Four Pillars of Quality: Envisioning Change in ISO 15189

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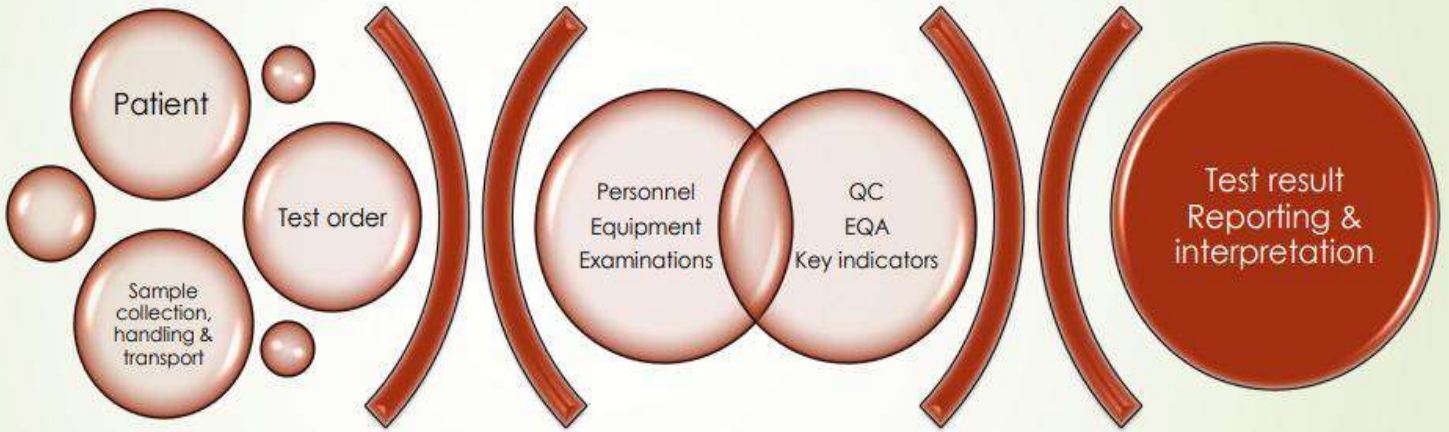
Objectives

- Understand the link between quality and standards
- Review the history of ISO 15189
- Hear about the process to review, revise and continually improve ISO standards
- Find out what to expect in the next revision of ISO15189 Medical laboratories – Requirements for quality and competence
- Discover other ISO standards available to help medical laboratorie

QUALITY MANAGEMENT IN THE LABORATORY



Pre-analytical Analytical Post analytical

Policies, processes, procedures, documented information

CONTINUAL IMPROVEMENT

What is a Standard

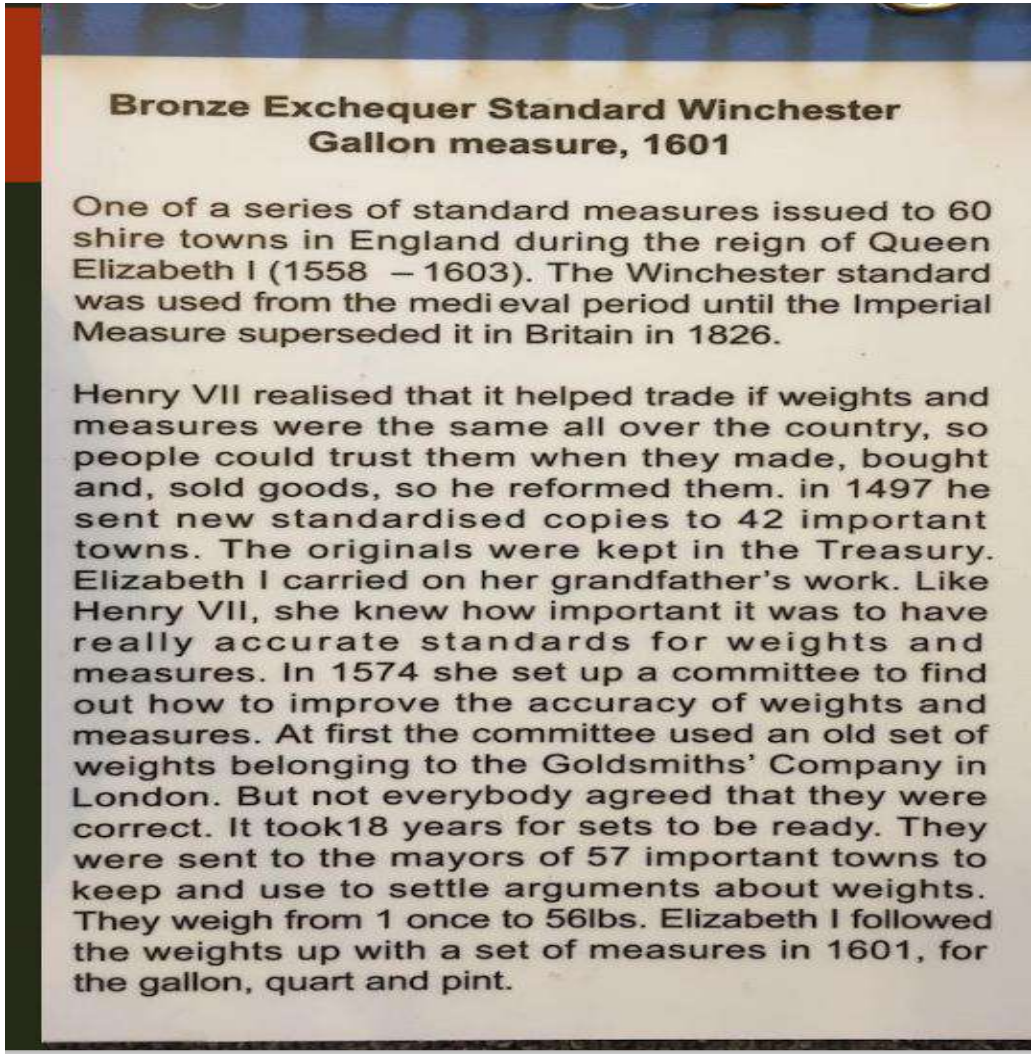
A Standard:

