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# QMS06-A3

## Quality Management System: Continual Improvement; Approved Guideline—Third Edition

**SAMPLE**

This guideline considers continual improvement as an ongoing, systematic effort that is an essential component of a quality management system. A continual improvement program may consist of fundamental processes and common supporting elements described in this guideline.

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

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# Quality Management System: Continual Improvement; Approved Guideline—Third Edition

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## Abstract

Clinical and Laboratory Standards Institute document QMS06-A3—*Quality Management System: Continual Improvement; Approved Guideline—Third Edition* 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 (OFIs); selecting an opportunity; generating solution(s); implementing solution(s); evaluating the effect of 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.

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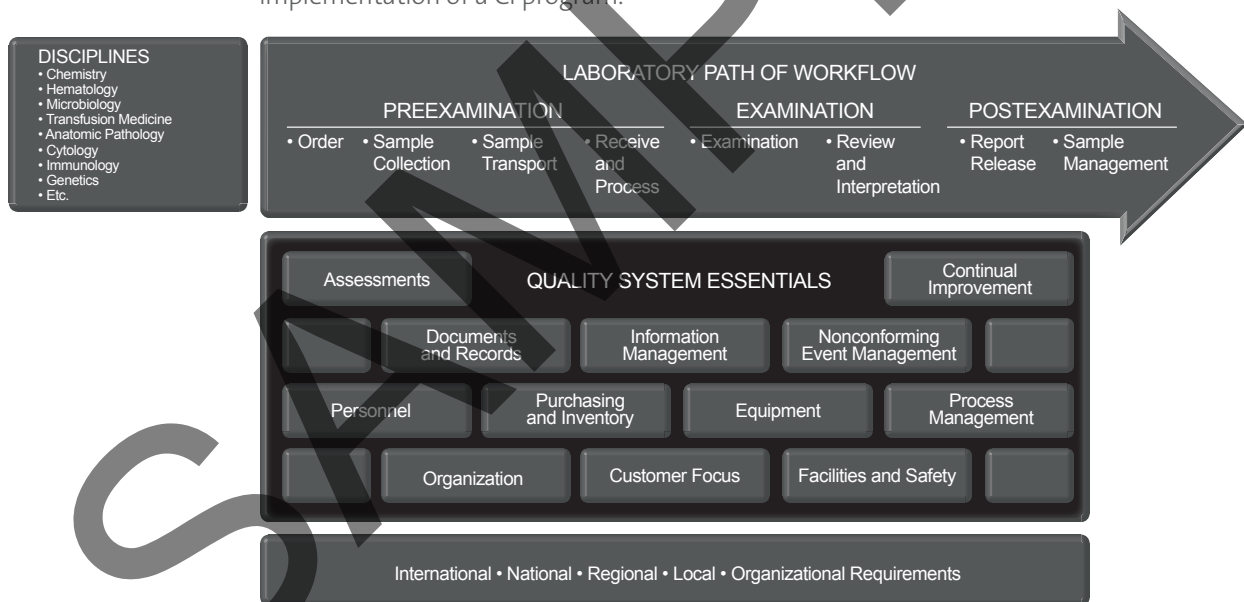
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## Foreword

Continual improvement (CI), as one of the QSEs, is critical to optimizing the effectiveness of a QMS and sustaining quality. Described in this document are common supporting elements and fundamental processes of a CI program. The common supporting elements are applied throughout all the improvement processes. The CI processes may occur in order, as discussed in this guideline, or individually, depending on the need of the organization and type of improvement initiative.

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

CI is one of the 12 quality system essentials (QSEs) described in CLSI document QMS01,<sup>1</sup> which describes a structured approach to organizing, creating, and maintaining the necessary information for the QSEs. The quality management system model depicted in Figure 1 demonstrates how 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. This document is designed to guide the user in the development and implementation of a CI program.



**Figure 1. The Quality Management System Model<sup>1</sup>**

If a QSE is missing or not well implemented, problems may occur in either or all preexamination, examination, and postexamination laboratory activities. For example, when the laboratory lacks defined processes for properly installing, calibrating, and maintaining its analyzers so they work effectively, there are problems in examination processes.

