CLINICAL AND LABORATORY STANDARDS INSTITUTE®

6th Edition

CLSI QMS01™

A Quality Management System Model for Laboratory Services

Sample

CLSI QMS01 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.

CLSI QMS01-Ed6
November 2026
Replaces CLSI QMS01-Ed5

A Quality Management System Model for Laboratory Services

Laura McClannan, MT(ASCP)SBB, CQA(ASQ)

Lucia M. Berte, MA, MT(ASCP)SBB, DLM, CQA(ASQ)CMQ/OE

Abstract

CLSI QMS01—*A Quality Management System Model for Laboratory Services* provides the necessary background information and infrastructure to develop a QMS that meets the laboratory's quality objectives and is consistent with the quality objectives of health care services. CLSI QMS01 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.

CLSI. *A Quality Management System Model for Laboratory Services.* 6th ed. CLSI guideline QMS01 (ISBN 978-1-68440-344-8 [Print]; ISBN 978-1-68440-345-5 [Electronic]). Clinical and Laboratory Standards Institute, USA, 2026.

Sample

The CLSI consensus process, which is the mechanism for moving a document through 2 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in technology may affect the procedures, methods, and protocols in a standard or guideline, users should replace outdated editions with the current editions of CLSI documents.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

CLINICAL AND LABORATORY STANDARDS INSTITUTE®

Copyright ©2026 Clinical and Laboratory Standards Institute. Except as stated below, any reproduction of content from a CLSI copyrighted standard, guideline, or other product or material requires express written consent from CLSI. All rights reserved. Interested parties may send permission requests to permissions@clsi.org.

CLSI hereby grants permission to each individual member or purchaser to make a single reproduction of this publication for use in its laboratory procedures manual at a single site. To request permission to use this publication in any other manner, e-mail permissions@clsi.org.

To read CLSI's full Copyright Policy, please visit our website at https://clsi.org/terms-of-use/.

Suggested Citation

CLSI. *A Quality Management System Model for Laboratory Services.* 6th ed. CLSI guideline QMS01. Clinical and Laboratory Standards Institute; 2026.

Previous Editions:

July 1998, October 1999, February 2003, November 2004, June 2011, June 2019

Sample

CLSI QMS01-Ed6

ISBN 978-1-68440-344-8 (Print)

ISBN 978-1-68440-345-5 (Electronic)

ISSN 1558-6502 (Print)

ISSN 2162-2914 (Electronic) Volume 46, Number 18

Contents

Abstract i
Committee Membership iii
Foreword vii
Chapter 1: Introduction 1
1.1 Scope 2
1.2 Background 2
1.3 Terminology 4
Chapter 2: The Quality Management System Model 7
2.1 How the Quality Management System Model Was Developed 8
2.2 The Quality System Essentials 13
2.3 Documenting the Quality Management System 15
Chapter 3: Quality System Essentials 19
3.1 Organization and Leadership 20
3.2 Customer Focus 29
3.3 Facilities and Safety Management 32
3.4 Personnel Management 41
3.5 Supplier and Inventory Management 45
3.6 Equipment Management 51
3.7 Process Management 56
3.8 Documents and Records Management 66
3.9 Information Management 71
3.10 Nonconforming Event Management 77
3.11 Assessments 81
3.12 Continual Improvement 87
Chapter 4: The Laboratory's Path of Workflow 91
4.1 Preexamination Processes 95
4.2 Examination Processes 98
4.3 Postexamination Processes 100
4.4 Consultation on Application of Examination Results to Patient Care 103
4.5 Using the Path of Workflow to Improve Laboratory Services 103

Sample

Contents (Continued)