- Specifies requirements
- Prescribes methods
- Gives recommendations
- Offers guidance

Standards are not New!!

Winchester Standard…..

Imperial Measure Standard…



Bronze Exchequer Standard Winchester Gallon measure, 1601

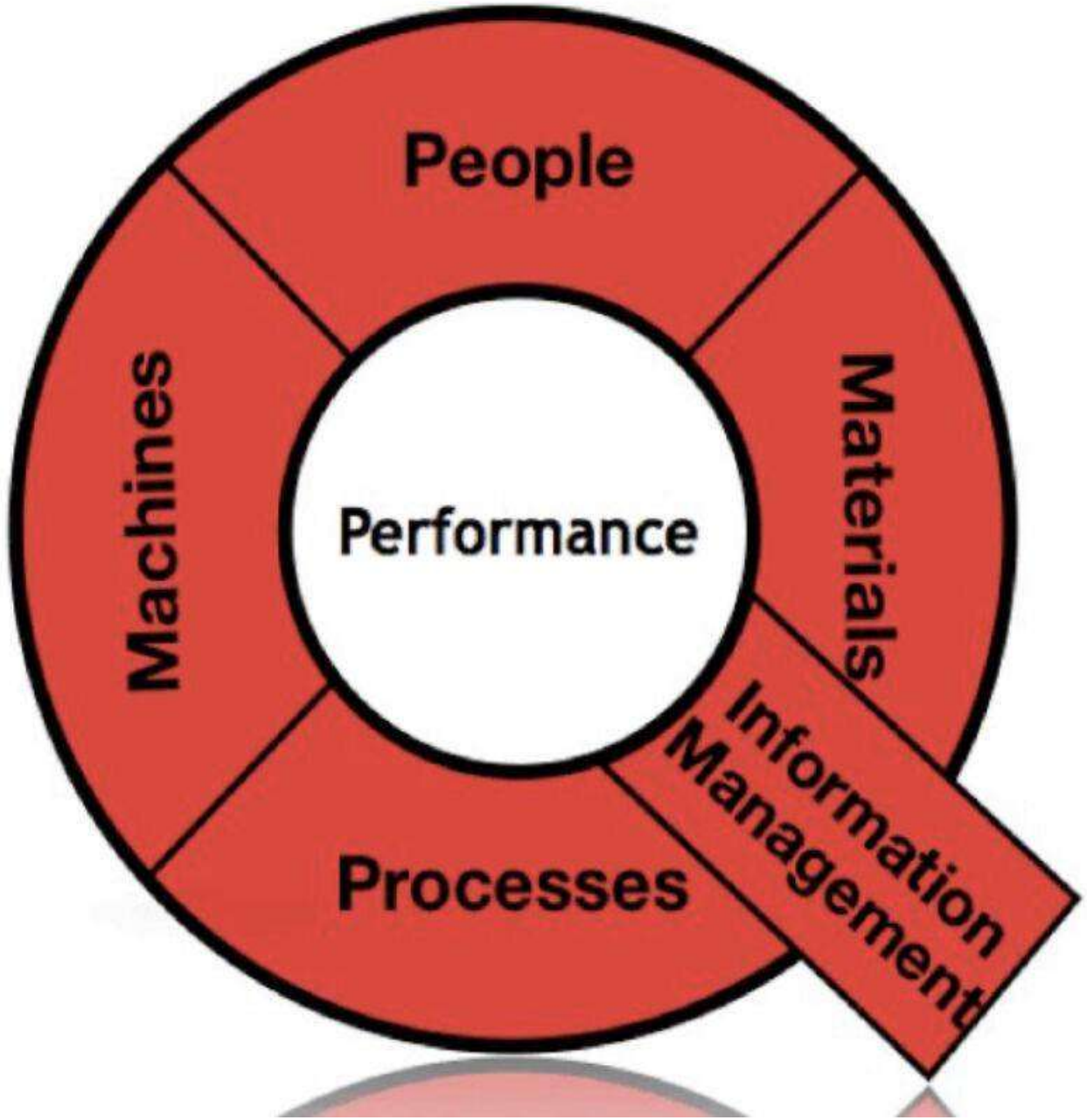
One of a series of standard measures issued to 60 shire towns in England during the reign of Queen Elizabeth I (1558 – 1603). The Winchester standard was used from the medi eval period until the Imperial Measure superseded it in Britain in 1826.

