Quality Management for the Medical Laboratory

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Chair – Program Office for Laboratory Quality Management
Medical Director for Quality – LifeLabs BC
Books Worth Reading

- The Deming Method by M. Walton (1986)
- CLSI HS1- A Quality Management System Model for Health Care
- CLSI GP26:A3 - Application of a Quality Management System Model for Laboratory Services
Outline

• Why Medical Labs need Quality Management
• Abbreviated History of Quality Management
• History’s evolution to Standards and Guidelines
• Quality Partnerships
• Progress to the Quality Toolbox
Seventy percent of clinical medicine decision making is predicated upon, or confirmed by, or documented by medical laboratory test results.

Dighe, A. S.,
Medicolegal liability in laboratory medicine,
Semin Diagn Pathol, 2007
• In the United States there are between 7 and 10 Billion laboratory tests reported annually.
  Boone DJ, IQLM, 2005

• 15% of patients in a 5 country study receive either incorrect or delayed reports on abnormal results.
  Boone DJ, IQLM, 2005
Management by the Moment
Management by the Moment

You can try to fix them...
But they never go away!

Management by the Moment
So the better approach is…

An systemic approach of organization, plan, review, and action gives you the best chance of success.
Why Medical Labs need Quality Management

• Medical Laboratories
  – Highly complex operations
  – Individuals doing complex tasks
  – Absolute need for Accuracy
  – Absolute need for Confidentiality
  – Absolute need for Time Effectiveness
  – Absolute need for Cost Effectiveness
Quality Management is not new

1922 - Walter Shewhart

Western Electric
Bell Telephone Laboratories
Statistical Process Control
Management Principles

1940 - J Edwards Deming - The Fourteen Points
1. Create **constancy of purpose** of product and service
2. Adopt a new philosophy (**mistakes are unacceptable**)  
3. Cease dependence on mass inspection
4. Stop the process of awarding business on price alone.
**5. Improve constantly and forever** the production and service
6. Institute **training**
7. Institute **leadership**
8. Drive out **fear**
9. **Break down barriers** between staff areas.
10. Eliminate slogans and targets
11. Eliminate numerical quotas
12. Remove barriers to pride in workmanship
13. Institute **vigorous education and retraining**
**14. Take action to accomplish the transformation**
J Edwards Demining – The seven *deadly* diseases

1. Lack of constancy of purpose
2. Emphasis on short term profits
3. Evaluation by performance
4. Mobility of Management
5. Running a company on visible figures alone.
6. Excessive medical costs.
7. Excessive costs or warranty.
• In the U.S. industry did not want to listen
• But Japan did.
Philip Crosby
1926-2001
Doing it right the first time

THE FOUR ABSOLUTES

• Quality is conformance to requirements
• The system of Quality is prevention.
• The performance standard is zero defects
• The measurement of quality is the price of non-conformity.
Philip Crosby
1926-2001
Doing it right the first time

• Quality is conformance to requirements

Who sets the requirements?
✓ Regulators
✓ Respected Authority
✓ Professional Bodies
✓ Customers
✓ Internal Audit
Standards and Quality Management

- Facilities
- Personnel
- Documentation & Control
- Technical
- Assessment
- Continual Improvement
- Customer Satisfaction
- Organization & Management
Standards and Quality Management

- Facilities
- Personnel
- Documentation & Control
- Technical
- Assessment
- Monitor Audit Review
- Continual Improvement
- Customer Satisfaction
- Organization & Management
- Environment and Safety
- Training and Competency
- Policy Process SOPs
- Supply Chain Inventory Equipment Testing Collection Reporting
- Responsibility Authority
- Quality Management
So what happens if you focus all your energy on one component
The system starts to fall apart QUICKLY
But if there is ONE to spend a LOT of time with…
But if there is ONE to spend a LOT of time with…
Continual Improvement through audit and assessment

Internal Audits
Quality Control

ASSESSMENT

EQA
Accreditation
Continual Improvement through Addressing and Preventing error

METRICS (Quality Indicators)

