Basic Quality Management Systems

Essentials for Quality Management in the Medical Laboratory

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with contributions from
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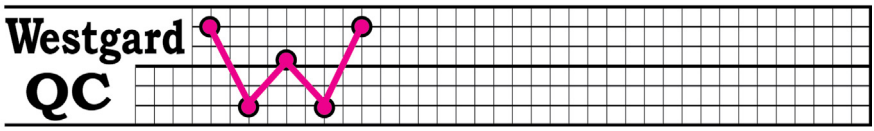

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Preface: Managing the Quality of Laboratory Testing Processes

In 1986, Patricia Barry and I authored a book titled *Cost-Effective Quality Control: Managing the Quality and Productivity of Analytical Processes* [1]. That book introduced industrial principles of Total Quality Management (TQM) and demonstrated their application to analytical testing in Medical Laboratories. We paid particular attention to optimizing the quality and productivity (or cost) through optimization of Statistical QC procedures. We outlined the principles and approach that has guided our work on analytical quality management ever since. The foundation of TQM, together with enhancements from Six Sigma Quality Management, still provides the basis for ongoing improvement of quality in the Medical Laboratory.

This book also begins with the principles of quality management, as described in the ISO 15189 global standard for medical laboratories [2]. ISO 15189 represents the adaptation of industrial quality management for the particular application in medical laboratories. ISO standards, by their nature, provide *general* advice on what needs to be done, but the standards do not provide the details on *how* to do it. The ISO approach provides flexibility for implementing the guidance and permits adaptation for the particular operating conditions in a medical laboratory and the economic and legal environment in different countries. The difficulty for many laboratories is figuring out the "how to do it" part, which has become a crucial issue now that ISO 15189 is being adopted as the laboratory accreditation model in many countries. It is the purpose of this book to provide some practical guidance on "how to do it".

In today's vernacular, the principles of quality management are embodied in a Quality Management System (QMS). "How to do it" involves the implementing a QMS that includes both management and technical requirements, as described in ISO 15189. In this context, the first part of this book focuses on the "management" requirements and the second part on the "technical" requirements.

James O. Westgard, Ph.D. Madison, Wisconsin, 2014

How this book is structured

Part I – Basic Quality Management Systems for Regulation and Accreditation – reviews management requirements and outlines the steps for QMS implementation. Chapters 1 through 3 provide a description of QMS, review QMS essentials, and discuss the specific ISO 15189 management requirements. Guidance for implementation is provided in chapter 4 through 6. Deming's Plan-Do-Check-Act cycle (PDCA) provides the basic organization for the implementation plan. Chapter 7, written by Leo Serrano and Cheryl Wildermuth, describes a real world application in the first laboratory to be accredited by the College of American Pathologists CAP-ISO 15189 program.

Part II – Six Sigma Quality Management Systems for Examination Procedures – focuses on the technical requirements, particularly those for the assurance of quality in the analytic or examination procedures. Chapters 8 through 15 provide guidance for developing a scientific QMS, defining quality for intended use, selecting examination procedures, validating the performance of examination procedures, designing SQC procedures, formulating a Total Quality Control plan, monitoring nonconformities, and determining the uncertainty of measurements. These chapters provide the "how to do it" guidance for some of the most difficult technical requirements. They feature Sigma-metric tools to support quantitative assessments of laboratory tests and scientific guidance for managing and improving the quality of those tests.

Acknowledgements

A special thank you to Leo Seranno and Cheryl Wildermuth for authoring chapter 7 and providing a real world example of the implementation of the CAP-ISO 15189 guidelines.

The Wallace H. Coulter Foundation stimulated the development of this book with their support for Spanish translations of our books on *Basic Method Validation* and *Basic QC Practices* (as well as this book). We thank Dr. Gabriel Migliarino and Evangelina Hernandez for providing the Spanish translations and also for providing their insights on ISO 15189 accreditation in chapter 17.

It has been a privilege to author this book together with my son Sten, who has provided the motivation for Westgard QC to move forward in this area, as well as providing the technical support for converting my drafts into a finished product. It has been one of the great pleasures in my career to work with Sten on the development of the books and training materials and to have his support and participation in our educational programs. This is the tenth book published by Westgard QC! Few scientists have the resources to promote their ideas with minimum "editorial" oversight. I am one of those lucky few, thanks to Sten.

About the authors and contributors

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A Note on ISO standards and CLSI guidelines

This book discusses many different standards and guidelines related to Quality Management Systems, including ISO 15189 and CLSI EP23A. We should note that CLSI has *trademarked* EP23, and that they are extremely careful in their commercial use of that guideline.

In that spirit, readers should note that each standard, guideline, and regulation is inevitably a moving target. ISO and CLSI continuously review and attempt to improve their documents, issuing an update or revision every few years. The regulatory and accreditation bodies (CLIA, CAP, JC, A2LA, COLA, etc.) do the same. Thus, the specific language of some of these standards will change. However, as you are probably well aware, major changes in regulatory policy are infrequent. It is unlikely that significant changes will occur that change the goals of these organizations and their recommendations.

It is also important to note that this book is NOT meant to replace or substitute for ISO standards or CLSI guidelines. Laboratories are strongly encouraged to purchase the specific documents that they intend to implement in their operations. For a laboratory that intends to implement a Quality Management System, it will not be sufficient to read this book alone.

