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QMS04-A2

Laboratory Design; Approved Guideline—Second Edition



This document provides a foundation of information about laboratory design elements and guidance to help define the issues to be considered when designing a clinical laboratory.

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

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Clinical and Laboratory Standards Institute
950 West Valley Road, Suite 2500
Wayne, PA 19087 USA
P: 610.688.0100
F: 610.688.0700
www.clsi.org
standard@clsi.org

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Karen K. Mortland, AIA, MT(ASCP)
Anne C. Belanger, MA, MT(ASCP)
Rodney S. Markin, MD, PhD
Patrick J. Maul, MBA, MT(ASCP)
Jonathan Y. Richmond, PhD

Abstract

CLSI document QMS04-A2—*Laboratory Design; Approved Guideline—Second Edition* is written for laboratory personnel responsible for, or involved in, the design of a laboratory. This guideline addresses selected nonstructural elements that affect the planning, layout, and safety of a clinical laboratory. The elements addressed include space, casework, equipment, classifications, health and safety, ventilation, lighting, plumbing, electrical, and communications.

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Committee Membership

Area Committee on General Laboratory Practices

**Sheila M. Woodcock, MBA,
FCSMLS(D)
Chairholder
QSE Consulting
Rose Bay, Nova Scotia, Canada**

**Albert Rabinovitch, MD, PhD
Vice-Chairholder
Abbott Hematology
Santa Clara, California**

Eric Arendash, MT(ASCP)
Centers for Medicare & Medicaid
Services
Philadelphia, Pennsylvania

Lucia M. Berte, MA, MT(ASCP)SBB,
DLM; CQA(ASQ) CQM
Quality Systems Consultant
Broomfield, Colorado

Theresa Billups, MBA,
MT(ASCP)DLM
Remel, Inc.
Lake Charles, Louisiana

Margaret M. Grimes, MD
Medical College of Virginia Campus
Richmond, Virginia

Bruce D. Tually, BAppSc, MAppSc
Hunter Area Pathology Service
New South Wales, Australia

Advisors

Eileen Carreiro-Lewandowski,
CLS(NCA)
University of Massachusetts
N. Dartmouth, Massachusetts

Kay M. Creed
Bon Secours Health Partners
Laboratories
Richmond, Virginia

Dennis J. Ernst, MT(ASCP)
Center for Phlebotomy Education
Ramsey, Indiana

Steven I. Gutman, MD, MBA
FDA Ctr. for Devices/Rad. Health
Rockville, Maryland

Stephen J. Sarewitz, MD
Valley Medical Center
Renton, Washington

Jennifer Schiffgens, MBA, MT(ASCP)
California Pacific Medical Center
San Francisco, California

Daniel W. Tholen, MS
American Association for Laboratory
Accreditation
Traverse City, Michigan

Marla Thomas, HT(ASCP)
Litton Pathology Associates
Blue Springs, Missouri

Eleanor M. Travers, MD, MHA
State of Connecticut Department of
Public Health
Hartford, Connecticut

Working Group on Laboratory Design

**Karen K. Mortland, AIA, MT(ASCP)
Chairholder
Mortland Planning & Design, Inc.
Chicora, Pennsylvania**

Anne Belanger, MA, MT(ASCP)
Healthcare Standards Consultants
Lake Toxaway, North Carolina

Brad W. Jensen, MD
Southwest Washington Medical Center
Vancouver, Washington

Rodney S. Markin, MD, PhD
University of Nebraska Medical Center
Omaha, Nebraska

Patrick Maul, MBA, MT(ASCP)
BD Healthcare Consultant
Holland, Pennsylvania

Jonathan Richmond
Jonathan Richmond & Associates
Southport, North Carolina

Staff

Clinical and Laboratory Standards
Institute
Wayne, Pennsylvania

John J. Zlockie, MBA
Vice President, Standards

Jennifer K. McGeary, MT(ASCP),
MSHA
Staff Liaison

Donna M. Wilhelm
Editor

Melissa A. Lewis
Assistant Editor

Acknowledgement

CLSI acknowledges the following individuals for their special contributions to this revision of the QMS04 guideline:

Lucia M. Berte, MA, MT(ASCP)SBB, DLM; CQA(ASQ) CQM
Broomfield, Colorado

Albert Rabinovitch, MD, PhD
Santa Clara, California

Sheila M. Woodcock, MBA, FCSMLS(D)
Rose Bay, Nova Scotia, Canada

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Foreword

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, cabinetry, equipment, classifications, ventilation, lighting, plumbing, electrical, and data encourages asking the pertinent questions and facilitates wise choices during reviews of existing laboratories and planning of new or remodeled laboratories. Many existing laboratories were designed when the requirements for each of these areas were different. It is more important than ever that laboratories are designed to enable personnel to more easily and effectively respond to technological and procedural changes.

The advent of automation and instrument consolidation changes has permitted performance of more procedures in a smaller space. However, with the addition of new, specialized procedures and enhanced code requirements, overall scope of laboratory operations has generally expanded.

CLSI document QMS04-A2—*Laboratory Design; Approved Guideline—Second Edition* 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 QMS04-A2 is intended to encourage its frequent use throughout the laboratory design process. One aspect of this document 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. Many of the references cited in this document refer to US requirements; however, it is important for the 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 document is not intended to be an end to the process, but more a start in the right direction.

Key Words

Architecture, design, engineering, equipment, safety, space, utilities, workflow

Laboratory Design; Approved Guideline—Second Edition

1 Scope

Laboratory design includes many activities that, when thoughtfully and carefully applied, culminate in a well-conceived and highly functional laboratory. This document addresses selected, nonstructural elements of laboratory design that affect the planning, layout, and safety of the clinical laboratory. These elements include space, workflow, casework, equipment, classifications, ventilation, lighting, plumbing, electrical, and communications. This document is intended to give 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.

2 Introduction

Clinical laboratories are struggling to adapt and adjust to a myriad of changes that have come about through technological advances, increased computerization, and a decreased workforce. Laboratorians are confronted with new procedures and equipment that must be incorporated into their facilities to stay on the clinical and the competitive cutting edge. Many laboratory managers have found it necessary to either replace or remodel existing facilities to maintain the functional viability of their laboratories.

At this juncture laboratory managers encounter another legacy of change: the proliferation of building codes that must be addressed in the laboratory design process. A consequence of technologies that include chemicals and biohazards is the multitude of code requirements generated in response. More than an occupancy permit is dependent upon strict adherence to these codes; accreditation is also conditional on the incorporation of code requirements.

It is not reasonable to expect laboratory managers to be intimately familiar with thousands of pages of changing and seemingly contradictory regulations, or to master architecture and engineering in their spare time. That is the province of consultants, architects, and engineers who specialize in laboratory design, as well as code enforcement officers. It is preferable that managers have a general feel for space requirements, codes, and regulations that impact their laboratories. An awareness of the various regulatory agencies and the areas that they designate as hazardous will provide an alert to potential dangers and noncompliance in existing and new facilities.

3 Definitions

accreditation body – authoritative body that provides third-party attestation that a laboratory fulfills specified requirements and is competent to perform specific tasks¹; **NOTE:** The authority of an accreditation body is typically derived from government.

acids – chemicals with pH lower than 7; **NOTE:** Acids can cause serious burns on human skin and many other materials.

acoustics – the study of sound; **NOTE:** This is used in determination of the sound absorbance and transmission properties of various materials used in a construction project.

addendum//addenda – request for information adding to or clarifying the construction bidding documents; **NOTE:** These are generally issued during the bidding phase as part of the construction contract documents.