

Subcategory), High Complexity, or Any Combination of These Tests, and Subpart P—Quality Assurance for Moderate Complexity (Including the Subcategory) or High Complexity Testing, or Any Combination of These Tests, into a new Subpart J—Facility Administration for Nonwaived Testing, and Subpart K—Quality Systems for Nonwaived Testing. Below, we have only set forth substantive revisions to subparts J and K.

*Subpart J—Facility Administration for Nonwaived Testing*

- We revised the heading of subpart J to read Facility Administration for Nonwaived Testing.
- We revised subpart J to consist of §§ 493.1100 through 493.1105.
- We specified now at § 493.1100 that laboratories performing nonwaived testing must meet the applicable standard level requirements in §§ 493.1101 through 493.1105.
- We added the requirement now at § 493.1101(c) that laboratories must comply with Federal, State, and local requirements concerning laboratories and ensure that adequate safety precautions are in place to provide protection from laboratory hazards.
- We revised the language now at § 493.1101(d) (formerly at § 493.1204(b)) requiring safety procedures to be accessible rather than posted.
- We clarified the record keeping requirements now at § 493.1101(e) for laboratories to store and maintain records in a manner that ensures proper preservation. This clarification applies to the requirements now at § 493.1771(c) and (d), and former §§ 493.1105, 493.1107, and 493.1221 introductory text.
- We removed the language formerly at § 493.1103(c) regarding laboratories providing oral instruction to patients as a supplement to written instructions, when appropriate.
- We clarified the requirement now at § 493.1103(d) (formerly at § 493.1271) that the facility must report transfusion reactions to the laboratories and, as appropriate, to Federal and State authorities.
- We revised the language now at § 493.1105(a)(3)(i) (formerly at § 493.1221) to specify that the laboratory must retain records of test system performance specifications that the laboratory establishes or verifies under § 493.1253 for the period of time the laboratory uses the test system but no less than 2 years.
- We revised the language now at § 493.1105(a)(3)(ii) (formerly § 493.1107 introductory text) and § 493.1105(a)(6)(i) (formerly § 493.1109 introductory text)

to specify the record retention requirements for immunohematology and blood and blood products to ensure consistency with the FDA requirements.

- We revised the requirement now at § 493.1105(a)(6) (formerly § 493.1109 introductory text) to remove the words “exact duplicate” and specify that the laboratory must be able to retrieve a copy of the original report.

*Subpart K—Quality Systems for Nonwaived Testing*

- We revised the heading of subpart K to read “Quality Systems for Nonwaived Testing.”
- We revised subpart K to consist of §§ 493.1200 through 493.1299.
- We revised the introductory text now at § 493.1200 to provide an overview of quality systems, including the importance of ongoing assessment of these systems, and the laboratory’s responsibility for establishment and maintenance of appropriate policies and procedures.
- We removed the lead-in paragraph formerly at § 493.1201(a) explaining the division between general QC and the QC for the specialties and subspecialties.
- We removed the requirement formerly at § 493.1201(a)(1) regarding the clearance process for alternative QC procedures that were never established by the FDA.
- We removed the requirement formerly at § 493.1203 regarding the clearance process for moderate complexity testing.
- We redesignated the requirement formerly at § 493.1205 regarding test methods, equipment, instrumentation, reagents, materials, and supplies. We incorporated the majority of these provisions into § 493.1252. The requirements formerly at § 493.1205(b) are now at § 493.1101(b) and the biologic product dating requirements formerly at § 493.1205(e) are now at § 493.1271(b).
- We removed the requirement formerly at § 493.1213(b)(1) regarding the QC clearance process for the manufacturer’s process for verification of performance specifications for new patient testing devices introduced by the laboratory.
- We removed the requirement formerly at § 493.1215(a)(1) regarding the CLIA QC clearance process for maintenance of equipment, instruments, and test systems.
- We removed the requirement formerly at § 493.1217(a) regarding the CLIA QC clearance process for use of the manufacturer’s instructions for calibration and calibration verification procedures.

- We removed the requirement formerly at § 493.1217(b)(2)(ii)(B)(1) (calibration verification requirement) regarding use of calibration materials traceable to a reference method or reference material of known value to allow flexibility in choosing material for calibration verification.

- We removed the requirements formerly at § 493.1225, the Condition of Microbiology, as it is a duplicate of the requirements under the Conditions of Bacteriology, Mycobacteriology, Mycology, Parasitology, and Virology, now at §§ 493.1201, 493.1202, 493.1203, 493.1204, and 493.1205, respectively.

- We clarified the requirement now at § 493.1236 (formerly at § 493.1707) that laboratories must verify the accuracy of any analyte, specialty, or subspecialty when it is assigned a proficiency testing score that does not reflect laboratory test performance.

- We added the requirement now at § 493.1236(c)(2) that laboratories verify twice annually the accuracy of tests listed in subpart I for which compatible PT material is not available from approved PT programs.

- We removed the requirement formerly at § 493.1237, the Condition of Diagnostic Immunology, as it is a duplicate of the requirements under the Conditions of Syphilis Serology and General Immunology now at §§ 493.1207 and 493.1208, respectively.

- We revised the language now at § 493.1241(b) (formerly at § 493.1105) to clarify that an oral request for laboratory tests is permitted only if laboratory requests written or electronic authorization for testing within 30 days of the oral request and documents the efforts made to obtain a written or electronic authorization.

- We revised the language now at § 493.1241(c)(3) (formerly at § 493.1105(e) and (f)) to specify that the test requisition must solicit the patient’s sex and age or date of birth.

- We added the requirement now at § 493.1241(c)(5) (formerly § 493.1105(f)) that the laboratory must ensure that the test requisition solicits the source of the specimen when appropriate.

- We revised the language now at § 493.1241(c)(7) (formerly at § 493.1105(e)) removing the age or date of birth requirement for Pap smear requisitions because it is now a requirement for all test requisitions at § 493.1241(c)(3).

- We revised the requirement now at § 493.1241(e) (formerly § 493.1701) to provide clarification that if the laboratory transcribes or enters test requisition or authorization information into a record system or laboratory information system, the laboratory must