CLINICAL AND LABORATORY STANDARDS INSTITUTE®

4th Edition

QMS03

Training and Competence Assessment

This guideline provides a structured approach for developing effective laboratory personnel training and competence assessment programs.

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

Clinical and Laboratory Standards Institute

Setting the standard for quality in medical laboratory testing around the world.

The Clinical and Laboratory Standards Institute (CLSI) is a not-for-profit membership organization that brings together the varied perspectives and expertise of the worldwide laboratory community for the advancement of a common cause: to foster excellence in laboratory medicine by developing and implementing medical laboratory standards and guidelines that help laboratories fulfill their responsibilities with efficiency, effectiveness, and global applicability.

Consensus Process

Consensus—the substantial agreement by materially affected, competent, and interested parties—is core to the development of all CLSI documents. It does not always connote unanimous agreement, but does mean that the participants in the development of a consensus document have considered and resolved all relevant objections and accept the resulting agreement.

Commenting on Documents

CLSI documents undergo periodic evaluation and modification to keep pace with advancements in technologies, procedures, methods, and protocols affecting the laboratory or health care.

CLSI's consensus process depends on experts who volunteer to serve as contributing authors and/or as participants in the reviewing and commenting process. At the end of each comment period, the committee that developed the document is obligated to review all comments, respond in writing to all substantive comments, and revise the draft document as appropriate.

Comments on published CLSI documents are equally essential, and may be submitted by anyone, at any time, on any document. All comments are managed according to the consensus process by a committee of experts.

Appeals Process

When it is believed that an objection has not been adequately considered and responded to, the process for appeals, documented in the CLSI Standards Development Policies and Processes, is followed.

All comments and responses submitted on draft and published documents are retained on file at CLSI and are available upon request.

Get Involved—Volunteer!

Do you use CLSI documents in your workplace? Do you see room for improvement? Would you like to get involved in the revision process? Or maybe you see a need to develop a new document for an emerging technology? CLSI wants to hear from you. We are always looking for volunteers. By donating your time and talents to improve the standards that affect your own work, you will play an active role in improving public health across the globe.

For additional information on committee participation or to submit comments, contact CLSI.

Clinical and Laboratory Standards Institute
950 West Valley Road, Suite 2500
Wayne, PA 19087 USA
P: +1.610.688.0100
F: +1.610.688.0700
www.clsi.org
standard@clsi.org

QMS03, 4th ed.
December 2016
Replaces QMS03-A3

Training and Competence Assessment

Laura McClannan, MS, MT(ASCP)SBB, CQA(ASQ)
Lucia M. Berte, MA, MT(ASCP)SBB, DLM, CQA(ASQ)CMQ/OE
Maureen E. Ahler, MSQA, MT(ASCP)
Sarah F. Bennett, MT(ASCP)
Loralee Coe
Elizabeth A. Glaister
Catherine M. Johnson, MA, MT(ASCP)
Barbara Litsenberger, MEd, MT(ASCP)SBB
Karen H. Walsh, MS, MT(ASCP), CPHQ, CLSSMBB
Richard Warren, MHA, MT(ASCP)SH, DLM
Janette Wassung

Abstract

Clinical and Laboratory Standards Institute guideline QMS03—*Training and Competence Assessment* provides the necessary background information and processes to develop training and competence assessment programs that meet regulatory and accreditation requirements and help ensure knowledgeable and competent personnel in all laboratory disciplines. An effective training program sets the expectation that personnel need to learn and apply the laboratory and organization's processes and procedures. A competence assessment program ensures that personnel continue to perform the learned processes and procedures correctly so that the laboratory's quality goals and objectives can be achieved. Training and competence assessment programs are important components of a QMS.

Clinical and Laboratory Standards Institute (CLSI). *Training and Competence Assessment.* 4th ed. CLSI guideline QMS03 (ISBN 1-56238-802-9 [Print]; ISBN 1-56238-803-7 [Electronic]). Clinical and Laboratory Standards Institute, 950 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2016.

Suggested Citation

CLSI. *Training and Competence Assessment*. 4th ed. CLSI guideline QMS03. Wayne, PA: Clinical and Laboratory Standards Institute; 2016.

