

History of Quality for the Modern Medical Laboratory

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Many laboratorians think of quality management, and the focus on error and safety as something new and current. Nothing could be further from the truth. While it may be true that today we have many more organizations, information sources, and agencies available today, the quest for quality partnerships has always been with us. Laboratories have always depended upon guidance developing organizations, such as CLSI (formerly NCCLS) for assistance in procedures, and accreditation programs, and EQA to challenge us. Every laboratory knows and understands that the quality of the laboratory is directly related to the quality and reliability of the equipment and reagents they use, and the companies that supply them. And the role of public demand is loud and clear. Quality is the result of a true team effort.

Quality Management as a discipline and focus of interest is not new. Indeed it dates back to the days of Shewart and Deming in the 1920's and 1930's. These techniques are truly tried and tested. And Canada and Canadians have played a major role in their development, through the early years of development, through the creation of International standards, and through leadership.

Every laboratory needs to be engaged in the quality process. Quality Management Systems have worked in the military, in government, in industry, and in service. They will work in the medical laboratory as well.

Why do laboratory errors occur?

Understaffed

Inadequate
Attention
To Detail

Poor
Sample Control

Poor
Workload
Management

Poor
Quality
Management

Poor Results
Verification

Time
Pressures

Non-validated
Tests

Quality
Control &
Assessment

Problem solving in the 21st Century

1. Create an agency

- **Joint Committee on Accreditation of Healthcare Organizations**
- **Canadian Council for Healthcare Services Accreditation**
- **Centers for Disease Control Division of Laboratory Systems**
- **International Organization for Standardization**

- **Institute of Medicine**
- **Agency for Healthcare Research and Quality**

- **Institute for Healthcare Improvement**
- **Institute for Quality in Laboratory Medicine**
- **International Society for Quality in Healthcare**
- **CSA's National Committee for Medical Laboratory Quality Systems**

2. Find a group to work with



3. Create a workable work system

- Consensus standards of national or international origin
- A clear declaration of policy
- Improved quality monitoring
- Improved tracking of outcomes
- Improved awareness of client satisfaction

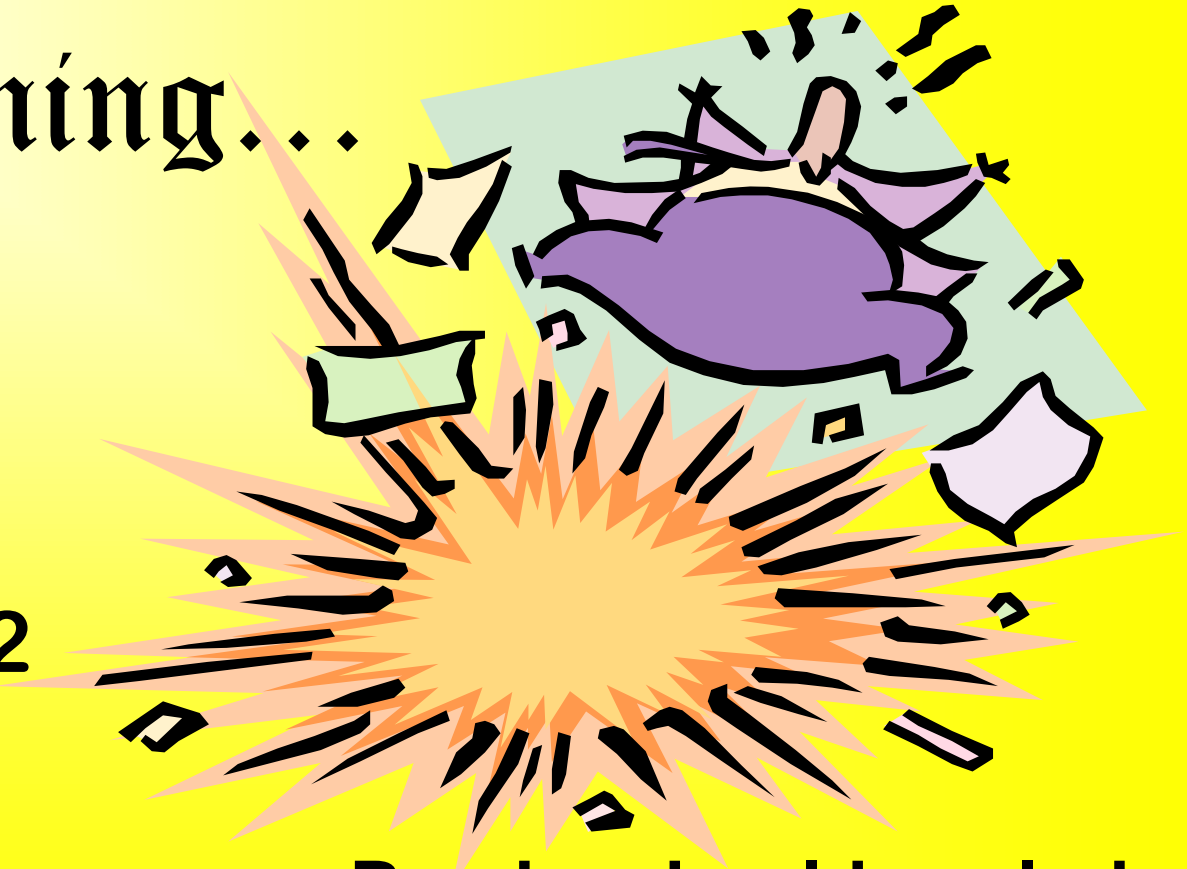
Established Quality Systems for Medical Laboratories

