
Michael Noble MD FRCPC
CMPT/POLQM
University of British Columbia
Vancouver BC Canada
mnoble@mail.ubc.ca
What is Quality Management?

Quality Management is a systematic approach to organizational improvement.

Today’s Quality Management Systems are the end product over 100 years of knowledge and experience.

Quality Management Systems provide a composite approach to address and protect:

- Organization
- Suppliers
- Institutions
- Management
- Customers
- Community
- Staff
- Partnerships
- Environment

from the hazards and risks associated with faulty and inconsistent practices which result in dissatisfaction, unacceptable outcomes.
Why Quality Management?

The benefits of an active Quality Management System are too powerful to disregard.

- A structured approach to organization and management
- More knowledgeable and effective management
- More knowledgeable and cohesive staff
- Organizational harmony and culture
- More effective and efficient delivery of product and service
- Fewer errors (especially repeat errors!)
- Reduced cost and increased savings
- Greater management and staff satisfaction
- Greater customer satisfaction
- Greater community satisfaction
- Reduced risk
- Reduced liability
Many Avenues to Medical Laboratory Quality Management
• In 1994 the international community of medical laboratories met to discuss if there was a need to create a set of Quality requirements to help standardize the management principles for medical laboratories anywhere in the world.
What is ISO 15189:2012?

• With the authority of the International Organization for Standardization (ISO) the document developed was entitled *ISO 15189:2003 - Medical Laboratories: Particular Requirements for Quality and Competence*

• The document is now in its third iteration.
<table>
<thead>
<tr>
<th>Why Adopt ISO 15189:2012?</th>
<th>ISO 15189 has many positive features:</th>
</tr>
</thead>
<tbody>
<tr>
<td>It has been embraced in total or in part by medical laboratories in more than 55 countries.</td>
<td>It was developed by representative from 33 different countries representing regions across all continents (except Antarctica).</td>
</tr>
<tr>
<td>It is written consistent with internationally accepted precepts of Quality Management.</td>
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<tr>
<td>It is consistent with the common practices accepted by medical laboratories.</td>
<td></td>
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<tr>
<td>It is consistent with accreditation body requirements for Quality everywhere in the world.</td>
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</tr>
<tr>
<td>ISO requires regular review and if appropriate, refreshment, every 5 years</td>
<td></td>
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</table>
The following principles apply to adopting any voluntary Quality Management standard:

1. Read the document.
2. Does it meet your needs?
3. Perform a Gap Analysis
4. Prepare the Laboratory
5. Develop an implementation plan
6. Repeat the Gap Analysis?
7. Determine your state of readiness
8. Make the Accreditation decision
9. Commit to the standard
Steps to Adoption

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Steps to Adoption

1. Read the document.
1. Read the document.

- International standards follow precise language patterns that can make interpretation challenging.
  
  - **Normative statements**
    
    - These are statements within the standard that are REQUIRED. They use the word “**SHALL**” which is understood to mean “**MUST**”.
    
    - Standard writers try to avoid the term “**SHALL NOT**”. Every attempt to avoid the negative is made. This can cause complication or confusion.
1. Read the document.

- **Informative statements**
  - These are statements within the standard that are used for recommendations or guidance. They use the words such as "MAY" or "SHOULD" or "CAN" or "IT IS RECOMMENDED THAT". These are not requirements, but should be considered as helpful advice.

- **Conditional statements**
  - In some situations, Terms such as "TO THE EXTENT POSSIBLE" are used with normative clauses. This means that the requirement would apply, unless there is an extenuating circumstance, such as a over-riding national regulation which would take priority.
1. **Read the document.**

— **Style**

— *Standards are written using generalized statements.*
  Standards are not regulations. They are not written to specifically cover every situation and circumstance.

— *Standards are written concisely.*
  Standards tend to use very clipped language which may be both subtle and nuanced. Standards are not books and rarely contain more than 30 pages of text. While they may contain informative statements, the true meaning of standards may be open to interpretation.
1. **Read the document.**

- Take away message when considering adopting a new standard.
  - *The more you learn, the more you know.*

There is value in learning more about voluntary standards from informed people before making a final commitment to adopt and embrace them for your organization.

