

(a) Possess a current license as a laboratory technologist issued by the State, if such licensing exists; and

(b)(1) Have earned a bachelor's degree in medical technology from an accredited university; or

(2) Have successfully completed 3 years of academic study (a minimum of 90 semester hours or equivalent) in an accredited college or university, which met the specific requirements for entrance into a school of medical technology accredited by an accrediting agency approved by the Secretary, and has successfully completed a course of training of at least 12 months in such a school; or

(3) Have earned a bachelor's degree in one of the chemical, physical, or biological sciences and, in addition, has at least 1 year of pertinent full-time laboratory experience or training, or both, in the specialty or subspecialty in which the individual performs tests; or

(4)(i) Have successfully completed 3 years (90 semester hours or equivalent) in an accredited college or university with the following distribution of courses—

(A) *For those whose training was completed before September 15, 1963.* At least 24 semester hours in chemistry and biology courses of which—

(1) At least 6 semester hours were in inorganic chemistry and at least 3 semester hours were in other chemistry courses; and

(2) At least 12 semester hours in biology courses pertinent to the medical sciences; or

(B) *For those whose training was completed after September 14, 1963.*

(1) 16 semester hours in chemistry courses that included at least 6 semester hours in inorganic chemistry and that are acceptable toward a major in chemistry;

(2) 16 semester hours in biology courses that are pertinent to the medical sciences and are acceptable toward a major in the biological sciences; and

(3) 3 semester hours of mathematics; and

(ii) Has experience, training, or both, covering several fields of medical laboratory work of at least 1 year and of such quality as to provide him or her with education and training in medical technology equivalent to that de-

scribed in paragraphs (b)(1) and (2) of this section; or

(5) With respect to individuals first qualifying before July 1, 1971, the technologist—

(i) Was performing the duties of a laboratory technologist at any time between July 1, 1961, and January 1, 1968, and

(ii) Has had at least 10 years of pertinent laboratory experience prior to January 1, 1968. (This required experience may be met by the substitution of education for experience); or

(6) Achieves a satisfactory grade in a proficiency examination approved by HHS.

[58 FR 39155, July 22, 1993]

§ 493.1495 Standard; Testing personnel responsibilities.

The testing personnel are responsible for specimen processing, test performance and for reporting test results.

(a) Each individual performs only those high complexity tests that are authorized by the laboratory director and require a degree of skill commensurate with the individual's education, training or experience, and technical abilities.

(b) Each individual performing high complexity testing must—

(1) Follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results;

(2) Maintain records that demonstrate that proficiency testing samples are tested in the same manner as patient specimens;

(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;

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(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

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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;

(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—