

GP18-A2
Vol. 27 No. 7
Replaces GP18-A
Vol. 18 No. 3

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.



Clinical and Laboratory Standards Institute

Advancing Quality in Healthcare Testing

The Clinical and Laboratory Standards Institute (CLSI, formerly NCCLS) is an international, interdisciplinary, nonprofit, standards-developing, and educational organization that promotes the development and use of voluntary consensus standards and guidelines within the healthcare community. It is recognized worldwide for the application of its unique consensus process in the development of standards and guidelines for patient testing and related healthcare issues. Our process is based on the principle that consensus is an effective and cost-effective way to improve patient testing and healthcare services.

In addition to developing and promoting the use of voluntary consensus standards and guidelines, we provide an open and unbiased forum to address critical issues affecting the quality of patient testing and health care.

PUBLICATIONS

A document is published as a standard, guideline, or committee report.

Standard A document developed through the consensus process that clearly identifies specific, essential requirements for materials, methods, or practices for use in an unmodified form. A standard may, in addition, contain discretionary elements, which are clearly identified.

Guideline A document developed through the consensus process describing criteria for a general operating practice, procedure, or material for voluntary use. A guideline may be used as written or modified by the user to fit specific needs.

Report A document that has not been subjected to consensus review and is released by the Board of Directors.

CONSENSUS PROCESS

The CLSI voluntary consensus process is a protocol establishing formal criteria for:

- the authorization of a project
- the development and open review of documents
- the revision of documents in response to comments by users
- the acceptance of a document as a consensus standard or guideline.

Most documents are subject to two levels of consensus—"proposed" and "approved." Depending on the need for field evaluation or data collection, documents may also be made available for review at an intermediate consensus level.

Proposed A consensus document undergoes the first stage of review by the healthcare community as a proposed standard or guideline. The document should receive a wide and thorough technical review, including an overall review of its scope, approach, and utility, and a line-by-line review of its technical and editorial content.

Approved An approved standard or guideline has achieved consensus within the healthcare community. It should be reviewed to assess the utility of the final document, to ensure attainment of consensus (i.e., that comments on earlier versions have been satisfactorily addressed), and to identify the need for additional consensus documents.

Our standards and guidelines represent a consensus opinion on good practices and reflect the substantial agreement by materially affected, competent, and interested parties obtained by following CLSI's established consensus procedures. Provisions in CLSI standards and guidelines may be more or less stringent than applicable regulations. Consequently, conformance to this voluntary consensus document does not relieve the user of responsibility for compliance with applicable regulations.

COMMENTS

The comments of users are essential to the consensus process. Anyone may submit a comment, and all comments are addressed, according to the consensus process, by the committee that wrote the document. All comments, including those that result in a change to the document when published at the next consensus level and those that do not result in a change, are responded to by the committee in an appendix to the document. Readers are strongly encouraged to comment in any form and at any time on any document. Address comments to Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, PA 19087, USA.

VOLUNTEER PARTICIPATION

Healthcare professionals in all specialties are urged to volunteer for participation in CLSI projects. Please contact us at customerservice@clsi.org or +610.688.0100 for additional information on committee participation.

GP18-A2
ISBN 1-56238-631-X
ISSN 0273-3099

Volume 27 Number 7

Laboratory Design; Approved Guideline—Second Edition

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 GP18-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.

Clinical and Laboratory Standards Institute (CLSI). *Laboratory Design; Approved Guideline—Second Edition*. CLSI document GP18-A2 (ISBN 1-56238-631-X). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2007.

The Clinical and Laboratory Standards Institute consensus process, which is the mechanism for moving a document through two or more levels of review by the healthcare community, is an ongoing process. Users should expect revised editions of any given document. Because rapid changes in technology may affect the procedures, methods, and protocols in a standard or guideline, users should replace outdated editions with the current editions of CLSI/NCCLS documents. Current editions are listed in the CLSI catalog, which is distributed to member organizations, and to nonmembers on request. If your organization is not a member and would like to become one, and to request a copy of the catalog, contact us at: Telephone: 610.688.0100; Fax: 610.688.0700; E-Mail: customerservice@clsi.org; Website: www.clsi.org

Copyright ©2007 Clinical and Laboratory Standards Institute. Except as stated below, neither this publication nor any portion thereof may be adapted, copied or otherwise reproduced, by any means (electronic, mechanical, photocopying, recording, or otherwise) without prior written permission from Clinical and Laboratory Standards Institute ("CLSI").

