

§ 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

(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;

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(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]

§ 493.1425 Standard; Testing personnel responsibilities.

The testing personnel are responsible for specimen processing, test performance, and for reporting test results.

(a) Each individual performs only those moderate complexity tests that are authorized by the laboratory director and require a degree of skill commensurate with the individual's education, training or experience, and technical abilities.

(b) Each individual performing moderate complexity testing must—

(1) Follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results;

(2) Maintain records that demonstrate that proficiency testing samples are tested in the same manner as patient samples;

(3) Adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed;

(4) Follow the laboratory's established corrective action policies and procedures whenever test systems are not within the laboratory's established acceptable levels of performance;

(5) Be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the technical consultant, clinical consultant or director; and

(6) Document all corrective actions taken when test systems deviate from the laboratory's established performance specifications.

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LABORATORIES PERFORMING HIGH COMPLEXITY TESTING

§ 493.1441 Condition: Laboratories performing high complexity testing; laboratory director.

The laboratory must have a director who meets the qualification requirements of § 493.1443 of this subpart and provides overall management and direction in accordance with § 493.1445 of this subpart.

§ 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