CLINICAL AND LABORATORY STANDARDS INSTITUTE®

1st Edition

QMS17

External Assessments, Audits, and Inspections of the Laboratory

This guideline provides recommendations for establishing and maintaining a process to assist the laboratory in achieving a continuous state of readiness for assessment by an external organization. This includes selecting and evaluating an external assessment organization, preparing for and undergoing a successful assessment, and sustaining ongoing readiness for assessment.

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 advances 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.

Appeal Process

When it is believed that an objection has not been adequately considered and responded to, the process for appeal, 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

QMS17, 1st ed.
August 2017

External Assessments, Audits, and Inspections of the Laboratory

Joan M. Carlson, MLT(CMLTA), BSc(MLS), MT(ASCP)
Tania Motschman, MS, MT(ASCP)SBB, CQA(ASQ)
Deirdre Astin, MS, MT(ASCP)
Paul Bachner, MD
Lou Ann Barnett, PhD, MT(ASCP), PMP, CCRP, CLS
Kathleen A. Grindle, MT(ASCP), CQA(ASQ)CPGP
Karen Heaton, MLT(CMLTA)
Heather Meyer, MT(ASCP), CQE(ASQ)
Daniel J. Scungio, MT(ASCP), SLS
Gary K. Yamamoto
Janette Wassung

Abstract

Clinical and Laboratory Standards Institute guideline QMS17—*External Assessments, Audits, and Inspections of the Laboratory* outlines the process of selecting an assessment organization, preparing the laboratory for assessment, undergoing the assessment, responding to any deficiencies, and sustaining the state of readiness in a logical, ongoing cycle. This guideline provides expert information from laboratory professionals, industry, and accreditation organization perspectives to assist laboratories in planning for and attaining successful external assessments. External assessments include audits, inspections, site visits, and surveys of laboratories and may also apply to some laboratory industry settings.

Clinical and Laboratory Standards Institute (CLSI). *External Assessments, Audits, and Inspections of the Laboratory.* 1st ed. CLSI guideline QMS17 (ISBN 1-56238-822-3 [Print]; ISBN 1-56238-823-1 [Electronic]). Clinical and Laboratory Standards Institute, 950 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2017.

CLINICAL AND LABORATORY STANDARDS INSTITUTE®

Suggested Citation

CLSI. *External Assessments, Audits, and Inspections of the Laboratory.* 1st ed. CLSI guideline QMS17. Wayne, PA: Clinical and Laboratory Standards Institute; 2017.

ISBN 1-56238-822-3 (Print)

ISBN 1-56238-823-1 (Electronic)

ISSN 1558-6502 (Print)

ISSN 2162-2914 (Electronic)

Volume 37, Number 11

Contents

Foreword

Quality system essential (QSE) Assessments 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 Assessments, is a building block to quality and is necessary to support any laboratory's path of workflow from preexamination to examination to postexamination.