Where this book can be helpful is to give an overview and a comparison of ISO and CLSI (and other) recommendations. Laboratories may be able to decide *which* documents to purchase, as well as how to reconcile the differences between the different standards and guidelines.

The unique feature of this book is the Sigma-metric approach. While the other recommendations tend to be vague on how to implement and monitor the specifics of a quality management system, this book is very quantitative and data-driven. Assessing your processes on the sigma scale will give you a concrete estimate of the performance of your QMS. The combination of the Six Sigma approach with Quality Management System concepts can provide powerful tools and techniques to your laboratory.

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Part One: Basic Quality Management Systems for Regulation and Accreditation

Part Two: Six Sigma Quality Management Systems for Examination Procedures

But Wait, That's Not All!

Readers who visit Westgard Web can gain access to online extras, such as a full reference list, glossary of terms, links to spreadsheets, checklists, worksheets, and other downloads related to this book.

Go to **http://www.westgard.com/qmsextras.htm**

Part I. Basic Quality Management Systems for Regulation and Accreditation

The first part of this book presents a broad perspective of management and technical requirements for laboratory accreditation, with a focus on the plan and process for implementing a Quality Management System. It emphasizes the management responsibility to make a commitment to quality and implement a quality system that supports all laboratory personnel in their efforts to produce quality test results and continually improve production processes.

Chapter 1 – Understanding Quality Management Systems – introduces Deming's Plan-Do-Check-Act cycle (PDCA) as the fundamental building block for a QMS.

Chapter 2 – Reviewing QMS Essentials – compares and contrasts the principles and approaches of Total Quality Management, the US CLIA regulations for laboratories, the WHO/CLSI/CDC quality system essentials, and the ISO 15189 guidance.

Chapter 3 – Focusing on ISO 15189 – enumerates the list of management and technical requirements to provide an overview of the complete QMS for a medical laboratory.

Chapter 4 – Preparing for QMS Implementation – reviews Deming's principles for Total Quality Management and his requirements for implementation, along with other more specific guidance for implementation in medical laboratories.

Chapter 5 – Implementing Management Requirements – provides a step-by-step description of a PDCA plan for addressing the ISO 15189 management requirements.

Chapter 6 – Implementing Technical Requirements – provides a step-by-step description of a PDCA plan for addressing the ISO 15189 technical requirements.

Chapter 7 – A Lab's Journey to CAP-ISO 15189 Accreditation – presents the real world experience of one laboratory's effort to achieve accreditation.

1. Understanding Quality Management Systems

There is extensive literature about quality management in medical laboratories. Topics frequently include Quality Control, Quality Assurance, Quality Assessment, Quality Improvement, and Quality Planning, which are all part of Quality Management today. In addition, there is discussion of Quality Indicators, Lean Management, Six Sigma, Risk Analysis, ISO standards, and CLSI guidelines. For laboratory scientists, it's a challenge to integrate all these programs, guidelines, standards, and tools into a cohesive Quality Management System, whose purpose is to define the organizational structure and essential activities that are necessary to achieve quality in routine laboratory services.

W. Edwards Deming, who is often considered the father of Quality Management, described a "system" as a "series of functions or activities within an organization that work together for the aim of the organization" [1]. The parts of the system are interdependent and therefore require management to keep them in balance. Deming often referred to "optimization of the system" as the responsibility of management. He suggested that an orchestra was a good example of a system and that the conductor was a manager responsible for optimizing quality and performance.

Today there is a new emphasis on Quality Management Systems in medical laboratories and an increased recognition that management leadership and commitment are essential to guarantee the quality in all activities and processes in the laboratory. In effect, this is the second coming (or re-discovery) of the Total Quality Management principles and lessons learned back the 1990s when healthcare organizations began to adopt industrial models for Quality Management. The ISO 15189 standard adapts industrial principles and concepts specifically for application in the medical laboratory, creating a global standard for quality and competence in medical laboratories [2]. In addition, CLSI has developed detailed guidance for development of QMS in healthcare organizations [3] and medical laboratories [4]. CLSI's Quality System Essentials (QSEs) emphasize organization, customer focus, facilities and safety, personnel,

equipment, process management, documents and records, information management, nonconforming event management, assessments, and continual improvement.

All of these activities are part of current management practices and are already included in regulatory and accreditation requirements. So what is new and different about a Quality Management System?

ISO/CLSI definitions of terms

The language of quality today is defined by ISO (International Organization for Standardization) in an effort to standardize terminology for world-wide commerce. Because of that focus on commerce, business and industry are the main drivers and contributors to ISO standard development. CLSI functions as an agent of ISO for development of standards of practice for medical laboratories. In that role, CLSI provides a "harmonized terminology database" that is accessible at www.clsi.org.

