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2nd Edition

CLSI QMS25™

Handbook for Developing a Laboratory Quality Manual

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CLSI QMS25 assists laboratories in developing a quality manual—a vital component of implementing and maintaining a complete laboratory quality management system.

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CLSI QMS25-Ed2
November 2026
Replaces CLSI QMS25-Ed1

Handbook for Developing a Laboratory Quality Manual

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Abstract

CLSI QMS25—*Handbook for Developing a Laboratory Quality Manual* is a useful tool for laboratories beginning to implement a QMS or those looking for a new perspective on laboratory quality management. CLSI QMS25 contains answers to commonly asked questions about quality manuals, suggestions for elements to include, useful appendixes, and templates for preparing quality management policies. Information in CLSI QMS25 aligns with the QMS approach published in CLSI QMS01.[1]

CLSI. *Handbook for Developing a Laboratory Quality Manual.* 2nd ed. CLSI product QMS25 (ISBN 978-1-68440-338-7 [Print]; ISBN 978-1-68440-339-4 [Electronic]). Clinical and Laboratory Standards Institute, USA, 2026.

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Suggested Citation

CLSI. *Handbook for Developing a Laboratory Quality Manual*. 2nd ed. CLSI product QMS25. Clinical and Laboratory Standards Institute; 2026.

Previous Edition:

January 2017

Sample

CLSI QMS25-Ed2

ISBN 978-1-68440-338-7 (Print)

ISBN 978-1-68440-339-4 (Electronic)

ISSN 1558-6502 (Print)

ISSN 2162-2914 (Electronic)

Volume 46, Number 17

Contents

Abstract i
Foreword vii
Chapter 1: Introduction 1
1.1 Scope 2
1.2 Background 2
1.3 Terminology 3
Chapter 2: Answers to Questions About a Quality Manual 5
2.1 What Is a Quality Manual? 6
2.2 Why Is a Quality Manual Beneficial? 8
2.3 What Is the Quality Manual Used for? 9
2.4 Who Should Write the Quality Manual? 9
2.5 When Should the Quality Manual Be Written? 10
Chapter 3: Guidance for Contents of a Quality Manual 11
3.1 Introduction and Purpose 12
3.2 Vision and Mission Statements 12
3.3 Scope 13
3.4 Quality Policy 13
3.5 Quality Goals and Objectives 13
3.6 Examples of Quality Manual Policies, Goals, and Objectives 14
3.7 Elements of the Quality Management System 16
3.8 Supporting Documents 17
3.9 Appendixes (Optional) 18
Chapter 4: Getting Started 19
4.1 Using the Provided Templates to Develop Quality System Essential Policies 20
4.2 Use and/or Modify the Laboratory's Current Documents 21
4.3 Documenting Quality System Essential Processes 23
4.4 Writing Quality System Essential Procedures 23
4.5 Table of Contents for a Quality Manual 24
Chapter 5: Conclusion 25

Sample

Contents (Continued)

Chapter 6: Supplemental Information 27
References 28
Additional Resources 30
Appendix A. Structure and Contents of a Template for a Quality System Essential–Based Policy 31
Appendix B1. Organization and Leadership 32
Appendix B2. Customer Focus 35
Appendix B3. Facilities and Safety Management 37
Appendix B4. Personnel Management 40
Appendix B5. Supplier and Inventory Management 42
Appendix B6. Equipment Management 44
Appendix B7. Process Management 46
Appendix B8. Documents and Records Management 48
Appendix B9. Information Management 50
Appendix B10. Nonconforming Event Management 52
Appendix B11. Assessments 54
Appendix B12. Continual Improvement 56
Appendix C. Crosswalk of Quality System Essentials to Related Clauses of ISO 15189 and ISO/IEC 17025 58
Appendix D1. Example Quality Process Flow Chart: "Documents Management Process" 60
Appendix D2. Example of the Inter-Relationships Between Training and Competence Assessment 61
Appendix D3. Example Quality Process Flow Chart: "Nonconforming Event Response Process" 62
Appendix D4. Example Quality Process Flow Chart: "The Audit Process" 63
Appendix D5. Example Quality Process Flow Chart: "Process Management Process" 64
Appendix E1. Example Quality Procedure: "Correcting a Laboratory Paper Record Procedure" 65
Appendix E2. Example Quality Procedure: "Electronic Reporting of a Laboratory Nonconforming Event Procedure" 66
Appendix F1. Example of a Quality Manual Table of Contents With Process and Other Supporting Documents Included in the Supporting Documents Section 67
Appendix F2. Example of a Quality Manual Table of Contents With Process and Other Supporting Documents Included in the Applicable QSE Section 68
The Quality Management System Approach 70

