AGHPF

Improving the quality of life...

AGQC

Improving the quality of life...

QCHRM

Building strong teams...

The AG Group is a 20+ year consortium providing consultancy services to the public and private sectors to improve organisational quality systems and reduce waste based on industry and international standards, leading to international certification

ISO 9001:2015 | I4001:2015 | 45001:2018

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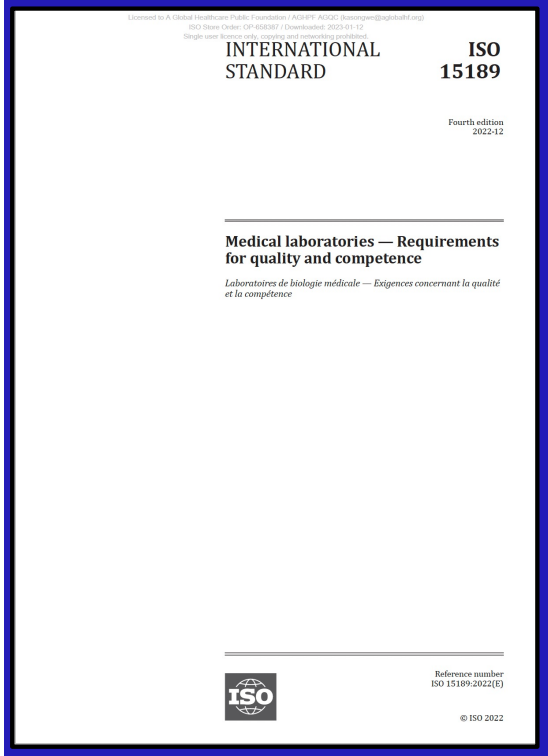

Facility Level Implications

ISO 15189:2022 - 4th Edition

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Terms and definitions

- Terms have increased from 27 to 32
- Some maintained while others completely removed
- Some maintained but definitions changed
- Some changes to definition minor while others major

Terms and definitions

Term	3rd Edition	4th Edition	*Extent of Change*
Competence	Demonstrated ability to apply knowledge and skills	Demonstrated ability to apply knowledge and skills **to achieve intended results" in 2022 version**	**Minor**
Laboratory management	Person(s) who direct and manage the activities of a laboratory	person(s) with **responsibility for, and authority** over a laboratory	**Major**
Quality indicator	Measure of the degree to which a set of inherent characteristics fulfills requirements	Measure of the degree to which **a number of characteristics** of an object fulfills requirements-	**Minor**

Changes to Terms

ADDED 15

- Bias/measurement bias
- Clinical decision limit
- Commutability of a reference material
- Complaint
- Consultant
- Examination
- External Quality Assessment
- Impartiality
- Internal quality control
- Invitro diagnostic medical device
- Lab user
- Management system
- Measurement accuracy
- Patient
- Trueness/measurement trueness

REMOVED 10

- Accreditation
- Alert interval/critical interval
- Automated selection & reporting of results
- Lab director
- Non-conformity
- Process
- Quality
- Quality Management Systems
- Quality policy
- Quality objective

Special Note

- The inclusion of point-of-care testing (POCT) in the main standard
- The importance of risk management
- ISO17025 (2017) is the parent document for ISO15189
- As this is a normative reference for ISO15189 we needed to revise it to comply with the structure
- The standard is a minimum requirement not a maximum
- The expectation is that laboratories should seek to be the best they can, not just reach the minimum set out by the standard
- It is patient focus
- From preventive action to risk and opportunities
- Record retention time based on risk
- EQA program must fulfill the requirements of ISO/IEC17043

Special Note -EQA

7.3.7.3 External quality assessment (EQA)

When selecting EQA program(s), the laboratory should consider the type of target value offered.

NOTE Examples of such materials may include:

— certified reference materials;

— samples previously examined;

— material from cell or tissue repositories;

— exchange of samples with other laboratories;

— control materials that are tested daily in interlaboratory comparison programmes.

