D5425

(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

§493.1253 Standard: Establishment and verification of performance specifications

(b)(3) Determination of calibration and control procedures. The laboratory must determine the test system's calibration procedures and control procedures based upon the performance specifications verified or established under paragraph (b)(1) or (b)(2) of this section.

Interpretive Guidelines §493.1253(b)(3)

Through the verification/establishment process, the laboratory defines the frequency for calibration and control performance as well as the type, number, and concentration of calibration and control materials used to monitor, detect error, and evaluate method performance. The frequency for calibration and control performance must not be less than the frequency specified in the manufacturer's instructions.

In establishing the calibration and quality control frequency, the laboratory must consider:

- Test system instrument/reagent stability, including relocation;
- Frequency with which the test is performed;

- Technique dependence of the method;
- Frequency of quality control failures; and
- Training, experience, and competency of technical personnel.

For additional criteria in determining calibration and quality control frequency refer to §§493.1255 and 493.1256.