What's new in ISO 15189: 2012?

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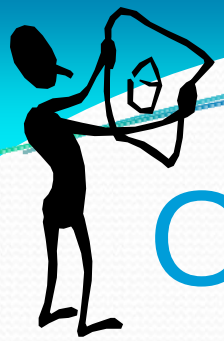
APHL Webinar
11 September 2013



Objectives

- ✓Review the history and development of ISO 15189
- ✓Introduce and review the major clauses and sub-clauses
- ✓Highlight differences between the 2nd edition (2007) and 3rd edition (2012)
- ✓Compare structure with ISO 9000 series
- ✓Discuss use of 15189 by laboratory management and accreditation bodies

International Organization for Standardization (ISO)

- A worldwide federation of national standards bodies from more than 145 countries, one from each country.
- Established in 1947 and based in Geneva.
- Its mission is to promote the development of standardization and related activities in the world with a view to facilitating the international exchange of goods and services, and to developing cooperation in the spheres of intellectual, scientific, technological and economic activity.
- Work is done by Technical Committees (TCs)
- American National Standards Institute (ANSI) is the sole U.S. representative of ISO.

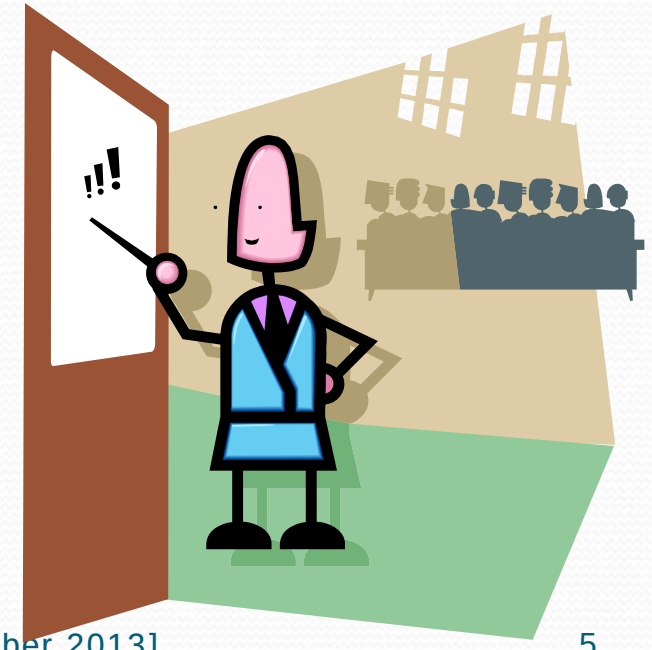
A Brief History of ISO and Medical Laboratories

- ISO (at the request of the United States) invited the international medical laboratory community to a meeting in Philadelphia in May/June 1995 to discuss the possibility of a single harmonizing standard for medical laboratories
- Attended by: Laboratorians
- Accreditation bodies
- Medical device manufacturers
- Metrologists
- Calibration authorities
- Medical laboratory consultants
- Organizational representatives
  - CAP, WHO, WASP, OECD,EDMA, IBWM,ELM,IFCC, ILAC, AACC

ISO Technical Committee (TC) 212: Clinical laboratory testing and in vitro diagnostic test systems

- Scope: Standardization and guidance in the field of laboratory medicine and in vitro diagnostic test systems. This includes quality management, pre- and post-analytical procedures, analytical performance, laboratory safety, reference systems, and quality assurance.
- Initiated in June 1995
- 25 = Total number of published ISO standards
- 34 = Participating countries
- 22 = Observing countries

[as of August 2013]



