

UBC Quality Management Seminar Series

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Chair POLQM

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UBC

During This Seminar

Introduction and History

Errors and Costs and
Standards and Requirements

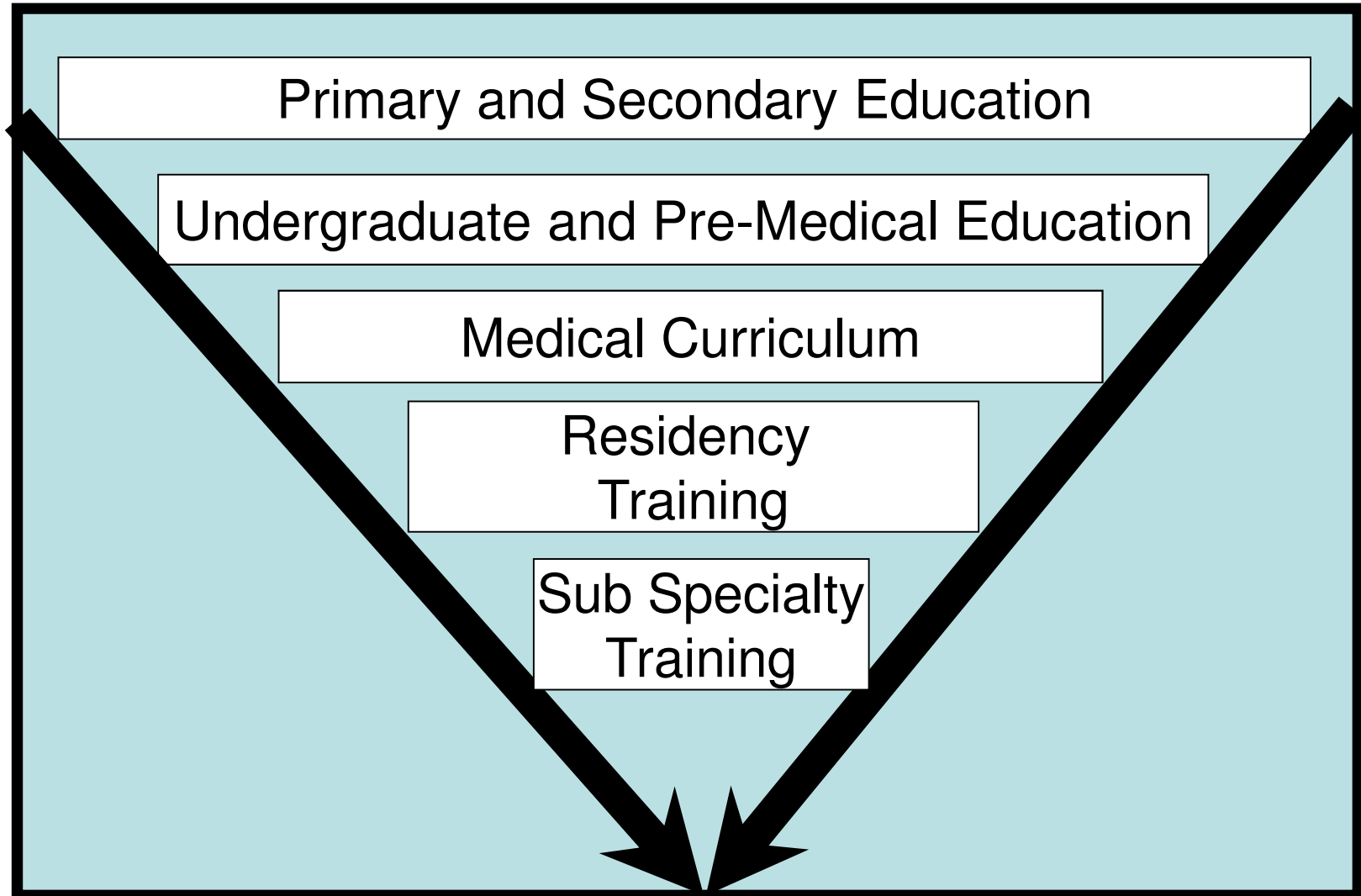
Applying Quality to the Medical Laboratory

The Quality Roles and Responsibilities
and Opportunities for
Medical Laboratory Leadership

Who is Michael Noble

- Medical Microbiologist
- Long time interest and study in many aspects of Quality
 - Chair: Clinical Microbiology Proficiency Testing program
 - Chair: UBC Program Office for Laboratory Quality Management
 - Chair: Canadian Advisory Committee to International Organization for Standardization (ISO) Technical Committee 212 Quality Management and in vitro diagnostics
 - (Past) Chair: Canadian General Standards Board Technical Committee for Transportation Packaging for Dangerous Goods.
 - (Past) Chair: Canadian Standards Association National Committee for Medical Laboratory Quality Systems
 - (Past) Medical Director for Quality – LifeLabs BC
 - (Past) Chair: Canadian EQA Advisory Group on Antimicrobial Resistance.

Path to Laboratory Medicine



Laboratory are Complex Units With Many Core Criticalities

- Human Resources
- Financial
- Operational
- Project
- Supplies
- Test
- Safety and Security
- Risk •
- Quality •
- Equipment •
- Patient Care •
- Information •
- Change •
- Customer satisfaction •

**Each Criticality Requires its own
Management Competency**

Many Skill Sets Required

Clinical Case Management

Human Resource Management

Safety Management

Supply Management

Information Management

Risk Management

Financial Management

Operational Management

Project Management

Change Management

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Fortunately
Quality Management
overlaps with all criticalities



Quality within Pathology

- **Pathology**

- Pathos (Greek)– disease, suffering
- Logia (Greek) – study, sciences, body of knowledge
 - Haematology or Microbiology or Immunology or Histology

- **Qualitology**

- A body knowledge or study about a total sum of topic properties (*qualitas* – Latin)

- » *Quality is a unique subset of information relevant to the laboratory*
- » *Quality is definable and measurable*
- » *Quality has its own measurement tools*
- » *Quality has measurable outcomes.*

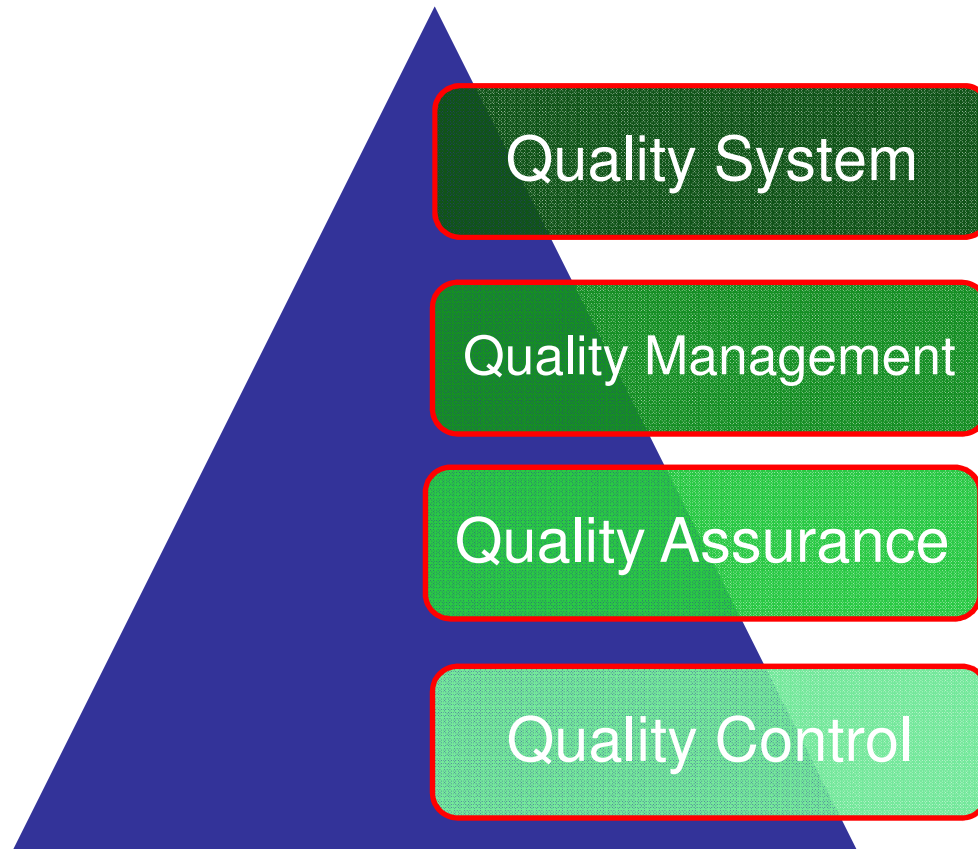
Seminar Series Themes

- Quality Management is a body of knowledge you need to know
- The Laboratorian has lots of support for implementing Quality (Quality Partners)
- Laboratory Errors are Costly.
- There is one Quality Management Structure with many tools in the Toolbox.

