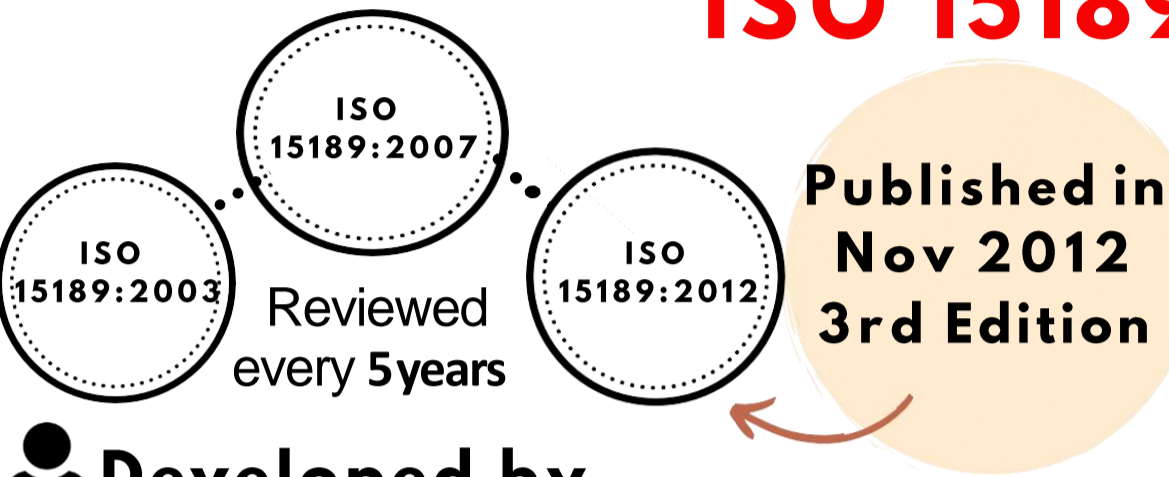




Accreditation for a Better Medical Laboratory Quality

ISO 15189:2012



KEY IMPROVEMENTS

- Focus on risk management
- Clarify the differences between validation and verification
- Clause 5.8 is split into requirements for reporting (5.8) and release of results (5.9)
- New section 5.10 Laboratory information management is added

Developed by
ISO Technical Committee (TC) 212

Why it is revised?

2003: Guideline for medical lab to build quality management system

2007: Minor revision with some add-ons

2012: Complete revision with specific ways on how to meet the criteria and more focus on risk analysis

Why is ISO 15189 created?

Previously, medical laboratories were based on ISO/IEC17025 but it is not effective, because medical laboratories have different settings than normal calibrating or testing laboratories

- Objectives**
- Create failure-resistant systems to catch mistakes before becoming problems
 - Reduce errors by getting things right at first time
 - Identify opportunities for improvement at all times
 - Empower staff by involving them in problems solving and implementation of solutions

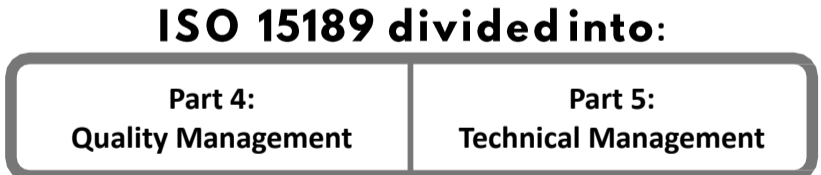
Standard is based on
ISO/IEC 17025 and ISO 9001

ISO/IEC 17025: General requirements for the competence of testing and calibration laboratories

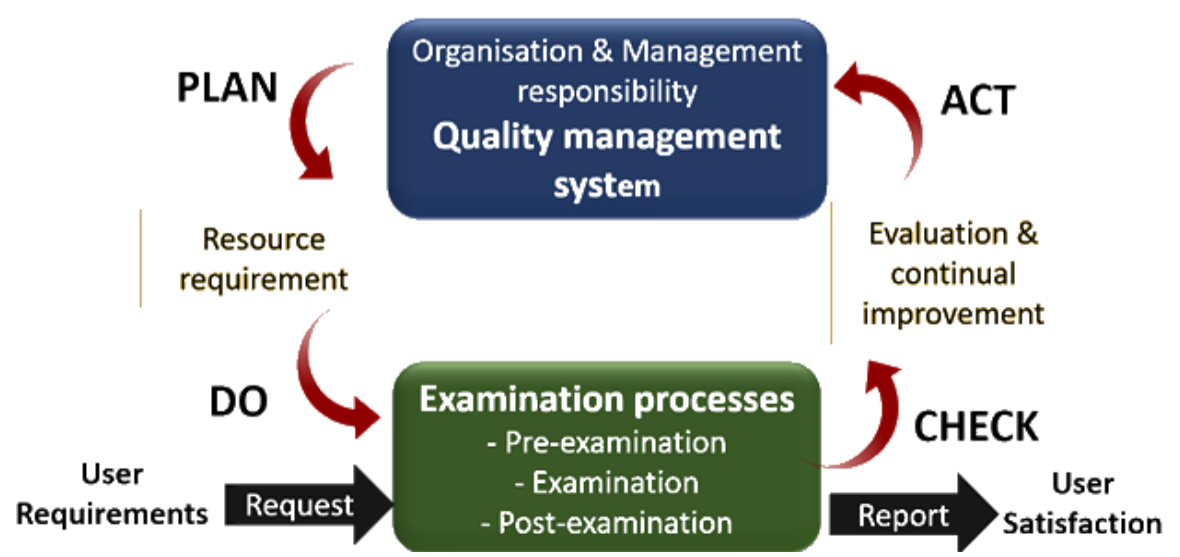
ISO 9001: Quality management systems requirements

ISO 15189: **Quality and competence in medical laboratories + customers' satisfaction**

- + Benefits**
- Improvement to lab management and performance
 - Competitive advantages:
 - Mark of quality and competency
 - Credibility and recognition
 - Reimbursement of fees in healthcare financing or insurance schemes
 - Increase prospects for international market



Who is involved?
All employees at ALL levels of medical laboratories.



Schneider, F., Maurer, C., & Friedberg, R. C. (2017). International Organization for Standardization (ISO) 15189. *Annals of laboratory medicine*, 37(5), 365-370.

International Organization for Standardization (2012). ISO 15189 Medical laboratories - Requirements for quality and competence, 3rd ed. Geneva: *The Organization*.

Pereira P., (2017). ISO 15189:2012 Medical laboratories – Requirements for quality and competence. Retrieved from <https://www.westgard.com/iso-15189-2012-requirements-1.htm>.

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