CLINICAL AND LABORATORY STANDARDS INSTITUTE®

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QMS06-A3

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

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.

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

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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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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,[1] 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.

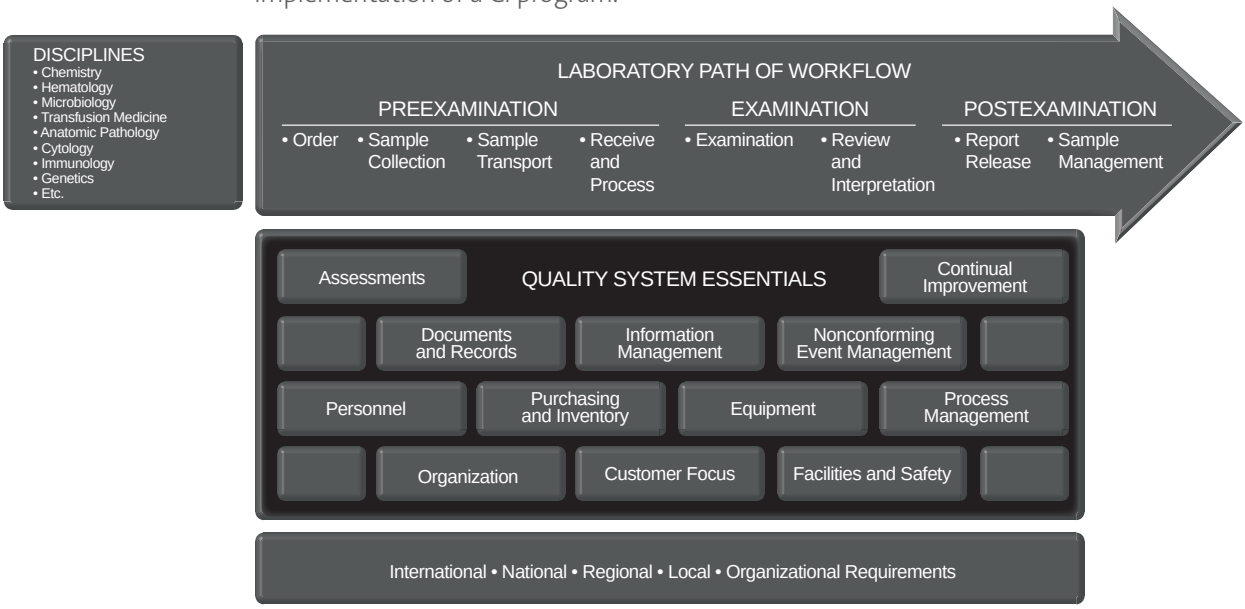

Figure 1. The Quality Management System Model[1]

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

Overview of Changes From GP22-A2

This document replaces the second edition of the approved guideline GP22-A2, which was published in 2004. Several changes were made in this edition, including the following:

- Expansion of the five key quality system components to a CI program that includes discussion on CI fundamental processes and CI common supporting elements
- Alignment with new or changed international, national, and accreditation requirements for laboratories since the last version of this guideline
- Additional examples of documents and forms that can be used or modified as needed for implementing a CI program

Key Words

Continual improvement (CI), continuous quality improvement (CQI), problem solving, process improvement, quality, quality assessment, quality assurance (QA), quality improvement (QI), quality management system (QMS), total quality management (TQM)

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