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.

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Training and Competence Assessment

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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.

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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.

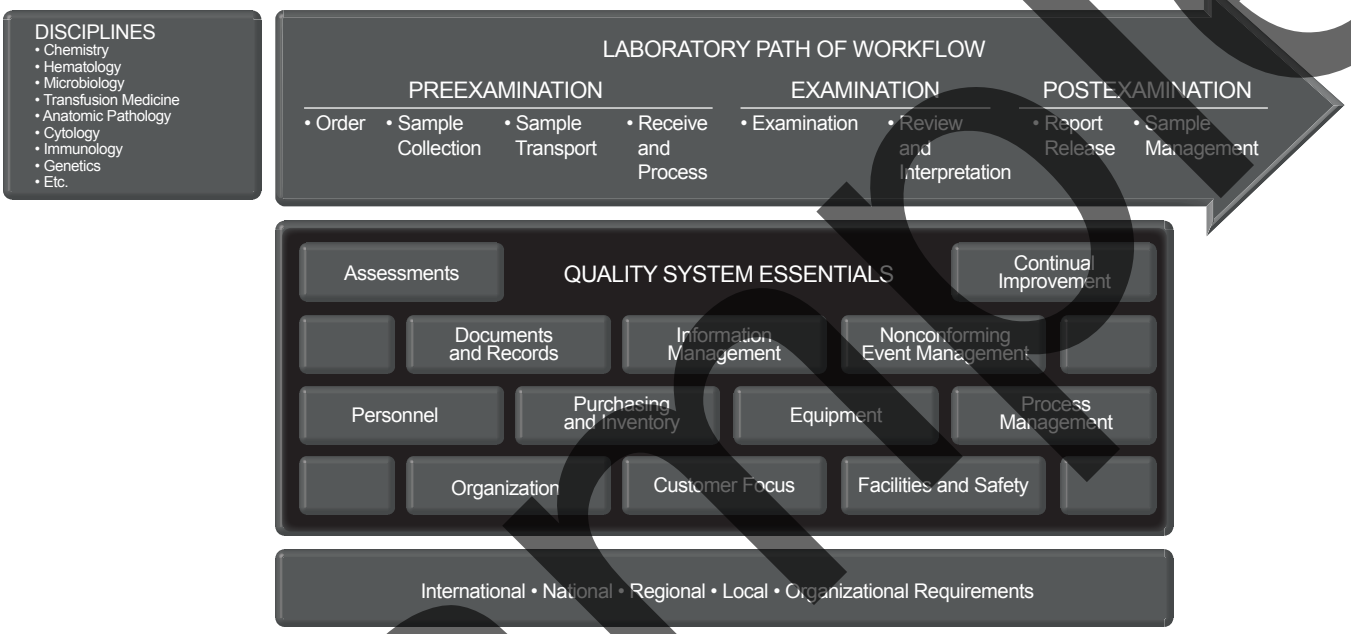

Figure 1. The Quality Management System Model (see CLSI document QMS01[1]). The 12 QSEs are building blocks necessary to support any laboratory's path of workflow and laboratory disciplines. This figure represents how the 12 QSEs support a clinical laboratory's disciplines.

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

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

The Quality Management System Approach

Clinical and Laboratory Standards Institute (CLSI) subscribes to a quality management system (QMS) approach in the development of standards and guidelines, which facilitates project management; defines a document structure using a template; and provides a process to identify needed documents. The QMS 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

QMS03 covers 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.

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								
QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01
							QMS02				
QMS14											
			QMS16								
						QMS18					
QMS20											

Related CLSI Reference Materials*

QMS01 **Quality Management System: A Model for Laboratory Services. 4th ed., 2011.** This document provides a model for medical laboratories that will assist with implementation and maintenance of an effective quality management system.

QMS02 **Quality Management System: Development and Management of Laboratory Documents. 6th ed., 2013.** This document provides guidance on the processes needed for document management, including creating, controlling, changing, and retiring a laboratory's policy, process, procedure, and form documents in both paper and electronic environments.

QMS14 **Quality Management System: Leadership and Management Roles and Responsibilities. 1st ed., 2012.** This guideline presents concepts and information intended to assist a laboratory in meeting leadership requirements for its quality management system. Guidance is provided for leaders to effectively design, implement, and maintain the cultural, structural, and functional aspects of their laboratory's organization that are critical to managing and sustaining quality.

QMS16 **Laboratory Personnel Management. 1st ed., 2015.** This guideline describes the process for meeting the regulatory and accreditation requirements of personnel management in the laboratory environment. This guideline offers suggestions and examples on managing the processes required for laboratory personnel to fully achieve laboratory management's operational and quality goals.

QMS18 **Process Management. 1st ed., 2015.** This guideline describes four requirements for managing laboratory processes and provides suggestions for effectively meeting regulatory and accreditation requirements, optimizing efficient use of resources, and contributing to patient safety and positive outcomes.

QMS20 **Understanding the Cost of Quality in the Laboratory. 1st ed., 2014.** This report provides guidance to a laboratory in understanding and managing the different types of quality costs that affect processes, services, and financial well-being.

* 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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