CLSI hereby grants permission to each individual member or purchaser to make a single reproduction of this publication for use in its laboratory procedure manual at a single site. To request permission to use this publication in any other manner, contact the Executive Vice President, Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA.

Suggested Citation

(Clinical and Laboratory Standards Institute. *Laboratory Design; Approved Guideline—Second Edition*. CLSI document GP18-A2 [ISBN 1-56238-631-X]. Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2007.)

Proposed Guideline

December 1994

Approved Guideline

April 1998

Approved Guideline—Second Edition

February 2007

ISBN 1-56238-631-X

ISSN 0273-3099

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 GP18 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

Contents

Abstracti

Committee Membership..... iii

Forewordix

1 Scope.....1

2 Introduction.....1

3 Definitions1

 3.1 Acronyms.....8

 3.2 Abbreviations.....9

 3.3 Conversion Factors9

4 Design Process10

 4.1 The Project Team.....11

 4.2 Planning and Programming.....13

 4.3 Schematic Design20

 4.4 Design Development.....23

 4.5 Construction Documents.....25

 4.6 Bidding and Negotiation26

 4.7 Construction.....27

 4.8 Moving In30

 4.9 Phasing.....30

 4.10 Lean Design Concepts30

5 Laboratory Equipment33

 5.1 Equipment Documentation33

 5.2 Automated Sample Handling Technology/Systems37

 5.3 Planning for Future Equipment.....39

 5.4 Summary Points.....40

6 Biohazards40

 6.1 Determining Biosafety Levels41

 6.2 Designing for Biosafety Levels41

 6.3 Bioterrorism44

 6.4 Security45

 6.5 Summary Points.....45

7 Health and Safety45

 7.1 Laboratory Classification.....45

 7.2 Flammable Storage47

 7.3 Wall Construction49

 7.4 Fire Egress49

 7.5 Fire Alarms51

 7.6 Fire Extinguishers51

 7.7 Hazardous Equipment.....52

 7.8 Handwashing52

 7.9 Emergency Eyewash Stations and Flood Showers52

 7.10 Acoustics.....53

Contents (Continued)

7.11	Ergonomics	54
7.12	Summary Points	54
8	Space Determination	55
8.1	Working Laboratory Space	55
8.2	Specialized Laboratory Areas	57
8.3	Laboratory Support Spaces	61
8.4	Laboratory Employee Spaces	65
8.5	Patient Support Spaces	67
8.6	Utility Space	68
8.7	Net vs. Gross Square Feet	68
8.8	Relationships	69
8.9	Laboratory Casework	69
8.10	Summary Points	71
9	Finishes	71
9.1	Casework	72
9.2	Flooring	73
9.3	Walls	73
9.4	Ceilings	73
10	Ventilation in Laboratory Design	73
10.1	Temperature and Humidity	73
10.2	Criteria for Supply and Exhaust	74
10.3	Air Changes	75
10.4	Pressurization	76
10.5	Hood Types	77
10.6	Redundancy in HVAC Systems	82
10.7	Control	82
10.8	Code and Safety Issues	82
10.9	Summary Points	84
11	Electrical and Communications	85
11.1	Electrical	85
11.2	Communication	86
11.3	Summary Points	86
12	Lighting	86
12.1	Lighting Levels	86
12.2	Location of Lights	87
12.3	Light Fixtures	87
12.4	Expandability	88
12.5	Codes, Regulations, and Safety	89
12.6	Summary Points	89
13	Plumbing	89
13.1	Tap Water	89
13.2	Deionized (DI) Water	89
13.3	Sinks	89
13.4	Emergency Eye Wash	90
13.5	Emergency Flood Shower	90

Contents (Continued)

13.6	Gases.....	90
13.7	Waste Water.....	91
13.8	Sprinkler Systems	91
13.9	Flexibility.....	91
13.10	Summary Points.....	91
14	Conclusion	92
	Appendix. Code/Design Resources.....	93
	References.....	96
	Additional Resources	98
	Summary of Comments and Subcommittee Responses.....	99
	Summary of Delegate Comments and Working Group Responses	100
	The Quality System Approach.....	104
	Related CLSI/NCCLS Publications	105

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 GP18-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 GP18-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.