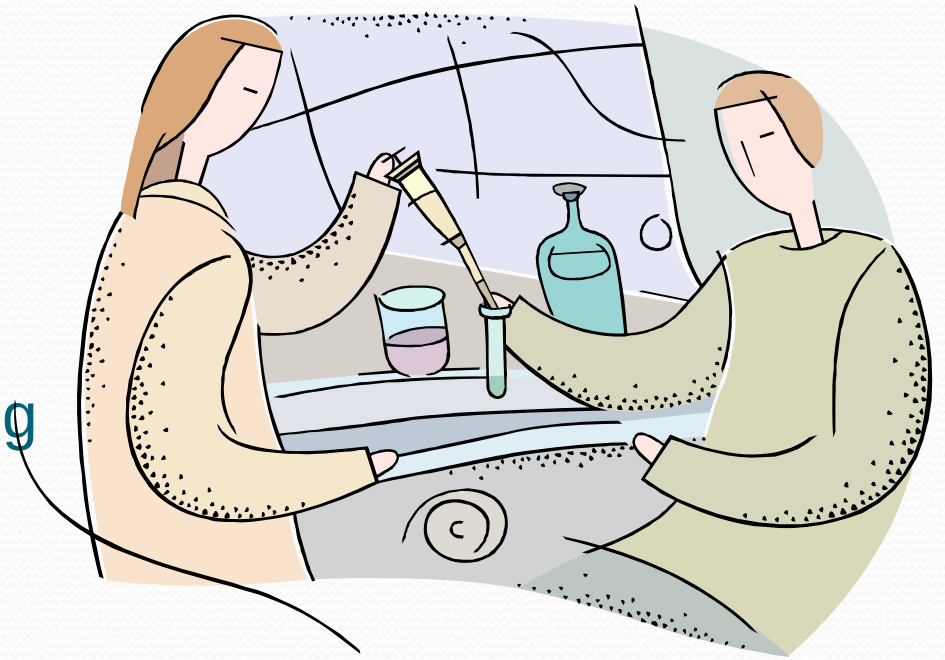
ISO Technical Committee 212 Working Groups

- **Working Group 1 - Quality and competence in the medical laboratory**
  Quality Management in the Clinical Laboratory; Pre- and post-analytical procedures for the clinical laboratory; Clinical laboratory safety; Quality assurance, including external quality assessment and internal; Ethics in laboratory medicine; quality control, and accreditation for clinical laboratory medicine
- **Working Group 2 - Reference systems**
  Contents and description of reference measurement procedures; Contents and description of reference materials; Requirements for laboratories performing reference procedures; reference procedures utilizing nominal and ordinal scales
- **Working Group 3 - In vitro diagnostic products**
  Identification and determination of analytical and clinical performance; Determination of desirable performance criteria for blood glucose monitors; Recommendations for validation of user quality control; Symbols used in labeling of in vitro diagnostic products
- **Working Group 4 - Antimicrobial susceptibility testing**

Standards Developed by ISO TC 212

25 standards in the areas of

- Laboratory Quality Management
- Safety
- Risk
- Point of Care
- Calibrators
- Validation
- Susceptibility Testing
- Traceability
- Labelling
- Quality Control

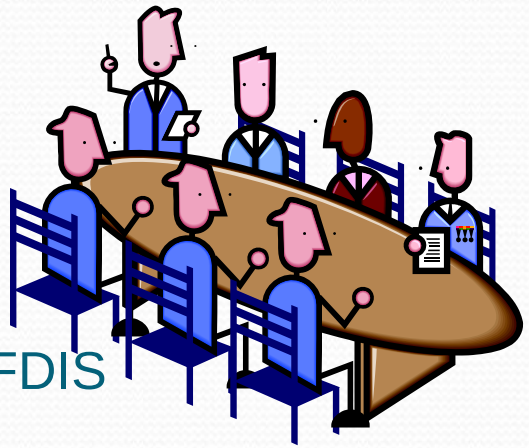


US Participation in ISO Technical Committee 212

- US Technical Advisory Group (TAG) participates in ISO TC 212 activities
- As of June 2012, 107 members form the US TAG as either Voting Members or Observers.
- CLSI serves as TAG administrator
- CLSI also serves as Secretariat for the four TC 212 Working Groups
- US TAG members participate in all four working groups
- Representatives from all laboratory disciplines, several organizations, IVD manufacturers, laboratorians, etc.

