

D6078

(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

§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.

Interpretive Guidelines §493.1443

When qualifying a Laboratory Director, please refer to section 353(i)(3) of the PHS Act 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.”

(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 §493.1443(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 §493.1443(b)(1)(ii)

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, will 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 as required by the board to be eligible to take the examination and must have confirmation of eligibility status.

(b)(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

(b)(2)(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

Interpretive Guidelines §493.1443(b)(2)(i)

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 phase 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)(2)(ii) Have at least 2 years of experience directing or supervising high complexity testing; or

Interpretive Guidelines §493.1443(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 §493.1445.

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.

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

(b)(3)(i) Be certified and continue to be certified by a board approved by HHS; or

Interpretive Guidelines §493.1443(b)(3)

See §493.2 for the definition of an accredited institution.

To qualify as a laboratory director of high complexity testing on or after February 24,

2003, individuals possessing a Ph.D. or Dr.P.H. must be board certified by an approved board.

“Certified” means the individual has completed all the designated board’s requirements, including the examination.

Currently approved boards are:

ABB - American Board of Bioanalysis,

ABB public health microbiology certification,

ABCC - American Board of Clinical Chemistry,

ABFT - American Board of Forensic Toxicology (limited to individuals with a doctoral degree)*,

ABHI - American Board of Histocompatibility and Immunogenetics,

ABMGG - American Board of Medical Genetics and Genomics (formerly ABMG - American Board of Medical Genetics),

ABMLI - American Board of Medical Laboratory Immunology,

ABMM - American Board of Medical Microbiology,

NRCC - National Registry for Certified Chemists (limited to individuals with a doctoral degree)*,

***NOTE:** ABFT and NRCC also certify non-doctoral individuals; however, the director of high-complexity testing must have a doctoral degree.

An acceptable doctoral degree is a Doctor of Philosophy – Ph.D., Doctor of Science – D.Sc. If acceptable to the board, a Doctor of Dental Surgery – D.D.S., *Doctor of Veterinary Medicine – D.V.M.*, Doctor of Public Health – Dr.P.H.

Laboratory testing of non-human specimens is not acceptable experience, e.g., environmental, animal testing.

(b)(3)(ii) Before February 24, 2003, must have served or be serving as director of a laboratory performing high complexity testing and must have at least--

(b)(3)(ii)(A) Two years of laboratory training or experience, or both; and

(b)(3)(ii)(B) Two years of laboratory experience directing or supervising high complexity testing.

(b)(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or

Interpretive Guidelines §493.1443(b)(4)

An individual is qualified as a laboratory director if he or she was serving as a laboratory director on or before February 28, 1992. After February 28, 1992, individuals must meet the requirements at §493.1443(b)(1)-(3) to qualify as a laboratory director for high complexity.

In accordance with the regulations, the requirements listed below may be used only for individuals meeting these qualifications and functioning in the position as of February 28, 1992.

The requirements for a laboratory director under 42 CFR 493.1415, published March 14, 1990 (55 FR 9538) are as follows:

- (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 possess 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 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 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.

(b)(5) On or before February 28, 1992, be qualified under State law to direct a laboratory in the State in which the laboratory is located; or

Interpretive Guidelines §493.1443(b)(5)

Those individuals qualified after February 28, 1992, as directors solely under State law, will not meet this requirement.

(b)(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification.