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1st Edition

QMS25

Handbook for Developing a Laboratory Quality Manual

This handbook assists laboratories in developing a quality manual—a vital component of implementing and maintaining a complete laboratory quality management system.

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Handbook for Developing a Laboratory Quality Manual

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Abstract

Clinical and Laboratory Standards Institute product QMS25—*Handbook for Developing a Laboratory Quality Manual* is a useful tool for laboratories just beginning to implement a QMS or those looking for a new perspective on laboratory quality management. This handbook contains answers to commonly asked questions about quality manuals, suggestions for elements to include, useful appendixes, and templates for preparing quality management policies. Information in this handbook aligns with the QMS approach previously published in CLSI document QMS01[1] and CLSI product *The Key to Quality*™.[2]

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Contents

Contents (Continued)

Foreword

A quality manual provides laboratory leadership, personnel, and accreditors with a description of the laboratory's QMS, ie, the intent for how the laboratory will:

- Ensure quality.
- Practice good quality management.
- Meet regulatory, accreditation, and customer requirements.

Included in this handbook are:

- Answers to the most commonly asked questions about a quality manual
- Guidance on how to develop a quality manual
- Templates for organizing laboratory management information into easily understood policies, processes, and procedures for each quality system essential (QSE)
- Examples of flow charts for QSE processes
- Example of a procedure for a QSE process

NOTE: The guidance provided in this handbook represents suggestions and recommendations by the authors for good practice and does not necessarily reflect the views of the organizations they represent.

NOTE:

A quality manual provides laboratory leadership, personnel, and accreditors with a description of the laboratory's QMS.

KEY WORDS

Quality manual **Quality objectives** **Quality policy**

Chapter 1

Introduction

This chapter includes:

- Handbook's scope and applicable exclusions
- Background information pertinent to the handbook's content
- Abbreviations and acronyms used in the handbook

Handbook for Developing a Laboratory Quality Manual

NOTE:

This handbook can be used to:

- Develop a quality manual for the first time.
- Restructure and revise laboratory administrative and quality documents.

1 Introduction

1.1 Scope

This handbook provides a structured means for laboratory management and personnel to develop a quality manual for the first time or to restructure and revise a quality manual from a laboratory's existing administrative and quality documents.

This handbook can be used by:

- New and current laboratory management personnel to learn about the QMS policies, processes, and procedures in their laboratory
- Laboratory quality managers for developing needed quality processes, procedures, and forms and for ensuring effective implementation of the QMS
- Medical and public health laboratories
- Blood gas laboratories
- Research laboratories
- Veterinary laboratories

Applicable portions of this handbook can also assist public health and environmental laboratories meet international requirements for quality manuals.[3]

NOTE:

The laboratory's quality manual organizes information in a useful way to:

- Train new management and supervisory personnel.
- Orient personnel to the QMS.
- Meet regulatory and accreditation requirements.

1.2 Background

Laboratories dutifully write and maintain "procedures manuals" to provide instructions to personnel on how to do their work and how to comply with regulatory and accreditation requirements. These manuals contain documents that describe the laboratory's **technical** work activities, which range from collecting specimens from patients to reporting laboratory examination results. Although there is no requirement for a procedures manual for management personnel, the laboratory usually maintains a large "administrative manual" that contains various policies, memoranda, and other documents describing nontechnical work and organizational information. These manuals are often not arranged in a useful fashion and are not typically used for training new laboratory supervisory and management personnel about laboratory quality.

Creating a quality manual provides a means for describing and documenting the laboratory's QMS. In addition, the manual organizes laboratory administrative and management information in a useful way for training new management and supervisory personnel, for orienting personnel to the QMS, and for meeting regulatory and accreditation

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

QMS25 covers the QSEs 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	X	X	X	X	X	X	X	X	X	X	X
K2Q	K2Q	K2Q	K2Q	K2Q	K2Q	K2Q	K2Q	K2Q	K2Q	K2Q	K2Q
QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01
							QMS02				
			QMS03								
		QMS04									
				QMS05							
											QMS06
									QMS11		
										QMS12	
					QMS13						
QMS14											
										QMS15	
			QMS16								
						QMS18					
QMS20											

Related CLSI Reference Materials*

K2Q **The Key to Quality™. 2nd ed., 2013.** This product provides fundamental information for implementing and sustaining a quality management system (QMS). It also includes information on the 12 quality system essentials (QSEs) for building a QMS; the policies, processes, and procedure requirements for each QSE; and, how to apply the QSEs in the laboratory environment.

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.

QMS03 **Training and Competence Assessment. 4th ed., 2016.** This guideline provides a structured approach for developing effective laboratory personnel training and competence assessment programs.

QMS04 **Laboratory Design. 3rd ed., 2016.** This guideline provides a foundation of information about laboratory design elements and guidance to help define issues to consider when designing a medical laboratory.

QMS05 **Quality Management System: Qualifying, Selecting, and Evaluating a Referral Laboratory. 2nd ed., 2012.** This guideline provides recommended criteria and easily implemented processes for qualifying, selecting, and evaluating a referral laboratory.

QMS06 **Quality Management System: Continual Improvement. 3rd ed., 2011.** 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.

