

§493.1411 Technical Consultant Qualifications (Moderate Complexity)

The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section.

- (a) The technical consultant must possess a current license issued by the State in which the laboratory is located, if such licensing is required.
- (b) The technical consultant must—
 - (1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; **and**
 - (ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; **or**
 - (2)(i) 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; **and**
 - (ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); **or**
 - (3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; **and**
 - (ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; **or**
 - (4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; **and**
 - (ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible.

Note: The technical consultant requirements for “laboratory training or experience, or both” in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

§493.1449 Technical Supervisor Qualifications (High Complexity)

The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical supervision for each of the specialties and subspecialties of service in which the laboratory performs high complexity tests or procedures. The director of a laboratory performing high complexity testing may function as the technical supervisor provided he or she meets the qualifications specified in this section.

- (a) The technical supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; **and**
- (b) The laboratory may perform anatomic and clinical laboratory procedures and tests in all specialties and subspecialties of services except histocompatibility and clinical cytogenetics services provided the individual functioning as the technical supervisor –
 - (1) Is a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; **and**
 - (2) Is certified in both anatomic and clinical pathology by the American board of Pathology or the American Osteopathic Board of Pathology or possesses qualifications that are equivalent to those for such certification.
- (c) If the requirement of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of ***bacteriology***, the individual functioning as the technical supervisor must –
 - (1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; **and**
 - (ii) Be certified in clinical pathology by the American Board of Pathology or American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; **or**
 - (2)(i) 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; **and**
 - (ii) Have at least one year of laboratory training or experience, or both, in high complexity testing with in the specialty of ***microbiology*** with a minimum of 6 months experience in high complexity testing within the subspecialty of ***bacteriology***; **or**
 - (3)(i) Have earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; **and**
 - (ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of ***microbiology*** with a minimum of 6 months experience in high complexity testing within the subspecialty of ***bacteriology***; **or**
 - (4)(i) Have earned a master’s degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; **and**
 - (ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of ***microbiology*** with a minimum of 6 months experience in high complexity testing within the subspecialty or ***bacteriology***; **or**
 - (5)(i) Have earned a bachelor’s degree in a chemical, physical, or biological science or medical technology from an accredited institution; **and**

- (ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of *microbiology* with a minimum of 6 months experience in high complexity testing within the subspecialty of *bacteriology*.

The subspecialties of (d) mycobacteriology, (e) mycology, (f) parasitology and (g) virology have the same Technical Supervisor qualifications as the subspecialty of bacteriology.

- (h) If requirements of paragraph(b) of this section are not met and the laboratory performs tests in the specialty of *diagnostic immunology*, the individual functioning as the technical supervisor must –

- (1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; **and**
 - (ii) Be certified in clinical pathology by the American Board of Pathology or the Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; **or**
- (2)(i) 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; **and**
 - (ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of *diagnostic immunology*; **or**
- (3)(i) Have an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution; **and**
 - (ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of *diagnostic immunology*; **or**
- (4)(i) Have earned a master's degree in a chemical, physical, biological, or clinical laboratory science or medical technology from an accredited institution; **and**
 - (ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of *diagnostic immunology*; **or**
- (5)(i) Have an earned bachelor's degree in a chemical, physical, biological, or medical technology from an accredited institution; **and**
 - (ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of *diagnostic immunology*.

The specialties of (i) Chemistry and (j) Hematology have the same Technical Supervisor qualifications as Diagnostic Immunology.

- (k) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of *cytology*, the individual functioning as the technical supervisor must –

- (1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; **and**
 - (ii) Meet one of the following requirements—

- (A) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; **or**
 - (B) Be certified by the American Society of Cytology to practice cytopathology or possess qualifications that are equivalent to those required for such certification;
- (2) An individual qualified under 493.1449(b) or paragraph (k)(1) of this section may delegate some of the cytology technical supervisor responsibilities to an individual who is in the final year of full-time training leading to certification specified in paragraphs (b) or (k)(1)(ii)(A) of this section provided the technical supervisor qualified under 493.1449(b) or paragraph (k)(1) of this section remains ultimately responsible for ensuring that all of the responsibilities of the cytology technical supervisor are met.
- (l) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of *histopathology*, the individual functioning as the technical supervisor must –
- (1) Meet one of the following requirements:
 - (i)(A) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; **and**
 - (B) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification.
 - (ii) An individual qualified under 493.1449(b) or paragraph (l)(1) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraph (b) or (l)(1)(i)(B) of this section, the responsibility for examination and interpretation of histology specimens.
- (2) For tests in *dermatopathology*, meet one of the following requirements:
- (i)(A) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located **and** –
 - (B) Meet one of the following requirements:
 - (1) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; **or**
 - (2) Be certified in dermatopathology by the American Board of Dermatology and the American Board of Pathology or possess qualifications that are equivalent to those required for such certification; **or**
 - (3) Be certified in dermatology by the American Board of Dermatology or possess qualifications that are equivalent to those required for such certification; **or**
 - (ii) An individual qualified under 493.1449(b) or paragraph (l)(2)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (l)(2)(i)(B) of this section, the responsibility for examination and interpretation of dermatopathology specimens.

The subspecialty of (l)(3) ophthalmic pathology, and specialties of (m) oral pathology, (n) radiobioassay, (o) histocompatibility and (p) clinical cytogenetics are not included in this handout due to their infrequent application. If you need assistance regarding these regulations, contact the West Virginia Office of Laboratory Services.

(q) If the requirement of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of *immunohematology*, the individual functioning as the technical supervisor must –

(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; **and**

(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; **or**

(2)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; **and**

(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing for the specialty of immunohematology.

Note: The technical supervisor requirements for “laboratory training or experience, or both” in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service.

§493.1489 Testing Personnel Qualifications (High Complexity)

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;

(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.