CLINICAL AND LABORATORY STANDARDS INSTITUTE®

3rd Edition

QMS04

Laboratory Design

This guideline provides a foundation of information about laboratory design elements and guidance to help define issues to consider when designing a medical laboratory.

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

Clinical and Laboratory Standards Institute

Setting the standard for quality in medical laboratory testing around the world.

The Clinical and Laboratory Standards Institute (CLSI) is a not-for-profit membership organization that brings together the varied perspectives and expertise of the worldwide laboratory community for the advancement of a common cause: to foster excellence in laboratory medicine by developing and implementing medical laboratory standards and guidelines that help laboratories fulfill their responsibilities with efficiency, effectiveness, and global applicability.

Consensus Process

Consensus—the substantial agreement by materially affected, competent, and interested parties—is core to the development of all CLSI documents. It does not always connote unanimous agreement, but does mean that the participants in the development of a consensus document have considered and resolved all relevant objections and accept the resulting agreement.

Commenting on Documents

CLSI documents undergo periodic evaluation and modification to keep pace with advancements in technologies, procedures, methods, and protocols affecting the laboratory or health care.

CLSI's consensus process depends on experts who volunteer to serve as contributing authors and/or as participants in the reviewing and commenting process. At the end of each comment period, the committee that developed the document is obligated to review all comments, respond in writing to all substantive comments, and revise the draft document as appropriate.

Comments on published CLSI documents are equally essential, and may be submitted by anyone, at any time, on any document. All comments are managed according to the consensus process by a committee of experts.

Appeals Process

When it is believed that an objection has not been adequately considered and responded to, the process for appeals, documented in the CLSI Standards Development Policies and Processes, is followed.

All comments and responses submitted on draft and published documents are retained on file at CLSI and are available upon request.

Get Involved—Volunteer!

Do you use CLSI documents in your workplace? Do you see room for improvement? Would you like to get involved in the revision process? Or maybe you see a need to develop a new document for an emerging technology? CLSI wants to hear from you. We are always looking for volunteers. By donating your time and talents to improve the standards that affect your own work, you will play an active role in improving public health across the globe.

For additional information on committee participation or to submit comments, contact CLSI.

Clinical and Laboratory Standards Institute
950 West Valley Road, Suite 2500
Wayne, PA 19087 USA
P: +1.610.688.0100
F: +1.610.688.0700
www.clsi.org
standard@clsi.org

QMS04, 3rd ed.
June 2016
Replaces QMS04-A2

Laboratory Design

Karen K. Mortland, RA, MT(ASCP)
Peter Gupta
Steven J. LaCroix, MS, CBSP
Jason Majorowicz
Patrick J. Maul, MBA, MT(ASCP)
Vassilios I. Nicolaou, AIA, NCARB
Daniel J. Scungio, MT(ASCP), SLS
Samya Semaan-Heart, MT, MPH, FACHE
Anand K. Seth, PE, CEM, CPE
Adam Walter, CSSMBB / CLA
Kurukula AC Wickramaratne, MBBS, DPath, MD
Terry Williams, M.Arch, MS

Abstract

Clinical and Laboratory Standards Institute guideline QMS04—*Laboratory Design* is written for laboratory personnel responsible for, or involved in, the design of a laboratory. This guideline covers selected nonstructural elements that affect the planning, layout, and safety of a medical laboratory. The elements discussed include space, casework, equipment, classifications, health and safety, ventilation, lighting, plumbing, electrical systems, and communications.

Clinical and Laboratory Standards Institute (CLSI). *Laboratory Design.* 3rd ed. CLSI guideline QMS04 (ISBN 1-56238-936-X [Print]; ISBN 1-56238-937-8 [Electronic]). Clinical and Laboratory Standards Institute, 950 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2016.

Suggested Citation

CLSI. *Laboratory Design.* 3rd ed. CLSI guideline QMS04. Wayne, PA: Clinical and Laboratory Standards Institute; 2016.

