

D6143

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§493.1461 Standard: General supervisor qualifications

(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--

(b)(1) Laboratory director under §493.1443; or

(b)(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--

(c)(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

Interpretive Guidelines §493.1461(c)(1)(i)

See §493.2 for the definition of and guidance for an accredited institution.

(c)(1)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing; or

(c)(2)(i) Qualify as testing personnel under §493.1489(b)(2); and

(c)(2)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing; or

(c)(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.

(c)(3)(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.

(c)(4) On or before September 1, 1992, have served as a general supervisor of high complexity testing and as of April 24, 1995--

(c)(4)(i) Meet one of the following requirements:

(c)(4)(i)(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.

(c)(4)(i)(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 the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician).

(c)(4)(ii) Have at least 2 years of clinical laboratory training, or experience, or both, in high complexity testing; or

(c)(5) On or before September 1, 1992, have served as a general supervisor of high complexity testing and--

(c)(5)(i) Be a high school graduate or equivalent; and

(c)(5)(ii) Have had at least 10 years of laboratory training or experience, or both, in high complexity testing, including at least 6 years of supervisory experience between September 1, 1982 and September 1, 1992.

(d) For blood gas analysis, the individual providing general supervision must--

(d)(1) Be qualified under §§493.1461(b)(1) or (2), or 493.1461(c); or

(d)(2)(i) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and

(d)(2)(ii) Have at least one year of laboratory training or experience, or both, in blood gas analysis; or

(d)(3)(i) Have earned an associate degree related to pulmonary function from an accredited institution; and

Interpretive Guidelines §493.1461(d)(3)(i)

NOTE: Many blood gas systems are categorized as moderate complexity tests; therefore, only moderate complexity personnel requirements are applicable. To determine which tests are categorized as waived or nonwaived (i.e., moderate or high complexity tests), refer to the "Specific List For Categorization of Laboratory Test Systems, Assays, and Examinations by Complexity" (<http://www.gpo.gov/fdsys/pkg/FR-1995-05-15/pdf/95-11653.pdf>). Test systems, assays, and examinations not yet classified are considered high complexity.

(d)(3)(ii) Have at least two years of training or experience, or both in blood gas analysis.

(e) The general supervisor requirement is met in histopathology, oral pathology, dermatopathology, and ophthalmic pathology because all tests and examinations, must be performed:

(e)(1) In histopathology, by an individual who is qualified as a technical supervisor under §§493.1449(b) or 493.1449(l)(1);

(e)(2) In dermatopathology, by an individual who is qualified as a technical supervisor under §§493.1449(b) or 493.1449(l) or (2);

(e)(3) In ophthalmic pathology, by an individual who is qualified as a technical supervisor under §§493.1449(b) or 493.1449(1)(3); and

(e)(4) In oral pathology, by an individual who is qualified as a technical supervisor under §§493.1449(b) or 493.1449(m).

Interpretive Guidelines §493.1461(e)

In the case of gross examinations, the technical supervisor may delegate to individuals qualified under §493.1489 the responsibility for the physical examination/description, including color, weight, measurement and other characteristics of the tissue; or other mechanical procedures for which a specific written protocol has been developed.

The technical supervisor is ultimately responsible for the diagnosis related to the gross examination and must sign the examination report. The technical supervisor is not required to provide direct on-site supervision but is responsible for the accuracy of all test results reported. All physical examinations/descriptions of tissue including color, weight, measurement and other characteristics of the tissue; or other mechanical procedures including dissection, inking, marking, and specific orientation for diagnostic interpretation performed in the absence of the technical supervisor by individuals qualified under §493.1489 should be reviewed within 24 hours by the technical supervisor. All microscopic tissue examinations must be performed by individuals qualified under §493.1449(b), (l) or (m), as appropriate.

There should be documentation of the identity of the personnel performing the grossing portion of the test. The name does not necessarily need to be included in the final report because the final report is under the responsibility of the technical supervisor. The decision to include the name/initials of the person grossing in the final report is a laboratory decision, and does not fall under the CLIA requirements. The grossing information should be recorded and maintained to show who performed the test, somewhere in the test record. During a Mohs procedure the surgical test requisition may be the surgical report. D5787 §493.1283(a)(4)

§493.1462 General supervisor qualifications on or before February 28, 1992.

To qualify as a general supervisor under §493.1461(c)(3), an individual must have met or could have met the following qualifications as they were in effect on or before February 28, 1992.

(a) Each supervisor possesses a current license as a laboratory supervisor issued by the State, if such licensing exists; and

(b) The laboratory supervisor--

(b)(1) Who qualifies as a laboratory director under §493.1406(b)(1), (2), (4), or (5) is also qualified as a general supervisor; therefore, depending upon the size and functions of the laboratory, the laboratory director may also serve as the laboratory supervisor; or

(b)(2)(i) Is a physician or has earned a doctoral degree from an accredited institution with a major in one of the chemical, physical, or biological sciences; and

(b)(2)(ii) Subsequent to graduation, has had at least 2 years of experience in one of the laboratory specialties in a laboratory; or

(b)(3)(i) Holds a master's degree from an accredited institution with a major in one of the chemical, physical, or biological sciences; and

(b)(3)(ii) Subsequent to graduation has had at least 4 years of pertinent full-time laboratory experience of which not less than 2 years have been spent working in the designated specialty in a laboratory; or

(b)(4)(i) Is qualified as a laboratory technologist under §493.1491; and

(b)(4)(ii) After qualifying as a laboratory technologist, has had at least 6 years of pertinent full-time laboratory experience of which not less than 2 years have been spent working in the designated laboratory specialty in a laboratory; or

(b)(5) With respect to individuals first qualifying before July 1, 1971, has had at least 15 years of pertinent full-time laboratory experience before January 1, 1968; this required experience may be met by the substitution of education for experience.