CLINICAL AND LABORATORY STANDARDS INSTITUTE®

April 2009

GP31-A

Laboratory Instrument Implementation, Verification, and Maintenance; Approved Guideline

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

Setting the standard for quality in clinical laboratory testing around the world.

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For further information on committee participation or to submit comments, contact CLSI.

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CLINICAL AND LABORATORY STANDARDS INSTITUTE®

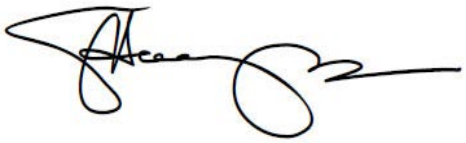
Dear Colleague:

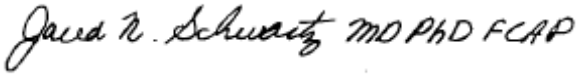
Assessing instrument performance is an essential part of the quality program of every laboratory. *Laboratory Instrument Implementation, Verification, and Maintenance; Approved Guideline* (GP31-A) provides critical information on instrument performance criteria in a systematic and easy-to-use format.

GP31 is the successor to *Laboratory Instrument Evaluation, Verification and Maintenance Manual*, developed by the College of American Pathologists' Environmental Safety and Health Resource Committee. Working with the CAP, the Clinical and Laboratory Standards Institute has published GP31-A as an important addition to the portfolio of standards and guidelines for laboratory quality. 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 make this guideline available to the patient-testing community as an important new resource. Future editions of this document will continue to be developed through CLSI's consensus process; therefore, users are encouraged to submit comments on the technical content and applicability of the document. We anticipate that the success of this project will encourage other organizations to submit broad-based documents for development within the CLSI consensus process.

Sincerely,





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GP31-A
Vol. 29 No. 11
Replaces GP31-P
Vol. 27 No. 12

ISBN 1-56238-697-2
ISSN 0273-3099

Laboratory Instrument Implementation, Verification, and Maintenance; Approved Guideline

Volume 29 Number 11

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Abstract

Clinical and Laboratory Standards Institute document GP31-A—*Laboratory Instrument Implementation, Verification, and Maintenance; Approved 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.

Clinical and Laboratory Standards Institute (CLSI). *Laboratory Instrument Implementation, Verification, and Maintenance; Approved Guideline*. CLSI document GP31-A (ISBN 1-56238-697-2). Clinical and Laboratory Standards Institute, 950 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2009.

Suggested Citation

CLSI. *Laboratory Instrument Implementation, Verification, and Maintenance; Approved Guideline*. CLSI document GP31-A. Wayne, PA: Clinical and Laboratory Standards Institute; 2009.

Proposed Guideline
June 2007

Approved Guideline
April 2009

ISBN 1-56238-697-2
ISSN 0273-3099

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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.

Key Words

Instrumentation, maintenance, performance verification

Laboratory Instrument Implementation, Verification, and Maintenance; Approved Guideline

1 Scope

This guideline provides a basic understanding of the considerations for the implementation, verification, and maintenance of laboratory 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. It is intended for use by laboratory directors, managers, supervisors, technologists, and others responsible for routine calibration, verification, maintenance, and operation of laboratory equipment. 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. This guideline supports activities described in Quality System Essential (QSE): Equipment.

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.