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.

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Laboratory Design

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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.

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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.

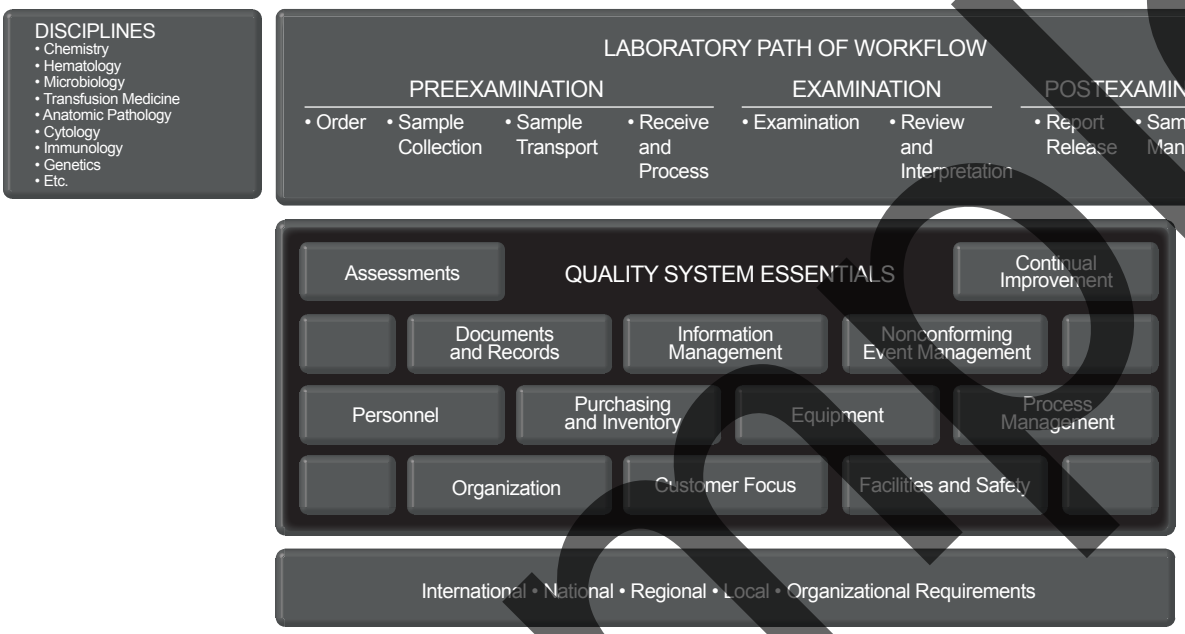

Figure 1. The Quality Management System Model for Laboratory Services (see CLSI document QMS01[1]). The 12 QSEs function as building blocks necessary to support any laboratory's path of workflow and laboratory disciplines. This figure represents how the 12 QSEs support a medical laboratory's disciplines.

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.

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.

IMPORTANT NOTE:

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

The Quality Management System Approach

Clinical and Laboratory Standards Institute (CLSI) subscribes to a quality management system (QMS) approach in the development of standards and guidelines, which facilitates project management; defines a document structure using a template; and provides a process to identify needed documents. The QMS approach applies a core set of "quality system essentials" (QSEs), basic to any organization, to all operations in any health care service's path of workflow (ie, operational aspects that define how a particular product or service is provided). The QSEs provide the framework for delivery of any type of product or service, serving as a manager's guide. The QSEs are as follows:

Organization	Personnel	Process Management	Nonconforming Event Management
Customer Focus	Purchasing and Inventory	Documents and Records	Assessments
Facilities and Safety	Equipment	Information Management	Continual Improvement

QMS04 covers the QSE indicated by an "X." For a description of the other documents listed in the grid, please refer to the Related CLSI Reference Materials section on page 168.

Organization	Customer Focus	Facilities and Safety	Personnel	Purchasing and Inventory	Equipment	Process Management	Documents and Records	Information Management	Nonconforming Event Management	Assessments	Continual Improvement
		X									
						GP40					
K2Q	K2Q	K2Q	K2Q	K2Q	K2Q	K2Q	K2Q	K2Q	K2Q	K2Q	K2Q
QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01

Related CLSI Reference Materials*

GP40 **Preparation and Testing of Reagent Water in the Clinical Laboratory. 4th ed., 2012.** This document provides guidelines on water purified for clinical laboratory use; methods for monitoring water quality and testing for specific contaminants; and water system design considerations.

K2Q **The Key to Quality™. 2nd ed., 2013.** This product provides fundamental information for implementing and sustaining a quality management system (QMS). It also includes information on the 12 quality system essentials (QSEs) for building a QMS; the policies, processes, and procedure requirements for each QSE; and, how to apply the 12 QSEs in the laboratory environment.

QMS01 **Quality Management System: A Model for Laboratory Services. 4th ed., 2011.** This document provides a model for medical laboratories that will assist with implementation and maintenance of an effective quality management system.

* CLSI documents are continually reviewed and revised through the CLSI consensus process; therefore, readers should refer to the most current editions.

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