WhitePaper

ISO 15189 Medical Laboratories:
Understanding the Four Components of a Quality Management System

Useful Information for Clinical Laboratories and Anatomic Pathology Groups

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Table of Contents

Chapter 1:

Executive Overview

To improve the accuracy of results, medical labs around the world have begun adopting ISO 15189: Medical laboratories—particular requirements for quality and competence.

Medical laboratories are a critical part of the healthcare system. A patient's diagnosis and treatment are often based on test results, and an incorrect test result could lead to a misdiagnosis — which could have potentially fatal consequences. This is why accurate test results are critical — each and every time a test is conducted. To improve the accuracy of results, medical labs around the world have begun adopting ISO 15189: *Medical laboratories—particular requirements for quality and competence.* The standard requires medical labs to implement a quality management system. This requires them to document all their processes and procedures to ensure lab technologists always understand and follow the correct method when conducting a test.

This white paper provides an overview of the four main components of a quality management system:

Management Responsibility. Management responsibility includes a firm commitment to quality and effective strategic planning for the organization. Top management must demonstrate its commitment to the quality management system so all staff understand it is a strategic goal for the organization.

Resource Management. Management must allocate and manage the resources needed to implement the quality management system.

Service Realization. This is the actual service provided by your organization. In a lab, this is the pre-analytical, analytical, and

post-analytical phases of examination and the associated quality assurance activities.

Measurement, Analysis & Improvement. This is the check phase achieved through implementing processes for continual improvement.

The Deming Cycle

The white paper also examines the Deming Cycle, which organizations can use to achieve continual improvement for their quality management system. The Deming Cycle has four phases that organizations should constantly loop through:

Plan. Establish objectives and processes.

Do. Implement the processes.

Check. Monitor and measure progress.

Act. Take action to continually improve.

Chapter 2:

Introducing the Four Components of a Quality Management System

To deliver consistent, reliable test results each and every time a medical test is conducted, medical labs are also implementing ISO-based quality management systems.

Medical laboratories around the world are moving toward adopting ISO 15189: *Medical laboratories—particular requirements for quality and competence* to improve patient safety. The goal of ISO 15189, as with all ISO standards, is to create standardized processes that ensure staff understand and always follow correct procedures to produce consistent results each time a process is undertaken.

The airline, automotive, and food services industries use quality management systems to deliver safe products that customers can trust. Quality management systems ensure pilots understand and always follow landing protocols each and every time they land a plane. It means that cars come off the assembly line with all their parts in place exactly as they should be. And it means that customers walking into a fast-food place in Chicago will get exactly the same kind of burger as a person ordering one in Atlanta.

To deliver consistent, reliable test results each and every time a medical test is conducted, medical labs are also implementing ISO-based quality management systems. A quality management system, according to Meyer as cited by Fourie, is: "A system designed to manage the continual improvement of all processes in an organization in order to meet customer expectations."[1] In the case of medical labs, the primary expectation is accurate test results. A quality management system can help labs deliver on that promise. ISO-based

1 Fourie M. A systems approach to quality assurance and self-evaluation. South African Journal of Higher Education. 2000;14(2), 50-55.

quality management systems contain four components: management responsibility; resource management; service realization; and measurement, analysis, and improvement.

a. Management Responsibility

Management support is critical to the success of a quality management system. Management is responsible for the strategic planning of a business, and this includes a commitment to quality. Though a quality management system affects every staff member and every facet of an organization, it begins with a firm commitment by management, which must integrate it into the organization's strategic plan. Specifically, ISO 15189 states: "Laboratory management shall have responsibility for the design, implementation, maintenance and improvement of the quality management system."

Management is responsible for the creation of a quality policy, for evaluating the success of the quality management system and areas that need to be improved, and for ensuring customer requirements are both understood and met.

b. Resource Management

Creating a strategy is not enough. Top management must also ensure an organization has enough staff to effectively carry out that strategy and that staff are provided with the tools, supplies, and resources they need to properly conduct their job. This includes providing a suitable work environment. Laboratory equipment suppliers must be evaluated to ensure the resources they supply meet regulatory and organizational requirements.

c. Service Realization

In a laboratory, these are the pre-analytical, analytical, and post-analytical phases of a laboratory examination. Reliable test results

Creating a strategy is not enough. Top management must also ensure an organization has enough staff to effectively carry out that strategy and that staff are provided with the tools, supplies, and resources they need to properly conduct their job.

A major goal of any quality management system is continual improvement, and this is achieved by measuring and analyzing the performance of the quality management system and then acting on those findings.

are critical to patient safety and to achieve reliable results, top management at a lab must ensure its staff understand the proper processes and procedures to follow for each type of examination a laboratory conducts and that those procedures are followed each and every time. This means labs must carefully document their interconnected processes and procedures and make them available for staff to follow. Controlling access to these documents is the key to ensuring staff are always viewing the latest version. If a staff member inadvertently follows an old procedure, it could lead to an error.

d. Measurement, Analysis, and Improvement

A major goal of any quality management system is continual improvement, and this is achieved by measuring and analyzing the performance of the quality management system and then acting on those findings. An organization must determine which metrics to measure based on the strategies of an organization. If faster turnaround time is a goal, then a lab may measure the amount of time it takes to process tests, analyze the results to find bottlenecks, and put solutions in place. This process will be repeated on a regular interval unless the organization changes its strategic direction and new metrics for measurement and analysis are identified.

Chapter 3:

Management Responsibility: Committing to Quality and Effective Strategic Planning

Objective #1: Management Responsibility

Management's commitment to the quality system must be ongoing — it cannot set up a quality policy and then ignore it.

Without commitment from the top management at an organization, a quality management system cannot succeed. Management must take responsibility for the organization's quality management system. In fact, management is responsible for establishing the quality policy and processes and ensuring the organization has the resources required to meet those goals. The quality policy must be created with customer requirements in mind and must help the organization reach its strategic goals, serve customer needs, and comply with statutory and regulatory requirements.

Management's commitment to the quality system must be ongoing — it cannot set up a quality policy and then ignore it. It must ensure there are enough resources available to meet the requirements of the quality management system. Management must also commit to continually improving the quality management system by measuring and analyzing the success of the QMS and acting upon those results.[2]

a. Quality Manager

Management must appoint a representative who is responsible for ensuring that the processes for maintaining the quality management system are implemented and maintained. This individual does not

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2 ISO 9001:2008(E) 5.1, *Management commitment.*

need the title "Quality Manager," but regardless of title, he or she must report directly to the level of management at which decisions are made on laboratory policy and resources.

Quality managers ensure that everyone within the organization understands and complies with the quality management system. They report to top management on the state of the quality management system — how well it's performing and how it can be improved.

Patients are consumers of laboratory services, and customer relationship management is part of a quality manager's job.