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Foreword

A quality manual provides laboratory leadership, personnel, and accreditors with a description of the laboratory's QMS, ie, the intent for how the laboratory will:

- Ensure quality.
- Practice good quality management.
- Meet regulatory, accreditation, and customer requirements.

Included in CLSI QMS25 are:

- Answers to the most commonly asked questions about a quality manual
- Guidance on how to develop a quality manual
- Templates for organizing laboratory management information into easily understood policies, processes, and procedures for each quality system essential (QSE)
- Examples of flow charts for QSE processes
- Example of a procedure for a QSE process

Overview of Changes

CLSI QMS25-Ed2 replaces CLSI QMS25-Ed1, published in 2017. Several changes were made in this edition, including:

- Revising the Foreword and 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 QMS01[1]

NOTE: The content of CLSI QMS25 is supported by the CLSI consensus process and does not necessarily reflect the views of any single individual or organization.

KEY WORDS

quality manual **quality objectives** **quality policy**

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Chapter 1

Introduction

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Handbook for Developing a Laboratory Quality Manual

1 Introduction

1.1 Scope

CLSI QMS25 provides a structured means for laboratory management and personnel to develop a quality manual for the first time or to restructure and revise a quality manual from a laboratory's existing administrative and quality documents. CLSI QMS25 can be used by:

- New and current laboratory management personnel to learn about the QMS policies, processes, and procedures in their laboratory
- Laboratory quality managers for developing needed quality processes, procedures, and forms and for ensuring effective implementation of the QMS
- Medical laboratories
- Blood gas laboratories
- Blood donor and pretransfusion testing laboratories
- Clinical research laboratories
- Veterinary laboratories

Applicable portions of CLSI QMS25 can also assist public health and environmental laboratories meet international and national requirements for a quality manual.[2,3]

1.2 Background

Laboratories dutifully write and maintain "procedures manuals" to provide instructions to personnel on how to do their work and how to comply with regulatory and accreditation requirements. These manuals contain documents that describe the laboratory's **technical** work activities, which range from collecting specimens from patients to reporting laboratory examination results. Although there is no requirement for a procedures manual for management personnel, the laboratory usually maintains a large "administrative manual" that contains various policies, memoranda, and other documents describing nontechnical work and organizational information. These manuals are often not arranged in a useful fashion and are not typically used for training new laboratory supervisory and management personnel about laboratory quality.

Creating a quality manual provides a means for describing and documenting the laboratory's QMS. In addition, the manual organizes laboratory administrative and management information in a useful way for training new management and supervisory personnel, for orienting personnel to the QMS, and for meeting regulatory and accreditation requirements. CLSI QMS25 guides the laboratory in developing a quality manual. The manual in CLSI QMS25 reflects the CLSI QMS described in CLSI QMS01.[1]

A QMS is a system for designing, implementing, maintaining, and managing quality in an organization and demonstrates management's commitment to quality to all personnel. It outlines the framework in which the organization continually monitors its processes, identifies problems, improves processes, and ensures quality is built into the services provided. Implementing a QMS enhances the opportunity to deliver consistent, high-quality, and cost-effective examinations, products, and services.

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PRINT ISBN 978-1-68440-338-7

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