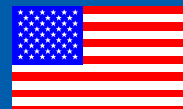


GP17-A3
Vol. 32 No. 9
Replaces GP17-A2
Vol. 24 No. 13

Clinical Laboratory Safety; Approved Guideline—Third Edition

This document contains general recommendations for implementing a high-quality laboratory safety program, which are provided in a framework that is adaptable within any laboratory.

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



Clinical and Laboratory Standards Institute

Advancing Quality in Health Care Testing

Clinical and Laboratory Standards Institute (CLSI) is an international, interdisciplinary, nonprofit, standards developing, and educational organization that promotes the development and use of voluntary consensus standards and guidelines within the health care community. We are recognized worldwide for the application of our unique consensus process in the development of standards and guidelines for patient testing and related health care issues. Our process is based on the principle that consensus is an effective way to improve patient testing and health care 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 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 appropriate consensus committee.

CONSENSUS PROCESS

CLSI's voluntary consensus process establishes formal criteria for the following:

- Authorization of a project
- Development and open review of documents
- Revision of documents in response to users' comments
- Acceptance of a document as a consensus standard or guideline

Invitation for Participation in the Consensus Process

Core to the development of all CLSI documents is the consensus process. Within the context and operation of CLSI, voluntary consensus is substantial agreement by materially affected, competent, and interested parties that may be obtained by following the consensus procedures defined in

CLSI's Administrative Procedures. 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 are willing to accept the resulting agreement. CLSI documents are expected to undergo evaluation and modification in order to keep pace with advancements in technologies, procedures, methods, and protocols affecting the laboratory or health care.

Comments on Draft Documents

CLSI's voluntary consensus process depends on experts who 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. All comments along with the committee's responses are retained on file at CLSI and are available upon request.

Comments on Published Documents

The comments of users of published CLSI documents are essential to the consensus process. Anyone may submit a comment. All comments are addressed according to the consensus process by a committee of experts. A summary of comments and committee responses is retained on file at CLSI and is available upon request. Readers are strongly encouraged to comment at any time on any document.

APPEALS PROCESS

CLSI consensus procedures include an appeals process that is described in detail in the CLSI Administrative Procedures.

VOLUNTEER PARTICIPATION

Health care professionals in all specialties are urged to volunteer for participation in CLSI projects.

For further 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
610.688.0100
F: 610.688.0700
www.clsi.org
standard@clsii.org

GP17-A3

ISBN 1-56238-797-9 (Print)

ISBN 1-56238-798-7 (Electronic)

ISSN 1558-6502 (Print)

Volume 32 Number 9

ISSN 2162-2914 (Electronic)

Clinical Laboratory Safety; Approved Guideline—Third Edition

Terry Jo Gile, MT(ASCP), MA.Ed.

Miki Van Houten, MT(ASCP)

Michelle L. Altrich, PhD

Charles R. Cook

Jerry L. Harris, MD

Timothy A. Johnson, MBS, CT/SLS (ASCP)^{CM}, CQA(ASQ)

Daniel J. Scungio, MT(ASCP), SLS

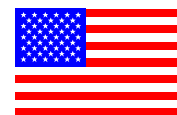
Elizabeth G. Weirich, MS, CBSP

Abstract

Clinical and Laboratory Standards Institute document GP17-A3—*Clinical Laboratory Safety; Approved Guideline—Third Edition* is written for laboratorians who are responsible for developing and implementing a safety program. Aspects of a safety program addressed in this guideline include maintenance and inspection, personal safety, and warning signs and labels. The guideline also addresses fire prevention, electrical and radiation safety, and other potential laboratory hazards.

Clinical and Laboratory Standards Institute (CLSI). *Clinical Laboratory Safety; Approved Guideline—Third Edition*. CLSI document GP17-A3 (ISBN 1-56238-797-9 [Print]; ISBN 1-56238-798-7 [Electronic]). Clinical and Laboratory Standards Institute, 950 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2012.

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 health care 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 documents. Current editions are listed in the CLSI catalog and posted on our website at www.clsi.org. 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 ©2012 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, 950 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087, USA.

Suggested Citation

CLSI. *Clinical Laboratory Safety; Approved Guideline—Third Edition*. CLSI document GP17-A3. Wayne, PA: Clinical and Laboratory Standards Institute; 2012.

