CMS- 2226-F: 42 CFR 493 Medicare, Medicaid, and CLIA Programs; Laboratory Requirements Relating to Quality Systems and Certain Personnel Qualifications; Final Rule on January 24, 2003, with an effective date of April 24, 2003.

Subpart K, Part 1, Quality System for Nonwaived Testing; General Laboratory Systems, Preanalytic Systems & Analytic Systems, Section 493.1255(b):

Standard: Calibration and calibration verification procedures

(b) Perform and document calibration verification procedures –
- (b)(1) Following the manufacturer's calibration verification instructions;
- (b)(2) Using the criteria verified or established by the laboratory under Section 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.

The College of American Pathology (CAP) position regarding calibration verification:

"Calibration or calibration verification must be performed at least once every 6 months, as specified under CLIA-88 regulations at 42CFR493.1255(b)(3). Successful calibration verification certifies that the calibration is still valid; unsuccessful calibration verification requires remedial action, which usually includes recalibration. The performance of recalibration or a calibration verification procedure resets the calendar to a new maximum 6-month interval before the next required reassessment. Methods that are recalibrated more frequently than every 6 months do not require a separate calibration verification procedure.

The recalibration interval is established by each laboratory. Manufacturers of method systems often recommend a standard interval when the method system is stable. The recalibration interval may be extended if calibration verification is performed and the results meet the established criteria of the laboratory. Criteria for determining the recalibration interval include:

1. a change of chemically or physically active or critical reagents
2. QC fails to meet established criteria
3. after major maintenance or service
4. calibration verification data fail laboratory acceptance criteria
5. when recommended by the manufacturer

Each laboratory must establish its own criteria for recalibration interval."

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The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) position regarding calibration verification:

"The 2004 Comprehensive Accreditation Manual (CAM) has a footnote in the Clinical Chemistry Standards section to Standard QC.6.20 that states that moderate and high complexity instrumentation are currently required to perform calibration verification every six months. This was presented in the 2004 CAM as a footnote because the publication had already gone to print at the time of the recently adopted CLIA-88 requirements. We are reviewing the changes to CLIA for potential changes to our 2005 standards manual publication. Any requirements that are more stringent will have to be integrated into our standards."

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