

ISO 15189:2022 in Clinical Biochemistry Laboratories: A Practical Review for Quality Improvement

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Abstract: Background: ISO 15189:2022 is the latest international standard that defines the requirements for quality and competence in medical laboratories. Compared with previous editions, it places greater emphasis on patient safety, risk-based thinking, impartiality, digitalization, personnel competence, and continual quality improvement. Clinical biochemistry laboratories play a vital role in patient diagnosis and treatment; therefore, effective implementation of ISO 15189:2022 is essential to ensure reliable, accurate, and timely laboratory services.

Objective: This review aims to provide a comprehensive overview of the requirements of ISO 15189:2022 and their practical implementation in clinical biochemistry laboratories. It highlights the major changes introduced in the 2022 edition and discusses their significance in improving laboratory quality management systems.

Methods: This review is based on an analysis of ISO 15189:2022 requirements, relevant CLSI guidelines, NABL accreditation criteria, and published scientific literature related to laboratory quality management and clinical biochemistry practice.

Results: The review summarizes key aspects of laboratory organization, personnel competence, equipment management, reagent control, sample management, method verification and validation, measurement uncertainty, internal quality control, external quality assessment, risk management, document control, internal audits, management review, and continual improvement. Practical examples relevant to routine clinical biochemistry laboratories are included to facilitate effective implementation.

Keywords: ISO 15189:2022, Clinical Biochemistry, Medical Laboratory, Quality Management System, NABL, Laboratory Accreditation, Method Verification, Internal Quality Control, Risk Management, Patient Safety.

I. INTRODUCTION

Clinical biochemistry laboratories are an integral part of modern healthcare systems, providing laboratory data that support disease diagnosis, therapeutic decision-making, patient monitoring, and preventive healthcare. It is estimated that a large proportion of clinical decisions are influenced by laboratory test results. Therefore, the accuracy, reliability, and timeliness of laboratory reports directly affect patient safety and the quality of medical care. Maintaining high standards of quality throughout the pre-analytical, analytical, and post-analytical phases is essential for ensuring dependable laboratory services.

The International Organization for Standardization (ISO) developed ISO 15189 – Medical Laboratories: Requirements for Quality and Competence as a globally recognized standard specifically designed for medical laboratories. Unlike general quality management standards, ISO 15189 integrates technical competence with quality management principles, addressing every aspect of laboratory operations, including personnel competence, equipment management, examination procedures, quality assurance, information management, and continual improvement.



The publication of ISO 15189:2022 represents a significant advancement in laboratory quality management. The revised standard adopts a risk-based approach, strengthens requirements related to impartiality and confidentiality, encourages digital transformation, and emphasizes competence-based laboratory practices. It also aligns more closely with other international standards such as ISO/IEC 17025:2017 while maintaining a strong focus on patient-centered laboratory services.

Clinical biochemistry laboratories perform a wide range of investigations, including glucose, renal function tests, liver function tests, lipid profile, cardiac biomarkers, electrolytes, hormones, therapeutic drug monitoring, and many other biochemical analyses. These investigations require standardized analytical methods, validated procedures, effective quality control systems, competent personnel, and continuous monitoring to ensure accurate and clinically reliable results. Even minor errors during sample collection, transportation, analysis, calibration, or result reporting may significantly affect patient management.

Accreditation according to ISO 15189:2022 provides objective evidence that a laboratory operates under a robust quality management system and consistently delivers technically valid results. The implementation of the standard not only improves analytical quality but also enhances patient safety, operational efficiency, regulatory compliance, staff competence, and clinician confidence. Furthermore, laboratories implementing ISO 15189:2022 are better prepared to identify risks, manage nonconformities, improve documentation practices, and establish a culture of continual quality improvement.

