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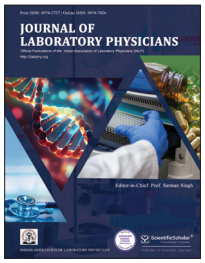
Journal of Laboratory Physicians

Article in Press



Review Article

Translating global standards to local practice: Comparing International Organization for Standardization 15189:2012 and 2022 with implementation insights from the National Accreditation Board for Testing and Calibration Laboratories 112 in India

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Received: 03 October 2025
Accepted: 04 December 2025
Epub Ahead of Print: 19 February 2026
Published:

DOI
10.25259/JLP_316_2025

Quick Response Code:

ABSTRACT

The International Organization for Standardization (ISO) 15189 is the global benchmark for quality and competence in medical laboratories, ensuring the reliability of patient test results. The newly released ISO 15189:2022 replaces the earlier 2012 edition and introduces several key structural and conceptual changes. The 2022 edition is reorganized into five clauses: General requirements, structural and governance, resource, process, and management system, bringing greater clarity and embedding risk-based thinking throughout the laboratory's operations. Major updates include strengthened requirements for risk management, impartiality, laboratory director accountability, and the integration of point-of-care testing (POCT). In the Indian context, the National Accreditation Board for Testing and Calibration Laboratories (NABL 112) provides a localized interpretation of these global standards. It introduces practical measures such as classifying laboratories based on patient load (Micro and Mini laboratories), mandating full-time quality managers, and providing detailed protocols for equipment calibration, quality control (QC), and information system validation. Several NABL specifications extend beyond the ISO baseline, such as daily internal QC. This review provides a comparative assessment of the major changes between the 2012 and 2022 versions of ISO 15189 and interprets these updates within the Indian context through NABL 112. Furthermore, it discusses common implementation challenges based on the author's real-world audit observations and offers practical suggestions to address these gaps. This analysis aims to guide laboratory professionals, clinicians, and administrators in navigating accreditation, thereby supporting safer and more dependable healthcare delivery in India.

Keywords: Accreditation, Calibration, Laboratory, Patient-centered care, Point-of-care testing, Quality control

INTRODUCTION

The International Organization for Standardization (ISO) 15189 standard specifies requirements for quality and competence in medical laboratories, with the objective to ensure quality assurance across the total testing process, thereby supporting evidence-based clinical decision-making, enhancing patient safety, and strengthening public health surveillance through reliable and patient-focused services. The latest edition, ISO 15189:2022, introduces significant updates over the 2012 version, emphasizing a risk-based approach, patient-centered outcomes, and alignment

with ISO/International Electrotechnical Commission (IEC) 17025:2017.[1-3]

The National Accreditation Board for Testing and Calibration Laboratories (NABL), an Indian accreditation body, provides guidance for interpreting ISO 15189:2022 through its NABL 112 documents for the national healthcare context.[3,4] NABL 112 offers practical adaptations to support laboratory compliance and assist assessors, considering the country's diverse laboratory landscape.[4,5]

This review provides a comparative assessment of the major structural and conceptual changes between the 2012 and 2022 versions of ISO 15189, with a specific focus on interpreting these updates within the Indian context through NABL 112. By integrating this standard comparison with field-based observations, the article aims to serve as a practical resource for clinicians, laboratory professionals, and healthcare administrators in navigating the accreditation transition.

MATERIALS AND METHODS

This review was conducted using a structured, multimethod approach to ensure a comprehensive and practical analysis of the updates in ISO 15189:2022 and their interpretation in the Indian context. The methodology comprised three key components:

1. ***Systematic clause-by-clause comparative analysis***
   A side-by-side comparison of the ISO 15189:2012 and ISO 15189:2022 standards was performed to identify all major structural, terminological, and conceptual changes.
2. ***Contextual interpretation via NABL 112***
   The ISO changes were then analyzed against the NABL 112 document to highlight NABL's specific adaptations, elaborations, and mandates that go beyond the ISO text.
3. ***Synthesis of field experience***
   The comparative analysis was validated and enriched using insights from the authors' direct experience as NABL assessors and laboratory professionals. Observations from numerous assessments and audits were synthesized to identify recurring implementation challenges and formulate the practical solutions.

