



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

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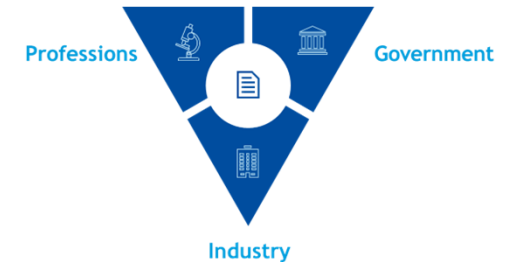
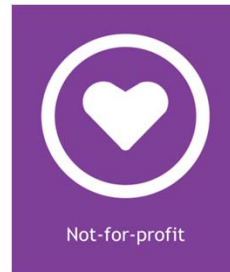


Presentation Overview

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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 accrediting 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

- 4th edition = 2022 version
- Replaces 3rd 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

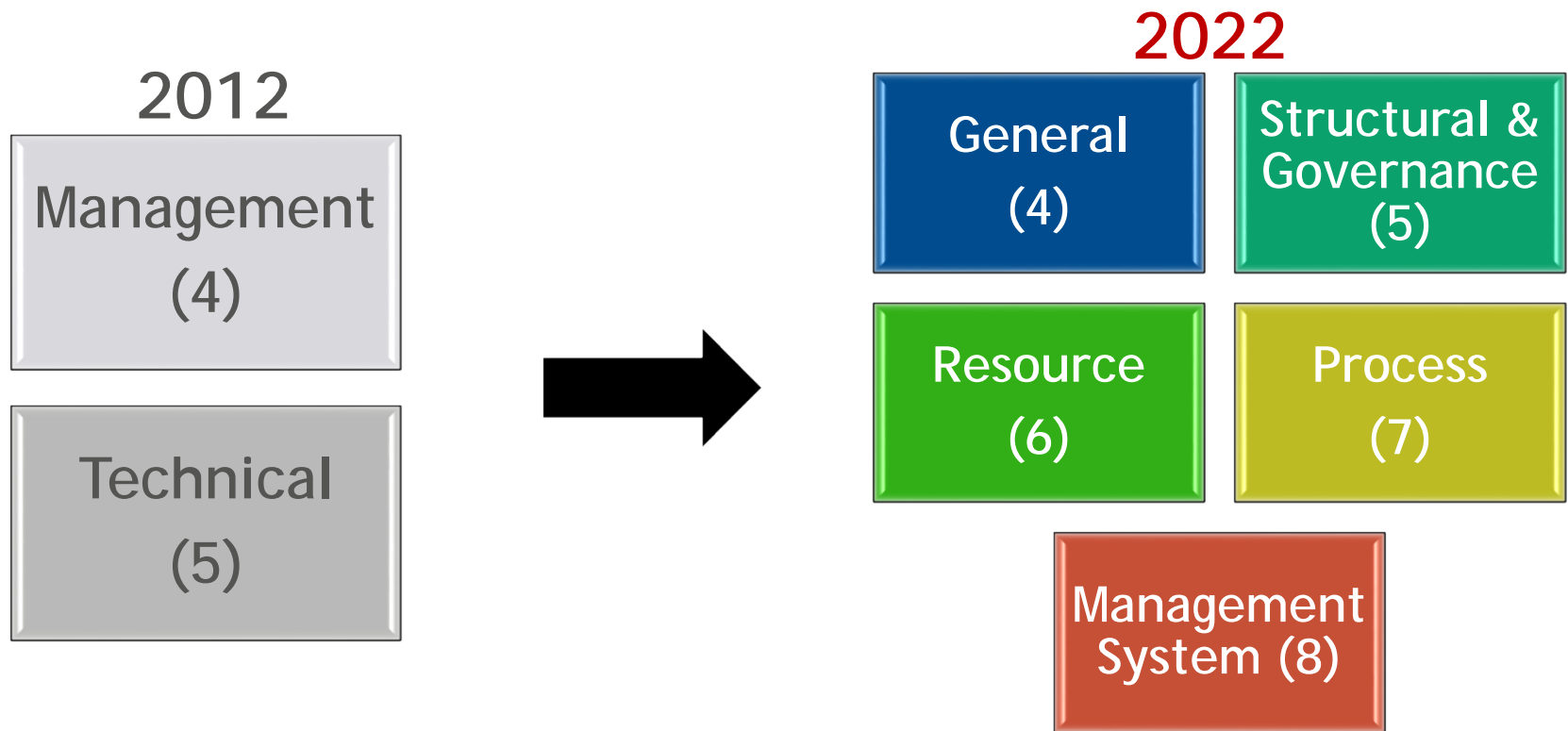
- Bias / Measurement Bias
- Clinical Decision Limit Examination
- Commutability of a Reference Material / Commutability
- Complaint
- Consultant
- Examination Procedure
- External Quality Assessment
- Impartiality
- In Vitro Diagnostic Medical Device (IVD)
- Laboratory User
- Management System
- Measurement 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