This review provides a comprehensive overview of ISO 15189:2022 with special emphasis on its practical implementation in clinical biochemistry laboratories. The article discusses the major changes introduced in the 2022 edition, key quality management requirements, laboratory competence, method verification, internal and external quality assurance, measurement uncertainty, risk management, internal audits, management review, and continual improvement. Practical recommendations are included to facilitate effective implementation of the standard in routine clinical biochemistry laboratories and to support laboratories preparing for accreditation or maintaining accredited status.

II. IMPACT OF THE REVISION ON THE STANDARDS EVOLUTION

The publication of ISO 15189:2022 represents a significant milestone in the evolution of quality management systems for medical laboratories. The revised standard reflects the growing complexity of healthcare services, rapid technological advancements, increasing automation, digital transformation, and the need for enhanced patient safety. Rather than introducing isolated changes, ISO 15189:2022 adopts a comprehensive approach that integrates quality management with technical competence, risk management, and continual improvement.

One of the most important developments in the revised standard is the incorporation of risk-based thinking into routine laboratory activities. Laboratories are expected to proactively identify, evaluate, and mitigate risks that may affect the quality of examination results or patient safety. This approach shifts laboratory management from reactive corrective actions to preventive quality management.

The revised standard also strengthens the concept of personnel competence. While earlier editions emphasized qualifications and training, ISO 15189:2022 requires laboratories to demonstrate and continuously assess competency through education, practical skills, performance evaluation, and ongoing professional development. This ensures that laboratory personnel remain competent despite technological and procedural changes.

Another major advancement is the increased emphasis on patient-centered laboratory services. The standard recognizes that every laboratory process, from sample collection to result reporting, ultimately influences patient care. Consequently, laboratories are encouraged to improve communication with clinicians, reduce turnaround time, minimize diagnostic errors, and enhance the overall reliability of laboratory services.



The revision also addresses the growing use of laboratory information systems (LIS), electronic records, and digital communication. New requirements related to information management, data integrity, cybersecurity, confidentiality, and traceability support the safe and effective management of laboratory information in increasingly digital healthcare environments.

Furthermore, ISO 15189:2022 aligns more closely with modern international quality management principles and harmonizes several concepts with ISO/IEC 17025 while maintaining its specific focus on medical laboratories. This alignment facilitates consistency across accreditation systems and supports international recognition of accredited laboratories.

Overall, the evolution of ISO 15189 demonstrates a transition from a compliance-oriented quality system toward a patient-focused, risk-based, competence-driven, and continuously improving management framework. Successful implementation of these revised requirements enables clinical biochemistry laboratories to deliver more reliable results, strengthen patient safety, improve operational efficiency, and maintain global accreditation standards.

III. ACCREDITATION TRENDS AND INTEGRATION WITH REGULATORY FRAMEWORKS

Accreditation has become a globally recognized mechanism for demonstrating the competence and quality of medical laboratories. Over the past two decades, healthcare systems have increasingly emphasized standardized laboratory practices to improve patient safety, ensure reliable diagnostic services, and promote international confidence in laboratory results. Consequently, accreditation according to ISO 15189 has emerged as the benchmark for quality and technical competence in medical laboratories.

The publication of ISO 15189:2022 reflects the evolving expectations of healthcare regulators, accreditation bodies, and patients. The revised standard supports a risk-based, patient-centered approach that aligns laboratory quality management with contemporary healthcare requirements. This evolution has encouraged laboratories worldwide to adopt systematic quality management systems rather than focusing solely on regulatory compliance.

In many countries, laboratory accreditation is closely integrated with national regulatory frameworks. Accreditation bodies evaluate laboratories against ISO 15189 requirements while ensuring compliance with applicable legal, ethical, and healthcare regulations. This integration promotes consistency in laboratory practices, facilitates regulatory oversight, and strengthens public confidence in diagnostic services.

In India, the National Accreditation Board for Testing and Calibration Laboratories (NABL) provides accreditation to medical laboratories based on ISO 15189 requirements. NABL accreditation supports laboratories in implementing standardized procedures, improving technical competence, enhancing quality assurance, and meeting national regulatory expectations. Accredited laboratories are expected to maintain documented quality management systems, participate in external quality assessment programmes, conduct regular internal audits, perform management reviews, and demonstrate continual improvement.

