

(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)(I) 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]

§493.1451 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

§ 493.1453

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 training 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

42 CFR Ch. IV (10–1–14 Edition)

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);

(5) Must ensure that each individual examining gynecologic preparations participates in an HHS approved cytology proficiency testing program, as specified in § 493.945 and achieves a passing score, as specified in § 493.855; and

(6) If responsible for screening cytology slide preparations, must document the number of cytology slides screened in 24 hours and the number of hours devoted during each 24-hour period to screening cytology slides.

[57 FR 7172, Feb. 28, 1992, as amended at 58 FR 5235, Jan. 19, 1993; 68 FR 3714, Jan. 24, 2003]

§ 493.1453 Condition: Laboratories performing high complexity testing; clinical consultant.

The laboratory must have a clinical consultant who meets the requirements of § 493.1455 of this subpart and provides clinical consultation in accordance with § 493.1457 of this subpart.

§ 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