

Progress and Process in International Laboratory Quality

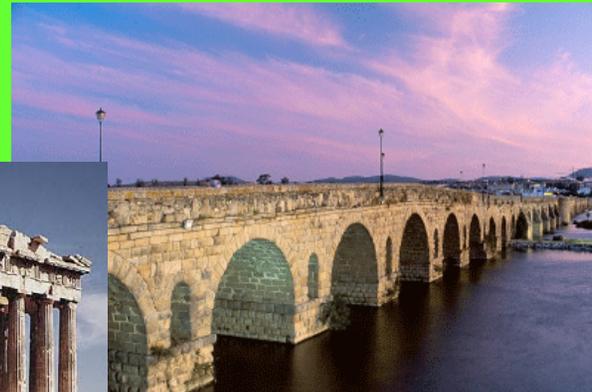
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Clinical Microbiology Proficiency Testing program
Program Office for Laboratory Quality Management
University of British Columbia
Vancouver BC



History of Quality

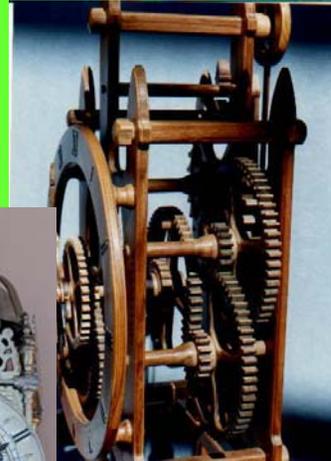
- Evidence of Quality Control, Measurement
 - Roman roads
 - Greek architecture
 - India architecture



- Evidence of inspection, quality assurance, standards, trueness.

- 1000-1300

- Germany
- France
- United Kingdom



Early China and Quality

Zhou Dynasty

1100 BC to 800 BC

Documentary evidence of

Manufacturing standards,

Quality control,

Standard operating procedures,

Quality assurance marking





Zhou Dynasty Folklore

commitment to standards and
measures

Fuxi, the first ancestor of human beings was also the inventor of the rule and yardstick



International Organization for Standardization

 **National Standard of Canada**
CAN/CSA-ISO 9001-00
(ISO 9001:2000)

International Standard ISO 9001:2000 (third edition, 2000-12-15) has been adopted without modification as CSA Standard CAN/CSA-ISO 9001-00, which has been approved as a National Standard of Canada by the Standards Council of Canada.
ISBN 1-55324-405-2 December 2000

Quality management systems — Requirements

Systèmes de management de la qualité — Exigences



Reference number
ISO 9001:2000(E)

© ISO 2000

Coordinated activities to direct and control an organization with respect to quality.