History of ISO 15189

- 1994-1995 NCCLS (now CLSI) Conference to establish an international standard for medical laboratory quality – Establishment of TC 212 and WG1
- 1996-1969 Gather & review standards (CAP, NYS, ISO Guide 25, etc)
- 1998 Document takes shape; considerable debate within WG1 regarding alignment with ISO Guide 25 (later 17025) or with ISO 9000
- 2003 Publish 15189:2003
- 2004 Begin Revision
- 2007 Publish 15189:2007 (2nd Edition)
- 2007-2011 Continue revisions and distribution to all members for comments
- 2011 November: final review and preparation of FDIS
- 2012 Voting and publication 15189 (3rd Edition)



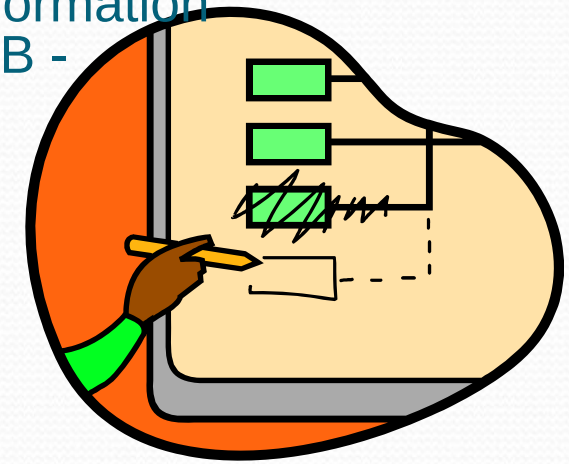
What stays the same?

Overall structure identical in 15189:2012, 15189:2007, and ISO/IEC 17025:2005

- 1 Scope
- 2 Normative references
- 3 Terms and definitions
- 4 Management requirements
- 5 Technical requirements

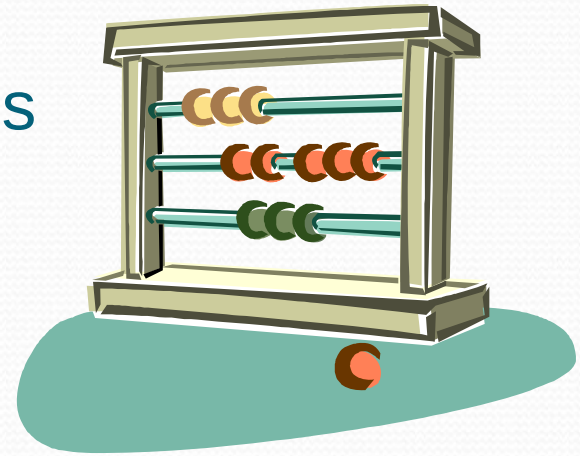
What's changed?

- Several new clauses/subclauses
- A more logical ordering of subclauses under each clause; reflects the flow of activities in a laboratory setting
- Improved layout and listing of subclauses to make it easier to identify specific subclauses within the document
- Two new normative sections (5.9 and 5.10)
- Clause 5.8 of ISO 15189:2007 has been split into the requirements for reporting (5.8) and release of results (5.9)
- 5.10 is a new section in relation to Laboratory Information Management which has been taken from Annex B - this was previously informative
- Amended sections – almost all
- Editorial changes – some significant
- Deletions – few
- Additional details provided without changing the intent of the requirements.



Level of detail increased

- ISO 15189 Section 4 Management requirements:
  - 2nd edition = 3,700 words
  - 3rd edition = 5,200 words
- ISO 15189 Section 5 Technical requirements:
  - 2nd edition = 5,600 words
  - 3rd edition = 7,900 words
- CLIA Subpart K
  - Quality Systems = 9,700 words
- CLIA Subpart M
  - Personnel = 15,100 words



Approx word counts

What's changed?

The Title!

