GP31-P
Vol. 27 No. 12

Laboratory Instrument Implementation, Verification, and Maintenance; Proposed Guideline

PLEASE

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This proposed document is published for wide and thorough review in the new, accelerated Clinical and Laboratory Standards Institute (CLSI) consensus-review process. The document will undergo concurrent consensus review, Board review, and delegate voting (i.e., candidate for advancement) for 60 days.

Please send your comments on scope, approach, and technical and editorial content to CLSI.

Comment period ends

6 August 2007

The subcommittee responsible for this document will assess all comments received by the end of the comment period. Based on this assessment, a new version of the document will be issued. Readers are encouraged to send their comments to Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA; Fax: +610.688.0700, or to the following e-mail address: customerservice@clsi.org.

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COMMENT

This guideline provides information about assessing instrument performance and function from the time of instrument purchase to the routine performance of clinical testing.

A guideline for global application developed through the Clinical and Laboratory Standards Institute consensus process.

CLINICAL AND LABORATORY STANDARDS INSTITUTE®
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COLLEGE OF AMERICAN PATHOLOGISTS
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Clinical and Laboratory Standards Institute

Advancing Quality in Healthcare Testing

The 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 testing and related healthcare issues. Our process is based on the principle that consensus is an effective and cost-effective way to improve patient testing 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 testing 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 the 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.

Dear Colleague:

Assessing instrument performance and function from the time of instrument purchase to the routine performance of clinical testing is of significant value to laboratorians. *Laboratory Instrument Implementation, Verification, and Maintenance; Proposed Guideline* (GP31-P) provides useful information on instrument performance criteria in a systematic and easy-to-use format.

It has been a long-term goal of CLSI to make its voluntary consensus process available to the clinical laboratory testing and healthcare communities for review of documents developed by other organizations. GP31, originally developed by the CAP Environmental Safety and Health Resource Committee, has successfully completed its initial consensus-review and revision cycle. In response to one of CLSI's overriding organizational goals—achieving harmonization in its standards and guidelines wherever possible—this guideline has been harmonized with local and regional requirements, and applicable international standards.

CLSI and CAP are pleased to have collaborated on this joint project. Through the CLSI 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 CLSI consensus process.

Sincerely,

Robert L. Habig

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Laboratory Instrument Implementation, Verification, and Maintenance; Proposed Guideline

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Abstract

Clinical and Laboratory Standards Institute document GP31-P—*Laboratory Instrument Implementation, Verification, and Maintenance; Proposed Guideline* provides recommendations for achieving accurate, precise, and high-quality data for patient care at a reasonable cost. The guideline includes recommended instrument performance criteria that should be considered; discussion of proper functioning of instrumentation based on theory or experience, when necessary; and references for further information. The intent of this guideline is to provide useful information in a systematic and easy-to-use format.

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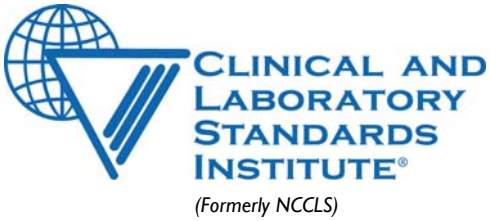

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Foreword

Today's clinical and pathology laboratory is challenged to provide accurate, precise, and high-quality data for patient care at a reasonable cost. Laboratory directors and managers must make appropriate decisions in selection of instrumentation. Once those decisions are made, these persons must, with their chosen instrumentation, adequately and efficiently verify and maintain performance.

Many manufacturers and providers of instrumentation offer assistance in selection, as well as performance verification and maintenance. However, the laboratory director is ultimately responsible for the quality of the laboratory results. This guideline provides recommendations for instrument performance criteria, discusses proper functioning based on theory or experience, and references further information. The intent of this guideline is to provide useful information in a systematic and easy-to-use format.

Invitation for Participation in the Consensus Process

An important aspect of the development of this and all Clinical and Laboratory Standards Institute documents that should be emphasized is the consensus process. Within the context and operation of Clinical and Laboratory Standards Institute, the term "consensus" means more than agreement. In the context of document development, "consensus" is a process by which Clinical and Laboratory Standards Institute, its members, and interested parties (1) have the opportunity to review and to comment on any Clinical and Laboratory Standards Institute publication; and (2) are assured that their comments will be given serious, competent consideration. Any Clinical and Laboratory Standards Institute document will evolve as will technology affecting laboratory or healthcare procedures, methods, and protocols; and therefore, is expected to undergo cycles of evaluation and modification.

