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Laboratory Documents: Development and Control; Approved Guideline—Fifth Edition

This document provides guidance on development, review, approval, management, and use of policy, process, and procedure documents in the medical laboratory community.

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

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Laboratory Documents: Development and Control; Approved Guideline—Fifth Edition

Lucia M. Berte, MA, MT(ASCP), SBB, DLM; CQA(ASQ)CQMgr
Donald R. Callihan, PhD
Joan Carlson, MLT(CSMLA), BSc(MLS), MT(ASCP)
Beverly J. Charlton, CLC(AMT)
Christine D. Flaherty, MHA, MT(ASCP)
Mary H. Hopper, MA, MT(ASCP)
Barb Kirkley, MT(ASCP)
Oliver Ndimbie, MD, FCAP
Jennifer Schiffgens, MBA, MT(ASCP)
Peggy J. Stupca, MS, CLSp(CG)
Nita Sudderth, MT(ASCP), CQMgr(ASQ)
Joyce I. Wilson, MS, MT(ASCP)
Shelia M. Woodcock, MBA, FCSMLS(D)

Abstract

Clinical and Laboratory Standards Institute document GP2-A5—*Laboratory Documents: Development and Control; Approved Guideline—Fifth Edition* presents the important components of writing and managing documents for the clinical laboratory. This guideline describes common and specific sections for inclusion in laboratory documents. Several examples of process and procedure documents for preexamination, examination, and postexamination laboratory activities are provided in the form of appendixes; such appendixes are simply illustrative, and not prescriptive.

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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)CQMgr.
Quality Systems Consultant
Westminster, Colorado

Theresa D. Billups, MBA,
MT(ASCP)DLM
Remel Inc.
Lake Charles, Louisiana

Margaret M. Grimes, MD
Virginia Commonwealth University
Richmond, Virginia

Bruce David Tually, BAppSc,
MAppSc
Hunter Area Pathology Service
New South Wales, Australia

Advisors

Kay M. Creed
St. Mary's Hospital
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
Litton Pathology Associates
Blue Springs, Missouri

Eleanor M. Travers, MD, MHA
State of Connecticut Dept. of Public
Health
Hartford, Connecticut

Working Group on Technical Procedure Manuals

**Lucia M. Berte, MA, MT(ASCP),
SBB, DLM; CQA(ASQ)CQMgr
Chairholder
Quality Systems Consultant
Westminster, Colorado**

Donald R. Callihan, PhD
BD Diagnostic Systems
Sparks, Maryland

Joan Carlson, MLT(CSMLS),
BSc(MLS), MT(ASCP)
University of Alberta Hospital
Edmonton, Alberta, Canada

Beverly J. Charlton, CLC(AMT)
University of Pittsburgh Medical
Center
Pittsburgh, Pennsylvania

Christine D. Flaherty, MHA,
MT(ASCP)
Sutter Health
Sacramento, California

Mary H. Hopper, MA, MT(ASCP)
Mayo Clinic
Rochester, Minnesota

Barb Kirkley, MT(ASCP)
The Cleveland Clinic Foundation
Cleveland, Ohio

Oliver Ndimbie, MD, FCAP
Abbott Diagnostics
Irving, Texas

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

Peggy J. Stupca, MS, CLSp(CG)
Mayo Clinic
Rochester, Minnesota

Nita Sudderth, MT(ASCP),
CQMgr(ASQ)
UroCor, Inc.
Oklahoma City, Oklahoma

Joyce I. Wilson, MS, MT(ASCP)
University of Alabama-Birmingham
Hospital
Birmingham, Alabama

Sheila M. Woodcock, MBA,
FCSMLS(D)
QSE Consulting
Rose Bay, Nova Scotia, Canada

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

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Foreword

Previous editions of CLSI document GP2 have focused on essential elements to include in laboratory examination procedures.

This edition of GP2 has been renamed and reorganized to provide:

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

The information and examples provided in this edition are also consistent with the guidance described in CLSI/NCCLS document GP26—*Application of a Quality Management System Model for Laboratory Services*.

This edition of GP2 is applicable to any size, scope, or specialty of laboratory, including point-of-care testing, wherever the laboratory may be in the transition of its quality program from traditional quality control and quality assurance practices to the concepts of quality management systems.

GP2-A5 is a *guideline* for how to implement requirements that have been established by regulatory and accrediting organizations and international standards for laboratory documents and procedures manuals. **GP2-A5 is not a standard**; that is, this guideline does not set requirements for laboratory documents and procedures. **Instead, this guideline describes what laboratories need to do to meet published regulations and accreditation requirements and international standards.**¹⁻⁷

The words “must” and “shall” reflect language used in the requirements of regulatory and accreditation organizations; therefore, these words do not appear in the text of this guideline. Instead, the guideline text reads, “the laboratory needs to...,” followed by a description of the activity(ies) that will fulfill requirements. If a laboratory follows the guidance described herein, it will provide better and clearer communications and instructions for laboratory staff, in addition to experiencing better performance on regulatory and accreditation inspections and certification audits (for international standards).

A Note on Terminology

Clinical and Laboratory Standards Institute (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, ISO, and CEN documents; and that legally required use of terms, regional usage, and different consensus timelines are all obstacles to harmonization. In light of this, CLSI recognizes that harmonization of terms facilitates the global application of standards and is an area of immediate attention.

In order to align the use of terminology in this document with that of ISO, the terms *preexamination*, *examination*, and *postexamination* have been adopted in place of pretest, test, and posttest, and the term *sample* replaces the term *specimen* where appropriate. The users of GP2-A5 should understand that the

fundamental meanings of the terms are identical in many cases, and are defined in the guideline's Definitions section (see Section 3). The terms in this document are consistent with those defined in the ISO 15189, ISO 17025, and ISO 9000 series of standards.

Key Words

Computer procedure, document, document management, electronic procedures, laboratory procedure, laboratory process, procedures manual, technical procedures

Laboratory Documents: Development and Control; Approved Guideline—Fifth Edition

1 Scope

This publication describes how to:

- identify laboratory procedures using work processes in the laboratory’s operational path of workflow; and
- write procedures for preexamination, examination, and postexamination laboratory activities.

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

2 Introduction

The laboratory needs to provide carefully documented instructions—in the form of procedures—for all activities that support the performance of laboratory examinations.¹⁻⁷ These instructions provide essential information for both new and experienced employees about how to perform all their job tasks—including nonexamination tasks, such as collecting blood samples and using the laboratory’s computer system.

Written procedures should encompass a single 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-A5 is intended for use by the following:

- administrative and technical personnel who develop laboratory documents;
- manufacturers; and
- educators.

3 Definitions

conformance – fulfillment of a requirement (ISO 9000).⁸

document – any recorded item of a factual or informative nature, either paper or electronic.

examination – set of operations having the object of determining the value or characteristics of a property (ISO 15189)¹; **NOTE 1:** In some countries and disciplines (e.g., microbiology), an examination is the total activity of a number of tests, observations, or measurements (ISO 15189)¹; **NOTE 2:** In this document, the term “examination” replaces the term “test”; however, for the purposes of this guideline, readers can consider the terms equivalent.

form – a paper or electronic document on which the results from the performance of a procedure or other information are captured, and after which becomes a record.

policy – a documented statement of overall intentions and directions defined by those in the organization and endorsed by management.