STRUCTURAL EVOLUTION OF ISO 15189:2022

A key evolution in the 2022 standard is its applicability to the full spectrum of modern laboratory models. This includes high-throughput centralized facilities, mobile units, point-of-care testing (POCT), and small specialty laboratories, ensuring consistent quality standards across diverse service delivery models.

NABL 112 guidance reinforces this expanded scope for POCT, immunohematology, histocompatibility, and immunogenetics. It further mandates that any satellite laboratory or mobile facility linked to a main laboratory must comply fully with ISO 15189:2022.

DESCRIPTION AND TYPE OF LABORATORY

NABL 112 introduces two new categories of medical laboratories based on daily patient sample load: micro laboratories (up to 25 patients/day) and mini laboratories (26-50 patients/day). These categories supplement the existing small-to-very-large laboratory (51-1000 patients/day) classifications, enabling more accurate assessment and tailored support for smaller diagnostic facilities.[4]

TERMS AND DEFINITIONS

ISO 15189:2022 streamlines terminology by removing redundant terms from the 2012 version and introducing new ones to reflect current laboratory practices. Notable additions include concepts such as measurement bias, commutability of reference material, impartiality, and quality indicators. Some terms have been refined for clarity; for example, "critical alert" is now "clinical decision limit" to better describe thresholds requiring urgent medical action. NABL 112 adopts 22 of these updated definitions, with others addressed contextually in its guidance.[4,5]

REORGANIZATION OF CLAUSES IN ISO 15189:2022

In ISO 15189:2012, operational requirements were organized into two broad clauses: management and technical.[2] The management section combined ethical principles with operational requirements, providing a comprehensive framework but often blurring the distinction between foundational ethical values and routine management responsibilities.

The 2022 revision introduces a more structured approach by expanding the operational requirements into five distinct clauses.[1] This redistribution enhances clarity, functional alignment, and accountability by categorizing requirements more meaningfully. It effectively differentiates between foundational ethical principles, operational responsibilities, and technical processes, thereby facilitating the implementation of a more robust and patient-focused quality management system. In addition, the restructuring aligns ISO 15189 with ISO/ISE 17025:2017 and positions management requirements at the end of the document, supporting a more logical, risk-based, and patient-centered quality system.[6] The structural evolution of ISO 15189 from the two-pillar model (2012) to an integrated process model (2022) is depicted in Figure 1.

The key differences between ISO 15189:2012 and ISO 15189:2022, along with the corresponding NABL 112

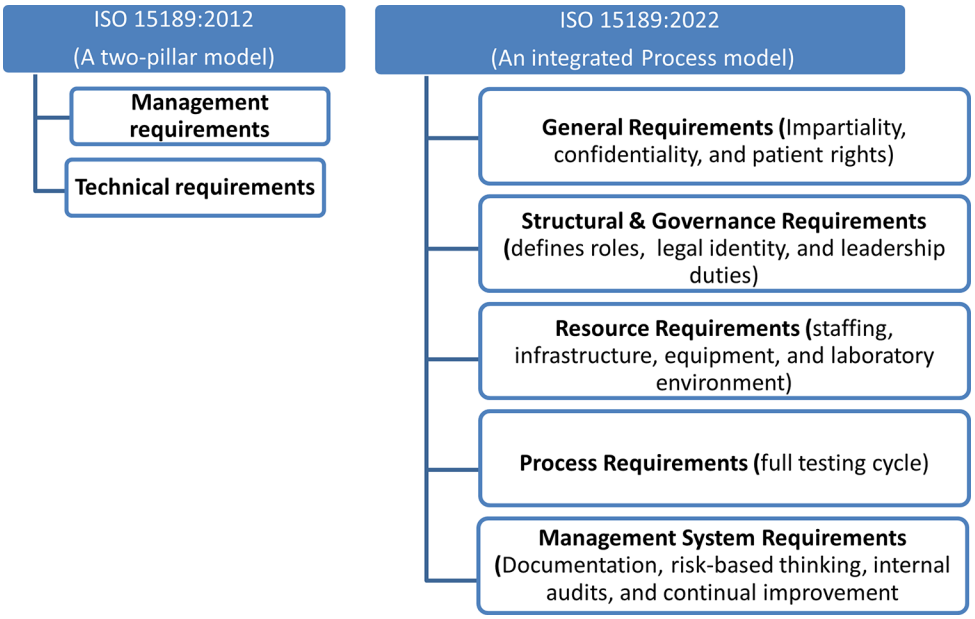

Figure 1: Reorganization of clauses in International Organization for Standardization 15189:2022.

interpretations, are summarized in Table 1. Common implementation challenges associated with ISO 15189:2022/ NABL 112 clauses and their corresponding practical solutions are presented in Table 2.

