

requirements of § 493.1449 of this subpart and provides technical supervision in accordance with § 493.1451 of this subpart.

**§ 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 specialty 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 com-

plexity 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 spe-

cialty 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 (1)(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 (1)(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 certification 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

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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]

**§ 493.1451 Standard: Technical supervisor responsibilities.**

The technical supervisor is responsible for the technical and scientific oversight of the laboratory. The technical supervisor is not required to be on site at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide supervision as specified in (a) of this section.

(a) The technical supervisor must be accessible to the laboratory to provide on-site, telephone, or electronic consultation; and

(b) The technical supervisor is responsible for—

(1) Selection of the test methodology that is appropriate for the clinical use of the test results;

(2) Verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system;

(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered;

(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;

(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications;

(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly;

(7) Identifying training needs and assuring that each individual performing tests receives regular in-service train-

ing and education appropriate for the type and complexity of the laboratory services performed;

(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to—

(i) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing;

(ii) Monitoring the recording and reporting of test results;

(iii) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records;

(iv) Direct observation of performance of instrument maintenance and function checks;

(v) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and

(vi) Assessment of problem solving skills; and

(9) Evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

(c) In cytology, the technical supervisor or the individual qualified under § 493.1449(k)(2)—

(1) May perform the duties of the cytology general supervisor and the cytotechnologist, as specified in §§ 493.1471 and 493.1485, respectively;

(2) Must establish the workload limit for each individual examining slides;

(3) Must reassess the workload limit for each individual examining slides at least every 6 months and adjust as necessary;

(4) Must perform the functions specified in § 493.1274(d) and (e);