CLINICAL AND LABORATORY STANDARDS INSTITUTE®

6th Edition

# QMS02

## Quality Management System: Development and Management of Laboratory Documents, 6th Edition



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.

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

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# Quality Management System: Development and Management of Laboratory Documents; Approved Guideline—Sixth Edition

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## Abstract

Clinical and Laboratory Standards Institute document QMS02-A6—*Quality Management System: Development and Management of Laboratory Documents; Approved Guideline—Sixth Edition* presents the important components of creating, evaluating, approving, controlling, changing, and retiring documents used in the laboratory environment. This guideline describes the processes needed in a document management system, whether paper-based or electronic. Key features of electronic document management systems are described. Several examples of process and procedure documents for preexamination, examination, and postexamination laboratory activities are included.

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## Foreword

Control of documents and records (DR) is critical to optimizing the effectiveness of a QMS and sustaining quality. This guideline encourages using an organized process-based approach for implementing and managing a program to develop and control the medical laboratory's many documents. In an environment of document management, only approved versions of paper-based or electronic documents are available for use by staff in all locations where they are needed.

DR is one of the 12 quality system essentials (QSEs) in CLSI document GP26,[1] which describes a structured approach to organizing, creating, and maintaining the necessary information for the QSEs. The QMS model depicted in Figure 1 demonstrates how each QSE, such as DR, is a building block to quality that is necessary to support any laboratory's path of workflow (POW) from preexamination to examination to postexamination. This document is designed to guide the user in the development and implementation of a document management system.


**Figure 1. The Quality Management System Model (see CLSI document GP26)[1]**

If a QSE is missing or not well implemented, problems may occur in any or all preexamination, examination, and postexamination laboratory activities, as well as laboratory management activities. For example, when the laboratory lacks defined processes for properly installing, calibrating, and maintaining its instruments so they work effectively, problems will occur in examination processes.

The requirements for QSE DR can be summarized as:

- Development and maintenance of a document management system
- Development and maintenance of a record management system

The current edition of QMS02 will focus only on the processes within a document management system.

### Overview of Changes From GP02-A5

Previous editions of QMS02 have focused on essential elements to include in laboratory examination procedures.

# Quality Management System: Development and Management of Laboratory Documents; Approved Guideline—Sixth Edition

## 1 Scope

This guideline presents evidence-based suggestions for preparing different types of laboratory documents. In addition, a process is described for how laboratory documents can be managed and controlled 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.

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

QMS02 is a *guideline* for how to implement requirements established in international standards, and by regulatory and accrediting organizations for laboratory documents and procedures manuals. ***QMS02 is not a standard;*** that is, this guideline does not set requirements for laboratory documents and procedures. **Instead, this guideline describes what laboratories need to do to meet published regulations, accreditation requirements, and international standards[2-13] for documents and document management, and provides suggestions and examples for fulfilling the requirements.**

## 2 Introduction

All work happens in processes—that is, sequences of activities that a laboratory needs to perform in a specific order, and correctly, to transform a given input into the desired output. Laboratories need to communicate both the sequence of activities (ie, process) as well as the instructions for how to perform a given process activity (ie, procedure). Documented processes and procedures provide essential information for both new and experienced employees about how to perform all of their job tasks—including tasks not related to directly performing examinations, such as training, competence assessment, collecting blood samples, and using the laboratory's computer system.

To provide structure for the document management system described in this guideline, a process for how a laboratory can manage and control its documents is introduced. The flow chart starts with awareness of a need for a new document and proceeds through the lifespan of a document from development, evaluation, approval, distribution, review, change, and finally retirement. Figure 2 shows the activities and decisions in an effective document management process. Each main activity in the process is shown in a box; decisions made regarding documents are shown in a diamond as a question with a yes/no answer. Each activity, with its respective decisions and actions, is discussed in a separate section of this guideline; section numbers are shown to the left of the respective activities. Additional information to assist with developing a document management system is found in later sections.

This guideline provides several examples of common laboratory processes and procedures. Laboratories are encouraged to use these examples as starting points for documenting their own processes and procedures. Although there are specified international standard, regulatory, and accreditation requirements for needed contents of laboratory procedures manuals, *there are no specific requirements*

*for the formats* of laboratory documents. Therefore, this guideline presents evidence-based suggestions for document formats that effectively communicate management's message to staff about how to do the laboratory's work.[14]

