

A Guide for Laboratories Performing CLIA Non-waived Testing in Free-Standing Emergency Care Facilities (FEMCF)

FEMCF draft rules, 25 Texas Administrative Code Section 131.45 (d.), pertains to the clinical laboratory and pathology services to be provided for patient care at an FEMCF.

§131.45(d.) (1):

Laboratory and Pathology Services. The FEMCF shall maintain directly, or have available adequate laboratory services to meet the needs of its patients.

Laboratory services shall comply with the Clinical Laboratory Improvement Amendments of 1988 (CLIA 1988), in accordance with the requirements specified in 42 Code of Federal Regulations (CFR), §§493.1- 493.1780. CLIA 1988 applies to all FEMCFs with laboratories that examine human specimens for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.

The laboratory services to be provided by the FEMCF to meet the needs of patients in emergent situations should be determined by the facility medical director along with input from the medical staff of the facility and based on proven knowledge and experience in the practice of emergency medicine. The specific clinical laboratory tests required to “meet the needs of patients” in emergent situation are variable, depending upon the medical condition of the patient presenting to the facility and the vital clinical information that the attending physician needs to assess, diagnose, and treat the patient’s condition appropriately.

If any laboratory testing is performed on-site at the FEMCF, the facility will be required to apply for and obtain CLIA certification appropriate for the type of clinical laboratory testing performed at the facility. The following is the web address of the CLIA website where additional information about the program can be obtained, including how to apply for CLIA certification: <http://www.cms.hhs.gov/clia/>,

The following are examples of basic clinical laboratory tests typically ordered in a hospital emergency department to meet the needs of the patients. This list is not all inclusive

Hematology

- Complete Blood Count (white cells (WBC), red cells (RBC), hemoglobin (Hgb), hematocrit (HCT), red cell indices (MCV, MCH, MCHC), platelets (Plt), white cell differential, and mean platelet volume (MPV)).
- Coagulation : International Normalization Ratio (INR), Prothrombin Time (PT), and Partial Thromboplastin Time (PTT)

Chemistry

- Urinalysis (UA)
- Basic Metabolic Profile (sodium (Na), potassium (K), chloride (Cl), carbon dioxide (CO₂), glucose, blood urea nitrogen (BUN), and creatinine)

- Liver or Hepatic panel: (aspartate aminotransferase (AST or SGOT), alanine aminotransferase (ALT), alkaline phosphatase (ALK), γ -glutamyl transferase (GGTP), bilirubin (Total and Direct), total protein, and albumin.)
- Amylase
- Cardiac Injury Assessment: (creatin kinase (CK), CK-MB (CK isoenzyme specific to cardiac muscle), troponin-I, and myoglobin.)
- Arterial Blood Gas (ABG – pH, PCO₂, CO₂ content, PO₂ , O₂ saturation,)

Toxicology

- Therapeutic drugs
 - Cardiotropics (examples: digoxin, digitoxin, procainamide, Quinidine, Lidocaine, propranolol)
 - Anticonvulsives (examples: Phenobarbital, Phenytoin, Priidone, Ethsuximide, Carbaazapine, Valproic Acid)
 - Antiasthmatics (example: Theophylline,)
 - Drugs used to treat mental disorders: (examples: Lithium, tricyclic antidepressants)
- Screening tests for drugs of abuse (cocaine, opiates, methadone, amphetamines, benzodiazepines, phencyclidine (PCP), barbiturates, methaqualone, cannabis (marijuana / THC), and lysergic acid diethylamide (LSD).)
- Ethyl Alcohol
- Acetylsalicylic acid (aspirin)
- Acetaminophen (Tylenol)

Endocrinology

- Chorionic Gonadotropin (qualitative (urine), quantitative B HCG (serum))
- Thyroid Stimulating Hormone (TSH)

Microbiology (Bacteriology, Virology, Mycology, & Parasitology)

- Gram stain
- Potassium hydroxide prep (KOH)
- Vaginal Wet Prep
- Rapid Strep A screening test
- Rapid Influenza A and B screening test
- Other rapid screening tests
 - Respiratory syncytial virus (RSV)
 - Rotavirus
 - Clostridium difficile

Clinical laboratory tests are categorized depending on test methodology (complexity) by the Food and Drug Administration (FDA). All tests will fall into one of three complexity categories under CLIA: waived, moderately complex, or highly complex.

