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## Clinical Laboratory Technical Procedure Manuals; Approved Guideline—Fourth Edition

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Lucia M. Berte, MA, MT(ASCP) SBB, DLM; CQA(ASQ)CQMgr  
Beverly J. Charlton, CLC(AMT)  
Barb Kirkley, MT(ASCP)  
Jennifer Schiffgens, MBA, MT(ASCP)  
Joyce I. Wilson, MS, MT(ASCP)  
Sheila M. Woodcock, MLT, ART, MBA



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### Abstract

*Clinical Laboratory Technical Procedure Manuals; Approved Guideline—Fourth Edition* (NCCLS document GP2-A4) presents the important components of writing and managing procedures for the clinical laboratory. This guideline describes common and specific sections that should be included when developing laboratory procedures. Several examples of procedures for preanalytic, analytic, and postanalytic laboratory activities are provided in the form of appendixes; such appendixes are simply illustrative, and not prescriptive.

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## Foreword

Previous editions of NCCLS document GP2 have focused on essential elements to include in laboratory analytic test procedures.

This edition of GP2 has been expanded to provide:

- guidelines for writing procedures for the preanalytic, analytic, and postanalytic activities that represent the laboratory's path of workflow;
- guidelines for writing procedures specifically for multitest automated analyzers;
- an introduction to the management and control of laboratory procedure documents after they are approved for use; and
- the use of process flowcharts to depict the linkages between laboratory procedures.

The information and examples provided in this edition are also consistent with the guidance described in NCCLS document GP26—*A Quality System Model for Health Care*.

This edition of GP2 is applicable to any size laboratory, wherever it may be in the transition of its quality program from traditional quality control and quality assurance practices to the concepts of quality systems management.

## Key Words

Document management, electronic procedures, laboratory procedure, procedure manual, technical procedures

## **Clinical Laboratory Technical Procedure Manuals; Approved Guideline—Fourth Edition**

### **1 Introduction**

The laboratory should provide carefully documented instructions—in the form of procedures—for all activities that support the performance of analytic testing. These instructions provide essential information for both new and experienced employees on how to perform all their job tasks—including nontesting tasks such as collecting blood specimens and using the laboratory's computer system.

Written procedures should encompass an entire task from start to finish. Therefore, it makes sense to write separate instructions for tasks that are performed at different times by different people.

GP2-A4 is intended to be used by the following persons:

- administrative and technical personnel who write laboratory procedures;
- manufacturers; and
- educators.

### **2 Scope**

This publication describes how to:

- identify laboratory procedures using the laboratory's operational path of workflow; and
- write procedures for preanalytic, analytic, and postanalytic laboratory activities.

In addition, this edition of GP2 provides useful information about preparing, approving, maintaining, changing, and reviewing laboratory documents.

### **3 Definitions<sup>a</sup>**

**Document**, *n* – Any recorded item of a factual or informative nature, either paper or electronic.

**Form**, *n* – A paper or electronic document on which the results from the performance of a procedure or other information are captured.

**Policy**, *n* – A written statement of overall intentions and directions defined by those in the organization and endorsed by management.

**Procedure**, *n* – A specified way to perform an activity; **NOTE:** For a quality system, a procedure is a set of instructions that describe the stepwise actions to be taken to complete activities identified in processes.

**Process**, *n* – Set of interrelated or interacting activities that transform inputs into outputs; **NOTE:** It may be documented as flowcharts or tables that describe the path of operational workflow in the laboratory.

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<sup>a</sup> Some of these definitions are found in NCCLS document NRSL8—*Terminology and Definitions for Use in NCCLS Documents*. For complete definitions and detailed source information, please refer to the most current edition of that document.  
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**Related NCCLS Publications\***

- GP17-A**      **Clinical Laboratory Safety; Approved Guideline (1996).** This document contains general guidelines for implementing a high-quality laboratory safety program. The framework is adaptable to any laboratory.
- GP21-A**      **Training Verification for Laboratory Personnel; Approved Guideline (1995).** This document provides background and recommends an infrastructure for developing a training verification program that meets quality/regulatory objectives.
- M29-A2**      **Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline—Second Edition (2001).** Based on U.S. regulations this document provides guidance on the risk of transmission of hepatitis viruses and human immunodeficiency viruses in any laboratory setting; specific precautions for preventing the laboratory transmission of blood-borne infection from laboratory instruments and materials; and recommendations for the management of blood-borne exposure.
- NRSCL8-A**    **Terminology and Definitions for Use in NCCLS Documents; Approved Standard (1998).** This document provides standard definitions for use in NCCLS standards and guidelines, and for submitting candidate reference methods and materials to the National Reference System for the Clinical Laboratory (NRSCL).

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\* Proposed- and tentative-level documents are being advanced through the NCCLS consensus process; therefore, readers should refer to the most recent editions.