



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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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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Contents

Abstract	i
Committee Membership	iii
Foreword	viii
Chapter 1: Introduction	1
1.1 Scope	1
1.2 Background	2
1.3 Terminology	4
Chapter 2: Training and Competence Assessment Programs	9
Chapter 3: Training Program	13
3.1 Training Needs Are Identified	14
3.2 Training Plan Is Developed	16
3.3 Training Is Conducted	21
3.4 Training Program Is Evaluated	25
Chapter 4: Competence Assessment Program	29
4.1 Competence Assessment Needs Are Identified	30
4.2 Competence Assessment Plan Is Developed	31
4.3 Competence Assessment Is Conducted	39
4.4 Personnel Competence Is Evaluated	43
4.5 Effectiveness of the Competence Assessment Program Is Evaluated	45
Chapter 5: Records Management	49
5.1 Records Systems	50
5.2 Records Storage	51
5.3 Records Retention	51
Chapter 6: How to Get Started	53
6.1 Preexamination Processes	55
6.2 Examination Processes	55
6.3 Postexamination Processes	56
6.4 Where to Begin	56
Chapter 7: Quality System Essentials	57
7.1 Quality System Essentials as the Management Infrastructure for Developing Training and Competence Assessment Programs	58
7.2 Quality System Essential Considerations for a Training and Competence Assessment Program	58
Chapter 8: Conclusion	61

Contents (Continued)

Chapter 9: Supplemental Information	63
References	64
Appendix A. Components of a Laboratory Training Program	68
Appendix B. Example of a Policy for Quality System Essential Personnel	69
Appendix C. Sample Examination Process: “Analyzer Set-up and Run Process”	72
Appendix D. Learning Domain Levels and Examples of Objective Verbs	73
Appendix E. Alignment of Learning Domains and Levels With Learning Objectives, Instructional Strategies, and Assessments Methods	74
Appendix F1. Sample Training Guide Form	75
Appendix F2. Sample Trainer Responsibilities Form	76
Appendix F3. Sample Learner Responsibilities Form	77
Appendix G1. Sample Training Checklist Form	78
Appendix G2. Example of Training Checklist	79
Appendix H1. Sample Learner Evaluation Form	82
Appendix H2. Sample Training Evaluation Form	83
Appendix I. Sample Training Schedule Form	84
Appendix J1. Example of a Training Guide for the ABC Analyzer Testing Process	85
Appendix J2. Example of Trainer Responsibilities for ABC Analyzer Testing Process	86
Appendix J3. Example of Learner Responsibilities for ABC Analyzer Testing Process	87
Appendix J4. Example of a Training Schedule for the ABC Analyzer Testing Process	88
Appendix J5. Example of a Training Checklist for the ABC Analyzer Testing Process	89
Appendix J6. Example of a Direct Observation Checklist for the ABC Analyzer Testing Process	90
Appendix J7. Example of a Written Assessment for the ABC Analyzer Testing Process	91
Appendix J8. Example of Learner Evaluation of Training for the ABC Analyzer Testing Process	92
Appendix K. Training Tips	93
Appendix L. Sample Group Training Records	95
Appendix M1. Generic Blood Sample Collection Process Flow Chart	96
Appendix M2. Sample Laboratory Receipt Process Flow Chart	97
Appendix N. Example of an Annual Competence Assessment Plan for a Laboratory Assistant	98
Appendix O. Example of an Annual Competence Assessment Plan for a Laboratory Technologist/Scientist	101
Appendix P. Test System–Based Competence Plans and Assessments	107
Appendix Q. Example of a Pathologist/Laboratory Director Competence Assessment	119
Appendix R1. Preparing a Direct Observation Checklist	120

Contents (Continued)

Appendix R2. Example of a Direct Observation Form for Technologists	121
Appendix R3. Example of a Direct Observation Form for Laboratory Assistants	123
Appendix R4. Example of a Direct Observation Checklist for a Procedure.	125
Appendix S1. Sample Competence Assessment Form for Quantitative Testing.	126
Appendix S2. Sample Competence Assessment Form for Qualitative Testing	127
Appendix T. Sample Written Assessment Form	128
Appendix U. Sample Form for Follow-up of Competence or Learning Assessment Requiring Remediation	129
The Quality Management System Approach	130
Related CLSI Reference Materials	132

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 QMS01¹ 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 QMS01¹). 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.

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.

NOTE:

People are the most valuable resource of the organization.

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

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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