Previous Editions:

December 1994, April 1998, February 2007

ISBN 1-56238-936-X (Print)

ISBN 1-56238-937-8 (Electronic)

ISSN 1558-6502 (Print)

ISSN 2162-2914 (Electronic)

Volume 36, Number 8

Committee Membership

Consensus Council

Carl D. Mottram, RRT, RPFT, FAARC
Chairholder
Mayo Clinic
USA

J. Rex Astles, PhD, FACB, DABCC
Centers for Disease Control and Prevention
USA

Lucia M. Berte, MA, MT(ASCP)SBB, DLM; CQA(ASQ)CMQ/OE
Laboratories Made Better!
USA

Karen W. Dyer, MT(ASCP), DLM
Centers for Medicare & Medicaid Services
USA

Dennis J. Ernst, MT(ASCP), NCPT(NCCT)
Center for Phlebotomy Education
USA

Thomas R. Fritsche, MD, PhD, FCAP, FIDSA
Marshfield Clinic
USA

Mary Lou Gantzer, PhD, FACB
BioCore Diagnostics
USA

Loralie J. Langman, PhD
Mayo Clinic
USA

Joseph Passarelli
Roche Diagnostics Corporation
USA

James F. Pierson-Perry
Siemens Healthcare Diagnostics Inc.
USA

Andrew Quintenz
Bio-Rad Laboratories, Inc.
USA

Robert Rej, PhD
New York State Department of Health – Wadsworth Center
USA

Zivana Tezak, PhD
FDA Center for Devices and Radiological Health
USA

Document Development Committee on Laboratory Design

Karen K. Mortland, RA, MT(ASCP)
Chairholder
Mortland Planning & Design, Inc.
USA

Vassilios I. Nicolaou, AIA, NCARB
Nicolaou Design and Technology, LLC
USA

Daniel J. Scungio, MT(ASCP), SLS
Sentara Healthcare
USA

Samya Semaan-Heart, MT, MPH, FACHE
North Florida/South Georgia VA Health System
USA

Anand K. Seth, PE, CEM, CPE
Cannon Design
USA

Adam Walter, CSSMBB / CLA
BD
USA

Kurukula AC Wickramaratne, MBBS, DPath, MD
University of Ruhuna
Sri Lanka

Terry Williams, M.Arch, MS
State of Washington Public Health Labs
USA

Staff

Clinical and Laboratory Standards Institute
USA

Jennifer K. Adams, MT(ASCP), MSHA
Project Manager

Megan L. Tertel, MA, ELS
Editorial Manager

Joanne P. Christopher, MA, ELS
Editor

Alexander B. Phucas
Editor

Michael A. Russell, MA
Editor

Acknowledgment

CLSI, the Consensus Council, and the Document Development Committee on Laboratory Design gratefully acknowledge the following volunteers for their important contributions to the development of this guideline:

Peter Gupta
Canada

Steven J. LaCroix, MS, CBSP
State of Washington Public Health Labs
USA

Jason Majorowicz
Mayo Clinic
USA

Patrick J. Maul, MBA, MT(ASCP)
BD Diagnostics - Healthcare Consulting
USA

Contents

Contents (Continued)

Contents (Continued)

Foreword

Quality system essential (QSE) Facilities and Safety is one of the 12 QSEs described in CLSI document QMS01[1] and the CLSI product The Key to Quality™,[2] 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, such as Facilities and Safety, is a building block to quality and is necessary to support any laboratory's path of workflow from preexamination to examination to postexamination.

