§ 493.1405 Standard; Laboratory director qualifications. The laboratory director must be qualified to manage and direct the laboratory personnel and the performance of moderate complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R of this part. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and
(b) The laboratory director 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 had laboratory training or experience consisting of: (A) At least one year directing or supervising non-waived laboratory testing; or (B) Beginning September 1, 1993, have at least 20 continuing medical education credit hours in laboratory practice commensurate with the director responsibilities defined in § 493.1407; or (C) Laboratory training equivalent to paragraph (b)(2)(ii)(B) of this section obtained during medical residency. (For example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (3) Hold an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution; and (i) Be certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or the American Board of Medical Laboratory Immunology; or (ii) Have had at least one year experience directing or supervising non-waived laboratory testing; (4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; (ii) Have at least one year of laboratory training or experience, or both in non-waived testing; and (iii) In addition, have at least one year of supervisory laboratory experience in non-waived testing; or (5)(i) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution; (ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing; and (iii) In addition, have at least 2 years of supervisory laboratory experience in non-waived testing; (6) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under § 493.1406; or (7) On or before February 28, 1992, qualified under State law to direct a laboratory in the State in which the laboratory is located.

[57 FR 7172, Feb. 28, 1992, as amended at 58 FR 5233, Jan. 19, 1993]

493.1443 Standard; Laboratory director qualifications. The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director 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) Be a doctor of medicine, a 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 (i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (ii) Have at least 2 years of experience directing or supervising high complexity testing; or (3) Hold an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution and— (i) Be certified and continue to be certified by a board approved by HHS; or (ii) Before February 24, 2003, must have served or be serving as a director of a laboratory performing high complexity testing and must have at least— (A) Two years of laboratory training or experience, or both; and (B) Two years of laboratory experience directing or supervising high complexity testing. (4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or (5) On or before February 28, 1992, be qualified under State law to direct a laboratory in the State in which the laboratory is located; or (6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification.

[57 FR 7172, Feb. 28, 1992, as amended at 58 FR 5234, Jan. 19, 1993; 59 FR 62609, Dec. 6, 1994; 62 FR 25858, May 12, 1997; 63 FR 55034, Oct. 14, 1998; 65 FR 82944, Dec. 29, 2000; 68 FR 3713, Jan. 24, 2003]

493.1461 Standard: General supervisor qualifications. The laboratory must have one or more general supervisors who, under the direction of the laboratory director and supervision of the technical supervisor, provides day-to-day supervision of testing personnel and reporting of test results. In the absence of the director and technical supervisor, the general supervisor must be responsible for the proper performance of all laboratory procedures and reporting of test results. (a) The general supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The general supervisor must be qualified as a— (1) Laboratory director under § 493.1443; or (2) Technical supervisor under § 493.1449. (c) If the requirements of paragraph (b)(1) or paragraph (b)(2) of this section are not met, the individual functioning as the general supervisor must— (1)(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 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; and (ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing; or (2)(i) Qualify as testing personnel under § 493.1489(b)(2); and (ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing; or (3)(i) Except as specified in paragraph (3)(ii) of this section, have previously qualified as a general supervisor under § 493.1462 on or before February 28, 1992. (ii) *Exception.* An individual who achieved a satisfactory grade in a proficiency examination for technologist given by HHS between March 1, 1986 and December 31, 1987, qualifies as a general supervisor if he or she meets the requirements of § 493.1462 on or before January 1, 1994." (4) On or before September 1, 1992, have served as a general supervisor of high complexity testing and as of April 24, 1995— (i) Meet one of the following requirements: (A) Have graduated from a medical laboratory or clinical laboratory training program approved or accredited by the Accrediting Bureau of Health Education Schools (ABHES), the Commission on Allied Health Education Accreditation (CAHEA), or other organization approved by HHS. (B) Be a high school graduate or equivalent and have successfully completed an official U.S. military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician). (ii) Have at least 2 years of clinical laboratory training, or experience, or both, in high complexity testing; or (5) On or before September 1, 1992, have served as a general supervisor of high complexity testing and— (i) Be a high school graduate or equivalent; and (ii) Have had at least 10 years of laboratory training or experience, or both, in high complexity testing, including at least 6 years of supervisory experience between September 1, 1982 and September 1, 1992. (d) For blood gas analysis, the individual providing general supervision must— (1) Be qualified under §§ 493.1461(b) (1) or (2), or 493.1461(c); or (2)(i) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (ii) Have at least one year of laboratory training or experience, or both, in blood gas analysis; or (3)(i) Have earned an associate degree related to pulmonary function from an accredited institution; and (ii) Have at least two years of training or experience, or both in blood gas analysis.