Alignment with ISO/IEC 17025:2017

ISO 15189:2022 Impact on POCT Standard (ISO 22870:2016)

← ICS ← 03 ← 03.120 ← 03.120.10

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 transcutaneous 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
 - 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**
 - Ensured access to equipment for correct performance of lab activities
 - Ensured requirements met for equipment outside of lab's permanent control or manufacturer's functional specifications
 - All equipment items uniquely labelled/identified with maintained register
 - 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**
 - 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)
 - Lab director = ensures processes are evaluated for effectiveness and modified (when deemed ineffective)

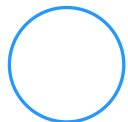
Increased emphasis on risk management

Documentation Updates in 2022 Version

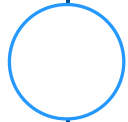


- Formatting **changes for management system documentation** → categorization into subsections
 - General, competence & quality, evidence of commitment, documentation, and personnel access
- More **emphasis on document control** including creation, amendment and retention of records (new subsections)
- Management system documents ***not required to be contained in a quality manual***

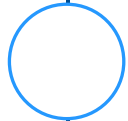
ISO 15189 Document Comparison - “Crosswalk”



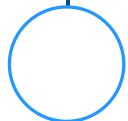
Located within updated 2022 version under [Annex C](#)



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



ISO 15189:2022 - Adobe Acrobat Pro

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ISO 15189:2022(E)

Annex C
(informative)

Comparison between ISO 15189:2012 and ISO 15189:2022 (this document)

Table C.1 — Comparison between ISO 15189:2012 and ISO 15189:2022 (this document)

ISO 15189:2012	ISO 15189:2022 (this document)
Foreword	Foreword
Introduction	Introduction
1 Scope	1 Scope
2 Normative references	2 Normative references
3 Terms and definitions	3 Terms and definitions
4 Management requirements	4 General requirements
4.1 Organization and management responsibility	4.1 Impartiality
4.1.1 Organization	4.2 Confidentiality
4.1.1.1 General	4.2.1 Management of information
4.1.1.3 Ethical conduct [includes confidentiality in (e)]	4.2.2 Release of information
4.1.1.2 Legal entity	4.2.3 Personnel responsibility
4.1.1.4 Laboratory director	5 Structural and governance requirements
4.1.2 Management responsibility	5.1 Legal Entity
4.1.2.1 Management commitment	5.2 Laboratory director
	5.2.1 Laboratory director competence
	5.2.2 Laboratory director responsibilities
	5.2.3 Delegation of duties
	5.3 Laboratory activities
	5.3.1 General
	5.3.2 Conformance with requirements
	5.4.1 General
	5.4.2 Quality management

8.27 x 11.69 in

ISO 15189 Document Comparison - “Crosswalk” Example

ISO 15189:2012	ISO 15189:2022
4.14.5 Internal audit	8.8.3 Internal audits
4.14.6 Risk management	5.6 Risk management 8.5 Actions to address risks and opportunities for improvement 8.5.1 Identifications of risks and actions taken 8.5.2 Acting on risks and opportunities for improvements
4.14.7 Quality indicators	5.5 Objectives and policies d) 8.8.2 Quality indicators



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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<https://clsi.org/>

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