This guideline provides a model for medical laboratories to organize the implementation and maintenance of an effective quality management system.

A guideline for global application developed through the Clinical and Laboratory Standards Institute consensus process.
A Quality Management System Model for Laboratory Services

Anne T. Daley, MS, MT(ASCP)DLM, CMQ/OE(ASQ)CSBB, CLC(AMT)
Lucia M. Berte, MA, MT(ASCP)SBB, DLM, CQA(ASQ)CMQ/OE
Kris R. Arney, MT(ASCP)
Connie Lien Adams
Jenny Bazov, MSc, CQA(ASQ)
Michael B. Cohen, MD
Kenra Ford, LSSGB, MBA, MT(ASCP)
Mary Galloway, MS

David Kimes
Elizabeth McBride, MLT, BSc, MLS, LQM, CQA(ASQ)
Laura McClannan, MS, MT(ASCP)SBB, CQA(ASQ)
Phillip P. Morehouse, MLT, CMQ/OE(ASQ)
Tania Motschman, MS, MT(ASCP)SBB
Amy Pennock, MS, CQE(ASQ)
Tiea Theurer, MT(ASCP), MQ/OL(ASQ), MPA, PMP, CQE(ASQ)
Janette Wassung

Abstract

Clinical and Laboratory Standards Institute guideline QMS01—A Quality Management System Model for Laboratory Services provides the necessary background information and infrastructure to develop a quality management system that meets the laboratory’s quality objectives and is consistent with the quality objectives of health care services. This guideline provides a structure for a comprehensive, systematic approach to building quality into the laboratory’s processes, assessing the laboratory’s performance, implementing quality improvements, and assisting in preparing for or maintaining accreditation.


The Clinical and Laboratory Standards Institute consensus process, which is the mechanism for moving a document through two or more levels of review by the health care community, is an ongoing process. Users should expect revised editions of any given document. Because rapid changes in technology may affect the procedures, methods, and protocols in a standard or guideline, users should replace outdated editions with the current editions of CLSI documents. Current editions are listed in the CLSI catalog and posted on our website at www.clsi.org.

If you or your organization is not a member and would like to become one, or to request a copy of the catalog, contact us at:

P: +1.610.688.0100  F: +1.610.688.0700  E: customerservice@clsi.org  W: www.clsi.org
# Contents

Abstract ......................................................................................................................... i  
Committee Membership. ............................................................................................... iii 
Foreword .......................................................................................................................... ix 

**Chapter 1: Introduction** ............................................................................................ 1  
1.1 Scope ....................................................................................................................... 2  
1.2 Background ............................................................................................................. 2  
1.3 Terminology ........................................................................................................... 4 

**Chapter 2: The Quality Management System Model.** ............................................. 13  
2.1 How the Quality Management System Model Was Developed ............................. 14  
2.2 The Quality System Essentials ............................................................................. 20  
2.3 Documenting the Quality Management System .................................................. 22 

**Chapter 3: Quality System Essentials.** ................................................................... 27  
3.1 Organization and Leadership ............................................................................... 28  
3.2 Customer Focus .................................................................................................... 40  
3.3 Facilities and Safety Management ........................................................................ 45  
3.4 Personnel Management ....................................................................................... 56  
3.5 Supplier and Inventory Management ..................................................................... 61  
3.6 Equipment Management ...................................................................................... 67  
3.7 Process Management ............................................................................................ 75  
3.8 Documents and Records Management .................................................................. 88  
3.9 Information Management .................................................................................... 94  
3.10 Nonconforming Event Management .................................................................. 101  
3.11 Assessments ....................................................................................................... 106  
3.12 Continual Improvement ...................................................................................... 113 

**Chapter 4: The Laboratory's Path of Workflow.** ....................................................... 117  
4.1 Preexamination Processes .................................................................................... 121  
4.2 Examination Processes ....................................................................................... 125  
4.3 Postexamination Processes .................................................................................. 128  
4.4 Consultation on Application of Examination Results to Patient Care ................. 131  
4.5 Using the Path of Workflow to Improve Laboratory Services ............................. 132
Contents (Continued)