- The name of the standard has been changed to: ***Medical laboratories - Requirements for quality and competence***
- The former title was: *Medical laboratories - Particular requirements for quality and competence*

Foreword

- ISO 15189:2012 now includes a foreword describing the ISO process

New terms and definitions (section 3)

- 3.2 *alert interval/critical interval*
- 3.3 *automated selection and reporting of results*
- 3.5 *competence*
- 3.6 *documented procedure*
- 3.8 *interlaboratory comparison*
- 3.12 *nonconformity*
- 3.13 *point-of-care testing / POCT / near patient testing*
- 3.17 *process*
- 3.18 *quality*
- 3.19 *quality indicator*
- 3.21 *quality policy*
- 3.22 *quality objective*
- 3.25 *turnaround time*
- 3.26 *validation*
- 3.27 *verification*

Deleted terms and definitions (section 3)

- 3.2 *accuracy of measurement*
- 3.5 *laboratory capability*
- 3.8 *measurement*
- 3.13 *quantity*
- 3.17 *traceability*
- 3.18 *trueness of measurement*
- 3.19 *uncertainty of measurement*

Some occur in: ISO/IEC 17000, *Conformity assessment —Vocabulary and general principles*
ISO/IEC Guide 2, *Standardization and related activities — General vocabulary*
ISO/IEC Guide 99, *International vocabulary of metrology — Basic and general concepts and associated terms (VIM)*

4 Management requirements

ISO 15189:2007		ISO 15189:2012	
4.1	Organization and management	4.1	Organization and management responsibility
		4.1.1	Organization
		4.1.2	Management responsibility
4.2	Quality management system	4.2	Quality management system
		4.2.1	General requirements
		4.2.2	Documentation requirements
4.4	Review of contracts	4.4	Service agreements
		4.4.1	Establishment of service agreements
		4.4.2	Review of service agreements

4.2: Quality management system

- The quality management system shall provide for the integration of all processes required to fulfill its quality policy and objectives and meet the needs and requirements of the users. The laboratory shall:
  - determine the processes;
  - determine the sequence and interaction of these processes;
  - determine criteria and methods needed to ensure that both the operation and monitoring of these processes are effective.

4 Management requirements

ISO 15189:2007		ISO 15189:2012	
4.5	Examination by referral laboratories	4.5	Examination by referral laboratories
		4.5.1	Selecting and evaluating referral laboratories and consultants
		4.5.2	Provision of examination results
4.13	Quality and technical records	4.13	Control of records

4 Management requirements

ISO 15189: 2007		ISO 15189:2012	
4.14	Internal audits	4.14	Evaluation and audits
		4.14.1	General
		4.14.2	Periodic review of requests, and suitability of procedures, and sample requirements
		4.14.3	Assessment of user feedback
		4.14.4	Staff suggestions
		4.14.5	Internal audit
		4.14.6	Risk management
		4.14.7	Quality indicators
		4.14.8	Reviews by external organizations

4.13 Evaluation and audits

- **4.13.4: Staff suggestions.** Laboratory management shall encourage staff to make suggestions for the improvement of any aspect of the laboratory service. Suggestions shall be evaluated, implemented as appropriate and feedback provided to the staff. Records of suggestions and action taken by the management shall be maintained.
- **4.13.6: Risk management.** The laboratory shall evaluate the impact of work processes and potential failures on examination results as they affect patient safety, and shall modify processes to reduce or eliminate the identified risks and document decisions and actions taken.
- **4.14.8 Review by external organizations.** When reviews by external organizations indicate the laboratory has nonconformities or potential nonconformities, the laboratory shall take appropriate immediate actions and, as appropriate, corrective action or preventive action to ensure continuing compliance with the requirements of this International Standard. Records shall be kept of the reviews and of the corrective actions and preventive actions taken.

4 Management requirements

ISO 15189:2007		ISO 15189:2012	
4.15	Management review	4.15	Management requirements
		4.15.1	General
		4.15.2	Review input
		4.15.3	Review activities
		4.15.4	Review output

5 Technical requirements

ISO 15189:2007		ISO 15189:2012	
5.1	Personnel	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

5 Technical requirements

ISO 15189:2007		ISO 15189:2012	
5.2	Accommodation and environmental conditions	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