The increasing adoption of digital laboratory information systems, automation, electronic health records, and data security measures has further strengthened the relationship between accreditation and regulatory compliance. ISO 15189:2022 includes enhanced requirements for information management, confidentiality, data integrity, and traceability, ensuring that laboratories can effectively manage both technical and regulatory responsibilities in modern healthcare environments.

Overall, current accreditation trends demonstrate a transition from periodic compliance assessments toward continuous quality improvement, risk management, and patient-focused laboratory services. The integration of ISO 15189:2022 with national regulatory frameworks enables clinical biochemistry laboratories to achieve international recognition while maintaining compliance with local legal and professional requirements. Such integration ultimately contributes to improved diagnostic accuracy, enhanced patient safety, operational excellence, and sustained confidence in laboratory services.



IV. TECHNOLOGICAL ADVANCEMENTS IN CLINICAL BIOCHEMISTRY LABORATORIES

Rapid technological advancements have significantly transformed the practice of clinical biochemistry, improving the accuracy, efficiency, and reliability of laboratory services. Modern laboratories increasingly rely on advanced analytical instruments, laboratory automation, digital information systems, and artificial intelligence (AI)-supported technologies to meet the growing demand for high-quality diagnostic services. These innovations have enhanced laboratory performance while supporting the implementation of quality management systems such as ISO 15189:2022.

One of the most significant developments is the adoption of fully automated clinical chemistry analyzers capable of processing a large number of samples with minimal manual intervention. Automation reduces analytical variability, minimizes human error, improves turnaround time (TAT), and increases laboratory productivity. Integrated pre-analytical and post-analytical automation further enhances sample handling, identification, centrifugation, storage, and result reporting.

The widespread implementation of Laboratory Information Systems (LIS) has revolutionized laboratory workflow by enabling electronic test ordering, barcode-based sample identification, automated result transmission, data storage, audit trails, and quality monitoring. Integration of LIS with Hospital Information Systems (HIS) and Electronic Health Records (EHR) facilitates seamless communication between laboratories and healthcare providers, improving clinical decision-making and patient care.

Advances in quality assurance technologies have also strengthened laboratory performance. Modern analyzers provide real-time quality control monitoring, automated calibration verification, delta checks, instrument maintenance alerts, and analytical performance indicators. Statistical quality control software and sigma metrics assist laboratories in continuously monitoring analytical performance and identifying opportunities for quality improvement.

Emerging technologies such as artificial intelligence (AI), machine learning, big data analytics, and cloud-based laboratory management systems are increasingly being incorporated into laboratory operations. These technologies support predictive maintenance, intelligent quality monitoring, workflow optimization, data analysis, and early identification of analytical errors. Although their application continues to evolve, they have considerable potential to improve laboratory efficiency and patient safety.

ISO 15189:2022 recognizes the growing importance of digital technologies by strengthening requirements related to information management, data integrity, cybersecurity, confidentiality, and traceability. Laboratories implementing modern technologies must ensure that computerized systems are appropriately validated, regularly maintained, protected against unauthorized access, and capable of maintaining complete audit trails.

Overall, technological advancements have shifted clinical biochemistry laboratories toward more efficient, standardized, and patient-centered services. Successful integration of automation, digital information systems, and advanced quality management tools enables laboratories to improve analytical accuracy, operational efficiency, regulatory compliance, and continual quality improvement while meeting the evolving expectations of modern healthcare.

V. PATIENT-CENTERED STRATEGIES IN CLINICAL BIOCHEMISTRY LABORATORIES

Patient-centered care has become a fundamental principle of modern healthcare and is strongly reflected in the requirements of ISO 15189:2022. The standard emphasizes that laboratory services should be designed to meet the needs of patients and healthcare providers by ensuring accurate, timely, safe, and reliable diagnostic results. Since laboratory findings influence a significant proportion of clinical decisions, every phase of the testing process should focus on improving patient outcomes and minimizing the risk of diagnostic errors.

