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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 ™
(Formerly NCCLS)

Clinical and Laboratory Standards Institute

Advancing Quality in Healthcare Testing

Clinical and Laboratory Standards Institute (CLSI formerly NCCLS) is an international, interdisciplinary, nonprofit, standards-developing, and educational organization that promotes the development and use of voluntary consensus standards and guidelines within the healthcare community. It is recognized worldwide for the application of its unique consensus process in the development of standards and guidelines for patient examination and related healthcare issues. Our process is based on the principle that consensus is an effective and cost-effective way to improve patient examination and healthcare 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 examination and health care.

PUBLICATIONS

A document is published as a standard, guideline, or committee 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 Board of Directors.

CONSENSUS PROCESS

The CLSI voluntary consensus process is a protocol establishing formal criteria for:

- the authorization of a project
- the development and open review of documents
- the revision of documents in response to comments by users
- the acceptance of a document as a consensus standard or guideline.

Most documents are subject to two levels of consensus—"proposed" and "approved." Depending on the need for field evaluation or data collection, documents may also be made available for review at an intermediate consensus level.

Proposed A consensus document undergoes the first stage of review by the healthcare community as a proposed standard or guideline. The document should receive a wide and thorough technical review, including an overall review of its scope, approach, and utility, and a line-by-line review of its technical and editorial content.

Approved An approved standard or guideline has achieved consensus within the healthcare community. It should be reviewed to assess the utility of the final document, to ensure attainment of consensus (i.e., that comments on earlier versions have been satisfactorily addressed), and to identify the need for additional consensus documents.

Our standards and guidelines represent a consensus opinion on good practices and reflect the substantial agreement by materially affected, competent, and interested parties obtained by following CLSI's established consensus procedures. Provisions in CLSI standards and guidelines may be more or less stringent than applicable regulations. Consequently, conformance to this voluntary consensus document does not relieve the user of responsibility for compliance with applicable regulations.

COMMENTS

The comments of users are essential to the consensus process. Anyone may submit a comment, and all comments are addressed, according to the consensus process, by the committee that wrote the document. All comments, including those that result in a change to the document when published at the next consensus level and those that do not result in a change, are responded to by the committee in an appendix to the document. Readers are strongly encouraged to comment in any form and at any time on any document. Address comments to Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, PA 19087, USA.

VOLUNTEER PARTICIPATION

Healthcare professionals in all specialties are urged to volunteer for participation in CLSI projects. Please contact us at customerservice@clsi.org or +610.688.0100 for additional information on committee participation.

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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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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

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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.

