
42 C.F.R. § 493.1256

Standard: Control procedures.

- (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process.
- (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in § 493.1253(b)(3).
- (c) The control procedures must—
- (1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance.
 - (2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance.
- (d) Unless CMS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must—
- (1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at §§ 493.1261 through 493.1278.
 - (2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section.

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