The complexity of any test can be determined through a search of the test categorization database on the FDA website at

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm>

All laboratories that perform nonwaived testing (including PPM), must have a Laboratory Director, Technical Consultant (Moderate Complexity Testing), Technical Supervisor (High Complexity Testing), and Clinical Consultant that meet specific education, training and experience under 43 CFR, Subpart M, §§ 492.1351 – 492.1495: Personnel Requirements for Nonwaived Testing. Proof of these requirements for the Laboratory Director must be provided and submitted with the application for CLIA certification.

Information to be submitted with the application includes:

- Verification of State Licensure, as applicable
- Documentation of qualifications:
 - Education (copy of Diploma, transcript from accredited institution, CMEs),
 - Credentials, and
 - Laboratory experience (must be clinical experience).

Additional information about CLIA laboratory personnel requirements is available at <http://wwwn.cdc.gov/clia/regs/toc.aspx> and <http://www.cms.hhs.gov/clia/>.

If you have any questions about any of this material, please contact the State Agency Zone office in the area where your facility is located.

Zone 1: Austin (512) 834-6650 ext 6792

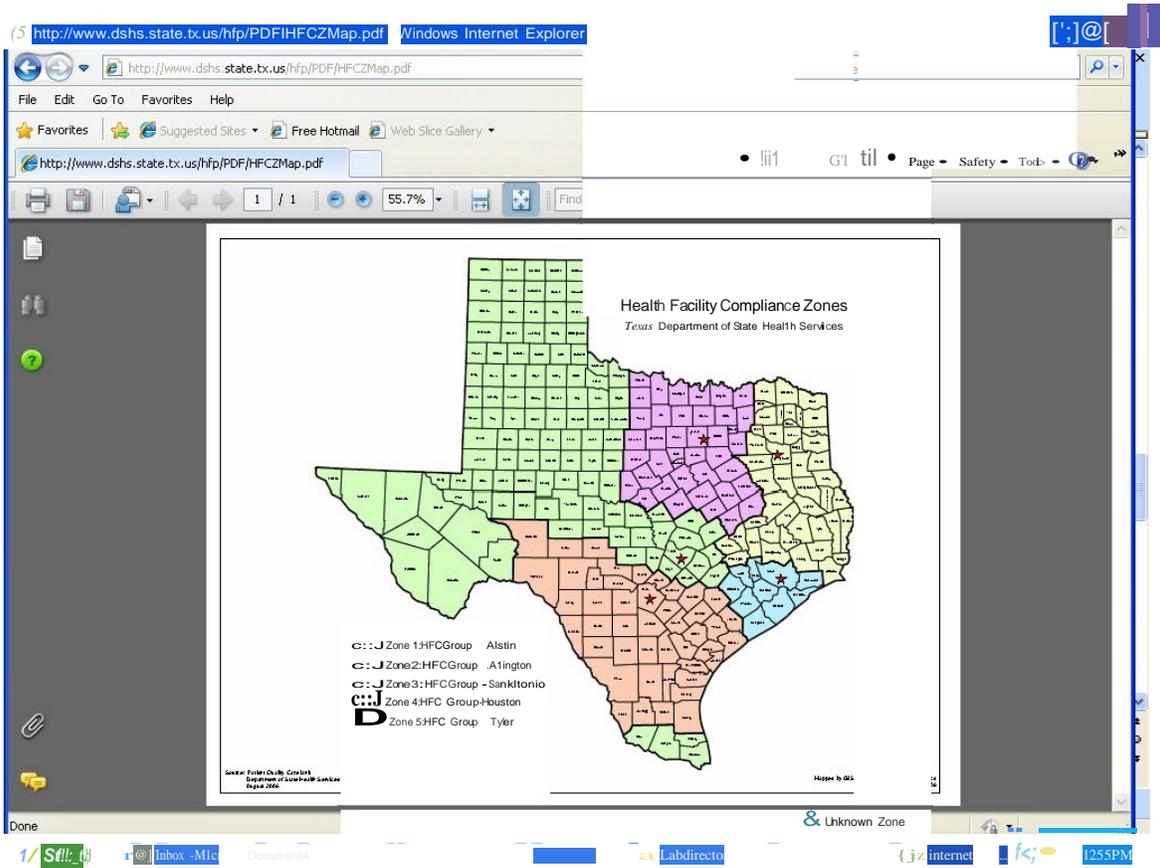
Zone 2: Arlington (817) 264-4752

Zone 3: San Antonio (210) 534-8857 ext 2925

Zone 4: Houston (713) 767-3340

Zone 5: Tyler (903) 533-5379

ZONE MAP



The following are excerpts from 42 CFR Part 143, Appendix C Interpretive Guidelines for Subpart M – Personnel for Nonwaived Testing - Qualifications for the Laboratory Director, Technical Consultant, Technical Supervisor, and Clinical Consultant.

The complete test can be found at <http://wwwn.cdc.gov/clia/regs/toc.aspx>

Subpart M--Personnel for Nonwaived Testing

§493.1351 General.

This subpart consists of the personnel requirements that must be met by laboratories performing moderate complexity testing, PPM procedures, high complexity testing, or any combination of these tests.

Laboratories Performing Provider-Performed Microscopy (PPM) Procedures

§493.1353 Scope.

In accordance with §493.19(b), the moderate complexity procedures specified as PPM procedures are considered such only when personally performed by a health care provider during a patient visit in the context of a physical examination. PPM procedures are subject to the personnel requirements in §§493.1355 through 493.1365. Interpretive Guidelines§493.1353

PPM procedures are exempt from routine inspections only when performed under the auspices of a Certificate of Provider Performed Microscopy Procedures.

D5980

§493.1355 Condition: Laboratories performing PPM procedures; laboratory director.

The laboratory must have a director who meets the qualification requirements of §493.1357 and provides overall management and direction in accordance with §493.1359.

D5981

§493.1357 Standard; laboratory director qualifications.

