CLINICAL AND LABORATORY STANDARDS INSTITUTE®

4th Edition

CLSI QMS06™

Quality Management System: Continual Improvement

CLSI QMS06 presents continual improvement (CI) as an ongoing, systematic effort that is an essential component of a quality management system. A CI program consists of fundamental processes and common supporting elements.

A guideline for global application developed through the Clinical and Laboratory Standards Institute consensus process

CLSI QMS06-Ed4
July 2025
Replaces CLSI QMS06-A3

Quality Management System: Continual Improvement

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Abstract

CLSI QMS06—*Quality Management System: Continual Improvement* includes written and graphic descriptions of fundamental processes and common supporting elements in a continual improvement program. It provides the user with definitions, concepts, models, and tools for implementing an effective program. The fundamental processes include identifying opportunities for improvement, selecting an opportunity, generating solution(s), implementing solution(s), evaluating the effect of the solution(s), and integrating and sustaining improvement(s). These processes are supported by common elements of management review, teamwork, improvement models and tools, documents and records, change management, risk management, and communication.

CLSI. *Quality Management System: Continual Improvement*. 4th ed. CLSI guideline QMS06 (ISBN 978-1-68440-287-8 [Print]; ISBN 978-1-68440-288-5 [Electronic]). Clinical and Laboratory Standards Institute, USA, 2025.

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Suggested Citation

CLSI. *Quality Management System: Continual Improvement*. 4th ed. CLSI guideline QMS06. Clinical and Laboratory Standards Institute; 2025.

Previous Editions:
April 1997, August 1999, November 2004, June 2011

CLSI QMS06-Ed4

ISBN 978-1-68440-287-8 (Print)

ISBN 978-1-68440-288-5 (Electronic)

ISSN 1558-6502 (Print)

ISSN 2162-2914 (Electronic)

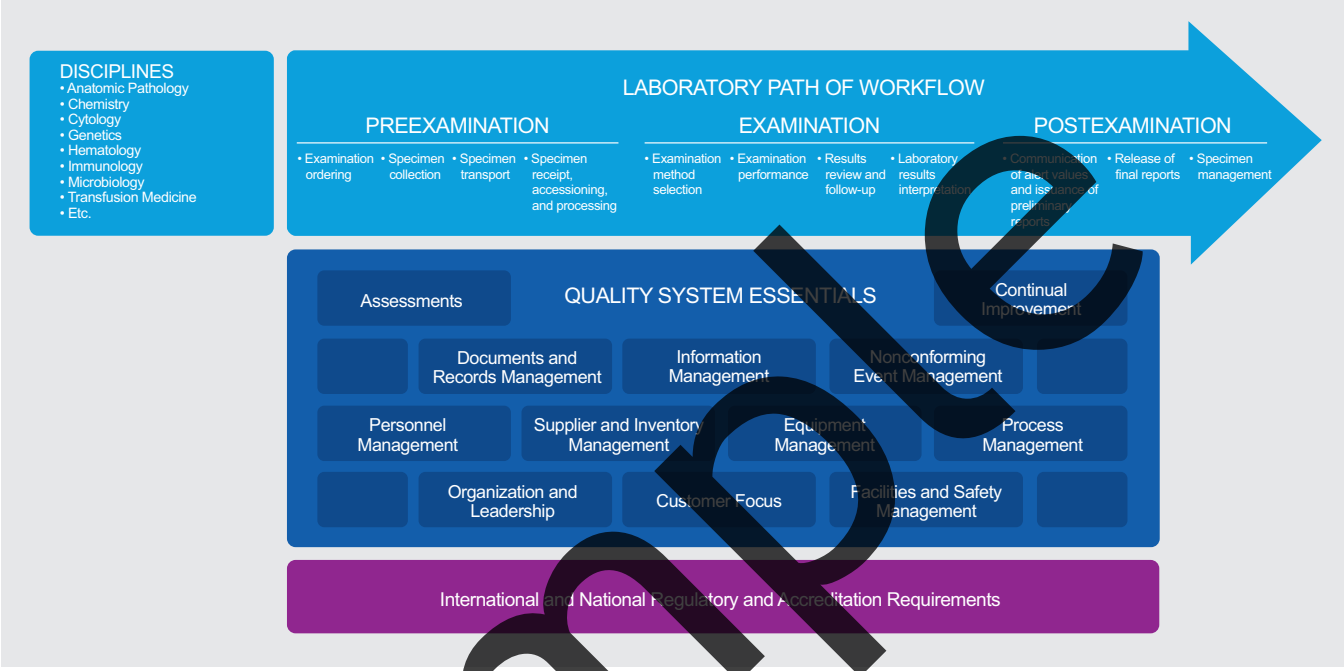
Volume 45, Number 10

Contents

Contents (Continued)