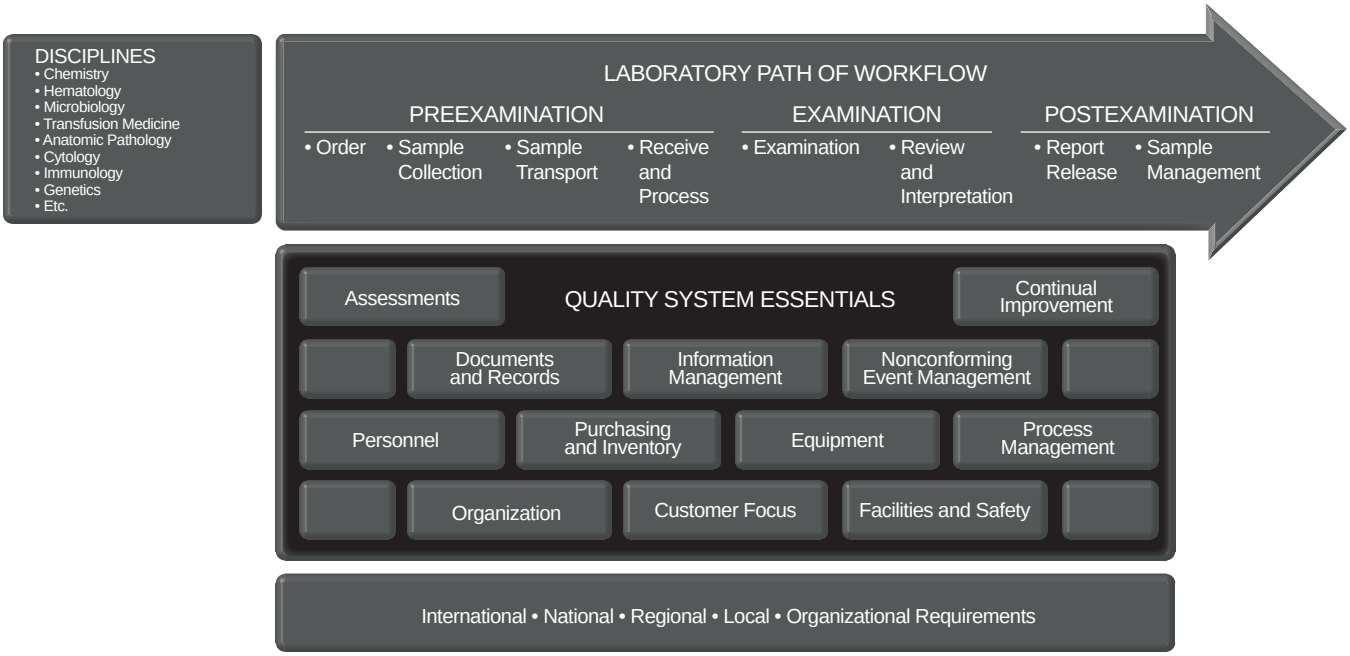

Figure 1. The Quality Management System Model for Laboratory Services (see CLSI document QMS01[1]). The 12 QSEs function as building blocks necessary to support any laboratory's path of workflow and laboratory disciplines. This figure represents how the 12 QSEs support a medical laboratory's disciplines.

QSEs are the foundational building blocks that function effectively to support the laboratory's path of workflow. If a QSE is missing or not well implemented, problems will occur in preexamination, examination, and postexamination laboratory activities. For example, when the laboratory lacks defined processes for establishing and maintaining adequate space, workflow, and environmental conditions, the quality of work may be affected and safety of patients and staff compromised.

International guidance related to 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[3]
- Requirements for both quality management and technical operations of testing and calibration laboratories[4]
- Standards for quality management and technical operations in the medical laboratory environment[5]

Optimal laboratory design requires a careful blend of many design elements, which can be effectively accomplished only if opportunities, possibilities, and potential problems are well understood. A good understanding of the design issues that affect space, workflow, casework, equipment, classifications, ventilation, lighting, plumbing, electrical systems, and communications encourages asking pertinent questions and facilitates wise choices during reviews of existing laboratories and planning of new or remodeled laboratories.

This guideline provides a foundation of information about laboratory design elements and guidance to help define consideration of issues when designing a laboratory.