The requirements for QSE Continual Improvement can be summarized as:

- ▶ Participation in quality improvement activities at the organizational level
- ▶ Use of a defined strategy for CI



# Introductory Chapters

These chapters include:

## 1 Scope

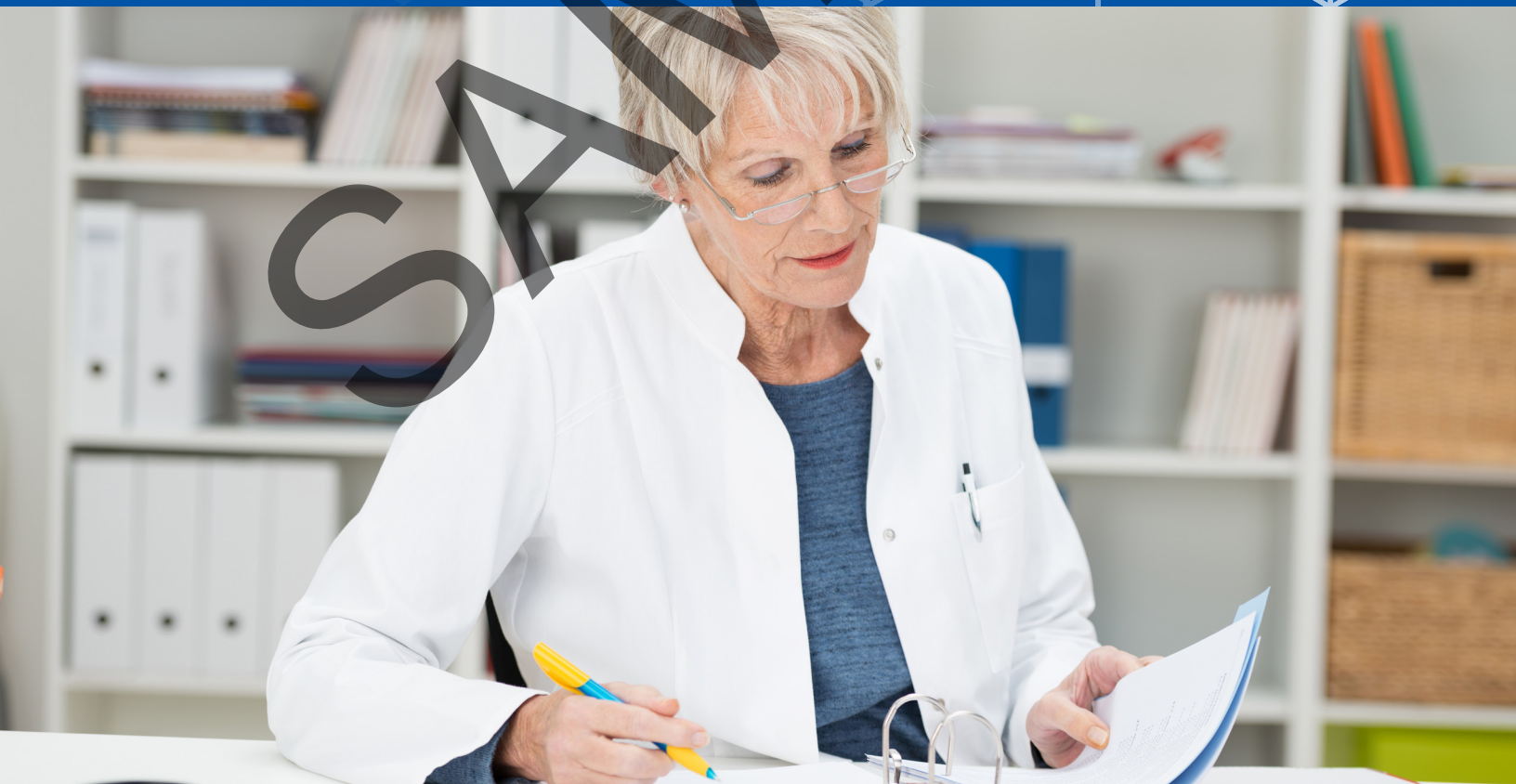
- ▶ Document scope and applicable exclusions

## 2 Introduction

- ▶ Introductory and background information pertinent to the document content

## 3 Terminology

- ▶ Terms and definitions used in the document
- ▶ Abbreviations and acronyms used in the document





# Quality Management System: Continual Improvement; Approved Guideline—Third Edition

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## 1 Scope

This guideline 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 the following:

- ▶ Identifying opportunities for improvement (OFIs)
- ▶ Selecting an opportunity
- ▶ Generating solution(s)
- ▶ Implementing solution(s)
- ▶ Evaluating effect of 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

This guideline is intended for use by all organizations and individuals involved in the management or execution of preexamination, examination, and postexamination phases of the medical laboratory. This document may be applicable to other laboratories and nonlaboratory settings.

