

(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]

§ 493.1457 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 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.

§ 493.1459 Condition: Laboratories performing high complexity testing; general supervisor.

The laboratory must have one or more general supervisors who are qualified under § 493.1461 of this subpart to provide general supervision in accordance with § 493.1463 of this subpart.

§ 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