Clause 4: General requirements

Clause 4 establishes the core ethical principles of impartiality, confidentiality, and patient rights as the foundation of a laboratory's quality system, mandating a shift from passive compliance to proactive, documented governance. The standard now requires laboratories to manage ethical risks proactively. This involves:

Impartiality

Moving beyond a generic declaration, laboratories must continuously identify, document, and mitigate potential risks to impartiality, such as conflicts of interest or undue influence.

Confidentiality

Robust safeguards are mandated, including signed confidentiality agreements for all staff at recruitment, regular training, and formal agreements with patients to protect their information.

Patient rights and transparency

A key update is the extension of patient rights. Laboratories are now required to proactively inform patients of any incidents that caused or had the potential to cause harm (e.g., sample mislabeling or delays in reporting results). This commitment to transparency must be supported by mandatory documentation of the incident and the steps taken to mitigate its impact, ensuring accountability.

Implementation challenges and solutions

A common challenge observed during assessments is that laboratories often limit impartiality to a policy statement without demonstrating how risks such as conflicts of interest or undue influence are identified, monitored, and mitigated. Staff are not always sensitized to these risks, leading to gaps in practical implementation. To address this, laboratories should establish a structured process for ongoing risk assessment, train staff to recognize and report potential threats to impartiality, and implement monitoring systems with documented corrective and preventive actions.[7]

Clause 5: Structural and governance requirements

Clause 5 establishes the foundational framework for laboratory leadership, accountability, and operational scope, moving from broad principles to specific, measurable actions.

Leadership and accountability

The laboratory director's responsibilities are expanded to include risk management, with qualifications aligning with the laboratory's disciplines. While overall responsibility remains with the director, duties can be delegated with clear documentation. Notably, NABL 112 allows for part-time

Table 1: Key changes from ISO 15189:2012–2022 and NABL 112 interpretations.

Aspect	ISO 15189:2012	ISO 15189:2022	NABL 112 specificity
Structure	2 operational clauses	5 operational clauses (clauses 4–8)	Adapts 5 operational clause structure
Laboratory categorization	Not specified	Not specified	Classifies laboratories (e.g., micro, small) by patient load; defines required consultants and director terms
Confidentiality, impartiality and patient rights	Stated as principle	Proactive management required; must identify/document risks and inform patients of incidents	Adds implementation guidance to reinforce proactive approach (e.g., agreements, transparency protocols)
Laboratory Director	Defined responsibilities	Enhanced accountability	Allows part-time directors for small/micro laboratories (minimum 4 h/day)
Quality manager	Full-time designated employee	Not a separately designated role; functions can be integrated	Mandates a full-time employee for quality system functions
POCT and scope	Brief; reference to ISO 22870	Formally included, makes ISO 22870 obsolete	Explicitly includes POCT, immunohematology, histocompatibility; satellite/mobile facilities must comply
Facilities and safety	General requirements	General requirements	Detailed guidance on staff safety, ergonomic design, and physical risk mitigation
Equipment management	General requirements for calibration and maintenance	General requirements for calibration and maintenance	Specifies step-by-step process for installation, calibration, and maintenance
Process focus	Emphasis on documented procedures	Emphasis on understanding the process rather than just following documented procedures; focus on competence	Retains quality manual while aligning with competence and specify record retention periods
Referral laboratories	General requirements for selection	General requirements for selection	Detailed criteria and process for selecting and regularly reviewing referral laboratories
LIS verification	Implied under general verification	Mandatory requirement	Mandates bi-annual verification and describes the specific process for LIS verification with minimum of 10 different types of samples/tests
Quality indicators	Implied under quality assurance	Explicitly mandated to monitor performance across the testing cycle	Provides an implementation framework tailored to Indian laboratories
Risk management	Implied	Separate clause; mandated throughout every process	Reinforced with practical guidance (e.g., risk registers, mitigation plans)
IQC	General rules	Risk-based frequency	Specify frequency of running IQC (at least two levels daily)
Result harmonization and comparability.	Implied	Explicit requirement for harmonization when different methods, equipment, or personnel are used; requires regular comparability studies	Mandates comparability studies at least twice-yearly using patient samples and statistical tools