QMS11 **Nonconforming Event Management. 2nd ed., 2015.** Grounded in the principles of quality management, risk management, and patient safety, this guideline provides an outline and content for developing a program to manage a laboratory's nonconforming events.

QMS12 **Development and Use of Quality Indicators for Process Improvement and Monitoring of Laboratory Quality. 1st ed., 2010.** This document provides guidance on development of quality indicators and their use in the medical laboratory.

* CLSI documents are continually reviewed and revised through the CLSI consensus process; therefore, readers should refer to the most current editions.

Related CLSI Reference Materials (Continued)

QMS13 **Quality Management System: Equipment. 1st ed., 2011.** This guideline provides recommendations for establishing equipment management processes from selection through decommission of equipment used in the provision of laboratory services.

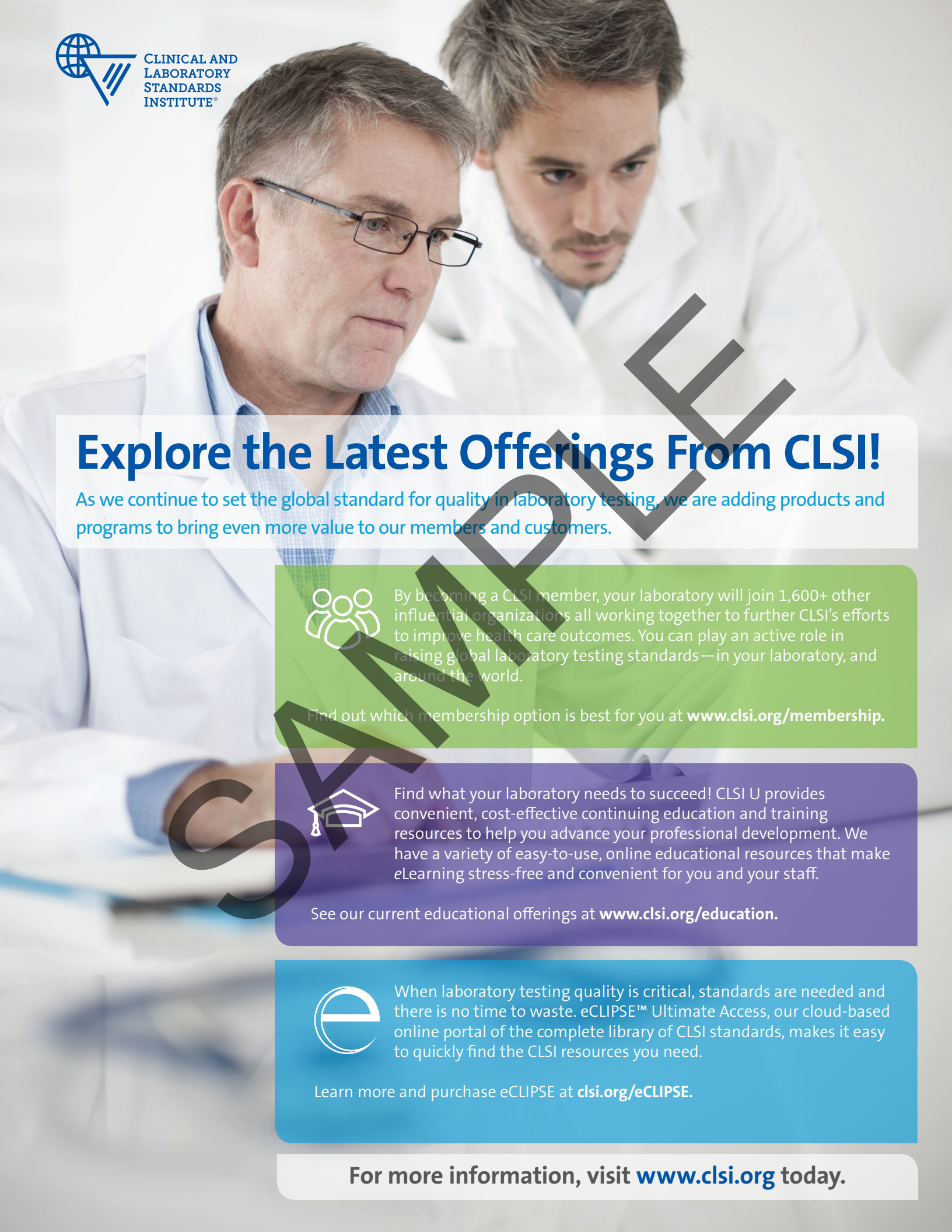
QMS14 **Quality Management System: Leadership and Management Roles and Responsibilities. 1st ed., 2012.** This guideline presents concepts and information intended to assist a laboratory in meeting leadership requirements for its quality management system. Guidance is provided for leaders to effectively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

QMS15 **Assessments: Laboratory Internal Audit Program. 1st ed., 2013.** This document provides guidance for how a laboratory can establish an internal audit program to enhance the quality of its services through continual improvement. Whereas an audit program defines the "who," "what," "when," "where," and "how" of meeting requirements for internal auditing, the audit process describes the details of how to conduct individual laboratory internal audits.

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.



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