The laboratory director must be qualified to manage and direct the laboratory personnel and the performance of PPM procedures as specified in §493.19(c) and must be eligible to be an operator of a laboratory within the requirements of subpart R of this part.

(a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if the licensing is required.

(b) The laboratory director must meet one of the following requirements:

(b)(1) Be a physician, as defined in §493.2.

(b)(2) Be a midlevel practitioner, as defined in §493.2, authorized by a State to practice independently in the State in which the laboratory is located.

(b)(3) Be a dentist, as defined in §493.2.

D5983

§493.1359 Standard; PPM laboratory director responsibilities.

The laboratory director is responsible for the overall operation and administration of the laboratory, including the prompt, accurate, and proficient reporting of test results. The laboratory director must—

D5985

§493.1359 Standard; PPM laboratory director responsibilities.

(a) Direct no more than five laboratories; and

D5987

§493.1359 Standard; PPM laboratory director responsibilities.

(b) Ensure that any procedure listed under §493.19(c)--

(b)(1) Is personally performed by an individual who meets the qualification requirements in §493.1363; and

(b)(2) Is performed in accordance with applicable requirements in subparts H, J, K, and M of this part.

Laboratories Performing Moderate Complexity Testing

§493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director.

The laboratory must have a director who meets the qualification requirements of §493.1405 of this subpart and provides overall management and direction in accordance with §493.1407 of this subpart.

Interpretive Guidelines §493.1403:

The Condition: laboratory director is not met when the laboratory director:

- Position is not filled;
- Is not qualified; or
- Does not fulfill the laboratory director's responsibilities.

An individual qualified as laboratory director may not qualify as a technical consultant in a particular specialty or subspecialty unless he or she has the required testing experience.

D6001

§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

Interpretive Guidelines §493.1405

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."

D6002

§493.1405 Standard; Laboratory director qualifications.

must be eligible to be an operator of a laboratory within the requirements of subpart R of this part.

D6003

§493.1405 Standard; Laboratory director qualifications.

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

(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.

(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 CME providers, please see the CLIA web page at www.cms.hhs.gov/clia.

(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 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)(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 and guidance for 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.

D6004

§493.1407 Standard; Laboratory director responsibilities.

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations.

