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QMS03-A3

Training and Competence Assessment; Approved Guideline—Third Edition

This document provides background information and recommended processes for the development of training and competence assessment programs that meet quality and regulatory objectives.

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

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Clinical and Laboratory Standards Institute
950 West Valley Road, Suite 2500
Wayne, PA 19087 USA
P: 610.688.0100
F: 610.688.0700
www.clsi.org
standard@clsi.org

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Training and Competence Assessment; Approved Guideline— Third Edition

Lucia M. Berte, MA, MT(ASCP)SBB, DLM; CQA(ASQ)CMQ/OE

Michael L. Bishop, MS, CLS(NSA)

Natalie Ortoli Drew, MT(ASCP)

Christine D. Flaherty, MHA, MT(ASCP)

Marghoob Hasan

Wadid Sadek, PhD

Jennifer Schiffgens, MBA, MT(ASCP)

Nita Sudderth, MT(ASCP), CQMgr(ASQ)

Miki Van Houten, MT(ASCP)

Sheila M. Woodcock, MBA, FCSMLS(D)

Abstract

Clinical and Laboratory Standards Institute document QMS03-A3—*Training and Competence Assessment; Approved Guideline—Third Edition* provides the necessary background information and processes to permit clinical services to develop training and competence assessment programs that will meet specific quality and regulatory objectives. To be effective, training must be built on a solid foundation of documented operations processes and procedures with accompanying training documents. The competence of staff to perform their respective assigned tasks needs to be assessed initially after training and periodically thereafter. This guideline provides a structured approach for using documented work processes, related procedures, training guides, and assessment tools for the development of training and competence assessment programs.

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Committee Membership

Area Committee on Quality Systems and Laboratory Practices

**Sheila M. Woodcock, MBA,
FCSMLS(D)
Chairholder
QSE Consulting
Rose Bay, Nova Scotia, Canada**

**Albert Rabinovitch, MD, PhD
Co-Vice-Chairholder
NovoMetrics, Inc.
Mountain View, California**

**Carl D. Mottram, BA, RRT, RPFT,
FAARC
Co-Vice-Chairholder
Mayo Clinic
Rochester, Minnesota**

Eric Arendash, MT(ASCP)
Centers for Medicare & Medicaid
Services
Philadelphia, Pennsylvania

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

Theresa Billups, MBA, MT(ASCP)DLM
Remel, Inc.
Lake Charles, Louisiana

Margaret M. Grimes, MD
Medical College of Virginia Campus
Richmond, Virginia

Devery Howerton, PhD
Centers for Disease Control and
Prevention
Atlanta, Georgia

Peter L. Minetti, CQA, CQE,
CQMgr(ASQ)
Fujirebio Diagnostics, Inc.
Malvern, Pennsylvania

Bruce D. Tually, BAppSc, MAppSc
Hunter Area Pathology Service
New South Wales, Australia

Advisors

Eileen Carreiro-Lewandowski,
CLS(NCA)
University of Massachusetts
N. Dartmouth, Massachusetts

Kay M. Creed
Bon Secours Health Partners
Laboratories
Richmond, Virginia

Dennis J. Ernst, MT(ASCP)
Center for Phlebotomy Education
Ramsey, Indiana

Steven I. Gutman, MD, MBA
FDA Ctr. for Devices/Rad. Health
Rockville, Maryland

Stephen J. Sarewitz, MD
Valley Medical Center
Renton, Washington

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

Daniel W. Tholen, MS
American Association for Laboratory
Accreditation
Traverse City, Michigan

Staff

Clinical and Laboratory Standards
Institute
Wayne, Pennsylvania

Lois M. Schmidt, DA
*Vice President, Standards
Development and Marketing*

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

Melissa A. Lewis
Editor

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

Marghoob Hasan
Clinsys Clinical Research Ltd.

Nita Sudderth, MT(ASCP), CQMgr(ASQ)
DIANON, A LabCorp Company
Oklahoma City, Oklahoma

Michael L. Bishop, MS, CLS(NSA)
Wyndgate Technologies
Chapel Hill, North Carolina

Zakir Nagar
Okhla
India

Miki Van Houten, MT(ASCP)
Oregon Public Health Laboratory
Portland, Oregon

Natalie Ortolí Drew, MT(ASCP)
Yale New Haven Hospital
New Haven, Connecticut

Wadid Sadek, PhD
St. Helen Medical Center
S. Burlington, Vermont

Sheila M. Woodcock, MBA, FCSMLS(D)
QSE Consulting
Rose Bay, Nova Scotia, Canada

Christine D. Flaherty, MHA, MT(ASCP)
Sutter Health Sacramento Sierra
Region Laboratories
Sacramento, California