ISO: International Organization for Standardization, NABL 112: National Accreditation Board for Testing and Calibration Laboratories, POCT: Point-of-care testing, LIS: Laboratory information system, IQC: internal quality control

directors (minimum 4 h/day) in small or micro laboratories. Furthermore, while ISO 15189 does not mandate a dedicated quality manager, NABL 112 specifies that the individuals responsible for the quality management system must be full-time employees, a significant adaptation for the Indian context.

Expanding operational scope and defining performance

The standard formally expands the scope of activities to include POCT, mobile laboratories, and off-site sample handling, requiring these services to meet the same rigorous standards as the main facility. To monitor performance within this expanded scope, laboratories must define measurable quality indicators across the entire testing cycle, enabling data-driven evaluation and continual improvement in service delivery. In addition, laboratories must actively engage with users regarding test selection and result interpretation and maintain documentation to demonstrate that advisory support has been provided.

Table 2: Implementation challenges and solutions across key ISO 15189:2022/NABL 112:2022 clauses.

Clause	Key challenges	Solutions
4. General requirements	Impartiality not visibly monitored; staff not sensitized	Regular training, risk monitoring, documented CAPA
5. Structural and governance	Director appears disengaged; risk actions not verified	Active involvement, structured risk-action-follow-up cycle
6. Resource requirements	Vendors/referral laboratories not monitored; reagent verification incomplete; staff competency gaps	Regular vendor audits, lot verification SOPs, scheduled competency assessments, ISO 17025-accredited calibration
7. Process requirements	Policies for oral requests, compromised samples unclear; inadequate transport checks; no contingency for automated reporting	SOPs for sample acceptance, transport audits, contingency and manual verification for report release
8. Management system	Quality indicators poorly defined; management review minutes incomplete	SOP-defined indicators, detailed meeting minutes with assigned responsibilities and timelines

ISO: International Organization for Standardization, NABL 112: National Accreditation Board for Testing and Calibration Laboratories, CAPA: Corrective and preventive actions, SOPs: Standard operative procedure

Systematic risk management

A major addition in the 2022 standard is the requirement for a more structured and systematic approach to risk management. Laboratories must proactively identify, assess, and mitigate risks at every stage of testing, from specimen collection and transport to equipment performance, staff competency, and even supply chain reliability [Figure 2].[8]

This process must be thoroughly documented, with mitigation measures recorded and reviewed annually or when processes change, ensuring proactive safeguarding of patient safety and result validity.

Implementation challenges and solutions

Laboratory directors, though permitted to delegate responsibilities, are often not visibly engaged in daily governance, weakening accountability. To address this, directors should actively participate in key activities such as quality indicator reviews, management meetings, and oversight of risk management.[9] Another issue is incomplete risk management; many laboratories conduct risk assessments, but they often stop at identification without clearly documenting corrective actions or evaluating their effectiveness. To bridge this gap, laboratories should adopt a structured risk management cycle that not only identifies risks but also tracks mitigation measures, assigns responsibilities, and documents follow-up reviews to confirm effectiveness.[9,10]

Clause 6: Resource requirements

This clause establishes the foundational elements essential for ensuring laboratory reliability, safety, and quality, with NABL 112 providing specific, risk-based adaptations for the Indian context.