Henry VII realised that it helped trade if weights and measures were the same all over the country, so people could trust them when they made, bought and, sold goods, so he reformed them. in 1497 he sent new standardised copies to 42 important towns. The originals were kept in the Treasury. Elizabeth I carried on her grandfather's work. Like Henry VII, she knew how important it was to have really accurate standards for weights and measures. In 1574 she set up a committee to find out how to improve the accuracy of weights and measures. At first the committee used an old set of weights belonging to the Goldsmiths' Company in London. But not everybody agreed that they were correct. It took18 years for sets to be ready. They were sent to the mayors of 57 important towns to keep and use to settle arguments about weights. They weigh from 1 once to 56lbs. Elizabeth I followed the weights up with a set of measures in 1601, for the gallon, quart and pint.

Why standards?

Primary aims of standardization:

- Fitness for purpose
- Interchangeability
- Variety reduction
- Compatibility
- Health and safety
- Environmental protection
- Better utilization of resources
- Better communication and understanding
- Enable transfer of technology
- Removal of trade barriers


People
Materials
Information Management
Processes
Machines
Performance

ISO 15189:2012 Introduction

- “A clinical laboratory’s fulfilment of the requirements of this International Standard means the laboratory meets both the technical competence requirements and the management system requirements that are necessary for it to consistently deliver technically valid results”

History of ISO standards

- Founded in 1947 by a group of delegates from 25 countries, the 67 original technical committees of ISO came together with a unified goal of ensuring products and services are safe, reliable, and of good quality. The very first ISO standard, called "ISO/R 1:1951" – was first published in 1951 to set a standard reference temperature for industrial length measurements. Today, that standard still exists (after many updates) as ISO 1:2002.
- Over the decades following, ISO created committees and published standards for everything from units of measure to freight containers and environmental quality.
  - It was not until 1987 that ISO 9001 – one of the most recognizable standards today – was published as ISO's first quality management standard.
  - The environmental standard ISO 14001 followed in 1996, and ISO has only increased its output of new guidance since, branching out into fields such as information security, social responsibility, energy management, and even corporate integrity.
  - ISO TC212 *Clinical laboratory testing and in vitro diagnostic systems* was formed in 1994 and the quality management standard for laboratories ISO15189 was first published in 2003

Some ISO TC212 Facts

SCOPE

Standardization and guidance in the field of laboratory medicine and in vitro diagnostic test systems. This includes, for example, quality management, pre- and post-analytical procedures, analytical performance, laboratory safety, reference systems and quality assurance

- One of more than 300 technical committees (TC)
- 45 participating member countries, 21 observing members
- Published 36 standards, 18 under development
- 5 Working Groups
  - WG1 Quality and competence in the medical laboratory
  - WG2 Reference systems
  - WG3 in vitro diagnostic products
  - WG4 Microbiology and molecular diagnostics
  - WG5 Laboratory biorisk management