Chapter 5: Implementing the Quality Management System 105
5.1 Planning for the Quality Management System 106
5.2 Preparing the Rationale for a Quality Management System 107
5.3 Performing a Quality System Essential Gap Analysis to Identify What Needs to Be Done 110
5.4 Determining Priorities for Quality System Essential Implementation 111
5.5 Plan for Implementing the Quality Management System 114
5.6 Communicating, Educating, and Training 119
Chapter 6: Applying Quality Management Beyond the Laboratory to a Health Care Organization's Services 125
6.1 A Service Unit's Path of Workflow 126
6.2 The Laboratory as a Model for Other Services 127
Chapter 7: Conclusion 129
Chapter 8: Supplemental Information 133
References 134
Appendix A. Quality System Essentials With ISO 15189, ISO/IEC 17025, and ISO 9001 139
Appendix B1. Directions for Performing a Gap Analysis 142
Appendix B2. Excerpts From the CLSI Quality Management System Gap Analysis Tool 143
Appendix B3. Example of Quality Management System Implementation Plan Progress Chart 145
Appendix C. Quality Management System Implementation Plan: Examples of Actions 147
Appendix D1. Path of Workflow Example for Blood Transfusion 150
Appendix D2. Path of Workflow Example for Medication Use 151
Appendix D3. Path of Workflow Example for Diagnostic Imaging 152
Appendix D4. Path of Workflow Example for Respiratory Therapy 153
The Quality Management System Approach 154

Sample

Foreword

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

CLSI QMS01 is intended as a reliable, practical, and easily understood perspective that can be implemented in any laboratory.

CLSI 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. **CLSI QMS01 is not a standard;** that is, it **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.

Overview of Changes

CLSI QMS01-Ed6 was revised in 2026 under the Limited Revision Process and replaces CLSI QMS01-Ed5, published in 2019. Several changes were made in this edition, including:

- Revising the terminology subchapter to align with the current template.
- Removing definitions that are now maintained in the CLSI Harmonized Terminology Database Quality Glossary.
- Updating references to existing CLSI documents and inserting references to new CLSI documents
- Updating content to align with CLSI QMS25[1]

NOTE: The content of CLSI QMS01 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 indicators
quality management system
quality objectives
quality policy
quality system essentials

Sample

Chapter 1

Introduction

Sample

A Quality Management System Model for Laboratory Services

1 Introduction

1.1 Scope

The QMS model described in CLSI QMS01 can be used in laboratories worldwide. CLSI QMS01 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 CLSI QMS01 are universal and applicable to any size laboratory, whether simple or complex, and any laboratory discipline. CLSI QMS01 is intended for laboratory directors, managers, supervisors, quality managers, and others responsible for implementing, evaluating, and maintaining the laboratory's QMS.

1.2 Background

CLSI QMS01 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.[2-12]

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.

Medical laboratory quality has evolved over several decades, with the initial focus on QC of examination methods expanding to QA of process performance, and now, implementation of a QMS for an integrated systematic approach to quality throughout the entire laboratory. Table 1 compares these 3 different aspects of quality.

Sample

© Clinical and Laboratory Standards Institute. All rights reserved.

Discover How CLSI Can Improve Your Organization

The leading source for the latest medical laboratory standards.



CLSI membership lets you directly impact best practice standards used to improve patient care worldwide—standards you use every day. Membership provides you with standards access, volunteering opportunities, influence in the standards development process, networking opportunities, discounts, and more.

Discover the membership option for you at **clsi.org/join.**

Our educational and training programs provide convenient, cost-effective continuing education and training resources to help you advance your professional development. We have a variety of easy-to-use, online educational resources and in-person trainings that make learning stress-free and convenient for you and your staff.

See our current offerings at **clsi.org/global-training.**

Ensure high-quality laboratory testing with CLSI standards. eCLIPSE Ultimate Access™, our complete online library of standards, makes it easy for you and your staff to quickly find the CLSI resources you need. Read, search, link, annotate, bookmark, and share notes with your staff, all within one easy-to-use platform.

Learn more at **clsi.org/eCLIPSE.**

Sample

Sample



CLINICAL AND LABORATORY STANDARDS INSTITUTE®

PRINT ISBN 978-1-68440-344-8

ELECTRONIC ISBN 978-1-68440-345-5

CLSI QMS01-Ed6