D5439

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§493.1255 Standard: Calibration and calibration verification procedures

(b) Perform and document calibration verification procedure -

(b)(1) Following the manufacturer's calibration verification instructions;

(b)(2) Using the criteria verified or established by the laboratory under §493.1253(b)(3)--

(b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and

(b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and

(b)(3) At least once every 6 months and whenever any of the following occur:

(b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes.

(b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance.

(b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem.

(b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

Interpretive Guidelines §493.1255(b)

The calibration verification requirements may be met by verifying the procedure using a high-level material such as a control, calibration material, or patient specimen and diluting it to cover the reportable range if allowed by the manufacturer.

Control activities routinely used to satisfy the requirement for §493.1256 do **not** satisfy the calibration verification requirements.

EXCEPTIONS:

1. Laboratories must perform and document calibration procedures following the manufacturer's test system instructions, using calibration materials provided or specified, and at a frequency that is recommended by the manufacturer. Where the manufacturer does not provide such instruction, the laboratory may calibrate using 3 or more levels of calibration materials that include a low, mid, and high value at least every 6 months.

2. *If the laboratory performs a calibration protocol using 3 or more levels of calibration materials that include a low, mid, and high value at least every 6 months, the calibration verification requirement is met.*

3. For automated cell counters, the calibration verification requirements are considered met if the laboratory follows the manufacturer's instructions for instrument operation and tests 2 levels of control materials each day of testing provided the control results meet the laboratory's criteria for acceptability. This exception does not apply to centrifugal hematology test systems.

4. For automated chemistry analyzers, the calibration verification requirements are considered met if the laboratory follows the manufacturer's instructions for instrument operation and routinely tests three levels of control materials (lowest level available, mid-level, and highest level available) more than once each day of testing, the control material results meet the laboratory's criteria for acceptability and the control materials are traceable to National Institute of Standards and Technology (NIST) reference materials.

Calibration materials, proficiency testing samples with known results, or control

materials with known values may be used to perform calibration verification. For these materials, the laboratory must define acceptable limits for the difference between the measured value obtained, versus the actual concentration of the materials.

NOTE: PT samples can only be used after the event cut-off date.

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

If a manufacturer provides reagents for a test where all of the reagents for a test are packaged together, calibration verification is not required for each additional reagent package with the same lot number that is received in the same shipment. For example, if the laboratory receives 12 packs of reagents and the laboratory has verified calibration for at least one of the 12 packs of reagents, then the laboratory does not have to verify calibration for the remaining 11 packs of reagents provided that all 12 packs of reagents have the same lot number and were received on the same shipment to the laboratory. However, this exception does not override the requirement to perform calibration verification as specified at 493.1255(b)(3).

5. Calibration verification is not required on:
    - Instruments that are factory or manufacturer calibrated and/or
    - Tests that are considered non-quantitative (e.g., Prothrombin time and Activated Clotting Time, which are measured in units of time)

When reviewing the laboratory's maintenance and function check records as required in §493.1254, determine whether the laboratory performed calibration verification when major maintenance occurred or critical parts were replaced.
The actual measurement(s) taken, reactions and/or observations must be recorded.

Probes §493.1255(b)

If a laboratory does not perform calibration verification after a complete change of reagents, what data does the laboratory have to document that changing reagent lot numbers does not affect the reportable range of patient test results, and does not adversely affect control results?