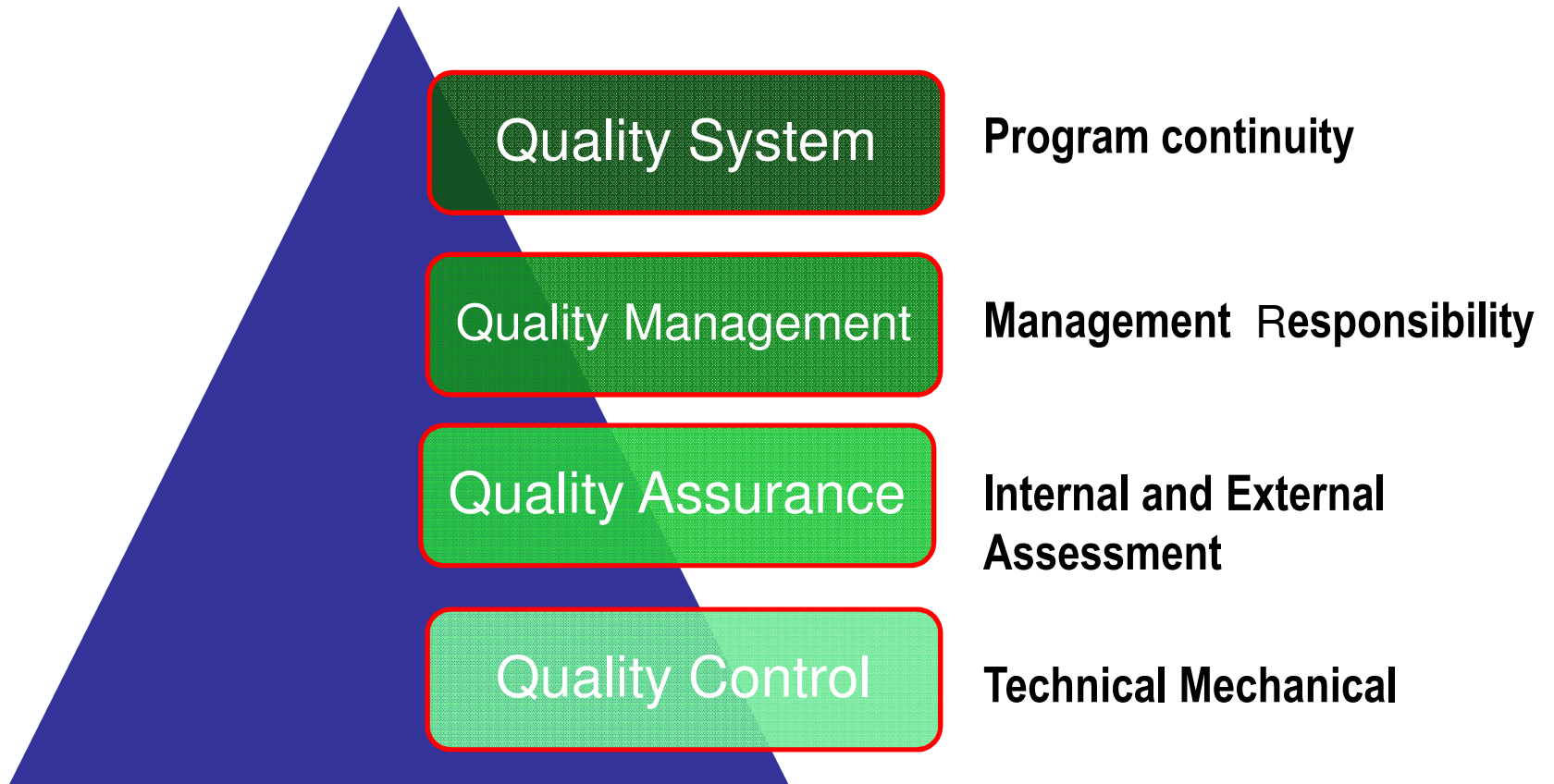
Definitions of Quality

- Quality is the meeting of requirements.
- Quality is the recognition of zero tolerance for error.
- Quality is the process of decision and action based on objective determination.
- Quality is the commitment to continual improvement.
- Quality is the performance of duties correctly the first time, every time.

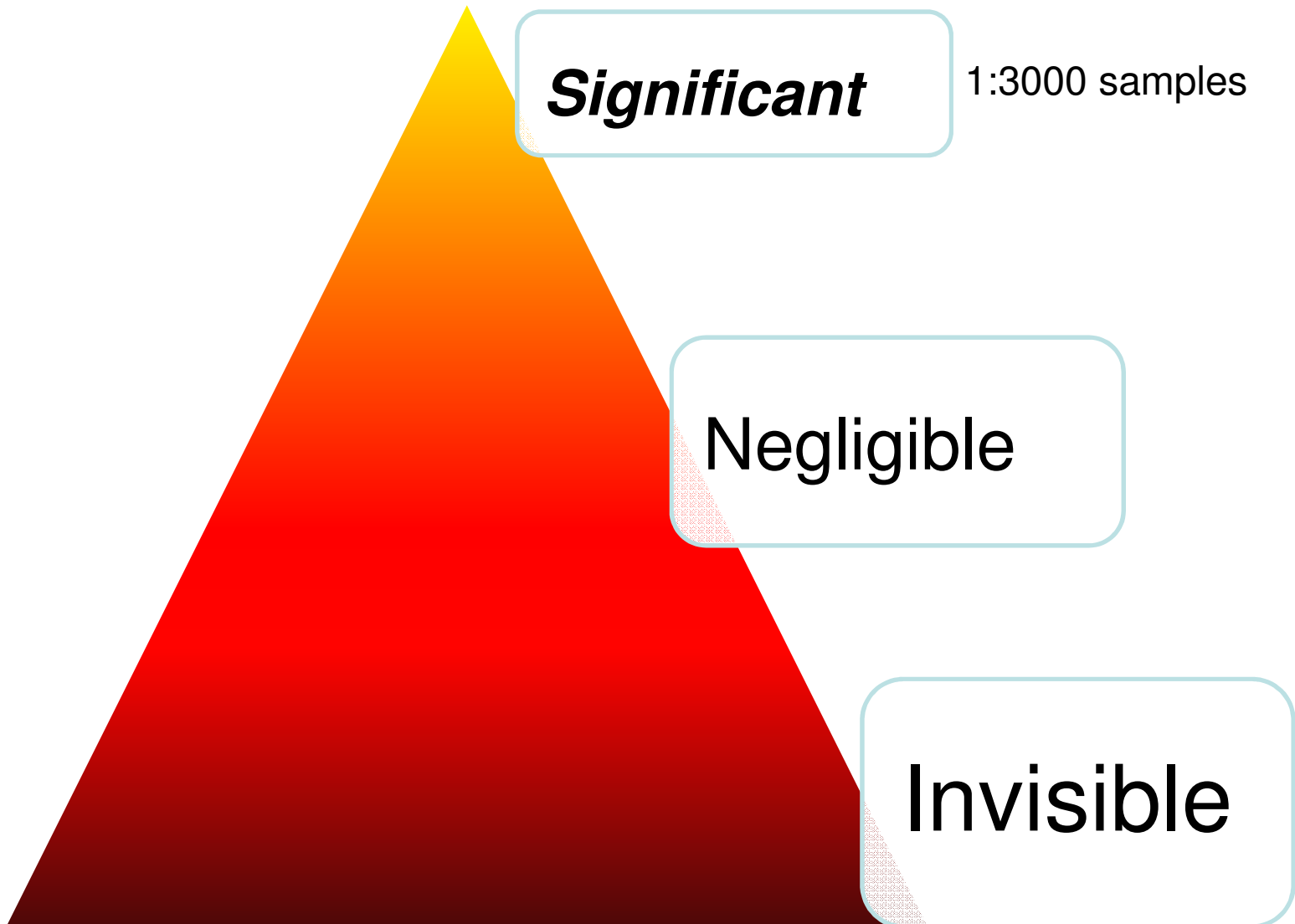
Error Prevention through Quality Management