- Conferences
- Courses
- Colleagues
- Consultants
2. Does it meet your needs?
2. *Does it meet your needs?*

- Adoption of Voluntary standards has costs:
  - **TIME:** Count on 2-5 person-years of time
  - **EFFORT** May require physical changes
  - **ENERGY** Many decisions and changes will be made
  - **MONEY** Overtime
    - Consultants
    - Accreditation
    - Active Program Changes.
2. *Does it meet your needs?*

- Adoption of Voluntary standards should be a business decision with a cohesive business cost-benefit plan.
  - Can we afford to adopt the standard?
  - Can we afford to maintain the standard?
  - Will the standard pay for itself over time?
  - Can we afford to **NOT** adopt the standard
Steps to Adoption

3. *Perform a Gap Analysis*
3. Perform a Gap Analysis

- W. Edwards Deming and the Quality Cycle
3. Perform a Gap Analysis

- W. Edwards Deming and the “Standards” Cycle
What is a *Gap* Analysis?

Where I am **NOW**

Where I **WANT TO BE** Tomorrow
What is a *Gap* Analysis?

Where I am **NOW**
- Select External Internal Auditor

Where I **WANT TO BE** Tomorrow
- Perform External Internal Audit
- Define and Calculate GAP
- Establish Next Steps
What is a *Gap* Analysis?

**GAP ANALYZER’S TASK**

- Formal True Review
- Measure Performance
- Provide Report
- Provide Recommendations

**Where I am NOW**

- Select External Internal Auditor

**Where I WANT TO BE Tomorrow**

- Perform External Internal Audit
- Define and Calculate GAP
- Establish Next Steps
What is a **Gap Analysis**?

**Where I am NOW**
- Select External Internal Auditor
- Perform External Internal Audit

**Where I WANT TO BE Tomorrow**
- Define and Calculate GAP
- Establish Next Steps

<table>
<thead>
<tr>
<th>REQUIREMENTS ASSESSED</th>
<th>REQUIREMENTS MET</th>
</tr>
</thead>
<tbody>
<tr>
<td>120</td>
<td>110</td>
</tr>
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</table>

92%
Steps to Adoption

4. *Prepare the Laboratory*
4. Prepare the Laboratory

Feigenbaum Rule

While Management has 80 percent of the responsibility for Quality and Change Management, if everyone does not participate, the chances for success are NIL.
4. Prepare the Laboratory

- Information
- Culture
- Education
- Guidance
4. Prepare the Laboratory

- Developing a Culture of Quality
- Leading through Shared Responsibilities
- Information
- Education
- Guidance

- Progress Reports Timetable
- Continuing Education and Dialogue
Many Faces to Continuing Education

Lunch and Learn” Seminars
Discussion Programs
Internal Speakers
Invited Speakers
Workshops and Conferences
Educational Postings
Newsletters
Blogs
Twitter
4. Prepare the Laboratory

Organizational Culture

1. A *measurable* pattern of such collective behaviors and assumptions that people share within an organization.

2. The meanings that the people attach to their actions

3. Organization values, visions, norms, working language, systems, symbols, beliefs and habits.

4. Organizational culture affects the way people and groups interact with each other, with clients, and with stakeholders.

5. The pattern of behaviours and values that are taught to new organization members.
Culture of Quality

Practice of Quality

Culture of Quality
4. Prepare the Laboratory

As you go through the process of preparation consider:

1. If you are running a successful laboratory, you likely only need fine tuning rather than an overhaul.
2. The concept of “Meet or Exceed” standards is NONSENSE.
3. When writing procedures, write down WHAT YOU ARE DOING and not WHAT YOU WANT OTHERS TO THINK WHAT YOU ARE DOING.
4. If there is a HARD WAY and an EASY WAY, do it the EASY WAY.
5. The point of the exercise is to build a SUSTAINABLE CULTURE that will support SUSTAINABLE PRACTICES.
5. Develop an Implementation Plan

There are a number of laboratory domains that will likely need revisions:

1. Policies, Mission, Vision
2. Quality Indicators (Measurement tools)
3. Document Creation and Document Control
4. Supply Management
5. Physical Plant
6. Equipment
7. Quality Control routines (including Measurement Uncertainty)
8. Personnel training and competencies
9. Proficiency testing
10. Management Review
Steps to Adoption

5. Develop an implementation plan
5. Develop an Implementation Plan

Set your Goals with Identified Tasks, Assigned Responsibilities and Achievable Timelines.

