

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]

**§ 493.1413 Standard; Technical consultant responsibilities.**

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

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

(b) The technical consultant is responsible for—

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

(2) Verification of the test procedures performed and the 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 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 moderate 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.

**§ 493.1415 Condition: Laboratories performing moderate complexity testing; clinical consultant.**

The laboratory must have a clinical consultant who meets the qualification requirements of § 493.1417 of this part and provides clinical consultation in accordance with § 493.1419 of this part.

**§ 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]

**§ 493.1419 Standard; Clinical consultant responsibilities.**

The clinical consultant provides consultation regarding the appropriateness of the testing ordered and interpretation of test results. The clinical consultant must—

(a) Be available to provide clinical consultation to the laboratory's clients;

(b) Be available to assist the laboratory's clients in ensuring that appropriate tests are ordered to meet the clinical expectations;

(c) Ensure that reports of test results include pertinent information required for specific patient interpretation; and

(d) Ensure that consultation is available and communicated to the laboratory's clients on matters related to the quality of the test results reported and their interpretation concerning specific patient conditions.

**§ 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel.**

The laboratory must have a sufficient number of individuals who meet the qualification requirements of § 493.1423, to perform the functions specified in § 493.1425 for the volume and complexity of tests performed.

**§ 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