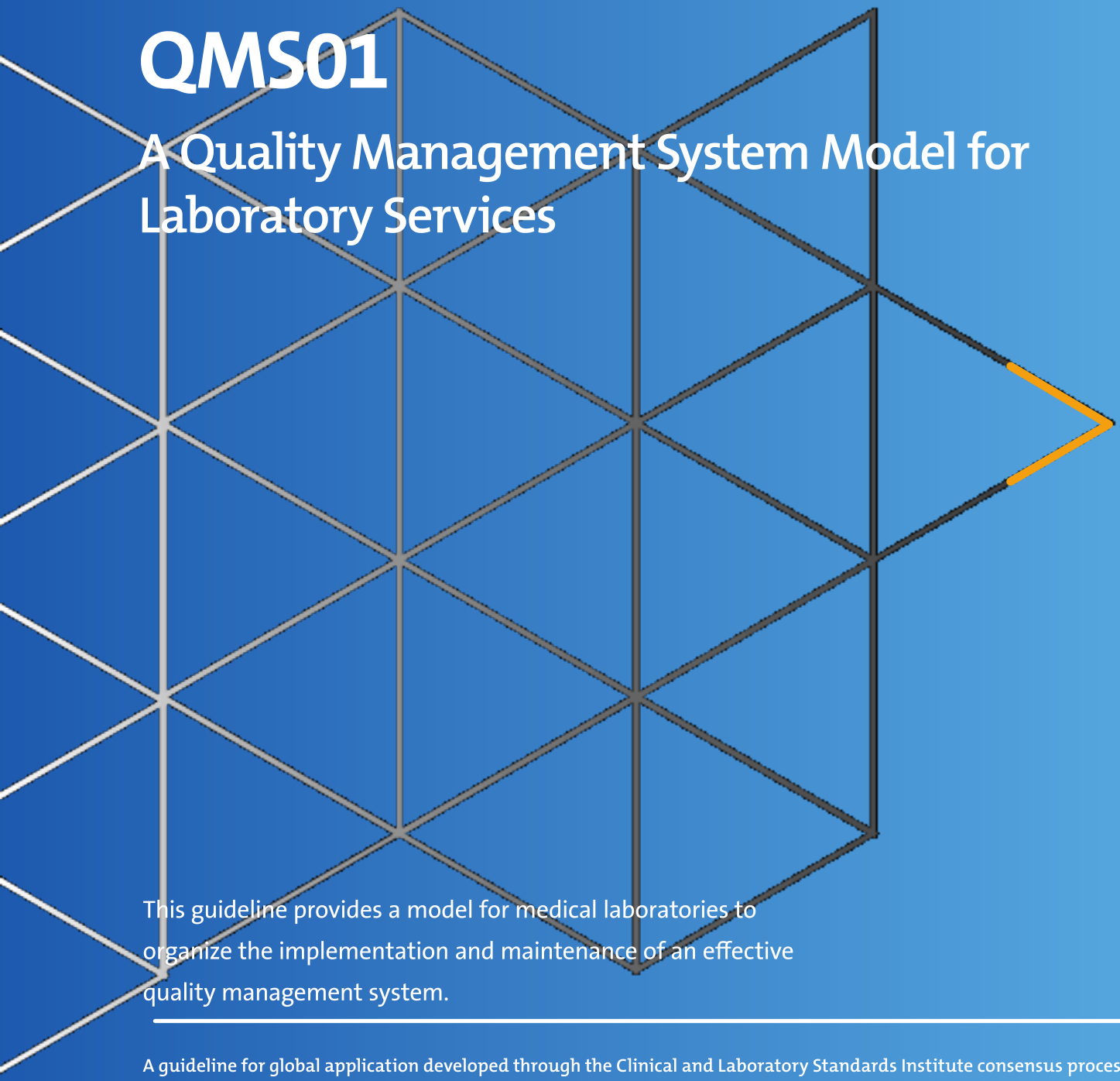
CLINICAL AND LABORATORY STANDARDS INSTITUTE®

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.

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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.

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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 The historical perspective of quality control and quality assurance as defining quality needs to be superseded by a more comprehensive view of internationally accepted quality practices applied to a laboratory's entire scope of work.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.