



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.

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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 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.

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Foreword

Quality system essential (QSE) Assessments is one of the 12 QSEs described in CLSI document QMS01¹ and CLSI product *The Key to Quality*^{TM,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.

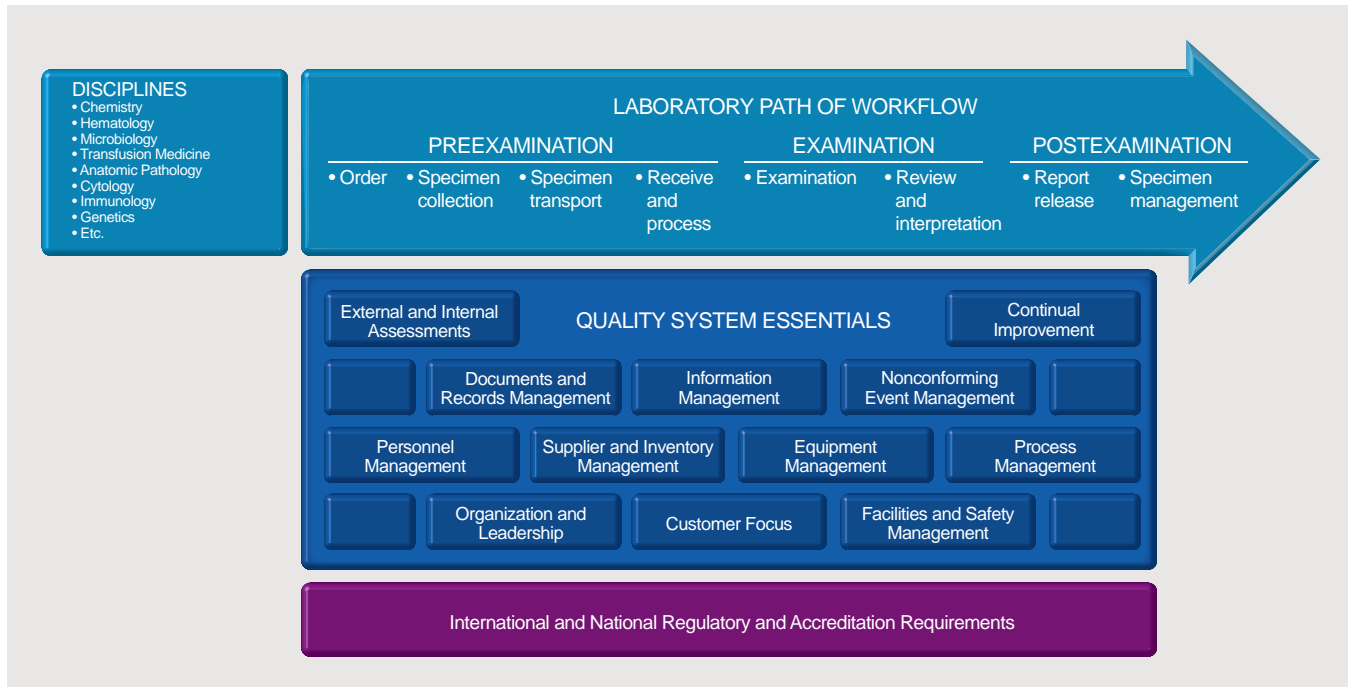


Figure 1. The Quality Management System Model for Laboratory Services (see CLSI document QMS01¹). The 12 QSEs are building blocks necessary to support any laboratory's path of workflow and laboratory disciplines. This figure represents how the 12 QSEs support a medical laboratory's disciplines.

