

“§§ 493.1105(a)(7)(i)(A) and 493.1274(f)(2)”.

18. Subpart J, consisting of §§ 493.1100 through 493.1105, and subpart K, consisting of §§ 493.1200 through 493.1299, are revised to read as follows:

**Subpart J—Facility Administration for Nonwaived Testing**

Sec.

- 493.1100 Condition: Facility administration.
- 493.1101 Standard: Facilities.
- 493.1103 Standard: Requirements for transfusion services.
- 493.1105 Standard: Retention requirements.

**Subpart K—Quality Systems for Nonwaived Testing**

- 493.1200 Introduction.
- 493.1201 Condition: Bacteriology.
- 493.1202 Condition: Mycobacteriology.
- 493.1203 Condition: Mycology.
- 493.1204 Condition: Parasitology.
- 493.1205 Condition: Virology.
- 493.1207 Condition: Syphilis serology.
- 493.1208 Condition: General immunology.
- 493.1210 Condition: Routine chemistry.
- 493.1211 Condition: Urinalysis.
- 493.1212 Condition: Endocrinology.
- 493.1213 Condition: Toxicology.
- 493.1215 Condition: Hematology.
- 493.1217 Condition: Immunohematology.
- 493.1219 Condition: Histopathology.
- 493.1220 Condition: Oral pathology.
- 493.1221 Condition: Cytology.
- 493.1225 Condition: Clinical cytogenetics.
- 493.1226 Condition: Radiobioassay.
- 493.1227 Condition: Histocompatibility.

**General Laboratory Systems**

- 493.1230 Condition: General laboratory systems.
- 493.1231 Standard: Confidentiality of patient information.
- 493.1232 Standard: Specimen identification and integrity.
- 493.1233 Standard: Complaint investigations.
- 493.1234 Standard: Communications.
- 493.1235 Standard: Personnel competency assessment policies.
- 493.1236 Standard: Evaluation of proficiency testing performance.
- 493.1239 Standard: General laboratory systems assessment.

**Preanalytic Systems**

- 493.1240 Condition: Preanalytic systems.
- 493.1241 Standard: Test request.
- 493.1242 Standard: Specimen submission, handling, and referral.
- 493.1249 Standard: Preanalytic systems assessment.

**Analytic Systems**

- 493.1250 Condition: Analytic systems.
- 493.1251 Standard: Procedure manual.
- 493.1252 Standard: Test systems, equipment, instruments, reagents, materials, and supplies.
- 493.1253 Standard: Establishment and verification of performance specifications.

- 493.1254 Standard: Maintenance and function checks.
- 493.1255 Standard: Calibration and calibration verification procedures.
- 493.1256 Standard: Control procedures.
- 493.1261 Standard: Bacteriology.
- 493.1262 Standard: Mycobacteriology.
- 493.1263 Standard: Mycology.
- 493.1264 Standard: Parasitology.
- 493.1265 Standard: Virology.
- 493.1267 Standard: Routine chemistry.
- 493.1269 Standard: Hematology.
- 493.1271 Standard: Immunohematology.
- 493.1273 Standard: Histopathology.
- 493.1274 Standard: Cytology.
- 493.1276 Standard: Clinical cytogenetics.
- 493.1278 Standard: Histocompatibility.
- 493.1281 Standard: Comparison of test results.
- 493.1282 Standard: Corrective actions.
- 493.1283 Standard: Test records.
- 493.1189 Standard: Analytic systems assessment.

**Postanalytic Systems**

- 493.1290 Condition: Postanalytic systems.
- 493.1291 Standard: Test report.
- 493.1299 Standard: Postanalytic systems assessment.

**Subpart J—Facility Administration for Nonwaived Testing**

**§ 493.1100 Condition: Facility administration.**

Each laboratory that performs nonwaived testing must meet the applicable requirements under §§ 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7).

**§ 493.1101 Standard: Facilities.**

(a) The laboratory must be constructed, arranged, and maintained to ensure the following:

(1) The space, ventilation, and utilities necessary for conducting all phases of the testing process.

(2) Contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized.

(3) Molecular amplification procedures that are not contained in closed systems have a uni-directional workflow. This must include separate areas for specimen preparation, amplification and product detection, and, as applicable, reagent preparation.

(b) The laboratory must have appropriate and sufficient equipment, instruments, reagents, materials, and supplies for the type and volume of testing it performs.

(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.

(d) Safety procedures must be established, accessible, and observed to

ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.

(e) Records and, as applicable, slides, blocks, and tissues must be maintained and stored under conditions that ensure proper preservation.

**§ 493.1103 Standard: Requirements for transfusion services.**

A facility that provides transfusion services must meet all of the requirements of this section and document all transfusion-related activities.

(a) *Arrangement for services.* The facility must have a transfusion service agreement reviewed and approved by the responsible party(ies) that govern the procurement, transfer, and availability of blood and blood products.

(b) *Provision of testing.* The facility must provide prompt ABO grouping, D(Rho) typing, unexpected antibody detection, compatibility testing, and laboratory investigation of transfusion reactions on a continuous basis through a CLIA-certified laboratory or a laboratory meeting equivalent requirements as determined by CMS.

(c) *Blood and blood products storage and distribution.* (1) If a facility stores or maintains blood or blood products for transfusion outside of a monitored refrigerator, the facility must ensure the storage conditions, including temperature, are appropriate to prevent deterioration of the blood or blood product.

(2) The facility must establish and follow policies to ensure positive identification of a blood or blood product recipient.

(d) *Investigation of transfusion reactions.* The facility must have procedures for preventing transfusion reactions and when necessary, promptly identify, investigate, and report blood and blood product transfusion reactions to the laboratory and, as appropriate, to Federal and State authorities.

**§ 493.1105 Standard: Retention requirements.**

(a) The laboratory must retain its records and, as applicable, slides, blocks, and tissues as follows:

(1) *Test requisitions and authorizations.* Retain records of test requisitions and test authorizations, including the patient's chart or medical record if used as the test requisition or authorization, for at least 2 years.

(2) *Test procedures.* Retain a copy of each test procedure for at least 2 years after a procedure has been discontinued. Each test procedure must include the dates of initial use and discontinuance.