Chapter 5: Implementing the Quality Management System ......................................................... 133
  5.1 Planning for the Quality Management System ............................................................... 134
  5.2 Preparing the Rationale for a Quality Management System ......................................... 135
  5.3 Performing a Quality System Essential Gap Analysis to Identify What Needs to Be Done ............ 140
  5.4 Determining Priorities for Quality System Essential Implementation .............................. 141
  5.5 Plan for Implementing the Quality Management System .................................................. 144
  5.6 Communicating, Educating, and Training ....................................................................... 150

Chapter 6: Applying Quality Management Beyond the Laboratory to a Health Care Organization’s Services ........................ 155
  6.1 A Service Unit's Path of Workflow .............................................................................. 156
  6.2 The Laboratory as a Model for Other Services ............................................................. 158

Chapter 7: Conclusion ................................................................................................................... 159

Chapter 8: Supplemental Information .......................................................................................... 163

References .................................................................................................................................. 164
  Appendix B1. Directions for Performing a Gap Analysis ......................................................... 174
  Appendix B2. Excerpts From the CLSI Quality Management System Gap Analysis Tool ................ 175
  Appendix B3. Example of Quality Management System Implementation Plan Progress Chart ........... 177
  Appendix C. Quality Management System Implementation Plan: Examples of Actions ...................... 179
  Appendix D1. Path of Workflow Example for Blood Transfusion .............................................. 186
  Appendix D2. Path of Workflow Example for Medication Use .................................................... 187
  Appendix D3. Path of Workflow Example for Diagnostic Imaging .............................................. 188
  Appendix D4. Path of Workflow Example for Respiratory Therapy ............................................. 189

The Quality Management System Approach .................................................................................. 190

Related CLSI Reference Materials .............................................................................................. 193
Foreword

Increased awareness of the costly personal and economic effects of medical errors has underscored the importance of managing quality in health care services. In the present environment of limited resources, quality cannot be taken for granted by those who fund, receive, or provide laboratory services. The historical perspective of quality control and quality assurance as defining quality needs to be superseded by a more comprehensive view of internationally accepted quality practices applied to a laboratory’s entire scope of work.

This guideline is intended as a reliable, practical, and easily understood perspective that can be implemented in any laboratory.

QMS01 is a guideline that can help laboratories implement a QMS to achieve quality laboratory services and meet international standards and regulatory and accreditation requirements. QMS01 is not a standard; that is, this guideline does not set requirements for implementing a QMS. Rather, it reorganizes existing requirements for medical laboratories into a more understandable approach. It can be used along with other quality-related documents to design the foundation necessary to achieve an efficient, effective, and sustainable QMS.

NOTE:

QMS01 is not a standard; it simply reorganizes existing requirements in a more understandable way.
Overview of Changes

This guideline replaces the previous edition of the approved guideline, QMS01-A4, published in 2011. Several changes were made in this edition, including:

• Shifted focus from process and procedural details for implementing the CLSI QMS model to an overview of specific required processes in the QMS, with referral to the library of QMS guidelines listed in the Related CLSI Reference Materials section for process and procedure details
• Described the patient’s relationship to the QMS
• Aligned guidance with any new or changed international, regulatory, and accreditation requirements for laboratories since the last edition
• Added suggestions for providing a rationale to laboratory leadership for implementing and maintaining a QMS
• Described a practical strategy for implementing a laboratory QMS

NOTE: The content of this guideline is supported by the CLSI consensus process and does not necessarily reflect the views of any single individual or organization.

KEY WORDS

Examination processes
Path of workflow
Postexamination processes
Preexamination processes
Quality
Quality assurance
Quality control
Quality cost management
Quality indicators
Quality management
Quality management system
Quality system essentials
Chapter 1

Introduction

This chapter includes:

- Guideline’s scope
- Background information pertinent to the guideline’s content
- “Note on Terminology” that highlights particular use and/or variation in use of terms and/or definitions
- Terms and definitions used in the guideline
- Abbreviations and acronyms used in the guideline
A Quality Management System Model for Laboratory Services

1 Introduction

1.1 Scope

The QMS model described in this guideline can be used in laboratories worldwide. This guideline is intended for use primarily by:

- Medical laboratories
- Blood gas laboratories
- Blood donor and pretransfusion testing laboratories
- Public health laboratories
- Clinical research laboratories

However, the QMS model is also applicable to other types of laboratories, including but not limited to:

- Food laboratories
- Environmental laboratories
- Veterinary laboratories

The 12 quality system essentials (QSEs) described in this guideline are universal and applicable to any size laboratory, whether simple or complex, and any laboratory discipline. This guideline is intended for laboratory directors, managers, supervisors, quality managers, and others responsible for implementing, evaluating, and maintaining the laboratory’s QMS.