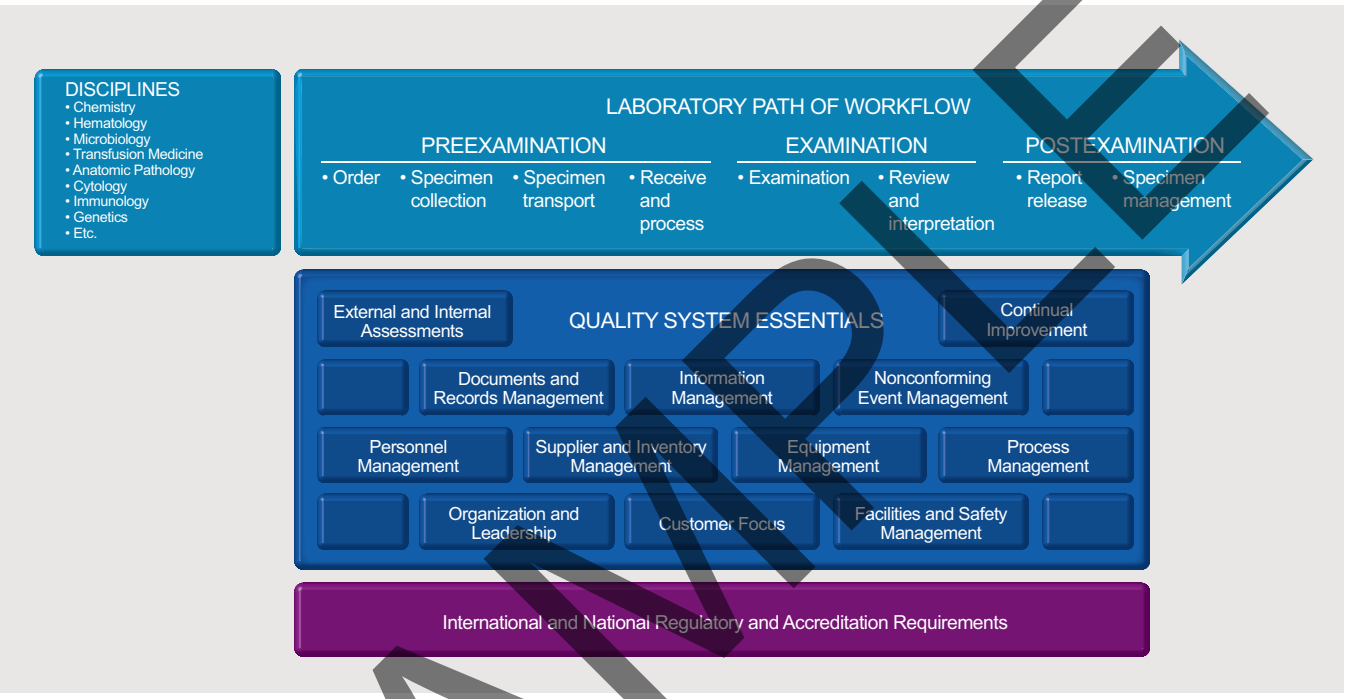

Figure 1. The Quality Management System Model for Laboratory Services (see CLSI document QMS01[1]). The 12 QSEs are building blocks necessary to support any laboratory's path of workflow and laboratory disciplines. This figure represents how the 12 QSEs support a medical laboratory's disciplines.

QSEs are the foundational building blocks that function effectively to support the laboratory's path of workflow. If a QSE is missing or not well implemented, problems will occur in preexamination, examination, and postexamination laboratory processes. For example, when the laboratory lacks processes for external assessments, there may be problems with attaining accreditation status.

International guidance related to the QSEs and the laboratory's path of workflow is available. Topics include:

- A process-based model for quality that any business should use to manage its operations, with information relating directly to the QSEs[3]
- Requirements for both quality management and technical operations of testing and calibration laboratories[4]
- Standards for quality management and technical operations in the medical laboratory environment[5]

QMS17 is a **guideline** for how to implement requirements established by customers, regulators, and accreditation organizations.[3-14] **QMS17 is not a standard;** that is, this guideline **does not set requirements** for external assessments. Instead, this guideline describes what laboratories need to do to meet applicable regulatory and accreditation requirements for external assessments and provides suggestions and examples for fulfilling the requirements.

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

External assessment organization

Nonconformances

Recommendations

Requirements

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

External Assessments, Audits, and Inspections of the Laboratory

1 Introduction

1.1 Scope

QMS17 provides guidance for establishing and maintaining a process to assist the laboratory in achieving a continuous state of readiness for assessment by an external assessment organization. It provides general guidance for:

- Seeking an assessment for the first time
- Considering whether to use a new external assessment organization
- Improving laboratory processes to achieve and sustain positive assessment outcomes

This guideline is intended for use by individuals responsible for the laboratory's external assessment activities. These individuals may include laboratory leadership and management, quality coordinators, compliance officers, clinical research coordinators, and administrative and technical personnel, as well as individuals who want to increase their knowledge in this area. This guideline may be applied to laboratories of any size and functional complexity, including but not limited to:

- Medical laboratories
- Public health laboratories
- Research laboratories
- Cell therapy and tissue processing laboratories
- Veterinary laboratories
- Food laboratories
- Environmental laboratories

This guideline may also have some application in laboratory industry settings, such as manufacturing of blood products, kits, and reagents.

