Everything you want to know about ISO 15189:2012 Medical Laboratories – Requirements for Quality and Competence

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ISO 15189

Medical Laboratories: Requirements for Quality and Competence

- The history of 15189: why and how it. was developed
- The links between 15189 and related standards on safety and risk and Point-of-Care and Deming.
- The Quality Core of 15189:
  - Management Responsibility
  - Quality and its tools for error awareness and detection:
  - Quality Manager
  - Quality Manual
  - Quality Assessment including:
  - Accreditation, PT, and
  - Document Control and
  - Internal Audit and Indicators
  - Error Remediation and Correction
  - Error Prevention
  - Monitoring for Customer Satisfaction
  - Management Review
- Accreditation to 15189 ?
- The future of 15189
- The participation opportunities with 15189

Prior to 1980

- Medical laboratories were becoming more sophisticated:
  - Automated analysis equipment was being introduced
  - Quality Control was present but non-standardized
  - Each European country had its own accreditation process.
  - College of American Pathologists were accrediting laboratories by checklists
  - Proficiency testing was non-standardized

By 1994…

- Automated equipment was becoming more reliable, more available.
- College of American Pathologists was accrediting laboratories consistent with American law (CLIA)
- Proficiency Testing was becoming more standardized
- Non medical laboratories (and some medical) were being accredited to Guide 25.
- There was a need for a new Quality standard for medical laboratories

International Organization for Standardization

International Organization for Standardization (ISO)
announced request for laboratorians
to meeting in Philadelphia
to determine if there was interest in
development of
a new technical committee
to develop a new standard for
medical laboratory quality

A New Technical Committee was proposed

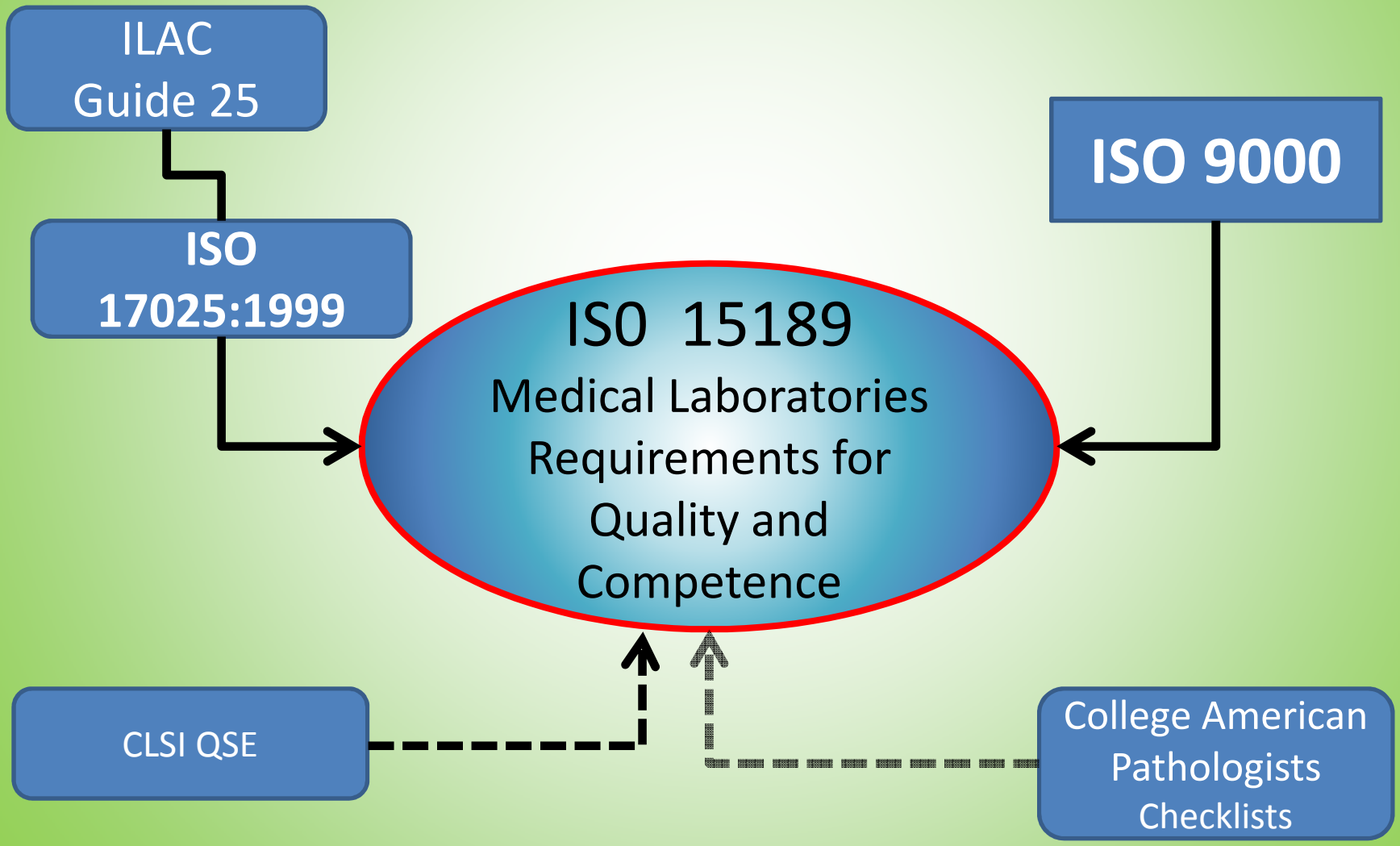
ISO Committee Name:	ISO TC 212
Committee Title:	in Vitro diagnostics and Quality
Secretariat Country:	United States
Secretariat Organization:	CLSI
Number of countries	33 (All continents represented)

