Setting the **Global Standard for Quality**in Laboratory Testing

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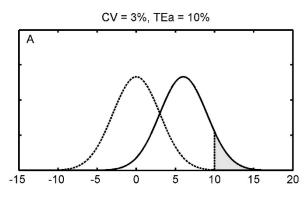
To: Recipients of C24, 4th ed.

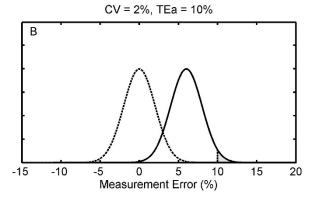
From: Jennifer K. Adams, MT(ASCP), MSHA

Subject: Clarifications and Corrections

This notification is to inform you of clarifications and corrections made to CLSI document C24, *Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions*, 4th ed. The clarifications and/or corrections are shown as highlighted and/or stricken text in the items listed below.

• Additional clarifying text was added to the legend for Figures 2A and 2B on page 13.

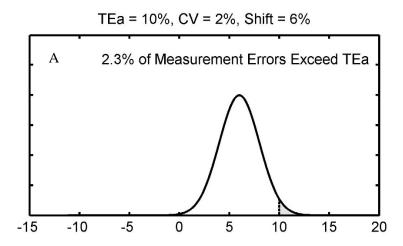


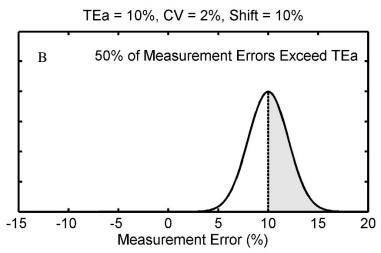


Abbreviations: CV, coefficient of variation; TEa, allowable total error.

Figures 2A and 2B. Illustration of the Effect of Shift in Measurement Error Under Different CVTEa Conditions at the Same TEa. The shaded areas represent the fraction with error that exceeds TEa.

- A correction was made in the fifth paragraph of Subchapter 3.3.2, Imprecision. The text
 was revised to read, "For example, for a procedure calibrated every dayin every run,
 measurements over 20 days fairly reliably represent that source of variability, as well as
 other sources of variability that are exercised every day (eg, pipetting error)."
- A clarification was made to the legend for Figures 3A and 3B on page 21.





Abbreviations: CV, coefficient of variation; TEa, allowable total error.

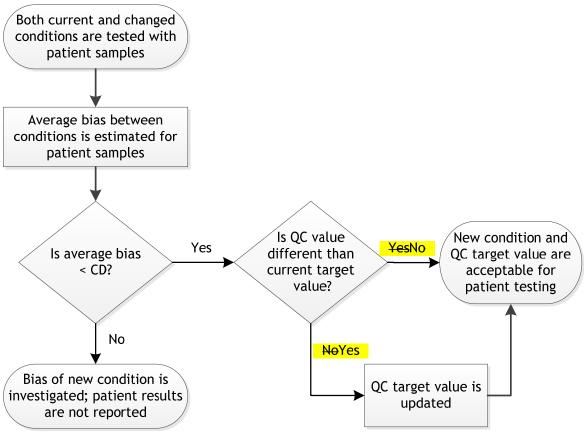
Figures 3A and 3B. Influence of the Magnitude of a Change in Bias for a Measurement Procedure on the Number of Patient Results Affected by the Error Condition. The shaded areas represent the fraction with an error condition that exceeds TEa.

- A minor editorial change was made in Subchapter 5.1.1, Sources of Information. The text in the first paragraph was revised to read, "The recommendations from this conference were updated in 2014.^{32,33} The strategic conferences described three models of goal setting listed in descending order of preference."
- A clarification was made in the second paragraph of Subchapter 5.3.1, Stable Total Imprecision (Standard Deviation) for Each Control Material. The text was revised to read, "Once enough QC results have been accumulated for the new measurement procedure, the initial SD should be updated to reflect additional sources of variability that influence

the long-term estimate of SDthe long-term variability of the new measurement procedure."

A change was also made in the fifth paragraph of Subchapter 5.3.1. The reference was changed from CLSI document EP15⁴⁸ to CLSI document EP26,⁴⁶ ie, "For some measurement procedures, QC materials may exhibit a change in numeric values when a reagent lot is changed (see CLSI document EP15⁴⁸EP26⁴⁶)."

An editorial correction was made to Figure 4 on page 30.



^{*} Five basic symbols are used in process flow charts: Oval (signifies the beginning or end of a process), Arrow (connects process activities), Box (designates process activities), Diamond (includes a question with alternative "Yes" and "No" responses), Pentagon (signifies another process).

Abbreviations: CD, critical difference that would alter a decision made for patient care; QC, quality control. Figure 4. Flow Chart for Verifying Performance Following Any Change in Conditions That Alters the QC Target Value Without Affecting the Results for Patient Specimens.* A change in conditions could be a new reagent lot, a component replacement, maintenance, or other procedure that may affect the QC differently than it affects the patient results.

 A minor clarifying change was made to the second to last paragraph in Subchapter 8.4, Select Quality Control Strategy. The text was revised to read, "This QC strategy, including number of controls, rule selection, and frequency of measurement, is determined by the laboratory director in order to meet the needs of the patients served."

If you require any additional clarification regarding these corrections, please contact CLSI Customer Service (customerservice@clsi.org).

We appreciate your commitment to CLSI, and regret any inconvenience.