Start with the Major Deficiencies on the Gap Analysis.

Fine tune the Minor Deficiencies

Keep Everyone informed about Progress

Stick to the Plan
### Gantt Chart your plan

<table>
<thead>
<tr>
<th>Time</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
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## Timetable to Success
### How long does preparation take?

<table>
<thead>
<tr>
<th></th>
<th>6 mo</th>
<th>9 mo</th>
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<th>18 mo</th>
<th>24 mo</th>
<th>30 mo</th>
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<tr>
<td>Community</td>
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<td>Small Lab</td>
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<tr>
<td>New Lab</td>
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</tbody>
</table>
Steps to Adoption

6. Repeat the Gap Analysis?

7. Determine your state of readiness
What is a *Gap* Analysis?

If you are under 85%, you are not ready

Requirements Assessed: 120
Requirements Met: 110

92%

Where I am **NOW**

- Select External Internal Auditor
- Perform External Internal Audit

Where I **WANT TO BE** Tomorrow

- Define and Calculate GAP
- Establish Next Steps

If you are under 85%, you are not ready.
7. When is your laboratory “Ready for Quality”? 

- On a metric level
  - Have a Gap Analysis measure of meeting 90% plus of requirements and NO major deficiencies.

- On a process level
  - Going to full accreditation mode is not a major or immediate priority.
Steps to Adoption

8. Make the Accreditation decision
8. Make an Accreditation Decision

Do you want Quality or Accreditation or Both?

Laboratory Accreditation can be a valuable asset but is NOT the only choice.
8. Make an Accreditation Decision

Do you want Quality or Accreditation or Both?

ACCREDITATION IS A VALUABLE PROCESS THAT CONTRIBUTES GREATLY TO QUALITY, BUT IT IS NOT A UNIVERSAL REQUIREMENT FOR ALL MEDICAL LABORATORIES IN ALL COUNTRIES

External Assessment
Recommendations
Positive Support
Updates
Support Commitment
Validation
Confirmation
Certificate

External Point of View
External Timetable
Cost
Quality without Accreditation

Rarely Works

• It is very difficult to sustain even over the short term the commitment and effort required without external validation and support.

• 75 percent of organizations that commit to ISO9001:2000 fail to maintain their quality system.

Paradoxes of ISO 9000 Performance: A Configurational Approach

Olivier Boiral and Nabil Amara

QMJ VOL. 16, no. 3/© 2009, ASQ: 36-60
Steps to Adoption

9. *Commit to the standard*
9. Commit to the Standard

• Being accredited the first time is an **ACHIEVEMENT** for which a laboratory can be pleased.

• Being accredited the second time is an **ACCOMPLISHMENT** of which the laboratory can be proud.

• *The goal of process is not the receipt of a certificate; it is the confidence that the laboratory provides better and safer care with fewer errors and continuous focus on improvement.*
Workshop Exercise

• In the next phase of this workshop we will look at a number of clauses within ISO15189:2012, and discuss:

  1. What is the purpose off the clause
  2. How would you implement the clause
  3. How would you accomplish the clause
  4. How would you document the activity.
4.2.2.2 Quality manual

The laboratory shall establish and maintain a quality manual that includes:

a) the quality policy (4.1.2.3) or makes reference to it;
b) a description of the scope of the quality management system;
c) a presentation of the organization and management structure of the laboratory and its place in any parent organization;
d) a description of the roles and responsibilities of laboratory management (including the laboratory director and quality manager) for ensuring compliance with this International Standard;
e) a description of the structure and relationships of the documentation used in the quality management system;
f) the documented policies established for the quality management system and reference to the managerial and technical activities that support them.

All laboratory staff shall have access to and be instructed on the use and application of the quality manual and the referenced documents.
Quality Policy - Mission and Vision Statements

Innovation
Education
Quality Assessment
Continual Improvement

We at CMPT are a university-based, peer-directed program that provides innovative external quality assessment for microbiology laboratories providing services for public and patient health.

Our vision is to be recognized provincially, nationally, and internationally as a valued contributor of EQA innovation, education and as passionate advocates for continued quality improvement in EQA for the benefit of healthcare, our participants and our program.

