§493.1405 Standard; Laboratory director qualifications

The laboratory director must be qualified to manage and direct the laboratory personnel and the performance of moderate complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R of this part.

Interpretive Guidelines §493.1405

When qualifying a Laboratory Director, please refer to section 353(i)(3) of the PHS Act as amended by the TEST Act, which now states, "No person who has owned or operated a laboratory which has had its certificate revoked may, within 2 years of the revocation of the certificate, own or operate a laboratory for which a certificate has been issued under this section (see §493.1840), except that if the revocation occurs pursuant to paragraph (4) the Secretary may substitute intermediate sanctions under subsection (h) instead of the 2-year prohibition against ownership or operation which would otherwise apply under this paragraph. The certificate of a laboratory which has been excluded from participation under the Medicare program under title XVIII of the Social Security Act [42 U.S.C.A. § 1395 et seq.] because of actions relating to the quality of the laboratory shall be suspended for the period the laboratory is so excluded."

(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

Interpretive Guidelines §493.1405(a)

The term “State” as used in this provision, includes the District of Columbia, the Commonwealth of Puerto Rico, the Commonwealth of Northern Mariana Islands, the Virgin Islands, Guam and American Samoa.

(b) The laboratory director must--

> **(b)(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**
>
> **(b)(1)(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**

Interpretive Guidelines §493.1405(b)(1)(ii)

Board certified means the individual has completed all the designated board's requirements, including the examination. If the director is named in a current edition of "The Official American Board of Medical Specialties (ABMS) Directory of Board Certified Medical Specialists (published by ABMS by Elsevier, 11830 Westline Industrial Drive, St. Louis, Missouri 63146, 1-866-856-8075) as appropriately board certified, this may be accepted as evidence of certification without needing further documentation. You may make a notation of this in the laboratory's file.

Qualifications that are equivalent for certification include board eligibility (i.e., the individual meets all education, training or experience requirements to take the examination, but has not actually taken and successfully completed the examination.) An individual who wishes to qualify as a director must supply evidence of this eligibility status. The designated boards, upon request, send a letter to the individual confirming his/her eligibility status. Note that some boards set time restrictions for taking the examination. For purposes of the regulations, the individual must meet the education, training or experience required by the board to be eligible to take the examination and must have confirmation of eligibility status.

(b)(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

Interpretive Guidelines §493.1405(b)(2)(i)

Individuals who have earned a Doctor of Optometry are qualified to serve as a laboratory director of certain moderate complexity tests under CLIA, but only for test procedures performed in their specialty area. [Ref: S&C-05-44] Optometrists may perform tests that are FDA-approved or cleared, of waived or moderate test complexity with the specimen source of tears such as lactoferrin, adenovirus, IgE, and osmolality.

(b)(2)(ii) Have had laboratory training or experience consisting of:

Interpretive Guidelines §493.1405(b)(2)(ii)

The type of experience required under this regulation is **clinical** in nature. This means directing or supervising personnel who examine and perform tests on human specimens for the purpose of providing information that is used in diagnosing, treating, and monitoring a patient's condition. This experience may include the laboratory director personally examining and performing tests on patient specimens. Patient or medically oriented experience, which is defined as the ordering of tests and interpreting and applying the results of these tests in diagnosing and treating a patient's illness, is **unacceptable** to meet the requirement for laboratory training or experience.

The laboratory director should have documentation, e.g., signed procedure manuals, test reports, worksheets and workcards, that indicates the director assumes the responsibilities in §493.1407.

Teaching experience directly related to a medical technology program, clinical laboratory sciences program, or a clinical laboratory section of a residency program is considered acceptable experience. Research experience is also acceptable experience if it is obtained while performing tests on human specimens.

Ophthalmologists with a doctor of medicine (MD) degree are qualified to direct moderate complexity laboratories, provided they have had at least one year of experience directing or supervising moderate complexity laboratories, or have obtained at least 20 CMEs in laboratory practice commensurate with the laboratory director's responsibilities in §493.1407. [Ref: S&C-05-44]

> **(b)(2)(ii)(A) At least one year directing or supervising non-waived laboratory testing; or**
>
> **(b)(2)(ii)(B) Beginning September 1, 1993, have at least 20 continuing medical education credit hours in laboratory practice commensurate with the director responsibilities defined in §493.1407; or**

Interpretive Guidelines §493.1405(b)(2)(ii)(B)

The 20 CMEs must be obtained prior to qualifying as a laboratory director. The CME courses must encompass preanalytic, analytic, and postanalytic phases of testing, and be of such quality as to provide the physician with education equivalent to the experience described in §493.1405(b)(2)(ii)(A). Courses related to laboratory payment and CPT coding would not fulfill this requirement.

