

requirements at § 493.1215, Equipment maintenance and function checks. Other commenters requested clarification. One commenter felt that the requirements were too stringent, and another offered specific language for revision. One commenter felt CMS, not the manufacturer, should establish the frequency for performing function checks.

*Response:* Equipment maintenance and function checks are necessary to ensure accurate and reliable test performance. We are relocating the requirement formerly at § 493.1215 (now at § 493.1254) and renaming it Maintenance and function checks. Laboratories using unmodified manufacturers' equipment, instruments, or test systems must perform maintenance and function checks as defined by the manufacturer with at least the frequency specified by the manufacturer. Laboratories must also document maintenance and function checks performed. We are adding language at § 493.1254(a)(2) requiring that function checks be within the manufacturer's established limits before conducting patient testing. We are also retaining the present requirement (now at § 493.1254(b)) for laboratories to establish protocols that ensure proper test system performance, accurate and reliable test results and test reporting for equipment, instruments, or test systems developed in-house, commercially available but modified by the laboratory, or when protocols for maintenance and function checks are not provided by the manufacturer. In addition, laboratories must document the maintenance and function checks performed.

Under this final rule, we are not defining intervals for the performance of maintenance or function checks because the manufacturer is better able to define the appropriate procedures and intervals necessary to maintain and ensure proper equipment, instrument, and test system performance.

*Comment:* Several commenters suggested that § 493.1217, calibration and calibration verification, or substantially equivalent requirements, should also apply to FDA-approved or cleared, unmodified moderate complexity testing at § 493.1202(c). In addition, we received comments requesting clarification of § 493.1217. One commenter stated that CMS, not the manufacturer, should establish the frequency of calibration. A manufacturer commented that a loose interpretation of the calibration verification requirement to assay calibration materials in the same manner as patient samples is needed for certain blood gas analytes because

buffers and gases used to calibrate the instruments are not like patient samples and cannot be assayed in the same manner as patient samples.

*Response:* We agree with the commenters and are specifying in this final rule that effective, April 24, 2003, calibration and calibration verification requirements (now at § 493.1255) will apply to all nonwaived testing.

To respond to the commenters' concerns that the calibration and calibration verification requirements are unclear, we are making some minor revisions in language for clarification purposes and removing duplicate requirements. For example, the definitions of calibration and calibration verification and reportable range are being slightly modified (now at § 493.2). We are also removing the requirement formerly at § 493.1217(b)(2)(ii)(B)(1) for laboratories to perform calibration verification using calibration materials appropriate for the methodology and, if possible, traceable to a reference method or reference material of known value to allow laboratories flexibility in choosing materials for calibration verification.

In addition, we are retaining the requirement for laboratories, at a minimum, to perform calibration and calibration verification procedures using the manufacturers' test system instructions and the criteria verified or established by the laboratory formerly at §§ 493.1217(b)(1) and 493.1217(b)(2) (now at §§ 493.1255(a)(1), 493.1255(a)(2), 493.1255(b)(1) and 493.1255(b)(2)). We are also retaining the requirement that calibration must be performed whenever calibration verification procedures are unacceptable and calibration verification be performed using a minimum of 3 values to verify the laboratory's reportable range, at least once every 6 months or whenever an event occurs as specified formerly at § 493.1217(b)(2)(ii)(C) (now at § 493.1255(b)(3)).

In response to the comment that the frequency of calibration be mandated by CMS, we are retaining the requirement formerly at § 493.1217(b)(1) (now at § 493.1255(a)) that requires laboratories to calibrate according to the manufacturer's instructions, if provided, and the laboratory's specifications. We believe that laboratories should perform calibration at the interval specified by the manufacturer to ensure proper instrument and test system performance. For calibration verification formerly at § 493.1217(b)(2) (now at § 493.1255(b)), laboratories are to follow the manufacturer's specifications and the laboratory's established protocols for calibration verification that must be performed at least once every 6 months.

We believe this is the maximum interval allowable for verifying accuracy and stability. In addition, we are emphasizing that these regulations set forth minimal requirements. In establishing or verifying performance specifications as required at § 493.1253, the laboratory may find it necessary to calibrate or verify calibration more frequently or to use more calibration materials than required at § 493.1255.

In response to the comment concerning the inability of testing calibration materials (buffers and gases) in the same manner as patient specimens when verifying the calibration of blood gas assays, we are retaining the additional requirements for routine chemistry formerly at § 493.1245 (now at § 493.1267) that supersede the general calibration and calibration requirements at § 493.1255. Section 493.1267(a) specifically addresses calibration and calibration verification of blood gas analyses and states the laboratory must calibrate or verify calibration according to the manufacturer's specifications and with at least the frequency recommended by the manufacturer. As long as the laboratory follows the manufacturer's calibration and calibration verification instructions for the blood gas instrument, the CLIA requirements for calibration and calibration verification are met.

*Comment:* We received many comments concerning various components of § 493.1218, Control procedures. Some commenters misread the CLIA regulation, and others offered specific language for revision. Most commenters opposed testing two levels of control material each day of use. One commenter indicated that the CLIA requirements are burdensome and will increase the cost of testing. Some commenters expressed concern that the requirements are arbitrary and do not recognize unit use test systems. Another commenter asked if procedural controls may be used to satisfy the control requirements.

*Response:* We appreciate the commenters' concerns about the frequency and costs of performing control testing. However, CLIA regulations will continue to describe the purpose of control procedures, that is, to assess the accuracy and precision of test performance. The control procedures must monitor the complete analytical process by detecting immediate errors (those that occur due to test system failure, adverse environmental conditions or operator performance problems) and monitor over time the accuracy and precision of test performance that can be influenced by