



December 2016

To: Recipients of C24, 4th edition
From: Jennifer K. Adams, MT(ASCP), MSHA
Subject: Editorial omission in Subchapters 8.2 and 8.4

This notification is to inform you of an editorial omission in CLSI document C24, *Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions*. 4th ed. In response to comments received during the Proposed Draft voting stage, two examples detailed in Chapter 8 were changed by increasing the number of concentrations for TSH from two (2) to three (3) and decreasing the number of concentrations for calcium from three (3) to two (2) (see Tables 3 and 4 in subchapters 8.3 and 8.4). However, the associated text in Subchapters 8.2 and 8.4 was not changed to reflect the changes made in the examples. Therefore, edits to Subchapters 8.2 and 8.4 were made for consistency.

The revisions to Subchapter 8.2 on page 43 are shown as highlighted and stricken text shown below.

For both TSH and calcium, commercially available QC materials are selected due to appropriate concentrations, product stability, and shelf life. ~~Two~~ **Three** concentrations are ~~suitable~~ **available** for TSH ~~its measurement performance is excellent relative to the TEa requirement (see Subchapter 8.4 and Table 4)~~ **because both very low and high values are medically meaningful.** ~~Three~~ **Two** concentrations are available for calcium because ~~its measurement performance is marginally adequate relative to the TEa requirement (see Subchapter 8.4 and Table 4)~~ **the measuring interval is relatively small and performance is similar at all concentrations.**

The revision to Subchapter 8.4 on page 44 is shown as stricken text shown below.

The estimated Sigma metrics for calcium suggest that small changes in measurement procedure performance may affect medical decisions. Identifying small changes in performance entails more complex QC rules involving a multirule approach designed to increase the probability of detecting a change in measurement procedure performance, while keeping false rejections to a tolerable frequency. A candidate strategy is using 1_{3s} , 2_{2s} , 4_{1s} and R_{4s} rules together with two QC concentrations at every QC event. Adding a CUSUM or EWMA rule would also be useful to identify trends before a significant error condition might occur.

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.