5 Technical requirements

ISO 15189:2007		ISO 15189:2012	
5.3	Laboratory equipment	5.3	Laboratory equipment, reagents, and consumables
		5.3.1	Equipment
		5.3.1.1	General
		5.3.1.2	Equipment - acceptance testing
		5.3.1.3	Equipment- instructions for use
		5.3.1.4	Equipment - calibration and metrological traceability
		5.3.1.5	Equipment- maintenance and repair
		5.3.1.6	Equipment- adverse incident reporting
		5.3.1.7	Equipment records
		5.3.2	Reagents and consumables
		5.3.2.1	General
		5.3.2.2	Reagents and consumables – reception and storage
		5.3.2.3	Reagents and consumables – acceptance testing
		5.3.2.4	Reagents and consumables – inventory management
		5.3.2.5	Reagents and consumables – instructions for use
		5.3.2.6	Reagents and consumables – adverse incident reporting
		5.3.2.7	Reagents and consumables – records

5 Technical requirements

ISO 15189:2007		ISO 15189:2012	
5.4	Pre-examination procedures	5.4	Pre-examination processes
		5.4.1	General
		5.4.2	Information for patients and users
		5.4.3	Requests form information
		5.4.4	Primary sample collection and handling
		5.4.4.1	General
		5.4.4.2	Instructions for pre-collection activities
		5.4.4.3	Instructions for collection activities
		5.4.5	Sample transportation
		5.4.6	Sample reception
		5.4.7	Pre-examination handling, preparation, and storage

5 Technical requirements

ISO 15189:2007		ISO 15189:2012	
5.5	Examination procedures	5.5	Examination processes
		5.5.1	Selection, verification, and validation of examination procedures
		5.5.1.2	Verification of examination procedures
		5.5.1.3	Validation of examination procedures
		5.5.1.4	Measurement uncertainty of measured quantity values
		5.5.2	Biological reference intervals or clinical decision values
		5.5.3	Documentation of examination procedures

5 Technical requirements

ISO 15189:2007		ISO 15189:2012	
5.6	Assuring quality of examination procedures	5.6	Ensuring quality of examination procedures
		5.6.1	General
		5.6.2	Quality control
		5.6.2.2	Quality control materials
		5.6.2.3	Quality control data
		5.6.3	Interlaboratory comparisons
		5.6.3.1	Participation
		5.6.3.2	Alternative approaches
		5.6.3.3	Analysis of interlaboratory comparison samples
		5.6.3.4	Evaluation of laboratory performance
		5.6.4	Comparability of examination results

5 Technical requirements

ISO 15189:2007		ISO 15189:2012	
5.7	Post-examination procedures	5.7	Post-examination processes
		5.7.1	Review of results
		5.7.2	Storage, retention and disposal of clinical samples
5.8	Reporting of results	5.8	Reporting of results
		5.8.1	General
		5.8.2	Report attributes
		5.8.3	Report content
		5.9	Release of results
		5.9.1	General
		5.9.2	Automated selection and reporting of results
		5.9.3	Revised reports

5 Technical requirements

ISO 15189:2007		ISO 15189:2012	
Annex B	Recommendations for laboratory information systems (LIS)	5.10	Laboratory information management
		5.10.1	General
		5.10.2	Authorities and responsibilities
		5.10.3	Information system management
Annex C	Ethics in laboratory medicine	4.1.1.3	Ethical conduct

5.10.3 Information system management

The system(s) used for the collection, processing, recording, reporting, storage or retrieval of examination data and information shall be:

- a) validated by the supplier and verified for functioning by the laboratory before introduction, with any changes to the system authorized, documented and verified before implementation;
- b) documented, and the documentation, including that for day to day functioning of the system, readily available to authorized users;
- c) protected from unauthorized access;
- d) safeguarded against tampering or loss;
- e) operated in an environment that complies with supplier specifications or, in the case of non-computerized systems, provides conditions which safeguard the accuracy of manual recording and transcription;
- f) maintained in a manner that ensures the integrity of the data and information and includes the recording of system failures and the appropriate immediate and corrective actions;
- g) in compliance with national or international requirements regarding data protection.

