



CLINICAL AND  
LABORATORY  
STANDARDS  
INSTITUTE.

2nd 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.

## External Assessments, Audits, and Inspections of the Laboratory

Lucia M. Berte, MA, MLS(ASCP)SBB, DLM, CQA(ASQ)CMQ/OE  
E. Jayne Scoggin, BA, CT, CG, MB(ASCP), CQA(ASQ)  
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 on-site and virtual audits, inspections, site visits, and surveys of laboratories and can also apply to some laboratory industry settings.

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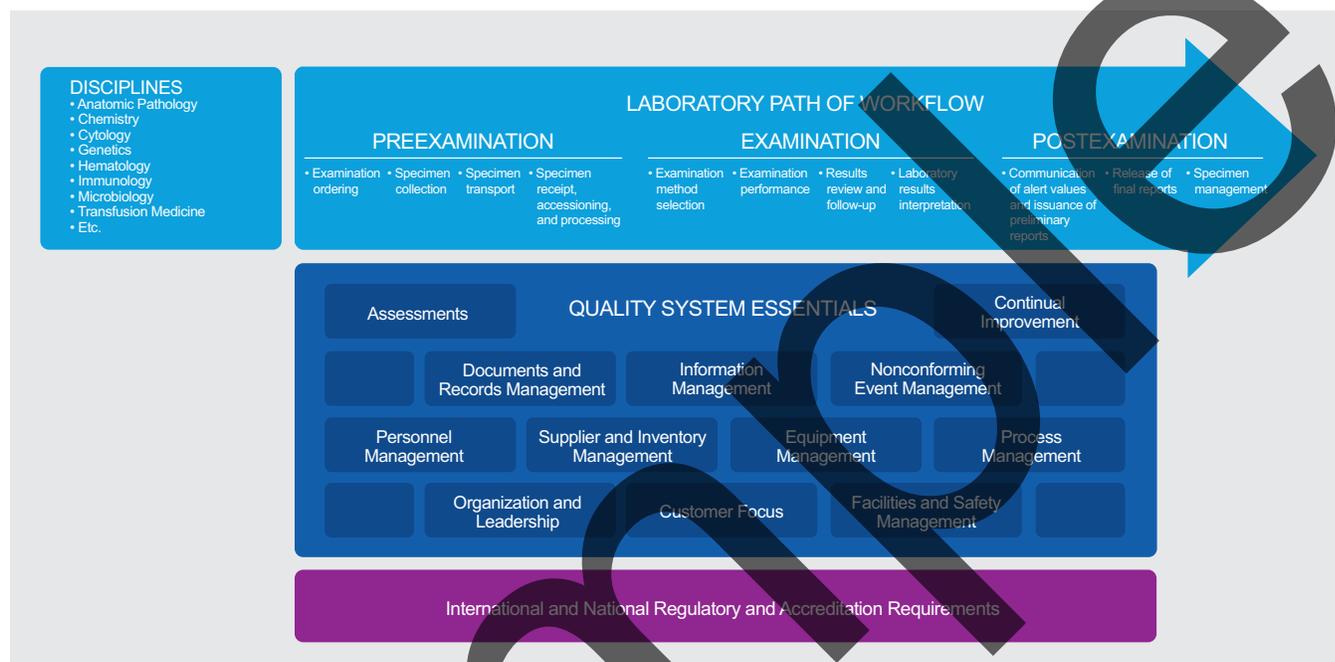
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## Foreword

Quality system essential (QSE) Assessments is one of the 12 QSEs described in CLSI document QMS01,<sup>1</sup> which provides the necessary background information and guidance to develop and maintain a QMS. The QMS model depicted in Figure 1 demonstrates that 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.



Abbreviations: QMS, quality management system; QSE, quality system essential.

**Figure 1. The QMS Model for Laboratory Services (see CLSI document QMS01<sup>1</sup>).** 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 and workflow for examinations.

QSEs are the foundational building blocks that function effectively to support the laboratory's path of workflow. When a QSE is missing or poorly implemented, problems will occur in preexamination, examination, and postexamination laboratory processes. For example, when the laboratory lacks processes for external assessments, there might 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<sup>2</sup>
- Requirements for both quality management and technical operations of testing and calibration laboratories<sup>3</sup>
- Standards for quality management and technical operations in the medical laboratory environment<sup>4</sup>

QMS17 is a **guideline** for how to implement requirements established by customers, regulators, and accreditation organizations.<sup>2,3</sup> **QMS17 is not a standard;** that is, this guideline **does not set requirements** for external assessments. Rather, it provides suggestions and examples for fulfilling the requirements.