4th edition

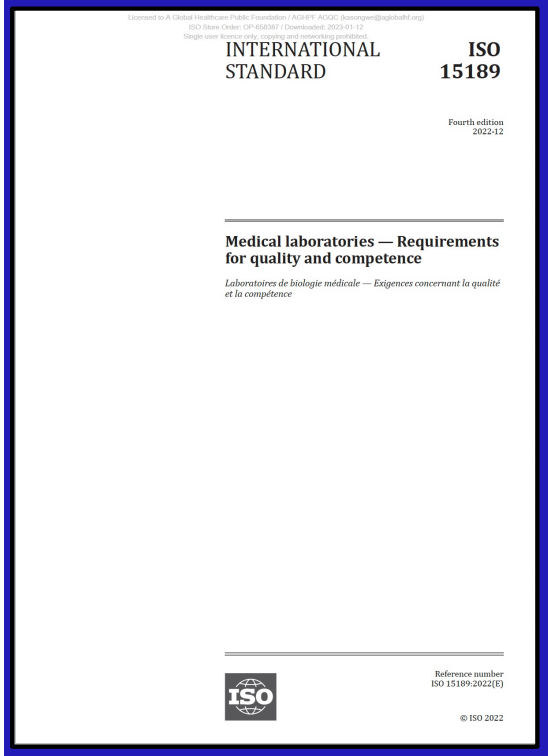
Target values are:

1) independently set by a reference method, or

2) set by overall consensus data, and/or

3) set by method peer group consensus data, or

4) set by a panel of experts.



Laboratory Gap Analysis & Transition plan

ISO 9001:2015 | I4001:2015 | 45001:2018

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Lab transition plan -Note

A transition period of 3 years has been agreed from the date of publication (Dec 06th 2022) for accredited bodies to review the requirements and bring their operations and processes in line with the requirements of the new ISO 15189:2022.

Submission of a transition plan should be supported by documentation **demonstrating how** new or changed requirements are met.

Effective implementation will be assessed at the site visit.

However, if the Laboratory considers that it currently meets a changed requirement and does not need to make changes to its system, then this should be stated in the template

Accredited laboratories - 4 Steps

currently accredited to ISO 15189:2012 are required

1- Review the revised standard

2- Gap analysis

3- Establish transition plan

4- Document gap analysis and transition Plan

Accredited labs -Post site visit

1. Mandatory Improvement Actions Reports(IARs) which are raised against the new standard will need to **be cleared prior to the grant of accreditation**

2. If the accredited lab **fails to demonstrate conformity** to ISO 15189:2022 and/or clear those improvements actions raised before the transition deadline, the body shall be **suspended for a maximum of 6 months**

3. If the body **fails to address those actions required** to complete the transition process within this timeframe, this will result in the **withdrawal of accreditation for ISO 15189:2012**

New Application

1. All **new applications**/extensions to scope received after accreditation body date lines **shall be assessed against ISO 15189:2022**

2. For existing applicants, assessments which are scheduled to take place after 01 January 2024 shall be against ISO 15189:2022. (UKAS)

Validity of ISO 15189:2012 -
ISO 15189:2012 Medical laboratories – Requirements for quality and competence
ceases to be valid as of 06 December 2025

Gap Analysis - How to…!

Name of Organisation	
Accreditation Number	
Date of Submission	

CLAUSE	ISO 15189:2012	CLAUSE	ISO 15189:2022	EXTENT OF CHANGE	DETAILS OF CHANGES WITHIN YOUR MANAGEMENT SYSTEM WHICH HAVE/WILL BE TAKEN TO ADDRESS CHANGES

Key - Extent of Change:

- **Structural** – Requirement remains the same but is under a new clause number
- **Minor** – Wording of the requirement has changed but overall intent is consistent
- **Major** – Changes will require the CAB to implement new or change existing practice
- **New** – New requirement(s)/concept(s) not in previous version of the standard

Gap Analysis– Example

CLAUSE	ISO 15189:2012	CLAUSE	ISO 15189:2022	EXTENT OF CHANGE	DETAILS OF CHANGES WITHIN YOUR MANAGEMENT SYSTEM WHICH HAVE/WILL BE TAKEN TO ADDRESS CHANGES
4.1.1.1	General	5.3.2	Laboratory activities: Conformance with requirements	Structural	N/A
		8.1.3	Management System Awareness	New	