Interpretive Guidelines §493.1407

If the laboratory has more than one person qualifying as director, the laboratory is required to designate one individual who has ultimate responsibility for overall operation and administration of the laboratory. The requirement that a laboratory must be under the direction of a qualified person is not automatically met simply because the director meets the education and experience requirements. It must be demonstrated that the individual is, in fact, providing effective direction over the operation of the laboratory.

In determining whether the director responsibilities are met, consider deficiencies found in other conditions, e.g., facility administration, general laboratory systems, preanalytic systems, analytic systems, postanalytic systems, and proficiency testing.

a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of §§493.1409, 493.1415, and 493.1421, respectively. Interpretive Guidelines §493.1407(a)

If the laboratory director is not qualified as a technical consultant or clinical consultant, he or she must employ individuals meeting the appropriate qualifications.

D6033

§493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant.

The laboratory must have a technical consultant who meets the qualification requirements of §493.1411 of this subpart and provides technical oversight in accordance with §493.1413 of this subpart.

Interpretive Guidelines §493.1409

The Condition of technical consultant is not met when the technical consultant:

- Position is not filled;
- Is not qualified; or
- Does not fulfill the technical consultant's responsibilities.

D6034

§493.1411 Standard; Technical consultant qualifications.

The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section.

Interpretive Guidelines §493.1411

The type of experience required under this regulation is clinical in nature. This means, examination and test performance on human specimens for purposes of obtaining information for the diagnosis, treatment, and monitoring of patients, or for providing information to others who will do the diagnosing and treating of the patient's condition. 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 term "laboratory training or experience" means that the individual qualifying has the training and experience in the specialties and subspecialties in which the individual is providing technical consultation. Technical consultants should have documentation of hands-on testing experience. This documentation may consist of, but is not limited to, the individual's initials on worksheets or work cards, attestation of the laboratory director to the experience the individual has, or formal laboratory rotation through a medical residency program or laboratory internship program. 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.

D6035

§493.1411 Standard; Technical consultant qualifications.

(a) The technical consultant must possess a current license issued by the State in which the laboratory is located, if such licensing is required.

(b) The technical consultant 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

§493.1411(b)(1)(ii) Guidelines:

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 technical consultant 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 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

(b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or

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

(b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or

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

(b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible.

Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

Interpretive Guidelines §493.1411(b)(3)-(b)(4)

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

Some examples of how the one-year requirement for training or experience can be met are:

- Medical technology internship;
- 1 year experience performing non-waived tests in a particular specialty(ies) or subspecialty(ies); or
- Performance of non-waived testing in a particular specialty(ies) or subspecialty(ies) on a part-time basis, equivalent to 2080 hours.

NOTE: §493.1411(b)(4) requires 2 years of laboratory training or experience and can be met by any combination equivalent to 2 years of laboratory training or experience.

D6036

§493.1413 Standard; Technical consultant responsibilities.

The technical consultant is responsible for the technical and scientific oversight of the laboratory.

Interpretive Guidelines §493.1413

In a specialty in which neither the director nor testing personnel can qualify to provide technical consultation, the laboratory may engage the services of a qualified person either on a part-time or full-time basis for this service. Under these circumstances, the qualified person is not required to be on the premises full-time or at all times tests are being performed in his/her specialty(ies). However, the technical consultant must be available to provide consultation and should spend time in the laboratory sufficient to supervise the technical performance of the staff in his/her specialty(ies).

D6056

§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.

Interpretive Guidelines §493.1415

The Condition of clinical consultant is not met when the clinical consultant:

- Position is not filled;
- Is not qualified; or
- Does not fulfill the clinical consultant's responsibilities.

D6057

§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.

D6058

§493.1419 Standard; Clinical consultant responsibilities.

The clinical consultant provides consultation regarding the appropriateness of the testing ordered and interpretation of test results.

D6076

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.

InterpretiveGuidelines§493.1441

The Condition of laboratory director is not met when the laboratory director:

- Position is not filled;
- Is not qualified; or
- Does not fulfill the laboratory director responsibilities.

D6077

§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.

InterpretiveGuidelines§493.1443

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."

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.

D6078

§493.1443 Standard; Laboratory director qualifications.