Proposed Guideline

1989

Tentative Guideline

April 1994

Approved Guideline

September 1996

Approved Guideline—Second Edition

April 2004

Approved Guideline—Third Edition

June 2012

ISBN 1-56238-797-9 (Print)
ISBN 1-56238-798-7 (Electronic)
ISSN 1558-6502 (Print)
ISSN 2162-2914 (Electronic)

Committee Membership

Consensus Committee on Quality Systems and Laboratory Practices

**Carl D. Mottram, BA, RRT, RPFT,
FAARC
Chairholder
Mayo Clinic
Rochester, Minnesota, USA**

**Devery Howerton, PhD, MS,
MT(ASCP)SI
Vice-Chairholder
Centers for Disease Control and
Prevention
Atlanta, Georgia, USA**

Deirdre Astin, MS, MT(ASCP)
New York State Department of Health
Albany, New York, USA

Michael B. Cohen, MD
ARUP Laboratories
Salt Lake City, Utah, USA

Nancy Dubrowny, MS, MT(ASCP)SC
BD Preanalytical Systems
Franklin Lakes, New Jersey, USA

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

Michelle Jenkins, MS, MT(AMT) ASQ,
CQE
Abbott Diagnostics
Irving, Texas, USA

Michelle McLean, MS, MT(ASCP)
Greiner Bio-One North America,
Inc.
Raleigh, North Carolina, USA

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

Tonya Wilbon, BS, M(ASCP)
FDA Center for Devices and
Radiological Health
Rockville, Maryland, USA

Document Development Committee on Clinical Laboratory Safety

**Terry Jo Gile, MT(ASCP), MA.Ed.
Chairholder
Safety Lady LLC
North Ft. Myers, Florida, USA**

**Miki Van Houten, MT(ASCP)
Vice-Chairholder
Oregon State Public Health
Laboratory
Hillsboro, Oregon, USA**

Michelle L. Altrich, PhD
ViraCor – IBT Laboratories
Lee's Summit, Missouri, USA

Charles R. Cook
Pennsylvania Department of Health
Lionville, Pennsylvania, USA

Jerry L. Harris, MD
Pathology Associates
Tallahassee, Florida, USA

Timothy A. Johnson, MBS, CT/SLS
(ASCP)^{CM}, CQA(ASQ)
Allina Medical Laboratories
Minneapolis, Minnesota, USA

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

Elizabeth G. Weirich, MS, CBSP
Centers for Disease Control and Prevention
Atlanta, Georgia, USA

Staff

Clinical and Laboratory Standards
Institute
Wayne, Pennsylvania, USA

Luann Ochs, MS
Senior Vice President – Operations

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

Megan P. Larrisey, MA
Editor

Ryan J. Torres
Assistant Editor

Contents

Abstract.....i

Committee Membership..... iii

Foreword..... vii

1 Scope.....1

2 Terminology.....1

 2.1 A Note on Terminology1

 2.2 Definitions1

 2.3 Abbreviations and Acronyms2

3 Roles and Responsibilities3

 3.1 Laboratory Director3

 3.2 Safety Officer.....4

 3.3 Staff.....4

4 Planning for Safety5

 4.1 Identification and Assessment of Hazards5

 4.2 Designing for Safety5

 4.3 Signage7

 4.4 Security9

5 General Safety Program.....9

 5.1 Engineering Controls9

 5.2 Personal Protective Equipment12

 5.3 Work Practice Controls.....16

 5.4 Emergency Aids.....18

 5.5 Personnel Responsibility.....19

 5.6 Transport and Shipment of Specimens21

 5.7 Waste Disposal22

 5.8 Ergonomics22

6 Specialized Safety Programs.....22

 6.1 Blood-borne Pathogens and Biosafety.....22

 6.2 Special Requirements for Working in Microbiology Laboratories.....24

 6.3 Chemical Hygiene.....27

 6.4 Radiation Safety.....40

7 Fire Prevention.....41

 7.1 Construction.....41

 7.2 Alarm Systems41

 7.3 Fire Risk Reduction Strategies.....41

 7.4 Fire Prevention and Training Programs41

 7.5 Firefighting Equipment.....42

8 Emergency Management43

 8.1 Evacuation43

 8.2 Electrical Equipment.....43

 8.3 Compressed and Liquefied Gases44

Contents (Continued)