(e) The general supervisor requirement is met in histopathology, oral pathology, dermatopathology, and ophthalmic pathology because all tests and examinations, must be performed: (1) In histopathology, by an individual who is qualified as a technical supervisor under §§ 493.1449(b) or 493.1449(l)(1); (2) In dermatopathology, by an individual who is qualified as a technical supervisor under §§ 493.1449(b) or 493.1449(l) or (2); (3) In ophthalmic pathology, by an individual who is qualified as a technical supervisor under §§ 493.1449(b) or 493.1449(1)(3); and (4) In oral pathology, by an individual who is qualified as a technical supervisor under §§ 493.1449(b) or 493.1449(m).

[57 FR 7172, Feb. 28, 1992, as amended at 58 FR 5235, Jan. 19, 1993; 58 FR 39155, July 22, 1993; 60 FR 20049, Apr. 24, 1995]

§ 493.1449 Standard; Technical supervisor qualifications. 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 required for such certification. (c) If the requirements 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 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 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 (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 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 of 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. (d) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of mycobacteriology, 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 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 or 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 within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; 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 within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; 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 of mycobacteriology; 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 mycobacteriology. (e) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of mycology, 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 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 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 mycology; 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 within the speciality of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; 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 of mycology; 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 mycology. (f) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of parasitology, 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, 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 within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; (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 within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; 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 of parasitology; 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 parasitology. (g) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of virology, 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 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 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 virology; 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 within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; 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 of virology; 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 virology. (h) If the 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 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 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 within 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 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 for the specialty of diagnostic immunology. (i) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of chemistry, 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 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 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry; 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 within the specialty of chemistry; 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 chemistry; 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 for the specialty of chemistry. (j) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of hematology, 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, 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 for the specialty of hematology (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); 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 within the specialty of hematology; 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 hematology; 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 for the specialty of hematology. (k)(1) 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— (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 histopathology 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. (3) For tests in ophthalmic pathology, 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) Must 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 by the American Board of Ophthalmology or possess qualifications that are equivalent to those required for such certitication and have successfully completed at least 1 year of formal post-residency fellowship training in ophthalmic pathology; or (ii) An individual qualified under § 493.1449(b) or paragraph (1)(3)(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 (1)(3)(i)(B) of this section, the responsibility for examination and interpretation of ophthalmic specimens; or (m) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of oral pathology, the individual functioning as the technical supervisor must meet one of the following requirements: (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 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 oral pathology by the American Board of Oral Pathology or possess qualifications for such certification; or

(3) An individual qualified under § 493.1449(b) or paragraph (m) (1) or (2) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (m) (1) or (2) of this section, the responsibility for examination and interpretation of oral pathology specimens. (n) If the requirements of paragraph (b) of this section are not met and the laboratory

performs tests in the specialty of radiobioassay, 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, 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 radiobioassay; 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 within the specialty of radiobioassay; 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 radiobioassay; 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 for the specialty of radiobioassay. (o) If the laboratory performs tests in the specialty of histocompatibility, the individual functioning as the technical supervisor must either— (1)(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 training or experience that meets one of the following requirements: (A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or (B)(*1*) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and (*2*) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility; or (2)(i) Have an earned doctoral degree in a biological or clinical laboratory science from an accredited institution; and (ii) Have training or experience that meets one of the following requirements: (A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or (B)(*1*) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and (*2*) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility. (p) If the laboratory performs tests in the specialty of clinical cytogenetics, the individual functioning as the technical supervisor must— (1)(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 4 years of training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics; or (2)(i) Hold an earned doctoral degree in a biological science, including biochemistry, or clinical laboratory science from an accredited institution; and (ii) Have 4 years of training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics.

(q) If the requirements 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, 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 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. For example, an individual, who has a doctoral degree in chemistry and additionally has documentation of 1 year of laboratory experience working concurrently in high complexity testing in the specialties of microbiology and chemistry and 6 months of that work experience included high complexity testing in bacteriology, mycology, and mycobacteriology, would qualify as the technical supervisor for the specialty of chemistry and the subspecialties of bacteriology, mycology, and mycobacteriology.

[57 FR 7172, Feb. 28, 1992, as amended at 58 FR 5234, Jan. 19, 1993]

§ 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; (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.