ERROR – OFI- NON-CONFORMITY

Investigate for:
Impact – Underlying Cause - Risk

REMEDIAL
CORRECTIVE
PREVENTIVE

EVALUATE EFFECTIVENESS

MANAGEMENT REVIEW
Continual Improvement through continuing education
CLSI Quality Management
HS01:2001

Service’s Path of Workflow (work operations)
Pre-service  Service  Post-service

Quality System Essentials (QSEs)
- Documents and Records
- Organization
- Personnel
- Equipment
- Purchasing and Inventory
- Process Control
- Information Management
- Occurrence Management
- Assessment: External and Internal
- Process Improvement
- Customer Service and Satisfaction
- Facilities and Safety
A Pathologist from London gave a presentation on how he felt the great responsibility for being the sole person responsible for the quality of his medical laboratory.
A quality story…

EQALM 2007

A Pathologist from London gave a presentation on how he felt the great responsibility for being the sole person responsible for the quality of his medical laboratory.

He felt no relief when he was informed that while he was clearly important he was far from being the sole driver of his laboratory’s quality.
Quality Partnerships

- Laboratory Management
- Standards Development Bodies
- Accreditation Bodies
- Laboratory Quality Management
Quality Partnerships

When the Public shines a light on laboratory quality, smart laboratories listen.
Partners who can provide help
## Organizations: *the quality network*

<table>
<thead>
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Terms and Definitions

**Standard:**
Broad consensus document. Authorized by an authoritative body.

**Guideline:**
Consensus document.

**Regulation:**
A regulatory (licensure) requirement. A regulator can cite any source document.

2/20/2009
Many jurisdictions set their own standards, guidelines, regulations, requirements

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<td>– Lost trade opportunities</td>
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<td>– Lost research opportunities</td>
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<td>– Credibility Gap</td>
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<td>– May exclude opportunities for progress and growth.</td>
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Many jurisdictions set their own standards, guidelines, regulations, requirements

Advantages
- Fast
- Local Expertise
- Local Circumstance

Disadvantages
- Too introspective
- Expertise Gap
- Inconsistent with neighbours
- Lost trade/research opportunities
- Credibility Gap
- May become too detailed (vertical)

Lots of advantages to shared documents

2/20/2009
A Brief History…

• 1995
  The International Organization for Standardization (ISO) (at the request of the United States) invited the international medical laboratory community to a meeting in Philadelphia to discuss the possibility of a single harmonizing standard for medical laboratories
  – Attended by 33 countries from North America, South America, Europe, Asia, Australasia.
ISO Technical Committee 212
Clinical laboratory testing and in vitro diagnostic test systems

• 33 participating countries
  • Argentina (IRAM)
  • Australia (SA)
  • Austria (ON)
  • Belgium (NBN)
  • Brazil (ABNT)
  • Canada (SCC)
  • Chile (INN)
  • China (SAC)
  • Czech Republic (CNI)
  • Denmark (DS)
  • Finland (SFS)
  • France (AFNOR)
  • Germany (DIN)
  • Iran, Islamic Republic of (ISIRI)
  • Ireland (NSAI)
  • Israel (SII)
  • Italy (UNI)
  • Jamaica (BSJ)
  • Japan (JISC)
  • Korea, Republic of (KATS)
  • Malaysia (DSM)
  • Mexico (DGN)
  • Netherlands (NEN)
  • New Zealand (SNZ)
  • Norway (SN)
  • Portugal (IPQ)
  • Singapore (SPRING SG)
  • Spain (AENOR)
  • Sweden (SIS)
  • Trinidad and Tobago (TTBS)
  • Turkey (TSE)
  • United Kingdom (BSI)
ISO Technical Committee 212
Clinical laboratory testing and in vitro diagnostic test systems

