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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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Advancing Quality in Health Care Testing

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Clinical and Laboratory Standards Institute
940 West Valley Road, Suite 1400
Wayne, PA 19087 USA
610.688.0100
F: 610.688.0700
www.clsi.org
standard@clsi.org

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

Anne T. Daley, MS, MT(ASCP)DLM; CMQOE(ASQ)CSSBB

Marjorie Allen

Joan M. Carlson, MLT(ACMLT), BSc(MLS), MT(ASCP)

Christine Flaherty, MHA, CLS, CPHQ

Laurie Gillard, MS, MT(ASCP)SBB

Sharon E. Granade, MPH, MT(ASCP)

Kathleen A. Grindle, MT(ASCP), CQA(ASQ)

Debra Kuehl, MS, M(ASCP)

Lynn M. Padley, MT(ASCP)

Kim Walker, MS, RAC

Abstract

Clinical and Laboratory Standards Institute document GP22-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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Committee Membership

Consensus Committee on Quality Systems and Laboratory Practices

**Carl D. Mottram, BA, RRT, RPFT,
FAARC
Chairholder
Mayo Clinic
Rochester, Minnesota, USA**

**Devery Howerton, PhD
Vice-Chairholder
Centers for Disease Control and
Prevention
Atlanta, Georgia, USA**

Deirdre Astin, MS, MT(ASCP)
New York State Department of Health
Albany, New York, USA

Lucia M. Berte, MA, MT(ASCP)SBB,
DLM; CQA(ASQ) CQM
Laboratories Made Better!
Broomfield, Colorado, USA

Theresa Billups, MBA, MT(ASCP)DLM
Thermo Fisher Scientific
Lake Charles, Louisiana, USA

Michael B. Cohen, MD
University of Iowa
Iowa City, Iowa, USA

Nancy Dubrowny, MS, MT(ASCP)SC
BD Preanalytical Systems
Franklin Lakes, New Jersey, USA

Michelle Jenkins, MS, MT(AMT)
ASQ, CQE, CMQ/OE
Abbott Diagnostics
Irving, Texas, USA

Jennifer Schiffgens, MBA,
MT(ASCP)
California Pacific Medical Center
San Francisco, California, USA

Tonya Wilbon, BS, M(ASCP)
FDA Center for Devices and
Radiological Health
Rockville, Maryland, USA

(Standing) Subcommittee on Quality Management Systems

**Lucia M. Berte, MA, MT(ASCP)SBB,
DLM; CQA(ASQ)CMQ/OE
Chairholder
Laboratories Made Better!
Broomfield, Colorado, USA**

**Tania Motschman, MS,
MT(ASCP)SBB; CQA(ASQ)
Vice-Chairholder
Mayo Clinic
Rochester, Minnesota, USA**

Joan M. Carlson, MLT(ACMLT),
BSc(MLS)
Alberta Health Services – Edmonton
General Hospital
Edmonton, Alberta, Canada

Anne T. Daley, MS, MT(ASCP)DLM;
CMQ/OE(ASQ)CSSBB
Chi Solutions, Inc.
Ann Arbor, Michigan, USA

Christine Flaherty, MHA, CLS, CPHQ
Sutter Health Sacramento Sierra Region
Laboratories
Sacramento, California, USA

Willem Huisman, PhD
Medical Center Haaglanden
Den Haag, Netherlands

John Kim, PhD
Public Health Agency of Canada
Ottawa, Ontario, Canada

Debra Kuehl, MS, M(ASCP)
Centers for Disease Control and Prevention
Atlanta, Georgia, USA

Dave Petrich, MBA
AcroMetrix Corporation
Benicia, California, USA

Elizabeth Sheppard, MBA,
HT(ASCP)
Ventana Medical Systems, Inc.
Tucson, Arizona, USA

Miki Van Houten, MT(ASCP)
Oregon State Public Health
Laboratory
Hillsboro, Oregon, USA

Harriet R. Walsh, MA, MT(ASCP)
Centers for Medicare & Medicaid
Services
Baltimore, Maryland, USA

Working Group on Process Improvement

**Anne T. Daley, MS, MT(ASCP)DLM;
CMQOE(ASQ)CSSBB
Chairholder
Chi Solutions, Inc.
Ann Arbor, Michigan, USA**

Joan M. Carlson, MLT(ACMLT),
BSc(MLS), MT(ASCP)
Alberta Health Services – Regional
Laboratory Services
Edmonton, Alberta, Canada

Laurie Gillard, MS, MT(ASCP)SBB
Loyola University Medical Center
Maywood, Illinois, USA

Sharon E. Granade, MPH, MT(ASCP)
Centers for Disease Control and Prevention
Atlanta, Georgia, USA

Lynn M. Padley, MT(ASCP)
Mayo Clinic
Rochester, Minnesota, USA

Ana K. Stankovic, MD, PhD
BD
Franklin Lakes, New Jersey, USA

Valerie Wilson, MSc, MBA
Creative Quality Associates (Caribbean)
Limited
Carenage, Trinidad and Tobago

Staff

Clinical and Laboratory Standards
Institute
Wayne, Pennsylvania, USA

Luann Ochs, MS
*Vice President, Standards
Development*

Jennifer K. Adams, MT(ASCP),
MSHA
Staff Liaison

Melissa A. Lewis, ELS
Editorial Manager

Megan P. Larrisey, MA
Assistant Editor

Acknowledgment

CLSI, the Consensus Committee on Quality Systems and Laboratory Practices, the Standing Subcommittee on Quality Management Systems, and the Working Group on Process Improvement gratefully acknowledge the following volunteers for their important contributions to the development and/or completion of this document:

Maureen E. Ahler, MSQA, MT(ASCP), Kaiser Permanente Medical Care
Kathryn Connolly, MT(ASCP); CQA(ASQ), COLA
Christine D. Flaherty, MHA, CLS, CPHQ, Sutter Health Sacramento Sierra Region Laboratories
Kathleen A. Grindle, MT(ASCP), CQA(ASQ), Dartmouth-Hitchcock Medical Center
Debra Kuehl, MS, M(ASCP), Centers for Disease Control and Prevention
Wadid Sadek, PhD, Stuarts Draft, Virginia, USA (retired)
Caroline Satyadi, DLM(ASCP); MBA, MS, ESat Consulting, Inc.
Kim Walker, MS, RAC, Kim Walker Consulting

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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 GP26,¹ 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 Model¹

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)

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

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.

2 Introduction

A CI program is essential to an effective quality management system (QMS). This document provides guidance on how to approach improvement initiatives in a systematic and organized manner that produces sustainable outcomes. Definitions, concepts, methods, and tools discussed in this guideline were selected based on the level of common use within quality professions and are not meant as inclusive nor prescriptive.

CI, as described in Figure 2, consists of interrelated fundamental processes that can occur in a continuous manner along with common supporting elements that enable each process.