[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]

§ 493.1423 Standard; Testing personnel qualifications. Each individual performing moderate 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 or doctor of osteopathy licensed to practice medicine or osteopathy 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; or (2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (4)(i) Have earned a high school diploma or equivalent; and (ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. Such training must ensure that the individual has— (A) 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; (B) The skills required for implementing all standard laboratory procedures; (C) The skills required for performing each test method and for proper instrument use; (D) The skills required for performing preventive maintenance, troubleshooting and calibration procedures related to each test performed; (E) A working knowledge of reagent stability and storage; (F) The skills required to implement the quality control policies and procedures of the laboratory; (G) An awareness of the factors that influence test results; and (H) The skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results.

[57 FR 7172, Feb. 28, 1992, as amended at 58 FR 5234, Jan. 19, 1993]

493.1417 Standard; Clinical consultant qualifications. The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must— (a) Be qualified as a laboratory director under § 493.1405(b) (1), (2), or (3)(i); or (b) Be a doctor of medicine, doctor of osteopathy or doctor of podiatric medicine and possess a license to practice medicine, osteopathy or podiatry in the State in which the laboratory is located.

[57 FR 7172, Feb. 28, 1992, as amended at 58 FR 5234, Jan. 19, 1993]

§ 493.1455 Standard; Clinical consultant qualifications. The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must— (a) Be qualified as a laboratory director under § 493.1443(b)(1), (2), or (3)(i) or, for the subspecialty of oral pathology, § 493.1443(b)(6); or (b) Be a doctor of medicine, doctor of osteopathy, doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located.

[57 FR 7172, Feb. 28, 1992, as amended at 58 FR 5235, Jan. 19, 1993]

493.1411 Standard; Technical consultant qualifications. 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.

[57 FR 7172, Feb. 28, 1992, as amended at 58 FR 5234, Jan. 19, 1993]

§ 493.17 Test categorization. (a) *Categorization by criteria.* Notices will be published in the **Federal Register** which list each specific test system, assay, and examination categorized by complexity. Using the seven criteria specified in this paragraph for categorizing tests of moderate or high complexity, each specific laboratory test system, assay, and examination will be graded for level of complexity by assigning scores of 1, 2, or 3 within each criteria. The score of "1" indicates the lowest level of complexity, and the score of "3" indicates the highest level. These scores will be totaled. Test systems, assays or examinations receiving scores of 12 or less will be categorized as moderate complexity, while those receiving scores above 12 will be categorized as high complexity. Note: A score of "2" will be assigned to a criteria heading when the characteristics for a particular test are intermediate between the descriptions listed for scores of "1" and "3."

(1) *Knowledge.* (i) *Score 1.* (A) Minimal scientific and technical knowledge is required to perform the test; and (B) Knowledge required to perform the test may be obtained through on-the-job instruction. (ii) *Score 3.* Specialized scientific and technical knowledge is essential to perform preanalytic, analytic or postanalytic phases of the testing. (2) *Training and experience.*

(i) *Score 1.* (A) Minimal training is required for preanalytic, analytic and postanalytic phases of the testing process; and (B) Limited experience is required to perform the test. (ii) *Score 3.* (A) Specialized training is essential to perform the preanalytic, analytic or postanalytic testing process; or (B) Substantial experience may be necessary for analytic test performance. (3) *Reagents and materials preparation.* (i) *Score 1.* (A) Reagents and materials are generally stable and reliable; and (B) Reagents and materials are prepackaged, or premeasured, or require no special handling, precautions or storage conditions. (ii) *Score 3.* (A) Reagents and materials may be labile and may require special handling to assure reliability; or (B) Reagents and materials preparation may include manual steps such as gravimetric or volumetric measurements. (4) *Characteristics of operational steps.* (i) *Score 1.* Operational steps are either automatically executed (such as pipetting, temperature monitoring, or timing of steps), or are easily controlled. (ii) *Score 3.* Operational steps in the testing process require close monitoring or control, and may require special specimen preparation, precise temperature control or timing of procedural steps, accurate pipetting, or extensive calculations. (5) *Calibration, quality control, and proficiency testing materials.* (i) *Score 1.* (A) Calibration materials are stable and readily available; (B) Quality control materials are stable and readily available; and (C) External proficiency testing materials, when available, are stable. (ii) *Score 3.* (A) Calibration materials, if available, may be labile; (B) Quality control materials may be labile, or not available; or (C) External proficiency testing materials, if available, may be labile. (6) *Test system troubleshooting and equipment maintenance.* (i) *Score 1.* (A) Test system troubleshooting is automatic or self-correcting, or clearly described or requires minimal judgment; and (B) Equipment maintenance is provided by the manufacturer, is seldom needed, or can easily be performed. (ii) *Score 3.* (A) Troubleshooting is not automatic and requires decision-making and direct intervention to resolve most problems; or (B) Maintenance requires special knowledge, skills, and abilities. (7) *Interpretation and judgment.* (i) *Score 1.* (A) Minimal interpretation and judgment are required to perform preanalytic, analytic and postanalytic processes; and (B) Resolution of problems requires limited independent interpretation and judgment; and (ii) *Score 3.* (A) Extensive independent interpretation and judgment are required to perform the preanalytic, analytic or postanalytic processes; and (B) Resolution of problems requires extensive interpretation and judgment. (b) *Revisions to the criteria for categorization.* The Clinical Laboratory Improvement Advisory Committee, as defined in subpart T of this part, will conduct reviews upon request of HHS and recommend to HHS revisions to the criteria for categorization of tests. (c) *Process for device/test categorization utilizing the scoring system under § 493.17(a).* (1)(i) For new commercial test systems, assays, or examinations, the manufacturer, as part of its 510(k) and PMA application to FDA, will submit supporting data for device/test categorization. FDA will determine the complexity category, notify the manufacturers directly, and will simultaneously inform both CMS and CDC of the device/test category. FDA will consult with CDC concerning test categorization in the following three situations: (A) When categorizing previously uncategorized new technology; (B) When FDA determines it to be necessary in cases involving a request for a change in categorization; and (C) If a manufacturer requests review of a categorization decision by FDA in accordance with 21 CFR 10.75. (ii) Test categorization will be effective as of the notification to the applicant. (2) For test systems, assays, or examinations not commercially available, a laboratory or professional group may submit a written