Quality managers are also responsible for ensuring the customer's voice is heard and that customer needs are met. They must ensure staff throughout the organization understand and respect customer requirements.[3]

Medical labs have two types of customers: patients and healthcare personnel who order the examinations. Patients are consumers of laboratory services, and customer relationship management is part of a quality manager's job. That is, quality managers should understand as much as possible about who their clients are so they can meet their requirements, whether they are patients, physicians, nurses, etc. They must then promote those requirements to everyone within the organization. The trick, according to Craig Cochran, in his book, *Becoming a Customer-Focused Organization*, is not to "become preoccupied with internal processes and procedures."[4] Instead of looking inward, organizations must look outward.[5,6]

b. Quality Policy

The quality policy is the backbone of the quality management system — it is the framework on which the system is founded. It

3 ISO 9001:2008(E) 5.5.2, *Management representative.*
4 Cochran C. Becoming a Customer-Focused Organization. Chico, CA: Paton Press LLC; 2006.
5 ISO 9001:2008(E) 5.1, *Management commitment.*
6 ISO 9001:2008(E) 5.5.2, *Management representative.*

is top management's responsibility to lead the creation of a quality policy that is aligned with the organization's goals and purposes. It is not a static document. It must be reviewed regularly to ensure it is still suitable and relevant. Additionally, top management must create a framework that it can use to evaluate the effectiveness of its quality objectives and its ability to continually improve the quality management system. The quality policy must comply with all statutory and industry requirements and must be communicated to and understood by all of the staff.[7]

Commitment by top management must be another critical part of the quality policy, as it is a key requirement for a successful quality management system.

For medical laboratories setting up an ISO 15189 quality management system, a quality policy must include the following, as outlined by Clause 4.2.3:

a. Scope of service

b. Statement of the laboratory's standard of practice

c. Objectives of the QMS

d. Requirement that personnel understand and comply with the quality system

e. Commitment to good practice and quality

f. Commitment to comply with ISO 15189

Commitment by top management must be another critical part of the quality policy, as it is a key requirement for a successful quality management system.

The quality policy should be concise. An organization's processes and procedures are where a more detailed road map of its quality management system can be found. The quality policy is instead a brief document that defines the overall intentions and direction of the quality management system. It demonstrates the organization's

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7 ISO 9001:2008(E) 5.3, *Quality policy.*

commitment to its quality management system and a leadership that supports a culture of quality.

c. Strategic Planning

Although strategic planning is given only passing reference in ISO 15189, it is a critical part of a QMS. ISO 15189 states the laboratory director shall "plan, set goals, develop and allocate resources appropriate to the medical environment." ISO 9001, a normative document for ISO 15189, offers more details.[8]

An organization's processes and procedures are where a more detailed road map of its quality management system can be found.

It states top management shall establish quality objectives for all "relevant functions and levels within the organization." These objectives must meet product requirements, be measurable, and be consistent with the quality policy.

It is also essential to respect and maintain the integrity of the quality management system when planning and implementing changes to it.

d. Documentation of the System

Say what you do; do what you say. This is what documenting your system is all about. Your quality manual is the road map to your QMS. Working closely with those who perform the functions, you must carefully document everything you do in a set of processes and procedures. Once they are documented, you must ensure all staff understand and follow these processes and procedures. They must know where to find them and the documents must be controlled, so staff are always looking at the most recent version and not following old procedures. Without document control, staff may inadvertently

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8 Institute for Quality Management in Healthcare [Internet]. Module 2 – Quality Management: The Essential Cycle. Toronto (ON): Decoding ISO 15189™ Series. c2010 [updated 2010 Aug 24; cited 2010 Nov 1]. Available from: https://iqmh.org/ShopDecodingISOOverview/tabid/194/Default.aspx.

follow the wrong procedure when performing a test — which could lead to an incorrect result. This is why document control is critical.

There are four levels of documentation: policies, processes, procedures, and records.
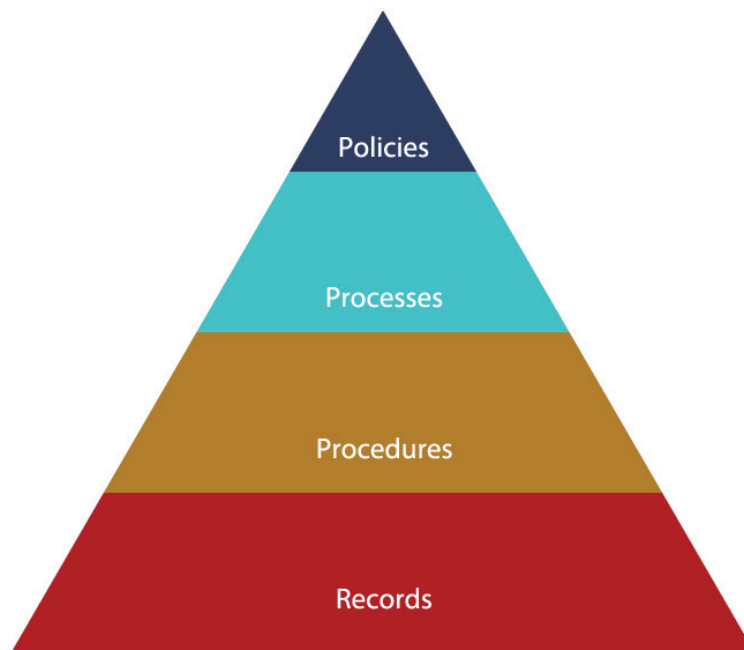
a. **Policies.** Policies are statements that describe what is done and why. They define goals, and briefly state intent and direction. They will form the basis of our quality manual and are high-level looks at topics such as personnel, inventory control, document control, strategic planning, etc. Organizations should have about seven to 12 policies that cover these topics.[9]

9   Institute for Quality Management in Healthcare [Internet]. Module 2 – Quality Management: The Essential Cycle. Toronto (ON): Decoding ISO 15189™ Series. c2010 [updated 2010 Aug 24; cited 2010 Nov 1]. Available from: https://iqmh.org/ShopDecodingISOOverview/tabid/194/Default.aspx.

b. **Processes.** A process is a series of interrelated steps involved in an activity that uses resources and is managed to transform inputs into outputs. Processes are usually documented in the form of a flowchart, and not as step-by-step instructions.[10]

c. **Procedures.** Procedures are the detailed step-by-step instructions that tell employees how to perform an activity, examination, or step in a process. It is essential to document not only technical instructions but other activities as well, such as how to respond to a complaint by a laboratory customer, instructions on how to use the IT system, and how to validate equipment before use. The documentation provides workers with transparency and clarification.[11]

d. **Records.** Records are anything that provides evidence. It is a history of what was done and cannot be changed. Examples of records include a filled-out or completed form, examination results and reports, and instrument printouts.[12]

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10 Ibid.
11 Ibid.
12 Institute for Quality Management in Healthcare [Internet]. Module 2 – Quality Management: The Essential Cycle. Toronto (ON): Decoding ISO 15189™ Series. c2010 [updated 2010 Aug 24; cited 2010 Nov 1]. Available from: https://iqmh.org/ShopDecodingISOOverview/tabid/194/Default.aspx.

There are three common mistakes organizations make when documenting systems.[13]

First, they document technical procedures only, but not management activities, such as the training and orientation of new employees and performance evaluation.

Second, they hire a consultant to write their procedures or purchase a commercial package of pre-written policies. Such packages may not reflect what they actually do. It is important to "say what you do and do what you say." To achieve this, those who perform an activity must play a key role in documenting the processes and procedures that describe it.

