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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.



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

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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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(Formerly NCCLS)

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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.

Related CLSI/NCCLS Publications*

- GP17-A2** **Clinical Laboratory Safety; Approved Guideline—Second Edition (2004).** 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.
- GP21-A2** **Training and Competence Assessment; Approved Guideline—Second Edition (2004).** This document provides background information and recommended processes for the development of training and competence assessment programs that meet quality/regulatory objectives.
- GP26-A3** **Application of a Quality Management System Model for Laboratory Services; Approved Guideline—Third Edition (2004).** This guideline describes the clinical laboratory's path of workflow and provides information for laboratory operations that will assist the laboratory in improving its processes and meeting government and accreditation requirements.
- HS1-A2** **A Quality Management System Model for Health Care; Approved Guideline—Second Edition (2004).** This document provides a model for providers of healthcare services that will assist with implementation and maintenance of effective quality management systems.
- M29-A3** **Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline—Third Edition (2005).** Based on U.S. regulations, this document provides guidance on the risk of transmission of infectious agents by aerosols, droplets, blood, and body substances in a laboratory setting; specific precautions for preventing the laboratory transmission of microbial infection from laboratory instruments and materials; and recommendations for the management of exposure to infectious agents.

* Proposed-level documents are being advanced through the Clinical and Laboratory Standards Institute consensus process; therefore, readers should refer to the most current editions.