- **CLSI** (formerly NCCLS)
 - **GP26-A2** Application of a Quality System Model for Laboratory Services; Approved Guideline—Second Edition
 - **HS01-A** A Quality System Model for Health Care; Approved Guideline
- **International Organization for Standardization**
 - **ISO 9001:2000** Quality Management
 - **ISO 15189:2003** Medical laboratories -- Particular requirements for quality and competence
 - **ISO 17025:1999** General requirements for the competence of testing and calibration laboratories

Historical Perspectives
For
Quality Laboratory
Management

In the Beginning...

Practical
Quality
Policy
1939-1942



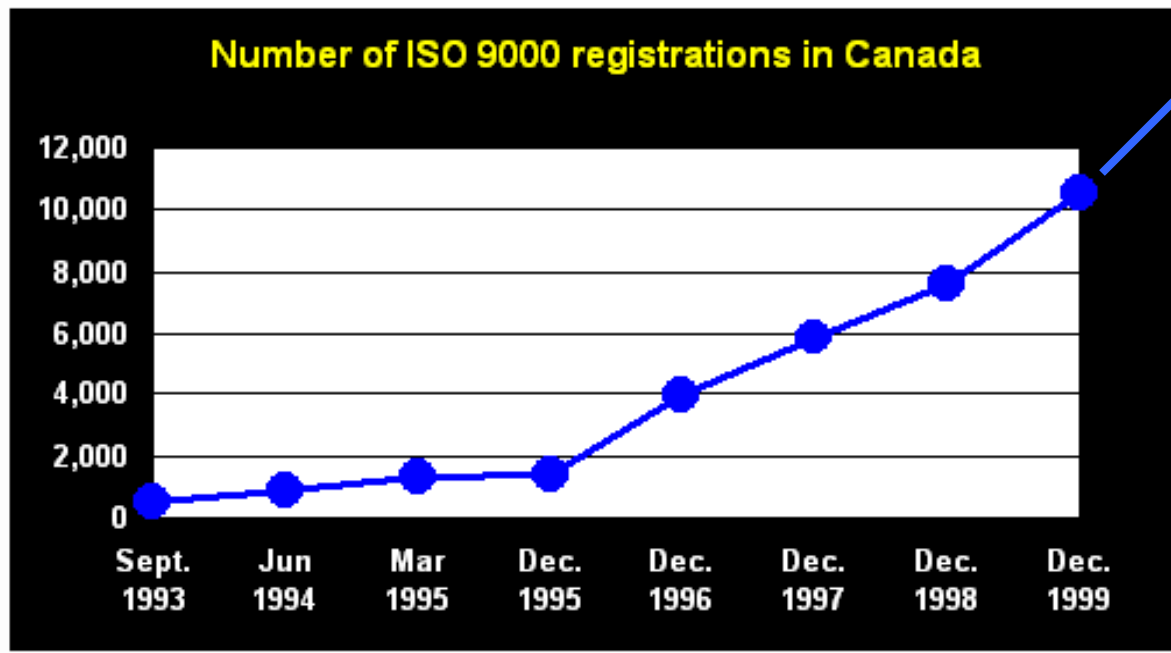
**Bombs should explode
when you want them to,
and not when you don't**

The March of Quality Management

1942-52	US Military develop requirements for contractors for shell, aircraft, missile suppliers (Quality without 100% inspection)
1947	International Organization for Standardization (ISO) created to adopt industrial standards
1959	US Department of Defense established MIL-Q-9858 quality management
1963	MIL-Q-9858 is internationalized as an ABCA standard
1968	NATO adopts MIL-Q-9858A as Allied Quality Assurance Publication 1 (AQAP-1)
1979	British Standards Institute (BSI) developed AQAP-1 for civilian use BS 5750
1987	ISO modifies and adopts BC5750 for international civilian use ISO 9000
1994-00	ISO issued ISO 9000:1994 and follows with ISO 9000:2000 .
2003	DoD drops MIL-Q-9858 in favor of ISO 9000:2000

History of ISO 9000 in Canada

Number of ISO 9000 registrations in Canada								
Jan. 1993	Sept. 1993	June 1994	March 1995	Dec. 1995	Dec. 1996	Dec. 1997	Dec. 1998	Dec. 1999
292	530	870	1290	1397	3955	5852	7585	10556



SCC

2000-09-25

Registrations in Canada continue to grow at 30% per year.