Here are the ISO/CLSI definitions of some of the common terms in quality management:

- **Quality management** – *coordinated activities to direct and control an organization with regard to quality. Note (GP29): Direction and control with regard to quality usually includes establishment of the quality policy and quality objectives, quality planning, quality control, quality assurance, and quality improvement.*
    - **Quality** – *degree to which a set of inherent characteristics fulfills requirements.*
    - **Quality policy** – *overall intentions and direction of an organization related to quality as formally expressed by top management*
    - **Quality objective** – *something sought, or aimed for, related to quality*

- **Quality planning** – *part of quality management focused on setting quality objectives and specifying necessary operational processes and related resources to fulfill the quality objectives.*

- **Quality control** – *part of quality management focused on fulfilling quality requirements.... Note 2. In health care testing, the set of procedures designed to monitor the test method and the results to ensure appropriate test system performance.... Note 8. The purpose of quality control is to ensure that all quality requirements are being met. Note 9: The set of mechanisms, processes, and procedures designed to monitor the measuring system to ensure the results are reliable for the intended clinical use.* [see CLSI database for complete definition and all the notes, which run more than a page]

- **Quality assurance** – *part of quality management focused on providing confidence that quality requirements will be fulfilled. Note 1: The practice that encompasses all procedures and activities directed toward ensuring that a specified quality of product is achieved and maintained. In the testing environment, this includes monitoring all the raw materials, supplies, instruments, procedures, sample collection/transportation/storage/processing, recordkeeping, calibrating and maintenance of equipment, quality control, proficiency testing, training of personnel, and all else involved in the production of the data reported.*

- **Quality improvement** – *part of quality management focused on increasing the ability to fulfill quality requirements.*

- **Quality management system** – *management system to direct and control an organization with regard to quality. Note 1: Systematic and process-oriented efforts are essential to meet quality objectives. Note 2: For the purposes of ISO 15189, the "quality" referred to in this definition relates to matters of both management and technical competence; Note 3: A quality management system typically includes the organizational structure, resources, processes, and procedures*

needed to implement quality management; Note 4: These principles include the following categories: documents and records, organization, personnel, equipment, purchasing and inventory, process management, information management, nonconforming event management, assessments, continual improvement, customer focus, and facilities and safety.

- **Quality system** – *the organizational structure, resources, processes, and procedures needed to implement quality management.* [same as note 3 above]
- **Quality System Essentials** – *coordinated management activities to direct and control an organization with regard to quality*. [the activities defined in note 4 above]

Practical Purpose of QMS

Quality objectives and requirements must be defined if quality is to be measurable and manageable.

Quality Management describes the activities that are necessary to achieve quality objectives and requirements.

A **Quality Management System** provides the organizational structure, processes, procedures, and tools for implementing the activities necessary to achieve the quality objectives and requirements.

Defining Quality Objectives and Requirements

Given the importance of defining quality objectives and requirements, the ISO definition of quality may need some additional explanation. Other definitions are helpful to supplement and expand its meaning, such as the following:

- Juran – *Quality is fitness for use.* [5]
- Deming – *Quality should be aimed at the needs of the customer.* [6]
- Crosby – *Quality is conformance to requirements.* [7]
- CDC 1986 – *Quality of a laboratory testing service depends on providing the totality of features and characteristics that conform to the stated or implied needs of users or customers.* [8]

Important points are (a) the focus on needs of users and customers to define requirements; (b) the phrase "totality of features and characteristics" which reveals that quality is multi-dimensional, e.g., right patient, right specimen, right turnaround time, right test result, right report format, right patient record, etc.; (c) recognition that needs may be stated or implied, e.g., turnaround time will be a *stated* need that can be defined by the user, whereas analytical quality is an *implied* need that must be defined by the laboratory based on the intended clinical use of the test results; (d) "conformance to requirements" reveals how quality itself can be measured by identifying non-conformities or defects.

Developing a QMS

The fundamental model for a quality management system is Deming's Plan-Do-Check-Act cycle, which embodies the principles of scientific investigation and objective decision-making. The PDCA cycle is commonly presented as shown in Figure 1-1.

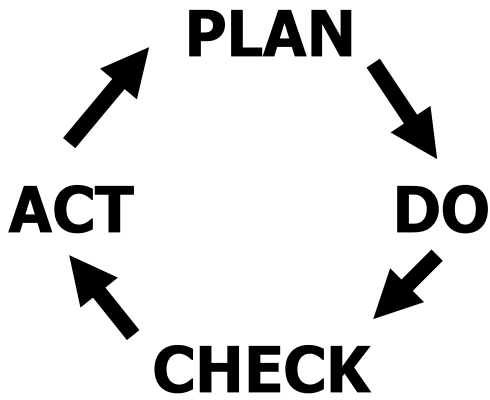

Figure 1-1. Deming's Plan-Do-Check-Act (PDCA) cycle.

- PLAN clearly aligns with quality planning.
- DO describes the policies, procedures, and processes for laboratory testing.

- CHECK involves quality control of the laboratory production processes.
- ACT relates to actions based on results obtained, such as decisions on the acceptability of production, root cause identification, quality improvement, etc.

Westgard TQM model. In adapting the Deming model for application in medical laboratories [9], the PDCA cycle can be expanded to include a component for quality assessment (QA) and also to provide a central focus on quality goals and objectives, as shown in Figure 1-2.

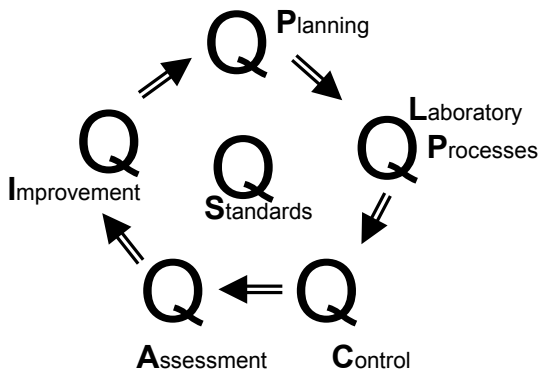

Figure 1-2. Total Quality Management Laboratory Process.

