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5th Edition

QMS01

A Quality Management System Model for Laboratory Services

This guideline provides a model for medical laboratories to organize the implementation and maintenance of an effective quality management system.

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

A Quality Management System Model for Laboratory Services

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Abstract

Clinical and Laboratory Standards Institute guideline QMS01—*A Quality Management System Model for Laboratory Services* provides the necessary background information and infrastructure to develop a quality management system that meets the laboratory's quality objectives and is consistent with the quality objectives of health care services. This guideline provides a structure for a comprehensive, systematic approach to building quality into the laboratory's processes, assessing the laboratory's performance, implementing quality improvements, and assisting in preparing for or maintaining accreditation.

Clinical and Laboratory Standards Institute (CLSI). *A Quality Management System Model for Laboratory Services*. 5th ed. CLSI guideline QMS01 (ISBN 978-1-68440-043-0 [Print]; ISBN 978-1-68440-044-7 [Electronic]). Clinical and Laboratory Standards Institute, 950 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2019.

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Suggested Citation

CLSI. *A Quality Management System Model for Laboratory Services*. 5th ed. CLSI guideline QMS01. Wayne, PA: Clinical and Laboratory Standards Institute; 2019.

Previous Editions:

July 1998, October 1999, February 2003, November 2004, June 2011

SAMPLE

ISBN 978-1-68440-043-0 (Print)

ISBN 978-1-68440-044-7 (Electronic)

ISSN 1558-6502 (Print)

ISSN 2162-2914 (Electronic)

Volume 39, Number 6

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Foreword

Increased awareness of the costly personal and economic effects of medical errors has underscored the importance of managing quality in health care services. In the present environment of limited resources, quality cannot be taken for granted by those who fund, receive, or provide laboratory services. The historical perspective of quality control and quality assurance as defining quality needs to be superseded by a more comprehensive view of internationally accepted quality practices applied to a laboratory's entire scope of work.

This guideline is intended as a reliable, practical, and easily understood perspective that can be implemented in any laboratory.

QMS01 is a **guideline** that can help laboratories implement a QMS to achieve quality laboratory services and meet international standards and regulatory and accreditation requirements. **QMS01 is not a standard**; that is, this guideline **does not set requirements** for implementing a QMS. Rather, it **reorganizes existing requirements** for medical laboratories into a more understandable approach. It can be used along with other quality-related documents to design the foundation necessary to achieve an efficient, effective, and sustainable QMS.

**NOTE:**

QMS01 **is not a standard**; it simply reorganizes existing requirements in a more understandable way.

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Overview of Changes

This guideline replaces the previous edition of the approved guideline, QMS01-A4, published in 2011. Several changes were made in this edition, including:

- Shifted focus from process and procedural details for implementing the CLSI QMS model to an overview of specific required processes in the QMS, with referral to the library of QMS guidelines listed in the Related CLSI Reference Materials section for process and procedure details
- Described the patient's relationship to the QMS
- Aligned guidance with any new or changed international, regulatory, and accreditation requirements for laboratories since the last edition
- Added suggestions for providing a rationale to laboratory leadership for implementing and maintaining a QMS
- Described a practical strategy for implementing a laboratory QMS