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

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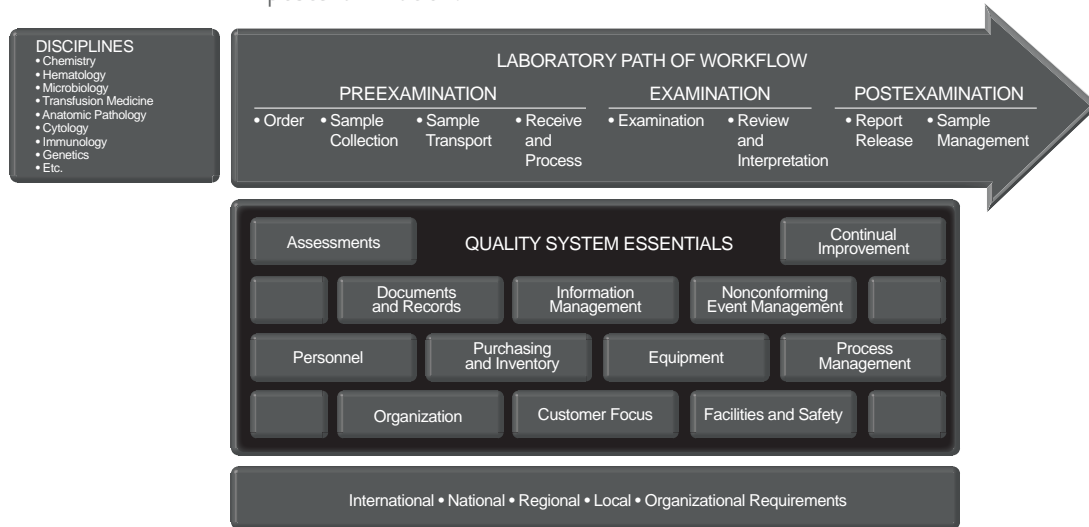
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Foreword

Quality system essential (QSE) Personnel is one of the 12 QSEs described in CLSI document QMS01,ⁱ which provides the necessary background information and guidance to develop and maintain a QMS. The QMS model depicted in the graphic below 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.



The Quality Management System Model for Laboratory Services (see CLSI document QMS01). The 12 QSEs function as building blocks that are necessary to support any laboratory's path of workflow and laboratory disciplines. This example represents how the 12 QSEs support a clinical laboratory's disciplines.

QSEs are the foundational building blocks that function effectively to support the laboratory's path of workflow. When a QSE is missing or not well implemented, problems will occur in preexamination, examination, and postexamination laboratory activities. For example, when the laboratory lacks defined processes for properly and effectively training its staff members and assessing their initial and ongoing competence, there will be problems in laboratory processes.

Increasing oversight by regulatory agencies, third-party payers, and the public has brought an intensified interest in the effects of quality,

KEY WORDS

- Assessment tools
- Competence assessment
- Flowcharting
- Procedures
- Processes
- Training assessment
- Training guides

ⁱ The revised Foreword, including the graphic below, are derived from CLSI document QMS01, published in June 2011.

productivity, and competition to the delivery of health care services. Fundamental to all quality management systems is the development and delivery of training and competence assessment programs.

Regulatory and accreditation agencies—as well as international standards for quality management systems—require that the organization have policies, processes, and procedures for training. In addition, assessment of competence in job tasks is required. These requirements apply to all persons whose work can affect the quality of the organization’s product or service; where volunteers are used in this regard, the requirements apply to them, as well.

QMS03-A3 will assist in the development of training and competence assessment programs to meet specific quality objectives in support of an organization’s mission statement. Standards for job performance are unique to each organization and are based on the competitive, economic, regulatory, and service environment in which the organization operates.

This guideline can be used by laboratories and health care organizations to ensure that training has taken place and is documented, and that the competence of personnel in their assigned job tasks is assessed initially after training and periodically thereafter. The recommendations contained herein are applicable when training new employees, introducing new processes or methods, assessing initial competence, and performing periodic reassessments of competence.

Important note: This document is a guideline and not a requirement, prepared at the request of health care professionals who needed direction on this subject. The sample forms included present one way of designing and documenting training and competence assessment, which fulfills regulatory and accreditation requirements and improves patient safety. However, health care services are free to use whatever means works for them to meet requirements.

 **NOTE:**

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The development and delivery of effective training and competence assessment programs is fundamental to a QMS.

 **REMINDER:**

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Regulatory and accreditation organizations and international standards all have requirements for both training and competence assessment of laboratory staff.

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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

