CLINICAL AND LABORATORY STANDARDS INSTITUTE®

7th Edition

CLSI QMS02™

Developing and Managing Laboratory Documents

CLSI QMS02 provides guidance on the processes needed for documents management, including creating, controlling, changing, and retiring a laboratory's policy, process, procedure, and form documents in both paper and electronic environments.

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

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Developing and Managing Laboratory Documents

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Abstract

Clinical and Laboratory Standards Institute document QMS02—*Developing and Managing Laboratory Documents* presents the important components of a program for documents management, including creating, reviewing, approving, maintaining, assessing, changing, and retiring documents used in the laboratory environment. This guideline describes the components of a documents management program, whether paper-based or electronic, and the related processes for creating and managing laboratory documents. Key features of electronic document management systems are also described. Several examples of process and procedure documents for quality management and preexamination, examination, and postexamination laboratory activities are included.

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The Consensus Council sets priorities for CLSI standards development and votes on Final Draft documents to confirm that process requirements have been met. Consensus Council members are listed on the CLSI website: https://clsi.org/standards-development/consensus-council/

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Foreword

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

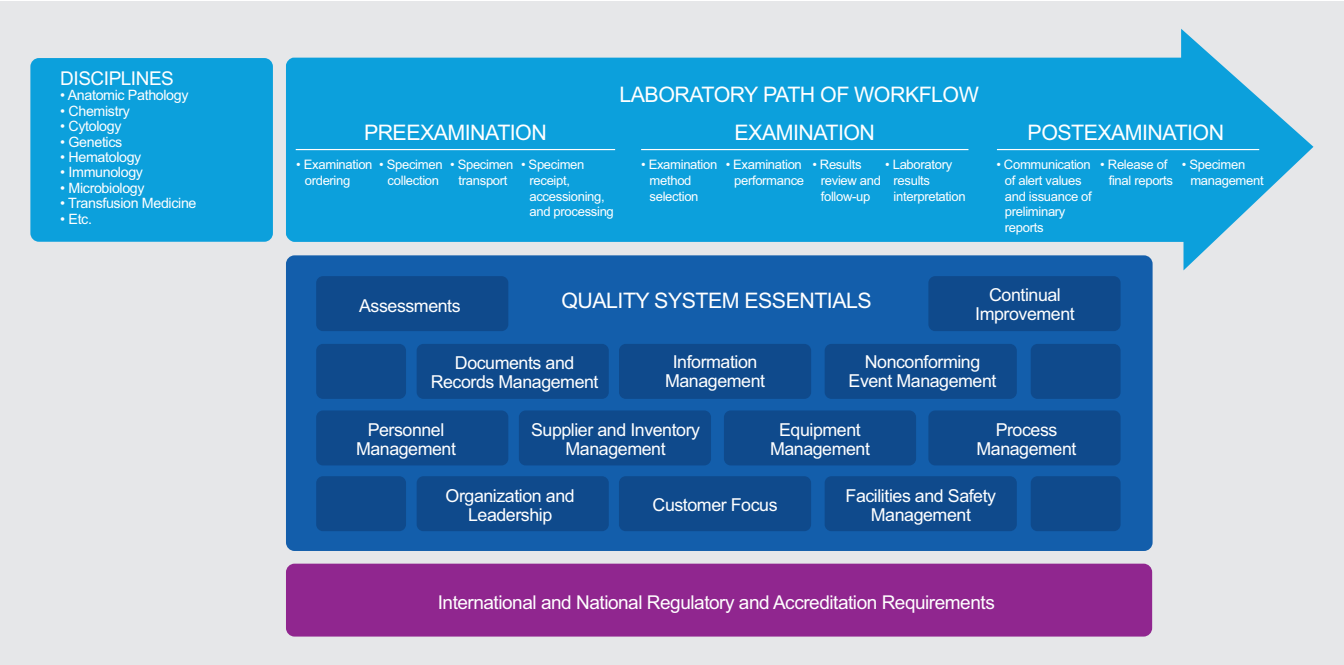

Figure 1. The QMS Model for Laboratory Services (see CLSI document QMS01[1]). The 12 QSEs are building blocks necessary to support any laboratory's path of workflow. This figure represents how the 12 QSEs support a medical laboratory's disciplines and stages of examination.

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. For example, when the laboratory lacks a defined process for managing its documents, it could be unable to:

- Develop documents uniformly across all laboratory sections and among personnel working in more than one section.
- Access the current approved versions of process and procedure documents for performing assigned job tasks.
- Train personnel or perform processes and procedures using current approved documents.
- Locate previous versions of laboratory documents needed to investigate a complaint or nonconforming event.

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]

QMS02 is a **guideline** that can help laboratories implement a laboratory documents management program and meet international standards and regulatory and accreditation requirements.[2-13] **QMS02 is not a standard;** that is, this guideline **does not set requirements** for managing documents. Rather, it provides suggestions and examples for fulfilling the requirements.

Overview of Changes

This guideline was revised in 2024 under the Limited Revision Process and replaces the 6th edition of the guideline, which was published in 2013. Several changes were made in this edition, including:

- Aligning QMS02 chapters and subchapters with CLSI document QMS26[14] to first discuss the components of a documents management program, followed by the processes for creating and managing individual documents.
- Aligning QMS02 with the updated CLSI document template.
- Updating information about electronic document management systems to provide additional guidance for use in medical laboratories.

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

document **documents management**

Chapter 1

Introduction

Developing and Managing Laboratory Documents

1 Introduction

1.1 Scope

This guideline presents the elements of a program for managing laboratory documents. In addition, an evidence-based process is described for preparing different types of laboratory documents from the time a need is recognized for a new or revised document, through the document's use and control, until the time it is retired. The information presented applies to both paper-based and electronic document management systems.

This guideline is applicable to documents used by medical laboratories of any size, complexity, or specialty, including point-of-care testing.

QMS02 is intended for use by the following:

- Administrative and technical personnel who develop laboratory documents
- Manufacturers
- Educators
- Regulatory and accreditation organizations

1.2 Background

All laboratories, regardless of size, generate important laboratory documents. Documents contain requirements and instructions for laboratory activities and need to be managed to be useful. The documents have to be accessible when they are active and properly stored or disposed of when they are retired or archived. Medical laboratories have become very complex; strategies to manage the types and volume of laboratory documents have also become increasingly complex. Regardless of the document type or medium, a documents management program provides a means to control each document throughout its lifespan. All personnel, from the newest person to the laboratory director, have a role in documents management. The benefits of a documents management program are presented in Table 1.