The new Standard

The creation of a new Quality standard
for medical laboratories took 7 years to develop.

- Name: ***Medical Laboratories – Particular Requirements for Quality and Competence***
- Number: ISO 15189
- First year Published: 2003
- Revised and Republished: 2007, 2012

Influences in the Development of ISO 15189



The Contents of ISO 15189

Management requirements

Organization and management responsibility
Quality management system
Document control
Service agreements
Examination by referral laboratories
External services and supplies
Advisory services
Resolution of complaints
Identification and control of nonconformities
Corrective action
Preventive action
Continual improvement
Control of records
Evaluation and audits
Management review

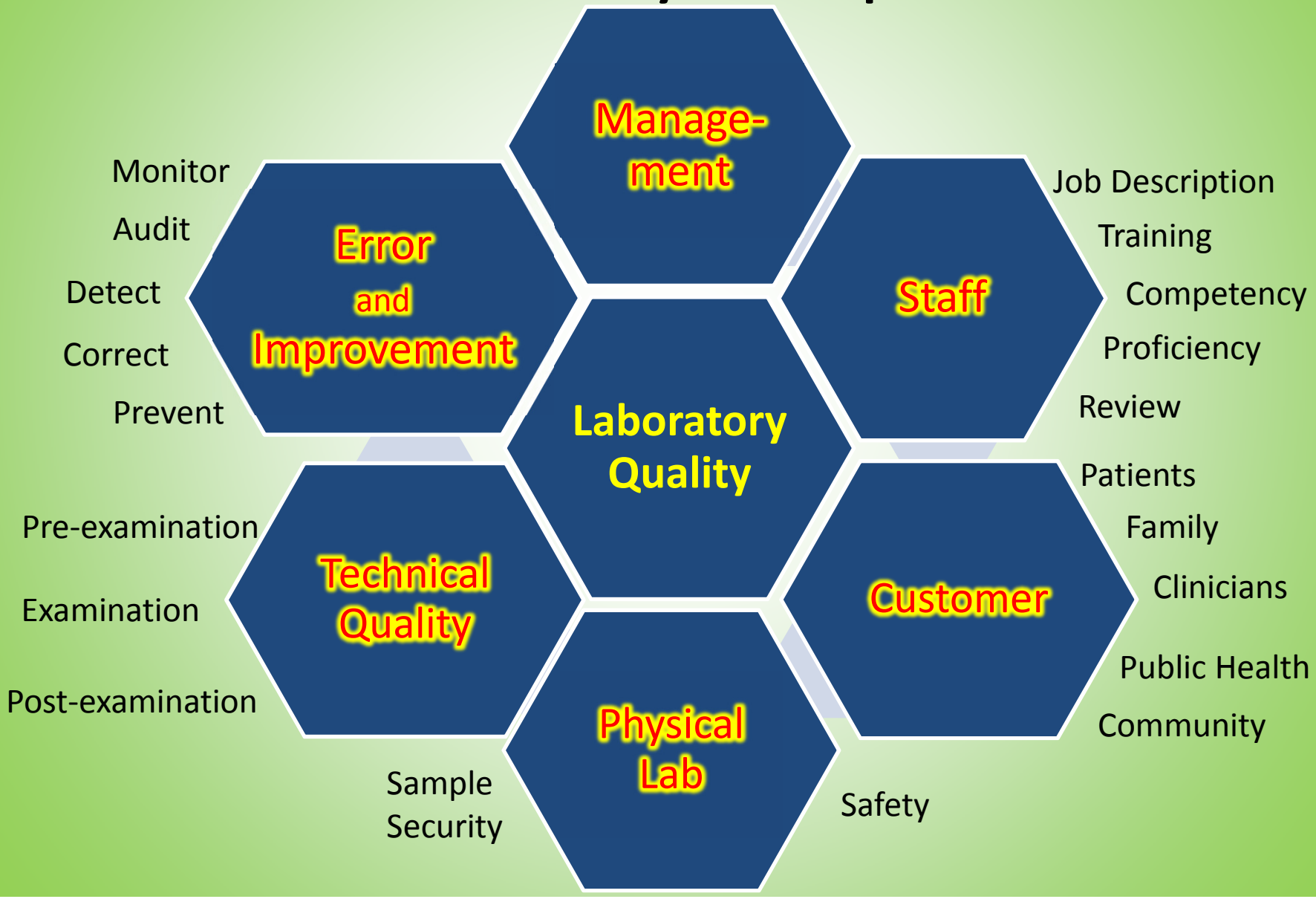
Technical Requirements

Personnel
Accommodation and environmental conditions
Laboratory equipment, reagents, and consumables
Pre-examination processes
Examination processes
Ensuring quality of examination results
Post-examination processes
Reporting of results
Release of results

Why ISO 15189 2003 became so significant

- Twenty three countries around the world adopted the standard within a year of publication (2004).
- By **2009** the standard was adopted by medical laboratories in 44 countries.
- By **2013** the standard was adopted by medical laboratories in over 60 countries.
- ISO 15189 is one of the fastest growing international quality standards in the world.