Gap Analysis - Example

CLAUSE	ISO 15189:2012	CLAUSE	ISO 15189:2022	EXTENT OF CHANGE	DETAILS OF CHANGES WITHIN YOUR MANAGEMENT SYSTEM WHICH HAVE/WILL BE TAKEN TO ADDRESS CHANGES
4.9	Identification and control of NCNs	7.5	Nonconforming work	Major	SOP for Handling NCs XXX-XXX revised to add utilization of risk analysis to define immediate actions, determining the need to recall released results, and review of NCs to determine need for corrective actions. In addition to immediate action, long term actions are to be implemented where applicable according to the added section 4.2 of SOP XXX-XXX. Revised the NC form to add a provision for documenting decision on acceptability of the identified NC.

Gap Analysis - Example

CLAUSE	ISO 15189:2012	CLAUSE	ISO 15189:2022	EXTENT OF CHANGE	DETAILS OF CHANGES WITHIN YOUR MANAGEMENT SYSTEM WHICH HAVE/WILL BE TAKEN TO ADDRESS CHANGES
5.4.3	Request form information	7.2.3	Pre-examination processes – Requests for providing laboratory examinations	Major	Revised the clinician handbook to offer more guidance to clinicians about clinical information relevant to laboratory result interpretation. We offered more guidance through the clinician handbook about the different acceptable laboratory request mediums ie paper request form when the electronic LIS is down and electronic request whenever the LIS is functioning (this requirement is also applicable when the clinician is sending a formal request following a verbal request). Communication channels for clarification of requests established and documented in the clinician handbook.

Transition Plan

ACTION	TIME	RESPONSIBLE PERSON
Example: develop training plan, update documentation, complete internal audit, notify customers, complete assessments		

Transition deadlines for accrediting bodies

SANAS	Jan 31st, 2023
KENAS	Sept 30th, 2023
SADCAS	June 14th, 2023
UKAS - UK	June 30th, 2023
NABL - India	June 30th, 2024
EGAC | TUNAC |ALGERAC |MAURITAS |ENAO |SOAC	To be announced

Key to Success

- Begin transition now
- Effective communication at all levels
- Involvement of everyone
- Strong management support
- Embrace continual improvement

People

with great passion

can make the

impossible

happen…

Acknowledgement

Thank You – Merci - Obrigado

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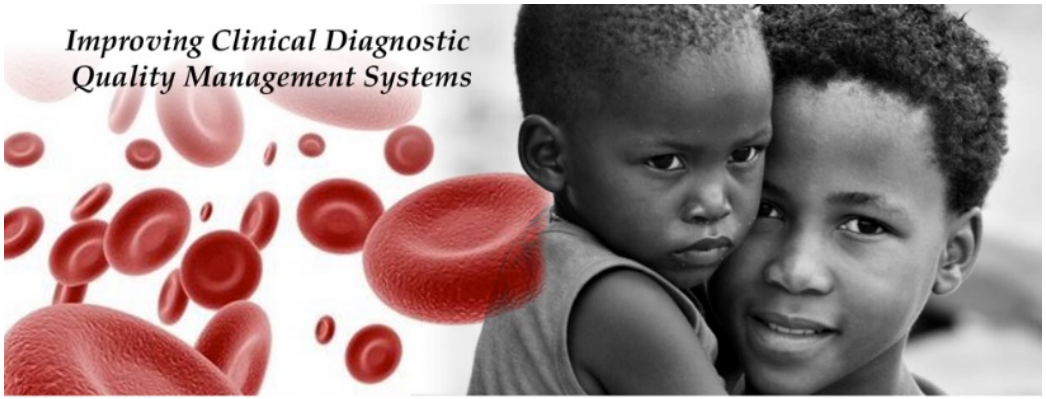
Discussion


Improving Clinical Diagnostic
Quality Management Systems


Q&A
Q&A