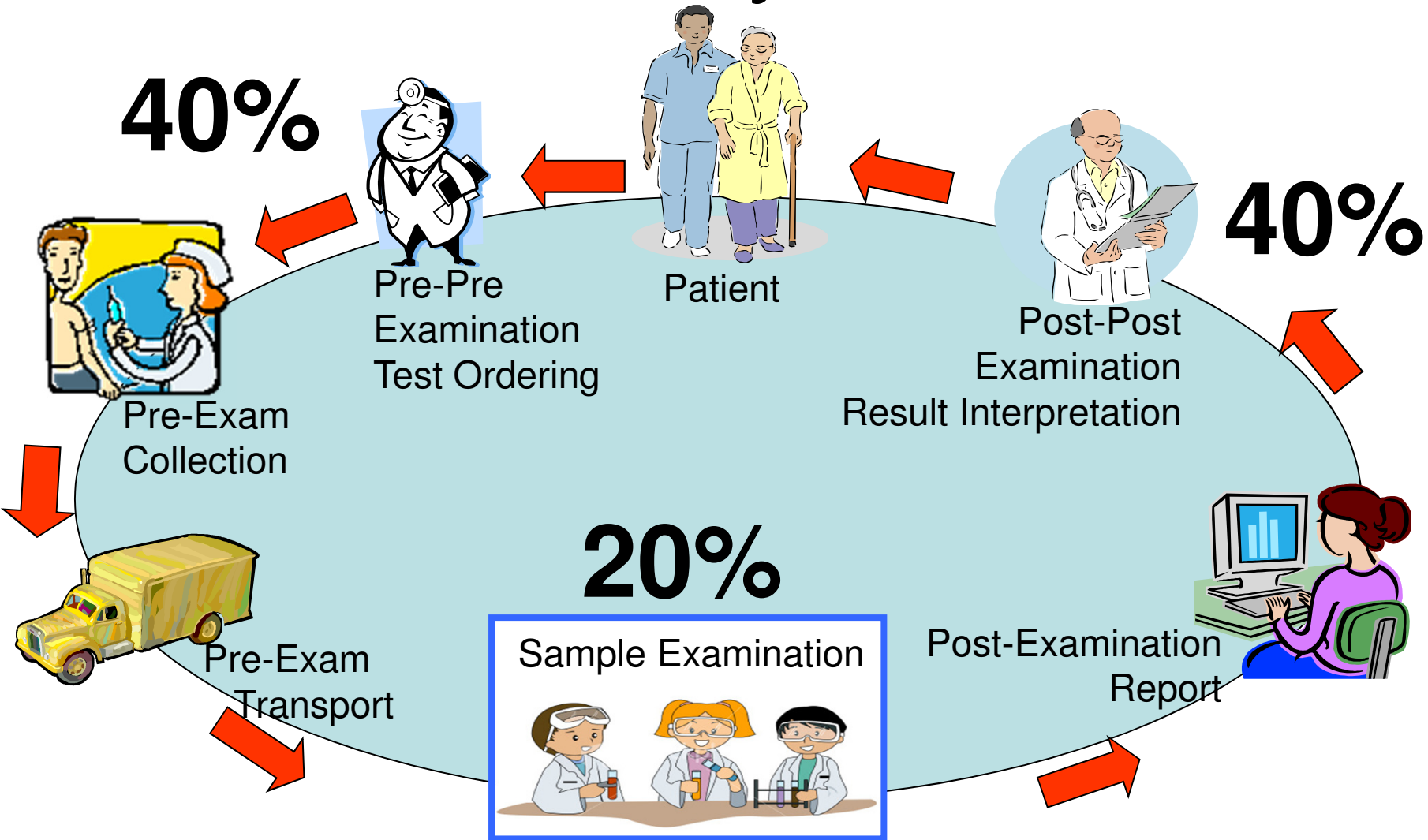
Error Prevention through Quality Management



Medical Laboratory Error



Laboratory Errors



Michael A Noble

Types of Laboratory Error

Pre-Exam

Wrong Patient
Wrong Collection
Wrong Transport
Wrong Accession

Examination

Poor QC
Contamination
Interference
Analyst Error
Mechanical Error
Misinterpretation

Post-Exam

Wrong Report
Poor Report
Late Report
Wrong Doctor
Wrong Patient

Error is Everywhere

Human Factors

- Laboratory Personnel
- Non-laboratory Personnel
- Patients

Testing Factors

- Reagents and Materials
- Equipment
- Procedures

Environmental Factors

- Safety
- Distractions
- Conditions
 - temperature, humidity, noise
- Space

Information Factors

- Patient Identification
- Sample Identification
- Physician Identification
- Data compiling
- Report Construction
- Report Transmission
- Data storage
- Date retrieval
- Printing

Error and the Medical Laboratory

Systemic Factors

No Job Description

No training or Poor training

No Continuing Education

No Competency Assessment

Procedure document errors

No maintenance programs

No monitoring program

Worksite environmental factors

Poor safety

Distractions

Poor or Absent Management

Individuals

Slips

Distractions

Health

Venal

Laboratory Errors Cost...