ISO 15189 is very comprehensive



Quality and CLSI QSEs *(revised)*

Structure

Organization

Management Responsibility

Personnel /Human Resources

Oversight and Improvement

Assessment

Occurrence Management

Process Improvement

Customer Satisfaction

Operations

Purchasing and Inventory

Equipment

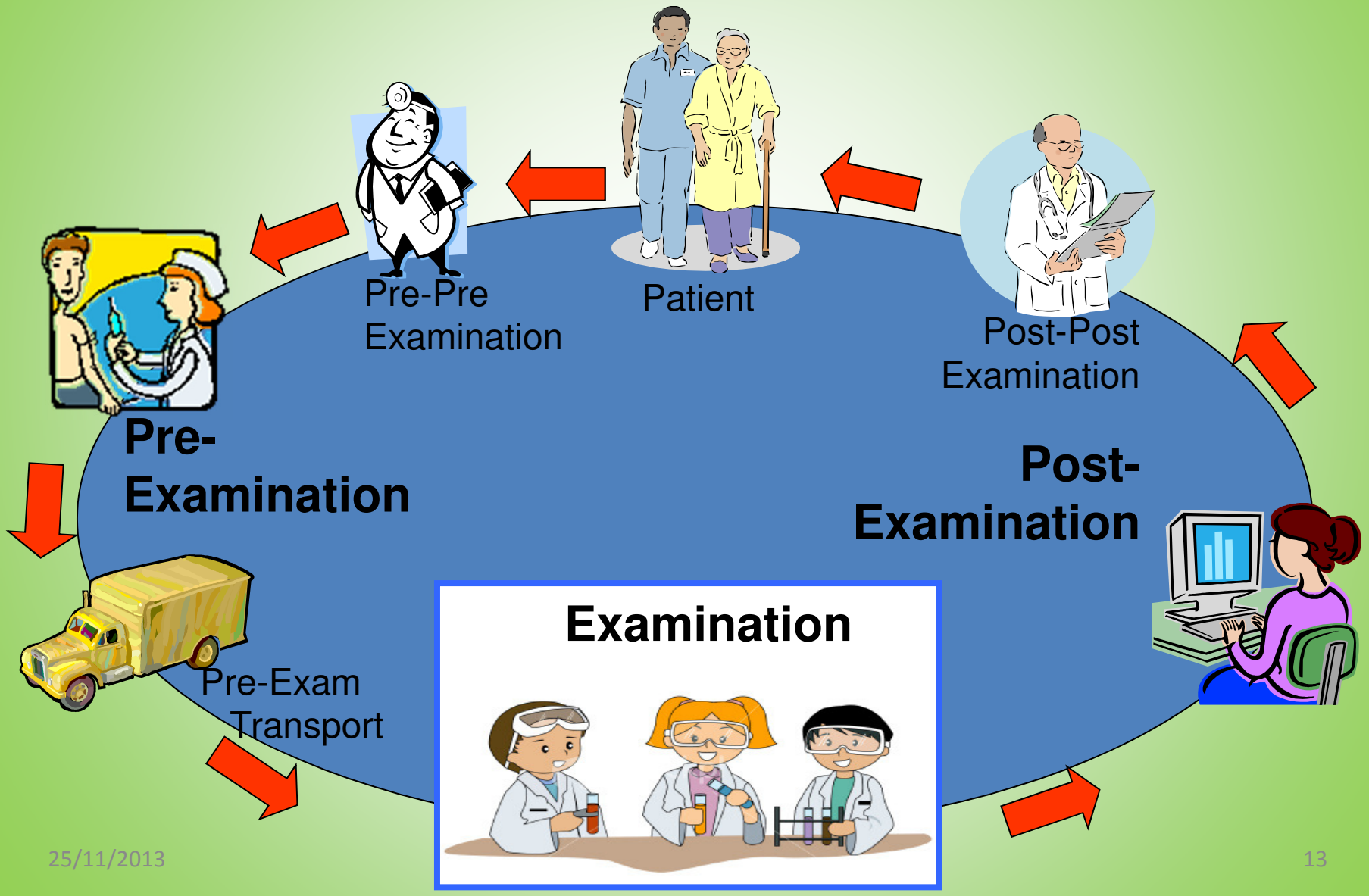
Documents and Records

Process Control / Management

Safety and Facilities

Information Management

The Laboratory Cycle



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Management responsibility

- **Management commitment**
- **Needs of users**
- **Quality policy**
- **Quality objectives and planning**
- **Responsibility, authority and interrelationships**
- **Communication**
- **Quality manager**

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Management review

Laboratory management shall review the quality management system at planned intervals to ensure its continuing suitability, adequacy and effectiveness and support of patient care.

The input to management review shall include information from the results of evaluations of at least the following:

Management Review

the periodic review of requests, and suitability of procedures and sample requirements;

assessment of user feedback;

staff suggestions ;

internal audits;

risk management;

use of quality indicators ;

reviews by external organizations;

results of participation in interlaboratory comparison programmes (PT/EQA);

monitoring and resolution of complaints;

performance of suppliers;
identification and control of nonconformities;

results of continual improvement including current status of corrective actions and preventive actions;

follow-up actions from previous management reviews;

changes in the volume and scope of work, personnel, and premises that could affect the quality management system;

recommendations for improvement, including technical requirements.

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Management review (report)

The output from the management review shall be incorporated into a record that documents decisions made and actions taken related to:

a) improvement of the effectiveness of the quality management system and its processes;

b) improvement of services to users;

c) resource needs.

NOTE:

The interval between management reviews should be no greater than 12 months; however, shorter intervals should be adopted when a quality management system is being established. Findings and actions arising from management reviews shall be recorded and reported to laboratory staff.

Laboratory management shall ensure that actions arising from management review are completed within a defined timeframe.

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Quality manager

a) ensuring that processes needed for the quality management system are established, implemented, and maintained;

b) reporting to laboratory management, ***at the level at which decisions are made***, on the performance of the quality management system and any need for improvement;

c) ensuring the promotion of awareness of users' needs and requirements throughout the laboratory

Customer-focused

- ISO 15189 speaks about two groups of customers:
  - There should be laboratory advisory panel that is constituted of users (clinicians) to provide advise and to the laboratory management
  - The should be a mechanism to capture customer complaints.

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  - There should be laboratory advisory panel that is constituted of users (clinicians) to provide advise and to the laboratory management
  - The should be a mechanism to capture customer complaints.
  - **No mention about other important customers of the laboratory:**
    - ✓ **Public Health**
    - ✓ **Community / Environment**

Quality Control

If conditions are not reproducible, results cannot be reproducible

Personnel Competency

Procedure Process

Procedure Documentation

Reagents and Materials

Equipment

Environment and Conditions

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Competency and Proficiency Assessment

Every person
who performs tasks that may influence Quality requires

Job Description

Training

Confirmation

A Re-Assessment Routine

Illness – Absence - Error

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Accommodation and environmental conditions

The laboratory shall have space allocated for the performance of its work that is designed to ensure the quality, safety and efficacy of the service provided to the users and the health and safety of laboratory personnel, patients and visitors.