A patient-centered laboratory begins with effective pre-analytical practices, including proper patient identification, clear communication, appropriate test selection, correct specimen collection, labeling, transportation, and storage. Standardized procedures and staff competency help reduce pre-analytical errors, which remain one of the most common causes of inaccurate laboratory results.



During the analytical phase, laboratories should implement validated examination procedures, robust internal quality control (IQC), external quality assessment (EQA), regular equipment maintenance, and continuous competency assessment of personnel. These measures ensure that laboratory results are accurate, reproducible, and clinically reliable, thereby supporting evidence-based medical decisions.

The post-analytical phase also plays a vital role in patient-centered care. Laboratories should establish efficient systems for result verification, timely reporting, critical value notification, and effective communication with clinicians. Interpretation support, where appropriate, and prompt reporting of urgent results contribute significantly to patient safety and improved clinical outcomes.

ISO 15189:2022 also encourages laboratories to monitor quality indicators such as turnaround time (TAT), specimen rejection rates, critical value reporting, customer complaints, and clinician feedback. Continuous monitoring of these indicators enables laboratories to identify opportunities for improvement and enhance the overall patient experience.

Effective communication between laboratory professionals, clinicians, nurses, and patients is another essential component of patient-centered laboratory services. Providing clear test instructions, maintaining confidentiality, ensuring informed specimen collection procedures, and responding promptly to clinical queries strengthen trust in laboratory services and improve healthcare delivery.

By integrating quality management principles with patient-focused practices, clinical biochemistry laboratories can reduce diagnostic errors, improve patient safety, enhance service quality, and support better clinical decision-making. The implementation of patient-centered strategies under ISO 15189:2022 ultimately contributes to higher standards of healthcare and increased confidence in laboratory services.

VI. RISK-BASED APPROACH IN ISO 15189:2022

The risk-based approach is one of the most significant enhancements introduced in ISO 15189:2022. Unlike earlier editions, which primarily focused on corrective actions after errors occurred, the revised standard emphasizes the proactive identification, assessment, control, and monitoring of risks that may affect laboratory quality, patient safety, and the reliability of examination results. This preventive approach enables laboratories to minimize errors before they occur and supports continual quality improvement.

In clinical biochemistry laboratories, risks may arise during the pre-analytical, analytical, and post-analytical phases of laboratory testing. Pre-analytical risks include incorrect patient identification, improper specimen collection, labeling errors, inadequate sample volume, transportation delays, and unsuitable storage conditions. Analytical risks may involve instrument malfunction, calibration failure, reagent deterioration, quality control failures, environmental conditions, or operator errors. Post-analytical risks include incorrect result verification, delayed reporting, transcription errors, failure to communicate critical values, and data management issues.

ISO 15189:2022 requires laboratories to establish a systematic process for identifying potential risks, evaluating their likelihood and impact, implementing appropriate control measures, and regularly reviewing the effectiveness of these measures. Risk assessment should be integrated into routine laboratory activities, including method verification, equipment management, information management, personnel competency, supplier evaluation, and quality assurance programmes.

Various risk assessment tools can be applied in clinical laboratories, including Failure Mode and Effects Analysis (FMEA), Risk Matrix, Root Cause Analysis (RCA), Fishbone (Ishikawa) Diagram, and Failure Investigation Reports. The selection of an appropriate tool depends on the complexity of the laboratory process and the nature of the identified risk. Documentation of risk assessments and subsequent actions provides objective evidence of compliance with ISO 15189:2022 requirements.

Risk management should not be viewed as a one-time activity but as a continuous process integrated with internal audits, quality indicators, management review, corrective actions, and continual improvement. Laboratories should periodically review identified risks, monitor the effectiveness of implemented controls, and update risk assessments whenever new equipment, examination procedures, software, or organizational changes are introduced.



