ISO TC212 – ENABLING STANDARDIZATION, QUALITY AND CUSTOMER SATISFACTION

Sheila Woodcock, ART, MBA, FCSMLS(D)

QSE Consulting Inc

Convenor ISO TC212 WG1

JMAC Symposium 2017/1/13

OBJECTIVES

- To introduce ISO TC212 and specifically consider documents published by ISO TC212 WG1
- To present a 5 year plan for WG1
- To understand the role of standards in facilitating international trade
- To consider how all laboratories can utilize international standards to ensure the quality of the product of their work and the satisfaction of their customers

ISO TC212

Clinical laboratory testing and in vitro diagnostic test systems

BACKGROUND

- Established in 1993, one of 238 Technical Committees
- 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.
- Five Working Groups:
  - WG1 Quality and competence in the medical laboratory
  - WG2 Reference systems
  - WG3 In vitro diagnostic products
  - WG4 Microbiology and molecular diagnostics
  - WG5 Biorisk management
- 39 Participating member countries and 20 Observer members

ISO TC212 WG1

QUALITY AND COMPETENCE IN THE MEDICAL LABORATORY

Has a portfolio of 5 active documents

- ISO15189 Medical laboratories – Requirements for quality and competence
- ISO15190 Medical laboratories – Requirements for safety
- ISO TS 22367 Medical laboratories – Reduction of error through risk management and continual improvement
- ISO 22870 POCT –Requirements for quality and competence
- ISO DTS 20658 Medical laboratories – Requirements for collection, transport and handling of samples

ISO15189 *MEDICAL LABORATORIES – REQUIREMENTS FOR QUALITY AND COMPETENCE*

- First published in 2003, minor revision 2007
- Revised version 2012
- Scope: This IS specifies requirements for quality and competence in medical laboratories.

This IS can be used by medical laboratories in developing their quality management systems and assessing their own competence. It can also be used for confirming or recognizing the competence of medical laboratories by laboratory customers, regulating authorities and accreditation bodies.

- Globally adopted as the preeminent quality management standard for medical laboratories
- Widely used by accreditation bodies
- Can be applied to all types of laboratories

ISO15190 *MEDICAL LABORATORIES – REQUIREMENTS FOR SAFETY*

- Currently under revision
- Scope: This international standard specifies requirements for safe practices in the medical laboratory
- First published in 2003, underwent systematic review 2009 and 2015
- Normative reference ISO15189:2003
- Originally expected to be used together with ISO15189
- Supports statutory and regulatory requirements for occupational health and safety

ISO 22870 *POINT-OF-CARE TESTING (POCT) – REQUIREMENTS FOR QUALITY AND COMPETENCE*

- First published in 2006
- Scope:

This document gives specific requirements applicable to point-of-care testing and is intended to be used in conjunction with ISO15189. 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 the home or in a community setting is excluded, but elements of this document can be applicable.

- Revised to update cross references to ISO 15189:2012 and new edition published in 2016

ISO TS 22367 *MEDICAL LABORATORIES – REDUCTION OF ERROR THROUGH RISK MANAGEMENT AND CONTINUAL IMPROVEMENT*

- First published in 2008
- Currently being revised to become an international standard
- New title: ISO22367 *Medical laboratories – Application of risk management to medical laboratory examinations*
- Aligned with ISO14971 *Medical devices – Application of risk management to medical devices*, the standard used by manufacturers

ISO 22367 *MEDICAL LABORATORIES – APPLICATION OF RISK MANAGEMENT TO MEDICAL LABORATORY EXAMINATIONS*

- New draft scope:

This document specifies a process for a medical laboratory to identify and manage the risks to patients, laboratory workers and service providers associated with medical laboratory examinations, including identification, estimation, evaluation, controlling and monitoring the risks.

The requirements of this document are applicable to all aspects of the examinations and services of a medical laboratory, including the pre-examination and post-examination aspects.

This document does not specify acceptable levels of risk

This document does not apply to risks from clinical decision making made post-examination.

This document does not apply to the management of risks affecting the medical laboratory enterprise that are addressed by ISO31000, such as business, economic, legal and regulatory risks.

ISO DTS 20658 *MEDICAL LABORATORIES – REQUIREMENTS FOR COLLECTION, TRANSPORT, RECEIPT AND HANDLING OF SAMPLES*

- New document, developed based on a Canadian standard document
- The draft document has received and addressed numerous comments and is expected to be published in 2017.
- Scope:

This document specifies requirements for the collection, transport, receipt and handling of samples intended for medical laboratory examinations.