Similar but Different

ILAC

International Laboratory
Accreditation Cooperation

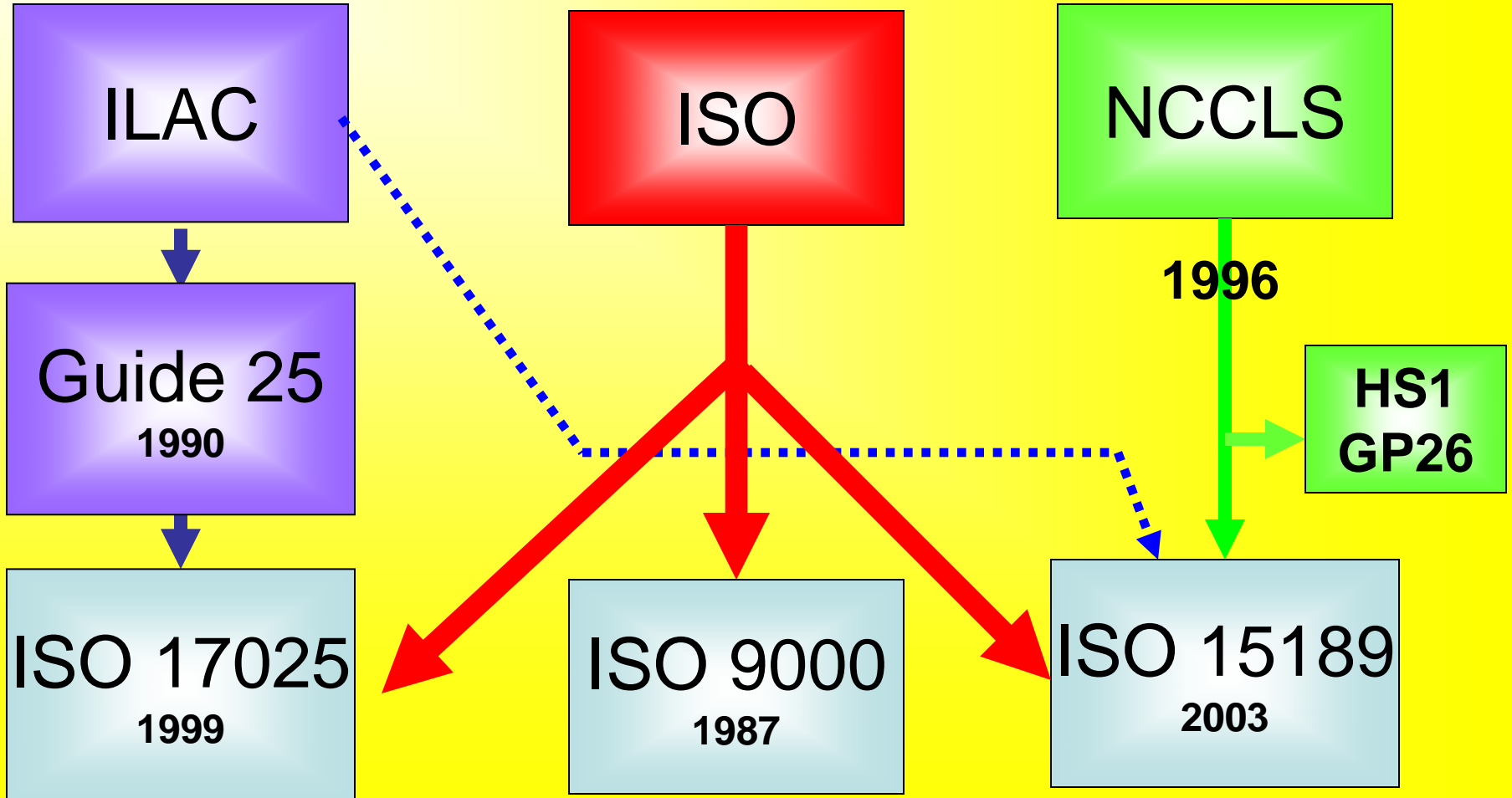
- 1986 Conference to establish a common guide for assessment of laboratories
- 1990 Guide 25
- 1994 Join with ISO
- 1999 ISO 17025
- 2005 Begin Revision