Types of ISO documents

- Management system standards: ISO 9001, ISO 14000,, ISO 20387 (for biobanks)
- Conformity assessment standards: ISO17025, ISO15189
- International Standard – the majority of ISO documents
- Technical Specification, reviewed after 3 years and expected to become a standard, or to be withdrawn after a maximum of 6 years
- Technical Report – guidance or support document
- All standards documents are subject to a systematic review every 5 years
  - Based on the vote at the time of review, a document may be confirmed, revised or withdrawn

ISO15189 *Medical laboratories – Requirements for quality and competence*

- First published in 2003
- 2nd edition in 2007 had minor edits to more closely align with the normative reference ISO/IEC 17025 *General requirements for the competence of testing and calibration laboratories*
- 3rd edition in 2012 had significant layout and editorial changes and brought Laboratory information management requirements into the document, previously in an informative Annex.
- Systematic review in 2017 led to a new revision of the standard now in progress

2017 survey of users of ISO15189

- Designed by a small group, representing; users, standards body, accreditation body and someone with a long history in WG1.
- Distributed worldwide
- All users invited to submit comments and opinions
- Questions divided the responses from laboratory workers and people working with accreditation bodies
- 1713 responses received from many countries and many different types of laboratories
- A lot of very useful information was obtained to be used in the revision process

ISO15189:2012 systematic review

- As required after 5 years, the document was posted for review and ballot at the end of 2017.
- TC members were asked to vote:
  - To confirm the document,
  - To revise the document, or
  - To withdraw the document
- The result of the ballot was inconclusive, divided between confirm and revise
- Decided to post a resolution recommending revision

Resolution posted for ballot June 2018

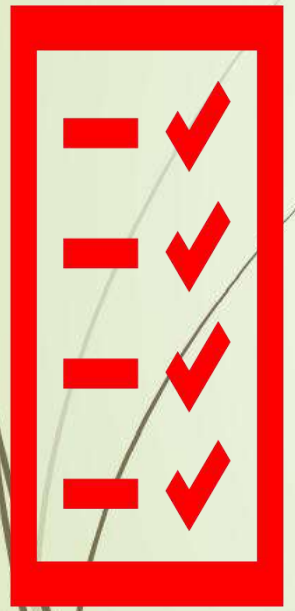
- This globally adopted standard advocates for continual improvement; therefore, there is an obligation to ensure that the document remains relevant and reflects current practices as well as future innovations in medical laboratories. In addition, it would be beneficial that a revised ISO 15189 consider the newly revised ISO/IEC 17025:2017.
- Considering that
  - 1) the current standard was published in 2012;
  - 2) a revision will probably take up to 4 years to complete; and,
  - 3) once a revised standard is published, the users of the standard will have at least a 2- or 3-year transition period to implement and/or conform to the new standard, a revised ISO 15189 will not be fully implemented before 2024 at earliest.
- Question: Do you approve the WG1 recommendation to revise ISO 15189:2012, Medical laboratories -- Requirements for quality and competence
- 29 countries voted 'yes', there were no negative votes, 14 abstained

Team approach to revision

- Project co-leaders appointed: **Sheila Woodcock and Cristina Draghici**
  - Cristina worked on the revision of ISO17025 and represents CASCO
  - CASCO has rules for conformity assessment documents used for accreditation
- 48 month revision period
- 7 Team Leaders appointed in November 2018