Time

Effort

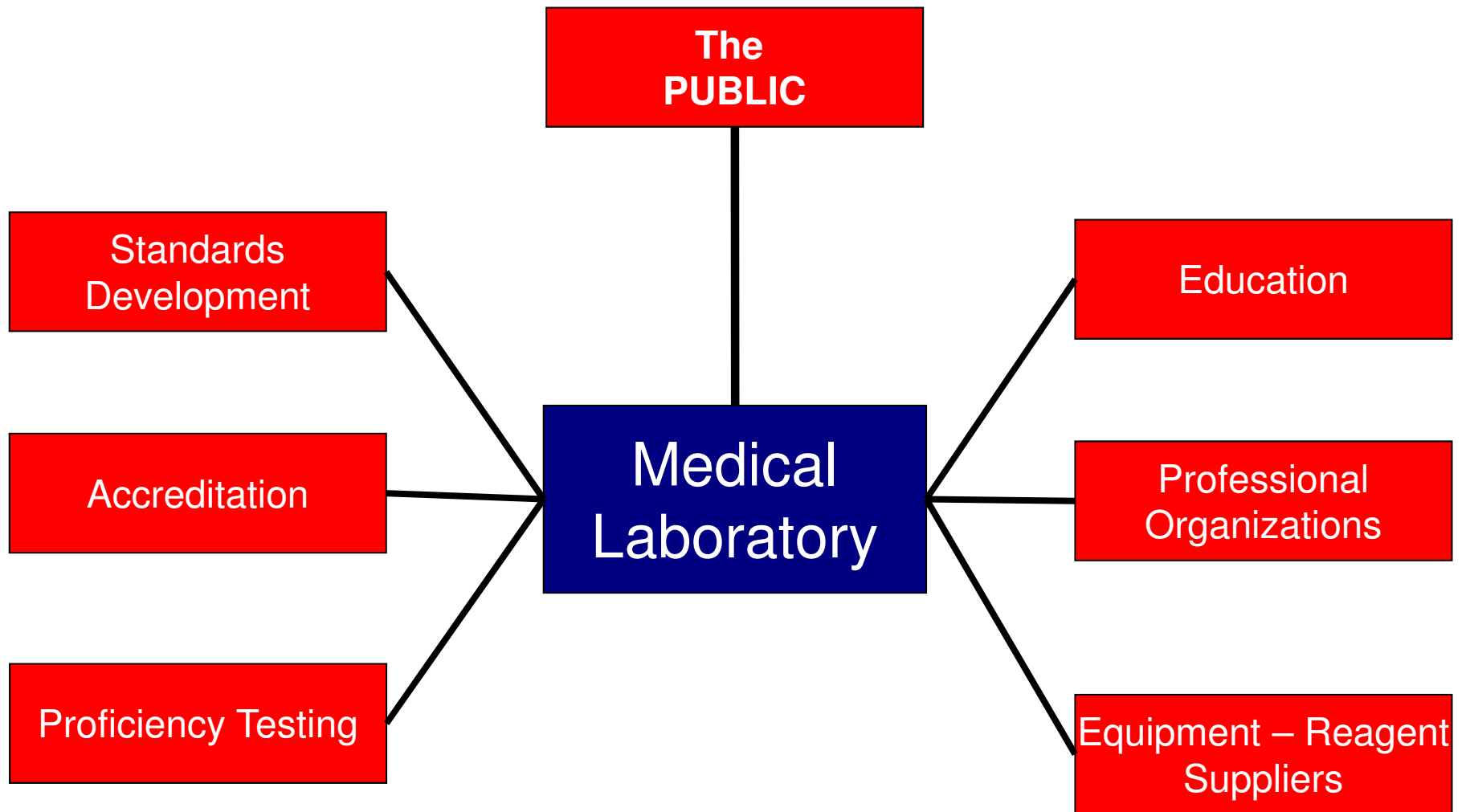
Energy

Money

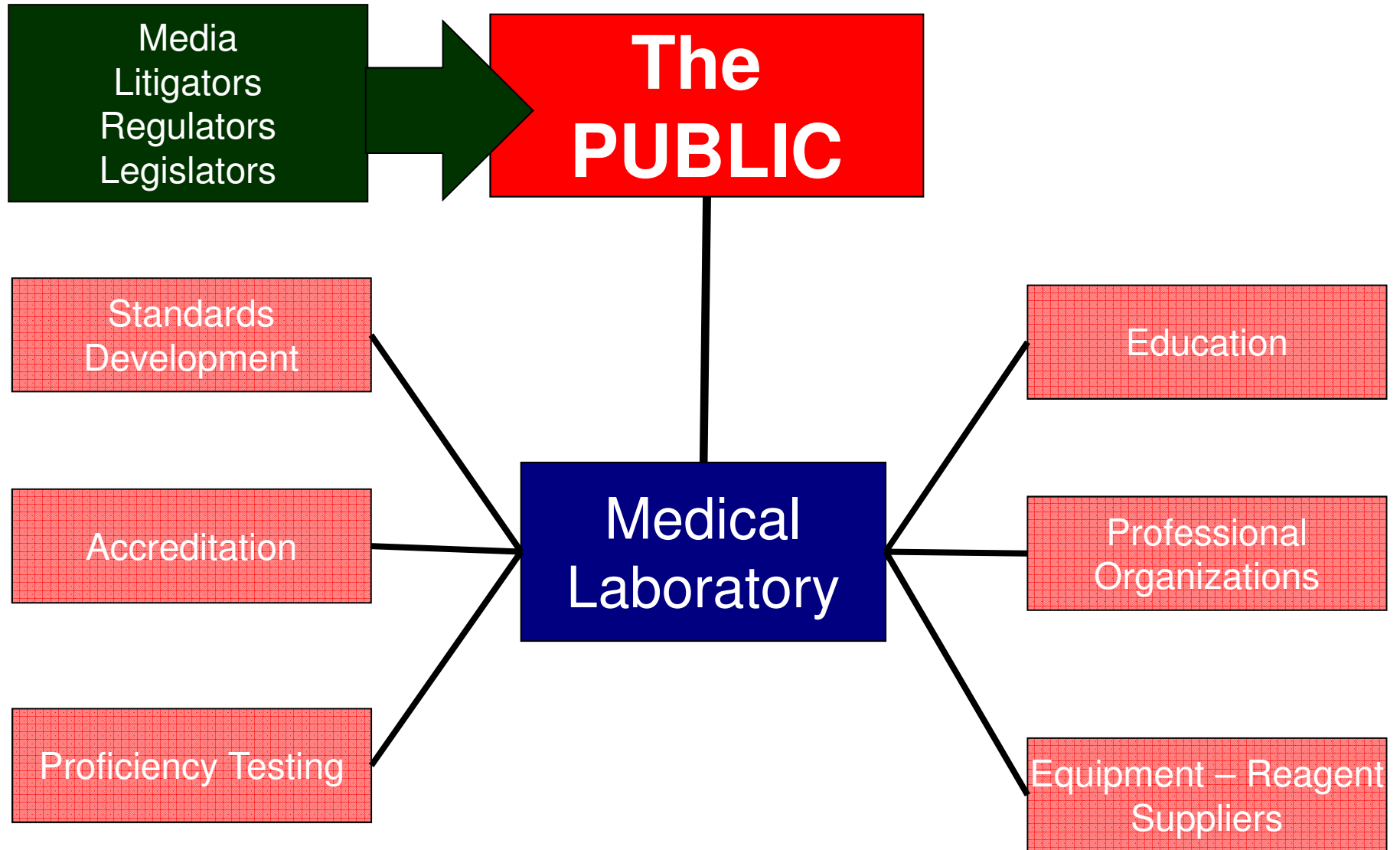
Credibility and Reputation



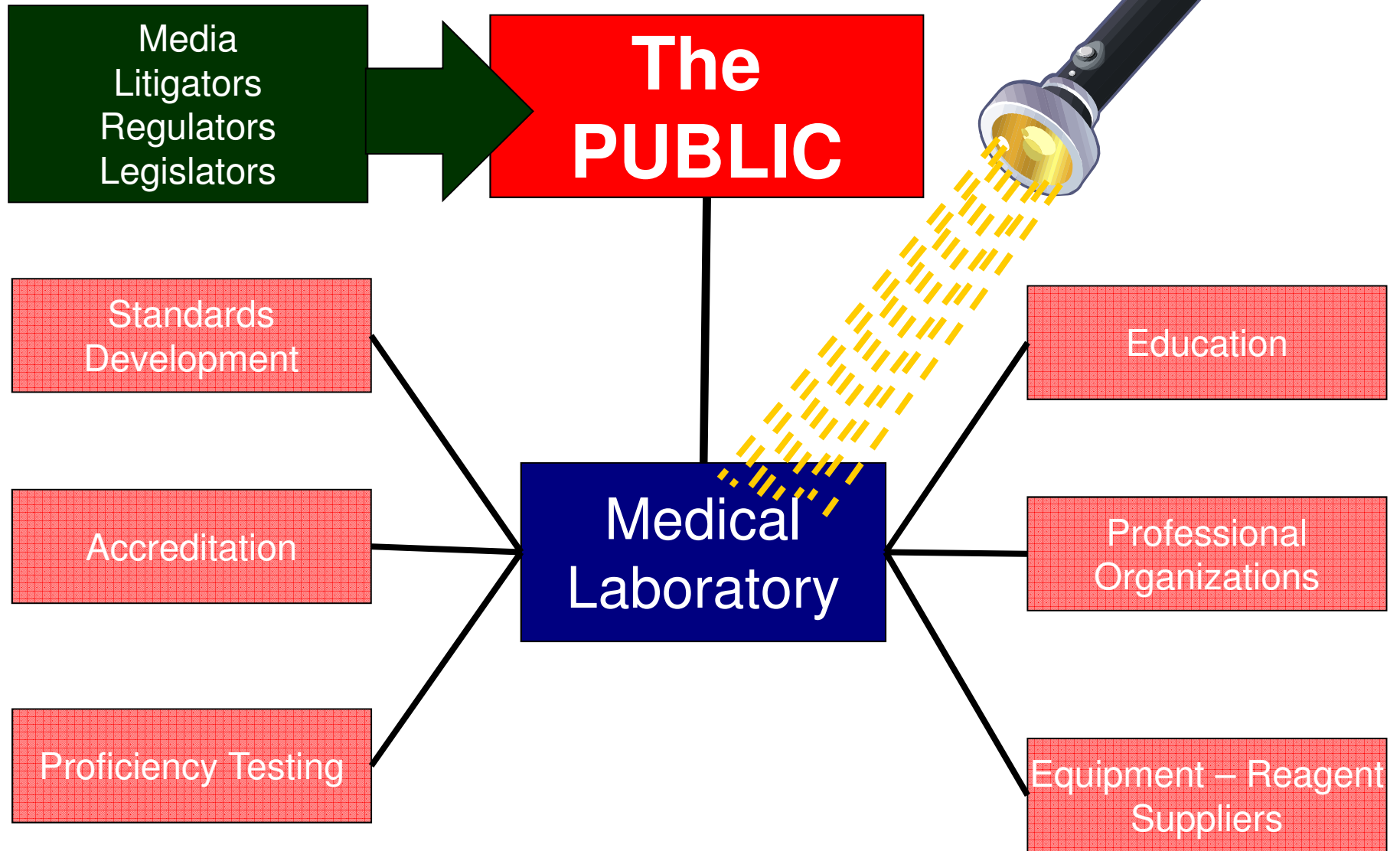
Quality Partners



Quality Partners



Quality Partners



Where is that light shining today?

Canada

- Eastern Health Newfoundland Labrador
- New Brunswick
- Quebec
- Ontario
 - Windsor
 - Laboratory overuse
- Saskatchewan
- British Columbia



Vancouver Sun - April 14, 2005

A chain of events that began in a microbiology laboratory in a Vancouver hospital may have helped avert a global pandemic sent a patient specimen to the National Microbiology Laboratory.

A mistake was found when the Vancouver hospital sent a sample from a female patient to the national lab for further testing to determine what subtype of influenza A she had. It turned out the sample had been cross-contaminated with [a PT sample containing Influenza] H2N2.

A review to find out precisely how the cross-contamination occurred. "It's a problem the lab is addressing. It's always a problem which laboratories can have, because it takes just minute traces for this to happen. "In a perfect world, cross-contamination would not occur..."

The saga of Charles Smith

- 1983 director of Hospital for Sick Children's Program in pediatric forensic pathology
- 1991: Complaints and concerns about interpretations of findings and reports which had lead to inappropriate convictions of parents and baby sitters. Followed by an extensive review of cases. 40 cases reviewed, 20 suspicious.
- 2002: Reprimand
- 2003: No longer allowed to perform autopsies
- 2007: Subject of Goudge Commission of Inquiry.
 - Insufficient training; absence of validation and verification of findings. Misleading statements and exaggerations of expertise.
- 2010: Compensations of \$250,000 per damaged case.

Newfoundland, Labrador 2005

- In May 2005 Eastern Health discovered errors in hormone receptor breast cancer test results from a histology lab in St. Johns, Newfoundland.
- Affected patients had been tested between 1997 and 2005.
- Up to 1,500 patients authorized for retesting based on indications of errors in original test result report.

Newfoundland, Labrador 2005

- After retesting, Eastern Health concluded that 383 patients had received erroneous results, of whom 117 required a change to their treatment programs.
- More than 100 of the women whose lab results were reviewed had died prior to this review.

Newfoundland, Labrador 2005

- A judicial enquiry, on Tuesday [March 2, 2009], reported that the protocols and procedures at the health authority at the centre of a breast-cancer-testing scandal in Newfoundland and Labrador were “so deficient as to be practically non-existent.”

- 2009: Breast cancer testing problems in Quebec.
- 2009: Whistleblower pathologist in Saskatchewan says shortage of pathologists in the province contributes to errors and misdiagnoses.
- 2010: Molecular diagnostics lab at Georgetown University Medical Center closed after failing proficiency testing.

Testing Problems-New Brunswick

February 2008, Miramichi, New Brunswick:

- Pathologist Rajgopal Menon, M.D., left his position as head of pathology at Miramichi Regional Hospital following a review of 227 cases of prostate and breast cancer biopsies from 2004-2005.

Testing Problems-New Brunswick

These independent reviews determined:

- 18% of the cases had incomplete results.
- 3% were misdiagnosed.
- 41 cases included incomplete protocols or examinations and or miscalculated the stage of the cancer.
- Compared to the original diagnosis, there were seven cases of undetected cancer, and four additional cases that were possibly cancerous.

Testing Problems-New Brunswick

- Health officials announced they would review as many as 24,000 cases.
- Menon characterized this review as “unjustified and unfair.”
- He filed a civil suit against the regional health authority.

Testing Problems-Manitoba

May, 2008, Winnipeg, Manitoba:

- Pathologist Robert Stark, M.D., was put on leave from his position as head of the pathology department at St. Boniface Hospital.
- The outside pathology review of this lab, including approximately 822 of the cases diagnosed from February 2008 and complex cancer cases dating back to March 2007, determined that errors were made in at least 42 cases and two patients received the wrong cancer diagnosis due to error.

Pathology Testing-Ontario

May, 2008, Owen Sound, Ontario:

- After routine quality control testing identified an error by pathologist Barry Sawka, M.D., at Owen Sound Hospital, a more detailed review of 600 of his cases was launched.
- Grey Bruce Health Services, the local health authority, determined that the error rate was 6%, which health officials stated was six times the “the normal error rate for pathologists.” These misdiagnoses lead to errors in treating patients.