NCCLS

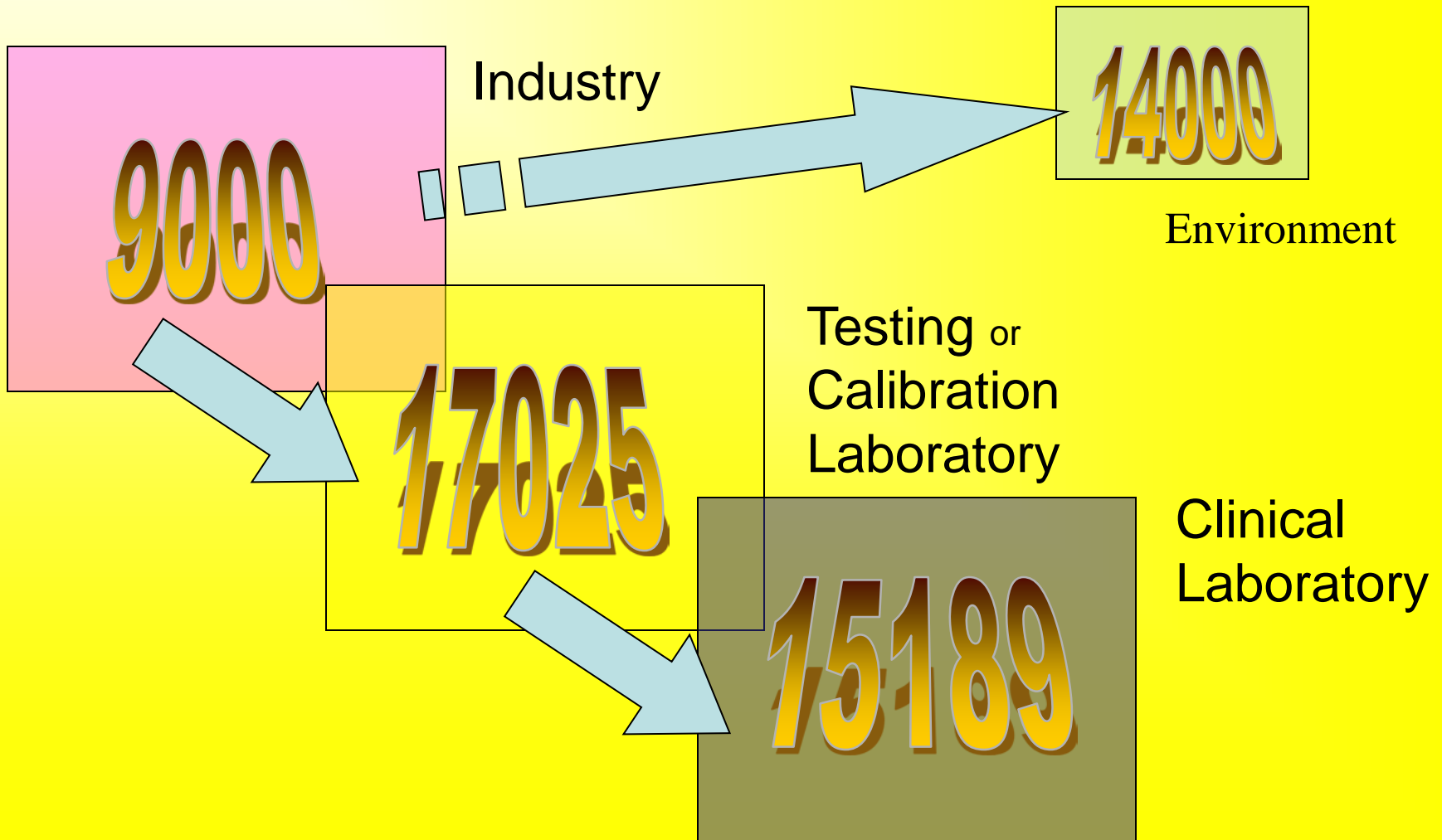
Clinical and Laboratory
Standards Institute

- 1995 Conference to establish an international standard for medical laboratory quality
- 1999 Vancouver conference begin align with Guide 25
- 2000 Dublin Conference to realign with 9000
- 2001 Sydney Conference to re-align with 17025
- 2003 Publish 15189
- 2004 Begin Revision

Working Together



ISO Family of QM Standards



Canada and the ISO Quality Process



Member of ABCA



Signatory of ISO



Secretariat for ISO 9000



Signatory of ILAC



Member TC 212

In Summary

- Principles for Quality Management date back more than 60 years.
- Quality Management has been an international initiative from the beginning.
- Quality Management has been a Canadian enterprise from the beginning.
- *Quality Management Systems have worked in the military, in government, in industry, and in service. Odds are they will work in the medical laboratory as well.*