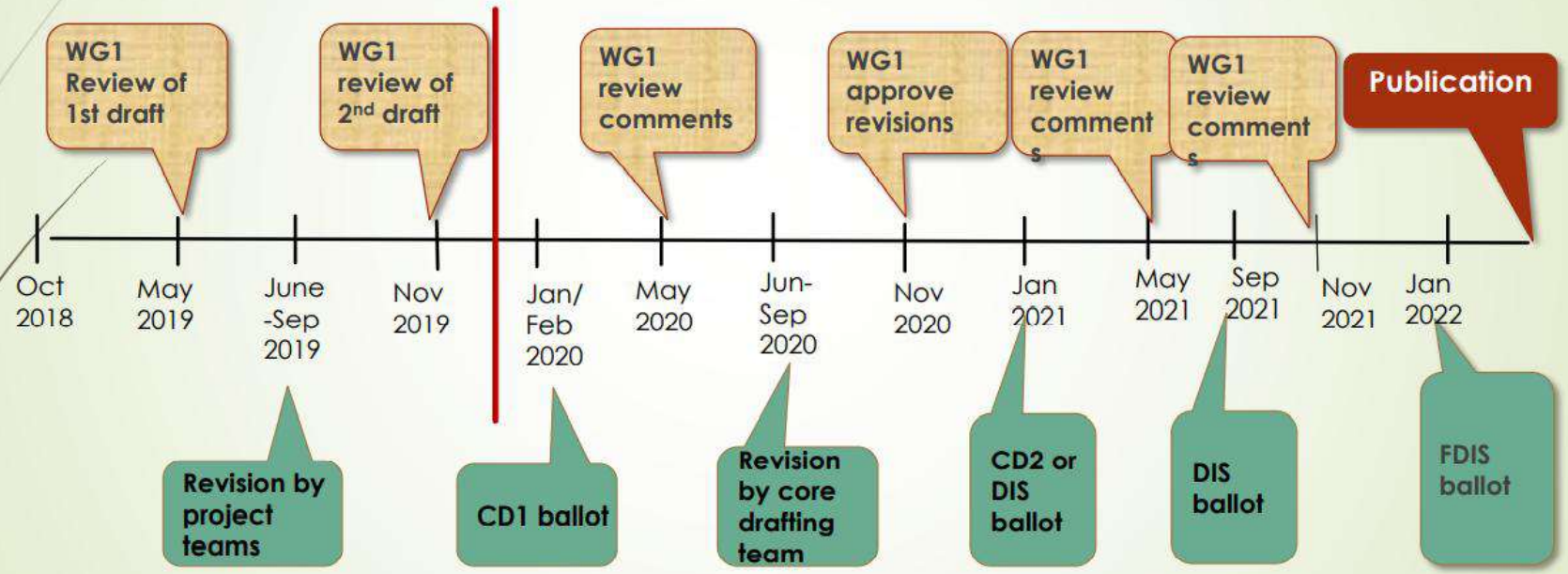
Team leader	Section
Beverley Rowbotham (AU)	General
William Castellani (USA)	Structural
Sabrina Chavez Lemus (MEX)	Resource/Personnel
Adrian Yeo (Singapore)	Resource/Equipment
David Ricketts (UK)	Process/pre-examination & examination
Marc Thelen (Netherlands)	Process/ensuring quality & post examination
Janette Wassung (South Africa)	Management system

ISO15189 supporting documents



- ISO 22870:2016 *Point of care testing (POCT) – Requirements for quality and competence*
- ISO15190:2019 (new) *Medical laboratories – Requirements for safety*
- ISO 22367:2019 (new) *Medical laboratories – Application of risk management to medical laboratories*
- ISO/TS 20658:2017 *Medical laboratories – Requirements for collection, transport, receipt and handling of samples*
- ISO/TS 20914:2019 *Medical laboratories – Practical guidance for the estimation of measurement uncertainty*
- ISO 35001:2019 *Biorisk management for laboratories and other related organisations*
- Documents developed in other WGs may also be relevant to specific laboratories e.g. molecular diagnostics

ISO 15189 Revision timeline



DRAFT INTERNATIONAL STANDARD
ISO/DIS 15189

ISO/TC **212** Secretariat: **ANSI**

Voting begins on:
2021-10-19

Voting terminates on:
2022-01-11

Medical laboratories — Requirements for quality and competence

Laboratoires de biologie médicale — Exigences concernant la qualité et la compétence

ICS: 11.100.01; 03.120.10

The Quality Management System

ISO 15189:2012

Management Clause 4.1-4.15
Technical Clause 5.1- 5.10

General requirements
Structural and governance requirements
Resource requirements
Process requirements
Management System Requirements

Clarity of words!!!

In this document, the following verbal forms are used:

- ‘shall’ indicates a requirement;
- ‘should’ indicates a recommendation;
- ‘may’ indicates a permission
- ‘can’ indicates a possibility or capability

What to expect: Management system options

- The laboratory shall establish, document, implement and maintain a management system that is capable of supporting and demonstrating the consistent achievement of the requirements of the document and assuring the quality of the laboratory results
- Laboratories can choose either Option A or Option B

Management system Option A

As a minimum, the management system of the laboratory shall address the following:

- management system documentation
- control of management system documents
- control of records
- actions to address risks and opportunities
- improvement
- corrective action
- internal audits
- management reviews

Subsequent clauses will list the actions required for each of these items, similar to Section 4 in ISO15189:2012

Management system Option B

- A laboratory that has established and maintains a management system, in accordance with the requirements of ISO 9001, and that is capable of supporting and demonstrating the consistent fulfilment of the requirements of (clauses xx to xx defined in Option A), also fulfils at least the intent of the management system requirements specified in Option A.
- This will usually require certification to ISO9001
- Formalizes a process defined in a joint communiqué by ISO (the International Organization for Standardization), ILAC (the International Laboratory Accreditation Cooperation) and the IAF (the International Accreditation Forum) in September 2009.