Windsor Ontario

Thursday, February 25, 2010

Probe into pathology reports could expand

- The Ontario government may consider issuing a directive to hospitals to check their pathology reports in light of revelations that a surgeon at a Windsor hospital performed unnecessary mastectomies on at least two women.
- Thousands of medical cases are currently under review at three hospitals in southwestern Ontario following the suspension of a pathologist.

Testing Problems-Quebec

May/June, 2009: Montreal, Quebec:

- The province's health department has ordered 2,100 new tests after a tiny pathology study exploded on the Quebec scene last week, suggesting that 15 to 30 per cent of breast-cancer tests were botched, throwing patients into a panic about the reliability of their tests and health status.

Montreal Gazette, June 6, 2009

Testing Problems-Quebec

- “Not only are Quebec's ill-equipped, underfunded and short-staffed laboratories under a microscope, but the government was forced to revise its standards and is now setting up a universal quality control program.
- “Effective immediately, all provincial labs will be required to have external audits of their tests. Some labs are already doing that.”

Montreal Gazette, June 6, 2009

Testing Problems-Quebec

- “Gaetan Barrette, head of Quebec's federation of medical specialists, said problems in the labs are long-term and systemic. It's not just breast cancer tests that are at risk, but all cancer testing, Barrette said.”

Montreal Gazette, June 6, 2009

Testing Problems-Quebec

- “St. Mary's Hospital Centre is the only Quebec facility to have a CAP accreditation, and it took a decade to achieve, said chief pathologist Ron Onerheim. Having no quality control program is a red flag, he said.”

Montreal Gazette, June 6, 2009

Quebec Specialists Speak

December 17, 2009 Press Conference

- *“The FMSQ is, however, disappointed that **the detection threshold selected was so high that that one wonders why it was even considered.**”*

*In fact, the great majority of patients whose [estrogen receptor] results ranged from 1% of positive cells to the 10% threshold stated at this morning’s press conference by the Minister and his experts, Drs Bernard Têtu and André Robidoux, **could benefit from an adjustment to their treatment in the same way as the 87 patients identified so far.**”*

Gaétan Barrette, MD, President, Quebec Association of Medical Specialists (FMSQ).

International Laboratory Errors

- 2007-2008: Inaccurate Vitamin D results at Quest Diagnostics Incorporated
(Estimated that as many as 500,000 patients affected over 18 months).
- In 2009, Quest Diagnostics and its subsidiary Nichols Institute Diagnostics entered into **\$302 million settlement** with U.S. Department of Justice related to problems with certain types of lab tests.

Globe and Mail

October 19, 2010

Ontario considers curbing vitamin D testing

Ministry advisory committee disputes health gains, insists money not a factor in recommendation

The much-hyped benefits of vitamin D have become so tantalizing that doctors in Ontario last year ordered nearly three-quarters of a million of the blood tests that determine a patient's level of the sunshine vitamin.

But the growing popularity has become a major issue. The provincial Ministry of Health is mulling over a proposal from its medical advisory committee to eliminate most of the discretion doctors have in asking for the \$50 tests and have them paid by the province.

“... epidemiology [is] a weak form of evidence and remains sceptical about the dramatic claims for vitamin D because they have not been confirmed by major clinical trials...”

What do all these cases have in common?

- Repetition of Problems that existed for a long time.
- No routine system of verification or validation of findings.
- No evidence of internal review.
- Absence or weakness of external monitoring.
- Once identified, the Public is outraged with legal and financial consequences.

There has got to be
a better way
Laboratory Quality Management

*The application of
Modern Quality Management Principles
Based on
Research and Development
Practice and Refinement
1920-2010*

History of Quality for the Modern Medical Laboratory

Michael A. Noble MD FRCPC

UBC Program Office for Laboratory Quality Management

Clinical Microbiology Proficiency Testing program

CSA National Committee for Medical Laboratory Quality Systems

In the Olden Days



Frederick Winslow Taylor

1890-1901

Engineer to management for the Manufacturing Investment Company of Philadelphia. Moved to Bethlehem Steel and developed high efficiency processes and high speed steel.

Known as the Father of scientific management and industrial efficiency

Replace rule-of-thumb work methods with methods based on a scientific study of the tasks. Scientifically select, train, and develop each employee rather than passively leaving them to train themselves.

“Provide” detailed instruction and supervision of each worker in the performance of that worker's discrete task.

Divide work nearly equally between managers and workers, so that the managers apply scientific management principles to planning the work and the workers actually perform the tasks.

Taylorism and the Industrial Process

- Through analysis of work, the "One Best Way" can be found.
- Enforced standardized practices are efficient practices.
- Precision through time and motion study
Henry Lawrence Gantt developer of the Gantt Chart 1910
- Pay for performance. Pay for precision.

Taylorism was immensely unpopular and unsustainable.

Seven Quality Makers



Walter Shewhart



W. Edwards Deming



Joseph Juran



Phillip Crosby



Taiichi Ohno



Armand V. Feigenbaum



Robert Galvin

Walter A. Shewhart

1891-1967

- PhD Physics UC (Berkeley)
- Engineer – Western Electric and Bell Laboratories.
- National Research Center and International Statistical Institute.
- The first integrator of statistical method, economic modelling, and manufacturing.
- The creator of the Quality Control Chart (1921)
 - Levey and Jennings modelled their chart from Shewhart
- The developer of the problem solving process referred to as Plan-Do-Check-Act (1931)

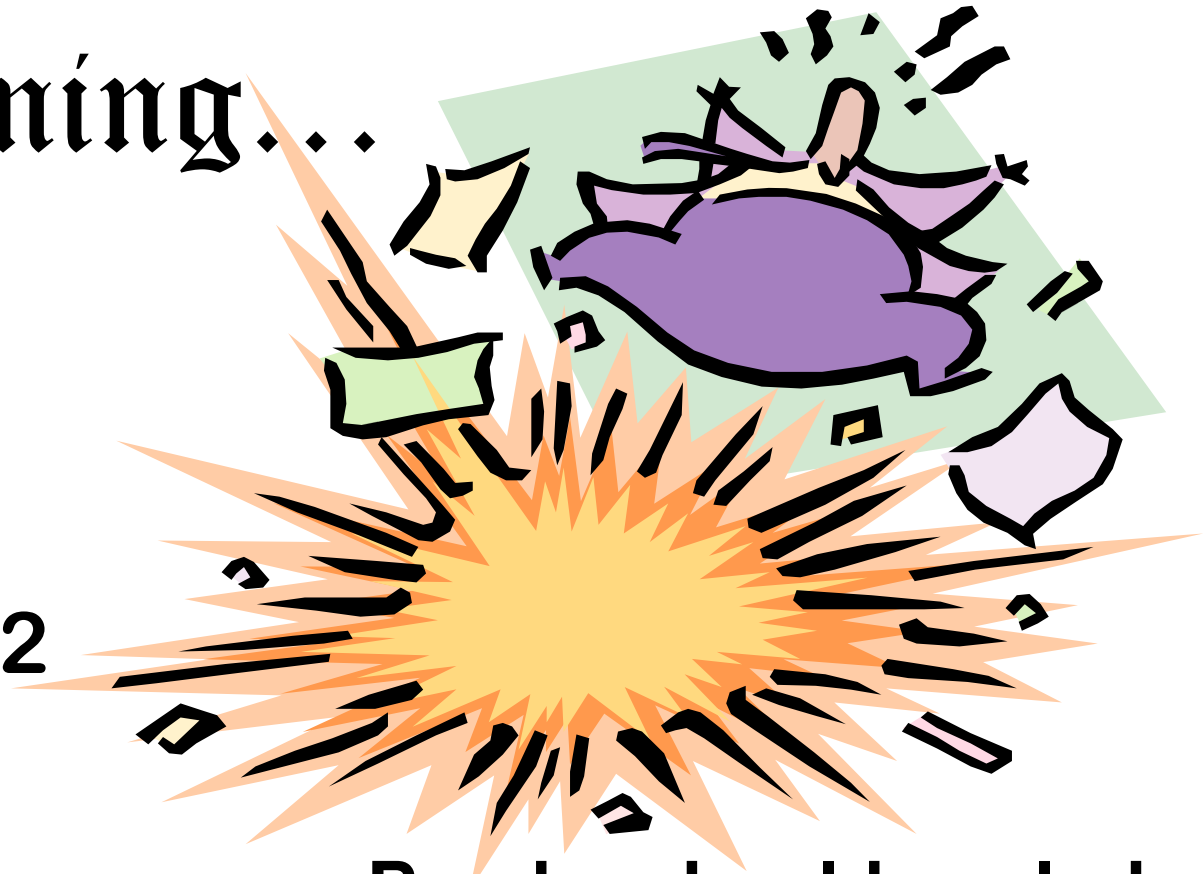
W. Edwards Deming

1900-1993

- Ph.D - Theoretical Physics. Yale university
- Laboratory research in the Department of Agriculture (development of nitrate fertilizers). Lecturer in Statistics.
- 1938-1946 Stanford University co-organizes management seminars with Deming to improve productivity and the quality of military equipment.
- In 1947 sent to Tokyo as advisor to Allied Forces Headquarters
- 1950 starts management seminars for Japanese executives.
- 1981-1993 seminar series for American executives.
- Evolution of PDCA to Plan-Do-Study-Act.