Foreword

Quality system essential (QSE) Continual Improvement (CI) is one of the 12 QSEs described in CLSI QMS01,[1] which provides the necessary background information and guidance to develop and maintain a QMS. The QMS model depicted in Figure 1 demonstrates that each QSE, such as CI, is a building block to quality and is necessary to support any laboratory's path of workflow from preexamination to examination to postexamination.



Abbreviations: QMS, quality management system; QSE, quality system essential.

Figure 1. The QMS Model for Laboratory Services (see CLSI QMS01[1]). The 12 QSEs are building blocks necessary to support any laboratory's path of workflow. This figure represents how the 12 QSEs support a medical laboratory's disciplines and stages of examination.

QSEs are the foundational building blocks that function effectively to support the laboratory's path of workflow. When a QSE is missing or poorly implemented, problems will occur in preexamination, examination, and postexamination processes.

International guidance for QSEs and the laboratory's path of workflow is available. Topics include:

- A process-based model for quality that any business should use to manage its operations, with information relating directly to the QSEs[2]
- Requirements for both quality management and technical operations of testing and calibration laboratories[3]
- Standards for quality management and technical operations in the medical laboratory environment[4]

CLSI QMS06 is a **guideline** that can help laboratories implement a CI program and meet international standards and regulatory and accreditation requirements.[2-12] **CLSI QMS06 is not a standard;** that is, CLSI QMS06 **does not set requirements** for implementing a CI program. Rather, it provides suggestions and examples for fulfilling the requirements.

Overview of Changes

CLSI QMS06-Ed4 was revised in 2025 under the Limited Revision Process and replaces CLSI QMS06-A3, which was published in 2011. Several changes were made in this edition, including:

- Revising the Foreword and Terminology sections to match the current template
- Removing definitions that are now housed in the Quality Glossary
- Updating references to CLSI documents and inserting references to new CLSI documents not available when CLSI QMS06 was originally published

NOTE: The content of CLSI QMS06 is supported by the CLSI consensus process and does not necessarily reflect the views of any single individual or organization.

KEY WORDS

continual improvement (CI)

continual quality improvement (CQI)

problem solving

process improvement

quality

quality assessment

quality assurance (QA)

quality improvement (QI)

quality management system (QMS)

Chapter 1

Introduction

Quality Management System: Continual Improvement

1 Introduction

1.1 Scope

CLSI QMS06 includes written and graphic descriptions of the fundamental processes and common supporting elements in a continual improvement (CI) program. It provides the user with definitions, concepts, methods, and tools for implementing an effective program and meeting applicable requirements. The CI fundamental processes include:

- Identifying opportunities for improvement (OFIs)
- Selecting an opportunity
- Generating solution(s)
- Implementing solution(s)
- Evaluating the effect of the solution(s)
- Integrating and sustaining improvement(s)

The CI common supporting elements include but are not limited to:

- Management review
- Teamwork
- Improvement models and tools
- Documents and records
- Change management
- Risk management
- Communication

Although quality professionals might differ on various CI definitions, concepts, models, and tools, CLSI QMS06 attempts to consolidate the vast amount of information available while remaining nonprescriptive. CLSI QMS06 encourages using an organized systematic approach to CI, so that optimal outcomes are achieved for the efforts expended.

CLSI QMS06 is intended for use by all organizations and individuals involved in the management or implementation of preexamination, examination, and postexamination phases of medical laboratory examinations. CLSI QMS06 may also be applicable to other laboratories and nonlaboratory settings.

CLSI QMS06 is not meant to be prescriptive, nor a comprehensive instructional manual for using the tools described. It does not cover content and detail covered in other CLSI documents or requirements specific to any regulatory or accreditation organization.

1.2 Background

A CI program is essential to an effective QMS. CLSI QMS06 provides guidance on approaching improvement initiatives in a systematic and organized manner that produces sustainable outcomes. Definitions, concepts, methods, and tools discussed in CLSI QMS06 were selected based on the level of common use within quality professions and are not meant as inclusive or prescriptive.

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PRINT ISBN 978-1-68440-287-8

ELECTRONIC ISBN 978-1-68440-288-5

CLSI QMS06-Ed4