QP refers to Quality Planning; QLP to Quality Laboratory Processes; QC to Quality Control; QA to Quality Assessment; QI to Quality Improvement; and QS to Quality Standards, which represent the quality policy, goals, objectives, and requirements that need to be achieved. It bears repeating that the term QA here refers to quality *assessment*, not quality *assurance*. Quality assessment provides for measuring and monitoring the "*totality of features and characteristics*," whereas quality control is focused on monitoring the analytical quality of the test results. In the CLIA regulations, QA always means quality assessment, rather that quality assurance. Quality assurance is the outcome of the entire quality management system.

Six Sigma DMAIC model. Another well-known version of the Deming model is found in Six Sigma Quality Management and is called DMAIC [9]. As shown in Figure 1-3, the steps or components start at the top with Define, then complete the cycle with Measure, Analyze, Improve, and Control. In this adaptation, the Define step relates to quality-planning and includes definition of quality objectives and requirements, the Measure step applies to determining the performance of a procedure, process, or product; the Analyze step involves evaluation of the observed quality, which naturally leads to the Improve step of the process; finally, Control here means maintaining the quality of the improved procedure, process, or product so that it continues to meet the quality objectives and requirements.

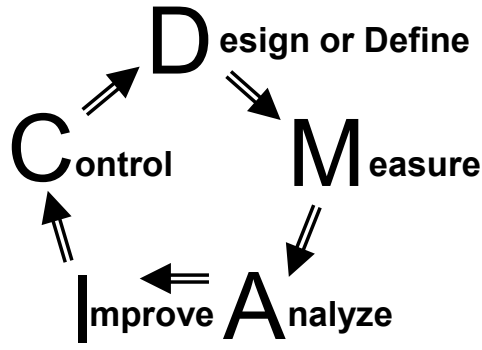

Figure 1-3. Six Sigma DMAIC Model for Process Improvement.

ISO 15189 PDCA model. The Deming cycle can also be applied to the ISO 15189 management and technical requirements, as described by Dr. David Burnett, who chaired the committee that developed the latest 2012 standard. Figure 1-4 represents Burnett's view of ISO as a process, rather than as a list of activities [Note that in the figure shown here, the PDCA cycle is presented as a clockwise rotation to have the same orientation as the other models.] This process perspective is not presented in the ISO standard itself, but Dr. Burnett features it in his public lectures about ISO 15189 and it is also presented in his book on ISO 15189 implementation[10].

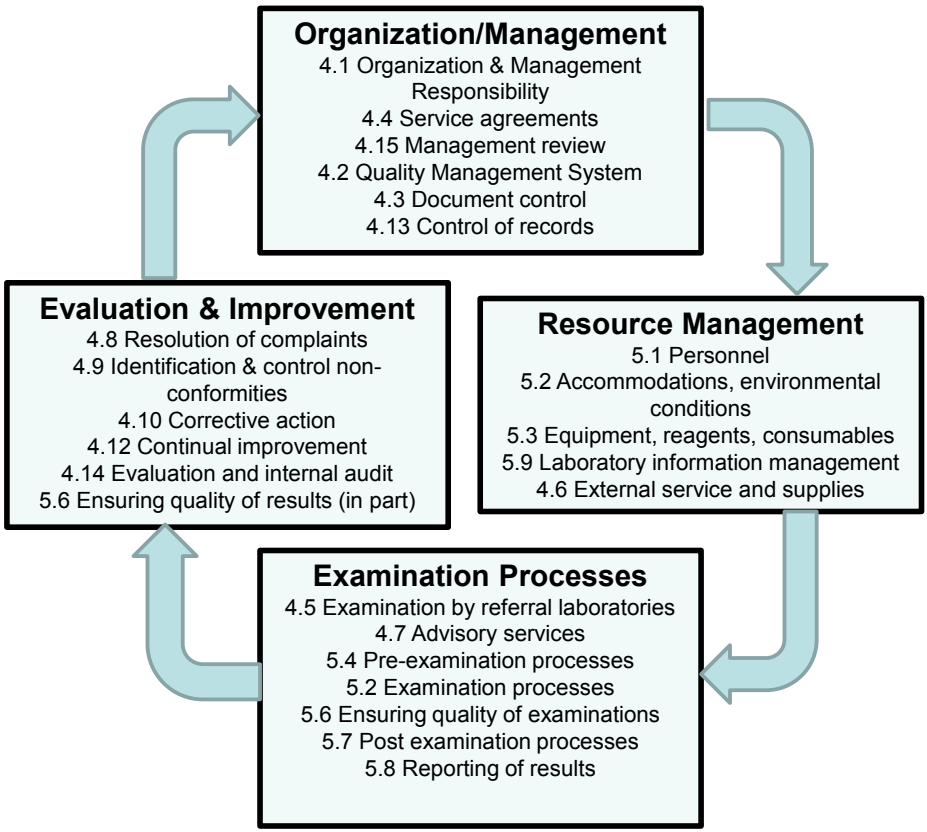

Figure 1-4. Burnett's PDCA Process model for ISO 15189 QMS.