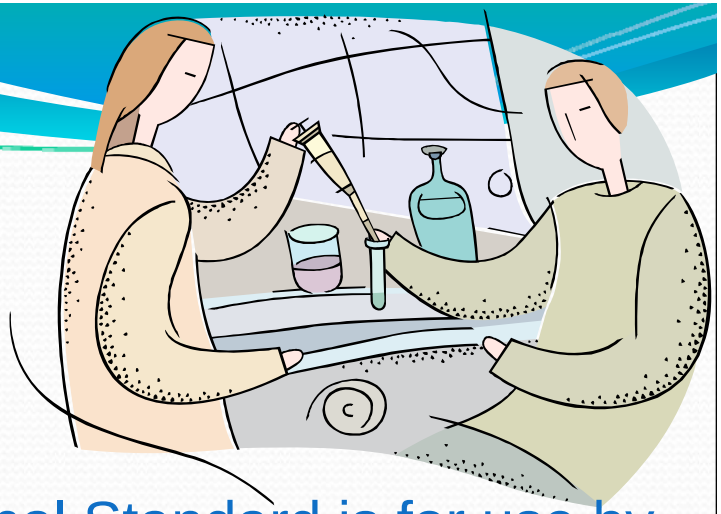
5.10.3 Information system management

- The laboratory shall verify that the results of examinations, associated information and comments are accurately reproduced, electronically and in hard copy where relevant, by the information systems external to the laboratory intended to directly receive the information (e.g. computer systems, fax machines, e-mail, website, personal web devices). When a new examination or automated comments are implemented, the laboratory shall verify that the changes are accurately reproduced by the information systems external to the laboratory intended to directly receive information from the laboratory.

Primary Role of ISO 15189

A Tool for Laboratorians?

or A Tool for Assessors?



"This International Standard is for use by medical laboratories in developing their quality management systems and assessing their own competence. Laboratory customers, regulating authorities and accreditation bodies may also use it for confirming or recognizing the competence of medical laboratories."

"This International Standard is not intended to be used as the basis for certification of laboratories."

ISO 9001:2008	ISO 15189:2012
4.2.4 Control of records	4.13 Control of records 5.1.9 Personnel records 5.3.1.7 Equipment records 5.8.5 Report content
5 Management responsibility	4 Management requirements
6 Resource management	5 Technical requirements
6.2.2 Competence, training and awareness	5.1.5 Training
6.3 Infrastructure	5.2 Accommodation and environmental conditions
6.4 Work environment	5.2.6 Facility maintenance and environmental conditions
7.1 Planning of product realization	4.4 Service agreements 4.7 Advisory services
7.4 Purchasing	4.6 External services and supplies
8.3 Control of nonconforming product	4.9 Identification and control of nonconformities 5.8.6 Revised reports

ISO 15189:2012 in Summary

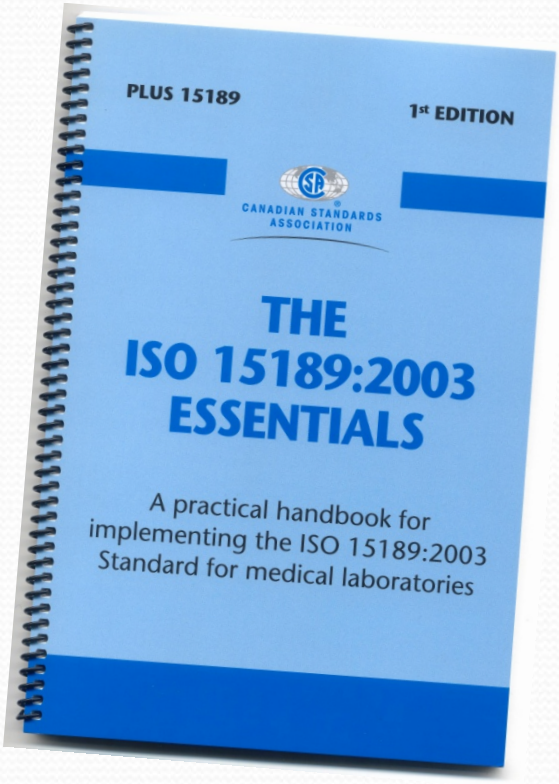
- Still a very broad and high level document
- The 3rd edition provides more clarity and better organization
- Content remains consistent with the history and tradition of quality management: Plan-Do-Check-Act; 14 Essentials of Deming; 4 Absolutes of Crosby
- Gaining much international use and respect
- Most laboratorians will be dealing directly and indirectly with its requirements
- Clinical laboratories have an international standard upon which they can base their quality management.