What to expect: Customer service

- The most recent edition of ISO 9001:2015 emphasizes the need to focus on the customer and the customer's needs.
- The laboratory's customers include the health professionals ordering tests, patients and sometimes other laboratories sending samples for testing.
- The laboratory will be expected to monitor and measure customer satisfaction

What to expect: Risk management

- ISO 9001:2015 introduces the concept of risk-based thinking
- In ISO15189:2012 section 4.11 requires preventive action, this will be replaced with risk-based thinking.
- The revised document will require the organization to assess the overall risks in the context of its operation and to incorporate actions to minimize risk in planning the quality management system.
- The recently revised ISO22367 *Medical laboratories – Application of risk management to medical laboratories* provides guidance on how to apply risk-based thinking.

What to expect: ISO 22870 and POCT

- ISO15189:2012 requires a laboratory to be responsible for all testing performed in a facility, this includes POCT
- ISO22870 repeats the requirements of ISO15189 by cross referencing the clauses.
- The intent is to incorporate ISO22870 into ISO15189, with a normative annex to cover specific requirements.
- ISO/TS 22583 *Guidance for supervisors and operators of point of care testing (POCT) equipment,* which addresses testing performed without laboratory supervision, published December 2019

What to expect: Other changes

- New section on ethics for the organization and for patients
- Referencing cybersecurity
- When making the document less prescriptive, some of the things that can be reduced are details of how to implement a QMS. It may not be necessary to specify things such as having a quality manual and a quality manager.
- ISO/TS 20658 *Medical laboratories – Requirements for collection, transport, receipt and handling of samples has been approved for revision to* become a standard, much of this information may not need to be repeated in ISO15189
- Can ISO15189 be written in a way that it can be applied to ALL laboratories, e.g. anatomic pathology, molecular diagnostics?

ISO 15189

ISO 15189:2012

- Clause 4: 4.1 – 4.15
- Clause 5: 5.1 - 5.10

1. Scope
2. Normative Reference
3. Terms and Definitions

ISO 15189:2022(DIS)

4.General Requirements(3)

5.Structural and Governance Requirements(6)

6.Resource Requirements(8)

7.Process Requirements(7)

8.Management System Requirements(9)

ISO 15189:2022 (DIS)

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

1. Scope

This document includes requirements for Point of Care Testing (POCT).

2. Normative references

ISO/IEC 17000:2020, *Conformity assessment*

ISO/IEC 17025:2017, *General requirements for the competence of testing and calibration laboratories*

3. Terms and definitions

4. General requirements

1. Impartiality

2. Confidentiality

3. Requirements regarding patients

5. Structural and governance requirements

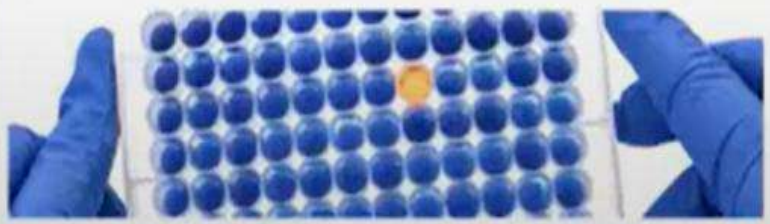
1. Legal entity
2. Laboratory director
3. Laboratory activities
4. Structure and authority
5. Objectives and policies
6. Risk management

6. Resource requirements

1. General
2. Personnel
3. Facilities and environmental conditions
4. Equipment
5. Equipment calibration and metrological traceability

