

(3) Adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed;

(4) Follow the laboratory's established policies and procedures whenever test systems are not within the laboratory's established acceptable levels of performance;

(5) Be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the general supervisor, technical supervisor, clinical consultant, or director;

(6) Document all corrective actions taken when test systems deviate from the laboratory's established performance specifications; and

(7) Except as specified in paragraph (c) of this section, if qualified under § 493.1489(b)(5), perform high complexity testing only under the onsite, direct supervision of a general supervisor qualified under § 493.1461.

(c) *Exception.* For individuals qualified under § 493.1489(b)(5), who were performing high complexity testing on or before January 19, 1993, the requirements of paragraph (b)(7) of this section are not effective, provided that all high complexity testing performed by the individual in the absence of a general supervisor is reviewed within 24 hours by a general supervisor qualified under § 493.1461.

[57 FR 7172, Feb. 28, 1992, as amended at 58 FR 5236, Jan. 19, 1993; 60 FR 20050, Apr. 24, 1995]

Subparts N–O [Reserved]

Subpart P—Quality Assurance for Moderate Complexity (Including the Subcategory) or High Complexity Testing, or Any Combination of These Tests

SOURCE: 57 FR 7183, Feb. 28, 1992, unless otherwise noted.

§ 493.1701 Condition: Quality assurance; moderate complexity (including the subcategory) or high complexity testing, or any combination of these tests.

Each laboratory performing moderate complexity (including the subcategory) or high complexity testing, or any combination of these tests, must establish and follow written policies and procedures for a comprehensive quality assurance program that is designed to monitor and evaluate the ongoing and overall quality of the total testing process (preanalytic, analytic, postanalytic). The laboratory's quality assurance program must evaluate the effectiveness of its policies and procedures; identify and correct problems; assure the accurate, reliable and prompt reporting of test results; and assure the adequacy and competency of the staff. As necessary, the laboratory must revise policies and procedures based upon the results of those evaluations. The laboratory must meet the standards as they apply to the services offered, complexity of testing performed and test results reported, and the unique practices of each testing entity. All quality assurance activities must be documented.

[60 FR 20050, Apr. 24, 1995]

§ 493.1703 Standard; Patient test management assessment.

The laboratory must have an ongoing mechanism for monitoring and evaluating the systems required under subpart J, Patient Test Management. The laboratory must monitor, evaluate, and revise, if necessary, based on the results of its evaluations, the following:

(a) The criteria established for patient preparation, specimen collection, labeling, preservation and transportation;

(b) The information solicited and obtained on the laboratory's test requisition for its completeness, relevance, and necessity for the testing of patient specimens;

(c) The use and appropriateness of the criteria established for specimen rejection;

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(d) The completeness, usefulness, and accuracy of the test report information necessary for the interpretation or utilization of test results;

(e) The timely reporting of test results based on testing priorities (STAT, routine, etc.); and

(f) The accuracy and reliability of test reporting systems, appropriate storage of records and retrieval of test results.

§ 493.1705 Standard; Quality control assessment.

The laboratory must have an ongoing mechanism to evaluate the corrective actions taken under § 493.1219, Remedial actions. Ineffective policies and procedures must be revised based on the outcome of the evaluation. The mechanism must evaluate and review the effectiveness of corrective actions taken for—

(a) Problems identified during the evaluation of calibration and control data for each test method;

(b) Problems identified during the evaluation of patient test values for the purpose of verifying the reference range of a test method; and

(c) Errors detected in reported results.

§ 493.1707 Standard; Proficiency testing assessment.

Under subpart H of this part, Proficiency Testing, the corrective actions taken for any unacceptable, unsatisfactory, or unsuccessful proficiency testing result(s) must be evaluated for effectiveness.

§ 493.1709 Standard; Comparison of test results.

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites.

(b) If a laboratory performs tests that are not included under subpart I of this part, Proficiency Testing Programs, the laboratory must have a sys-

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tem for verifying the accuracy of its test results at least twice a year.

[58 FR 5236, Jan. 19, 1993]

§ 493.1711 Standard; Relationship of patient information to patient test results.

For internal quality assurance, the laboratory must have a mechanism to identify and evaluate patient test results that appear inconsistent with relevant criteria such as—

(a) Patient age;

(b) Sex;

(c) Diagnosis or pertinent clinical data, when provided;

(d) Distribution of patient test results when available; and

(e) Relationship with other test parameters, when available within the laboratory.

§ 493.1713 Standard; Personnel assessment.

The laboratory must have an ongoing mechanism to evaluate the effectiveness of its policies and procedures for assuring employee competence and, if applicable, consultant competence.

§ 493.1715 Standard; Communications.

The laboratory must have a system in place to document problems that occur as a result of breakdowns in communication between the laboratory and the authorized individual who orders or receives the results of test procedures or examinations. Corrective actions must be taken, as necessary, to resolve the problems and minimize communication breakdowns.

[58 FR 5236, Jan. 19, 1993]

§ 493.1717 Standard; Complaint investigations.

The laboratory must have a system in place to assure that all complaints and problems reported to the laboratory are documented. Investigations of complaints must be made, when appropriate, and, as necessary, corrective actions are instituted.

§ 493.1719 Standard; Quality assurance review with staff.

The laboratory must have a mechanism for documenting and assessing