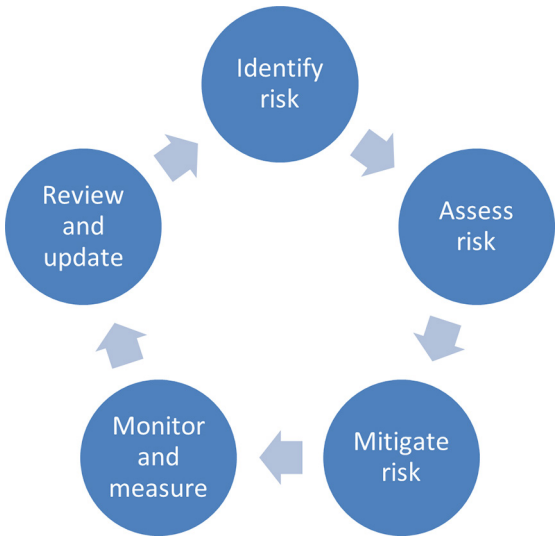

Figure 2: Laboratory risk management cycle.

Human resources

Laboratories must ensure staff are qualified, trained, and competency-assessed, with roles defined through authorization matrices. Staffing levels must align with test complexity and volume, with requirements scaled for laboratory size: large facilities require full-time consultants per discipline, medium laboratories need core discipline consultants, and small/micro laboratories may employ part-time consultants (minimum 4 h/day) with proper documentation of attendance and activities.[4]

Facility and safety

A greater emphasis is placed on a preventive, safety-oriented approach while retaining core requirements such as adequate

space, separation of incompatible activities, and prevention of cross-contamination. Greater emphasis is now placed on staff safety, ergonomic design, and risk mitigation. Laboratories must implement measures such as noise monitoring, chemical ventilation, and ergonomic workspaces to reduce long-term health risks. Electrical safety is strengthened with biannual verification of power points and prohibition of unsafe extension cords. Clear separation of pre-examination and testing areas is required to prevent interference and ensure process clarity.[4]

Equipment management

A rigorous, lifecycle-based approach is mandated for all equipment. Key requirements now include mandatory installation/operational/performance qualification for new or relocated devices and re-verification after significant changes. The scope of calibration is expanded to include POCT and non-analytical instruments (centrifuges, pipettes, incubators, and thermometers) with stringent requirements for traceability and data retention.[4] Table 3 summarized the core requirements for equipment, calibration, and environmental safety.[4]

Reagents and consumables

A structured, performance-based approach is required. This includes lot-specific acceptance testing (preferably with patient samples), use of Grade II water with documented water quality checks at defined intervals, and robust labeling and tracking systems for in-house reagents. Robust systems for tracking adverse incidents and recalls are mandatory, requiring documented investigations and corrective actions to ensure reagent integrity and patient safety.[4]

External services and agreements

Laboratory accountability is extended to all outsourced services. Formal agreements are required with users and POCT operators, ensuring transparency about accredited tests. This includes providing users with a clear list of accredited and non-accredited parameters, along with their methods and turnaround times, and making a directory of services readily available. For referral testing, laboratories must maintain formal documentation, including the accreditation status of referral laboratories and signed memoranda of understanding. A risk-based approach to sample transport and the acceptance of telepathology (with quality safeguards) are now formally recognized.[4]

Implementation challenges and solutions

Laboratories often fail to monitor vendors and referral laboratories at defined intervals, leading to unverified service quality. This can be addressed by establishing measurable vendor evaluation criteria and conducting regular, documented reviews. Upon receiving reagents and kits, checks for expiry, leakage, and transport temperature are sometimes overlooked; strict physical verification and its documentation upon receipt should be enforced before acceptance. Reagent lot verification is another weak area, where reliance on the manufacturer's claims replaces laboratory-defined acceptance criteria; instead, laboratories should verify lots against their own past performance data. Competency assessment of staff is also inconsistently performed, with intervals not always defined; this requires a structured, standard operating procedure (SOP) driven approach with documented evaluations (NABL 112 B). Finally, equipment calibration is sometimes outsourced to non-recognized providers, which risks traceability; compliance can be ensured by using calibration laboratories accredited to ISO/IEC 17025, with proper documentation of metrological traceability.

Clause 7: Process requirements

This clause establishes a patient-centered, risk-based framework for the total testing process.

Table 3: Summary of equipment, calibration, and environmental safety requirements.