## Overview of Changes

This guideline was revised in 2023 under the Limited Revision Process and replaces the first edition of the guideline, which was published in 2017. Several changes were made in this edition, including:

- Adding information on virtual external assessment
- Aligning QMS17 with the updated CLSI document template

**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

noncompliances

requirements

external assessment  
organization

recommendations

Sample

# Chapter 1

## Introduction

Sample

# 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

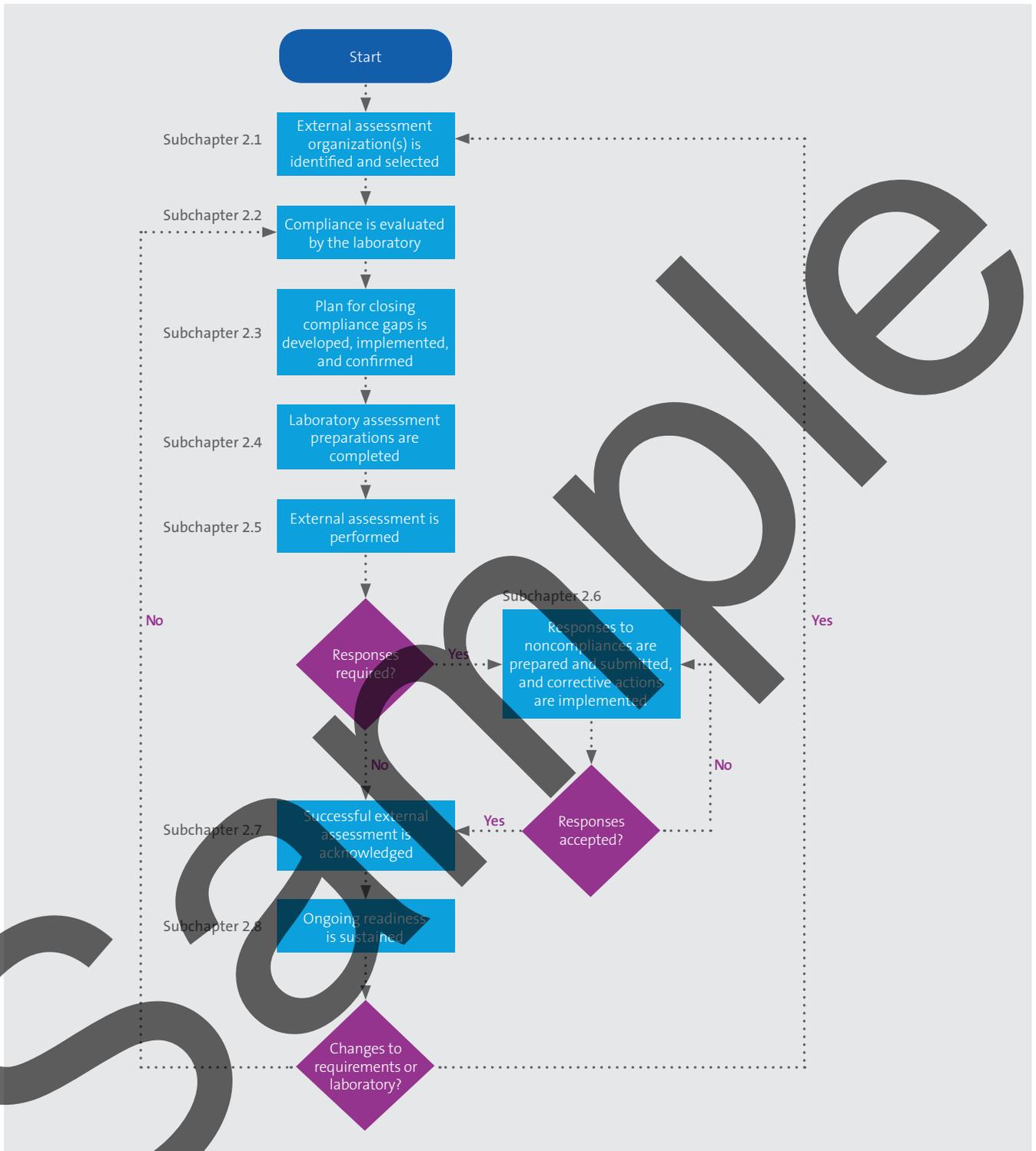
This guideline is intended for use by individuals responsible for the laboratory's external assessment activities. These individuals include laboratory leadership and management, quality coordinators, compliance officers, clinical research coordinators, and administrative and technical personnel, as well as individuals who want to increase their knowledge in this area. This guideline can 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 can 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 only the laboratory perspective.

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,<sup>14</sup> QMS12,<sup>15</sup> and QMS15<sup>16</sup> for information on PT, quality indicators, and internal auditing, respectively.



<sup>a</sup> Four basic symbols are used in this process flow chart: oval (signifies the beginning or end of a process), arrow (connects process activities), box (designates process activities), diamond (includes a question with alternative “Yes” and “No” responses).

**NOTE:** The external assessment process might differ among accreditation organizations.

**Figure 3. External Assessment Process Flow Chart<sup>a</sup>**

# Sample



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