Last, policies and procedures should reflect what an organization actually does — not wished-for outcomes or goals. Auditors will look for evidence that policies and procedures reflect reality, not desires.

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13 Ibid.

Chapter 4:

Resource Management: Applying Established Plans

Managing resources to effectively meet the requirements of the quality management system and customers means securing enough people and ensuring their competence, awareness, and training to meet those goals.

Objective #2: Resource Management

Top management must provide the resources necessary to both meet the quality management system requirements and to continually improve its effectiveness. It must also provide the resources needed "to enhance customer satisfaction by meeting customer requirements."[14]

Managing resources to effectively meet the requirements of the quality management system and customers means securing enough people and ensuring their competence, awareness, and training to meet those goals. It also means providing the right equipment, a suitable infrastructure and work environment, and supplies for personnel to do their job effectively.

a. Personnel

Management must ensure laboratory personnel are competent by determining if they have the appropriate education, training, skills, and experience.

They must determine what criteria to use to determine competence, provide personnel with required training or other appropriate action, and evaluate the effectiveness of the training. Personnel must understand why their competence is important and the role they play

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14 ISO 9001:2008(E) 6.1, *Provision of resources.*

in meeting an organization's quality objectives. An organization must also provide evidence of an employee's competence by maintaining records of education, training, skills, and experience.[15]

b. Accommodations and Environmental Conditions

Employee competence is not enough. Employees must also be provided with a suitable work environment that will allow them to carry out their activities to meet customer requirements and the requirements of the quality management system. This includes providing workspaces, equipment, and supplies, as well as supporting services, such as information systems.[16]

c. Laboratory Equipment

Your lab must have all the equipment required for the provision of its services. Labs must also put a process in place that describes how they select equipment. This should include a method for evaluating suppliers of laboratory reagents, supplies, and services. ISO 15189 clause 4.6.4 specifies labs must maintain records of these evaluations. Supplier evaluations can be done through the following methods:

a. A second-party audit on-site inspection

b. Requiring proof of external evaluation to the ISO 15189 standard

c. Asking companies to provide quality control records

But suppliers do not have to be ISO registered or accredited.

15 Institute for Quality Management in Healthcare [Internet]. Module 2 – Quality Management: The Essential Cycle. Toronto (ON): Decoding ISO 15189™ Series. c2010 [updated 2010 Aug 24; cited 2010 Nov 1]. Available from: https://iqmh.org/ShopDecodingISOOverview/tabid/194/Default.aspx.
16 ISO 9001:2008(E) 6.4, *Work environment.*

Chapter 5:

Service Realization: Identifying and Managing Activities

Plan a path of workflow so everyone understands how his or her tasks relate to others and what impact his or her activity has on the wider process.

Objective #3: Service Realization

a. Pre-analytical, analytical, and post-analytical phases of examinations and the associated quality assurance activities

"Service realization" is the actual service provided by your organization — in this case, the pre-analytical, analytical, and post-analytical phases of examinations and their associated quality assurance activities. It is important to think of your service as a process and to manage the interlinked activities within each of these phases. Plan a path of workflow so everyone understands how his or her tasks relate to others and what impact his or her activity has on the wider process. Documenting all linked activities with process maps will help staff understand the wider picture.[17]

1. **Pre-analytical phase**.[18] A large proportion of all errors occur during the pre- and post-analytical phases. If your laboratory is part of a hospital, it is essential to ensure related hospital systems comply with your quality management system requirements. In this way, medical laboratories can champion the introduction and adoption of quality management systems in the hospital. Your challenge will be to ensure that all elements of your quality management system have a link to pre-analytical processes.

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17 Institute for Quality Management in Healthcare [Internet]. Module 13 – Pre-Examination Process: You Get What They Give. Toronto (ON): Decoding ISO 15189™ Series. c2010 [updated 2010 Aug 24; cited 2010 Nov 1]. Available from: https://iqmh.org/ShopDecodingISOOverview/tabid/194/Default.aspx.
18 Ibid.

For example:

(a) Personnel performing phlebotomies and other sample collections must be trained and have their competence monitored periodically.

(b) Inventory used for sample collection must be controlled.

(c) Systems used to transport specimens to and from the laboratory must be validated as suitable.

(d) Instructions provided outside the laboratory must be document controlled and must be reviewed by laboratory personnel.

(e) Processes must be described, especially the linkages between pre-analytical processes and analytical testing.

(f) Continual improvement processes must encompass pre-analytical processes.

(g) Root causes of identified problems must be corrected, even if the root cause takes you outside the walls of your laboratory.

(h) The laboratory should monitor pre-analytical processes with its quality indicators, and act on the data gathered.

(i) Internal audits must include pre-analytical processes. Again, this will take you outside of the walls of your laboratory.

(j) Management reviews must include pre-analytical elements. Once more, this forces your laboratory outside of its walls.

2. **Analytical phase**.[19] All technical examination procedures must be documented and available at the workstation for staff who need it. The documentation can be in either electronic or paper form — but it must be controlled. That is, a system must be in place to ensure that staff are always looking at the most current

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19 Institute for Quality Management in Healthcare [Internet]. Module 14 – Examination Process: It's What We Do. Toronto (ON): Decoding ISO 15189™ Series. c2010 [updated 2010 Aug 24; cited 2010 Nov 1]. Available from: https://iqmh.org/ShopDecodingISOOverview/tabid/194/Default.aspx.

procedure. To maintain control of printed manuals, you must ensure the following:

(a) The distribution of printed copies is known and recorded for each applicable file.

(b) The responsibility for the printing of new and revised documents is defined.

(c) The responsibility for the removal of obsolete printed documents is defined.

3. **Post-analytical phase.**[20] It is important to pay attention to the post-analytical phase as a large proportion of errors occur during the pre- and post-analytical phases. If your laboratory is part of a hospital, it is essential to ensure your laboratory contributes effectively to the overall hospital system. This may be a challenge as the rest of the hospital may not understand the principles of quality management systems. But you must ensure all post-analytical processes are linked to your QMS.

For example:

(a) Your IT system and department must conform to your quality system.

(b) Instructions provided by third parties outside the laboratory must also be part of the document control process.

(c) You should map all processes and linkages between the analytical and post-analytical phases.

(d) Root causes of identified problems must be corrected, even if they are in the post-analytical phase and occur outside your laboratory.

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20 Institute for Quality Management in Healthcare [Internet]. Module 15 – Post-Examination Process: They Get What We Give. Toronto (ON): Decoding ISO 15189™ Series. c2010 [updated 2010 Aug 24; cited 2010 Nov 1]. Available from: https://iqmh.org/ShopDecodingISOOverview/tabid/194/Default.aspx.

(e) Post-analytical factors must be measured and analyzed to pursue continual improvement

(f) Internal audits and management reviews must include post-analytical processes.

Chapter 6:

Measurement, Analysis, and Improvement: Checking on Progress

A quality management system as described in ISO 9000:2008 and in ISO 15189:2007 provides the ideal tools to implement continual improvement: to improve your processes at every opportunity.