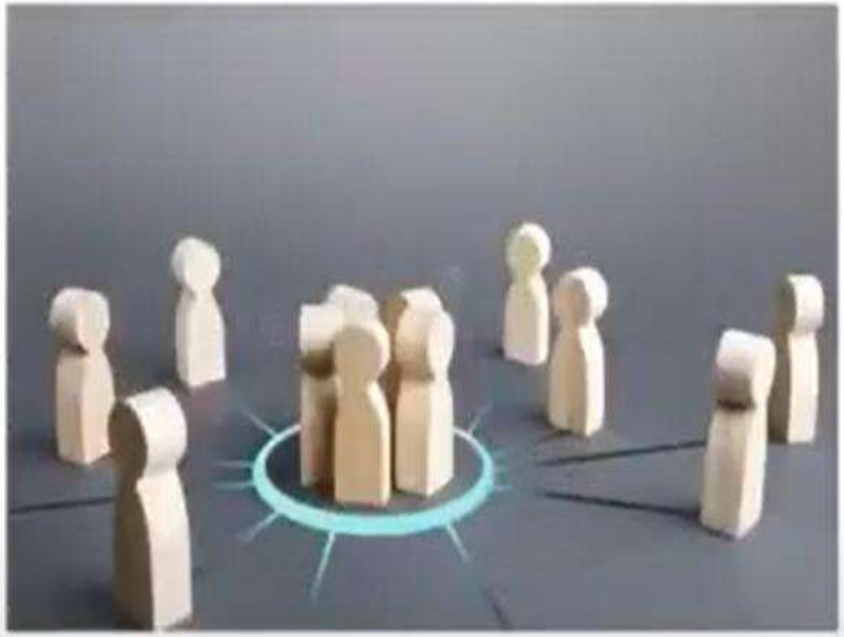
7. Process requirements

1. Pre-examination processes
2. Examination processes
3. Post examination processes
4. Nonconforming work
5. Control of data and information management
6. Complaints
7. Continuity and emergency preparedness planning



8. Management system requirements

1. General requirements and options
2. Management system documentation
3. Control of management system documents
4. Control of records
5. Actions to address risks and opportunities



8. Management system requirements

6. Improvement
7. Corrective Action
8. Evaluations
9. Management reviews

- 5.6 : Risk Management
- 6.2 : Continunal Improvement & Personal development
- 6.5: Metrological Traceability
- 7.1 : Pre-Examination requirements

Table B.1 — Correlation of ISO 15189:2012 to ISO 15189:2022

ISO 15189:2012	ISO 15189:2022
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	4.2.2 Release of information
[includes confidentiality in (e)]	4.2.3 Personnel responsibility
4.1.1.2 Legal entity	5 Structural requirements
4.1.1.4 Laboratory director	5.1 Legal Entity
4.1.2 Management responsibility	5.2 Laboratory director
4.1.2.1 Management commitment	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 Scope of laboratory activities
	5.3.2 Conformance with requirements
	5.4.1 General
	5.4.2 Quality management
4.1.2.2 Needs of users	4.3 Requirements regarding patients
	5.3.3 Advisory activities
4.1.2.3 Quality policy	5.5 Objectives and policies
4.1.2.4 Quality objectives and planning	5.5 Objectives and policies
4.1.2.5 Responsibility, authority, and interrelation-ships	5.4 Structure and authority
4.1.2.6 Communication	5.4.1 General b)
4.1.2.7 Quality manager	5.4.2 Quality management
4.2 Quality management system	8 Management system requirements
4.2.1 General requirements	8.1 General requirements and options
	8.1.1 General
	8.1.2 Fulfilment of management requirements
	8.1.3 Management system awareness

Table B.1 *(continued)*

ISO 15189:2012	ISO 15189:2022
4.2.2 Documentation requirements	8.2 Management system documentation
4.2.2.1General	8.2.1 General
4.2.2.2 Quality manual	See 5.5.3 NOTE
4.3 Document control	8.3 Control of management system documents 8.3.1 Control of documents 8.3.2 Management of documents
4.4 Service agreements 4.4.1 Establishment of service agreements 4.4.2 Review of service agreements	6.7 Service agreements
4.5 Examination by referral laboratories 4.5.1 Selecting and evaluating referral laboratories and consultants 4.5.2 Provision of examination results	6.8.2 Referral laboratories and consultants
4.6 External services and supplies	6.8 Externally provided products and services 6.8.3 Review and approval of externally provided products and services
4.7 Advisory services	5.3.3 Advisory activities
4.8 Resolution of complaints	7.6 Complaints 7.6.1 Process 7.6.2 Receipt of complaint 7.6.3 Resolution of complaint
4.9 Identification and control of nonconformities	7.4 Nonconforming work
4.10 Corrective action	8.7 Corrective action 8.7.1 Actions when nonconformity occurs 8.7.2 Actions appropriate to effects 8.7.3 Records of nonconformities 8.7.4 Reviews of records of nonconformities
4.11 Preventive action	8.5 Actions to address risks and opportunities 8.5.1 Identification of risks and opportunities 8.5.2 Acting on risks
4.12 Continual improvement	8.6 Improvement 8.6.1 Continual improvement 8.6.2 Laboratory patients, user and personnel feed-back
4.13 Control of records	8.4 Control of records 8.4.1 Creation of records 8.4.2 Amendment of records 8.4.3 Retention of records
4.14 Evaluation and audits 4.14.1 General	8.8 Evaluations 8.8.1 General