ISO Requirements versus QMS

The ISO 15189 management and technical requirements, as well as the US CLIA regulatory requirements, are often presented as items in checklists in order to facilitate inspection and accreditation. However, for practical applications in the laboratory, those activities must be organized to support the daily management of testing processes. That organization, along with support for implementation, defines the Quality Management System.

Given the inherent differences between laboratories based on their resources, skills, and missions, it is expected that Quality Management Systems will vary from one laboratory to another, yet they should all be designed to guarantee that the laboratory fulfills its quality objectives and requirements. Certain principles guide the formulation of all Quality Management Systems, certain approaches may prove to be useful in many laboratories (such as Six Sigma), and certain tools are almost universally needed (method validation protocols, SQC, PT/EQA), yet the organization and deployment in individual laboratories will depend on the available resources and skills.

What is different about QMS is not the activities or requirements necessary to guarantee the quality of laboratory tests, but how to organize and embed those activities to ensure quality in the daily management and production of laboratory tests. Deming's PDCA model provides the fundamental guidance for structuring Quality Management Systems, but needs to be adapted, expanded, and detailed for efficient and effective management of laboratory testing processes.

What's the point?

On the road to quality, there is an itinerary for the journey. That itinerary details the important landmarks along the way that contribute to the success of the journey. The implementation of that journey requires a map to effectively organize the trip and to identify the correct path. Quality management identifies the itinerary of activities; a quality system provides a plan or map for organizing and implementing those activities. There is a basic structure for maps (North is up, rivers are blue, interstate highways are bold, etc.) and likewise, there is a basic structure for a QMS in the form of Deming's PDCA model. The maps for individual states and the QMSs from one laboratory to another may differ, but they should maintain a commonality of structure and purpose even though there may be unique paths for each laboratory's journey.

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6. Implementing Technical Requirements

Establishing a QMS begins with the implementation of management requirements as the first phase and the implementation of technical requirements as the second phase. This doesn't necessarily mean the two phases have to be entirely sequential, only that management requirements must be considered first to ensure top level commitment and leadership and the availability of necessary resources. Top management and/or the Management Planning Team (MPT) could authorize a second Technical Planning Team (TPT) that would work in parallel to implement the technical requirements. That would help minimize the time for implementation, utilizing the scientific expertise of the laboratory analysts and supervisors, and achieving more widespread buy-in throughout the laboratory.

The implementation model recommended here follows Deming's Plan-Do-Check-Act cycle, is similar to the PDCA cycle for implementing management requirements, but focuses on the technical requirements found in section 5 of ISO 15189 [1] and the Process Control essentials in the WHO/CLSI/CDC methodology [2-4]. Figure 6-1 summarizes the implementation process.

PLAN stage of implementation

Top management must consider how and when to begin the implementation of technical requirements. The priorities are first to deal with management requirements for organization of the QMS, designation of a Quality Manager, formation of a Management Planning Team, definition of quality goals and objectives, analysis of gaps in quality practices, development of an action plan, and implementation of a document control system. The MPT should also consider how to share the responsibilities for the technical requirements (5.1) personnel, (5.2) accommodations and environmental conditions, and (5.3) laboratory equipment, reagents, and consumables.

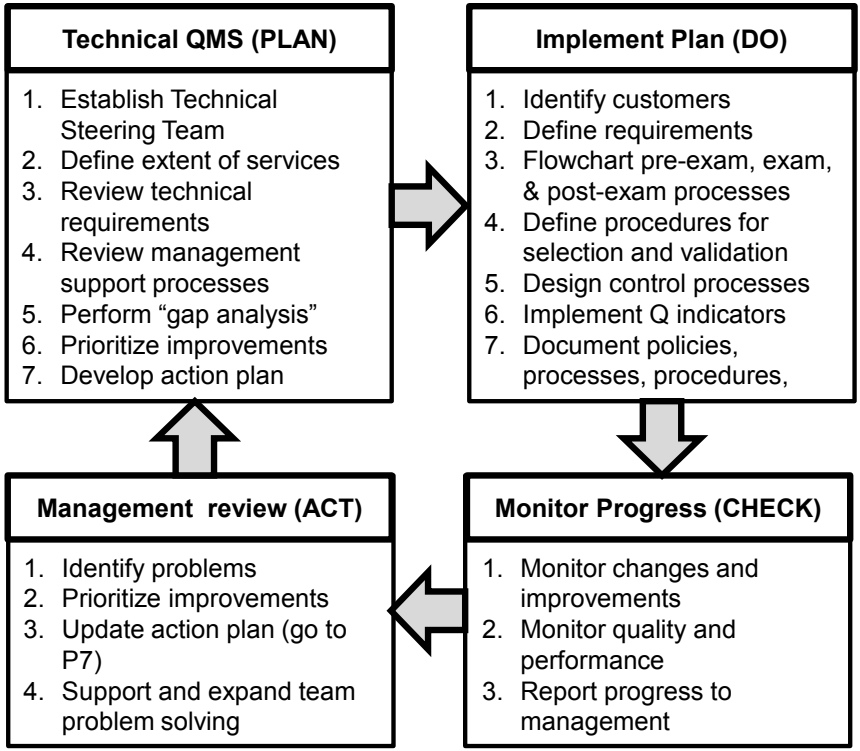

Figure 6-1. Plan for implementing QMS technical requirements.

