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Proceedings From the *QC for the Future* Workshop; A Report

CLINICAL AND LABORATORY STANDARDS INSTITUTE ™

(Formerly NCCLS)
Providing NCCLS standards and guidelines,
ISO/TC 212 standards, and ISO/TC 76 standards

Clinical and Laboratory Standards Institute

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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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Report

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Executive Summary

Because each clinical laboratory is unique, and because there are so many different variables that must be considered in designing quality systems for laboratory testing, identifying an approach to quality control (QC) that's applicable to all laboratories is not an easy task. The surveyor guidelines associated with the final CLIA rule published in 1992 set minimum QC requirements that regulators chose as a default after consulting nationally recognized experts and coming to no consensus on a solution for quality control. Because of technological advances, the "default" QC requirements are no longer appropriate for certain types of technology, and CLIA regulators are searching for alternatives.

In 2003, the final CLIA '88 regulation was published. The surveyor guidelines associated with the final regulation included three alternatives laboratories could use in lieu of the default QC requirements to accommodate today's more stable test systems and to provide laboratories with the opportunity to reduce the amount of QC they were performing. However, the new QC alternatives were challenged by many IVD manufacturers and laboratorians. Consequently, CLIA regulators are searching for ideas that can help build a new framework for laboratory QC.

Presenters at the conference provided an overview of recent advances in technology that are enhancing the quality of laboratory testing, and shared their ideas for a new approach to quality control. Potential new approaches discussed included a risk management model, a Six Sigma™[a] process, and a proposal called Option 4 that would allow manufacturers to validate their own QC protocols and submit them to the FDA for review.

Several speakers reminded attendees that any future QC framework must take into account the operator and the environment, as well as the analytical component of the test. Some pled the case for future technologies that make tests virtually impossible to perform incorrectly, while others endorsed continuing education and better training of the laboratory workforce as essential for providing safe laboratory testing.

In breakout sessions, meeting attendees expressed their ideas for improving quality control, which included suggestions such as using existing ISO and CLSI consensus documents as foundations for selecting quality control approaches, exploring Option 4 further, and evaluating new tools that monitor a number of laboratory parameters.

CMS announced that until QC policy is clarified, CLIA surveys will continue to be educational in terms of the new alternative QC requirements. The agency plans to conduct more meetings to further flesh out the new framework for QC.

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[a] Six Sigma is a trademark of Motorola, Inc.

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American Association for Clinical Chemistry
American Clinical Laboratory Association
American Medical Technologists
American Society for Clinical Laboratory Science
American Society for Clinical Pathology
American Society for Microbiology
Advanced Medical Technology Association (AdvaMed)
Centers for Disease Control and Prevention
Centers for Medicare & Medicaid Services
College of American Pathologists
CLMA
Clinical and Laboratory Standards Institute (CLSI)
COLA
Joint Commission on Accreditation of Healthcare Organizations
U.S. Food and Drug Administration

CLSI and the workshop co-sponsors anticipate that these proceedings will serve as a focal point for continued discussion and informed action on this important topic. One example of an initiative resulting from the workshop is a new CLSI consensus project on "Principles of Manufacturer's Validation of Risk Mitigation Using Quality Control" (EP22). Additional follow-up activities are expected. We invite you to contact CLSI or any of the workshop co-sponsors for future updates.

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Introduction

The Centers for Medicare and Medicaid Services (CMS) now has more than 185 000 laboratories in its database, ranging from full-service reference laboratories that perform tens of thousands of tests a day to small walk-in clinics that perform only a few tests a day. Approximately 42 000 of these laboratories are subject to the QC requirements in the Clinical Laboratory Improvement Amendments of 1988 (CLIA ’88).

Because each clinical laboratory is unique, and because there are so many different variables that must be considered in designing quality systems for laboratory testing, identifying an approach to QC that’s applicable to all laboratories traditionally hasn’t been an easy task, observed Thomas L. Hearn, PhD, President of Clinical and Laboratory Standards Institute (CLSI) and Associate Director of the Division of Laboratory Systems at the Centers for Disease Control and Prevention (CDC). “Advances in technology, and the performance of laboratory testing in a large range of settings with diverse system approaches to testing have driven government, industry, and laboratories to commit to working together to answer the critical question of how to effectively do quality control of laboratory testing,” he said.

As a first step in this process, CLSI, in conjunction with its organizing partners, convened the *QC for the Future* workshop in Baltimore, MD, on 18 March. The purpose of this workshop was to provide attendees with the opportunity to learn about current and new technologies for quality control, to discuss potential approaches for future quality control, and to develop new ideas for implementing quality control for the future. “The idea is to generate the framework for the development of future quality control consensus protocols,” Hearn told workshop attendees.

A Brief History of Laboratory QC Under CLIA ’88

In order to understand why a new framework for laboratory quality control is necessary, it’s important to examine CLIA’s role in the evolution of laboratory QC practices. Recognizing that sources of variation exist in every process, the framers of CLIA ’88 gave the Secretary of the Department of Health and Human Services the discretion to require each laboratory to maintain a quality assurance and quality control program adequate and appropriate for the validity and reliability of laboratory examinations and other procedures, explained Joe Boone, PhD, Associate Director for Science in the Division of Public Health Partnerships at CDC. “The desire was to preserve access, encourage new technologies, but still have cost-effective regulations,” Boone noted.

In the early 1990s, CLIA’s final rule was published. In the rule was a set of minimum quality control requirements that regulators chose as a default after consulting nationally recognized experts and coming to no consensus on a solution for quality control. The “default” QC requirements in the surveyor guidelines associated with the CLIA final rule require laboratories to run two liquid controls with each run of samples, and include special provisions for certain specialty and subspecialty areas of testing. “In that rule, we came out with requirements that were based on test complexity, but there was a phase-in for quality control provisions to permit the FDA to perform a review of the quality control procedures submitted by manufacturers and then phase those in for moderately complex tests if you followed the manufacturers’ instructions,” said Boone. Because of resource constraints, however, the FDA wasn’t able to implement that review. “This left us with a bit of a hole in the overall process,” Boone added.

Since the first CLIA ’88 regulation was published in 1992, test technology has changed tremendously, and the number of unit-use devices and waived tests on the market has increased dramatically. For some test systems, the capability to perform QC with the usual liquid-based control materials has been