ISO 15189:2022 Standard Overview
- Navigating the new with an understanding of the old

January 2023 LabCoP ECHO Session - ISO 15189:2022 Session #1

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Presentation Overview

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Organization Introduction

CLSI is a standards development organization that creates global best practices for laboratories.

CLSI is the ISO Secretariat for the ISO/TC 212 Committee, which is responsible for the standardization and guidance in the field of laboratory medicine and in vitro diagnostic test systems. CLSI manages the committee’s program of work through the ISO consensus process and provides administrative support.
ISO 15189:2022 Introduction
Introduction to ISO

ISO from “isos,” Greek for “equal”

“If two objects meet the same standard, then they are equal.”
Key ISO Standards

- ISO 9001 - Quality management systems
- ISO 17025 - Testing and calibration laboratories
- ISO 15189 - Medical laboratories
- ISO 22367 - Risk management
- ISO 15190 - Laboratory safety
- ISO 20658 - Sample collection and transport
- ISO 22870 - Point-of-care testing (POCT)
- ISO 17043 - Proficiency testing / External quality assessment
- ISO 19011 - Internal audit
- ISO 17011 - For accreditting bodies
Purpose & Scope of ISO 15189 Standard

*Promote welfare of patients and satisfaction of laboratory users through confidence in quality and competence in medical laboratories*

- Requirements for medical laboratory to plan and implement actions to address risks and opportunities for improvement
- Applicable to:
  - **Medical laboratories** → developing management systems and assessing competence
    - Applicable to users, regulatory authorities and accreditation bodies confirming / recognizing competence of medical laboratories
  - **POCT**
  - **Other healthcare services** (e.g., blood banks/transfusion services)
ISO 15189:2022 Standard Highlights

- 4\textsuperscript{th} edition = 2022 version
- Replaces 3\textsuperscript{rd} edition (ISO 15189:2012), which has been technically revised
- Aligned with ISO 22367, ISO 15190, and ISO 20658
- Incorporates POCT requirements and supersedes ISO 22870:2016, which is now withdrawn
- Formatting based in ISO 17025:2017
Content Overview of ISO 15189:2022 Standard

• The standard is divided into 8 major sections plus annexes (A-C)
  1. Scope
  2. Normative references
  3. Terms and definitions
  4. General requirements
  5. Structural and governance requirements
  6. Resource requirements
  7. Process requirements
  8. Management system requirements

• Sections 1, 2 and 3 are for guidance only and are not auditable
• The ‘meat’ of ISO 15189 resides in the requirements sections (5 total)
  – Laboratories must effectively satisfy these requirements to be accredited
Key Updates within ISO 15189:2022
New Terms and Definitions in 2022 Version

15 New Terms & Definitions for Review

- Bias / Measurement Bias
- Clinical Decision Limit Examination
- Commutability of a Reference Material / Commutability
- Complaint
- Consultant
- Examination Procedure
- External Quality Assessment
- Impartiality
- In Vitro Diagnostic Medical Device (IVD)
- Laboratory User
- Management System
- Measurement Accuracy / Accuracy of Measurement / Accuracy
- Measurement Uncertainty (MU)
- Patient
- Trueness / Measurement Trueness
Main Document Changes from 2012 to 2022 Version

• **Alignment with ISO/IEC 17025:2017** resulted in management requirements now appearing at the end of the 2022 version

• **Requirements for point-of-care testing (POCT), previously in ISO 22870, have been incorporated** and is a new inclusion within the scope of the 2022 version

• **Increased emphasis on risk management** within 2022 version
ISO 15189 Auditable Requirements Comparison

2012
Management (4)
Technical (5)

2022
General (4)
Structural & Governance (5)
Resource (6)
Process (7)
Management System (8)

Alignment with ISO/IEC 17025:2017

ISO 22870:2016
Point-of-care testing (POCT) — Requirements for quality and competence

This standard has been revised by ISO 15189:2022

Abstract

ISO 22870:2016 gives specific requirements applicable to point-of-care testing and is intended to be used in conjunction with ISO 15189. The requirements of this document apply when POCT is carried out in a hospital, clinic, and by a healthcare organization providing ambulatory care. This document can be applied to transthoracic measurements, the analysis of expired air, and in vivo monitoring of physiological parameters.

Patient self-testing in a home or community setting is excluded, but elements of this document can be applicable.

General information

Status: Withdrawn
Publication date: 2016-11

Requirements for POCT, previously in ISO 22870, incorporated
Equipment Updates in 2022 Version

• Highlighted risk management measures for equipment
  o Ensuring lab 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

• Addition of 6.4.2 equipment requirements
  o Ensured access to equipment for correct performance of lab activities
  o Ensured requirements met for equipment outside of lab’s permanent control or manufacturer’s functional specifications
  o All equipment items uniquely labelled/identified with maintained register
  o Maintain/replace equipment to ensure quality examination results

Increased emphasis on risk management
Quality Management Updates in 2022 Version

• More specific → internal/external lab personnel = responsible for management system (e.g., CQI focus)

• Focus on risk management within lab’s quality management
  o Establish, implement, and maintain processes for identifying risks of harm to patients and opportunities for improved patient care, and developing actions to address risks and OFIs (opportunities for improvement)
  o Lab director = ensures processes are evaluated for effectiveness and modified (when deemed ineffective)

*Increased emphasis on risk management*
Documentation Updates in 2022 Version

• Formatting changes for management system documentation → categorization into subsections
  o General, competence & quality, evidence of commitment, documentation, and personnel access

• More emphasis on document control including creation, amendment and retention of records (new subsections)

• Management system documents not required to be contained in a quality manual
ISO 15189 Document Comparison - “Crosswalk”

- Located within updated 2022 version under Annex C
- Compares all sections of previous 2012 version with the current version
- Effective way to familiarize you and your laboratory with revised content
- Allows for easier reference, comparison, and updating of laboratory documents and practices

[Table C.1 — Comparison between ISO 15189:2012 and ISO 15189:2022 (this document)]
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<td>8.8.3 Internal audits</td>
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<td>4.14.6 Risk management</td>
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<td>8.5 Actions to address risks and opportunities for improvement</td>
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Summary

- ISO 15189:2022 version replaces the previous 2012 version

- Many important updates to new 2022 version
  - Alignment with ISO/IEC 17025:2017
  - Requirements for POCT, previously in ISO 22870, incorporated
  - Increased emphasis on risk management
  - Specific focus on laboratory management and personnel
    - Especially in their roles/responsibilities to ensure effective management system implementation and risk management processes
  - Management system documents not required to be contained in a quality manual

- Utilize annexes within new 2022 version to better understand the relationship to other standards
Acknowledgement

- ASLM
Questions?
Thank You!

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