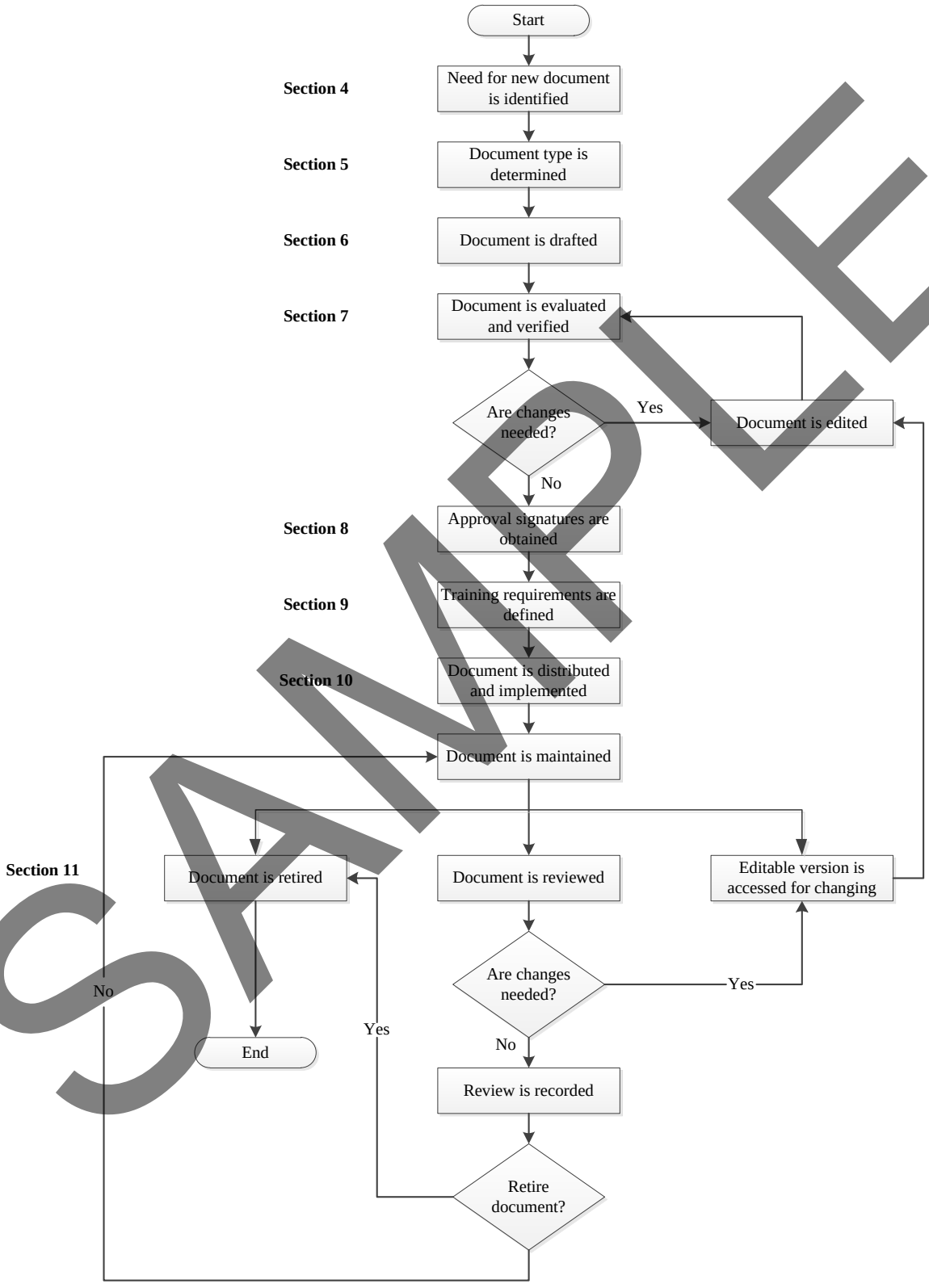


**Figure 2. Document Management Process.** This process shows the activities performed and decisions made throughout the lifespan of a document.



 

# The Quality Management System Approach

Clinical and Laboratory Standards Institute (CLSI) subscribes to a quality management system approach in the development of standards and guidelines, which facilitates project management; defines a document structure via a template; and provides a process to identify needed documents. The quality management system 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 as follows:

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

QMS02-A6 addresses 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 on the following page.

| Organization | Customer Focus | Facilities and Safety | Personnel | Purchasing and Inventory | Equipment | Process Management | Documents and Records | Information Management | Nonconforming Event Management | Assessments | Continual Improvement |
|---|---|---|---|---|---|---|---|---|---|---|---|
| GP26 | GP26 | GP26<br>H03 | GP21<br>GP26 | GP26<br>H03 | GP26 | GP26<br>H01<br>H03 | X<br>GP26 | GP26 | GP26 | GP26 | GP26 |

## 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 the laboratory's services, namely quality laboratory information.

QMS02-A6 does not address any of the clinical laboratory path of workflow steps. For a description of the documents listed in the grid, please refer to the Related CLSI Reference Materials section on the following page.

| **Preexamination** | | | | **Examination** | | | **Postexamination** | |
|---|---|---|---|---|---|---|---|---|
| Examination ordering | Sample collection | Sample transport | Sample receipt/processing | Examination | Results review and follow-up | Interpretation | Results reporting and archiving | Sample management |
| GP26<br>H03 | GP26<br>H01<br>H03 | GP26<br>H03 | GP26<br>H03 | GP26<br>H03 | GP26<br>H03 | GP26 | GP26 | GP26 |

## Related CLSI Reference Materials*

**GP21-A3** **Training and Competence Assessment; Approved Guideline—Third Edition (2009).** This document provides background information and recommended processes for the development of training and competence assessment programs that meet quality and regulatory objectives.

**GP26-A4** **Quality Management System: A Model for Laboratory Services; Approved Guideline—Fourth Edition (2011).** This document provides a model for medical laboratories that will assist with implementation and maintenance of an effective quality management system.

**H01-A6** **Tubes and Additives for Venous and Capillary Blood Specimen Collection; Approved Standard—Sixth Edition (2010).** This standard contains requirements for the materials, manufacturing, and labeling of venous and capillary blood collection devices.

**H03-A6** **Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard—Sixth Edition (2007).** This document provides procedures for the collection of diagnostic specimens by venipuncture, including line draws, blood culture collection, and venipuncture in children.



* CLSI documents are continually reviewed and revised through the CLSI consensus process; therefore, readers should refer to the most current editions.

 

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