(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--

- (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 InterpretiveGuidelines §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 and guidance for 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:

American Board of Bioanalysis (ABB),
American Board of Clinical Chemistry (ABCC),
American Board of Forensic Toxicology (ABFT),
American Board of Histocompatibility and Immunogenetics (ABHI),
American Board of Medical Genetics (ABMG),
American Board of Medical Laboratory Immunology (ABMLI),
American Board of Medical Microbiology (ABMM),
National Registry for Clinical Chemists (NRCC), or other board deemed comparable by HHS.
NOTE: ABFT and NRCC also certify non-doctorial 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 (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, 1988, 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, 1968, 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.

(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.

D6079

§493.1445 Standard; Laboratory director responsibilities.

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations.

Interpretive Guidelines §493.1445

The requirement that a laboratory must be under the direction of a qualified person is not automatically met simply because the director meets the education and experience requirements. It must be demonstrated that the individual is, in fact, providing effective direction over the operation of the laboratory.

In determining whether the director responsibilities are met, consider deficiencies found in other conditions, e.g., facility administration, general laboratory systems, preanalytic systems, analytic systems, postanalytic systems, and proficiency testing.

If the laboratory has more than one person qualifying as a director, one individual must be designated as accepting ultimate responsibility for the overall operation and administration of the laboratory.

(a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under §§493.1447, 493.1453, 493.1459, and 493.1487, respectively.

Interpretive Guidelines §493.1445(a)

An individual qualified as laboratory director under §493.1443 may not qualify as technical supervisor in a particular specialty or subspecialty unless he or she has the required training or experience. If the director of high complexity testing is not qualified to perform the duties of the technical supervisor or clinical consultant, he or she must employ individual(s) meeting the respective qualifications.

D6108

§493.1447 Condition: Laboratories performing high complexity testing; technical supervisor.

The laboratory must have a technical supervisor who meets the qualification requirements of §493.1449 of this subpart and provides technical supervision in accordance with §493.1451 of this subpart.

§493.1447 Guidelines:

The Condition of technical supervisor is not met when the technical supervisor:

- Position is not filled;

- Is not qualified; or
- Does not fulfill the technical supervisor responsibilities.

D6109

§493.1449 Standard; Technical supervisor qualifications.

The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical supervision for each of the specialties and subspecialties of service in which the laboratory performs high complexity tests or procedures. The director of a laboratory performing high complexity testing may function as the technical supervisor provided he or she meets the qualifications specified in this section.

Interpretive Guidelines §493.1449

The type of experience required under this regulation is clinical in nature. This means examination and test performance on human specimens for purposes of obtaining information for the diagnosis, treatment, and monitoring of patients, or for providing information to others who will do the diagnosing and treating of the patient's condition. 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 term "laboratory training or experience" means that the individual qualifying has the training in and the experience with the specialties and subspecialties in which the individual is performing technical supervision. For technical supervisor, the requirement for training or experience can be met through any combination of training and/or experience in high complexity testing. This can be acquired subsequent to, concurrent with, or prior to obtaining academic requirements.

Be flexible in evaluating laboratory training and experience. The specified training or experience may be acquired simultaneously in more than one specialty/subspecialty. Although it is unreasonable in §§493.1449(c)(5) and (j)(5) to expect four full-time years devoted only to high complexity microbiology testing and then four full-time years performing high complexity tests only in hematology, etc., to qualify under each specialty/subspecialty, it is necessary for the individual to have had continuous responsibilities in the specialty for the designated number of years and it would be more than simply performing an occasional test. Technical supervisors should have documentation of hands-on testing experience. This documentation may consist of, but is not limited to, the individual's initials on worksheets or work cards, attestation of the laboratory director to the experience the individual has, or formal laboratory rotation through a medical residency program or laboratory internship program.

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.

A year of laboratory training or experience is equivalent to 2080 hours and could extend over more than one 12 calendar-month period.

D6111

§493.1449 Standard; Technical supervisor qualifications.

