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Letter to the Editor

ISO 15189:2022; what's new in new?

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Dear Editor,

The 4th edition of ISO 15189, Medical Laboratories – Requirements for Quality and competence, has been published on December 2022. The first version of the document was issued in 2003. In 2007, it was revised and was aligned to ISO/IEC 17025.[1] Third edition was published in 2012, which added certain sections including laboratory information management.[2] The new edition, ISO 15189:2022, was prepared by Technical Committee ISO/TC 212, Committee for Clinical laboratory testing and in vitro diagnostic test systems, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 140, Committee for In vitro diagnostic medical devices, in accordance with the agreement on technical cooperation between ISO and CEN (Vienna Agreement).[3] As the parent documents, ISO 9001 and ISO 17025, have been updated, ISO 15189 required revisions to align with the format of these parent standards.[4] Annex B in the document compares ISO 9001:2015 and ISO 17025:2017 with ISO 15189:2022.

This standard promotes the welfare of patients and the satisfaction of laboratory users through confidence in the quality and competence of medical laboratories and it contains requirements for the medical laboratory to plan and implement actions to manage risks and opportunities for improvement. Benefits of this document's approach include: increasing the effectiveness of the management system, decreasing the probability of invalid results, and reducing potential harm to patients, laboratory personnel, the public, and the environment. This document is intended for use in medical laboratory disciplines, including Point-of-Care Testing (POCT) supporting services; however, it can be applied to users, vendors, regulatory authorities, accreditation bodies, other healthcare services, such as diagnostic imaging, respiratory therapy, physiological sciences, blood banks, and transfusion services. The use of this document facilitates cooperation between medical laboratories and other healthcare services, assists in the exchange of information, and the harmonization of methods and procedures. On top of that patient examination results get comparable between medical laboratories, regardless of city or country, when medical laboratories conform to this document.[3]

CHANGES IN NEW

The new standard is focused on risk management (aligned with ISO 22367:2020), the impact of services on patients, and opportunities for improvement within medical laboratories.[5] The layout of the standard has been modified as it has been aligned with its parent standards: ISO 17025:2017 and ISO 9001:2015. The terms and definitions have been reviewed with some inclusions, exclusions, updates, and a new ordering of entries. (Table. 1) "Quality manual" as in the previous edition, is not a specific requirement. However, information relating to the structure and function of the laboratory and its management system must be available for both the laboratory personnel and the users to access. The term "quality manager" is not included in the new edition of the standard but there is a requirement for laboratories to have personnel responsible for the implementation, monitoring, and improvement of the management system.[6]

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Table1: Terms and definitions included and excluded in ISO 15189: 2022

Included	Excluded
Bias/Measurement Bias	Accreditation
Clinical Decision Limit	Automated selection
Commutability of Reference Material/Commutability	Competence
Complaint	Critical interval
Consultant	Documented procedure
Examination Procedure	Laboratory director
External Quality Assessment	Laboratory management
Impartiality	Process
Internal Quality Control	Quality
In Vitro Diagnostic Medical Device (IVD)	Quality objectives
Laboratory User	Quality policy
Management System	
Measurement Accuracy/Accuracy of Measurement/Accuracy	
Measurement Uncertainty (MU)	
Patient	
Trueness/Measurement trueness	

Besides these, there are some major changes in this new standard. One of the major changes is that this version is less prescriptive than previous ones, which means the medical laboratory has the flexibility to meet and justify the requirements set out in the document. Another significant change from ISO 15189:2012 is that point of care testing (POCT) is now included in the new standard, so ISO 22870:2016 is withdrawn. There is an Annex in the standard to summarize the requirements for POCT.[5]

The main changes to sum up: [3]

- Alignment with ISO/IEC 17025:2017 resulted in the management requirements now appearing at the end of the document;
- Requirements for point-of-care testing (POCT), previously in ISO 22870, have been incorporated;
- Increased emphasis on risk management.

WHAT NEXT

To implement this standard, the medical laboratories should perform a gap analysis between the requirements of ISO 15189:2022 and the quality management system already in place. Since the POCT standard is integrated into the new ISO 15189, those organizations accredited to ISO 15189:2012, and those also accredited to ISO 22870:2016, will need transitional assessments and be accredited to the updated version of ISO 15189. The International Laboratory Accreditation Cooperation (ILAC) has set an implementation period of 3 years from the date of publication of this revised standard for accredited organizations to adopt the new standard. As most of the requirements in existing documents remain unchanged, laboratories which already have effective quality management systems should be able to adapt to the new requirements without any trouble.[5,6]

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