This document is applicable to medical laboratories and other medical services involved in pre-examination processes, such as the examination request, patient preparation and identification, sample collection, transport, receipt and storage.

PWI: GUIDANCE FOR POCT SUPERVISORS AND OPERATORS

- New preliminary work item from Australia for a Technical Specification document intended for use in locations performing POCT and lacking the support of medical laboratory professionals
- Examples of these locations are: pharmacies, long–term care facilities, outreach clinics in remote and rural settings, law enforcement, workplace health & safety, sporting facilities, the military and public areas such as shopping centres.
- Expected to be approved as a new work item in 2017

PWI: MEDICAL LABORATORIES – GUIDANCE ON APPLICATION OF TECHNICAL REQUIREMENTS IN ISO15189:2012 TO EMERGING MEASUREMENT TECHNOLOGIES

- New preliminary work item from Japan for a Technical Specification document for laboratories using molecular testing related technologies, such as clinical sequencing (NGS), microarray, etc.
- Intent is to harmonize various country specific documents into a single international document to enable emerging technologies to achieve accreditation to ISO15189:2012
- Project team identified to develop a New Work Item Proposal (NWIP)

OTHER PWIs

- Other topics introduced at the Kobe meeting are:
  - Documents of specific interest to anatomic pathologists
  - Electronic health records that take into account the specific needs of medical laboratories
  - Andrology, a document providing guidance for performance of semen analysis
  - External quality assurance and quality assessment in the medical laboratory.
- Delegates have been asked to develop topics into proposals for consideration

OTHER RELEVANT ISO DOCUMENTS

- ISO TC 212 WG2 together with WG1 is developing a Technical Specification document: Medical laboratories – Practical guide for measurement uncertainty.
- ISO TC 212 WG5 is developing ISO 35001 Biorisk management for laboratories and other related organizations, which needs to harmonize with ISO15190
- ISO TC 212 WG4 is developing a series of pre-examination documents specific to molecular diagnostics
- ISO TC276 WG2 Biobanks and bioresources is developing a comprehensive quality management standard for biobanks , which may have implications for some medical laboratories