(a) The technical supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and

(b) The laboratory may perform anatomic and clinical laboratory procedures and tests in all specialties and subspecialties of services except histocompatibility and clinical cytogenetics services provided the individual functioning as the technical supervisor--

(b)(1) Is 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)(2) Is certified in both anatomic and clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or Possesses qualifications that are equivalent to those required for such certification. Interpretive Guidelines

§493.1449(b)(2)

Qualifications that are equivalent for certification includes 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 technical supervisor 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 required by the board to be eligible to take the examination and must have confirmation of eligibility status.

(c) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of bacteriology, the individual functioning as the technical supervisor must—

(c)(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

(c)(1)(ii) Be certified in clinical pathology 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

InterpretiveGuidelines§493.1449(c)(1)(ii)

See §493.1449(b)(2) Guidelines.

(c)(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

(c)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or

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

InterpretiveGuidelines§493.1449(c)(3)(i)

See §493.2 for the definition of and guidance for accredited institutions.

(c)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or

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

(c)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or

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

(c)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology.

(d) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of mycobacteriology, the individual functioning as the technical supervisor must--

(d)(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

(d)(1)(ii) Be certified in clinical pathology 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

InterpretiveGuidelines§493.1449(d)(1)(ii)

See §493.1449(b)(2) Guidelines.

(d)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor or podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

(d)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or
(d)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and InterpretiveGuidelines §493.1449(d)(3)(i)

See §493.2 for the definition of and guidance for accredited institutions.

(d)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or

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

(d)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or

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

(d)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology.

(e) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of mycology, the individual functioning as the technical supervisor must--

(e)(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

(e)(1)(ii) Be certified in clinical pathology 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

InterpretiveGuidelines§493.1449(e)(1)(ii)

See §493.1449(b)(2) Guidelines.

(e)(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

(e)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or

(e)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and InterpretiveGuidelines §493.1449(e)(3)(i)

See §493.2 for the definition of and guidance for accredited institutions.

(e)(3)(ii) Have at least 1 year of laboratory training or experience, or both in high complexity testing within the speciality of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or

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

(e)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or

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

(e)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology.

(f) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of parasitology, the individual functioning as the technical supervisor must—

(f)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(f)(1)(ii) Be certified in clinical pathology 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 §493.1449(f)(1)(ii)

See §493.1449(b)(2) Guidelines.

(f)(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

(f)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology;

(f)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and Interpretive Guidelines

§493.1449(f)(3)(i)

See §493.2 for the definition of and guidance for accredited institutions.

(f)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; or

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

(f)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; or

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

(f)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology.

(g) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of virology, the individual functioning as the technical supervisor must--

(g)(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

(g)(1)(ii) Be certified in clinical pathology 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 §493.1449(g)(1)(ii)

See §493.1449(b)(2) Guidelines.

(g)(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

(g)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or

(g)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and Interpretive Guidelines

§493.1449(g)(3)(i)

See §493.2 for the definition of and guidance for accredited institutions.

(g)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or

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

(g)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or
(g)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and
(g)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology.
(h) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of diagnostic immunology, the individual functioning as the technical supervisor must-

(h)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and InterpretiveGuidelines §493.1449(h)(1)(i)

See §493.1449(b)(2) Guidelines.

(h)(1)(ii) Be certified in clinical pathology 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

(h)(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

(h)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology; or

(h)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and InterpretiveGuidelines §493.1449(h)(3)(i)

See §493.2 for the definition of and guidance for accredited institutions.

(h)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of diagnostic immunology; or

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

(h)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology; or

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

(h)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology.

(i) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of chemistry, the individual functioning as the technical supervisor must--

(i)(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

(i)(1)(ii) Be certified in clinical pathology 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

InterpretiveGuidelines§493.1449(i)(1)(ii)

See § 493.1449(b)(2)Guidelines:

(i)(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

(i)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry; or

(i)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and InterpretiveGuidelines §493.1449(i)(3)(i)

See §493.2 for the definition of and guidance for accredited institutions.

(i)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of chemistry; or

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

(i)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry; or

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

(i)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry.

(j) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of hematology, the individual functioning as the technical supervisor must--

(j)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(j)(1)(ii) Be certified in clinical pathology 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

InterpretiveGuidelines§493.1449(j)(1)(ii)

See §493.1449(b)(2) Guidelines.