The laboratory shall evaluate and determine the sufficiency and adequacy of the space allocated for the performance of the work.

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Facility maintenance and environmental conditions

Laboratory premises shall be maintained in a functional and reliable condition. Work areas shall be clean and well maintained.

The laboratory shall monitor, control and record environmental conditions, where they may influence the quality of the sample, results, and/or the health of staff.

Attention shall be paid to factors such as *light*, *sterility*, *dust, noxious or hazardous fumes*, *electromagnetic interference, radiation, humidity, electrical supply, temperature, sound and vibration levels and workflow logistics, as appropriate to the activities concerned so that these do not invalidate the results or adversely affect the required quality of any examination.*

The laboratory shall provide a quiet and uninterrupted work environment where it is needed.

Internal Audit

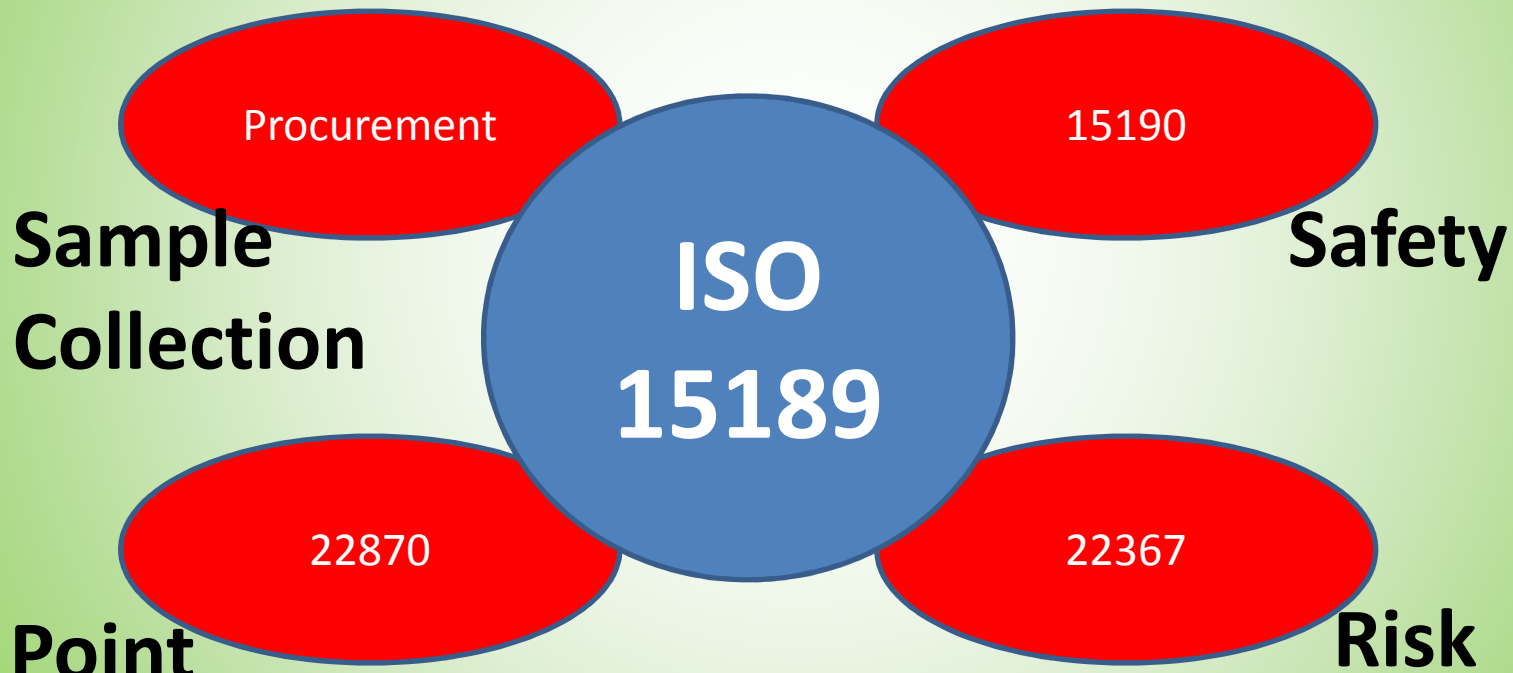
- An internal procedure for regular observation and improvement
  - May be done with own staff
  - May invite external staff
  - Planned and Organized
  - Focused
  - Evaluable

- ***If problems are detected, make the required adjustments early.***

Measurement Uncertainty

- Every step of a procedure has some degree of variation
- Variation is measurable
- Variation has an additive effect
- At a point accumulated variation can influence results interpretation
- To the extent possible, the laboratorian should be aware of the components that influence variation, and introduce strategies to minimize.

