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To: Recipients of EP15-A3

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

Subject: Corrections

This notification is to inform you of technical and editorial corrections made to CLSI document EP15-A3, *User Verification of Precision and Estimation of Bias; Approved Guideline—Third Edition*. The corrections are shown as highlighted and/or stricken text in the items listed below.

Technical correction:

- A correction was made in Section 3.5, The Verification Interval.

  In equation (11), a superscripted "2" was added after the closing parenthesis. The equation was revised to read:

$$df_C = \frac{\left(se_{\bar{\bar{x}}}^2 + se_{RM}^2\right)^2}{\frac{se_{\bar{\bar{x}}}^4}{df_{\bar{\bar{x}}}} + \frac{se_{RM}^4}{df_{RM}}}$$

Editorial corrections:

- Two consistency corrections were made throughout the document as necessary:
  - All instances of "s_R" and "s_{WL}" were corrected to use a lowercase "*s*."
  - All instances of "σ" in "σ_R" and "σ_{WL}" were italicized.

- Corrections were made in Section 2.3.5, Imprecision Estimates by One-Way Analysis of Variance.

  In the Abbreviations list in Table 4, two instances of "total" were italicized. The Abbreviations list was revised to read:

  Abbreviations: ANOVA, analysis of variance; *DF*, degrees of freedom; *DF*~~total~~*total*, total degrees of freedom; *MS*, mean squares; *SS*, sum of squares; *SS*~~total~~*total*, total sum of squares.

In the "Important Note" callout based on the last sentence of the last paragraph, the subscripted "*B*" was capitalized. The callout was revised to read, "Estimating and expressing s_R, ~~s_b~~s_B, and s_{WL} helps the laboratory identify and quantify the sources of uncertainty."

- A correction was made in the Upper Verification Limit section of Section 2.3.6.2, Performing the Comparisons. The "R" in "%CV$_R$" was italicized and subscripted. The text was revised to read, "...or as a %CV (%CV = %CV~~R~~$_R$ or %CV = %CV$_{WL}$)."

- A correction was made in Scenario E in Section 3.3, Target Values and Their Standard Errors. "se_{RM}" was italicized. The text was revised to read, "When working with a commercial QC material supplied with a TV for which the standard error cannot be estimated, set ~~se$_{RM}$~~se_{RM} = 0."

- Corrections were made in Section 3.5, The Verification Interval.

  In equation (14), the "s" in the first set of parentheses was italicized, italics were removed from "0.975," and the multiplication sign was changed to a multiplication dot. The equation was revised to read:

  $VI = \text{TV} \pm (m \bullet$ ~~s~~$se_c) = \text{TV} \pm (t_{$~~0.975~~$0.975}, df_c$ ~~×~~$\bullet\, se_c)$

  In Table 15B's title, "N_{RM}" was italicized and "*RM*" was subscripted. The text was revised to read, "…With Five Replicates per Run, and ~~NRM~~N_{RM} = 10, 20, 50, 100 and ≥ 200 Laboratories."

  In Table 15C's title, "*z*" was changed to "N_{RM}." The text was revised to read "…With Five Replicates per Run, and ~~z~~N_{RM} = 10, 20, 50, 100 and ≥ 200 Laboratories."

- A correction was made in the second paragraph of Section 3.6, Interpretation. Italics were removed from "0.975" and the multiplication sign was changed to a multiplication dot. The text was revised to read, "…compare the defined allowable bias to the expanded combined uncertainty (half width of the CI for the bias, $t_{$~~0.975~~$0.975}, df_c$ ~~×~~$\bullet\, se_c$)."

- A correction was made in Step 2 in Section 3.7.2, Worked Example 1B: Ferritin Precision Example in Section 2.3.10 Using Statistics From Manufacturer's Claims. The letter "A" was removed before the equation, and the unit of measure was changed from "g/L" to "µg/L." The equation was revised to read:

$$se_{RM} = \frac{s_{RM}}{\sqrt{nLab}} = \frac{4.5\ \mu\text{g/L}}{\sqrt{43}} = 0.69\ \mu\text{g/L}.$$

A correction was made in Step 9 in Section 3.7.5, Worked Example 3A: Testing of Sample Spiked With Digoxin Using Statistics From the Precision Experiment (Extremely High s_{WL} / s_R). A negative sign was added to "0.03." The text was revised to read, "The observed bias of −0.03 µg/L is not statistically significant."

- A correction was made in the second to last sentence in Section 3.7.7, Worked Example 4: Testing of Sample Spiked With Digoxin Using Statistics From the Manufacturer's Claims. The "*WL*" was subscripted. The text was revised to read, "The interpolated %CV~~*WL*~~*WL* claim was (6.48% + 1.91%) / 2 = 4.20%."

- A correction was made in Section B5 of Appendix B, Determining the Upper Verification Limit Factor, *F*. An end parenthesis was added after "34.17" and italics were removed from "UVL." The text was revised to read "(For example, in a study involving two samples, if $df = 20$, then $X2 = 34.17$). Then, calculate the ~~*UVL*~~UVL factor, $F = \sqrt{X2 / df}$."

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.