Category	Key requirement	NABL 112 specifics/notes
Equipment lifecycle	Installation/operational/ performance qualification	Required for all new, relocated, or significantly modified equipment.
	Re-verification	Mandatory after reagent, software, hardware changes, or major repairs.
Calibration scope	Expanded scope	Now explicitly includes POCT devices, centrifuges, pipettes, incubators, and thermometers.
	Calibration provider	Must be performed by NABL-accredited or other recognized calibration providers.
	Data retention	Raw calibration data must be retained; summary reports alone are insufficient.
Environmental safety	Temperature monitoring	24/7 monitoring mandated for critical storage; auto-defrost systems prohibited.
	Biosafety	Biosafety cabinets require functioning exhaust systems; open flames are banned.
	Specific checks	pH meters require daily two-buffer calibration.

NABL 112: National Accreditation Board for Testing and Calibration Laboratories, POCT: Point-of-care testing

Pre-examination

Now, this stage requires greater accountability from test request to sample receipt. Mandates include the clinical details on all requisitions, with oral requests permitted in emergencies, provided they are documented. Informed consent is required for procedures such as genetic testing or invasive sample collection. The handling of compromised samples (e.g., mislabeled, hemolyzed) must involve a documented risk assessment and clinical justification, with any associated risks communicated in the final report. Sample transport requires strict safeguards, including temperature control, triple packaging, and time-logging to ensure integrity and traceability.[10] Laboratories retain responsibility for externally collected samples, formalized through agreements, competence checks, and audits. The scope now formally recognizes telepathology (with safeguards for traceability and image quality) and POCT, requiring clearly defined responsibilities between the central laboratory and clinical units.

Examination and quality assurance

Rigorous verification is required for new tests and after significant changes, including equipment repair or method updates. Validation is necessary when methods are modified, such as unlisted matrices, altered sample handling, reagent changes, or shifts between qualitative and quantitative use. Records must demonstrate performance specifications and fitness-for-purpose. ISO 15189:2022 allows quality control (QC) frequency to be risk-based, whereas NABL 112 requires two levels of internal QC (IQC): daily and once per shift in 24 × 7 laboratories. Control materials must be stable, matrix-compatible, and span the full analytical range. Daily performance is tracked with Levey-Jennings charts and Westgard rules with monthly recalculation of mean, SD, and coefficient of variation (CV%). If commercial controls are unavailable, validated alternatives such as duplicate testing, moving averages, or inter-laboratory exchanges must be used.

Participation in ISO 17043-accredited external quality assessment/proficiency testing programs is mandatory for all applicable tests, including POCT. Failures require documented corrective action and clinical impact review. Where formal programs are absent (e.g., for ammonia, glucose-6-phosphate dehydrogenase, blood gases), alternatives such as replicate testing, inter-laboratory comparisons, or clinical correlation studies must be adopted. Comparability studies across systems and locations are required at least twice yearly using 10-20 patient samples. Statistical tools such as regression analysis or Bland-Altman plots should be applied; clinically significant differences must trigger a review of reference intervals.[11] NABL further requires histopathology-specific measures, correlating repeat specimens with prior slides, and comparison of frozen sections with final reports. Measurement uncertainty (MU) is mandatory for all quantitative tests, calculated using IQC (MU = CV% × 2). It must be regularly reviewed and applied in method verification, lot-to-lot kit checks, and threshold-based qualitative tests.

Clear, accountable, and traceable reporting

Reports must identify the authorized signatory and undergo documented review before release. Critical results must be clearly marked, and both critical and urgent results require prompt communication, documentation, and escalation protocols. All oral communications must be recorded, and policies for preliminary reporting are required for 24 × 7 laboratories.

Automated release is permitted for non-interpretative tests if systems are validated, outputs are labeled "Auto Verified," and these systems must include safeguards for errors and downtime. Reports must contain unique patient and sample identifiers, collection and issue dates, laboratory and user identifiers, methodology, reference intervals, decision limits, and decision-support tools. Research tests must be clearly labeled, and all report amendments must be traceable, with revised results issued as separate documents linked to the original.

Robust information management

Information systems are a core laboratory responsibility. All systems, computerized, hybrid, and manual systems must be validated, documented, and secured against unauthorized access. Cybersecurity, downtime planning, and audit trails are mandatory. NABL 112 specifies practical steps: half-yearly laboratory information system (LIS) verification with at least 10 different test types, validation of analyzers- LIS/hospital information system interfaces, role-based access control, and comprehensive audit trails linking user actions to data.