Table B.1 *(continued)*

ISO 15189:2012	ISO 15189:2022
4.14.2 Periodic review of requests, and suitability of procedures, and sample requirements	7.1.3 Primary sample collection and handling 7.1.3.1 General 7.2 Examination processes 7.2.1 General e)
4.14.3 Assessment of user feedback 4.14.4 Staff suggestions	8.6.2 Laboratory user and personnel feedback
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 8.5.1 Identifications of risks and actions taken 8.5.2 Acting on risks
4.14.7 Quality indicators	8.8.2 Quality indicators See also 5.5.5
4.14.8 Reviews by external organizations	
4.15 Management review	8.9 Management review
4.15.1 General	8.9.1 General
4.15.2 Review input	8.9.2 Review input
4.15.3 Review activities	
4.15.4 Review output	8.9.3 Review output
5 Technical requirements	6 Resource requirements
5.1 Personnel 5.1.1 General 5.1.2 Personnel qualifications 5.1.3 Job descriptions 5.1.4 Personnel introduction to the organizational environment 5.1.5 Training 5.1.6 Competence assessment 5.1.7 Review of staff performance 5.1.8 Continuing education and professional development 5.1.9 Personnel records	6.2 Personnel 6.2.1 General 6.2.2 Qualification, duties and responsibilities 6.2.4 Continuing education and professional development 6.2.5 Authorization
5.2 Accommodation and environmental conditions 5.2.1 General 5.2.2 Laboratory and office facilities 5.2.3 Storage facilities 5.2.4 Staff facilities 5.2.5 Patient sample collection facilities 5.2.6 Facility maintenance and environmental conditions	6.3 Facilities and environmental conditions 6.3.1 General 6.3.2 Facility controls 6.3.3 Storage facilities 6.3.4 Personnel facilities 6.3.5 Specimen collection facilities

Table B.1 *(continued)*

ISO 15189:2012	ISO 15189:2022
5.3 Laboratory equipment, reagents, and consumables	
5.3.1 Equipment	6.4 Equipment
5.3.1.1 General	6.4.1 General
5.3.1.2 Equipment acceptance testing	6.4.2 Equipment requirements
5.3.1.3 Equipment instructions for use	6.4.3 Equipment acceptance
5.3.1.4 Equipment calibration and metrological traceability	6.4.4 Equipment instructions for use
5.3.1.5 Equipment maintenance and repair	6.4.5 Equipment maintenance and repair
5.3.1.6 Equipment adverse incident reporting	6.4.6 Equipment adverse incident reporting
5.3.1.7 Equipment records	6.4.7 Equipment records
	6.5 Equipment calibration and metrological traceability
	6.5.1 Metrological traceability of equipment and method
	6.5.2 Metrological traceability of measurement results
5.3.2 Reagents and consumables	6.6 Reagents and consumables
5.3.2.1 General	6.6.1 Reagents and consumables – General
5.3.2.2 Reagents and consumables – reception and storage	6.6.2 Reagents and consumables – Receipt and storage
5.3.2.3 Reagents and consumables – acceptance testing	6.6.3 Reagents and consumables – Acceptance testing
5.3.2.4 Reagents and consumables – inventory management	6.6.4 Reagents and consumables – Inventory management
5.3.2.5 Reagents and consumables – instructions for use	6.6.5 Reagents and consumables – Instructions for use
5.3.2.6 Reagents and consumables – adverse incident reporting	6.6.6 Reagents and consumables – Adverse incident reporting
5.3.2.7 Reagents and consumables – records	6.6.7 Reagents and consumables – Records

Acknowledgements

- Professor White, Graham Professor
- AACB
- ISO
- AACC
- ASQ

HORIBA
Medical

Thank you!

Questions or comments?