Objective #4: Measurement, Analysis, and Improvement

The fourth component is the most difficult to implement. This is the "check" phase achieved through processes for measurement, analysis, and improvement. In order to realize any gains from implementing a quality system, that system must be focused on continual improvement. Continual improvement is a key concept of the quality management effort and is, in fact, a major goal of the system. A quality management system as described in ISO 9000:2008 and in ISO 15189:2007 provides the ideal tools to implement continual improvement: to improve your processes at every opportunity. There are four important tools. They are:

1. The use of quality indicators

2. The management of nonconformities, also known as occurrence management

3. Internal and external quality audits

4. Regular management review of the QMS

a. Focus on continual improvement

1. **The use of quality indicators.** Your organization and laboratory's strategy will guide the decision on what is important, indicate what metrics to measure, and what targets to strive for. If, for example, your laboratory is part of a hospital and one of the hospital's strategic goals is to reduce wait times, then the laboratory should have specific objectives to help meet that goal. If the hospital changes its goals, the lab must do likewise. Each specific objective or action plan needs a corresponding and systematic plan to measure the performance of that objective, using quality indicators.

   A quality indicator is a measurement and analysis to address how well the laboratory is meeting its customer's needs. It is critical to gather and use reliable data.

A quality indicator is a measurement and analysis to address how well the laboratory is meeting its customer's needs.

2. **The management of nonconformities, also known as occurrence management.** ISO 9000 defines a nonconformity as "non-fulfillment of a requirement." It is any instance where things don't go as planned or as defined. Requirements can be set through various methods: by law, by ISO standards, by an accrediting body, by customers, or by an organization's internal policies and procedures. It is important to recognize a nonconformity does not always result in an accident or an incorrect examination result. Nevertheless, it must be addressed. Nonconformities can happen at any point of the quality management system. For example, if employee performance evaluations fall behind, examinations may not be affected, but it is still a reportable nonconformity by your audit team.

Audits are a means of gathering factual, unbiased information about how well an organization's quality system is functioning.

3. **Internal and external quality audits.** A quality audit, as defined by the American Society for Quality, is "a planned, independent and documented assessment to determine whether agreed-upon requirements are being met." An audit is a formal, methodical process to determine conformance. There are two types of audits: internal and external. Internal audits are also sometimes called first-party audits. External audits can be second- or third-party audits. An example of a second-party audit is an audit conducted by your customer or by the nursing department at your hospital. Audits your lab undertakes of suppliers to ensure they meet your requirements are also considered second-party audits. Third-party audits occur when an independent audit organization, such as an ISO accreditation body, conducts an audit on your behalf to assess conformance to standards and grants certification or accreditation.

    Audits are a means of gathering factual, unbiased information about how well an organization's quality system is functioning.

4. **Regular management review of the QMS.** A management review is a review of the status and effectiveness of the quality management system. It gives management a venue to evaluate and analyze practices for the purpose of improving the quality management system. Management reviews include reviews of policies and records. They should result in an action plan for improvements and may also lead to changes in strategy. Management reviews are generally planned by the quality manager and should be conducted using documented processes and detailed procedures and templates so that management reviews are conducted in a consistent manner from year to year.

Chapter 7:

Understanding the Deming Cycle

a. Overview

To obtain continual improvement, it is essential to check on the progress and effectiveness of your plans and activities.

Continual improvement is one of the key goals of a quality management system and the best way to depict continual improvement is with the figure below depicting the Deming Cycle of Plan-Do-Check-Act. It was created by Shewhart and later modified by Deming. It is a four-step looping process:

1. **Plan.** Establish objectives and processes.

2. **Do.** Implement the processes.

3. **Check.** Monitor and measure processes.

4. **Act.** Take actions to continually improve.

b. An integral part of your quality management system

The Deming Cycle is essential to understanding how a quality management system should function. It is deceptively simple in that it is an easy-to-understand concept, but challenging to implement. All organizations and even individuals are usually adept with the implementation of the first two elements of the cycle, Plan and Do. But they often fall short, however, is in the Check and Act phases. To obtain continual improvement, it is essential to check on the progress and effectiveness of your plans and activities. Organizations need to measure and analyze the success of their efforts and act on those quality indicators.

c. Plan-Do-Check-Act[21]

Use the Plan-Do-Check-Act cycle not only for your quality system as a whole but for all of your projects.
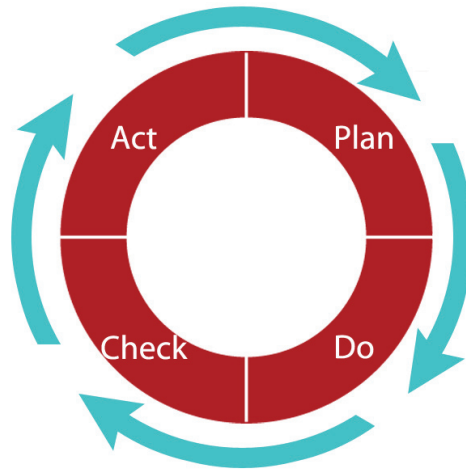
Plan:

1. Assess the current situation:
    • Create a flowchart.
    • Allow all players to gain a common understanding of how events link together. This is especially important if the players have only the perspective of their own role, but not an understanding of the entire process.
    • Be aware that sometimes flowcharts need to be created by physically walking through the process (i.e., literally following workers and tracking a tube of blood through all the steps).
    • In most cases, chart not just the steps but also the responsibilities, time, and tools needed.

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21 Institute for Quality Management in Healthcare [Internet]. Module 2 – Quality Management: The Essential Cycle. Toronto (ON): Decoding ISO 15189™ Series. c2010 [updated 2010 Aug 24; cited 2010 Nov 1]. Available from: https://iqmh.org/ShopDecodingISOoverview/tabid/194/Default.aspx.

2. Take baseline measurements:
    *   Surveys
    *   Internal audit
    *   Quality indicator monitoring

3. Create an awareness of the project:
    *   Convey the nature and urgency of the problem.
    *   Try to get people to recognize the need for change.
    *   Try to develop an economic case for the project to win support from senior management or present it as a potential risk. Quantify the potential financial and non-financial risks.

4. Define what "Success" is:
    *   How will it look or be measured?
    *   How will you know it was a success?
    *   What will you measure to determine if the objective has been accomplished?

5. Communicate:
    *   Communicate the goals and objectives clearly and frequently.
    *   Focus on common objectives before discussing areas of differences.
    *   Do something for others to create positive energy.

6. Determine the obstacles:
    *   Work to remove or reduce them.

7. Create (or participate on) a team:
    *   People support what they participate in creating.
    *   May involve people from formerly separate functional areas working together on a new process.
    *   Cover the full range of job functions that the process involves.
    *   The team itself can be managed through Plan-Do-Check-Act.

8. Design a new process:
   - Identify the problem or issue.
   - Search out the most likely root cause.
   - Identify potential solutions and select the best solution(s).
   - Design the improved process.

9. Align other systems to the new process.

10. Update documentation: process maps and procedures.

11. Train staff to the new process.

Do:

1. Implement the plan.

2. Go for early and visible wins.

Check:

1. Assess the effectiveness of the process through measurement and analysis of the outcomes:
   - Were targeted outcomes achieved?
   - Were there any additional unplanned benefits?
   - Was there a financial return on investment?
   - Did client satisfaction improve?

