CLINICAL AND LABORATORY STANDARDS INSTITUTE®

1st Edition

CLSI QMS28™

Laboratory Safety Management

CLSI QMS28 includes recommendations for developing, implementing, maintaining, and continually improving a laboratory safety management program. It covers equipment maintenance and inspection, personal safety, warning signs and labels, fire prevention, electrical and radiation safety, waste management, and other potential laboratory hazards.

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

CLSI QMS28-Ed1
August 2025
Replaces CLSI GP05-A3 and CLSI GP17-A3

Laboratory Safety Management

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Abstract

CLSI QMS28—*Laboratory Safety Management* is intended for laboratorians who are responsible for developing, implementing, maintaining, and continually improving a laboratory safety management program. Safety program aspects covered in CLSI QMS28 include equipment maintenance and inspection, personal safety, and warning signs and labels. CLSI QMS28 also discusses fire prevention, electrical and radiation safety, waste management, and other potential laboratory hazards.

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Contents

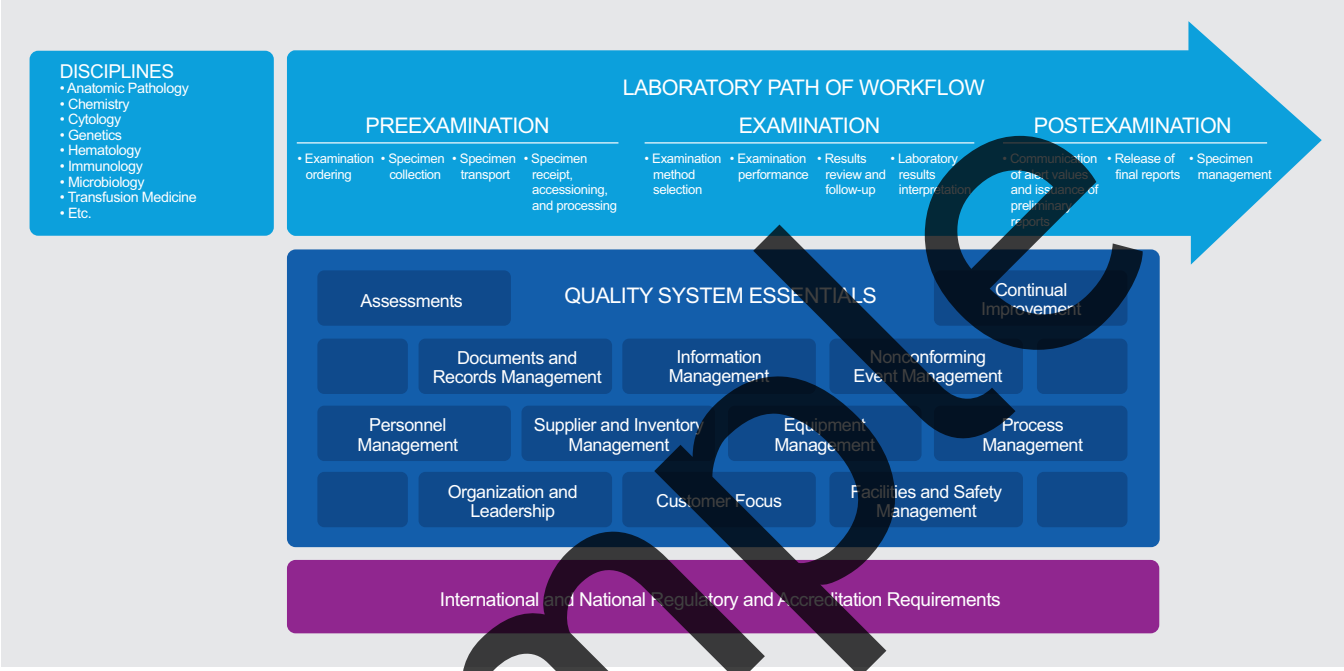
Contents (Continued)

Contents (Continued)

Contents (Continued)

Foreword

Quality system essential (QSE) Facilities and Safety Management is 1 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 shown in Figure 1 demonstrates that each QSE, such as Facilities and Safety Management, is a building block to quality and is necessary to support any laboratory's path of workflow from preexamination to examination to postexamination.



Abbreviations: QMS, quality management system; QSE, quality system essential.

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 will occur in preexamination, examination, and postexamination processes. For example, when the laboratory lacks a defined process to manage its personal protective equipment inventory, it could be unable to:

- Protect personnel who handle laboratory specimens during preexamination, examination, and postexamination phases of laboratory testing.
- Reduce the overall number of occupational injuries and exposures that affect laboratory personnel.

International guidance for 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 QMS28 is a **guideline** that can help laboratories implement a laboratory safety program and meet international standards and regulatory and accreditation requirements.[2-12] CLSI **QMS28 is not a standard;** that is, CLSI QMS28 **does not set requirements** for developing, implementing, maintaining, or continually improving a laboratory safety management program. Rather, it provides suggestions and examples for fulfilling the requirements.

Overview of Changes

CLSI QMS28-Ed1 replaces CLSI GP05-A3 and CLSI GP17-A3, published in 2011 and 2012, respectively. Several changes were made in this edition, including:

- Consolidating laboratory waste management guidelines
- Adding information on laboratory safety training and competence assessment
- Adding information on evaluating the success of the laboratory safety program

NOTE: The content of CLSI QMS28 is supported by the CLSI consensus process and does not necessarily reflect the views of any single individual or organization.

KEY WORDS

biological safety
chemical hygiene
laboratory safety
personal protective equipment
safety equipment

Chapter 1

Introduction

Laboratory Safety Management

1 Introduction

1.1 Scope

CLSI QMS28 is intended for laboratory directors, managers, and supervisors, as well as personnel who perform laboratory testing. Laboratory safety program aspects covered in CLSI QMS28 include equipment maintenance and inspection, personal safety, and warning signs and labels. In addition, CLSI QMS28 discusses radiation safety, fire prevention, electrical safety, and other potential laboratory hazards. Special considerations for anatomic pathology laboratories are also included. CLSI QMS28 emphasizes methods for avoiding waste generation and implementing waste minimization. Options for handling, packaging, labeling, storing, recycling, transporting, decontaminating, and disposing of each type of waste are also covered. CLSI QMS28 is written for laboratorians who develop and implement safety programs in medical laboratories; however, other types of laboratories will also find CLSI QMS28 useful.

CLSI QMS28 does not cover emergency management or provide detailed methods for preventing laboratory-acquired infections because information on these topics is available in the literature.

1.2 Standard Precautions

Because it is often impossible to know what isolates or specimens might be infectious, all patient and laboratory specimens are treated as infectious and handled according to "standard precautions." Standard precautions are guidelines that combine the major features of "universal precautions and body substance isolation" practices. Standard precautions cover the transmission of all known infectious agents and thus are more comprehensive than universal precautions, which are intended to apply only to transmission of bloodborne pathogens. Published guidelines are available that discuss the daily operations of diagnostic medicine in humans and animals while encouraging a culture of safety in the laboratory.[13] For specific precautions for preventing the laboratory transmission of all known infectious agents from laboratory instruments and materials and for recommendations for the management of exposure to all known infectious diseases, refer to CLSI M29.[14]

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.

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