request for categorization to PHS. These requests will be forwarded to CDC for evaluation; CDC will determine complexity category and notify the applicant, CMS, and FDA of the categorization decision. In the case of request for a change of category or for previously uncategorized new technology, PHS will receive the request application and forward it to CDC for categorization. (3) A request for recategorization will be accepted for review if it is based on new information not previously submitted in a request for categorization or recategorization by the same applicant and will not be considered more frequently than once per year. (4) If a laboratory test system, assay or examination does not appear on the lists of tests in the **Federal Register** notices, it is considered to be a test of high complexity until PHS, upon request, reviews the matter and notifies the applicant of its decision. Test categorization is effective as of the notification to the applicant. (5) PHS will publish revisions periodically to the list of moderate and high complexity tests in the **Federal Register** in a notice with opportunity for comment.

[57 FR 7139, Feb. 28, 1992, as amended at 58 FR 5222, Jan. 19, 1993]

§ 493.19 Provider-performed microscopy (PPM) procedures. (a) *Requirement.* To be categorized as a PPM procedure, the procedure must meet the criteria specified in paragraph (b) of this section. (b) *Criteria.* Procedures must meet the following specifications: (1) The examination must be personally performed by one of the following practitioners: (i) A physician during the patient's visit on a specimen obtained from his or her own patient or from a patient of a group medical practice of which the physician is a member or an employee. (ii) A midlevel practitioner, under the supervision of a physician or in independent practice only if authorized by the State, during the patient's visit on a specimen obtained from his or her own patient or from a patient of a clinic, group medical practice, or other health care provider of which the midlevel practitioner is a member or an employee. (iii) A dentist during the patient's visit on a specimen obtained from his or her own patient or from a patient of a group dental practice of which the dentist is a member or an employee. (2) The procedure must be categorized as moderately complex. (3) The primary instrument for performing the test is the microscope, limited to bright-field or phase-contrast microscopy. (4) The specimen is labile or delay in performing the test could compromise the accuracy of the test result. (5) Control materials are not available to monitor the entire testing process. (6) Limited specimen handling or processing is required. (c) *Provider-performed microscopy (PPM) examinations.* A laboratory may qualify to perform tests under this section if it restricts PPM examinations to one or more of the following procedures (or additional procedures added to this list as provided under paragraph (d) of this section), waived tests and no others: (1) All direct wet mount preparations for the presence or absence of bacteria, fungi, parasites, and human cellular elements. (2) All potassium hydroxide (KOH) preparations. (3) Pinworm examinations. (4) Fern tests. (5) Post-coital direct, qualitative examinations of vaginal or cervical mucous. (6) Urine sediment examinations. (7) Nasal smears for granulocytes. (8) Fecal leukocyte examinations. (9) Qualitative semen analysis (limited to the presence or absence of sperm and detection of motility). (d) *Revisions to criteria and the list of PPM procedures.* (1) The CLIAC conducts reviews upon HHS' request and recommends to HHS revisions to the criteria for categorization of procedures.
(2) HHS determines whether a laboratory procedure meets the criteria listed under paragraph (b) of this section for a PPM procedure. Revisions to the list of PPM procedures proposed by HHS are published in the **Federal Register** as a notice with an opportunity for public comment. (e) *Laboratory requirements.* Laboratories eligible to perform PPM examinations must— (1) Meet the applicable requirements in subpart C or subpart D, and subparts F, H, J, K, and M of this part. (2) Be subject to inspection as specified under subpart Q of this part.