P1. Establish a Technical Planning Team

In a small to moderate size laboratory, the Management Planning Team could also function as the Technical Planning Team. In a large laboratory, separate teams would be better to keep the sizes of the teams small and to provide specific focus for the management and technical planning activities. The Quality Manager must be a part of the TPT in order to coordinate the activities of the two teams. Other members should represent the pre-examination, examination, and post-examination phases of the testing process, along with the various laboratory disciplines, e.g., hematology, clinical chemistry, microbiology, blood bank, molecular diagnostics, etc. In a large laboratory, the TPT will also include Quality Specialists (those with

7: A Community Hospital Laboratory's Journey To CAP-ISO 15189 Accreditation

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A brief introduction

During Leo Serrano's tenure as laboratory director for the Avera McKenna Hospital and University Medical Center in Sioux Falls, South Dakota, the hospital was the first in the nation to achieve ISO 15189 accreditation through CAP. He has valuable insights into the accreditation process through uniquely American eyes.

Some of these observations were reported in the May 2009 issue of CAP Today, in the article by Anne Ford, *Making the Leap to ISO 15189 – What Lab Leaders Have Learned.*

Leo shared some of his experiences about the impact of achieving ISO 15189 on the hospital and its business:

"'We're already seeing the financial benefits pay off....We have a very strong research arm, the Avera Research Institute, and they are using our ISO accreditation to help them garner grants.... We've also been able to use it to our advantage as we have discussions with payers. When you can show them that your laboratory is 15189-accredited, that definitely gets their attention."

"'And then there are the non-financial rewards,' Leo continues, 'It gives us a significantly more powerful platform from which to tout the laboratory and its contributions to patient care and to quality. While we have consistently world-class turnaround times, world class error rates, we still had physicians who emphasized the outliers. This acheivement confirms what we had been telling them.'"

While Leo Serrano has since moved on to another institution, we are fortunate that he has agreed to share with us his past experiences with developing and implementing a Quality Management System.

Introduction

This is the true rendition of the journey to becoming the first hospital laboratory in the US to achieve CAP-ISO15189 accreditation. No names are used but otherwise the details are as they actually occurred. The basic layout of this chapter is following the PDCA format. As you take this journey, PDCA becomes second nature in helping you achieve success in any endeavor you choose to undertake. Our journey began when one of our senior pathologists approached us with the idea of being a "pilot site" for a new ISO based CAP Accreditation. A little investigation into the idea intrigued us and fit in to our organization's culture of excellence. The rest is history.

PLAN:

As you choose to undertake this journey, and it truly is a never-ending journey, the planning portion is critical to the success and smoothness of the process.

1. Obtaining Administrative Support

The first step of the journey was obtaining support from the hospital administration as well as from the pathologists. In order to obtain their support, it was important to demonstrate the advantages of obtaining a "world-class" internationally recognized accreditation. This required research into the ISO-15189:2007 standards and how they differed from our standard CAP accreditation standards. This was an interesting challenge since the laboratory was already widely recognized as a leading exponent of LEAN (Toyota Production System) and was accredited by the College of American Pathologists, the AABB and FDA (for our full service blood bank) and FACT (for our Stem Cell transplant processing lab). Why do we need another accreditation? What is the advantage? What is the burning platform?

2. Commitment to Quality Management

Because of our robust TPS/LEAN experience, we already had a strong and well-developed commitment to quality. Our MPT had several LEAN certified members. Many of the details that are important in

ISO-15189 were already in place; although in some areas, we had to expand or strengthen our efforts. Through planning and investigation, we were able to determine our strengths and weaknesses and work on those areas in need of shoring up.

Figure 7-1. The CAP-15189 experience at Leo Serrano's hospital

3. Determining Your Organization's Maturity

This is the most emotionally demanding portion of the preparation. It is not an easy thing to critique an organization that you and your team have been developing over the years. It requires a willingness to look outside of the bounds and think out of the box. Because the QMS manager had been away from the laboratory for a while, hers were fresh eyes looking at our operation, culture and processes. This became an invaluable tool.

Part II. Six Sigma QMSs for Examination Procedures

The first part of this book presents a broad perspective of management and technical requirements for laboratory accreditation. The second part provides a more detailed example of a QMS that is focused on the technical requirements, particularly the analytical quality of the examination procedure. Six Sigma concepts and metrics are applied to develop an objective, quantitative QMS, which we call a Six Sigma Quality Management System (***6σQMS***).

Our intention is to describe and develop this ***6σQMS*** as an extension of Deming's Plan-Do-Check-Act (PDCA) cycle. However, we do not provide a complete set of policies, processes, and procedures (that probably can't be done for all laboratories and all scenarios), but rather examples for specific technical requirements that require quantitative assessments and implementation guidance.

Chapter 8 – Developing a Scientific Quality System – provides an overview of the recommended Six Sigma Quality Management System, along with some illustrations of the tools and techniques that are applicable at different steps in the ***6σQMS***.

Chapter 9 – Defining Quality for Intended Use – focuses on the most critical step for making quality measurable. How good does an examination need to be?

Chapter 10 – Selecting an Examination Procedure – emphasizes the need to consider traceability as a critical characteristic in the choice of any examination procedure in order to achieve comparability of results across methods, laboratories, and countries.

Chapter 11 – Validating Performance of an Examination Procedure – describes how to assess quality on the Sigma Scale to provide a standard yardstick for measuring quality and making decisions about the acceptability of performance.