In the Beginning...

Practical
Quality
Policy
1939-1942



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

Deming's 14 Points

- Create constancy of purpose toward improvement of product and service,
- Adopt the new philosophy and take on leadership for change.
- Cease dependence on inspection. Achieve building quality into the product
- End awarding business on the basis of price tag. Move toward a single supplier for any one item, on a long-term relationship of loyalty and trust.
- Improve constantly to improve quality and productivity decrease costs.
- Institute training on the job.
- Institute leadership.
- The aim of supervision is to help people and machines do a better job.
- Drive out fear, so that everyone may work effectively for the company.
- Break down barriers between departments. Promote teamwork
- Eliminate slogans asking for zero defects.
- Eliminate management by objective or numbers. Substitute leadership.
- Remove barriers that rob people of their right to pride of workmanship.
- Institute a vigorous program of education and self-improvement.
- Put everybody in the company to work to accomplish the transformation.

Joseph M. Juran

1904-2008

- Bachelor of Engineering (BEng)-University of Minnesota
- engineer at Western Electric in Cicero, IL (chief for quality inspection).
- 1939-1946 - Lend-Lease Administration. improve purchasing and budgeting for arms and equipment.
- Post WWII taught industrial engineering at New York University.
- In 1951, the first edition *Quality Control Handbook*
- Established as a Quality Consultant.
- Visit to Japan (shortly after Deming) to lecture on quality control.

Philip B. Crosby

1926-2001

BA-Case Western Reserve, Ohio College of Podiatry.

Following WWII Series of Quality positions with Crosley Corp , Bendix Corporation, Martin Marietta Co and finally ITT as Vice President of Corporate Quality.

In 1979, Philip Crosby founded Philip Crosby Associates, which taught management teams how to get things done right the first time.

Author of 14 books on Quality Management.

Critical Crosby Concepts

- 1.Zero Tolerance for Error
- 2.Do it right the first time.

Crosby's 4 Quality Absolutes

- *The definition of quality is conformance to requirements*
 - **First meet the requirements and expectations of the customer.**
- *The system of quality is prevention*
 - **The error that does not occur, does not exist, and cannot be missed.**
- *The performance standard is zero defects*
 - **The purpose of continual improvement is to eliminate error.**
- *The measurement of quality is the price of nonconformance*
 - **Prices of nonconformance are ALL the expenses involved in doing things wrong and all the consequences that follow.**

Crosby's 14 steps to Quality Improvement

1. Management Commitment
2. Quality Improvement Team
3. Measurement
4. Cost of Quality
5. Quality Awareness
6. Corrective Action
7. Zero Defect Planning
8. Employee Education
9. Zero Defect Day
10. Goal Setting
11. Error-cause removal
12. Recognition
13. Quality Councils
14. Do it over again.

Taiichi Ohno

1915-1990

- Engineer – Toyota Motor Corporation
- Ohno participates and studies with Deming in Japan. Recognizes the importance of Keizen (continual improvement).
- 1950 leads the delegation to visit Ford Motor Company. While in Detroit, visits grocery Piggly Wiggly and has a “Eureka Moment” while watching a simple automatic drink resupplier.
- Ohno introduces orderliness to eliminate over-burden (muri), inconsistency (muna) and waste (muda) including:
 1. over-production
 2. motion (of operator or machine)
 3. waiting (of operator or machine)
 4. conveyance
 5. processing itself
 6. inventory (raw material)
 7. correction (rework and scrap)

Armand V. Feigenbaum

1922-

- PhD - Massachusetts Institute of Technology (Engineering and Economics).
- WWII, General Electric: Manager of Quality Control for deployed military supplies.
- 1958-1968: General Electric- Director of Manufacturing Operations.
- *Total quality control is the system for integrating the quality development, quality maintenance, and quality improvement to enable organizations to provide production and service at the most economical levels which allow full customer satisfaction.*

Feigenbaum

Quality Costs and Accountability

- **Close down the "hidden" plant.**
So much extra work is performed in correcting mistakes that there is effectively a hidden plant within any factory that consumes all the resources.
- **Accountability for quality:**
Because quality is everybody's job, it may become nobody's job. Quality must be actively managed and have visibility at the highest levels of management.

Robert Galvin

1922 -

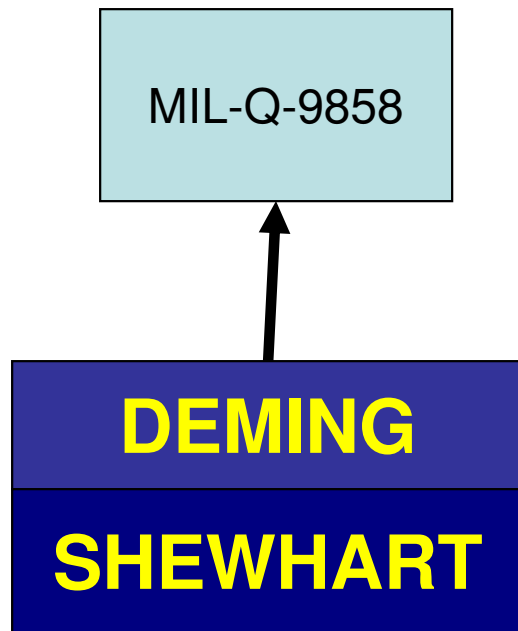
- Attending University of Notre Dame but left when US entered WWII.
- Son of the founder of Motorola
- Rose to President and CEO
- Strong supporter of TQM
- With Engineer Bill Smith Developed the Six Sigma program for Quality Management.