This guideline does not include details specific to the operations and processes of the external accreditation organizations and is intended to cover the laboratory perspective only.

This guideline does not cover proficiency testing (PT) or internal assessments (ie, developing an internal audit program or processes for conducting internal audits, or establishing a program to identify and monitor quality indicators). Refer to CLSI documents QMS24,[15] QMS12,[16] and QMS15[17] for information on PT.

NOTE:

This guideline does not cover proficiency testing (PT) or internal assessments.

REMINDER:

Refer to CLSI documents QMS24,[15] QMS12,[16] and QMS15[17] for information on PT.

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 that 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:

Organization	Personnel	Process Management	Nonconforming Event Management
Customer Focus	Purchasing and Inventory	Documents and Records	Assessments
Facilities and Safety	Equipment	Information Management	Continual Improvement

QMS17 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	
		GP17									
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								
											QMS06
									QMS11		
										QMS12	
QMS14											
										QMS15	
						QMS24				QMS24	QMS24

Path of Workflow

A path of workflow is the description of the necessary processes to deliver the particular product or service that the organization or entity provides. A laboratory path of workflow consists of the sequential processes: preexamination, examination, and postexamination and their respective sequential subprocesses. All laboratories follow these processes to deliver their services, namely quality laboratory information.

QMS17 does not cover any of the medical laboratory path of workflow processes. For a description of the documents listed in the grid, please refer to the Related CLSI Reference Materials section.

Preexamination				Examination			Postexamination	
Examination ordering	Sample collection	Sample transport	Sample receipt and processing	Examination	Results review and follow-up	Interpretation	Results reporting and archiving	Sample management
K2Q	K2Q	K2Q	K2Q	K2Q	K2Q	K2Q	K2Q	K2Q
QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01

Related CLSI Reference Materials*

GP17 **Clinical Laboratory Safety. 3rd ed., 2012.** This document contains general recommendations for implementing a high-quality laboratory safety program, which are provided in a framework that is adaptable within any laboratory.

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.

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.

QMS14 **Quality Management System: Leadership and Management Roles and Responsibilities. 1st ed., 2013.** 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.

* 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)

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.

QMS24 **Using Proficiency Testing and Alternative Assessment to Improve Medical Laboratory Quality. 3rd ed., 2016.** This guideline describes an approach for a complete proficiency testing (PT) process and provides assistance to laboratories in using PT as a quality improvement tool.

CLINICAL AND LABORATORY STANDARDS INSTITUTE®

Explore the Latest Offerings From CLSI!

As we continue to set the global standard for quality in laboratory testing, we are adding products and programs to bring even more value to our members and customers.

By becoming a CLSI member, your laboratory will join 1,600+ other influential organizations all working together to further CLSI's efforts to improve health care outcomes. You can play an active role in raising global laboratory testing standards—in your laboratory, and around the world.

Find out which membership option is best for you at **www.clsi.org/membership.**

Find what your laboratory needs to succeed! CLSI U provides convenient, cost-effective continuing education and training resources to help you advance your professional development. We have a variety of easy-to-use, online educational resources that make *e*Learning stress-free and convenient for you and your staff.

See our current educational offerings at **www.clsi.org/education.**

When laboratory testing quality is critical, standards are needed and there is no time to waste. eCLIPSE™ Ultimate Access, our cloud-based online portal of the complete library of CLSI standards, makes it easy to quickly find the CLSI resources you need.

Learn more and purchase eCLIPSE at **clsi.org/eCLIPSE.**

For more information, visit www.clsi.org today.

CLINICAL AND
LABORATORY
STANDARDS
INSTITUTE®

950 West Valley Road, Suite 2500, Wayne, PA 19087 USA

P: +1.610.688.0100 **Toll Free (US):** 877.447.1888 **F:** +1.610.688.0700

E: customerservice@clsi.org **www.clsi.org**

PRINT ISBN 1-56238-822-3

ELECTRONIC ISBN 1-56238-823-1