- 18 observing countries
  - Bulgaria (BDS)
  - Croatia (HZN)
  - Cuba (NC)
  - Cyprus (CYS)
  - Egypt (EOS)
  - Estonia (EVS)
  - Hong Kong, China (ITCHKSAR)
  - Hungary (MSZT)
  - India (BIS)
  - Luxembourg (ILNAS)
  - Malta (MSA)
  - Mongolia (MASM)
  - Russian Federation (GOST R)
  - Saudi Arabia (SASO)
  - Switzerland (SNV)
  - Thailand (TISI)
  - Uruguay (UNIT)
  - Zimbabwe (SAZ)

2/20/2009
The meeting was attended by the international community of laboratorians:

- Laboratorians
- Accreditation bodies
- Medical Device Manufacturers
- Metrologists
- Calibration authorities
- Medical Laboratory Consultants
- Organizational Representatives
  - CAP, WHO, WASP, OECD, EDMA, IBWM, ELM, IFCC, ILAC
ISO Technical Committee 212

- Working Groups
  - 1 - Quality and competence in the medical laboratory
  - 2 - Reference systems
  - 3 - In vitro diagnostic products
  - 4 - Antimicrobial susceptibility testing
Canadian Participation in
ISO Technical Committee 212

• Canadian Advisory Committee to ISO TC 212
• Required by Standards Council of Canada
• Hosted by Canadian Standards Association
• Participates in all four working groups

• Representatives from all laboratory disciplines.
• Regional representation
• Also responsible for CSA standards for medical laboratories (fume hoods, safety cabinets, sharps containers).
Standards Developed by ISO TC 212

• Seventeen standards in the areas of
  – Laboratory Quality Management
  – Safety
  – Risk
  – Point of Care
  – Calibrators
  – Validation
  – Susceptibility Testing
  – Traceability
  – Label Symbols

• Canadian lead writing teams
ISO 15189
The international standard for medical laboratory quality and competence
Laboratories and their standards: similar but different

2/20/2009
ISO 15189:2007 spans the world

2009

ISO 15189: 2007 is used 65 countries

<table>
<thead>
<tr>
<th>North America</th>
<th>Middle East</th>
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<td>Africa</td>
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<td>Caribbean</td>
<td>Australia</td>
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<tr>
<td>Europe</td>
<td>New Zealand</td>
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</table>

Everywhere except Antarctica
### Not all laboratories are the same

<table>
<thead>
<tr>
<th>Medical</th>
<th>A laboratory of many integrated procedures intended for diagnosis, confirmation, documentation of human health information</th>
<th>Community Hospital Public Health</th>
</tr>
</thead>
<tbody>
<tr>
<td>Testing</td>
<td>A laboratory of limited stand-alone procedures intended to confirm conformity of a product to its expected target or goal</td>
<td>Manufacturing Electrical Water Food Mining Public Health</td>
</tr>
<tr>
<td>Calibration</td>
<td>A laboratory of a very limited range of procedures intended to ensure traceability of equipment or material to highest level possible.</td>
<td>Reference NIST</td>
</tr>
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</table>
ISO 15189:2007
Medical Laboratories – particular requirements for quality and competence.

• First published in 2003
• Adopted as a Canadian National Standard
• Adopted as the basis for provincial accreditation in Ontario, Quebec, Atlantic Canada
• Recognized as the source for quality management in requirements Alberta, Saskatchewan, Manitoba.
• Recognized as a source of quality management requirements in British Columbia
• Quality and competence are holistic issues.
• 15189 is not laboratory discipline specific.
ISO 15189 requirements

Management Requirements
1. Organization
2. Quality Management System
3. Document Control
4. Review of Contracts
5. Referral Laboratories
6. External Services and Supplies
7. Identification and control of non-conformities
8. Corrective Actions
9. Preventive Actions
10. Continual Improvement
11. Quality and Technical Records
12. Internal Audits
13. Management Review

Technical Requirements
1. Personnel
2. Accommodation / environment
3. Laboratory Equipment
4. Pre-examination procedures
5. Examination procedures
6. Assuring quality of examinations
7. Post-examination procedures
8. Reporting Results
15189 Examples