Where can I get my copy?

- Electronic copies of ISO 15189:2012, *Medical laboratories Requirements for quality and competence* can be purchased from the CLSI website (www.clsi.org) by clicking on the Shop Tab and then entering 15189 in the "Search Store" box on the store or by entering the Shop Tab and then entering the ISO Documents category.
  Printed versions can be purchased by phone (610.688.0100 - credit card order) or fax (610.688.0700 - purchase order).

Companion documents

PLUS 15189 (2nd ed. pub. 2010) - The ISO 15189:2007 essentials - A practical handbook for implementing the ISO 15189:2007 standard for medical laboratories available from: http://shop.csa.ca



Stay tuned, work on PLUS 15189 (3nd ed) has commenced and should be available from CSA in early 2014.

Companion documents

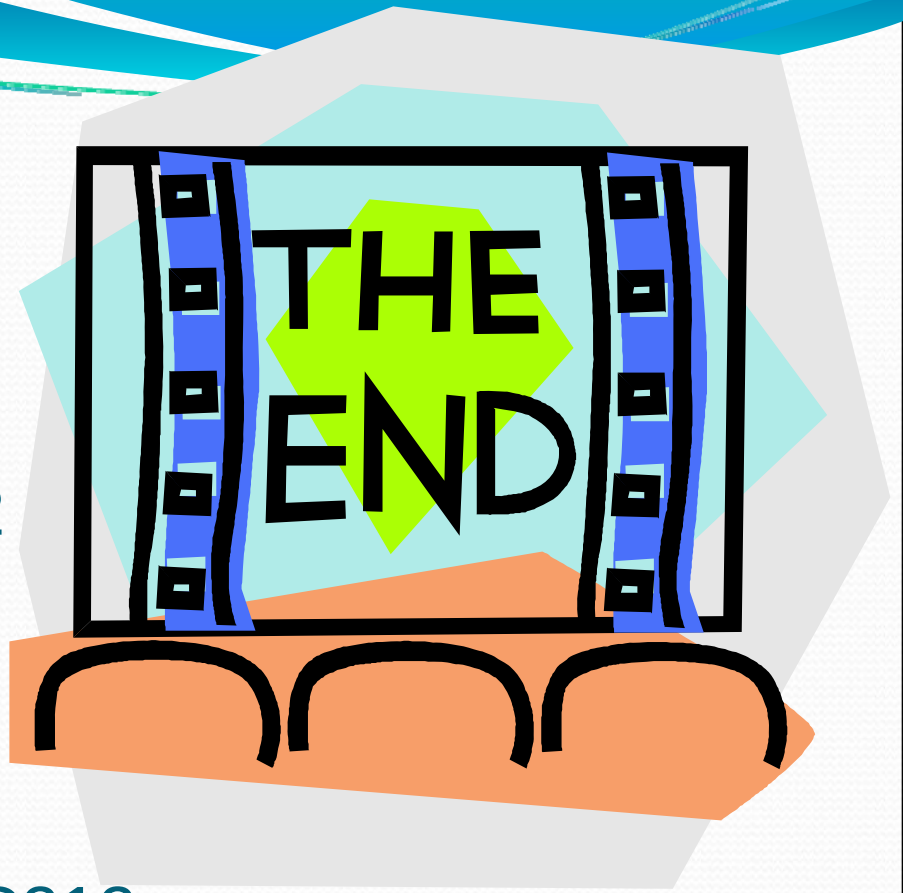
Since 15189:2012 is still rather new, there are few companion documents, but quite a few exist for 15189:2007 and will likely appear in updated revisions:

Practical application of ISO 15189 by accreditation bodies, Bella Ho http://www.ifcc.org/ifccfiles/docs/150412200403.pdf

Guidance for Laboratory Quality Manuals, QMPLS http://www.qmpls.org

ISO/TR 22869, Technical Report: Medical laboratories – Guidance on laboratory implementation of ISO 15189:2003 (Published 2005-02-15)

Questions?



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