POCT2-P
Vol. 27 No. 6

Implementation Guide of POCT1 for Healthcare Providers; Proposed Guideline

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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

7 May 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 document identifies and describes the particular features that a POCT1-compliant device should ideally have. These features are divided into obligatory and desirable categories. The guideline thus gives the healthcare provider or end user a practical basis for establishing a list of features or questions to be addressed by the vendor of a compliant device.

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

(Formerly NCCLS)

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.

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Abstract

Clinical and Laboratory Standards Institute document POCT2-P—*Implementation Guide of POCT1 for Healthcare Providers; Proposed Guideline* identifies and describes the particular features that a POCT1-compliant device should ideally have. These features are divided into obligatory and desirable categories. Key terms are identified and the most frequent use-cases are presented. The guideline thus gives the healthcare provider or end user a practical basis for establishing a list of features or questions to be addressed by the vendor of a compliant device. Where appropriate, it also indicates options that may be applicable. The guideline, at the same time, tries to be flexible in allowing for adaptation to specific cases and also in considering probable technological advances in the evolution of connectivity solutions. The use of this guideline should thus permit healthcare providers to acquire the device with a connectivity solution best suited to their needs and also to encourage the development of an acceptable industry-wide standard.

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Contents

Foreword

CLSI document POCT1—*Point-of-Care Connectivity* was developed and recently updated to provide the framework for engineers to design devices, work stations, and interfaces that allow multiple types and brands of point-of-care devices to communicate bidirectionally with access points, data managers, and laboratory information systems from a variety of vendors. POCT1 is an excellent document but is also very technical. This particularly applies to the annexes that comprise the bulk of the document. The document, as the name implies, presents information regarding the development of the interfaces necessary for the universal connectivity of point-of-care testing devices. The purpose of this connectivity standard, by reducing manual information entry and transfer, is to permit error-free point-of-care testing and result reporting along with optimal data capture for quality assurance purposes.

Because the document is very technical, there is some lack of understanding, even confusion, as to its practicality. The present guideline addresses this problem and is intended for use by healthcare providers and end users responsible for point-of-care testing. It will present some background on the rationale behind POCT1 and will describe the practical manner in which application of the standard to the POCT device/system should permit the flow of data between the testing system, the data manager and the LIS/HIS. In other words, it will define the practical features that the end user (healthcare provider) should expect to find and to be able to use for smooth capture and transfer of information between the device and the LIS/HIS. A separate guideline, intended to assist device manufacturers, will also be available.

The document defines the characteristics and features that should be expected in a connectivity-compliant device. Problems related to the availability or applicability of these features may occur and should be addressed in relation to the particular situation (hardware, environment, institutional information system, specific end use of the test/device, etc.).

Invitation for Participation in the Consensus Process

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

The Area Committee on Point-of-Care Testing 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 CLSI 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.

Key Words

Connectivity, compliant device, interfaces, point-of-care testing, wireless

Implementation Guide of POCT1 for Healthcare Providers; Proposed Guideline

1 Scope

This guideline will provide the healthcare provider or end user with clear, concise information on what features to expect in a connectivity-compliant device and practical advice on how to optimally apply these features to their daily operation/practice. It will also address possible pitfalls identified by the committee and its advisors. Where necessary or useful, it will define and explain, in nontechnical language, terms used in the POCT1 standard.

This guideline will not address manufacturer's requirements. It is intended that healthcare providers, by taking into account the information in this document, will be able to develop a list of questions, specific to the particular test and their site, which need to be addressed by potential vendors. This list of questions would be based on the features that a compliant device should have and that are described in this document. Given continuous changes in the area of POCT, as well as continuing technological advances, healthcare providers are encouraged to ask questions or request modifications that reflect these advances.

Some sections in this document provide an overview of desirable features in a compliant device and an example set of questions that may be put to potential vendors.

2 Introduction

Widespread concern among healthcare providers about the lack of standard, low-cost point-of-care connectivity solutions drove the formation of the Connectivity Industry Consortium (CIC). Prior to the CIC, each vendor developed their own proprietary means of communicating data from POCT devices. The physical connections, the wiring, even the language and communication format or protocol were different between devices and between manufacturers. For point-of-care programs utilizing devices from two or more vendors, transfer of data often required separate computer systems (called "data managers" by some manufacturers), with different functions and applications, separate docking stations, and sometimes even different wiring. Implementation of new POC devices was expensive and problematic, often requiring expensive institutional renovations that both limited the conversion of hospitals to new technologies and prevented the routine reporting and billing of POCT results. Management of the quality of POCT results and documentation for compliance with regulatory agencies was also complicated, because many hospitals continued with manual logs and reporting systems due to the cost of installing electronic networks that functioned only for a single device.

The first clear expression of the lack of POC-compliant devices/systems came from a 1998 survey conducted by the American Association of Clinical Chemistry (AACC) Point-of-Care Testing Division. In this survey, point-of-care customers highlighted the lack of acceptable connectivity and information management solutions as the most significant problem with point-of-care product offerings. In July 1999, at a day-long focus group hosted by Agilent Technologies, clinicians and clinical laboratorians from leading healthcare institutions developed and prioritized a list of connectivity requirements. Over the lifetime of the Consortium, the Provider Review Committee (PRC) refined and elaborated on these requirements in order to help guide the technical development efforts of the POCT1 standard. The end result of this process is that the objectives and design of POCT1 have been driven by requirements provided by leading users of point-of-care products.