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

Examination processes

Path of workflow

Postexamination processes

Preexamination processes

Quality

Quality assurance

Quality control

Quality cost management

Quality indicators

Quality management

Quality management system

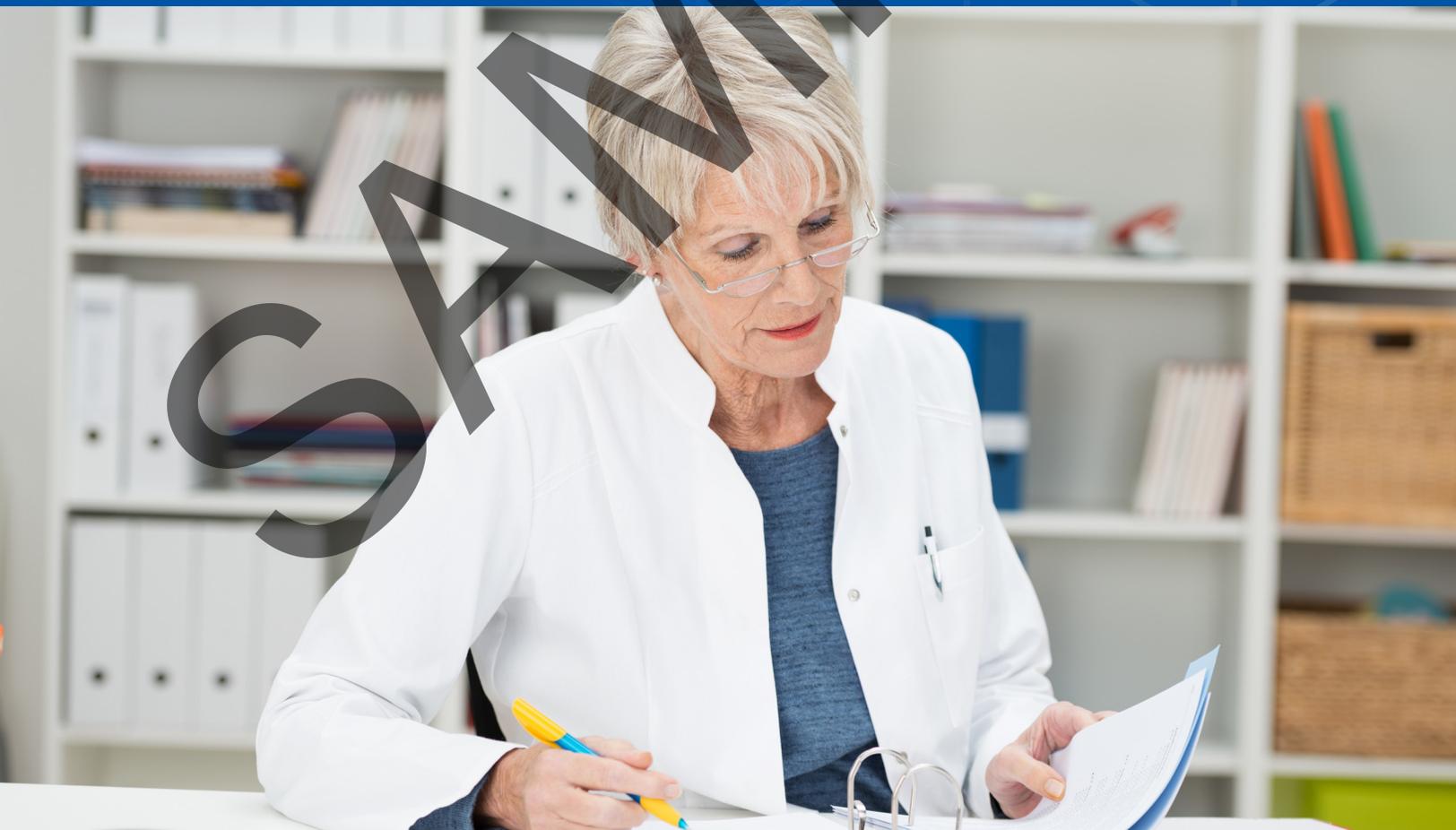
Quality system essentials

Chapter 1

Introduction

This chapter includes:

- Guideline's scope
- 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



A Quality Management System Model for Laboratory Services

1 Introduction

1.1 Scope

The QMS model described in this guideline can be used in laboratories worldwide. This guideline is intended for use primarily by:

- Medical laboratories
- Blood gas laboratories
- Blood donor and pretransfusion testing laboratories
- Public health laboratories
- Clinical research laboratories

However, the QMS model is also applicable to other types of laboratories, including but not limited to:

- Food laboratories
- Environmental laboratories
- Veterinary laboratories

The 12 quality system essentials (QSEs) described in this guideline are universal and applicable to any size laboratory, whether simple or complex, and any laboratory discipline. This guideline is intended for laboratory directors, managers, supervisors, quality managers, and others responsible for implementing, evaluating, and maintaining the laboratory's QMS.