The content and organization of this guideline are intended to encourage its frequent use throughout the laboratory design process. One aspect of this guideline that distinguishes it from other publications on laboratory design is the inclusion, where possible, of specific minimum and recommended guidelines. The minimum limits are limits at which laboratory safety or functionality begins to be compromised. Recommended guidelines are limits at which more acceptable levels of safety and functionality are attained. It is important for laboratory consultants, architects, and engineers to consult specific codes and local authorities during the design process to ensure that all criteria are met for that particular region or country. This guideline is not intended to be an end to the process, but, instead, a start in the right direction.

Although this guideline draws heavily from the recommended and mandated guidelines and regulations applicable to the United States, the material contained in this guideline may be useful for improving laboratory design throughout the world. Although QMS04 may be a useful resource for a wider audience, it is intended primarily to help the US user navigate through US requirements. Because laboratory design practices are heavily regulated and widely country specific, it has been determined that development of a comparable guideline intended for global application may not be feasible. However, the development of such a guideline may be possible in the future as part of a long-term effort to harmonize regulations and practices.

The unique tagline on the cover and the imprint of the US flag on the Abstract page and throughout the guideline footers call attention to QMS04's national focus and differentiate it from CLSI's global consensus documents.

NOTE:

Laboratory design includes:

- Space
- Workflow
- Casework
- Equipment
- Classifications
- Ventilation
- Lighting
- Plumbing
- Electrical systems
- Communications

NOTE:

During the design process, laboratory consultants, architects, and engineers should consult specific codes and local authorities to ensure that all criteria are met for their respective region or country.

NOTE:

Although QMS04 is intended primarily for US laboratories, the information may be a useful resource throughout the world.

Overview of Changes

Updates from the second edition include:

- Changes in codes, testing, equipment, and building systems
- Reorganization of information to align with the laboratory design process

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

Architecture
Design
Engineering
Equipment
Lean
Safety
Space
Utilities
Workflow

Chapter 1

Introduction

This chapter includes:

- Guideline's scope and applicable exclusions
- 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

Laboratory Design

1 Introduction

1.1 Scope

This guideline discusses selected elements of laboratory design that affect the planning, layout, and safety of the medical laboratory. These elements include space, workflow, casework, equipment, classifications, ventilation, lighting, plumbing, electrical systems, and communications. This guideline is intended to provide general guidance in laboratory design for those working in and managing laboratories.

Many important and specific issues that need consideration in a well-designed laboratory are beyond the scope of this guideline and are best worked through with the project's consultants, architects, and engineers. These issues could include structural issues, modifications to the overall base building, and changes to house utility systems.

1.2 Background

Laboratory design includes many activities that, when thoughtfully and carefully applied, culminate in a well-conceived and highly functional laboratory. Medical laboratories often struggle to adapt and adjust to an abundance of changes resulting from technological advances, increased computerization, and a decreased workforce. Laboratorians are confronted with new procedures and equipment that should be incorporated into their facilities to remain relevant and competitive. Many owners have found it necessary to either replace or remodel existing facilities to maintain the functional viability of their laboratories.

IMPORTANT NOTE:

Strict adherence to code requirements for chemicals and biohazards affects many aspects of laboratory design, from occupancy permits to accreditation.

At this point, laboratory managers encounter another legacy of change—the proliferation of building codes that need to be managed in the laboratory design process. One consequence of technologies that include chemicals and biohazards is the accompanying code requirements. Strict adherence to these codes affects many facets of the laboratory, from occupancy permits to accreditation.

It is not reasonable to expect laboratory managers to be intimately familiar with evolving regulations, or to master architecture and engineering. These areas are the provinces of consultants, architects, and engineers who specialize in laboratory design, as well as code enforcement officers. However, managers should have a general understanding of space requirements, codes, and regulations that affect their laboratories. Awareness of the various regulatory agencies' requirements, and the areas they designate as hazardous, allows laboratory managers to be alert to potential dangers and noncompliance in existing and new facilities.