For a list of some CME providers, please see the CLIA web page at www.cms.hhs.gov/clia. The list of courses on the CLIA web page is not all inclusive. Other courses may meet the criteria, but all courses must be accredited.
In evaluating the 20 CMEs, verify they include the laboratory director responsibilities detailed in §493.1407.

> **(b)(2)(ii)(C) Laboratory training equivalent to paragraph (b)(2)(ii)(B) of this section obtained during medical residency. (For example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or**

Interpretive Guidelines §493.1405(b)(2)(ii)(C)

The residency program should provide the director the knowledge in principles and theories of laboratory practice including: quality control and quality assessment, proficiency testing, the phases of the total process (i.e., preanalytic, analytic and postanalytic), as well as, general laboratory systems, facility administration, and development and implementation of personnel policy and procedure manuals. This training should also include hands-on laboratory testing.

(b)(3) Hold an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution; and

Interpretive Guidelines §493.1405(b)(3)

See §493.2 for the definition of an accredited institution.

> **(b)(3)(i) Be certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or the American Board of Medical Laboratory Immunology; or**
>
> **(b)(3)(ii) Have had at least one year experience directing or supervising non-waived laboratory testing;**

(b)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution;

> **(b)(4)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing; and**
>
> **(b)(4)(iii) In addition, have at least one year of supervisory laboratory experience in non-waived testing; or**

(b)(5)(i) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution;

> **(b)(5)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing; and**
>
> **(b)(5)(iii) In addition, have at least 2 years of supervisory laboratory experience in non-waived testing;**

(b)(6) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under §493.1406; or

Interpretive Guidelines §493.1405(b)(6)

For tests of moderate complexity, individuals qualify as laboratory directors, if on February 28, 1992, they previously qualified, or could have qualified under the Federal regulations, published on March 14, 1990, as a laboratory director. After February 28, 1992, individuals must meet the requirements at §§493.1405(b)(1)-(5) to qualify as a laboratory director, unless the individual can demonstrate compliance with §493.1405(b)(6), (that is, on February 28, 1992, he or she **could** have qualified as a laboratory director under Federal regulations published on March 14, 1990).

(b)(7) On or before February 28, 1992, qualified under State law to direct a laboratory in the State in which the laboratory is located.

§493.1406 Standard; Laboratory director qualifications on or before February 28, 1992

The laboratory director must be qualified to manage and direct the laboratory personnel and test performance.

(a) The laboratory director must possess a current license as a laboratory director issued by the State, if such licensing exists; and

(b) The laboratory director must:

(b)(1) Be a physician certified in anatomical 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;

(b)(2) Be a physician who:

(b)(2)(i) Is certified by the American Board of Pathology or the American Osteopathic Board of Pathology in at least one of the laboratory specialties; or

(b)(2)(ii) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board in one of the laboratory specialties; or

(b)(2)(iii) Is certified by the American Society of Cytology to practice cytopathology or possesses qualifications that are equivalent to those required for such certification; or

(b)(2)(iv) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties;

(b)(3) For the subspecialty of oral pathology only, be certified by the American Board of Oral Pathology, American Board of Pathology or the American Osteopathic Board of Pathology or possesses qualifications that are equivalent to those required for certification;

(b)(4) Hold an earned doctoral degree from an accredited institution with a chemical, physical, or biological science as a major subject and

(b)(4)(i) Is certified by the American Board of Medical Microbiology, the

American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board acceptable to HHS in one of the laboratory specialties; or

(b)(4)(ii) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties;

(b)(5) With respect to individuals first qualifying before July 1, 1971, have been responsible for the direction of a laboratory for 12 months between July 1, 1961, and January 1, 1968, and, in addition, either:

(b)(5)(i) Was a physician and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience;

(b)(5)(ii) Held a master's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience;

(b)(5)(iii) Held a bachelor's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 6 years of pertinent full-time laboratory experience; or

(b)(5)(iv) Achieved a satisfactory grade through an examination conducted by or under the sponsorship of the U.S. Public Health Service on or before July 1, 1970; or

(b)(6) Qualify under State law to direct the laboratory in the State in which the laboratory is located.

Note: The January 1, 1968 date for meeting the 12 months' laboratory direction requirement in paragraph (b)(5) of this section may be extended 1 year for each year of full-time laboratory experience obtained before January 1, 1958 required by State law for a laboratory director license. An exception to the July 1, 1971 qualifying date in paragraph (b)(5) of this section was made provided that the individual requested qualification approval by October 21, 1975 and had been employed in a laboratory for at least 3 years of the 5 years preceding the date of submission of his qualifications.