

GP17-A2
Vol. 24 No. 13
Replaces GP17-A
Vol. 16 No. 6

Clinical Laboratory Safety; Approved Guideline—Second 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 global application developed through the NCCLS consensus process.



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Dear Colleague:

Laboratory safety has always been a priority of NCCLS's Area Committee on General Laboratory Practices. It has also been a long-term goal of NCCLS to make its voluntary consensus process available to the clinical laboratory testing and healthcare communities for review of documents developed by other organizations. GP17, originally developed by the CAP Environmental Safety and Health Resource Committee, was the first such document to be advanced through the consensus process. With the publication of this approved-level, second edition guideline, NCCLS and the College of American Pathologists (CAP) have successfully completed another consensus-review and revision cycle.

One of NCCLS's overriding organizational goals is to achieve harmonization in its standards and guidelines wherever possible. This guideline has been harmonized with ISO 15190, *Medical laboratories—Requirements for safety* (an international standard that specifies requirements to establish and maintain a safe working environment in a medical laboratory). GP17-A2 provides practical information on the implementation of a laboratory safety program consistent with ISO 15190. The document has also been reformatted to present the content in a fashion similar to ISO 15190.

NCCLS and CAP are pleased to have collaborated on this joint project. Through the NCCLS process, we have again achieved the consensus of the patient-testing community on an important guideline for clinical laboratory safety. We anticipate that the success of this project will encourage other organizations to submit broad-based documents they develop to similar review within the NCCLS consensus process.

Sincerely,

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GP17-A2
ISBN 1-56238-530-5
ISSN 0273-3099

Volume 24 Number 13

Clinical Laboratory Safety; Approved Guideline—Second Edition

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Abstract

NCCLS document GP17-A2—*Clinical Laboratory Safety; Approved Guideline—Second 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.

NCCLS. *Clinical Laboratory Safety; Approved Guideline—Second Edition*. NCCLS document GP17-A2 (ISBN 1-56238-530-5). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2004.

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Suggested Citation

(NCCLS. *Clinical Laboratory Safety; Approved Guideline—Second Edition*. NCCLS document GP17-A2 [ISBN 1-56238-530-5]. NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2004.)

Proposed Guideline

1989

Tentative Guideline

April 1994

Approved Guideline

September 1996

Approved Guideline—Second Edition

April 2004

ISBN 1-56238-530-5

ISSN 0273-3099

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Foreword

Laboratory safety has always been a priority of NCCLS's Area Committee on General Laboratory Practices. It has also been a long-term goal of NCCLS to make its voluntary consensus process available to the clinical laboratory testing and healthcare communities for review of documents developed by other organizations. GP17 was the first document to have marked the successful advancement of a document, originally developed by another organization, through the consensus process. With the publication of this approved-level, second edition guideline, NCCLS and The College of American Pathologists (CAP) have successfully completed another consensus-review and revision cycle.

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 outcome for laboratory personnel and patients. Within this framework, reference is made to requirements that are mandated by United States (U.S.) federal and state regulations governing laboratory and clinical practices. These should be adhered to by all laboratories in the U.S. (and those dependent on U.S. federal funds). These recommendations can also form the basis for standards used by regulatory agencies. Laboratory personnel outside U.S. jurisdiction should consult, where necessary, their own government or accreditation authorities to determine if the requirements must or should apply.

NCCLS and CAP are pleased to have collaborated on this joint project and NCCLS gratefully acknowledges CAP's continuing assistance in assuring the success of this effort.

The Role of NCCLS and GP17 in the Harmonization Process

One of NCCLS's overriding organizational goals is the achievement of worldwide harmonization in its standards and guidelines wherever possible. NCCLS defines harmonization as a process of recognizing, understanding, and explaining differences while taking steps to achieve worldwide uniformity; and recognizes that harmonization is an evolutionary and educational process that begins with new projects and revisions of existing documents.

In response to this organizational policy, NCCLS, its Area Committee on General Laboratory Practices, and CAP's Safety Committee have, where appropriate, harmonized the GP17 guideline with ISO 15190, *Medical laboratories—Requirements for safety* (an international standard that specifies requirements to establish and maintain a safe working environment in a medical laboratory).¹ GP17-A2 has also been reformatted to present the content in a fashion similar to ISO 15190. GP17-A2 provides practical information on the implementation of a laboratory safety program consistent with ISO 15190.

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—Second Edition

1 Scope

GP17-A2—*Clinical Laboratory Safety; Approved Guideline—Second 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. 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.

2 Definitions

Major spill – A 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.

Standard precautions – Set of precautions applied to all patients designed to reduce risk of transmission of microorganisms in the healthcare setting; **NOTE:** All blood, tissue, body fluids, secretions, and excretions (except sweat) are considered potentially infectious.

Universal precautions – Set of precautions designed to reduce risk of transmission of HIV, hepatitis B virus, and other blood-borne pathogens in the healthcare setting; **NOTES:** a) All human blood, other body fluids containing visible blood, semen, vaginal secretions, tissue, and the following fluids (cerebrospinal, synovial, pleural, peritoneal, pericardial, and amniotic) are considered potentially infectious under standard precautions; b) Universal precautions do not apply to feces, nasal secretions, saliva (except in a dental setting), sputum, sweat, tears, urine, and vomitus unless they contain visible blood.

3 Management Requirements

The laboratory director is responsible for laboratory safety. The safety officer is to provide guidance to laboratory management (please refer to Section 5.1 for additional information).

4 Designing for Safety

4.1 General Design Requirements

Most states and some communities have established building codes containing specific architectural safety standards for laboratories. These include, but are not limited to, the following standards:

- space;
- casework/millwork/furnishings;
- storage (refrigerated and nonrefrigerated);
- ventilation in laboratory design;
- lighting; and
- fresh and waste water.