One Quality System

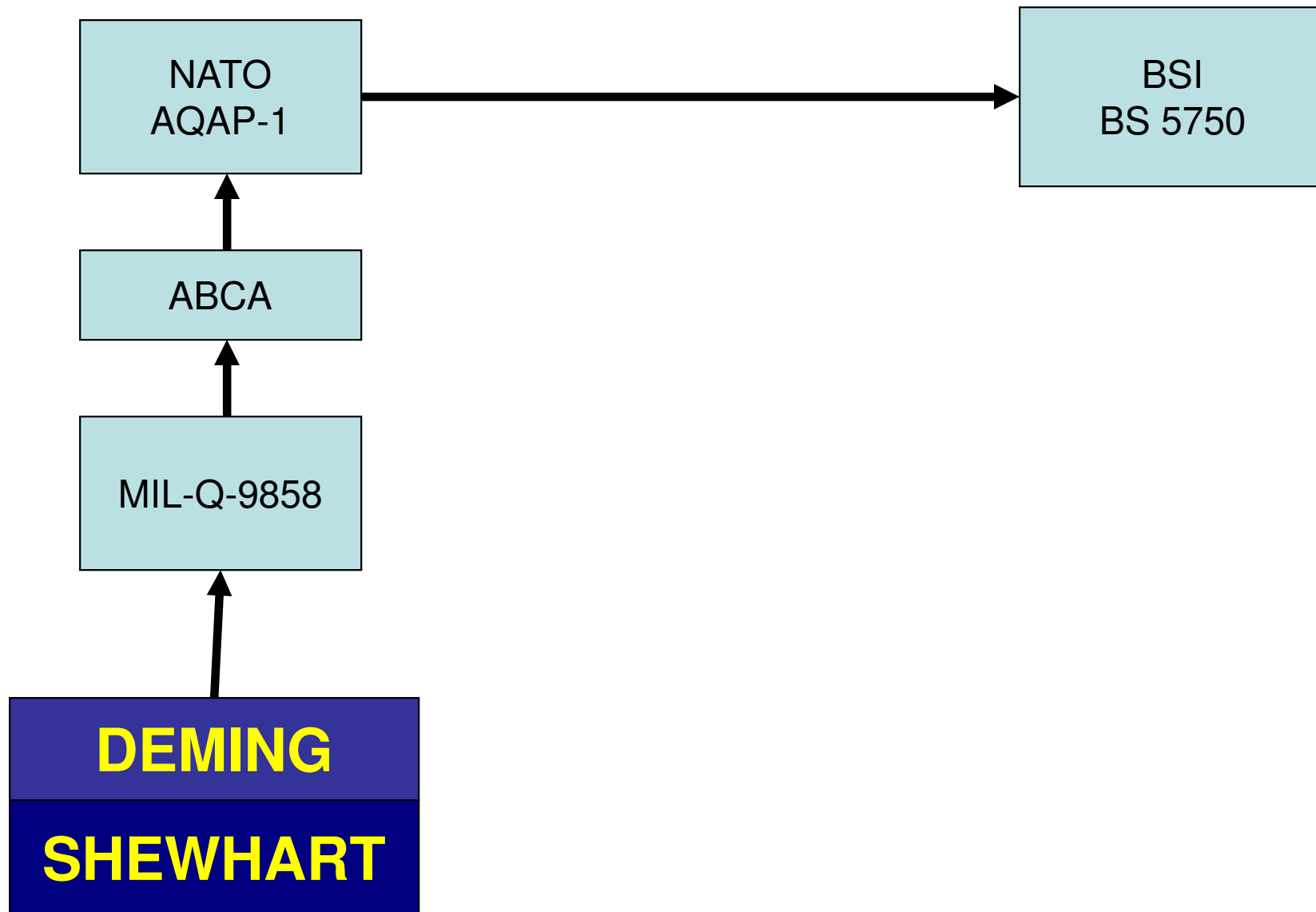
DEMING

SHEWHART

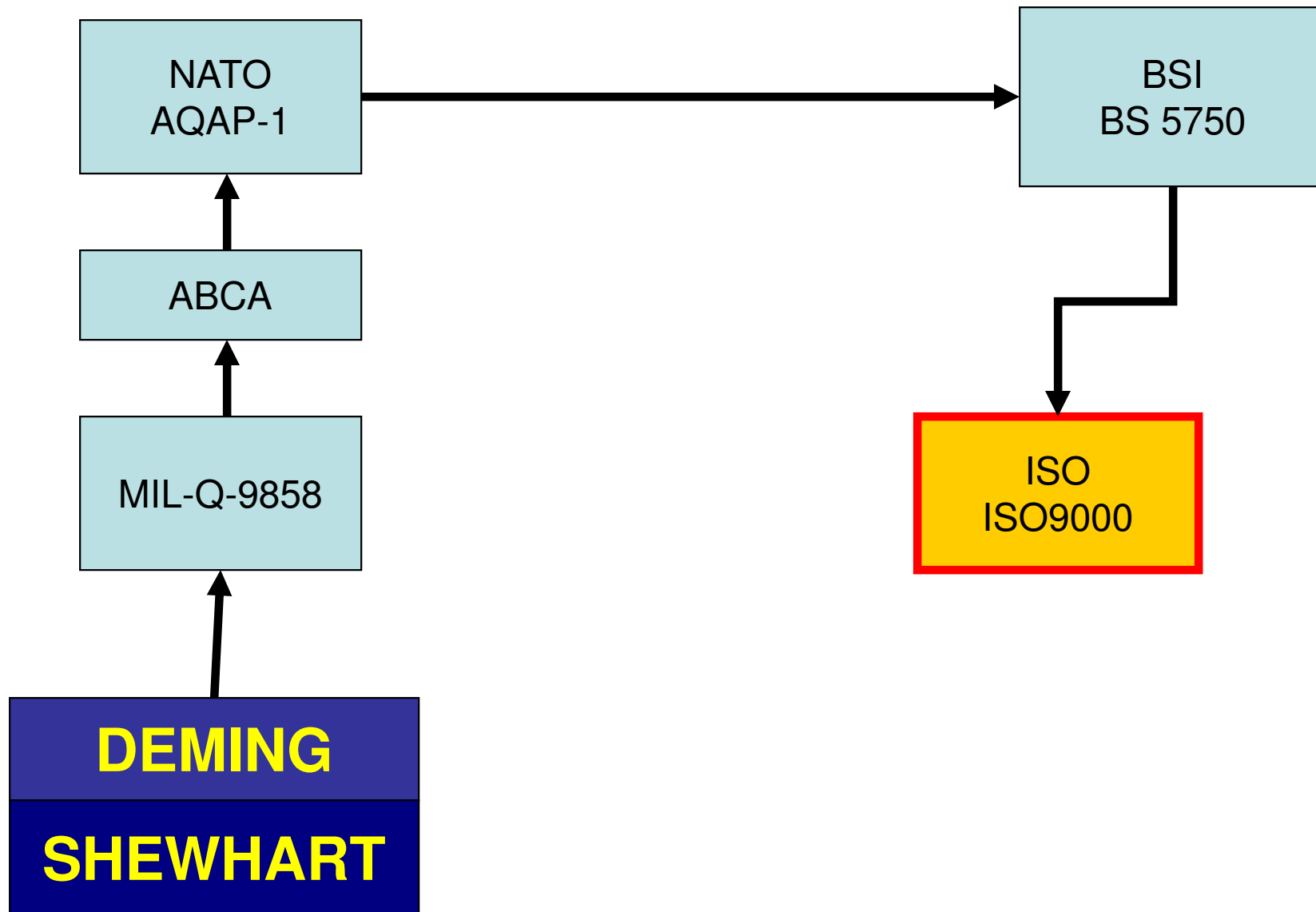
One Quality System



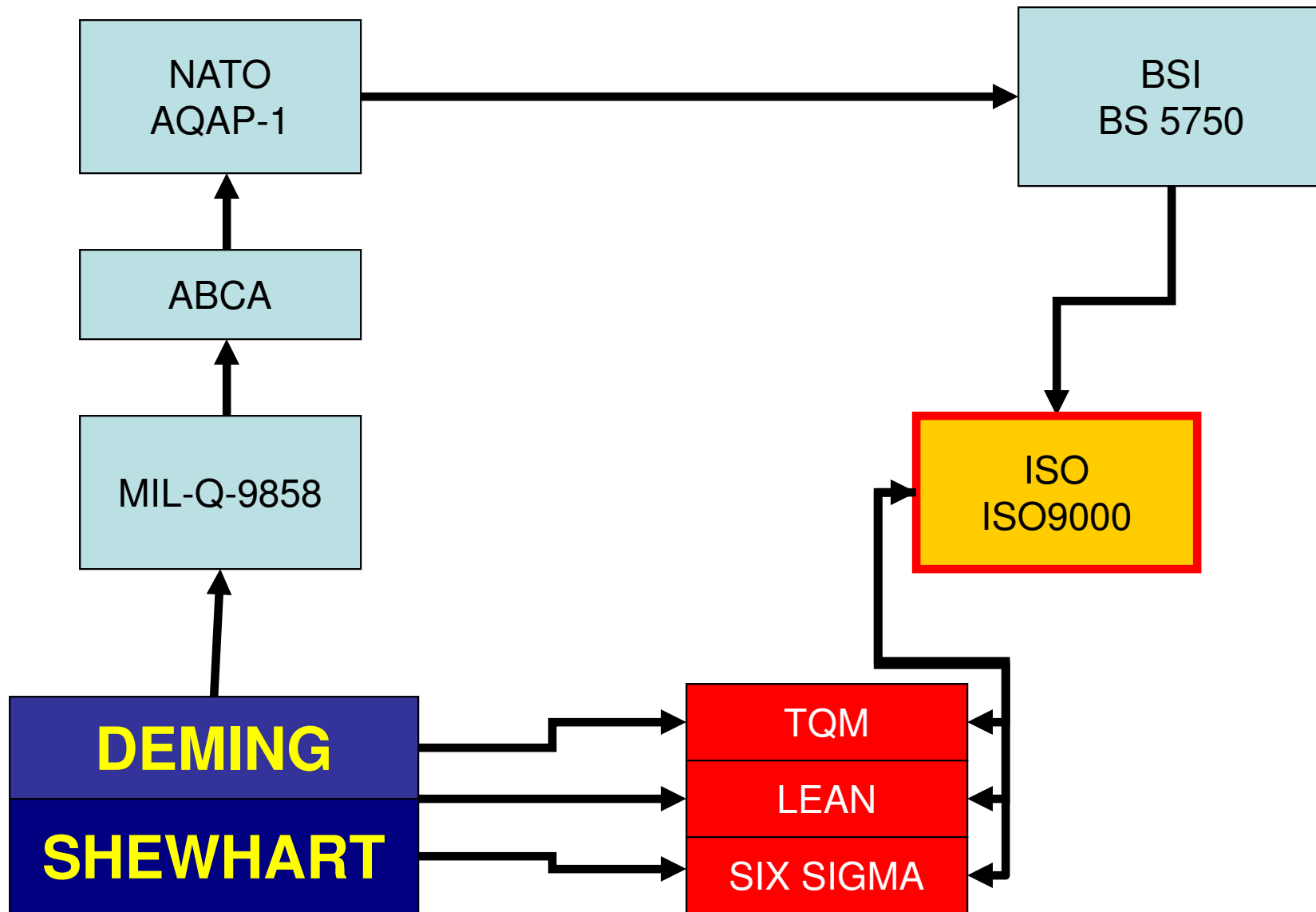
One Quality System



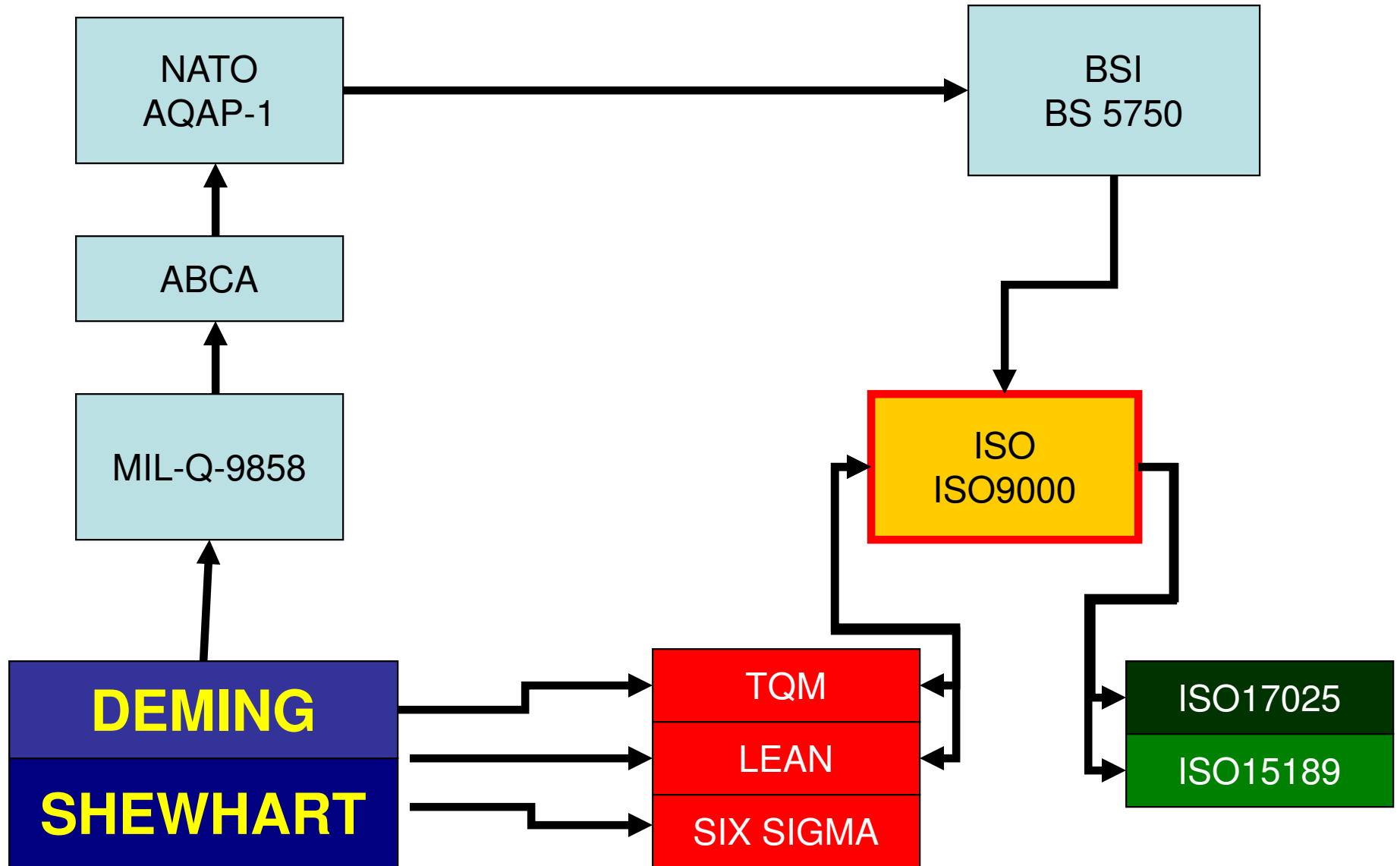
One Quality System



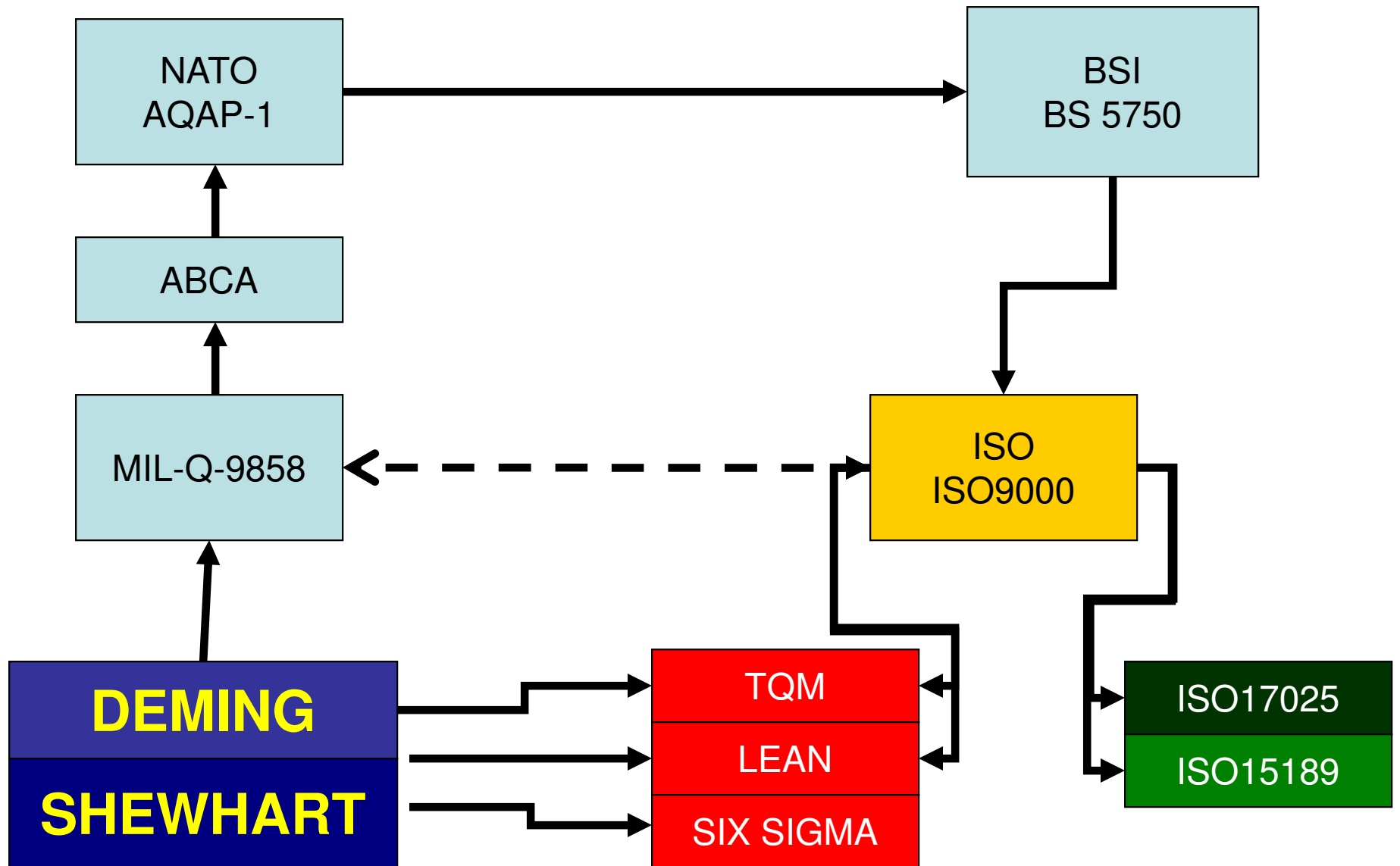
One Quality System



One Quality System



One Quality System



Canada and the Quality Process



Member of ABCA and NATO



Signatory of ISO



Secretariat for ISO 9000



Signatory of ILAC

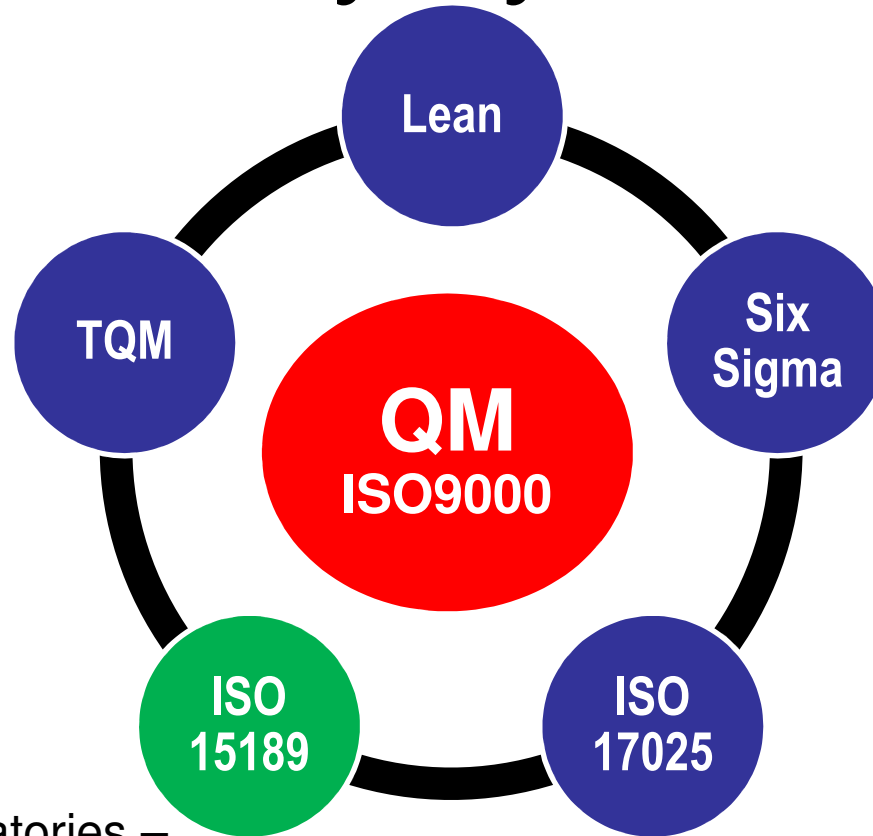


Member ISOTC212

In Summary

- Principles for Quality Management date back more than 60 years.
- Quality Management grew initially from a Military Mandate
- 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.*

There is One Quality System



Medical Laboratories –
Particular Requirements for
Quality and Competence

Some Sites to Visit

- CMPT www.CMPT.ca
- POLQM www.POLQM.ca
- Making Medical Lab Quality Relevant www.medicallaboratoryquality.com
- POLQM Weekend Workshop/ www.POLQMWeekendWorkshop.ca

Pre-Test Results

- 10 Questions
- 24 Responses
- Best Question Performance: 91.3%
- Worst Question Performance: 0
- Mean Performance 43.9%
- Median Performance 43.5%
- Mode Performance 39.1%