CLINICAL AND LABORATORY STANDARDS INSTITUTE®

1st Edition

CLSI QMS29™

Management Review

CLSI QMS29 provides information about the management review process, including the intent of management review, who should be involved in the review, and how the review can be conducted.

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 QMS29—*Management Review* describes the purpose and process for management review, including who should be involved, how it can be conducted, inputs, and the decisions and outcomes for action once the management review is completed.

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Foreword

Management review is a component of the Organization and Leadership quality system essential (QSE). Organization and Leadership is one of the 12 QSEs described in CLSI QMS01,[1] which provides the necessary background information and guidance to develop and maintain a QMS. The QMS model depicted in Figure 1 demonstrates how each QSE is a building block to quality and is necessary to support any laboratory's path of workflow from preexamination to examination to postexamination.

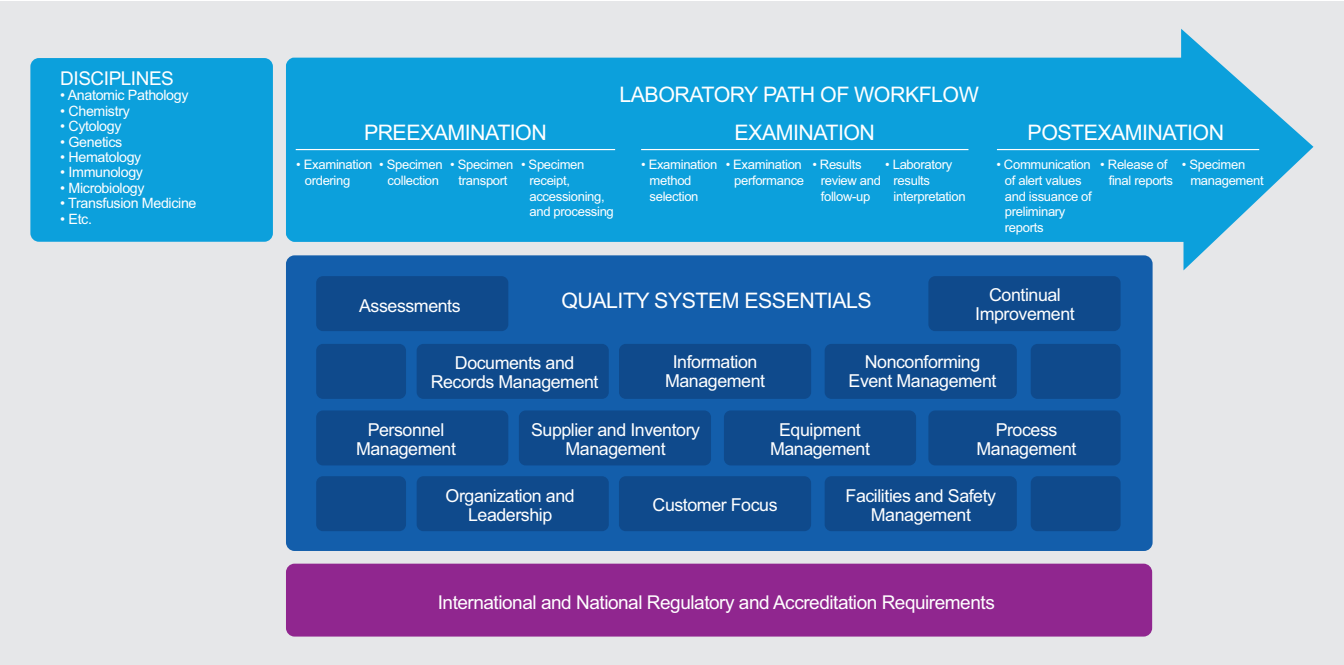

Figure 1. The QMS Model for Laboratory Services (see CLSI QMS01[1]). The 12 QSEs are building blocks necessary to support any laboratory's path of workflow. This figure represents how the 12 QSEs support a medical laboratory's disciplines and stages of examination.

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 occur in preexamination, examination, and postexamination processes.

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]

CLSI QMS29 is a **guideline** that can help laboratories implement a management review process and meet international standards and regulatory and accreditation requirements.[2-12] **CLSI QMS29 is not a standard;** that is, this guideline **does not set requirements** for implementing a management review process. Rather, it provides suggestions and examples for fulfilling the requirements.

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

input
laboratory management
management review
output
schedule

Chapter 1

Introduction

Management Review

1 Introduction

1.1 Scope

CLSI QMS29 helps laboratories develop, implement, and maintain a management review process. This guideline describes the purpose of management review and includes detailed descriptions of the development of a management review process, preparation of review materials, performance of the review, recording of decisions and outcomes, and follow-up actions taken. Ideas for how to present data and information in management review materials as well as templates for recording management reviews are also discussed.

CLSI QMS29 is designed primarily for use in medical laboratories; however, the concepts are generic and can be applied to research, public health, environmental, and veterinary laboratories. Regulatory and accreditation organizations could also benefit from the guidance provided.

CLSI QMS29 does not include QMS information, eg, continual improvement (CI) that might provide data for management review (see CLSI QMS06[13]).

1.2 Background

Management review provides an ongoing assessment of a laboratory's QMS and quality objectives and identifies areas for improvement. In addition, the review should assess whether the QMS supports the organization's and laboratory's strategic direction and vision or if revision is warranted. Laboratories that have implemented a QMS need to routinely assess the processes within the path of workflow and each quality system essential (QSE). Management review is scalable to any-size laboratory. Leadership and personnel should discuss the information presented and record the decisions and action items.

1.3 Terminology

CLSI, as a global leader in standardization, is firmly committed to achieving global harmonization whenever possible. Harmonization is a process of recognizing, understanding, and explaining differences while taking steps to achieve worldwide uniformity. CLSI recognizes that medical conventions in the global metrological community have evolved differently in different countries and regions and that legally required use of terms, regional usage, and different consensus timelines are all important considerations in the harmonization process. CLSI recognizes its important role in these efforts, and its consensus process focuses on harmonization of terms to facilitate the global application of standards and guidelines. Table 1 is provided to clarify the intended interpretations of common terms.