



5th Edition

# QMS01

## A Quality Management System Model for Laboratory Services

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.

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# A Quality Management System Model for Laboratory Services

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## 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.

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[QMS01, 5th ed.](#)

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# Contents

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|  |            |
|--|------------|
| Abstract .....   | i          |
| Committee Membership .....   | iii        |
| Foreword .....   | ix         |
| <b>Chapter 1: Introduction .....</b>   | <b>1</b>   |
| 1.1 Scope .....  | 2          |
| 1.2 Background .....   | 2          |
| 1.3 Terminology .....  | 4          |
| <b>Chapter 2: The Quality Management System Model .....</b>                  | <b>13</b>  |
| 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         |
| <b>Chapter 3: Quality System Essentials .....</b>                            | <b>27</b>  |
| 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        |
| <b>Chapter 4: The Laboratory's Path of Workflow .....</b>                    | <b>117</b> |
| 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)

|  |            |
|--|------------|
| <b>Chapter 5: Implementing the Quality Management System</b> .....   | <b>133</b> |
| 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        |
| <b>Chapter 6: Applying Quality Management Beyond the Laboratory to a Health Care Organization's Services</b> ..... | <b>155</b> |
| 6.1 A Service Unit's Path of Workflow .....  | 156        |
| 6.2 The Laboratory as a Model for Other Services .....   | 158        |
| <b>Chapter 7: Conclusion</b> .....   | <b>159</b> |
| <b>Chapter 8: Supplemental Information</b> .....   | <b>163</b> |
| <b>References</b> .....  | 164        |
| <b>Appendix A.</b> Quality System Essentials With ISO 15189:2012, ISO/IEC 17025:2017, and ISO 9001:2015 .....      | 171        |
| <b>Appendix B1.</b> Directions for Performing a Gap Analysis .....   | 174        |
| <b>Appendix B2.</b> Excerpts From the CLSI Quality Management System Gap Analysis Tool .....                       | 175        |
| <b>Appendix B3.</b> Example of Quality Management System Implementation Plan Progress Chart .....                  | 177        |
| <b>Appendix C.</b> Quality Management System Implementation Plan: Examples of Actions .....                        | 179        |
| <b>Appendix D1.</b> Path of Workflow Example for Blood Transfusion .....   | 186        |
| <b>Appendix D2.</b> Path of Workflow Example for Medication Use .....  | 187        |
| <b>Appendix D3.</b> Path of Workflow Example for Diagnostic Imaging .....  | 188        |
| <b>Appendix D4.</b> Path of Workflow Example for Respiratory Therapy .....   | 189        |
| <b>The Quality Management System Approach</b> .....  | 190        |
| <b>Related CLSI Reference Materials</b> .....  | 193        |

## Foreword

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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:

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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

Quality

Quality indicators

Path of workflow

Quality assurance

Quality management

Postexamination processes

Quality control

Quality management system

Preexamination processes

Quality cost management

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.<sup>1-12</sup>

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.

#### NOTE:

The complexity of laboratory services underlines the need for a systematic approach to provide a high level of service.