Chapter 12 – Designing SQC Procedures – addresses the critical ISO 15189 requirement that laboratories design QC procedures to verify the attainment of the intended quality of results.

Chapter 13 – Formulating Total Quality Control Plans – considers the broader issue of managing the quality of the Total Examination Process and the development of risk-based QC Plans.

Chapter 14 – Monitoring Nonconformities – recommends the broad application of Sigma metrics for Quality Indicators throughout the Total Examination Process and reviews the traditional "counting methodology" that can be used for pre- and post-examination characteristics.

Chapter 15 – Measuring the Uncertainty of Measurements – discusses issues related to measurement uncertainty and provides some practical guidance for monitoring the quality of examination processes.

Chapter 16 – Managing Quality in the Real World – summarizes our recommendations and advice and hopefully provides some perspective for how you can approach QMS in the real world.

Chapter 17 – Improving Quality in the Real World – This chapter is contributed by Gabriel Migliarino, PhD, and Evangelina Hernandez, MS, who have guided more than a dozen laboratories through the ISO 15189 accreditation process in Latin and South America. They provide their observations on the challenges that labs face not only from this region, but in any region of the world.

12. Designing SQC Procedures

All laboratories perform quality control, but merely analyzing controls does not ensure that the necessary quality is achieved. The necessary quality must be defined, as discussed in chapter 10. The performance of the examination procedure must be validated to achieve the quality for intended use, as discussed in chapter 12. In addition, Statistical QC procedures (SQC) must be properly designed and properly implemented to detect medically important errors that occur during routine service operation.

ISO 15189 [1] imposes a demanding requirement in Section 5.6.2.1 with the statement *"the laboratory shall design quality control procedures that verify the attainment of the intended quality of results"*. It is recommended that quality control materials be examined at a frequency that reflects the stability of the examination procedure and the patients' consequence of harm if erroneous results are produced. The laboratory should apply statistical control rules to make decisions on the acceptability of analytical results and the need to reject runs and repeat patient testing.

6σQMS Policy. The laboratory shall design Statistical Quality Control procedures to ensure the quality of routine testing meets the needs of the intended use of examination procedures.

Guidance on the design of SQC procedures can be found in ISO 151**98** (which should not be confused with 151**89**). The 15198 document [2] provides guidance to manufacturers on how to design SQC procedures and validate their performance:

"For existing IVD medical devices, conventional statistical quality control procedures (e.g. as described in CLSI C24) are considered adequate unless evidence from risk-monitoring activities indicates [other] quality control procedures are essential for maintaining risk at an acceptable level. In such cases, the quality control procedures shall be validated …. NOTE: Demonstration that a statistical quality control procedure will detect results that exceed predetermined limits does not require induction of actual failure modes. Validation may be based on statistical evaluation of the simulated effects of imprecision and/or bias on actual performance data obtained in routine operating mode."

There are two important considerations here: (a) SQC procedures can be readily validated based on existing information on their rejection characteristics, as determined from simulation studies documented in the clinical chemistry literature. (b) Validation of other non-SQC control procedures will require induction of actual failure modes to determine whether the QC procedures can detect medically important errors. Manufacturers can do this when they are validating new systems, but laboratories will find it very difficult to induce specific failures to validate detection of individual controls. SQC is important in the laboratory because it is an independent control mechanism that can be designed to detect medically important errors.

Quality-Planning Tools make it practical for laboratories to select the right SQC procedures. Power curves [3, 4] and critical-error graphs [5] have been used for planning SQC procedures for many decades. Today's version of the critical-error graph is known as the Sigma-metrics SQC Selection Tool and its application is illustrated in the CLSI C24A3 guidance for Statistical QC procedures [6]. Charts of Operating Specifications [7, 8] are a related tool and there are "normalized" charts that are available for manual applications [9]. There also are computer programs available, both an standalone automatic QC design program [10] and an online production tool.

6σQMS Process. The laboratory shall select SQC procedures on the basis of the quality required for intended use, the imprecision and bias observed for the examination procedure, and the known rejection characteristics of different control rules and different numbers of control measurements.

ISO 15198 makes reference to CLSI C24 [6], which discusses the principles of SQC and describes a process for selecting appropriate control rules and the number of control measurements to detect medically important errors. While C24A3 provides a Sigma SQC Selection Tool, it is also possible to employ Charts of Operating Specifications, thus there are two planning tools that are practical for use in the laboratory.

17. Improving Quality in the Real World

Editor's note: about Gabriel Migiliarino

In the last 6 years, Gabriel Migliarino and his consulting service have taken more than a dozen laboratories through the ISO 15189 accreditation process, in Argentina, Chile, the Dominican Republic, Mexico, Panama and Uruguay.

As a Quality Management System consultant, Dr. Migliarino has useful insights to share with us. Even though the resource and logistical environment of US hospitals are often far better than those of labs in Latin and South America, there are many common challenges and deficits that face labs all over the world.

We know Dr. Migliarino best from his collaboration with us in the translation projects sponsored by the Wallace Coulter Foundation. Dr. Migliarino delivers training in Latin and South America about verification of measurement procedures and internal statistical quality control. This workshop is delivered in 5 different countries in the area per year and has an estimated total duration of five years.

Experiences from the field

Gabriel Migliarino, PhD
Evangelina Hernandez, MS

Introduction

Each laboratory takes its own individual path towards Quality Management Systems accreditation but many share the same weaknesses and concerns during the journey.