The Suite of Medical Laboratory Quality Related Standards



The Future of ISO 15189

A long term standard that will be
the centre of medical laboratory quality
for years to come

?

Increasing presence in
newer geographic regions

?

Increasing Clinical Relevance
for the broadening community

?

Participation in the Development ISO 15189

- ISO is an international organization
- Most countries have a national standards body that participates with ISO
  SCC ANSI BSI DIN SASO
- National Standards Bodies can be approached to become P status members of ISO TC 212
- National Standards Bodies can identify individuals to participate in ISO TC 212 meetings

Application of ISO 15189:
Accreditation or Certification or Neither?

- Certification is the assessment of an organization to ensure that it is meeting the requirements of a required standard or regulation.
  - Certification is performed by certification bodies to meet the requirements of ISO9001
  - ISO ***DOES NOT GRANT*** Certification Bodies to assess for ISO15189

- Accreditation is the assessment of an organization to ensure that it is performing in accordance with the requirements of a required standard or regulation
  - Accreditation is performed by accreditation bodies to meet the requirements of accepted documents including, but not limited against ISO17025 and ISO15189.
  - ISO ***DOES GRANT*** accreditation Bodies to assess against ISO15189

Accreditation and Certification

For accreditation to be credible

- The organization should have prior knowledge of the document
- The accreditation team should be trained and competent and objective.
- The accreditation team should perform a full examination consistent with all the requirements of the document
- The accreditation team should provide and evaluation that is consistent with the requirements of the document
- The accreditation should be part of a regular and continuous improvement process.

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- The accreditation should be part of a regular and continuous improvement process.
- *The accreditation body should be prepared to have itself accredited by and authorized body (ISO17011)*
- *The primary task of the accreditation body should be performance of accreditation and not sales of proficiency testing or other ancillary services.*

Can a laboratory self-declare its Quality against ISO 15189?

No country can prohibit a laboratory deciding to implement and process 15189 by itself, without an evaluation by an Accreditation Body

NO mark NO certificate NO Public Display

In all likelihood,
an attempt to self-implement without oversight would likely fail

Sooner rather than later

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In all likelihood,
attempts to self-implement without oversight
would likely fail
sooner rather than later
from lack of motivation

How Can You Get a Copy of ISO 15189?

www.ISO.org

154 CHF

630 SAR

In Summary

- ISO 15189 principles
  - Laboratory Management has a responsibility to manage
  - The laboratory must know who are its users (customers) and meet their requirements
  - The physical laboratory should not interfere with laboratory workers or laboratory samples.

Why is ISO 15189: 2012 a special standard

1. It is a single document that can be used by medical laboratories around the world to unify efforts to improve patient care.
2. It is based on ISO9001 and ISO17025
3. ISO15189 does NOT require re-accreditation if the laboratory changes its method of analysis.
4. ISO publishes the document in multiple languages.
5. It can be used by authorized accreditation organizations anywhere.
6. ISO allows other accreditation bodies to adapt ISO 15189 to local circumstance.

in summary…

- International Organization for Standardization has been committed to assist medical laboratory quality improvement for more than 10 years.
- ISO 15189:2012 is a valuable tool that every country with an interest in medical laboratory quality can implement.
- ISO standards are enhanced by international participation.

Information and Learning on Quality

1. POLQM
2. Quality Workshops
3. Websites
   - *A. www.ASQ.org*
   - *B. www.ISO.org*
   - *C. www.CSA.ca*
   - *D. www.DarkDaily.com*
   - *E. www.medicallaboratoryquality.com*
   - *F. www.CMPT.ca*
4. *Activities*
   - *A. Participate in Internal Quality Opportunities*
   - *B. Participate in the Accreditation Process*
   - *C. Participate in Proficiency Testing opportunities.*
   - *D. Safety is an important component of Quality*