

QMS02-A6

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

Abstract.....	i
Committee Membership.....	iii
Foreword.....	ix
1 Scope.....	1
2 Introduction.....	1
3 Terminology.....	3
3.1 A Note on Terminology.....	3
3.2 Definitions.....	4
3.3 Abbreviations and Acronyms.....	4
4 Need for New Document.....	5
4.1 International Influence.....	5
4.2 The Quality Management System and Documentation Management.....	5
4.3 Documentation Hierarchy.....	5
4.4 Documentation Categories.....	6
5 Document Type Is Determined.....	7
5.1 Policies.....	8
5.2 Processes: Quality and Operations.....	8
5.3 Procedures and Job Aids: Quality and Operations.....	12
5.4 Form Identification.....	13
5.5 Putting It All Together.....	13
6 Document Is Drafted.....	14
6.1 Use of Document Templates.....	14
6.2 Template Types and the Document Hierarchy.....	16
6.3 Contents of Template Types.....	16
6.4 Sources of Information for Content for the Different Document Template Types.....	17
6.5 Composing the Draft Using the Selected Template.....	18
7 Draft Is Evaluated, Edited as Needed, and Verified.....	27
7.1 Selection of Document Reviewers.....	28
7.2 Reviewing Documents for Format and Content.....	28
7.3 Performing Electronic and Paper-based Reviews.....	29
7.4 Verifying that Documents Are Correct.....	29
8 Approval.....	29
9 Training Requirements Determined and Training Verified.....	31
10 Document Is Distributed and Implemented.....	32
11 Document Maintenance.....	32
11.1 Document Maintenance.....	32
11.2 Changing Documents.....	33
11.3 Retiring Documents.....	34
11.4 Master File.....	34
11.5 Document Archiving, Storage, and Retention.....	35
12 Control of Reference Documents.....	35

Contents (Continued)

13	Procedures Manuals	36
14	Key Features of Electronic Document Management System	37
14.1	Draft	38
14.2	Evaluation	38
14.3	Approval	39
14.4	Record of Acknowledgment	40
14.5	Publishing	40
14.6	Maintenance	41
14.7	Procedures Manuals	42
15	How to Get Started	43
16	Conclusion	43
	References	44
	Appendix A. Sample Policy: “Quality System Essential Facilities and Safety Policy”	45
	Appendix B. Sample Policy: “Quality System Essential Nonconforming Event Management Policy”	47
	Appendix C. Sample Quality Process for Quality System Essential Assessments: “Unannounced Inspection Day Process”	49
	Appendix D. Sample Preexamination Process: “Blood Sample Collection Process”	51
	Appendix E1. Sample Examination Process: “Analyzer Setup and Run Process”	52
	Appendix E2. Sample Examination Process: “Surgical Pathology Process”	53
	Appendix F. Sample Postexamination Process: “Critical Value Handling Process”	54
	Appendix G1. Sample Quality Procedure: “Correcting Laboratory Paper Record Procedure”	55
	Appendix G2. Sample Preexamination Procedure: “Identifying the Patient for Sample Collection Procedure”	56
	Appendix G3. Sample Microbiology Examination Procedure: “Urine Culture: Reading and Interpreting Procedure”	58
	Appendix G4. Sample Transfusion Medicine Examination Procedure: “Weak D (D ^u) Determination Procedure”	61
	Appendix G5. Sample Histology Examination Procedure: “Hematoxylin and Eosin Staining Procedure: Manual Method”	63
	Appendix G6. Sample Postexamination Procedure: “Critical Values Reporting Procedure”	65
	Appendix H1. Sample Job Aid: “Shared Testing Job Aid”	66
	Appendix H2. Sample Job Aid: “Draw Tubes and Minimum Fill”	67
	Appendix I1. Sample Form: “Document Management Form”	68
	Appendix I2. Sample Form: “ABO/Rh Discrepancy Worksheet”	69
	Appendix J. Suggested Contents of Templates for Laboratory Documents	71
	Appendix K1. How to Construct a Process Flow Chart	72
	Appendix K2. Sample Process Flow Chart: “Laboratory Sample Receiving Process”	75
	Appendix K3. Sample Process Flow Chart: “Bacteriology Culture Process”	76