In Latin and South America, scientists have not received a lot of education on "management." When laboratories seek accreditation, this is a new concept – to "manage quality" – for the laboratory. As mentioned on Chapter 5, the accreditation project comprises three stages: management requirements, technical requirements and accreditation.

What happens generally with the accreditation process in the Latin and South American region? The second stage, particularly the application of technical requirements (5.5 Analytical Procedures, 5.6 Quality Assurance of Analytical Results), often moves forward before the first stage (management requirements). Why? Applying technical requirements involves the area of operations where most laboratory scientists are more comfortable and more interested in making improvements. Most scientists are already working on the technical parts of measuring, monitoring, and improving quality. But "managing quality" is something new to them.

The Starting Point : Management Requirements

For most laboratories, starting the process of accreditation for Quality Management Systems, applying the management requirements of ISO 15189:2012 [1] standard moves forward slowly and with great difficulty.

Below we list the management requirements that generally present the most difficulty to our clients:

1. Documents
2. Quality Policy and Objectives
3. Nonconformities and corrective actions
4. Indicators

1. Documents. How to organize them.

Generally, the documents system has a basic common structure as shown on Figure 1.

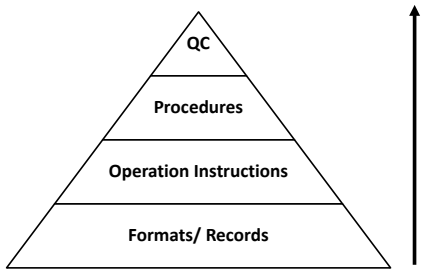

Figure 17-1 Document Pyramid

Quality Manual

The Quality Manual is the "Big Daddy" of all the documents in the Quality Management System and is therefore of crucial importance. Its function is to express the policies (intentions) of the company to comply with the regulatory requirements and criteria of the accreditation entity.

What we observe

Many times, the Quality Manual is a complex document, difficult to read and understand. Other times it is an almost exact copy of the ISO 15189:2012 standard, so generic and repetitive of the official requirements, it loses all usefulness for the laboratory.

What we recommend

Labs should focus on the idea that the Quality Manual is the foundation for the entire Quality Management System. If this is true, the Quality Manual must be as clear as possible. It has to concisely express the will of the laboratory to comply with the regulatory requirements, provide a guide to the documented procedures, and explain the activities to implement.

Other documents

The documents of the Quality Management System must show traceability, in the sense indicated by Figure 1. Namely, each document must have its "father/reference document" which enables tracing every procedure back to its foundation in the Quality Manual.

What we observe

We find many "orphan" documents, fatherless, and, consequently, not traceable to any part of the Quality Manual. It is most common to find forms and records that are controlled but without documentary traceability.

What we recommend

The first step is to identify all the procedures in the Quality Manual. Then, for instructions and forms, we suggest generating a coding

system that indicates the origin of each document. The codes enable the "traceability" of the procedures back to the references in the Quality Manual.

2. Quality Policy and Objectives. How to present them.

The Quality Policy reflects the laboratory's intentions concerning quality and is the reference framework to establish the Quality Objectives.

What we observe

Generally, we find Quality Policies are too complex and difficult to understand. Concerning Quality Objectives, they show several weaknesses, among them:

a. They are not coherent with the Quality Policy.
b. They are not concrete or measurable.
c. Sometimes they are not realistic or achievable, sometimes they are too easy (not ambitious).
d. They are not planned and lack follow-up.
e. They are not communicated to staff.

What we recommend

To establish a Quality Policy appropriate to the organization, it should be short and clear. It should be kept in mind that it must be communicated and understood within the organization; any member of the organization should be able to explain it.

To define coherent quality objectives, they should be SMART: Specific, Measurable, Achievable, Realistic and on Time.

Objectives must align with procedures, not only the operative procedures (pre-analytical, analytical and post-analytical) but also supportive (staff management, services and supplies management, among others). Remember that managing a system, and consequently its procedures, implies that you have established Quality Objectives.

Manage objectives according to the following stages:

1. Establish objectives.
2. Develop the general plan: scope, time frame, costs, specifications, risks.
3. Develop the resources plan: staff, materials, equipment, funding.
4. Implement: organization, communication, leadership, decision-making, problem-solving, monitoring, corrective actions.
5. Review: final evaluation, lessons learnt.

3. Nonconformities. Corrective Actions. How to identify and manage them.

The laboratory must have a procedure to identify and manage non-conformities on any aspect of the Quality Management System. The most common sequence, though not the only one, to treat non-conformities is as follows:

Stage 1. Identification of the nonconformity.
Stage 2. Immediate action.
Stage 3. Analysis of the root cause.
Stage 4. Corrective action.
Stage 5. Verification of the corrective action efficacy.

What we observe

There are several weaknesses that often occur.

1. Some nonconformities are not recorded in the system. According to our experience, we see see mainly four causes.
   a. Implementation of models centered on finding a culprit, not a root cause.
   b. Failure to identify nonconformities. In the absence of data, the staff doesn't even know a nonconformity has occurred.
   c. Notification and recording systems so complex and unwieldy that they are not used by the staff, so nonconformities are not recorded.
   d. Lack of confidence in the usefulness of the nonconformities management system (a consequence of causes 2 and 3 below).

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ISO 15189 sections

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