1.2 Background

This guideline continues to revise a model, first published in 1999, that assists laboratories with implementing and maintaining an effective QMS. This model contains the regulatory and accreditation requirements for quality management specified by international and national organizations.1-12

The goal of an effective and efficient laboratory is to consistently provide the appropriate examinations with accurate results in a timely manner and with the most judicious use of resources. This goal includes working with practitioners to ensure the appropriate examination is ordered and the results are interpreted correctly. The complexity of laboratory services underlines the need for a systematic approach to provide this high level of service. A laboratory QMS is a systematic approach that describes, documents, implements, measures, and monitors the effectiveness of laboratory work operations in meeting regulatory and accreditation requirements and that promotes the efficient use of resources. The ultimate goal of this activity is to meet the expectations of laboratory customers.
efforts, and its consensus process focuses on harmonization of terms to facilitate the global application of standards and guidelines. Table 3 is provided to clarify the intended interpretations of the following terms.

**Table 3. Common Terms or Phrases With Intended Interpretations**

<table>
<thead>
<tr>
<th>Term or Phrase</th>
<th>Intended Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>“Needs to” or “must”</td>
<td>Explains an action directly related to fulfilling a regulatory and/or accreditation requirement or is indicative of a necessary step to ensure patient safety or proper fulfillment of a procedure.</td>
</tr>
<tr>
<td>“Require”</td>
<td>Represents a statement that directly reflects a regulatory, accreditation, performance, product, or organizational requirement or a requirement or specification identified in an approved documentary standard.</td>
</tr>
<tr>
<td>“Should”</td>
<td>Describes a recommendation provided in laboratory literature, a statement of good laboratory practice, or a suggestion for how to meet a requirement.</td>
</tr>
</tbody>
</table>

### 1.3.2 Definitions

**accreditation** – process by which an authoritative organization gives formal recognition that a laboratory is competent to carry out specific tasks.

**assessment** – systematic process to collect and analyze data to determine the current, historical, or projected status of an organization, person, or project.

**audit** – systematic, independent, and documented process to obtain objective evidence and evaluate it objectively to determine the extent to which the audit criteria are fulfilled.

**calibration** – comparison of a measurement instrument or system of unverified accuracy to a measurement instrument or system of known accuracy to detect any variation from the required performance specification.

**calibration verification** – the assaying of calibration materials in the same manner as patient samples to confirm that the calibration of the instrument, kit, or test system has remained stable throughout the measurement range for patient test results.

**competence** – demonstrated ability to apply knowledge and skills to achieve intended results.

**compliance** – successful fulfillment of a rule such as a specification, standard, policy, regulation, or law.

**conformance/conformity** – fulfillment of a requirement.

**continual improvement** – recurring activity to enhance performance.

**corrective action** – action(s) to eliminate the cause and prevent recurrence of a nonconformity or other undesirable situation; **NOTE:** There can be more than one cause for a nonconformity or undesirable situation.
The Quality Management System Model

A QMS can be described as a set of essential building blocks needed for a laboratory’s work operations to fulfill stated quality objectives. A QMS manages the interacting processes and resources needed to provide value and realize results for laboratory customers and users.\(^{18}\)

2.1 How the Quality Management System Model Was Developed

The QMS model described in this guideline was derived from existing published requirements for medical laboratories; it imposes no new requirements. The model simply reorganizes individual quality requirements into topics familiar to laboratories. The model also uses a process approach, which incorporates plan-do-check-act and risk-based thinking perspectives.

2.1.1 Deriving the Quality System Essentials

The QMS model in this guideline was derived by sorting individual requirements from international and national regulations and standards, as well as published accreditation requirements for medical laboratories, into topics, ie, identifying all the requirements for a single subject such as laboratory equipment or personnel. Each topic’s requirements were then arranged into sequential order by how they should occur when a new laboratory or new laboratory service is set up. The resulting topics of requirements were recognized as fundamental building blocks of quality and were given the title of QSEs, as shown in Figure 1.

Figure 1. The QMS Model Foundation and QSEs