• Organization
  – A medical laboratory shall be a legal entity.
  – Medical laboratories shall be designed to meet patient needs.
  – Laboratory personnel responsibilities shall be defined.
  – Laboratory management shall provide personnel with the resources and authority to perform their duties.
  – Laboratory policies and procedures shall protect confidential information.
  – The laboratory shall appoint a quality manager.
  – The laboratory shall have technical management for overall responsibility of technical operations and the provision of resources needed to ensure the required quality of laboratory procedures.
15189 and the Laboratory Director

- The laboratory shall be directed by a person or persons having **executive responsibility** and the **competence** to assume responsibility for the services provided. *(note: competence is the product of basic, academic, postgraduate, continuing education, and training and experience of several years in a medical laboratory).*

- The laboratory director shall be responsible for **professional, scientific, consultative or advisory organization, administrative and educational matters**.

- *The laboratory director need not perform all responsibilities personally. However it is the laboratory director who remains responsible for the overall operation and administration of the laboratory, for ensuring quality services provided for patients.*
15189 and Management Review

- Laboratory management shall review the laboratory’s quality management system and **all of its medical services**, including examination and advisory activities to ensure their continuing suitability and effectiveness in support of patient care and to introduce any necessary changes or improvements.
- The results of the review shall be incorporated into a plan that includes goals, objectives and action plans.
- The typical period for conducting a management review is once every twelve months.
- Management review shall take into account, follow-up of previous review, status of corrective actions, reports from managers and supervisors, internal audits, assessments of external bodies, quality indicators, outcome of EQA, feedback (complaints), non-conformities, continual improvement processes, evaluation of suppliers.
Laboratory management shall have an organization plan, personnel policies and job descriptions that define qualifications and duties for all personnel.

Laboratory management shall authorize personnel to perform particular tasks.

Personnel shall have training specific to quality assurance and quality management for services offered.

There shall be a continuing education program available to staff at all levels.

Employees shall be trained to prevent or contain the effects of adverse incidents.

The competency of each person to perform assigned tasks shall be assessed following training and periodically thereafter. Retraining and reassessment shall occur when necessary.
15189 and the Quality Manager

• The laboratory shall appoint a quality manager with delegated **responsibility and authority to oversee compliance** with the requirements of the quality management system.

• The quality manager shall report directly to the level of laboratory management at which **decisions are made on laboratory policy** and resources.

• The quality manager shall **plan, organize and conduct internal audits**.
Addressing error

Establish Mechanisms of Detection

Investigate for:
Impact – Underlying Cause - Risk

REMEDIAL  CORRECTIVE  PREVENTIVE

EVALUATE EFFECTIVENESS

MANAGEMENT REVIEW
So, what can you say about quality management and ISO15189?

- Very broad document.
- Consistent with the history and tradition of quality management (PDCA, 14 Essentials, 4 Absolutes).
- Gaining much international use and respect.
- In one form or another, all laboratory physicians will be dealing directly and indirectly with the requirements cited in this document.
The Quality Toolbox

- Surveys
- Six Sigma
- Lean
- Metrics
- RISK
- FMEA
Tools in the Toolbox

• Mega-Tools
  – Lean
  – Six Sigma
  – Priority Matrices and Risk Assessment

• Tools/Techniques
  – Balanced Scorecards
  – Brainstorming
  – Control Charting
  – Flow Charting
  – Quality Indicators
  – Surveys
Historical References to LEAN

1915
Henry Ford

1950
Toyota
Taiichi Ohno

Industry
1988

Health Care
2000

Venetian Ship Building

Benjamin Franklin
Inventory waste

Eli Whitney
replacement parts

Frank Gilbreth
motion studies

Deming

Juran
Henry Ford

- Model T
- 1908-1915
- The automotive assembly line
  - 7 years in development.
  - A “slaughterhouse in reverse”.
  - Mass production by moving the product to the worker.