Contents (Continued)

Appendix K4. Table Format for the Document Management Process	77
Appendix L1. Sample Attributes for a Single Analyte on a Single Analyzer.....	78
Appendix L2. Attributes for Multiple Analytes on a Single Analyzer	79
Appendix L3. Attributes for a Single Analyte on Multiple Analyzers	80
Appendix M. Sample Checklist: Document Review Checklist	81
Appendix N. Sample Form: “Group Training Record”	83
Appendix O1. Sample Procedures Manual Table of Contents: “Transfusion Reaction Investigation Process”	84
Appendix O2. Sample Procedures Manual Table of Contents: “Automated Analyzer Operations Process”	85
Appendix P. Ten Rules for Laboratory Document Management.....	86
The Quality Management System Approach.....	88
Related CLSI Reference Materials	89

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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.

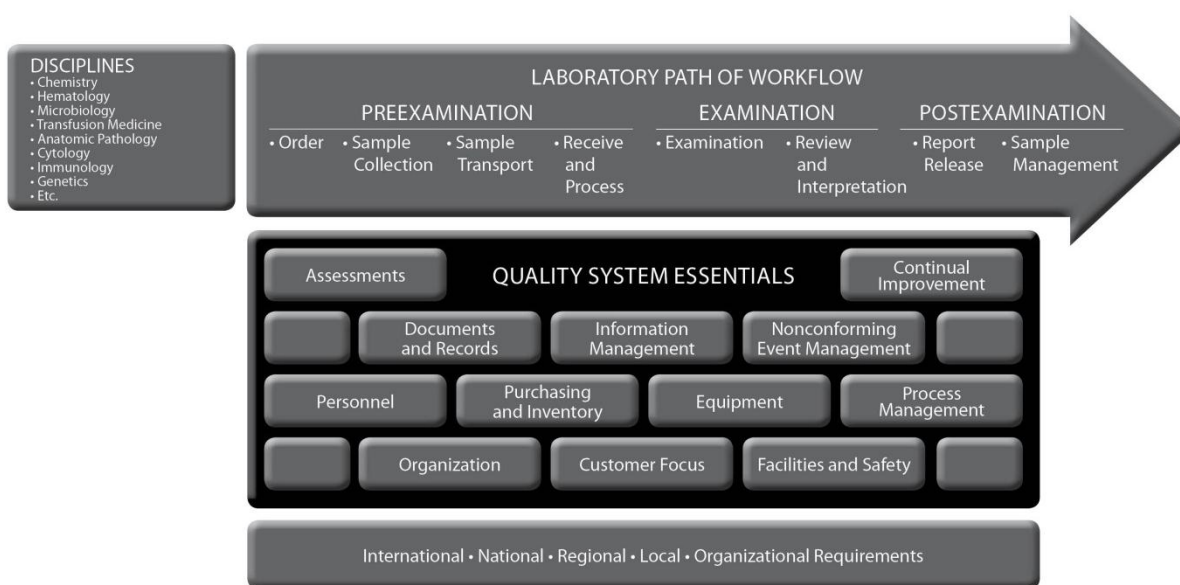


Figure 1. The Quality Management System Model (see CLSI document GP26)¹

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.

This edition of QMS02 has been reorganized to provide guidance for:

- Using an overall process for document management and control
- Using flow charts to depict the sequence of activities in laboratory processes
- Preparing instructions for performing procedures in the preexamination, examination, and postexamination processes in the laboratory's POW
- Preparing process and procedure documents specifically for multitest automated analyzers
- Writing procedures for the LIS
- Managing and controlling paper-based and electronic laboratory documents after they are approved for use

Key Words

Computer procedure, document, document control, document management, electronic procedures, laboratory procedure, laboratory process, procedures manual, technical 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 standards²⁻¹³ 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*