

experience between September 1, 1982 and September 1, 1992.

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§ 493.1463 [Amended]

45. In § 493.1463, all references to “§ 493.1489(b)(4)” are amended to read “§ 493.1489(b)(5).”

46. In § 493.1489, the introductory text to the section and to paragraph (b) are republished, paragraphs (b)(2) and (b)(4) through (b)(6) are revised, and paragraph (b)(7) is added to read as follows:

§ 493.1489 Standard; Testing personnel qualifications.

Each individual performing high complexity testing must—

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(b) Meet one of the following requirements:

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(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or—

(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes—

(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either—

- (1) 24 semester hours of medical laboratory technology courses; or
- (2) 24 semester hours of science courses that include—

- (i) Six semester hours of chemistry;
- (ii) Six semester hours of biology; and
- (iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and

(B) Have laboratory training that includes either of the following:

(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.)

(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing.

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(4) On or before April 24, 1995 be a high school graduate or equivalent and have either—

- (i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or
- (ii) Successfully completed an official U.S. military medical laboratory

procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician);

(5)(i) Until September 1, 1997—

(A) Have earned a high school diploma or equivalent; and

(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has—

(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens;

(2) The skills required for implementing all standard laboratory procedures;

(3) The skills required for performing each test method and for proper instrument use;

(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed;

(5) A working knowledge of reagent stability and storage;

(6) The skills required to implement the quality control policies and procedures of the laboratory;

(7) An awareness of the factors that influence test results; and

(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and

(ii) As of September 1, 1997, be qualified under § 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995;

(6) For blood gas analysis—

(i) Be qualified under § 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5);

(ii) Have earned a bachelor’s degree in respiratory therapy or cardiovascular technology from an accredited institution; or

(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or

(7) For histopathology, meet the qualifications of § 493.1449 (b) or (l) to perform tissue examinations.

§ 493.1495 [Amended]

47. In § 493.1495, all references to “§ 493.1489(b)(4)” are amended to read “§ 493.1489(b)(5).”

48. The heading to subpart P is revised to read as follows:

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

49. Section 493.1701 is revised to read as follows:

§ 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.

50. In § 493.1776, the introductory text of paragraphs (a), (b), and (b)(4) are republished and the heading and paragraphs (a)(3), (a)(4), (b)(1), (b)(4)(iii) and (b)(4)(iv) are revised to read as follows:

§ 493.1776 Condition: Inspection of laboratories issued a certificate for PPM procedures.

(a) HHS or its designee will conduct announced or unannounced inspections of any laboratory at any time during its hours of operation to—

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(3) Determine whether the laboratory is performing tests in addition to procedures specified as PPM procedures; and

(4) Collect information regarding the appropriateness of tests specified as PPM procedures.

(b) The laboratory may be required, as part of this inspection, to—(1) Permit HHS or its designee to interview all employees of the laboratory concerning the laboratory’s compliance with the applicable requirements of part 493. Requirements for the purposes of this section are located in subpart C or