History of Quality Management



MIL-Q-9858
1959

2004
US Military Replaces Mil-Q-9858 with ISO 9000:2000



NATO AQAP-1
1968



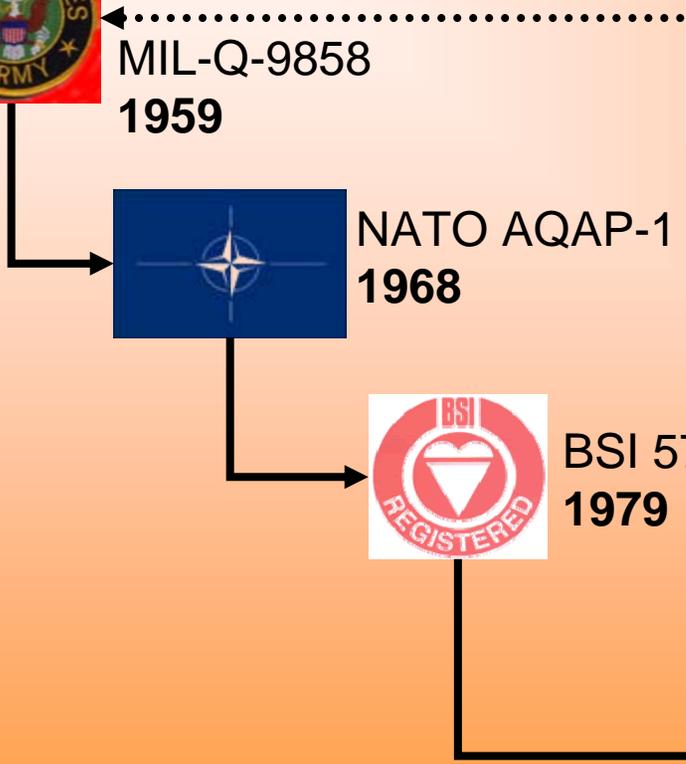