CMPT is committed to its Quality Management System, and regular review for continual improvement of its effectiveness.

CMPT is committed to regulatory requirements ISO 9001.

The CMPT Quality Policy is the framework for the regular establishment and monitoring and achievement of quality objectives.

CMPT is committed to regular review of the Quality Policy to ensure its suitability to the program.

Michael A. Noble, Chair
January 2012

SQP 001 G/01/2012
## Map of the Strategic Quality Plan

<table>
<thead>
<tr>
<th>ISO Clause</th>
<th>Clause</th>
<th>Qualifier</th>
<th>Relevant to Clause in the CMPT-ISO9001</th>
<th>Common</th>
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<td>SQF 011</td>
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</table>

**Clause in Standard**

**Clause in Manual**
A QUALITY MANUAL IS NOT ALWAYS A BOOK

POLICIES DO NOT HAVE TO BE WRITTEN IN PARAGRAPHS IF OTHER FORMATS ARE EASIER TO UNDERSTAND:

- FLOW CHARTS
- PICTURES
- AUDIO CLIPS
- VIDEO CLIPS

POLICIES NEED REGULAR REVIEW AND DOCUMENT CONTROL
ISO 15189:2012:
4.14.5 Internal Audits

The laboratory shall conduct internal audits at planned intervals to determine whether all activities in the quality management system, including pre-examination, examination, and post-examination:

a) conform to the requirements of this International Standard and to requirements established by the laboratory, and

b) are implemented, effective, and maintained.
For a copy of the Internal Audit Master form visit www.POLQM.ca
The laboratory shall seek information relating to user perception as to whether the service has met the needs and requirements of users. The methods for obtaining and using this information shall include cooperation with users or their representatives in monitoring the laboratory’s performance, provided that the laboratory ensures confidentiality to other users. Records shall be kept of information collected and actions taken.
How to collect user feedback

**Complaints and Kudos**

- Deposit forms
- Paper Surveys
- On-line Satisfaction Surveys
- Social Media
- Information Days
- Interviews
The laboratory shall establish quality indicators to monitor and evaluate performance throughout critical aspects of pre-examination, examination and post-examination processes.

**EXAMPLE** Number of unacceptable samples, number of errors at registration and/or accession, number of corrected reports.

The process of monitoring quality indicators shall be planned, which includes establishing the objectives, methodology, interpretation, limits, action plan and duration of measurement.

The indicators shall be periodically reviewed, to ensure their continued appropriateness.
<table>
<thead>
<tr>
<th><strong>OBJECTIVES (What and Why)</strong></th>
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<tbody>
<tr>
<td>Be specific about what information you plan to collect</td>
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</table>

| **COLLECTION METHODOLOGY:** (Who, How, When?) |  |
| Do you have the personnel, resources and time to collect the information thoroughly? |  |

| **GRAPHIC PRESENTATION** |  |
| What is the most effective way to portray the information collected? |  |

| **PRESET LIMITS: (Acceptable, Unacceptable, Critical)** |  |
| Are there existing performance benchmarks? |  |

| **INTERPRETATION** |  |
| How will the information you plan to collect reflect on your Quality? |  |

| **LIMITATIONS ON INTERPRETATION** |  |
| Could there be other possible interpretations of the information? |  |

| **ACTION PLAN FOR VARIOUS OUTCOMES AND INTERPRETATIONS.** |  |
| Can the information collected result in change? |  |
| At what point will collecting this specific information set be changed or come to an end? |  |

**For a copy of the Quality Indicator Worksheet**

visit

www.POLQM.ca
ISO 15189:2012

5.1.6 Competence assessment

Following appropriate training, the laboratory shall assess the competence of each person to perform assigned managerial or technical tasks according to established criteria.

Reassessment shall take place at regular intervals. Retraining shall occur when necessary.
How to measure Competency

- Direct observation
- On-line information challenge
- Proficiency Testing challenges
- Simulation challenges
How to measure Competency

• Direct observation
• On-line information challenge
• Proficiency Testing challenge
• Simulation challenge

The more threatening the challenge, the less useful the result
In summary

• Implementing a Quality Standard will take Time, Effort, Energy and Money

• Is the **COST** worth the **PRICE**?

**Yes?** or **Yes!**