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 QSEs³
- ▶ Requirements for both quality management and technical operations of testing and calibration laboratories⁴
- ▶ Standards for quality management and technical operations in the medical laboratory environment⁵

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

Nonconformances

Requirements

External assessment organization

Recommendations

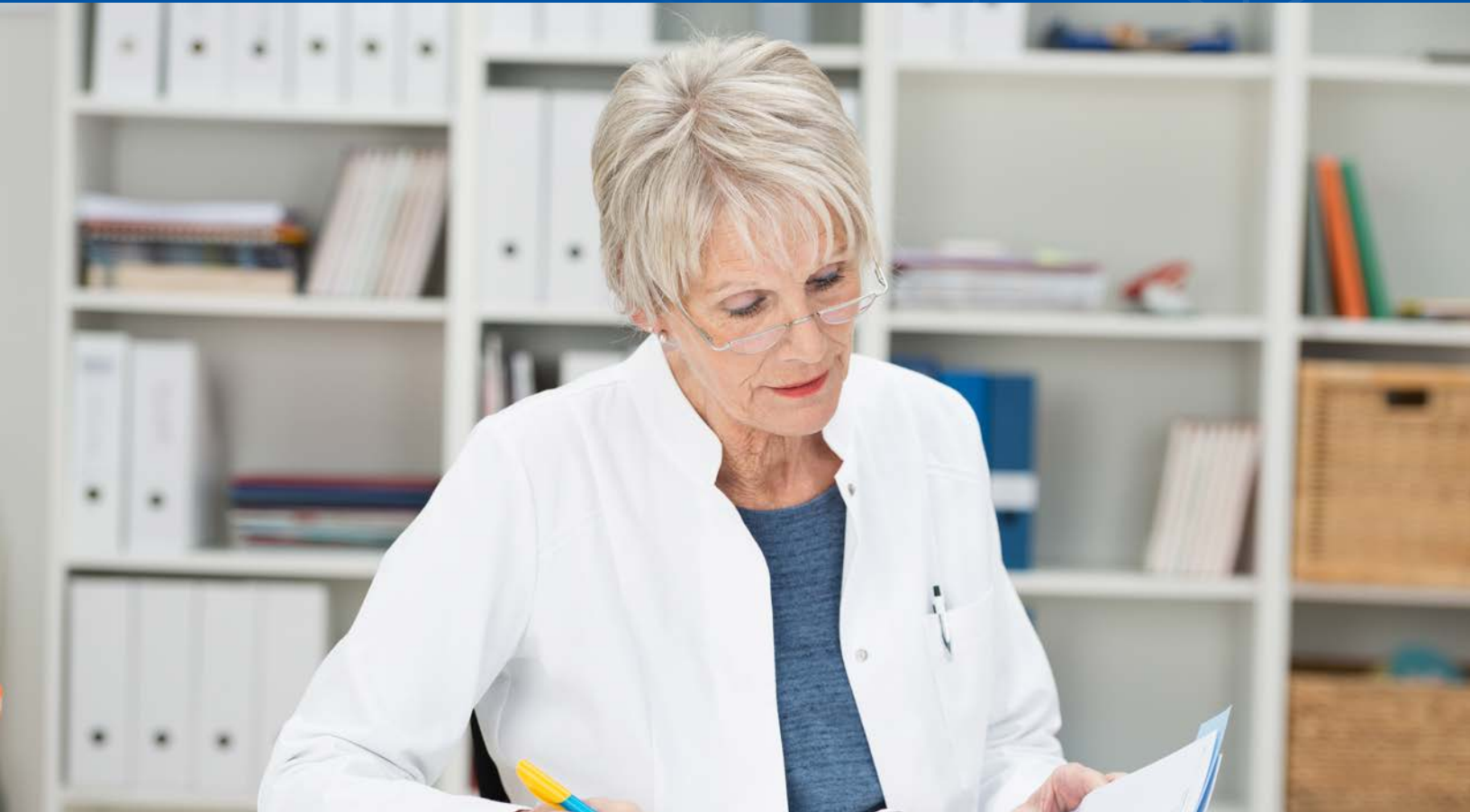
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Chapter 1

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



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 QMS15¹⁷ 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 QMS15¹⁷ for information on PT.