2. Use statistics where you can: average, range, mean, median, etc.

3. Work to transform qualitative data into numeric format through the use of frequencies by the use of scales (e.g., Likert scale: strongly agree, agree, neutral, disagree, strongly disagree).

4. Never try to take a measurement without first knowing:
    •   What data will you need?
    •   Who will supply the data?
    •   How will the data be transformed into information?
    •   How will the information be used?
    •   How will the information be communicated to others?

Act:

1. If it worked, standardize the new process and continue to monitor.

2. If it didn't work, make necessary adjustments or try something else.

3. Formulate action plans based on any problems.

4. Build on success by rewarding supporters and involving more people.

5. Continue the cycle.

Chapter 8:

Management reviews are a review of the status and effectiveness of the quality management system (QMS).

Case Study: Profile a laboratory that has successfully implemented ISO 15189 and the Deming Cycle

Introduction

William Osler Health System (Osler) is one of Canada's largest community hospital corporations, serving more than 1.3 million residents in Brampton, Etobicoke, and surrounding communities in the greater Toronto area in Ontario, Canada.

Osler is accredited to the ISO 15189-based OLA 15189Plus™ standard, a government-mandated accreditation program.

Accreditation to OLA 15189Plus™ has allowed Osler to demonstrate its ongoing commitment to patient safety, reduce errors, and establish its laboratory centres as leaders in quality management. A key part of Osler's strategy to make continuous improvements while meeting the OLA 15189Plus™ requirements is its management review.

Management reviews are a review of the status and effectiveness of the quality management system (QMS). They give management a venue to evaluate and analyze practices for the purpose of improving the QMS.

The management review was one of the last components of Osler's QMS since all other components needed to be in place first to fully assess the effectiveness of the entire system. The laboratory uses the Deming cycle Plan-Do-Check-Act (PDCA) method to conduct its annual management reviews.

The Challenge

Osler set up several objectives for its management reviews:
- Identify opportunities for improvement.
- Promote quality and customer satisfaction through periodic review of performance.
- Ensure the continued stability and effectiveness of the QMS.
- Involve management, technical leads, and all staff in the tracking, reporting, and monitoring of the process.

The Solution

Plan: Establish objectives and processes

To encourage participants to contribute to the effectiveness of the management review, preparation was essential. Osler's management review process included the following:
- Appoint a champion (quality manager) with designated responsibility and authority to develop, implement, manage, and maintain the management review process.
- Prepare a schedule and agenda of areas to be reviewed (the inputs).
- Determine which records (inputs) support the identified areas of measure (checklist).
- Create a list of management representatives to be involved.
- Detail procedures outlining how to conduct the management review.
- Develop a management review checklist to help the laboratory accomplish the results (outputs) of the review.

Do: Implement the process
- Management team analyzes the information (inputs) to determine if the target has been realized, if the action has been adequate or if further improvement is needed.

• Minutes are taken during the management review to provide a record.

The inputs for the management review include:
• Quality policies and objectives
• Internal and external audits
• Proficiency testing
• The laboratory quality report
• Status of previous management review action items
• Progress toward meeting goals and objectives
• Customer satisfaction and feedback
• Lab non-conformance reports with corrective actions
• Status of preventive and corrective actions
• Changes affecting the QMS
• Recommendations for improvement
• Workload/utilization
• Turnaround time
• Laboratory dashboards (quality indicator data)
• Evaluation of products and suppliers

Check: Monitor and measure progress
• Analyze all information to determine if the target has been realized, if the action has been adequate and if further improvement can be achieved.
• Prepare an outline of how the outputs will be addressed.
• Identify initiatives and course corrections to be taken.
• Create a corrective actions report with action plans and timelines:
    – Review of non-conformances, including customer complaints
    – Give patient safety issues a priority in any corrective action planning.
    – Determine the causes of the non-conformances.
    – Implement actions needed.
    – Review the corrective actions to determine their effectiveness.

Act: Take action for continual improvement

- Develop and implement action plans for improvements identified through the management review.

- Identify the issue to be resolved.

- Assign key responsibility and timelines for follow-up and completion .

- Determine corrective solutions for all non-conformances discovered during the internal audit process.

- Monitor the effectiveness of actions resulting from the management review through follow-up audits .

- Manage the process and complete pulse checks to ensure targets are met and findings are appropriate and/or actions redirected.

The Benefits

As a result of the management reviews, Osler implemented a quarterly dashboard system that provides the inputs for the management review (see Figure 1). The dashboard is aligned with Osler's corporate strategic planning and provides benchmarks in four key areas related to service quality: Acceptability, Efficiency, Leadership, and Clinical Performance.

"The dashboards are a strategic measurement and communication tool. They translate the laboratory mission, vision, and strategy through objectives and measures and provide a framework to describe the key elements in the achievement of Osler's strategy," said Pat Burton, the Quality Co-ordinator, Laboratory, for the William Osler Health System.

As a result of the management reviews, Osler implemented a quarterly dashboard system which provides the inputs for the management review (see Figure 1).

The Dashboards

- Each indicator in the dashboard is compared to a target.
- Variances determine how far a value is from the target and are expressed as a percentage. Green indicates good performance (≥ target), yellow is slightly below target, and red indicates need for improvement (≥ 5% below the mean).

Management reviews allow senior leadership at Osler to reaffirm their commitment to continually improving quality management data.

The dashboard system has proven to be an effective tool for management reviews as they help the management team easily identify areas requiring improvement and gauge the trending of performance as preventive and corrective actions are taken. The dashboards also effectively communicate QMS performance to the rest of the lab staff and the organization.

As laboratory and other staff are involved in the collection of data for the dashboard, it is also a way to involve frontline staff in the internal audit process.

With the use of dashboards, the management reviews have allowed Osler to effectively discover what is and is not working, and identify problems and risks before they can turn into adverse events. The organization has also been able to assess opportunities for improvement and the need for changes to its QMS. In addition, the reviews help Osler determine resource requirements to ensure the QMS remains effective. Management reviews allow senior leadership at Osler to reaffirm their commitment to continually improving quality management data. The dashboard has helped increase staff confidence as the data they collect are used in a meaningful way to make improvements.

As a result of implementing a quality management system and becoming accredited to an ISO 15189-based standard, Osler has reduced the number of patient identification errors by 40% and also

achieved a significant decrease in point-of-care testing errors and the blood culture contamination rate. Data collected by the lab created heightened awareness of these issues and helped drive educational programs that led to quality improvements.

Implementing OLA 15189Plus™ has also been beneficial. "As our QMS matured, we quickly realized we could make many of our quality improvement initiatives happen," Burton said. "The dashboard made it easy to recognize areas that needed improvement."

Management reviews are a means of ensuring the system continues to be effective as Osler's needs change and develop.

Some changes made as a result of implementing the ISO 15189-based QMS include:

- Automating pre-analytical sample processing and subsequent delivery of specimens to the sampling port of the analyzer at Brampton Civic Hospital. Speed and efficiency are critical elements to the laboratory, and this enabled Osler to significantly improve the turnaround time of lab results, improve staff productivity, reduce labor costs, spend less time on non-value-add tasks and more on value-add tasks — all without increasing the number of staff.
- Demonstrate an increase in workload in transfusion medicine to increase full-time employees.
- Replace capital equipment.
- Realize a cost savings through inventory control by replacing outdated products and reinvesting the savings.

