, risk assessments, training, and process changes will not only support compliance but also strengthen internal transparency and accountability.

A critical tool during the transition is a **Gap Analysis Matrix**, which compares each clause in ISO 15189:2022 with corresponding elements from the 2012 version. This clause-by-clause comparison helps identify missing elements, compliance gaps, and opportunities for improvement. The matrix should include columns for clause numbers, descriptions, compliance status, required actions, responsible personnel, and target completion dates. Using visual summaries like dashboards or heat maps can also help prioritize focus areas based on risk or audit readiness.

In summary, the transition from ISO 15189:2012 to ISO 15189:2022 is more than a compliance exercise—it is a pathway to operational excellence. The 2022 version equips laboratories to proactively manage risks, ensure ongoing competence, embrace innovation like POCT, and place patient outcomes at the center of their mission. Laboratories that fully embrace these changes will not only meet international accreditation requirements but will also position themselves as leaders in quality, reliability, and healthcare integration.

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