The effective implementation of a risk-based approach improves analytical reliability, reduces laboratory errors, strengthens patient safety, enhances regulatory compliance, and supports accreditation according to ISO 15189:2022. By fostering a culture of proactive risk management, clinical biochemistry laboratories can ensure consistent delivery of accurate, timely, and clinically reliable laboratory results.

VII. CHALLENGES AND LIMITATIONS IN THE IMPLEMENTATION OF ISO 15189:2022

Although ISO 15189:2022 provides a comprehensive framework for improving the quality and competence of medical laboratories, its implementation presents several practical challenges. Laboratories, particularly those operating in resource-limited settings, may encounter difficulties related to infrastructure, financial resources, trained personnel, technological adaptation, and organizational change. Addressing these challenges is essential for the successful implementation and sustainability of an effective quality management system.

One of the primary challenges is the financial investment required for accreditation. Laboratories often need to allocate significant resources for infrastructure development, equipment procurement, calibration services, quality control materials, external quality assessment (EQA) participation, laboratory information systems (LIS), staff training, and accreditation fees. Smaller laboratories may find these costs difficult to sustain.

Another important limitation is the availability of competent and adequately trained personnel. ISO 15189:2022 emphasizes competency-based assessment, continual professional development, and documented evidence of staff competence. Maintaining these requirements requires regular training programmes, competency evaluations, and continuous supervision, which may be challenging for laboratories experiencing workforce shortages or high staff turnover.

The implementation of a risk-based quality management system also represents a significant organizational challenge. Many laboratories have traditionally focused on corrective actions after nonconformities occur. Transitioning to proactive risk identification, risk assessment, and preventive control requires changes in laboratory culture, staff awareness, documentation practices, and leadership commitment.

Technological integration presents additional challenges. Laboratories adopting advanced automation, laboratory information systems (LIS), electronic records, and digital communication platforms must ensure system validation, cybersecurity, data integrity, confidentiality, and compatibility with existing healthcare information systems. Maintaining these systems requires specialized technical expertise and ongoing financial support.

Documentation requirements under ISO 15189:2022 can also be demanding. Laboratories must establish and maintain comprehensive documented information, including standard operating procedures (SOPs), quality manuals, competency records, equipment maintenance logs, risk assessments, quality indicators, internal audit reports, corrective actions, and management review records. Ensuring document control while minimizing administrative burden remains a practical challenge.

Furthermore, laboratories may face difficulties in maintaining continual improvement following accreditation. Sustaining compliance requires regular internal audits, participation in external quality assessment programmes, monitoring of quality indicators, periodic management reviews, and continuous evaluation of laboratory performance. Without sustained leadership commitment and staff engagement, quality management systems may gradually lose effectiveness.

Despite these challenges, the long-term benefits of ISO 15189:2022—including improved patient safety, enhanced diagnostic reliability, international recognition, increased operational efficiency, and strengthened clinician confidence—generally outweigh the limitations. Careful planning, adequate resource allocation, effective leadership, continuous staff education, and a culture of quality improvement are essential for overcoming implementation challenges and achieving sustainable accreditation.



VIII. OPPORTUNITIES AND FUTURE DIRECTIONS

The implementation of ISO 15189:2022 presents significant opportunities for the advancement of clinical biochemistry laboratories. As healthcare systems continue to evolve, laboratories are expected to provide not only accurate and timely test results but also greater value through quality improvement, innovation, and patient-centered services. The revised standard provides a strong framework for achieving these objectives by promoting technical competence, risk-based thinking, digital transformation, and continual improvement.

One of the major opportunities lies in the increasing adoption of laboratory automation and digital technologies. Modern clinical biochemistry laboratories are progressively integrating automated analyzers, robotic sample handling systems, laboratory information systems (LIS), artificial intelligence (AI), and machine learning tools to improve operational efficiency and reduce analytical errors. These technologies enhance workflow standardization, increase productivity, and support real-time quality monitoring.