- Faster
  - 12.5 to 1.5 worker hours/car
- Safer
  - Workers not roaming with tools
- Cheaper
  - Reduced unit pricing for cars
- Worker benefit
  - Highly paid salaries to workers

Unintended consequences both positive and negative shaped and reshaped the world.
Taiichi Ohno

- Toyota Production System
  - American Influences
    - Ford Motor Company
      - Excessive inventory
      - Workload was excessive and uneven
    - Piggly Wiggly Foods
      - Reordering and restocking inventory when needed
      - Just in Time ordering.
  - TPS is designed to
    - remove overburden (muri) and inconsistency (mura), and eliminate waste (muda).
• **The right process will produce the right results**
  – *Build a culture of stopping to fix problems, to get quality right the first time*
  – *Standardized tasks are the foundation for continuous improvement and employee empowerment*
  – *Use only reliable, thoroughly tested technology that serves your people and processes.*

• **Add value to the organization by developing your people and partners**
  – Grow leaders who thoroughly understand the work, live the philosophy, and teach it to others.
  – Develop exceptional people and teams who follow your company's philosophy.
  – *Respect your extended network of partners and suppliers by challenging them and helping them improve.*

• **Continuously solving root problems drives organizational learning**
  – Go and see for yourself to thoroughly understand the situation Make decisions slowly by consensus, thoroughly considering all options; implement decisions rapidly;
  – *Become a learning organization through relentless reflection and continuous improvement.*
# TPS (LEAN) JARGON

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<tr>
<th>Term</th>
<th>Description</th>
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<td>Muri, Mura, Muda</td>
<td>Overburden, Inconsistency, Waste</td>
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<tr>
<td>Seiri, Seiton, Seiso, Seiketsu, Shitsuke</td>
<td>Sort, Straighten, Shine, Standardize, Sustain</td>
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<tr>
<td></td>
<td>- Keep what you need; throw out the rest.</td>
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<td>- A place for everything and everything in its place.</td>
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<td></td>
<td>- Keep your workplace neat and clean.</td>
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<td></td>
<td>- Keep work practices consistent</td>
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<td>- Maintain and review your standards</td>
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<td>Five S</td>
<td>Tracing the Work Flow: Maximize Value – Eliminate waste</td>
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<tr>
<td>Value Streams</td>
<td>“Pull” performance – Piggly Wiggly Performance</td>
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<tr>
<td>Kanban</td>
<td>Reflection and Continuous Improvement</td>
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<tr>
<td>Poka Yoke</td>
<td>Error Proofing</td>
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<tr>
<td>Gemba</td>
<td>Go and See</td>
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</table>
Value Streams

Activity transforms - waiting is waste
Activity flows through pools of waste
Customers value active transformation and abhor waste
Value streaming: IDENTIFYING PROCESS WASTE

- COLLECTION
  - ACCESS
  - AVAILABILITY
  - COMPETENCY

- INVENTORY PROCESS
  - MONITORING
  - AVAILABILITY
  - ORDER
  - DELIVER

- CHECKING PROCESS
  - VERIFICATION
  - VALIDATION

- TRANSPORT
  - ACCESS
  - AVAILABILITY
  - ACTIVITY
  - ACCURACY

- TESTING PROCESS
  - PERSONNEL
  - EQUIPMENT
  - WORKSPACE
  - ENVIRONMENT

- INTERPRETATION PROCESS
  - CLINICAL
  - RELEVANCE
Process Mapping
Pre-Examination Procedures

**Physician**
- See patient
- Go to station
- Find chart
- Find order page
- Write order
- Flag chart
- Put in right pile
- Check order
- Transcribe order
- Contact lab

**Phlebotomists**
- Phlebotomist leaves
- Phlebotomist goes to ward
- Check room
- Find patient
- Check armband
- Check order
- Check requisition
- Check tubes
- Draw blood
- Check tubes
- Sign off requisition
- Time punch requisition
- Package Tubes
- Transport tubes

**Accessioning**
- Sample checked in
- Requisition time punched
- Sample unpackaged
- Tubes confirmed
- Tube numbers created
- Tubes number labeled
- Tube tops removed
- Centrifugation
- Aloquoting
IDENTIFYING WASTE IN LABORATORY TESTING

