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Perspective

Eye View Perspective on ISO15189:2022

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ISO 15189 (International Organization for Standardization) was developed in the year 2003 and has undergone various revisions. While the accreditation is purely voluntary, it is a mark of excellence worldwide. There are over 1000 medical laboratories in India that are now ISO15189 accredited. Since the last edition of 2012, there was constant feedback from the users and laboratories about clarity indefinitions of various terms like validation, verification, metrological traceability, etc. Also, other standards like ISO/IEC 17025:2017 and ISO 9001:2015 that were referenced in ISO 15189 had undergone revision. These revisions reinforce the importance of continually improving quality standards. Therefore, after 10 years, ISO15189 standards wereupdated, and the fourth edition of ISO 15189:2022 was published on December 6, 2022.[1]

In the latest fourth edition, there has been an overall change in the framework. Contrary to the previous two main sections- technical and management, the current revision has five sections that include general, structural, resource, process, and management system. The new version is more specific in its wording which helps users and laboratory personnel in getting the required information with ease.

As per the World Health Organization, patient safety is a fundamental component of Universal Health Coverage.[2] It is a prerequisite to strengthening healthcare delivery systems so that progress towards effective Universal Health Coverage (UHC) under Sustainable Development Goal 3 is made. In line with this, the revised edition of ISO 15189 standards for medical laboratories contains requirements that ensure that the risk to patients is central to the ethos of the medical laboratory's quality management system and its processes. The changes are patient-focused, and risk-based, with an emphasis on mitigating risk and highlighting the importance of continuous improvement within clinical laboratories. It adopts a less prescriptive approach to standards to provide medical laboratories with more flexibility to meet their requirements.

It contains requirements for the medical laboratory to plan and implement actions to address risks and opportunities for improvement. The risk management in ISO 15189:2022 states that laboratory management shall establish, implement, and maintain processes for

identifying risks of harm to patients and opportunities for improved patient care associated with its examinations and activities, and develop actions to address both risks and opportunities for improvement. Risk management measures for equipment are also highlighted in ISO 15189:2022. These measures include ensuring that the laboratory has appropriate safeguards to prevent unintended adjustments of equipment that can invalidate examination results and implementing procedures for adverse incident reporting to any manufacturer's recall. The laboratory director needs to ensure that these processes are evaluated for effectiveness and modified, as per the requirement. The COVID pandemic has exposed different risks pertaining to all sectors, particularly the supply chain system. As a learning from the pandemic, medical laboratories now are aware of the risk of being solely dependent on one vendor. Therefore, they now have backup vendors/ suppliers to maintain the quality and turn around of test results.

The revised standards placemedical laboratories in a stronger position in deciding how they do a specific task if the outcome remains the same, for instance, the addition of the phrase "as appropriate," allows the laboratory to determine what is felt appropriate for the work environment and situation and gives certain flexibility to justify why a particular requirement was not met. The phrasing complies with the ISO directives so, for example, there are still "shall" and "should" statements ("shall" indicating a mandatory requirement, "should" indicating a strong recommendation). There is greater use of qualifiers after "shall" statements.[3]

The other significant change from ISO 15189:2012 is the inclusion of point-of-care testing (POCT) in the standard's scope which means ISO 22870:2016 will be withdrawn. An Annex to summarize these requirements is added and there are references to the requirements for POCT included throughout the text. As per the new standards, laboratory-supported POCT should be included in the scope of the management system and should follow the requirements of the standard.

The new ISO 15189 document also brings in changes in Management System Documentation. It categorises the general requirements for management system documentation into the following sub-sections: documentation, personnel access, evidence of commitment, and competence and quality. Control of documents, with specific sub-sections on the creation of records, amendment of records, and retention of records, is dealt with in detail. ISO 15189:2012 standards required that the laboratory shall establish and maintain a quality manual whereas the new ISO 15189:2022 states that the management system documents can, but are not required to, be contained in a quality manual.

The authors suggest that at this stage, all laboratories should do a gap analysis to review the current quality standards against the required new standards and prepare accordingly within the given three years transitioning period. To conclude, ISO 15189:2022 helps in ensuring that patient care and safety are focused on while designing laboratory processes. The standards allow flexibility in clinically justifiable variations to help strengthen the laboratory operations to strive towards and fulfil the needs of patients within the scope of the ISO 15189 framework.

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