(j)(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

(j)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing for the specialty of hematology (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or

(j)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and InterpretiveGuidelines

§493.1449(j)(3)(i)

See §493.2 for the definition of and guidance for accredited institutions.

(j)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of hematology; or (j)(4)(i) Have

earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and

(j)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of hematology; or

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

(j)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of hematology.

(k)(1) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of cytology, the individual functioning as the technical supervisor must--

(k)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(k)(1)(ii) Meet one of the following requirements--

(k)(1)(ii)(A) Be certified in anatomic pathology 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

(k)(1)(ii)(B) Be certified by the American Society of Cytology to practice cytopathology or possess qualifications that are equivalent to those required for such certification;

InterpretiveGuidelines§493.1449(k)(1)(ii)(A)or(B)

See §493.1449(b)(2) Guidelines.

(k)(2) An individual qualified under Sec. 493.1449(b) or paragraph (k)(1) of this section may delegate some of the cytology technical supervisor responsibilities to an individual who is in the final year of full-time training leading to certification specified in paragraphs (b) or (k)(1)(ii)(A) of this section provided the technical supervisor qualified under Sec. 493.1449(b) or paragraph (k)(1) of this section remains ultimately responsible for ensuring that all of the responsibilities of the cytology technical supervisor are met.

(l) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of histopathology, the individual functioning as the technical supervisor must--

(l)(1) Meet one of the following requirements:

(l)(i)(A) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(l)(1)(B) Be certified in anatomic pathology 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;

Interpretive Guidelines §493.1449(l)(1)(i)(B)

See §493.1449(b)(2) Guidelines.

An individual who has successfully completed a training program in neuromuscular pathology approved by HHS may examine and provide reports for neuromuscular pathology. As of 7/03, HHS has approved The American Academy of Neurology Committee for Neuromuscular Pathology Training Program.

(l)(1)(B)(ii) An individual qualified under §493.1449(b) or paragraph (l)(1) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraph (b) or (l)(1)(i)(B) of this section, the responsibility for examination and interpretation of histopathology specimens.

(l)(2) For tests in dermatopathology, meet one of the following requirements:

(l)(2)(i)(A) 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--

(l)(2)(i)(B) Meet one of the following requirements: (l)(2)(i)(B)(1) Be certified in anatomic pathology 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

(l)(2)(i)(B)(2) Be certified in dermatopathology by the American Board of Dermatology and the American Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(l)(2)(i)(B)(3) Be certified in dermatology by the American Board of Dermatology or possess qualifications that are equivalent to those required for such certification; or

Interpretive Guidelines §493.1449(l)(2)(i)(B)(1),(2), or (3)

See §493.1449(b)(2) Guidelines.

(l)(2)(ii) An individual qualified under §493.1449(b) or paragraph (l)(2)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (l)(2)(i)(B) of this section, the responsibility for examination and interpretation of dermatopathology specimens.

(l)(3) For tests in ophthalmic pathology, meet one of the following requirements:

(l)(3)(i)(A) 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--

(l)(3)(i)(B) Must meet one of the following requirements:

(l)(3)(i)(B)(1) Be certified in anatomic pathology 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

(l)(3)(i)(B)(2) Be certified by the American Board of Ophthalmology or possess qualifications that are equivalent to those required for such certification and have successfully completed at least 1 year of formal post-residency fellowship training in ophthalmic pathology; or

Interpretive Guidelines §493.1449(l)(3)(i)(B)(1) or (2)

See §493.1449(b)(2) Guidelines.

(l)(3)(i)(B)(2)(ii) An individual qualified under §493.1449(b) or paragraph (1)(3)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (1)(3)(i)(B) of this section, the responsibility for examination and interpretation of ophthalmic specimens; or

(m) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of oral pathology, the individual functioning as the technical supervisor must meet one of the following requirements:

(m)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and--

(m)(1)(ii) Be certified in anatomic pathology 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

(m)(2) Be certified in oral pathology by the American Board of Oral Pathology or possess qualifications for such certification; or

(m)(3) An individual qualified under §493.1449(b) or paragraph (m) (1) or (2) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (m) (1) or (2) of this section, the responsibility for examination and interpretation of oral pathology specimens.