- **WAITING** for a test order
- **WAITING** for a requisition
- **WAITING** to collect a sample
- **WAITING** to transport a sample
- **WAITING** to accession a sample
- **WAITING** to start processing a sample
- **MOVING** to collect reagents at a distant location
- **MOVING** from one work station to another
- **SEARCHING** for an instrument or material essential for processing a sample
- **WAITING** to complete processing a sample
- **WAITING** to create a report
- **CREATING** an excessive report
- **CREATING** an non-interpretable report
- **WAITING** to transport a report
- **WAITING** for a report to be read
- **WAITING** for report-generated action
- **WAITING** to contact a report recipient
Reducing WASTE in the Medical Laboratory

- At-source Order Entry
- No-wait transport.
- Condensed workspace
- Structured workspace
- Continuous flow processing
- Automated Reporting
- Auto-released reporting
- Auto-interpreted reporting
Reducing WASTE in the Medical Laboratory

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Reducing WASTE in the Medical Laboratory

- Faster data entry
- Faster transport
- Reduced motion
- Faster report release
- Less tech time

- More entry error
- More transport cost
- More inflexibility
- Less personal report
- More I.T. time
LEAN’s Kanban trigger system

• A notification system that once activated triggers a response to start another process going.

• “Think about inventory notification cards”
  – If you can see this card, you are soon to run out of materials. Time to order more.
Poka Yoke: Error Proofing

- Placing workable limits that prevent an action from going wrong.
- In mechanical systems, it means adding design features that allow two units to only work in one position.
- An example in ECG testing
POKA YOKE reduces ECG Errors

RED RIBBON
RIGHT SIDE
RIGHT ARM
RIGHT WAY
IDENTIFYING PROCESS WASTE

**391x560**

**57x71**

**144x61**

**385x67**

**147x538**

**112x90**

**IDENTIFYING PROCESS WASTE**

- **5S**
- **Poka yoke**
- **INVENTORY PROCESS**
  - MONITORING
  - AVAILABILITY
  - ORDER
  - DELIVER
- **CHECKING PROCESS**
  - VERIFICATION
  - VALIDATION
- **TESTING PROCESS**
  - PERSONNEL
  - EQUIPMENT
  - WORKSPACE
  - ENVIRONMENT
- **INTERPRETATION PROCESS**
  - CLINICAL
  - RELEVANCY
- **COLLECTION**
  - ACCESS
  - AVAILABILITY
  - COMPETANCY
- **TRANSPORT**
  - ACCESS
  - AVAILABILITY
  - ACTIVITY
  - ACCURACY
Six Sigma: Quantitative Continual Improvement
Quality Management

- Organization & Management
- Facilities
- Personnel
- Documentation & Control
- Technical
- Assessment
- Customer Satisfaction
- Continual Improvement

Quality Management
When pretty good is not good enough

- In 1980 Canada Post did a study which demonstrated that 98 per cent of business mail was delivered on time.
- The conclusion was the Canada Post was working well.

But…
With 2 percent late mail…

- Canada Post delivered 50 Million pieces of business mail daily.
- Which meant another 1 million pieces of business mail were delivered late.
- And each year 260 million pieces of business mail were delivered late.
- With 10 million business mail receivers, each mail receiver could expect at least 2 late business mail deliveries every month.
Opportunity of Improvement for Canada Post

- Implement a quality management system
- Investigate why so many letters were being delivered late.
- Implement a plan to improve letter delivery.
- Develop a process for continual improvement
What is the Performance on a Test?

