



Envisioning change to ISO 15189

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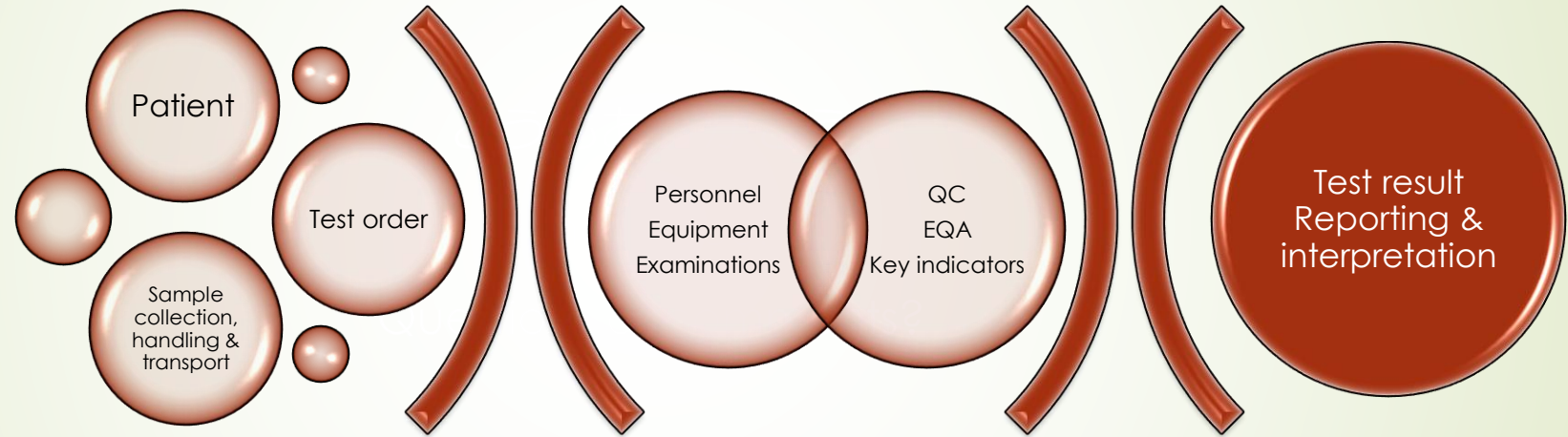
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Objectives

- Understand the link between quality and standards
- Review the history of ISO15189
- 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 laboratories

QUALITY MANAGEMENT IN THE LABORATORY



Pre-analytical

Analytical

Post analytical

Policies, processes, procedures, documented information

CONTINUAL IMPROVEMENT



ISO 15189:2012
Medical
laboratories –
Requirements
for quality
and
competence

“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”

ISO 15189:2012 Introduction



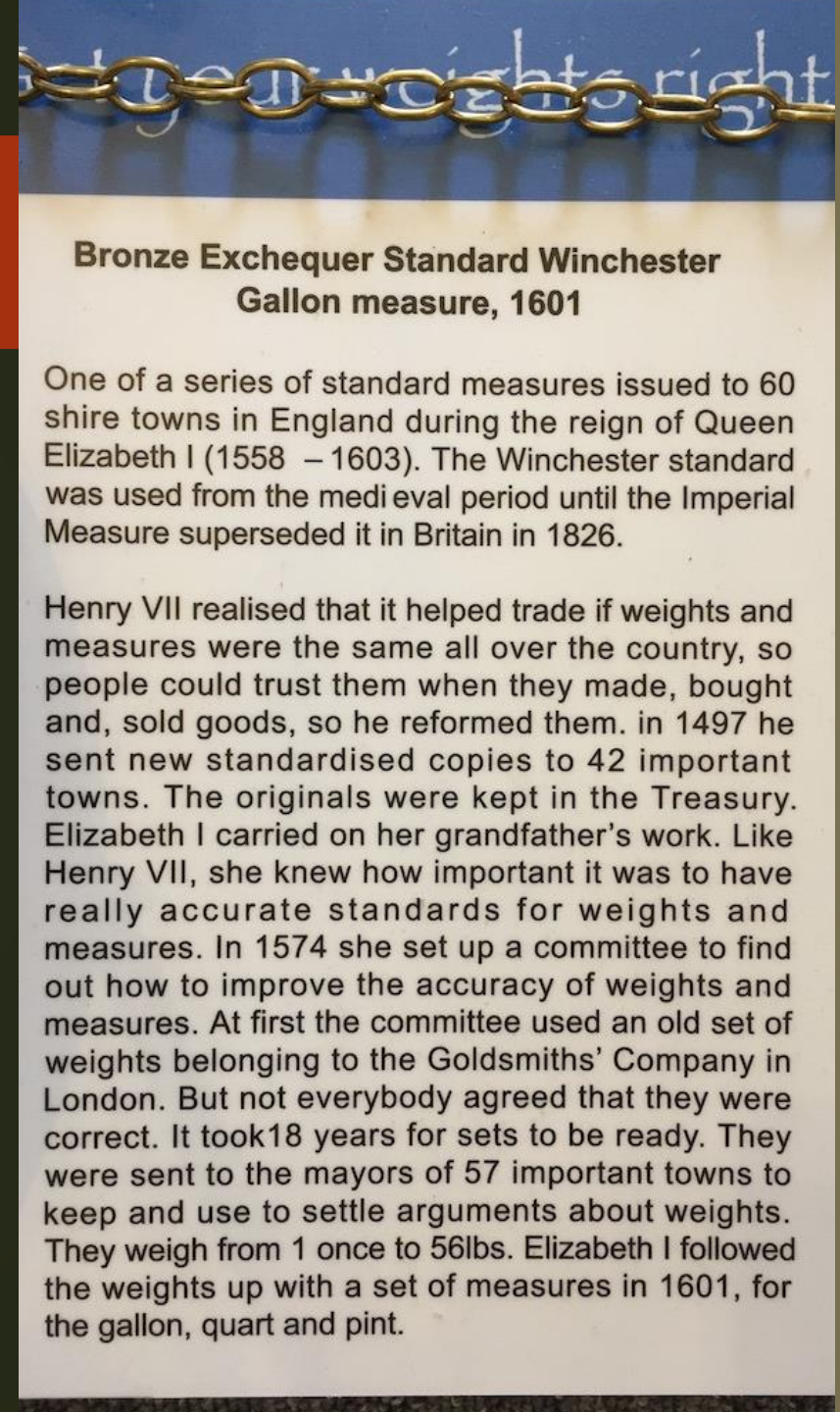
Why standards?