NOTE:

The complexity of laboratory services underlines the need for a systematic approach to provide a high level of service.

1.2 Background

This guideline continues to revise a model, first published in 1999, that assists laboratories with implementing and maintaining an effective QMS. This model contains the regulatory and accreditation requirements for quality management specified by international and national organizations.¹⁻¹²

The goal of an effective and efficient laboratory is to consistently provide the appropriate examinations with accurate results in a timely manner and with the most judicious use of resources. This goal includes working with practitioners to ensure the appropriate examination is ordered and the results are interpreted correctly. The complexity of laboratory services underlines the need for a systematic approach to provide this high level of service. A laboratory QMS is a systematic approach that describes, documents, implements, measures, and monitors the effectiveness of laboratory work operations in meeting regulatory and accreditation requirements and that promotes the efficient use of resources. The ultimate goal of this activity is to meet the expectations of laboratory customers.

efforts, and its consensus process focuses on harmonization of terms to facilitate the global application of standards and guidelines. Table 3 is provided to clarify the intended interpretations of the following terms.

Table 3. Common Terms or Phrases With Intended Interpretations

Term or Phrase	Intended Interpretation
“Needs to” or “must”	Explains an action directly related to fulfilling a regulatory and/or accreditation requirement or is indicative of a necessary step to ensure patient safety or proper fulfillment of a procedure
“Require”	Represents a statement that directly reflects a regulatory, accreditation, performance, product, or organizational requirement or a requirement or specification identified in an approved documentary standard
“Should”	Describes a recommendation provided in laboratory literature, a statement of good laboratory practice, or a suggestion for how to meet a requirement

1.3.2 Definitions

accreditation – process by which an authoritative organization gives formal recognition that a laboratory is competent to carry out specific tasks.¹

assessment – systematic process to collect and analyze data to determine the current, historical, or projected status of an organization, person, or project.¹⁷

audit – systematic, independent, and documented process to obtain objective evidence and evaluate it objectively to determine the extent to which the audit criteria are fulfilled.¹⁸

calibration – comparison of a measurement instrument or system of unverified accuracy to a measurement instrument or system of known accuracy to detect any variation from the required performance specification.¹⁹

calibration verification – the assaying of calibration materials in the same manner as patient samples to confirm that the calibration of the instrument, kit, or test system has remained stable throughout the measurement range for patient test results.

competence – demonstrated ability to apply knowledge and skills to achieve intended results.¹⁸

compliance – successful fulfillment of a rule such as a specification, standard, policy, regulation, or law.

conformance//conformity – fulfillment of a requirement.¹⁸

continual improvement – recurring activity to enhance performance.¹⁸

corrective action – action(s) to eliminate the cause and prevent recurrence of a nonconformity or other undesirable situation³; **NOTE:** There can be more than one cause for a nonconformity or undesirable situation.

2 The Quality Management System Model

A QMS can be described as a set of essential building blocks needed for a laboratory’s work operations to fulfill stated quality objectives. A QMS manages the interacting processes and resources needed to provide value and realize results for laboratory customers and users.¹⁸

2.1 How the Quality Management System Model Was Developed

The QMS model described in this guideline was derived from existing published requirements for medical laboratories; **it imposes no new requirements.** The model simply reorganizes individual quality requirements into topics familiar to laboratories. The model also uses a process approach, which incorporates plan-do-check-act and risk-based thinking perspectives.

2.1.1 Deriving the Quality System Essentials

The QMS model in this guideline was derived by sorting individual requirements from international and national regulations and standards, as well as published accreditation requirements for medical laboratories, into topics, i.e. identifying all the requirements for a single subject such as laboratory equipment or personnel. Each topic’s requirements were then arranged into sequential order by how they should occur when a new laboratory or new laboratory service is set up. The resulting topics of requirements were recognized as fundamental building blocks of quality and were given the title of QSEs, as shown in Figure 1.



Figure 1. The QMS Model Foundation and QSEs

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PRINT ISBN 978-1-68440-043-0

ELECTRONIC ISBN 978-1-68440-044-7