Previous Editions:

November 1994, December 1995, April 2004, February 2009

ISBN 1-56238-802-9 (Print)

ISBN 1-56238-803-7 (Electronic)

ISSN 1558-6502 (Print)

ISSN 2162-2914 (Electronic)

Volume 36, Number 16

Committee Membership

Consensus Council

Carl D. Mottram, RRT, RPFT, FAARC
Chairholder
Mayo Clinic
USA

J. Rex Astles, PhD, FACB, DABCC
Centers for Disease Control and Prevention
USA

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

Karen W. Dyer, MT(ASCP), DLM
Centers for Medicare & Medicaid Services
USA

Dennis J. Ernst, MT(ASCP), NCPT(NCCT)
Center for Phlebotomy Education
USA

Thomas R. Fritsche, MD, PhD, FCAP, FIDSA
Marshfield Clinic
USA

Mary Lou Gantzer, PhD, FACB
BioCore Diagnostics
USA

Loralie J. Langman, PhD
Mayo Clinic
USA

Joseph Passarelli
Roche Diagnostics Corporation
USA

James F. Pierson-Perry
Siemens Healthcare Diagnostics Inc.
USA

Andrew Quintenz
Bio-Rad Laboratories, Inc.
USA

Robert Rej, PhD
New York State Department of Health – Wadsworth Center
USA

Zivana Tezak, PhD
FDA Center for Devices and Radiological Health
USA

Document Development Committee on Training and Competence Assessment

Laura McClannan, MS, MT(ASCP)SBB, CQA(ASQ)
Chairholder
Laboratory Corporation of America
USA

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

Natalie Ortoli Drew, MT(ASCP)
Committee Secretary
Yale New Haven Hospital
USA

Sarah F. Bennett, MT(ASCP)
Centers for Medicare and Medicaid Services
USA

Catherine M. Johnson, MA, MT(ASCP)
Association of Public Health Laboratories
USA

Barbara Litsenberger, MEd, MT(ASCP)SBB
Mayo Clinic
USA

Karen H. Walsh, MS, MT(ASCP), CPHQ, CLSSMBB
Virtua – West Jersey Hospital
USA

Richard Warren, MHA, MT(ASCP)SH, DLM
St. Jude Children's Research Hospital
USA

Janette Wassung
PathCare Pathology Laboratory
South Africa

Staff

Clinical and Laboratory Standards Institute
USA

Jennifer K. Adams, MT(ASCP), MSHA
Project Manager

Megan L. Tertel, MA, ELS
Editorial Manager

Joanne P. Christopher, MA, ELS
Editor

Laura Martin
Editor

Michael A. Russell, MA
Editor

Acknowledgment

CLSI, the Consensus Council, and the Document Development Committee on Training and Competence Assessment gratefully acknowledge the following volunteers for their important contributions to the development of this guideline:

Maureen E. Ahler, MSQA, MT(ASCP)
Kaiser Permanente Medical Care
USA

Loralee Coe
Laboratory Corporation of America
USA

Elizabeth A. Glaister
Roche Diagnostics
USA

Contents

Contents (Continued)

Contents (Continued)

Foreword

In the QMS, quality system essential (QSE) Personnel—of which training and competence assessment is a part—is one of the 12 QSEs described in CLSI document QMS01[1] and CLSI product *The Key to Quality*™,[2] which provide the necessary background information and guidance to develop and maintain a QMS. The QMS model depicted in Figure 1 demonstrates how each QSE, such as Personnel, is a building block to quality and is necessary to support any laboratory's path of workflow from preexamination to examination to postexamination.