ISO PROCESSES

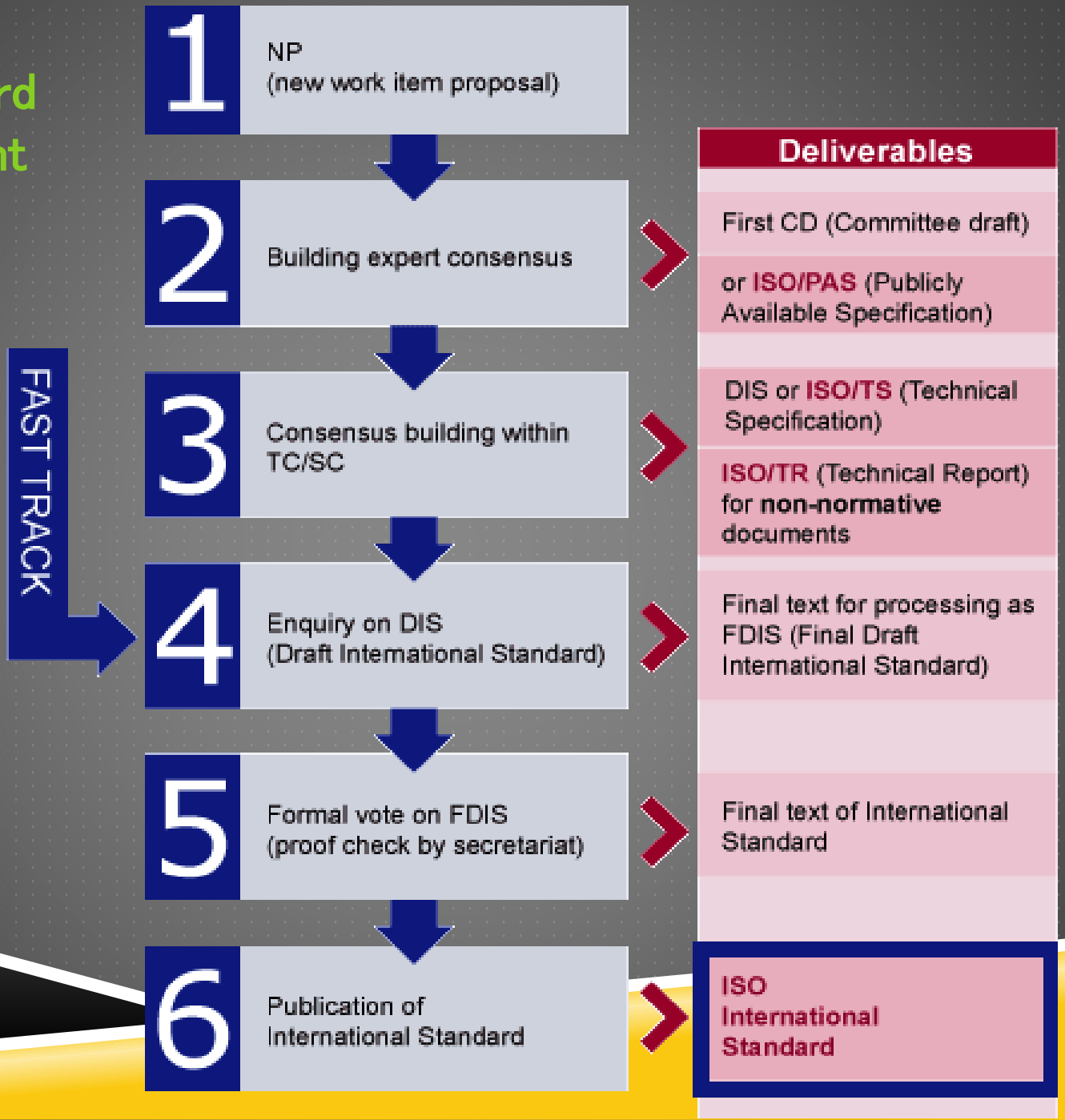
TYPES OF ISO DOCUMENTS

- Management system standard (e.g ISO9001, ISO17025, ISO15189)
- International Standard
- Technical Specification, which is expected to become a standard after 3 years
- Technical Report

ISO TERMINOLOGY

- PWI – preliminary work item
  - The starting point when a new item is suggested, may or may not be registered with ISO
- NWIP – New work item proposal
  - Official launch of a new document, requires ballot/vote
- WD – working draft
  - May be an internal WG document or part of the NWIP proposal
- CD – Committee draft
  - Document shared with all members of the TC for ballot, vote and comments
- DIS – Draft international standard
  - All countries and WGs receive document for comment and vote
- FDIS – final draft international standard
  - Not required if no technical comments received at DIS stage

ISO standard development process



ISO STANDARD DEVELOPMENT PROCESS

Product	Action	Timeline
PWI	Vote not mandatory	Not limited
NWIP	2 month ballot	Clock starts after ballot for 24 or 36 months
CD	2 month ballot	12 to 24 months after NWIP ballot
Possible CD2	After resolving many comments	
DIS	Member countries vote	24 months after NWIP ballot
FDIS	Only required if consensus not reached at CD stage	
Publication	After ISO editorial check	36 to 48 months after PWI

SYSTEMATIC REVIEW

- Required every 5 years to ensure ongoing relevance of documents
- All member countries asked to review document
- 5 month review period
- Vote options
  - Confirm
  - Require amendment or revision
  - Withdrawal

HOW ISO WORKS

- Each country chooses to be a member of ISO
- National standards body is the member and approves delegates to TCs
- Each TC has a business plan and documents are developed by subject matter experts in Working Groups (WG) or Subcommittees (SC)
- New documents are distributed to member countries for review, comments and voting to approve at draft and final stages
- Final documents are based on consensus decision, after all comments are considered
- Each country decides whether or not to adopt a new standard for use as a national standard


International Organization for Standardization ISO
International Standards for Business, Government and Society
Member countries
Technical Management Board (TMB)
Advisory/Mirror Committees
National delegates
SMEs
Technical Committees and Working Groups
Plenary meetings
1 x year
WG meetings
2 x year

5 year plan

ISO TC212 WG1

Year	Publish	Revise	New
2017	ISO TS20658 Medical Laboratories – Requirements for collection, transport, receipt and handling of samples	ISO15190 ISO22367	1. Guidance for POCT Supervisors and operators 2. Practical guide for the estimation of measurement uncertainty 3. Guidance on application of technical requirements in ISO15189:2012 to emerging technologies
2018	ISO22367 ISO15190 Practical guide for the estimation of measurement uncertainty	ISO15189	1. Guidance for POCT Supervisors and operators 2. Guidance on application of technical requirements in ISO15189:2012 to emerging technologies 3. Other PWIs
2019	Guidance for POCT Supervisors and operators ISO35001	ISO15189	1.Guidance on application of technical requirements in ISO15189:2012 to emerging technologies 2. Other PWIs
2020	Guidance on application of technical requirements in ISO15189:2012 to emerging technologies	ISO15189	
2021	ISO15189	ISO22870	

WHY ISO?