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

Standards are not new!

- ▶ When visiting England this year I took this photograph of the story telling how a standard for measuring a volume of liquid was first introduced in the year 1601



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 The Winchester standard was used from the medieval period until the Imperial Measure superseded it in Britain in 1826.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 took 18 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 ounce to 56 lbs. Elizabeth I followed the weights up with a set of measures in 1601, for the gallon, quart and pint.

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



ISO Principles

- ▶ ISO standards respond to a need in the market
 - ▶ New work items proposed by any member country are approved by vote
- ▶ ISO standards are based on global expert opinion
 - ▶ Subject matter experts from all interested countries work on a document
- ▶ ISO standards are developed through a multi-stakeholder process
 - ▶ Experts come from industry, users, academia, NGOs and government
- ▶ ISO standards are based on a consensus
 - ▶ Developing ISO standards is a consensus-based approach and comments from stakeholders are taken into account.



Why is global relevance important ?

Without international standards, there would be far less international trade, far less global prosperity, far fewer markets for exporters and far less variety for consumers.

Alan Wolff, Deputy Director-General of the World Trade Organization (WTO), speaking at the ISO General Assembly in Geneva 2018



**“Standards have
become the common
language of the world”**

*ISO President Xi Jinping of China
Annual Report 2016*

**“Without standards there
can be no improvement”**

Taiichi Ohno



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

Survey questions



Who are you?



Where do you work?



Is your laboratory accredited?



Which other ISO documents do you use?



Have you experienced difficulty interpreting the management requirements in ISO 15189, if yes, specify which clauses?



Have you experienced difficulty interpreting the technical requirements in ISO 15189, if yes, specify which clauses?



Any other comments?



ISO 15189:2012 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



Team members

- ▶ Names were submitted with Resolution ballot
- ▶ Attempted to balance representation from countries on all teams
- ▶ Total number of team members: 63
- ▶ Number of countries represented: 26



Mandate



- ▶ Step one – align ISO15189:2012 text with ISO17025:2017
- ▶ Identify gaps
- ▶ Ensure CASCO mandatory clauses are included
- ▶ Work towards being less prescriptive
- ▶ Reference other documents, do not repeat
- ▶ Consider survey feedback and comments received during systematic review and resolution



ISO 15189 supporting documents

- ISO 22870:2016 *Point of care testing (POCT) – Requirements for quality and competence*
- ISO 15190:2019 (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

May 2019

- ▶ Work done by all 7 teams was combined into a single document, for initial review
- ▶ Conclusion: ISO17025 can be used as a starting template
- ▶ Teams consolidated for next step:

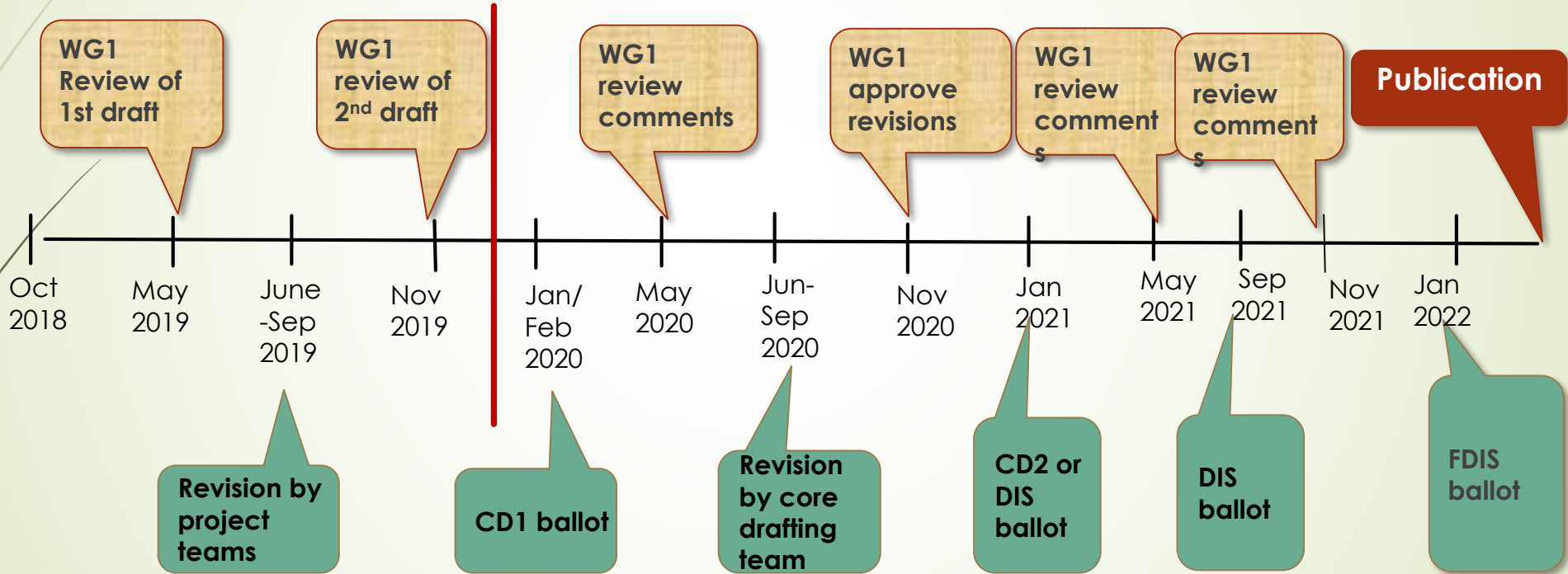
Team	Section(s)	Leaders
A	General, structural & management	Beverley Rowbotham, William Castellani & Janette Wassung
B	Resource: personnel & equipment	Sabrina Chavez Lemus & Adrian Yeo
C	Process: pre-examination & examination, ensuring quality & post examination	David Ricketts & Marc Thelen



November 2019

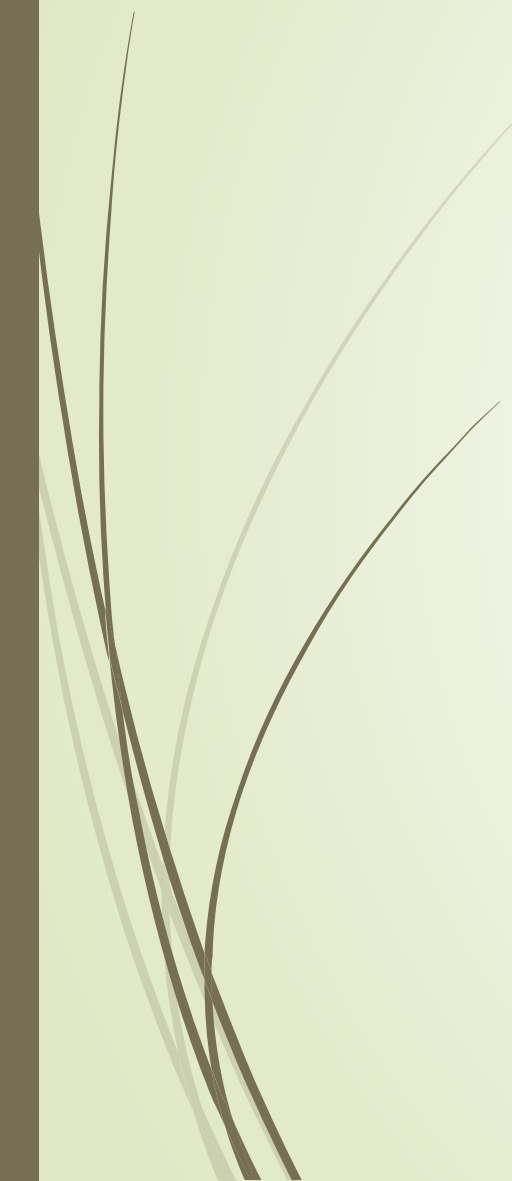
- ▶ Second compilation document shared with WG1 members and comments invited.
- ▶ Comments addressed at WG meeting
- ▶ Document revision to be completed January 2020 by core drafting team comprised of all team leaders
- ▶ All team members to review and comment
- ▶ CD ballot posted February 2020, closing early April
- ▶ All TC members invited to comment

ISO 15189 Revision timeline





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?



The future of ISO for medical laboratories

- ▶ Continually improving
 - ▶ Decreased time from idea to publication
 - ▶ More inclusive
 - ▶ Timely review and revision
- ▶ Need to consider emerging technologies
- ▶ More countries contributing
- ▶ Liaisons with other TCs
- ▶ Increased adoption and use of ISO documents



Thank you!

Questions or
comments?