[60 FR 20044, Apr. 24, 1995; 68 FR 50723, Aug. 22, 2003]

http://www.gpo.gov/fdsys/pkg/CFR-2003-title42-vol3/xml/CFR-2003-title42-vol3-part493.xml

493.1461 Standard: General supervisor qualifications. The laboratory must have one or more general supervisors who, under the direction of the laboratory director and supervision of the technical supervisor, provides day-to-day supervision of testing personnel and reporting of test results. In the absence of the director and technical supervisor, the general supervisor must be responsible for the proper performance of all laboratory procedures and reporting of test results. (a) The general supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The general supervisor must be qualified as a— (1) Laboratory director under § 493.1443; or (2) Technical supervisor under § 493.1449. (c) If the requirements of paragraph (b)(1) or paragraph (b)(2) of this section are not met, the individual functioning as the general supervisor must— (1)(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 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; and (ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing; or (2)(i) Qualify as testing personnel under § 493.1489(b)(2); and (ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing; or (3)(i) Except as specified in paragraph (3)(ii) of this section, have previously qualified as a general supervisor under § 493.1462 on or before February 28, 1992. (ii) *Exception.* An individual who achieved a satisfactory grade in a proficiency examination for technologist given by HHS between March 1, 1986 and December 31, 1987, qualifies as a general supervisor if he or she meets the requirements of § 493.1462 on or before January 1, 1994." (4) On or before September 1, 1992, have served as a general supervisor of high complexity testing and as of April 24, 1995— (i) Meet one of the following requirements: (A) Have graduated from a medical laboratory or clinical laboratory training program approved or accredited by the Accrediting Bureau of Health Education Schools (ABHES), the Commission on Allied Health Education Accreditation (CAHEA), or other organization approved by HHS. (B) Be a high school graduate or equivalent and have successfully completed an official U.S. military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician). (ii) Have at least 2 years of clinical laboratory training, or experience, or both, in high complexity testing; or (5) On or before September 1, 1992, have served as a general supervisor of high complexity testing and— (i) Be a high school graduate or equivalent; and (ii) Have had at least 10 years of laboratory training or experience, or both, in high complexity testing, including at least 6 years of supervisory experience between September 1, 1982 and September 1, 1992. (d) For blood gas analysis, the individual providing general supervision must— (1) Be qualified under §§ 493.1461(b) (1) or (2), or 493.1461(c); or (2)(i) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (ii) Have at least one year of laboratory training or experience, or both, in blood gas analysis; or (3)(i) Have earned an associate degree related to pulmonary function from an accredited institution; and (ii) Have at least two years of training or experience, or both in blood gas analysis.
(e) The general supervisor requirement is met in histopathology, oral pathology, dermatopathology, and ophthalmic pathology because all tests and examinations, must be performed: (1) In histopathology, by an individual who is qualified as a technical supervisor under §§ 493.1449(b) or 493.1449(l)(1); (2) In dermatopathology, by an individual who is qualified as a technical supervisor under §§ 493.1449(b) or 493.1449(l) or (2); (3) In ophthalmic pathology, by an individual who is qualified as a technical supervisor under §§ 493.1449(b) or 493.1449(1)(3); and (4) In oral pathology, by an individual who is qualified as a technical supervisor under §§ 493.1449(b) or 493.1449(m).

[57 FR 7172, Feb. 28, 1992, as amended at 58 FR 5235, Jan. 19, 1993; 58 FR 39155, July 22, 1993; 60 FR 20049, Apr. 24, 1995]

§ 493.1469 Standard: Cytology general supervisor qualifications. The cytology general supervisor must be qualified to supervise cytology services. The general supervisor in cytology must possess a current license issued by the State in which the laboratory is located, if such licensing is required, and must— (a) Be qualified as a technical supervisor under § 493.1449 (b) or (k); or (b)(1) Be qualified as a cytotechnologist under § 493.1483; and (2) Have at least 3 years of full-time (2,080 hours per year) experience as a cytotechnologist within the preceding 10 years