CLINICAL AND LABORATORY STANDARDS INSTITUTE®

2nd Edition

QMS18

Process Management

This guideline describes five requirements for managing laboratory processes and provides suggestions for effectively meeting regulatory and accreditation requirements, assessing process risks, optimizing efficient use of resources, and contributing to patient safety and positive outcomes.

A guideline for global application developed through the Clinical and Laboratory Standards Institute consensus process.

QMS18-Ed2
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Replaces QMS18-Ed1

Process Management

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Abstract

Clinical and Laboratory Standards Institute guideline QMS18—*Process Management* describes five published regulatory and accreditation requirements for management of laboratory processes. This guideline provides guidance, with explanations and examples, for meeting the five process management requirements as they apply to preexamination, examination, and postexamination processes. Because several other CLSI guidelines contain process management information for both laboratory examination and quality management processes, the examples in this guideline are for preexamination and postexamination processes.

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Foreword

Quality system essential (QSE) Process Management is one of the 12 QSEs described in CLSI document QMS01,[1] 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 Process Management, is a building block to quality and is necessary to support any laboratory's path of workflow from preexamination to examination to postexamination.

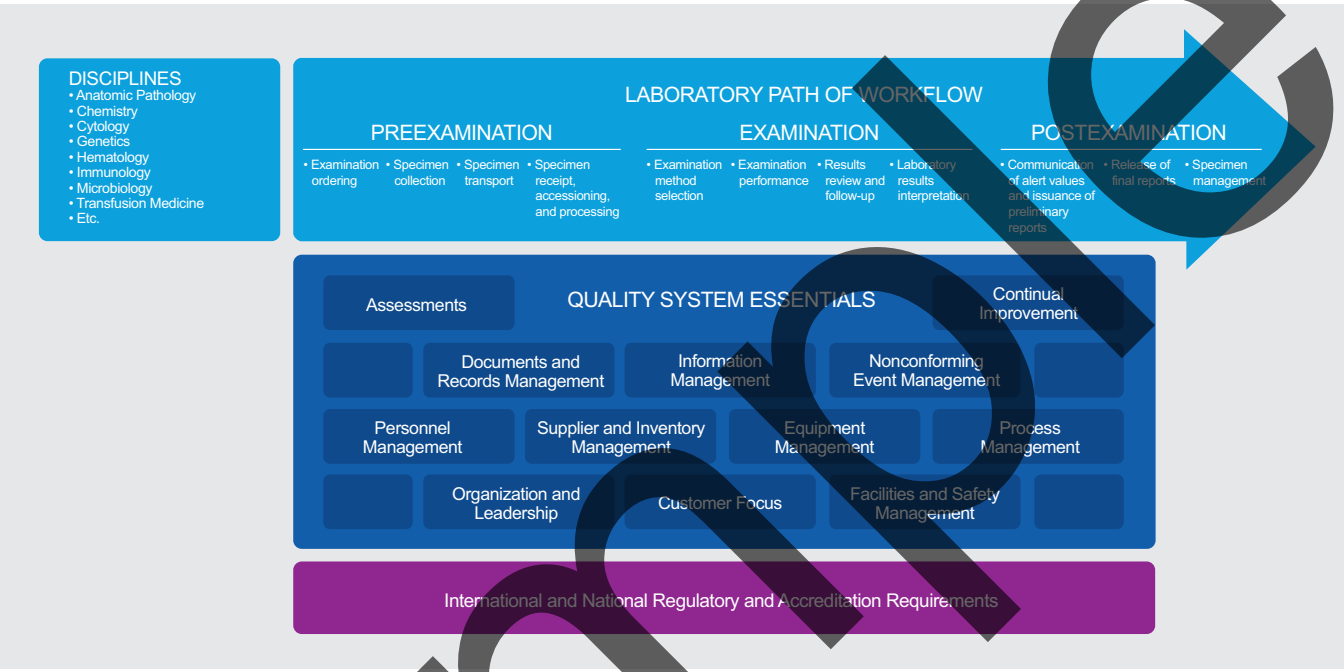

Figure 1. The QMS Model for Laboratory Services (see CLSI document QMS01[1]). The 12 QSEs are building blocks necessary to support any laboratory's path of workflow. This figure represents how the 12 QSEs support a medical laboratory's disciplines and stages of examination.

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 processes.

International guidance for 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[2]
- Requirements for both quality management and technical operations of testing and calibration laboratories[3]
- Standards for quality management and technical operations in the medical laboratory environment[4]

Developing, documenting, and managing the laboratory's technical and management processes are critical to optimizing the effectiveness of a QMS and sustaining quality. This guideline encourages using an organized approach for developing, assessing risks of, verifying or validating, controlling, and changing laboratory path of workflow processes. In an environment of process management, laboratory work processes are:

- Designed to meet applicable regulatory, accreditation, and customer requirements
- Assessed for risks to quality and patient safety
- Documented
- Verified or validated as working as intended, including risk controls, and assessed for readiness before implementation
- Monitored to ensure continued acceptable performance
- Changed in a controlled fashion

QMS18 is a **guideline** that can help laboratories implement and control laboratory processes and procedures and meet international standards and regulatory and accreditation requirements.[2-13] **QMS18 is not a standard;** that is, this guideline **does not set requirements** for process management. Rather, it provides suggestions and examples for fulfilling the referenced requirements.

Overview of Changes

This guideline replaces the first edition of the approved guideline, QMS18-Ed1, published in 2015. Several changes were made in this edition including:

- Adding the concept of assessing every new and changed process for risks to quality and patient safety and incorporating risk controls to detect and mitigate risks that cannot be eliminated
- Revising the process flow chart to include an activity box for risk assessment
- Adding appropriate wording about risk assessment in every text section where it is needed

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

change management
flow chart
process
process analysis
process management
validation
verification

Chapter 1

Introduction

Process Management

1 Introduction

1.1 Scope

This guideline provides a structured means for laboratory management and personnel to develop, assess, implement, monitor, and change laboratory work processes, with suggestions for how laboratories can meet the related regulatory and accreditation requirements. This guideline can be used for managing and delivering preexamination, examination, and/or postexamination workflow processes in laboratories of any size and functional complexity worldwide. This guideline can also be used for laboratories and other health care providers that perform point-of-care testing. Such laboratories include, but are not limited to, medical laboratories, public health laboratories, and physicians' offices. This guideline can also be used for developing and delivering quality management processes.

In any organization, two general types of risk are recognized:

- **Enterprise risk:** risk to the organization's reputation, financial stability, and continued ability to operate and stay in business.
- **Process risk:** risk in the organization's process activities that could compromise the quality of the process output and patient safety.

QMS18 focuses **only** on the second type of risk, ie, risks in laboratory processes.

This guideline does not provide details about information covered in other CLSI documents or available in published literature. Instead, this guideline provides a high-level overview in which to apply the detailed information.

The intended users of this guideline are:

- Managers, supervisors, and technical personnel who develop, perform, and oversee laboratory processes and procedures
- Pathologists, laboratory medical directors, and other medical and scientific personnel
- Regulatory and accreditation organizations
- Educators
- Manufacturers

Figure 10. Application of PDCA and DMAIC. The left side of this figure shows how the PDCA cycle applies to the process flow chart introduced in Chapter 2 (see Figure 2). The right side shows how the DMAIC phases apply.

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