8.4 Cryogenic Liquids.....45

9 Anatomic Pathology.....45

9.1 Cryostats and Microtomes45

9.2 Specific Procedures for Autopsy Areas47

9.3 Handling of Radioactive Surgical Pathology Specimens49

9.4 Disposal of Glass Slides and Paraffin Blocks.....49

10 Occupational Health and Safety.....49

10.1 Hepatitis B Vaccination49

10.2 Other Vaccinations50

10.3 Occupational Injuries.....50

10.4 Occupational Illness.....50

10.5 Reporting51

11 Training.....51

11.1 Schedule Training51

11.2 New Employee Orientation.....52

11.3 Training Design53

12 Documents and Records53

12.1 Documents53

12.2 Records54

13 Safety Program Evaluations.....56

13.1 Safety Program Audits.....56

14 Conclusion56

References.....57

Additional References.....61

Appendix A. Radiation Safety63

Appendix B. Sample Biological Safety Cabinet Checklist.....70

Appendix C. Sample Laboratory Safety Audit.....72

Appendix D. Globally Harmonized System Pictograms and Hazard Classes for Labeling of Hazardous Chemicals.....79

Appendix E. Examples of Formaldehyde Exposure and Ventilation Calculations.....80

Appendix F. Sample Declination Form for Hepatitis B Vaccine.....84

Appendix G. Sample After Action Report.....85

Appendix H. Sample Incident Report.....87

The Quality Management System Approach.....88

Related CLSI Reference Materials89

Foreword

This document constitutes a guide to quality clinical laboratory practices. However, other types of laboratories might find this guideline useful. Based on the cumulative experience of contributors and reviewers, it is expected that the recommendations will result in the best outcomes for laboratory personnel and patients. Within this framework, reference is made to requirements that are mandated by United States (US) federal and state regulations governing laboratory and clinical practices. All laboratories (including those dependent on US federal funds) should adhere to these requirements. These recommendations can also form the basis for standards developed by accreditation organizations for laboratory accreditation. Laboratory personnel outside US jurisdiction should consult, when necessary, their own government or accreditation authorities to determine if the requirements must or should apply.

This document replaces the second edition of the approved guideline, GP17-A2, which was published in 2004. Several changes were made in this edition; chief among them is alignment with CLSI's QMS approach and alignment with new or changed national and accreditation requirements for laboratories since the last version of this guideline. In addition, this version of GP17 is aligned with the United Nations' Globally Harmonized System of Classification and Labelling of Chemicals (GHS). GHS is a system that defines and classifies the hazards of chemical products, and communicates health and safety information on labels and material safety data sheets (called Safety Data Sheets, or SDSs, in GHS). The goal is that the same set of rules for classifying hazards, and the same format and content for labels and SDSs, will be adopted and used around the world. An international team of hazard communication experts developed GHS.¹

Key Words

Carcinogens, chemical hazards, compressed gases, electrical safety, hazardous waste disposal, laboratory safety, microbiological hazards, radiation safety, warning labels, warning signs

Clinical Laboratory Safety; Approved Guideline—Third Edition

1 Scope

Aspects of a safety program addressed in this guideline include maintenance and inspection, personal safety, and warning signs and labels. In addition, the guideline addresses fire prevention, electrical and radiation safety, and other potential laboratory hazards. Special considerations for anatomic pathology laboratories are also included. This guideline is written for laboratorians who are responsible for developing and implementing a safety program in medical laboratories. However, other types of laboratories will also find this guideline useful.

2 Terminology

2.1 A Note on Terminology

CLSI, as a global leader in standardization, is firmly committed to achieving global harmonization wherever 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 the United States, Europe, and elsewhere; that these differences are reflected in CLSI, International Organization for Standardization (ISO), and European Committee for Standardization (CEN) documents; and that legally required use of terms, regional usage, and different consensus timelines are all important considerations in the harmonization process. In light of this, CLSI's consensus process for development and revision of standards and guidelines focuses on harmonization of terms to facilitate the global application of standards and guidelines.

Additional important note:

Throughout this guideline, the phrase “the laboratory needs to” explains an action directly related to fulfilling requirements of international, national, and accreditation organizations. By taking the actions described in this guideline, the laboratory will fulfill requirements; means by which the requirements are met are left to the discretion of the laboratory unless otherwise specified.

The phrase “the laboratory should” describes a recommendation provided in laboratory literature, a statement of good laboratory practice, or a suggestion for how to meet a requirement.

2.2 Definitions

effluent – outflow or discharge of liquid waste, as from a sewage system, factory, or nuclear plant.

hazard statement – phrase assigned to a hazard class and category that describes the nature of the hazard or hazards.¹

major spill – spill that spreads rapidly, presents an inhalation hazard, endangers people or the environment, and/or involves personal injury or rescue and should be handled as an emergency by the department of public safety, fire department, or hazmat team.

pictogram – symbol plus other graphic elements intended to convey specific information about the hazards of the chemical¹; **NOTE:** Each pictogram consists of a different black symbol on a white background within a red diamond border.