

or equivalent within the preceding 5 years examining slide preparations under the supervision of a physician qualified under § 493.1449(b) or (k)(1), and before January 1, 1969, must have—

- (i) Graduated from high school;
- (ii) Completed 6 months of training in cytotechnology in a laboratory directed by a pathologist or other physician providing cytology services; and
- (iii) Completed 2 years of full-time supervised experience in cytotechnology; or

(5)(i) On or before September 1, 1994, have full-time experience of at least 2 years or equivalent examining cytology slide preparations within the preceding 5 years in the United States under the supervision of a physician qualified under § 493.1449(b) or (k)(1); and

(ii) On or before September 1, 1995, have met the requirements in either paragraph (b)(1) or (2) of this section.

[57 FR 7172, Feb. 28, 1992, as amended at 59 FR 685, Jan. 6, 1994]

§ 493.1485 Standard; Cytotechnologist responsibilities.

The cytotechnologist is responsible for documenting—

- (a) The slide interpretation results of each gynecologic and nongynecologic cytology case he or she examined or reviewed (as specified in § 493.1274(c));
- (b) For each 24-hour period, the total number of slides examined or reviewed in the laboratory as well as the total number of slides examined or reviewed in any other laboratory or for any other employer; and
- (c) The number of hours spent examining slides in each 24-hour period.

[57 FR 7172, Feb. 28, 1992, as amended at 68 FR 3714, Jan. 24, 2003]

§ 493.1487 Condition: Laboratories performing high complexity testing; testing personnel.

The laboratory has a sufficient number of individuals who meet the qualification requirements of § 493.1489 of this subpart to perform the functions specified in § 493.1495 of this subpart for the volume and complexity of testing performed.

§ 493.1489 Standard; Testing personnel qualifications.

Each individual performing high complexity testing must—

(a) Possess a current license issued by the State in which the laboratory is located, if such licensing is required; and

(b) Meet one of the following requirements:

(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution;

(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.

(3) Have previously qualified or could have qualified as a technologist under § 493.1491 on or before February 28, 1992;

§ 493.1491

42 CFR Ch. IV (10-1-06 Edition)

(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 (1) to perform tissue examinations.

[57 FR 7172, Feb. 28, 1992, as amended at 58 FR 5236, Jan. 19, 1993; 58 FR 39155, July 22, 1993; 60 FR 20050, Apr. 24, 1995]

§ 493.1491 Technologist qualifications on or before February 28, 1992.

In order to qualify as high complexity testing personnel under § 493.1489(b)(3), the individual must have met or could have met the following qualifications for technologist as they were in effect on or before February 28, 1992. Each technologist must—

(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—