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

### IMPORTANT NOTE:

A CI program is **essential** to an **effective** quality management system (QMS).

# The Quality Management System Approach

Clinical and Laboratory Standards Institute (CLSI) subscribes to a quality management system approach in the development of standards and guidelines, which facilitates project management; defines a document structure via a template; and provides a process to identify needed documents. The quality management system approach applies a core set of “quality system essentials” (QSEs), basic to any organization, to all operations in any health care service’s path of workflow (ie, operational aspects that define how a particular product or service is provided). The QSEs provide the framework for delivery of any type of product or service, serving as a manager’s guide. The QSEs are as follows:

Organization	Personnel	Process Management	Nonconforming Event Management
Customer Focus	Purchasing and Inventory	Documents and Records	Assessments
Facilities and Safety	Equipment	Information Management	Continual Improvement

QMS06-A3 addresses the QSE indicated by an “X.” For a description of the other documents listed in the grid, please refer to the Related CLSI Reference Materials section on page 136.

Organization	Customer Focus	Facilities and Safety	Personnel	Purchasing and Inventory	Equipment	Process Management	Documents and Records	Information Management	Nonconforming Event Management	Assessments	Continual Improvement
											X
						EP18			EP18	EP18	EP18
							GP02	GP02			
			QMS03								
QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01
						QMS11			QMS11		
											QMS12

## Path of Workflow

A path of workflow is the description of the necessary processes to deliver the particular product or service that the organization or entity provides. A laboratory path of workflow consists of the sequential processes: preexamination, examination, and postexamination and their respective sequential subprocesses. All laboratories follow these processes to deliver the laboratory’s services, namely quality laboratory information.

QMS06-A3 does not address any of the clinical laboratory path of workflow processes indicated in the grid below. For a description of the document listed in the grid, please refer to the Related CLSI Reference Materials section on the following page.

Preexamination				Examination			Postexamination	
Examination ordering	Sample collection	Sample transport	Sample receipt/ processing	Examination	Results review and follow-up	Interpretation	Results reporting and archiving	Sample management
QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01

## Related CLSI Reference Materials\*

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- EP18-A2** **Risk Management Techniques to Identify and Control Laboratory Error Sources; Approved Guideline—Second Edition (2009).** This guideline describes risk management techniques that will aid in identifying, understanding, and managing sources of failure (potential failure modes) and help to ensure correct results. Although intended primarily for in vitro diagnostics, this document will also serve as a reference for clinical laboratory managers and supervisors who wish to learn about risk management techniques and processes.
- GP02-A5** **Laboratory Documents: Development and Control; Approved Guideline—Fifth Edition (2006).** This document provides guidance on development, review, approval, management, and use of policy, process, and procedure documents in the medical laboratory community.
- QMS03-A3** **Training and Competence Assessment; Approved Guideline—Third Edition (2009).** This document provides background information and recommended processes for the development of training and competence assessment programs that meet quality and regulatory objectives.
- QMS01-A4** **Quality Management System: A Model for Laboratory Services; Approved Guideline—Fourth Edition (2011).** This document provides a model for medical laboratories that will assist with implementation and maintenance of an effective quality management system.
- QMS11-A** **Management of Nonconforming Laboratory Events; Approved Guideline (2007).** This guideline provides an outline and the content for developing a program to manage a health care service's nonconforming events that is based on the principles of quality management and patient safety.
- QMS12-A** **Development and Use of Quality Indicators for Process Improvement and Monitoring of Laboratory Quality; Approved Guideline (2010).** This document provides guidance on development of quality indicators and their use in the medical laboratory.

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\* CLSI documents are continually reviewed and revised through the CLSI consensus process; therefore, readers should refer to the most current editions.

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