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 DO WE NEED STANDARDS?

- Safety for workers and for customers
- To ensure quality of product or service
- For consistency and reliability
- For compatibility between locations performing the same activities
- To facilitate communication and collaboration

BENEFITS OF STANDARDS – FOR BUSINESS –

- Cost savings – help optimize operations and improve bottom line
- Enhanced customer satisfaction – help improve quality, customer satisfaction and increase sales
- Increased market share – help increase productivity and competitive advantage
- Support innovation
- Environmental benefits – help reduce negative impacts on the environment

Country A

My products or services meet Standard X. I want to sell them to country B

That's nice, but we only accept products or services that meet Standard Y

Country B

- Surprise costs
- Loss of economies of scale
- Information costs
- Conformity assessment costs

BENEFITS OF STANDARDS – FOR GOVERNMENT –

- Greater effect on economic growth than patents or licenses
- Can make ISO standards a regulatory requirement
- Remove trade barriers and ensure requirements for imports and exports are the same the world over
- Can be used as the basis for trade agreements
- Because ISO standards are developed by experts, governments can benefit from the opinion of experts without having to call on services directly

IMPROVING QUALITY IN THE LABORATORY

WHAT IS QUALITY?

- Quality is meeting the requirements
- Quality is doing it right, the first time
- The performance standard is zero defects
- The measure of quality is the cost of non-compliance (cost of poor quality)

Philip Crosby

Quality management is the structure of elements that allows an operation to achieve quality.

WHY DO ERRORS OCCUR?

Research has shown
that 95% of
incidents/errors
relate to process and only
5% to personnel

HOW CAN RISK BE MANAGED ?

Systematic application of

- Policies
- Processes
- Procedures

to the tasks of analyzing, evaluating, controlling, and monitoring risks in the provision and use of services.

QUALITY MANAGEMENT SYSTEM

QMS MANAGEMENT REQUIREMENTS

- Organization and management responsibility
- Quality management system
- Document control
- Service agreements
- Examination by referral laboratories
- External services and supplies
- Advisory services
- Risk management
- Continual improvement
- Control of records
- Evaluation and audits
- Management review

QMS TECHNICAL REQUIREMENTS

- Personnel
- Accommodation and environmental conditions
- Equipment, reagents and consumables
- Pre-examination processes
- Examination processes
- Ensuring quality of examination results
- Post-examination processes
- Reporting and release of results
- Laboratory information management

RISK MANAGEMENT

- External Audits and EQA
- Internal Audits
- Corrective Actions
- Opportunities for Improvement
- Preventive Actions

PERSONNEL

- System to support doing it right the first time
- Blame free culture, focus on process
- Job descriptions, orientation, training, competence assessment and performance reviews
- Understanding of and commitment to the QMS

HOW STANDARDS IMPACT OPERATIONS, CUSTOMERS, SAFETY AND STAFF

PROCESS

- Consists of multiple steps or actions
- Defines a function e.g. specimen handling
- Best depicted as a flow chart
- Describes how policy is carried out
- Process mapping can lead to improved efficiency
- Gap analysis determines the need for procedures

PROCESS COST APPROACH

1. *Cost of conformance*: the costs incurred to fulfill all the stated and implied needs of customers in the absence of failure
2. *Cost of nonconformance*: the costs incurred due to failure of the existing process

Need to track both

COST OF CONFORMANCE

- All costs of assuring quality, such as costs of prevention + all other operational costs including labour, materials, energy etc.
- Costs can be reduced by analyzing the various steps in a process
  - May see an opportunity to modify the process or even reengineer the process
  - Remove non value-added activities
- Need to look at material costs, labour costs, overhead costs e.g Introducing an inventory control system can reduce overhead costs

COST OF NONCONFORMANCE

- Cost due to failure of the existing process
  - Material cost
  - Labour cost
  - Repeat test cost in some cases
- Impact on workflow
- Customer dissatisfaction, loss of business

WHY LABS SHOULD USE STANDARDS

- Use of international standards ensures harmonization with other countries
- Can be used for product or service endorsement and provide competitive edge
- Accreditation demonstrates quality and competence
- Maximizes business productivity and cost effectiveness

SUMMARY

We have

- Reviewed the current work of ISO TC212 WG1 and looked ahead with a 5 year plan
- Outlined ISO processes and procedures
- Considered the broader benefits of ISO standards for business and governments
- Explored the link between standards and quality

どうもありがとう

Thank you!

Questions or comments?