Implementation challenges and solutions

Laboratories often lack defined policies for oral requests, compromised samples, add-on tests, and the permissible window period for acceptance, leading to inconsistent handling and patient safety risks.[5] To address this, explicit SOPs and staff training should guide specimen acceptance criteria and documentation. Another challenge is inadequate monitoring at specimen receiving, where checks for transport temperature, vial adequacy, and sample volume are overlooked. These must be systematically verified and documented, with periodic audits of sample transport using statistically adequate sample sizes. In reporting, many laboratories have no contingency plan for suspension

of automated release, creating delays and risks to timely communication. A robust fallback plan should be in place, with manual verification of automated release and LIS processes using representative sample sets.[5]

Clause 8: Management system requirements

Clause 8 redefines the management system from a standalone set of procedures into the core operational framework for the entire laboratory. It integrates risk-based thinking, documented processes, and performance evaluation into daily practice to drive continual improvement and ensure patient safety. The revised standard no longer mandates a quality manual but requires controlled documents to ensure competence and consistency. NABL 112, however, maintains the requirement for a quality manual and specific record retention periods to ensure audit readiness. Two dynamic processes energize this documentation framework:

Proactive risk and opportunity management

Laboratories must now systematically identify and address risks to impartiality and quality, as well as opportunities for improvement. NABL 112 operationalizes this through documented risk registers and mitigation plans.

Structured corrective and improvement actions

A closed-loop process is mandated for handling nonconformities. Findings from incidents, audits, and feedback must lead to documented corrective actions, the effectiveness of which must be verified, ensuring issues are resolved and not just noted.

The effectiveness of the integrated management system is validated through regular evaluation:

Internal audits

Laboratories must conduct audits covering all processes, including sample collection and POCT, at least annually, with documented follow-up on findings.

Management review

Top management is required to periodically review the system's suitability and effectiveness. These structured reviews must assess audit outcomes, risk assessments, corrective actions, and quality indicators, leading to documented decisions and resource allocation for improvement.

Implementation challenges and solutions

A common challenge is the inconsistent definition and documentation of quality indicators. Laboratories may select indicators without clearly specifying how they are measured, the formulas used, methods of data collection, frequency, or their presentation, which limits their usefulness for monitoring performance. To address this, SOPs should explicitly define each quality indicator, its calculation, collection process, and reporting frequency. Another challenge is the incomplete documentation of management review meetings. Minutes often lack details on discussion points, decisions made, assigned responsibilities, and timelines for action items.

CONCLUSIONS

The transition from ISO 15189:2012 to 2022 represents a paradigm shift from a rule-based to a risk and patient-focused laboratory accreditation system. NABL 112 contextualizes these global standards for India, providing practical guidance on staff roles, QC, equipment management, and security, applicable to both large and small laboratories.

Implementing these standards poses challenges such as ensuring staff competency, monitoring vendors and referrals, maintaining sample integrity, and documenting corrective actions. These can be addressed through structured SOPs, systematic risk assessments, and monitoring mechanisms, bridging gaps between policy and practice.

By emphasizing leadership, formal risk management, and measurable quality indicators, ISO 15189:2022 and NABL 112 enhance the reliability, accuracy, and traceability of laboratory results, enabling laboratories to move beyond compliance and contribute to safer, more effective patient care.

Author's contributions: RG and RA jointly conceived the study. RA provided the comparison framework, and RG drafted the manuscript. RA reviewed the manuscript. Both authors approved the final version.

Ethical approval: Institutional Ethical Committee approval is not required.
Declaration of patient consent: Patient's consent not required as there are no patients in this study.
Financial support and sponsorship: Nil.
Conflicts of interest: There are no conflicts of interest.
Use of artificial intelligence (AI)-assisted technology for manuscript preparation: The authors confirm that they have used artificial intelligence (AI)-assisted technology ChatGPT solely for language refinement and to improve the clarity of writing. No AI assistance was employed in the generation of scientific content, data analysis or interpretation.

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How to cite this article: Gupta R, Agarwal R. Translating global standards to local practice: Comparing ISO 15189:2012 and 2022 with implementation insights from the National Accreditation Board for Testing and Calibration Laboratories 112 in India. J Lab Physicians. doi: 10.25259/JLP_316_2025