Management reviews are a means of ensuring the system continues to be effective as Osler's needs change and develop. They help the lab bridge gaps internally and with external stakeholders. "OLA 15189Plus™ has solidly placed our laboratory as a leader in quality management in our organization and has brought us closer to achieving our mission to do the right test for the right patient the first time, on time every time!" Burton said.

Figure 1.

Laboratory Corporate Dashboard- "Vital Signs" 2009 2010

WILLIAM OSLER HEALTH SYSTEM

Legend: ■ At or above target   ■ Slightly below target ≥ 0.1-5%   ■ Needs Improvement > 5%

ACCEPTABILITY

CUSTOMER SATISFACTION MAY 09- CORPORATE ED

	Actual	Target	Variance
Quality results communicated in a timely manner		>80%	
Accuracy & Reliability of Lab results		>80%	
Lab Commitment to Continual Improvement		>80%	
Communication of results- clear/ timely manner		>80%	
Professional & Courteous lab staff		>80%	
Knowledge & Support of Lab staff		>80%	
Lab services are customer focused		>80%	
# of Customer Complaints		0	
# of Customer Compliments		1/mo	

STAFF SATISFACTION

	Actual	Target	Variance
Vacancy Rate		3.58	
Staff Turnover		4.8	

EFFICIENCY

	Actual	Target	Variance
Workload- 2009/2010		12,300,000	
Workload 2008/2009		10,173,389	

PAID HOURS

	Actual	Budget	Variance
FTEs		146.8	
Percent Orientation		0.0	
Percent Overtime		0	
Percent Sicktime		2	

LEADERSHIP

	Actual	Target	Variance
General Staff Meetings		12	
Quality Council Meetings		4	
Competency Assessment		9	
Performance Appraisals completed		70	
Employee Safety Incidents		0	

SAFETY LABORATORY ERRORS- MEDQM

	08 09	09 10	Variance
Laboratory Errors- All disciplines	# of errors	# of specimens	%
Laboratory Errors 2009/2010		1,064,815	HICL

SAFETY- CLINICAL PERFORMANCE

QMP-LS PERFORMANCE- EQA (EXTERNAL QUALITY ASSESSMENT)

	Actual %	Target %	Variance
Chemistry		98	
Cytology		≤1 major,≤3 minor	
Flow Cytometry		≤1 major,≤3 minor	
Hematology		98	
Histology		≤1 major,≤3 minor	
Microbiology		≤1 major,≤3 minor	
Trans Medicine		98	

EXTERNAL EQA-OTHER THAN QMPLS

	Actual %	Target %	Variance
Chemistry		98	
Flow Cytometry		98	
Hematology		98	
Histology		98	
Microbiology		98	
Trans Medicine		98	

ONTARIO LABORATORY ACCREDITATION (OLA)

	2009	2004	Variance
OLA Performance			
Major Non Conformance			
Minor Non Conformance			
Overall Performance			
**Provincial Average is 94%			

CRITICAL RESULT COMMUNICATION

	Actual	Target	Variance
% conformance		98	

AUDIT OF MANUAL TRANSCRIPTION

	Actual	Target	Variance
% conformance		98	
# of transcription errors		0	

REFERRAL LAB NON CONFORMANCE

	2008/2009	2009/2010	Variance
Referral Lab		17	
Public Health Lab		8	
Headwaters		11	

TURNAROUND TIME

ED

	Actual %	Target %	Variance
Hematology		90	
Coagulation		90	
Chemistry Routine		90	
Chemistry Cardiac		90	

CRITICAL CARE

	Actual %	Target %	Variance
Hematology		90	
Coagulation		90	
Chemistry Routine		90	
Chemistry Cardiac		90	

MEDICINE

	Actual %	Target %	Variance
Hematology		90	
Coagulation		90	
Chemistry Routine		90	
Chemistry Cardiac		90	

ONCOLOGY

	Actual %	Target %	Variance
Hematology		90	
Coagulation		90	
Chemistry Routine		90	

SURG PATHOLOGY & CYTOLOGY

	Actual %	Target %	Variance
Surg Pathology		80	
► Small Specimens		80	
► Big Specimens		80	
► Headwaters		80	
Cytology		80	
FNA		80	
Bone Marrow		80	

FROZEN SECTION TAT- Receipt to Report

	Actual %	Target %	Variance
FS Turnaround Time		90	
Average Minutes		20	

FROZEN SECTION TO FINAL DIAGNOSIS

	Actual %	Target %	Variance
Code 5-Disagreement		3	
Codes 1&2-Agreement		90	

Chapter 9:

Conclusion

Laboratories in hospitals become quality management champions and lead the way to a better healthcare organization in which the systematic shortcomings that lead to error are looked for and addressed.

An incorrect medical lab test could mean a patient is misdiagnosed and either does not get the treatment he or she needs or undergoes unnecessary procedures.

Quality management systems are designed to help organizations eliminate preventable errors. They require organizations to examine all of their processes and procedures, document them, relay them to employees, and evaluate their effectiveness.

ISO 15189:2007 *Medical laboratories* — Particular requirements for quality and competence draws together both a quality management system and technical requirements. Labs implementing the internationally recognized standard can help employees understand what procedures to follow and implement quality indicators to find weak points in their processes so they can improve them.

More important, clinical laboratories & anatomic pathology groups can address pre- and post-analytical processes where the bulk of errors occur. Laboratories in hospitals become quality management champions and lead the way to a better healthcare organization in which the systematic shortcomings that lead to error are looked for and addressed.

ISO 15189 encourages top-level management to take ownership of the quality management system by setting up the policies that guide it. Top management must also regularly examine the QMS and ensure it provides the resources necessary to enable staff to properly implement the policies as well as address shortcomings.

Medical laboratories play a key role in the quality of care a patient receives, and at its heart, ISO 15189 is about improving patient safety.

ISO 15189 is gaining traction both in the U.S and worldwide. It has been or is being adopted by accrediting bodies in Canada, New Zealand, Israel, Hong Kong, Thailand, Malaysia, China, and Japan.[22]

In Canada, accreditation to ISO 15189-based standards is mandatory in two provinces. The Ontario Laboratory Accreditation (OLA), an IQMH-partner, has already accredited more than 200 labs to the standard in the province of Ontario. In a 2009 survey of Ontario participants conducted by OLA, 94.3% of participants surveyed agreed that meeting the accreditation requirements enhanced their laboratory service.[23]

As ISO 15189 continues to gain momentum, more labs will adopt the standard in order to remain competitive. ISO 15189-based accreditation is already being offered by two major accreditation bodies in the U.S. Both organizations have already accredited labs using the standard.

Medical laboratories play a key role in the quality of care a patient receives, and at its heart, ISO 15189 is about improving patient safety. This is why medical laboratories around the world are adopting ISO 15189 as the standard of excellence for medical labs.

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22 Practical Application of ISO 15189 by accreditation bodies – A Comparison with ISO/IEC 17025 – 2004. http://www.ifcc.org/PDF/150412200403.pdf.
23 Coffey J. OLA participants provide positive feedback. QMP–LS News. 2009 March 136: 2-3.