BSI 5750
1979



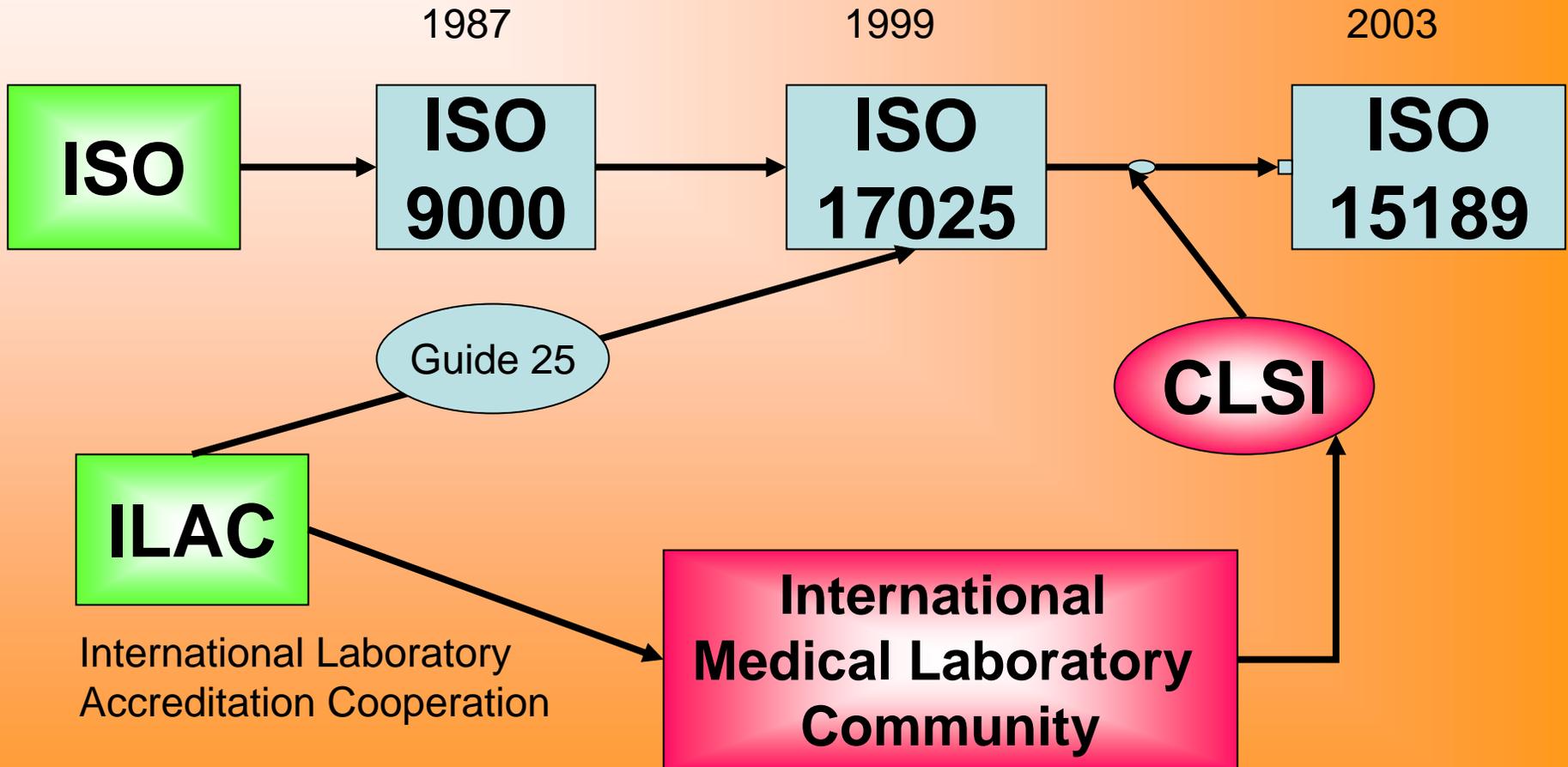
1967, 1988



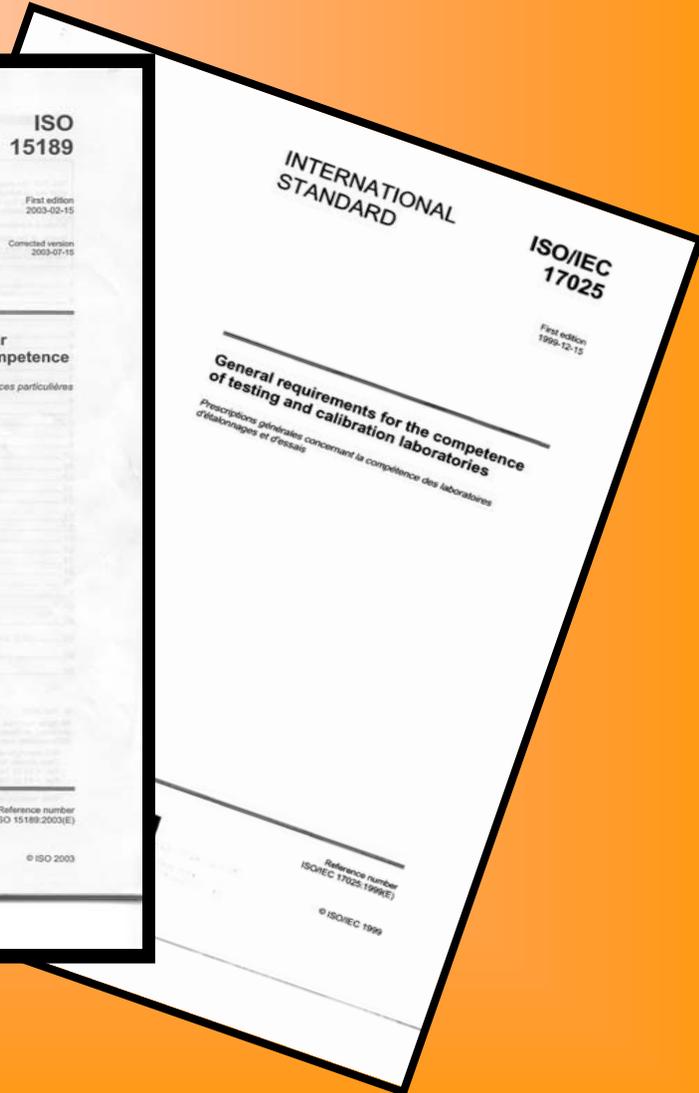
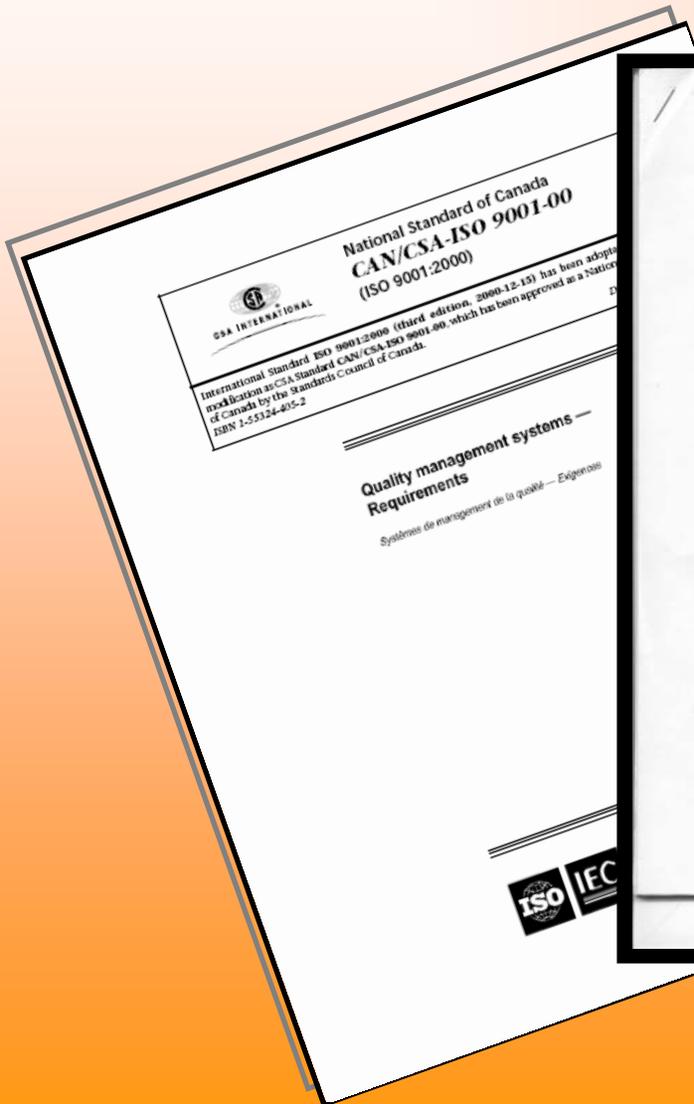
ISO 9000
1987, 2000