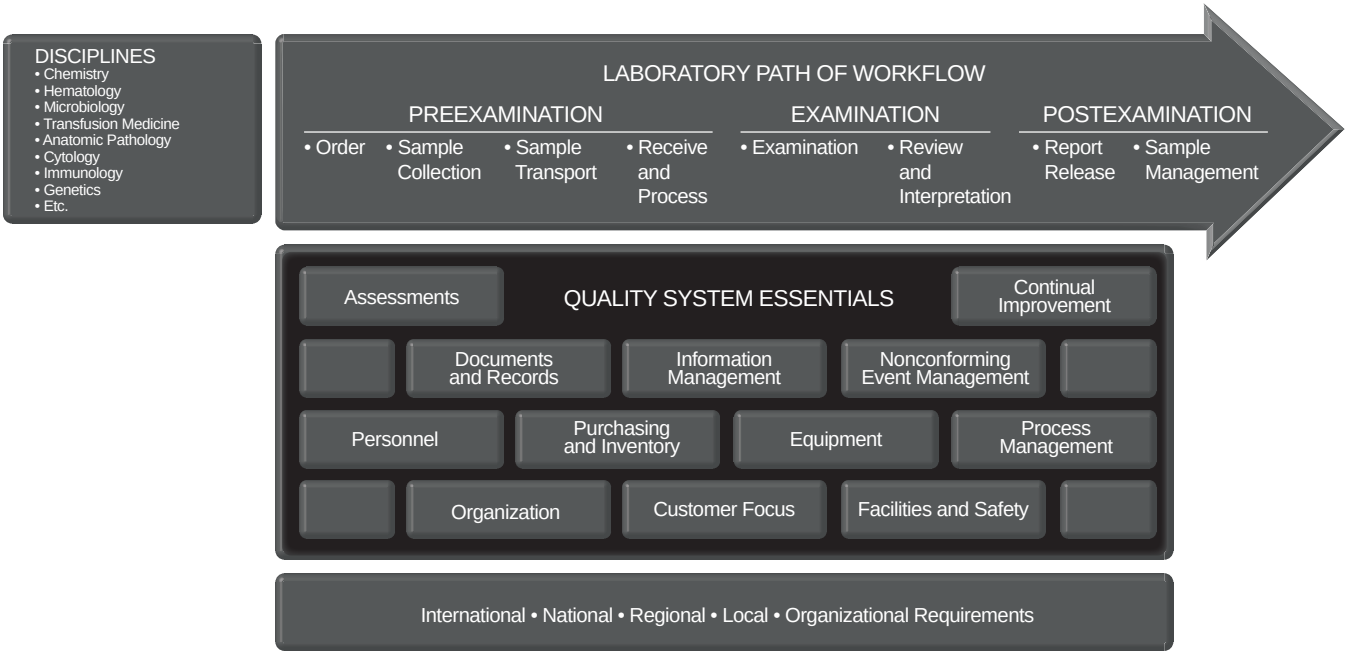

Figure 1. The Quality Management System Model (see CLSI document QMS01[1]). The 12 QSEs are building blocks necessary to support any laboratory's path of workflow and laboratory disciplines. This figure represents how the 12 QSEs support a clinical laboratory's disciplines.

NOTE:

People are the most valuable resource of the organization.

People are the most valuable resource of the organization. Effective training and competence assessment programs ensure personnel are knowledgeable and competent in their assigned roles and responsibilities.

Effective training and competence assessment programs:

- Ensure personnel performance results in consistent, predictable, and high-quality outcomes.
- Ensure performance of assigned job tasks remains constant.
- Verify that personnel have and can demonstrate the necessary knowledge, skills, and behaviors to perform their respective duties.

QMS03 is a **guideline** that can help laboratories implement regulatory and accreditation requirements for establishing training and competence assessment programs.[3-14] **QMS03 is not a standard;** that is, this guideline **does not set requirements** for implementing a training and competence assessment program. Instead, this guideline describes what laboratories need to do to meet applicable regulatory and accreditation requirements for training and competence assessment, and provides suggestions and examples for fulfilling the requirements.

NOTE:

QMS03 is not a standard; that is, this guideline does not set requirements for implementing a training and competence assessment program.

Overview of Changes

This guideline replaces the previous edition of the approved guideline, QMS03, published in 2009. Several changes were made in this edition, including:

- Development of a process flow for training and competence assessment
- Expansion of the competence assessment processes
- Addition of examples for test systems for competence assessment
- Information related to potential actions when performance is unacceptable

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

KEY WORDS

Assessment tools
Competence
Competence assessment
Training
Training assessment

This page is intentionally left blank.

Chapter 1

Introduction

This chapter includes:

- Guideline's scope and applicable exclusions
- Background information pertinent to the guideline's content
- "Note on Terminology" that highlights particular use and/or variation in use of terms and/or definitions
- Terms and definitions used in the guideline
- Abbreviations and acronyms used in the guideline

Training and Competence Assessment

1 Introduction

1.1 Scope

QMS03 provides the necessary background information and processes to develop training and competence assessment programs that meet regulatory and accreditation requirements and help ensure knowledgeable and competent personnel in all laboratory disciplines.[3-14]

QMS03 is intended for use by:

- Administrative and technical personnel who develop and deliver laboratory training and competence assessment programs
- Pathologists and laboratory medical directors
- Regulatory and accreditation organizations
- Educators

This guideline is designed primarily for use in medical laboratories; however, the concepts are generic and can be applied in point-of-care testing, as well as research, public health, and veterinary laboratories.

NOTE:

Regulatory and accreditation organizations require, for all persons whose work can affect the quality of the laboratory's products or services, that personnel are trained and their competence is periodically assessed.

1.2 Background

Knowledgeable and competent personnel who provide consistent, predictable, and high-quality outcomes are essential. Thus, international and national regulatory and accreditation organizations require that laboratories have policies, processes, and procedures for training personnel and assessing their initial and ongoing competence. These requirements apply to all persons whose work can affect the quality of the laboratory's products or services.

Effective training and competence assessment programs are a fundamental element of a QMS. The training program provides personnel with the information needed to perform their daily tasks and processes so that the laboratory can deliver high-quality services. To verify that performance of assigned tasks remains consistent, initial and periodic assessment of competence is needed.

1.2.1 Training

Training ensures that new and experienced personnel know their respective work processes and related procedures. Post-training assessment verifies that training was effective (ie, the individual can perform the assigned job tasks and is able to work independently).

Job training is an organized learning activity conducted in the work environment that provides information and knowledge needed for a