Sensitivity: 98 percent  Specificity: 99 percent
Prevalence in the Community of 100,000 people
0.1 per cent
Of 3056 positive tests,
2985 (99.3%) will be FALSE positives

Community of 100,000 with 10 per cent prevalence
Of 10,790 positive tests
990 (9.2%) will be FALSE positive
A March through Quality History

- BSI
- ISO
- ISO 9000
- ISO 17025
- ISO 15189
- NATO
- ABCA
- US Military
- Deming
- Shewhart
- CDC
- CLSI
- WHO
- THE WORLD

The diagram illustrates the evolution of quality standards and concepts from historical figures and organizations to modern international standards.
Galvin Manufacturing to Motorola

- Cellular Telephones
- Computer Parts
- Television
- Radio
- Battery Eliminator

Galvin Manufacturing
Galvin Manufacturing to Motorola

1986
Six Sigma
Continual Improvement

Cellular Telephones

Computer Parts

Television

Radio

Battery Eliminator
• In the U.S. industry did not want to listen
• But Japan did.
Six Sigma Cycle of Improvement

• **DMAIC**
  
  • *Define* process improvement goals that are *consistent* with customer demands and the enterprise strategy.
  
  • *Measure* key aspects of the current process and collect relevant data.
  
  • *Analyze* the data to verify cause-and-effect relationships. Determine what the relationships are, and attempt to ensure that all factors have been considered.
  
  • *Improve* or optimize the process based upon data analysis using techniques like Design of experiments.
  
  • *Control* to ensure that any deviations from target are corrected before they result in defects. Set up pilot runs to establish process capability, move on to production, set up control mechanisms and continuously monitor the process.
### Comparing Cycles

<table>
<thead>
<tr>
<th></th>
<th>PLAN</th>
<th>MEASURE</th>
<th>DO</th>
<th>CHECK</th>
<th>ACT</th>
<th>CERTIFY ORGANIZATION</th>
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<tr>
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Six Sigma Jargon

- EXEC
- LEAD
- Champions
- Master Black Belt
- Black Belt
- Green Belt
- Yellow Belt
- Team Members
# Definitions

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
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<tbody>
<tr>
<td><strong>Champion</strong></td>
<td>The Six Sigma Boss&lt;br&gt;Assigns and is Responsible for All Projects</td>
</tr>
<tr>
<td><strong>Master Black</strong></td>
<td>Hands on expert. &lt;br&gt;Mentors Black Belts and Below</td>
</tr>
<tr>
<td><strong>Black</strong></td>
<td>4-8 weeks of training&lt;br&gt;Full time team leader&lt;br&gt;Lead at least 1 major project to completion</td>
</tr>
<tr>
<td><strong>Green</strong></td>
<td>2-4 weeks of training&lt;br&gt;Part time practitioner&lt;br&gt;Implements 2-3 projects per year</td>
</tr>
<tr>
<td><strong>Yellow</strong></td>
<td>1 week of training&lt;br&gt;Participates in a number of projects per year</td>
</tr>
</tbody>
</table>
Who Makes a Green Belt a Green Belt?

• The Company
• The Company can hire a Six Sigma company
• In industry Sigma Belts have:
  – Caché
  – Credibility
  – Ties to income
Six Sigma Calculations

\[f(x) = \frac{1}{\sigma \sqrt{2\pi}} e^{-\frac{x^2}{2\sigma^2}}\]
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<th>Defects per Million Operations (DPMO)</th>
<th>Percent Error</th>
<th>Efficiency</th>
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What is improvement

• As DPMO goes down, Sigma goes up
• Operational goals should apply
  – What is desirable?
  – What is achievable?
  – What is affordable?
• A 1.5 short term Sigma Shift approximates an achievable long term expectation.
What Does Six Sigma Contribute?

• A reiteration of Shewhart and Deming for project oriented continual Improvement.

• A structured method for continual improvement.

• A structured mathematical model for enumerating error and improvement.
And in summary…

- Quality Management is an active process.
- Quality Management is framed on a Quality System.
- Quality Management activities are improved by using the Quality ToolBox.
In conclusion:

• Medical laboratories have a requirement and an expectation for quality.
• Medical laboratories have a network of quality partners with whom to interact.
• Medical laboratories have a history of quality management from other sectors from whom they can learn.
• Medical laboratories have an international standard upon which they can base their quality management.
Every Laboratorian has a responsibility and an obligation to be informed about quality and its management.