International Organizations: Working together



Quality Management and the Medical Laboratory



CLSI and Quality Management

Path of Workflow

Pre-Examination --- Examination --- Post-Examination

Quality System Essentials

Organization

Personnel

Equipment

Purchasing and Inventory

Process Control

Occurrence Management

Assessment: Internal and External

Information Management

Process Improvement

Documents and Records

Facilities and Safety

Customer Service

CLSI HS1 – A5 (2003)

**A quality
management system
model for health care**

CLSI GP 26 – A3 (2004)

**Application of a quality
management system
model for laboratory
services**

The Appeal of ISO

- Every country has an opportunity to participate.
- Every country has the opportunity to vote.
- Documents are sufficiently focused to ensure quality but are sufficiently open to allow local custom and interpretation.

The Appeal of ISO

- For some countries, it is easier for independent authorities to coalesce around an external document than to negotiate an internal agreement.

ISO 15189

Trail of International Acceptance

Australia

New Zealand

France

Germany

Belgium

Japan

Sweden

China*

Canada*

Mexico*

Caricom*

Thailand *

Tanzania *

Viet Nam*

*work in progress

Promised benefits from ISO standards

1. Increased Efficiency
2. Increased Revenue
3. Employee Morale
4. International Recognition
5. Factual Approach to Decision Making
6. Supplier Relationships
7. Documentation
8. Consistency
9. Customer Satisfaction
10. Improvement Processes

Demonstrated Benefits from ISO Certification

- 2-3 times more profitable than non-certified companies.
- Outperform on industry financial and sales measures.
- Higher market means with lower market variability as compared to non-certified companies.

Pinar and Ozgur
Qual Manage J.
2007

Evidence there is laboratory benefit to ISO 9001:2000

- Clinical Microbiology Proficiency Testing
 - Certified to ISO 9001:2000 since 2002 - 2007
 - Rework due to technical error and contamination reduced by 80%
 - All documented Opportunities for Improvement have documented follow-through
 - Consistent high annual ratings on composite client satisfaction scale.
 - Increased efficiency.
 - Increased visibility resulting in adjacency opportunities.
 - Accumulated debt (40% GAR) paid off with surplus in 2007 with no job losses.

Evidence there is benefit to ISO15189:2007

- Too early to say, but...
 - Most laboratories were already being accredited to other documents, especially ISO17025:1999.
 - Developing country programs are still early in their process.
 - Anecdotally, one province in Canada has had 4 years of experience and noting significant successes.
- Many laboratories that previously had not set up quality management systems are now engaged in quality and development.

In summary...

- The route to quality is not new in most sectors, but has been slow to come in the health care sector.
- The International standard for quality and competence for medical laboratories was only published in 2003, but has gained traction around the world.
- ISO standards for quality and competence have their core roots formulated around Mil-Q-9858.

In conclusion...



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