Appendices

A-1
About Gregory J. Flynn, B.Sc., MD, FRCPC
Chief Executive Officer, Institute for Quality Management in Healthcare
Managing Director, Quality Management Program—Laboratory Services

As the CEO for the Institute for Quality Management in Healthcare (IQMH), which he helped launch in 2009, and the Managing Director of the Quality Management Program—Laboratory Services (QMP–LS) since 2006, Dr. Flynn is dedicated to promoting patient safety and quality of care through the application of the principles of quality management. Dr. Flynn has served as the President of the Ontario Medical Association where he played a pivotal role in governance review and strategic planning. He has devoted much of his recent career to the improvement of quality in healthcare and was a member of the Province of Ontario's Provincial Advisory Group on Laboratory Reform. Dr. Flynn completed his pathology training in 1991 and has practiced both as a family physician and a pathologist. He is a much-sought-after speaker who has given several presentations on how to use the principles of quality management and risk assessment to improve patient care.

A-2

About Julie Coffey, MLT, ART, CQA, CMQ/OE (ASQ)

Staff Technologist and Quality Manager, Ontario Laboratory Accreditation,
Quality Management Program—Laboratory Services & Institute for Quality
Management in Healthcare

Julie Coffey is a Staff Technologist and Quality Manager from the Ontario Laboratory Accreditation (OLA) division of QMP–LS in Ontario, which is a partner of the Institute for Quality Management in Healthcare (IQMH). Ms. Coffey is the primary author of IQMH's Decoding ISO 15189™ web-based educational series designed to help labs prepare for ISO 15189 accreditation and implement a world-class, internationally-recognized quality management system. She is a Medical Laboratory Technologist, certified Quality Auditor, and a certified Manager of Quality/Organizational Excellence. She has played a key role in the development of the OLA 15189Plus™ accreditation program and its requirements since its inception in 2000. To date, she has coordinated and conducted more than 100 assessments of medical laboratories to the OLA 15189Plus™ standard. She has written numerous articles for QMP–LS News on the implementation of a quality management system and has given countless presentations on understanding OLA and ISO 15189.

A-3
About Institute for Quality Management in Healthcare

The Institute for Quality Management in Healthcare (IQMH) is dedicated to excellence in healthcare in order to promote patient safety and quality of care. IQMH helps healthcare organizations implement and develop their knowledge of quality management systems. IQMH offers ISO 15189-based accreditation, proficiency testing, guideline development expertise and ISO 15189 education tools.

IQMH's Decoding ISO 15189™ interactive online education series is designed to help labs gain international recognition by arming them with the tools and knowledge they need to implement an ISO 15189 quality management system and prepare for accreditation to the world-class standard. Decoding ISO 15189™ helps labs educate their staff on the standard and allows users to learn at their own pace by watching the modules at their convenience and referring back to them as they are implementing the standard. Decoding ISO 15189™ includes video coaching tips from experts and a library of downloadable PDFs, workbooks and templates. The 15 modules are a comprehensive guide that take labs through the steps they need to complete in order to meet ISO 15189 requirements and prepare for their assessment visit.

IQMH is a not-for-profit corporation that assists healthcare professionals in achieving high standards in quality management. As a partner with the Quality Management Program—Laboratory Services (QMP–LS), IQMH has over 30 years of expertise in quality management behind it.

A-4
About DARK Daily

"Dark Daily is a concise e-news/ management briefing on timely topics in clinical laboratory and anatomic pathology group management. It is a solution to the dilemma facing anyone in the laboratory profession.

DARK Daily is a concise e-news/management briefing on timely topics in clinical laboratory and anatomic pathology group management. It is a solution to the dilemma facing anyone in the laboratory profession. New developments, new technology, and changing healthcare trends make it imperative to stay informed to be successful. At the same time, the Internet, cell phones, blackberries, laptop computers and wireless devices are overwhelming any one individual's ability to absorb this crushing Tsunami of data.

DARK Daily is a quick-to-read, easy-to-understand alert on some key development in laboratory medicine and laboratory management. It has no counterpart in the lab world. Why? Because it is produced and written by the experts at THE DARK REPORT and The Dark Intelligence Group, who know your world, understand your needs and provide you with concise, processed intelligence on only those topics that are most important to you!

You will find DARK Daily to also be an exceptionally valuable resource in laboratory and pathology management. Some of the lab industry's keenest minds and most effective experts will be offering their knowledge, their insights and their recommendations on winning strategies and management methods. Many of these experts are unknown to most lab directors. As has proven true with THE DARK REPORT for more than a decade, DARK Daily will be your invaluable— and unmatched—resource, giving you access to the knowledge and experience of these accomplished lab industry professionals.

A-5
About The Dark Intelligence Group, Inc. and THE DARK REPORT

"Membership is highly-prized by the lab industry's leaders and early adopters. It allows them to share innovations and new knowledge in a confidential, non-competitive manner.

The Dark Intelligence Group, Inc., is a unique intelligence service, dedicated to providing high-level business, management and market trend analysis to laboratory CEOs, COOs, CFOs, pathologists and senior-level lab industry executives. Membership is highly-prized by the lab industry's leaders and early adopters. It allows them to share innovations and new knowledge in a confidential, non-competitive manner. This gives them first access to new knowledge, along with the expertise they can tap to keep their laboratory or pathology organization at the razor's edge of top performance.

It offers qualified lab executives, pathologists and industry vendors a rich store of knowledge, expertise and resources that are unavailable elsewhere. Since its founding in 1996, The Dark Intelligence Group and THE DARK REPORT have played in instrumental roles in supporting the success of some of the nation's best-performing, most profitable laboratory organizations.

The Dark Intelligence Group (TDIG) is headquartered in Austin, Texas. This location makes it very accessible for any laboratory organization seeking input, insight and support in developing their business operations, creating effective business strategies and crafting effective sales and marketing programs that consistently generate new volumes of specimens and increasing new profits. The Dark Intelligence Group, Inc. owns and operates two Web sites in the TDIG Website network:

http://www.DarkReport.com

http://www.DarkDaily.com

A-6
About the *Executive War College*
on Laboratory and Pathology Management

Every spring since 1996, the lab industry's best and brightest gather at the *Executive War College on Laboratory and Pathology Management* to learn, to share and to network. Many consider it to be the premier source of innovation and excellence in laboratory and pathology management.

Each year, a carefully selected line-up of laboratory leaders and innovators tell the story of how their laboratories are solving problems, tackling the toughest challenges in lab medicine and seizing opportunities to improve clinical care and boost financial performance. The *Executive War College* is the place to get practical advice and solutions for the toughest lab management challenges. A unique case study format brings participants face-to-face with their most successful peers. They tell, first hand, how their laboratory solved intractable problems and successfully used new technology.

Many lab management secrets are shared, along with specific "what-not-to-do's" gained from hard-won experience! It's not pie-in-the-sky theory, but useful knowledge that can be put to use in any lab. The *Executive War College* offers superlative networking, with lab administrators and pathologists attending from countries as far away as the United Kingdom, Germany, Brazil and Australia. It makes the *Executive War College* a melting pot for all the best ideas, new lab technologies and management strategies now reshaping the laboratory industry. It's also become a recruiting ground used by headhunters and major lab organizations.