Another important opportunity is the wider use of data analytics and quality indicators. Laboratories generate large volumes of analytical and operational data that can be used to monitor performance, identify trends, evaluate quality indicators, and support evidence-based decision-making. Continuous analysis of laboratory data enables early identification of process deviations, improves resource utilization, and strengthens patient safety.

The growing emphasis on personalized medicine and precision diagnostics also creates new opportunities for clinical biochemistry laboratories. Advanced biochemical testing, molecular diagnostics, biomarkers, and companion diagnostics are increasingly being incorporated into routine clinical practice. ISO 15189:2022 provides a quality framework that supports the reliable implementation of these emerging diagnostic technologies.

Future laboratory services will increasingly rely on interdisciplinary collaboration among laboratory professionals, clinicians, information technology specialists, biomedical engineers, and healthcare administrators. Effective collaboration will improve diagnostic interpretation, clinical consultation, quality improvement initiatives, and patient-centered healthcare delivery.

In addition, laboratories have opportunities to strengthen environmental sustainability by adopting energy-efficient equipment, reducing laboratory waste, optimizing reagent utilization, and implementing environmentally responsible practices without compromising analytical quality or patient safety.

The future direction of clinical biochemistry laboratories is expected to include greater integration of artificial intelligence, digital pathology, remote quality monitoring, cloud-based laboratory information systems, predictive analytics, and real-time quality dashboards. These innovations will facilitate proactive quality management, early detection of analytical problems, and more efficient laboratory operations.

Overall, ISO 15189:2022 serves as a strategic foundation for future-ready medical laboratories. Laboratories that embrace technological innovation, continuous education, evidence-based quality management, and patient-centered practices will be better positioned to meet evolving healthcare demands, achieve international accreditation standards, and contribute to improved clinical outcomes.

IX. CONCLUSION

ISO 15189:2022 represents a significant advancement in the quality management and technical competence requirements for medical laboratories. The revised standard extends beyond traditional quality assurance by integrating risk-based thinking, patient-centered care, personnel competency, information management, and continual improvement into a unified quality management framework. These enhancements enable clinical biochemistry laboratories to provide accurate, reliable, timely, and clinically relevant laboratory services while maintaining the highest standards of patient safety.

Successful implementation of ISO 15189:2022 requires strong leadership, competent personnel, standardized operating procedures, effective risk management, robust quality assurance programmes, and continuous monitoring of laboratory performance. The adoption of evidence-based practices, laboratory automation, digital information systems, and quality



indicators further strengthens laboratory operations and supports compliance with international accreditation requirements.

Despite challenges such as financial constraints, workforce development, technological adaptation, and documentation requirements, the long-term benefits of accreditation significantly outweigh these limitations. Laboratories that effectively implement ISO 15189:2022 can improve analytical quality, enhance operational efficiency, reduce laboratory errors, increase clinician confidence, and contribute to better patient outcomes. The standard also promotes a culture of continual improvement that encourages innovation, accountability, and sustainable quality practices.

As healthcare continues to evolve through advances in automation, artificial intelligence, digital health technologies, and precision medicine, clinical biochemistry laboratories must remain adaptable and committed to continuous quality improvement. ISO 15189:2022 provides a robust framework for meeting these evolving expectations while ensuring international recognition and regulatory compliance. Future laboratory success will depend not only on technical excellence but also on collaboration, innovation, competency development, and patient-centered service delivery.

In conclusion, ISO 15189:2022 serves as a comprehensive roadmap for achieving excellence in clinical biochemistry laboratories. Its effective implementation enhances diagnostic reliability, strengthens patient safety, supports accreditation, and contributes to the overall improvement of healthcare quality. Laboratories that embrace the principles of ISO 15189:2022 will be well-positioned to meet future challenges and deliver high-quality laboratory services that positively impact patient care.

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