CLSI Publishes New Guideline Describing the Principles of Estimating Measurement Uncertainty

Wayne, Pennsylvania, USA-The Clinical and Laboratory Standards Institute (CLSI) recently published Expression of Measurement Uncertainty in Laboratory Medicine; Approved Guideline (C51-A). This document describes a practical approach to assist clinical laboratories and in vitro diagnostic device manufacturers in developing and calculating useful estimates of measurement uncertainty, and illustrates their application in maintaining and improving the quality of measured values used in patient care.
C51 illustrates the assessment of measurement uncertainty with both bottom-up and top-down approaches. The bottom-up approach suggests that all possible sources of uncertainty are identified and quantified in an uncertainty budget. A combined uncertainty is calculated using statistical propagation rules. The top-down approach directly estimates the measurement uncertainty results produced by a measuring system. Methods to estimate the imprecision and bias are presented theoretically and in worked examples.

"Uncertainty is the modern way to describe the relevance of a result of measurement," states Anders Kallner, MD, PhD, Associate Professor of Clinical Chemistry, Karolinska Hospital, Stockholm, Sweden, and Chairholder of the document development committee. "This document describes the concept and how it can be used in practice in an easy and straightforward way."

The guideline discusses the definition of what is intended to be measured, lists sources of measurement uncertainty, describes the generation of statistical estimates of uncertainties and their combination, and discusses the use of uncertainty estimates.

The objectives of this document are to:

- Familiarize the reader with the concept of measurement uncertainty.
- Describe the processes of implementing the concept of measurement uncertainty in laboratory medicine.
- Describe the practical approaches to developing relevant and useful estimates of measurement uncertainty.
- Discuss the uses of the measurement uncertainty information obtained.

"Measurement uncertainty is a relatively recent, but essential concept for comparing measurements across time and place," explains David L. Duewer, PhD, Analytical Chemistry Division, National Institute of Standards and Technology, and a member of the document development committee. "The document, championed and guided by the late Richard R. Miller, Jr., seeks to help the clinical chemistry

communities better understand, make use of, and estimate measurement uncertainty."

The principles for expression of measurement uncertainty provided in the document illustrate how the components of measurement uncertainty can be combined to help estimate the performance characteristics that can be reliably achieved by the measuring system. The recommendations provided are consistent with the Guide to the expression of uncertainty in measurement (GUM) and with the International Organization for Standardization (ISO) standards concerned with laboratory accreditation.

CLSI and the Association of Public Health Laboratories (APHL) have announced a related webinar to this document. The webinar, Uncertainty in Measurements - Estimation and Practical Use, will take place on April 5, 2012 from 1:00 PM to 2:00 PM Eastern (US) Time. Dr. Kallner, the aforementioned Chairholder of the C51 document development committee and the speaker for this webinar, will discuss how uncertainty in measurement is internationally established in all fields of analytical chemistry, physics, and other disciplines.

CLSI is a volunteer-driven, membership-supported, nonprofit organization dedicated to developing standards and guidelines for the health care and medical testing community through a consensus process that balances the perspectives of industry, government, and the health care professions. For additional information, visit the CLSI website at www.clsi.org [1] or call 610.688.0100.

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