In the United Kingdom, The Dark Intelligence Group and the Association of Clinical Biochemists (ACB) have co-produced a meeting every February since 2003. Known at *Frontiers in Laboratory Medicine* (FiLM), it attracts laboratory leaders and innovators in the United Kingdom. Also featuring a case study format, this meeting pioneered the international laboratory side-by-side case study, where a North American laboratory and a United Kingdom laboratory prepare a comparison of best practices and an operational assessment of their two organizations.

In September 2005, a laboratory management meeting called *Executive Edge* was conducted in Toronto, Ontario, Canada, by The Dark Intelligence Group and QSE Consulting. It provided pathologists and lab directors in Canada with a customized meeting devoted to the strategic and operational issues of laboratory management in Canada.

A-7
About The Editor: Robert L. Michel
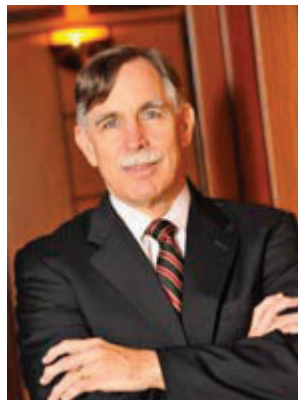
Robert L. Michel is a respected commentator, consultant, author, editor, speaker, and entrepreneur. He is a leading expert on the management of clinical laboratories and anatomic pathology group practices.

Lab Industry Leader and Consultant

Michel is Editor-In-Chief of The Dark Report <http://www.darkreport.com/index.htm> and President of The Dark Intelligence Group, Inc. Over the past three decades, he has provided strategic and tactical management services to a wide variety of companies, ranging from Fortune 100 firms like Procter & Gamble and Financial Corp. of America to leading laboratories ranging from Nichols Institute to hospital and health system laboratory organizations. He has a special talent for spotting new business opportunities in clinical diagnostics and identifying winning strategies to pursue them.

Some of his current and past clients include: Meridia Health System (Cleveland, OH), PACLAB Regional Laboratory Network (Seattle, WA), Consultants in Laboratory Medicine (Toledo, OH), PAML, Inc.(Spokane, WA), UMASS Healthcare Reference Laboratories (Worcester, MA), Ortho-Clinical Diagnostics (Raritan, NJ), Pathology Service Associates (Florence, SC), DIANON Systems, Inc, (Stratford, CT), Beaumont Health System (Detroit, MI), MedTox Laboratories, Inc. (St. Paul, MN), Joint Venture Hospital Laboratory Network (Detroit, MI), Bayer Diagnostics (Tarrytown, NY), Bio-Reference Laboratories, Inc. (Elmwood Park, NJ), Specialty Laboratories, Inc., (Santa Monica, CA), National Health Service-Pathology Services (London, England), Doctor's Laboratory (Valdosta, GA), Sysmex Corporation (Mundelein, IL), Pathologist's Medical Laboratory (La Jolla, CA), Abbott Laboratories (Abbott Park, IL), St. John Clinical Laboratory Pathology Laboratory (Detroit, MI), Esoterix, Inc.(Austin, TX), Beckman Coulter Corporation (Fullerton, CA), Health Care Systems, Johnson & Johnson (Atlanta, GA), ARUP Laboratories, Inc. (Salt Lake City, UT), Institute for Quality in Laboratory Medicine (Atlanta, GA), and American Society of Clinical Pathology (ASCP-Chicago, IL).

Michel was first to identify and describe many of the widely-used management strategies in the operation of clinical laboratories and pathology practices. He has one of the best track records of predictions in laboratory management over the past decade and a half.

Michel is a member of the Clinical Laboratory Management Association <http://www.clma.org/> (CLMA), the American Association of Clinical Chemistry <http://www.aacc.org/AACC/> (AACC), Specialized Information Publishers Association <http://www.newsletters.org/> (SIPA).

Popular Journalist, Author & Editor

Michel writes and edits The Dark Report <http://www.darkreport.com/>, a business intelligence service for pathologists and laboratory executives that, over its eleven years of publication, has garnered national and international respect of its ground-breaking coverage of events and industry trends within the laboratory profession.

International Meeting Innovator, Public Speaker

Michel is the Founder and Director of the Executive War College on Lab and Pathology Management <http://www.executivewarcollege.com/>. First conducted in 1996, this gathering has become the premier forum for laboratory management in the world. For pathologists, he developed the Pathologist's Income Symposium a meeting series which is exclusively focused on helping pathologists increase their practice income, as well as their professional income. Every September he hosts a meeting by The Dark Report called Lab Quality Confab <http://www.labqualityconfab.com/>. It is an annual gathering dedicated to advancing the knowledge, skills, and effectiveness of quality management practitioners in diagnostic medicine. Programs, LEAN information, and training are designed for every level of management and all levels of knowledge and experience. Diagnostic medicine, particularly the services of clinical laboratory, pathology, imaging, and radiology, make up the primary emphasis of the Lab Quality Confab.

Since 2004, he has co-produced Frontiers in Laboratory Medicine <http://www.frontiersinlabmedicine.com/> (FiLM) in the United Kingdom with the Association of Clinical Biochemists <http://www.

acb.org.uk/>. This meeting has quickly earned a reputation as the best source of laboratory best practices in Europe. In 2005, Michel co-produced Executive Edge <http://www.exec-edge.com/> in Canada with QSE Consulting. This meeting about strategic laboratory management innovations in Canada proved popular and is repeated in the fall since 2005.

Michel is regularly asked to address laboratory industry groups. In addition to regular speaking engagements throughout the United States, he has traveled to Brazil, England, Canada, Australia, Korea, Japan, Ireland, and South Africa to address laboratory audiences in those countries. Meeting participants regularly rate Michel's presentations as one of the best at the event.

Experienced Educator, Strategist, and Business Facilitator

Over the past decade and a half, Michel has been invited to provide Grand Rounds and teach clinical laboratory and pathology management at the pathology departments of such medical schools as University of Minnesota, University of California at Los Angeles and University of Texas Southwest/Houston. He has provided strategic assessments to laboratory organizations, IVD manufacturers, pathology groups, information technology vendors, biotech companies, and diagnostic start-up companies. He is regularly asked to facilitate strategic management retreats and business planning meetings for such clients as PAML, OML, Sysmex Corporation.

Michel received his B.A. in Economics from the University of California at Los Angeles. He is a native of Santa Ana, California and currently lives and works in Austin, Texas.

A-8

About Poonam Khanna

Media and Marketing Specialist

Institute for Quality Management in Healthcare and Quality
Management Program—Laboratory Services

Poonam Khanna is the Media and Marketing Specialist at the Institute for Quality Management in Healthcare (IQMH) and its partner, the Quality Management Program—Laboratory Services (QMP–LS). Poonam helped launch IQMH's website in 2009 and helped build the organization's brand identity. She also leads IQMH's social media and marketing strategy. Before joining IQMH, Poonam was the Associate Editor at *Computing Canada*, a leading business technology magazine. She has published hundreds of articles and holds a Master's degree in Political Theory.

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