

parameters for each lot of control material. In addition, we are clarifying that the requirement applies to controls with quantitative results. When calibration materials (not used to establish a cutoff value or calibrate the test system) are used as control materials, the laboratory must have statistical parameters for each lot of calibration material.

Comment: Some comments received were in reference to § 493.1219, Remedial actions. One commenter requested clarification and another requested deletion of § 493.1219(a)(2) that requires the laboratory to document all remedial action taken when patient test results are outside of the laboratory's reportable range for the test system. One individual asked for clarification of § 493.1219(d)(3) that requires the laboratory to maintain exact duplicates of both original and corrected reports for 2 years when errors in the reported test results are detected. One commenter suggested that no patient results that are less than the lowest calibrator or higher than the highest calibrator can be reported unless they are reported as less than or greater than the lowest or highest calibrator or the patient specimen is diluted to determine a higher value.

Response: The requirement formerly at § 493.1219(a)(2) (now at § 493.1282(b)(1)(ii)) requires documentation of all remedial actions (now "corrective" actions) when patient values are outside of the laboratory's reportable range of patient test results. The documentation can be an instrument printout or other document that reflects the problem, corrective action, and outcome. The laboratories must retain this information for the required period and the corrective actions themselves may be as elementary as diluting and retesting the specimen. We are not making any revisions to this requirement.

The requirement formerly at § 493.1219(d)(3) (now at § 493.1105(a)(6)) requires the laboratory to maintain a copy of the original report, or be able to retrieve a copy of the original report and the corrected report for 2 years. Copies of test reports may be manually written, photocopies, electronically generated, or maintained on microfilm provided they contain all of the information supplied on the original test record or report.

We agree with the suggestion that results outside of the reportable range of the test system may not be reported without corrective action or explanatory remarks. Therefore, requirements formerly at § 493.1219 (now at § 493.1282, Corrective actions) require

laboratories to have corrective action policies and procedures that are followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This includes policies governing the reporting of patient results that exceed the reportable range of the test system. The analytic assessment requirements at § 493.1289 require the laboratory to monitor and evaluate the corrective actions taken and revise policies and procedures as necessary to prevent recurrences of problems.

Comment: One commenter suggested that CLIA rules require all original worksheets and instrument printouts to be retained for 6 months, indicating that some laboratories destroy, delete, or erase records of unacceptable QC in order to avoid showing remedial action and reassessment of all patient tests results associated with the failure.

Response: We understand the concerns expressed by the commenter. However, we believe the CLIA regulations adequately address documenting all control procedures performed formerly at § 493.1221 (now at § 493.1256(g) and 493.1105(a)(3)), maintaining records of all control procedures performed formerly at § 493.1221 (now § 493.1105(a)(3)), assessing corrective actions taken formerly at § 493.1705 (now at §§ 493.1289(a) and (b)) and retention of the original worksheets and instrument printouts for a period of 2 years or more formerly at § 493.1107 (now at § 493.1105(a)(3)). We also believe that if the laboratory deletes or alters a control result in any manner, it is expected that the laboratory will document the exact circumstances in which deletion or alteration occurred and document all corrective actions taken to prevent reoccurrence.

Comment: One commenter felt that there should be a requirement that any abnormal, life-threatening, or panic value result obtained on a moderate complexity test should be repeated by a more accurate method of testing.

Response: The requirement formerly at § 493.1109(f) (now at § 493.1251(b)(13)) requires laboratories to develop written procedures for reporting life-threatening results (panic or alert values). In addition, under the requirement formerly at § 493.1109(f) (now § 493.1291(g)) laboratories must immediately alert the individual or entity that requested the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition. In addition, it is

the responsibility of each laboratory to ensure that the results it reports are accurate. Repeat testing is one method of verifying the test results. However, it is up to each laboratory to determine the protocols it will follow to confirm the test results that it reports.

Section 493.1223 Condition: Quality Control-Specialties and Subspecialties for Tests of Moderate or High Complexity, or Both

Specific comments received and response to comments regarding § 493.1223, specialty or subspecialty control requirements are set forth below.

Comment: One commenter stated that the specialty and subspecialty QC requirements are too lenient.

Response: The specialty and subspecialty QC requirements are minimum requirements that reflect good laboratory practice and must be followed by all laboratories performing nonwaived testing. However, based on the laboratory's establishment and verification of its test systems' performance specifications (now at § 493.1253), the laboratory may determine that, to ensure accurate and reliable test results, it must implement more stringent control procedures than the minimum requirements imposed. In addition, it is the laboratory director's responsibilities to ensure that the laboratory has systems that ensure the quality of the laboratory services provided and identify failures in quality as they occur (§§ 493.1407(e)(5) and 493.1445(e)(5)).

Comment: One commenter disagreed with § 493.1223 stating a laboratory could lose approval to perform testing in an entire specialty or subspecialty if it is deficient in performing QC for a single test. The commenter urged that the language be changed to "Failure to satisfy requirements for an individual test or analyte would result in loss of approval for that test or analyte only."

Response: We emphasize that CLIA certification of laboratories is not granted on a test-by-test basis, but by specialty or subspecialty of testing. Therefore, if a laboratory has significant problems related to only one test or analyte in a specialty or subspecialty and the laboratory fails to correct those problems, it could jeopardize its certification for the specialty or subspecialty area. For example, the laboratory is notified in writing of the deficiencies found during a survey and is given an opportunity to correct the deficiencies. If the laboratory does not correct the deficiencies, sanctions could be imposed as specified in Subpart R—Enforcement Procedures. Therefore, we are deleting the enforcement