D5437
(Rev. 140, Issued: 05-29-15, Effective: 05-29-15, Implementation: 05-29-15)

§493.1255 Standard: Calibration and calibration verification procedures

(a) Perform and document calibration procedures -

(a)(1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer;

(a)(2) Using the criteria verified or established by the laboratory as specified in §493.1253(b)(3)--

(a)(2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and

(a)(2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and

(a)(3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

Interpretive Guidelines §493.1255(a)

Laboratories must follow the manufacturer's instructions on carrying out the calibration and must follow or exceed the manufacturer's frequency recommendations for calibration.

The calibration requirement does not apply to a variety of procedures, which include, but are not limited to:

- Manual procedures not involving an instrument (e.g., microbiology cultures, Kirby-Bauer disk susceptibility tests, tilt-tube prothrombin time test systems, ABO group and D (Rho) typing);

- Microscopic procedures (e.g., KOH preparations, pinworm preparations, urine sediment analysis, all manual differential procedures, manual cytology screening procedures); and

- Test systems which include instruments that cannot be adjusted or calibrated because they are factory or manufacturer calibrated (e.g. unit use devices). This would include prothrombin time procedures on a fibrometer, or instruments that utilize a whole blood specimen and single unit use cartridge (PT/INR, Activated Clotting Time).

The term "calibration material" has generally replaced "standard" since many instruments now use serum-based reference materials. "Calibration material" means a solution that

has a known amount of analyte weighed in or has a value determined by repetitive testing using a reference/definitive test method or is traceable to a National Institute for Standards and Technology (NIST) Standard, if possible.

Test method calibration procedures must follow the manufacturer's instructions on carrying out the calibration and must follow or exceed the manufacturer's frequency recommendations for calibration. However, if a calibration system proves less stable than expected by the manufacturer, additional calibration materials and/or more frequent calibration may be required, as established or verified by the laboratory under §493.1253(b)(3).

The actual measurement(s) taken, reactions and/or observations must be recorded.

Probes §493.1255(a)

If the laboratory calculates values for one or more calibration materials, are the calculations correct, and do the records reflect that the measured values are within the laboratory's established limits for the calibration materials?