The Area Committee on Quality Systems and Laboratory Practices has attempted to engage the broadest possible worldwide representation in committee deliberations. Consequently, it is reasonable to expect that issues remain unresolved at the time of publication at the proposed level. The review and comment process is the mechanism for resolving such issues.

The Clinical and Laboratory Standards Institute voluntary consensus process is dependent upon the expertise of worldwide reviewers whose comments add value to the effort. At the end of a 60-day comment period, each subcommittee is obligated to review all comments and to respond in writing to all that are substantive. Where appropriate, modifications will be made to the document, and all comments along with the subcommittee's responses will be included as an appendix to the document when it is published at the next consensus level.

A Note on Terminology

CLSI, as a global leader in standardization, is firmly committed to achieving global harmonization wherever possible. Harmonization is a process of recognizing, understanding, and explaining differences while taking steps to achieve worldwide uniformity. 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. Implementation of this policy must be an evolutionary and educational process that begins with new projects and revisions of existing documents.

In order to align the usage of terminology in this document with that of ISO, the term *sample* has replaced the term s*pecimen* and the term *test* has replaced the term *examination.* The users of this guideline 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 3.1). The terms in this document are consistent with those defined in the ISO 15189 and ISO 9000 series of standards.

Key Words

Instrumentation, maintenance, performance verification

Laboratory Instrument Implementation, Verification, and Maintenance; Proposed Guideline

1 Scope

This guideline provides a basic understanding of the considerations for the implementation, verification, and maintenance of generic laboratory and pathology equipment. Recommendations are generic and not substitutes for specific information provided by a given instrument's manufacturer. This guideline discusses general purpose families of instruments, often adapted by the laboratory for specific tasks, and some area-specific instruments. Highly automated instruments that are designed and manufactured for *in vitro* diagnostic testing differ in functional and maintenance characteristics; refer to the specifications given by the manufacturer. Although this guideline is not a textbook of laboratory and pathology equipment, sufficient background information will be incorporated into the discussion when necessary for understanding the recommendations provided.

2 Introduction

Most results reported by clinical and pathology laboratories are generated by methods using analytical instruments. Although this guideline will discuss generic instruments, keep two issues in mind. First, manufacturers of instruments for *in vitro* diagnostic testing will provide instrument installation, verification, and maintenance requirements; these requirements must be followed to ensure proper function. Any additional recommendations in this guideline may supplement, but do not replace, manufacturers' requirements. In addition, the reliability of patient results depends on preexamination, examination, and postexamination factors that include generation of the requisition, preparation of the patient, sample collection and handling, testing, and reporting results. In order to monitor these factors, laboratories need a quality assurance program that evaluates each step in laboratory testing and provides information for maintaining and improving test results for patient care. This guideline describes a quality assurance program for instruments that evaluates instrument operation and stresses instrument maintenance. The purpose of performing routine maintenance and operational verification is to isolate the reasons for instrument-related failure of the testing process and, more importantly, to identify early instrument malfunction before these changes result in testing failure. This guideline provides information about assessing instrument performance and function from the time of instrument purchase to the routine performance of clinical testing.

Instrument verification and maintenance require keeping a wide variety of data that often predict testing problems and failures. Many problems commonly develop gradually over time, and their effects may be subtle and not readily detectable in the overall laboratory quality control program during the earlier stages of degradation. Failure of one component can be detrimental to the overall process and small errors can result in significant errors when propagated throughout the system. Anticipation of such problems is the motivation for a comprehensive instrument implementation, verification, and maintenance program.

Instrument and equipment maintenance minimizes the need for expensive repair service and maximizes the useful life of an instrument. Decreasing instrument breakdown is essential for uninterrupted laboratory operation, and has an impact on the primary laboratory function of expeditiously providing diagnostically significant patient test results. Careful instrument and equipment maintenance helps ensure that instruments will do what is expected of them when results are needed.

Although many sources are available to discuss the basic principles of laboratory and pathology instrumentation, guidelines that aid in evaluating, verifying, and maintaining this equipment are very rare.