(n) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of radiobioassay, the individual functioning as the technical supervisor must--

(n)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (n)(1)(ii) Be certified in clinical pathology 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 InterpretiveGuidelines §493.1449(n)(1)(ii)

See §493.1449(b)(2) Guidelines.

(n)(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

(n)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay; or

(n)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and InterpretiveGuidelines §493.1449(n)(3)(i)

See §493.2 for the definition of and guidance for accredited institutions.

(n)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of radiobioassay; or

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

(n)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay; or

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

(n)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay.

(o) If the laboratory performs tests in the specialty of histocompatibility, the individual functioning as the technical supervisor must either--

(o)(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; and

(o)(1)(ii) Have training or experience that meets one of the following requirements:

(o)(1)(ii)(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or

(o)(1)(ii)(B)(1) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and

(o)(2) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility; or

(o)(2)(i) Have an earned doctoral degree in a biological or clinical laboratory science from an accredited institution; and

Interpretive Guidelines §493.1449(o)(2)(i)

See §493.2 for the definition of and guidance for accredited institutions.

(o)(2)(ii) Have training or experience that meets one of the following requirements:

(o)(2)(ii)(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or

(o)(2)(ii)(B)(1) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and

(o)(2)(ii)(B)(2) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility.

(p) If the laboratory performs tests in the specialty of clinical cytogenetics, the individual functioning as the technical supervisor must-

(p)(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; and

(p)(1)(ii) Have 4 years of training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics; or

(p)(2)(i) Hold an earned doctoral degree in a biological science, including biochemistry, or clinical laboratory science from an accredited institution; and Interpretive Guidelines

§493.1449(p)(2)(i)

See §493.2 for the definition of and guidance for accredited institutions.

(p)(2)(ii) Have 4 years of training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics.

(q) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of immunohematology, the individual functioning as the technical supervisor must--

(q)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(q)(1)(ii) Be certified in clinical pathology 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 §493.1449(q)(1)(ii)

See §493.1449(b)(2) Guidelines.

(q)(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

(q)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing for the specialty of immunohematology.

Note: The technical supervisor requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service. For example, an individual, who has a doctoral degree in chemistry and additionally has documentation of 1 year of laboratory experience working concurrently in high complexity testing in the specialties of microbiology and chemistry and 6 months of that work experience included high complexity testing in bacteriology, mycology, and mycobacteriology, would qualify as the technical supervisor for the specialty of chemistry and the subspecialties of bacteriology, mycology, and mycobacteriology.

D6112

§493.1451 Standard: Technical supervisor responsibilities.

The technical supervisor is responsible for the technical and scientific oversight of the laboratory. The technical supervisor is not required to be on site at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide supervision as specified in (a) of this section.

Interpretive Guidelines §493.1451

In a specialty in which neither the director nor the general supervisor can qualify to provide technical supervision, the laboratory may engage the services of a qualified person either on a part-time or full-time basis for this service. The technical supervisor is not required to be on the premises full-time or at all times tests are being performed in his/her specialty(ies). However, the technical supervisor must be available to provide consultation and is required to spend an amount of time in the laboratory sufficient to supervise the technical performance of the staff in his/her specialty(ies). There should be documentation, such as a log book or notes from training which indicate the technical supervisor performs his/her assigned duties. The technical supervisor is responsible for evaluating the capabilities of the testing personnel and the general supervisor's testing performance.

D6134

§493.1453 Condition: Laboratories performing high complexity testing; clinical consultant. The laboratory must have a clinical consultant who meets the requirements of §493.1455 of this subpart and provides clinical consultation in accordance with §493.1457 of this subpart.

Interpretive Guidelines §493.1453

The Condition of clinical consultant is not met when the clinical consultant:

- Position is not filled;
- Is not qualified; or
- Does not fulfill the clinical consultant responsibilities.

D6135

§493.1455 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 §493.1443(b)(1), (2), or (3)(i) or, for the subspecialty of oral pathology, §493.1443(b)(6); or
- (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.

D6136

§493.1457 Standard; Clinical consultant responsibilities.

The clinical consultant provides consultation regarding the appropriateness of the testing ordered and interpretation of test results.