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.

D5990

§493.1361 Condition: Laboratories performing PPM procedures; testing personnel.

The laboratory must have a sufficient number of individuals who meet the qualification requirements of §493.1363 to perform the functions specified in §493.1365 for the volume and complexity of testing performed.

D5991

§493.1363 Standard; PPM testing personnel qualifications.

Each individual performing PPM procedures must--
(a) Possess a current license issued by the State in which the laboratory is located if the licensing is required; and
(b) 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, under the supervision of a physician or in independent practice if authorized by the State in which the laboratory is located.
(b)(3) Be a dentist as defined in §493.2 of this part.

D5993

§493.1365 Standard; PPM testing personnel responsibilities.

The testing personnel are responsible for specimen processing, test performance, and for reporting test results. Any PPM procedure must be--
(a) Personally performed by one of the following practitioners:
(a)(1) A physician during the patient's visit on a specimen obtained from his or her own patient or from a patient of a group medical practice of which the physician is a member or employee.
(a)(2) A midlevel practitioner, under the supervision of a physician or in independent practice if authorized by the State in which the laboratory is located, during the patient's visit on a specimen obtained from his or her own patient or from the patient of a clinic, group medical practice, or other health care provider, in which the midlevel practitioner is a member or an employee.

(a)(3) A dentist during the patient's visit on a specimen obtained from his or her own patient or from a patient of a group dental practice of which the dentist is a member or an employee; and

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D5995

§493.1365 Standard; PPM testing personnel responsibilities.

(b) Performed using a microscope limited to a brightfield or a phase/contrast microscope.

D6000

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.

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§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.*

(b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

D6005

§493.1407 Standard; Laboratory director responsibilities.

(c) The laboratory director must be accessible to the laboratory to provide onsite, telephone or electronic consultation as needed.

Interpretive Guidelines §493.1407(c)
If the director cannot practically provide personal, onsite supervision it must be demonstrated that the director:

- *Provides direction and consultation by telephone, as necessary; or*
- *Delegates to qualified personnel specific responsibilities as provided in the regulations.*

The laboratory director may reapportion to a technical consultant, in writing, the responsibilities in: §§493.1407(e)(3), (4), (5), (6), (7), (11), (12), and (13).

The laboratory director may reapportion to a clinical consultant, in writing, the responsibilities in: §§493.1407(e)(8) and (9).

D6006

§493.1407 Standard; Laboratory director responsibilities.

(d) Each individual may direct no more than five laboratories.

Interpretive Guidelines §493.1407(d)
An individual may serve as a director of 5 certified laboratories. An individual may serve as a technical consultant or clinical consultant for any number of laboratories.

D6007

§493.1407 Standard; Laboratory director responsibilities.

(e) The laboratory director must--
(e)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

D6010

§493.1407 Standard; Laboratory director responsibilities.

(e)(2) Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed and

Interpretive Guidelines §493.1407(e)(2)
OSHA/EPA issues cannot be cited using these requirements. If immediate jeopardy exists, the director should be informed immediately.

If you observe or obtain information regarding potential safety violations not applicable under CLIA, notify the appropriate State or local authority. Consult with the Regional Office (RO) for notification to other Federal agencies such as the Occupational Safety and Health Administration (OSHA) www.osha.gov, Environmental Protection Agency (EPA) www.epa.gov, or Nuclear Regulatory Commission (NRC). The appropriate Federal, State or local authority, if warranted, will investigate and, if necessary, conduct an on-site visit.

D6011

§493.1407 Standard; Laboratory director responsibilities.

provide a safe environment in which employees are protected from physical, chemical, and biological hazards;

D6012

§493.1407 Standard; Laboratory director responsibilities.

(e)(3) Ensure that--
(e)(3)(i) The test methodologies selected have the capability of providing the quality of results required for patient care;

D6013

§493.1407 Standard; Laboratory director responsibilities.

(e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and

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D6014

§493.1407 Standard; Laboratory director responsibilities.

(e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results;

D6015

§493.1407 Standard; Laboratory director responsibilities.

(e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed and that--

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D6016

§493.1407 Standard; Laboratory director responsibilities.

(e)(4)(i) The proficiency testing samples are tested as required under subpart H of this part;

D6017

§493.1407 Standard; Laboratory director responsibilities.

(e)(4)(ii) The results are returned within the timeframes established by the proficiency testing program;

D6018

§493.1407 Standard; Laboratory director responsibilities.

(e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; and

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D6019

§493.1407 Standard; Laboratory director responsibilities.

(e)(4)(iv) An approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory;

D6020

§493.1407 Standard; Laboratory director responsibilities.

(e)(5) Ensure that the quality control

D6021

§493.1407 Standard; Laboratory director responsibilities.

and quality assessment programs are established and maintained to assure the quality of laboratory services provided and

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D6022

§493.1407 Standard; Laboratory director responsibilities.

to identify failures in quality as they occur;

D6023

§493.1407 Standard; Laboratory director responsibilities.

(e)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;

D6024

§493.1407 Standard; Laboratory director responsibilities.

(e)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, and

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D6025

§493.1407 Standard; Laboratory director responsibilities.

that patient test results are reported only when the system is functioning properly;

D6026

§493.1407 Standard; Laboratory director responsibilities.

(e)(8) Ensure that reports of test results include pertinent information required for interpretation;

D6027

§493.1407 Standard; Laboratory director responsibilities.

(e)(9) Ensure that consultation is available to the laboratory's clients on matters relating to the quality of the test results reported and their interpretation concerning specific patient conditions;

D6028

§493.1407 Standard; Laboratory director responsibilities.

(e)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart;

D6029

§493.1407 Standard; Laboratory director responsibilities.

(e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results;

D6030

§493.1407 Standard; Laboratory director responsibilities.

(e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

D6031

§493.1407 Standard; Laboratory director responsibilities.

(e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and

D6032

§493.1407 Standard; Laboratory director responsibilities.

(e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

Interpretive Guidelines §493.1407(e)(14)
The director must assign, in writing, the duties/responsibilities to each person involved in all phases of the testing process. The list of assigned duties must be current.

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).

D6037

§493.1413 Standard; Technical consultant responsibilities.

The technical consultant is not required to be onsite at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide consultation, as specified in paragraph (a) of this section.

D6038

§493.1413 Standard; Technical consultant responsibilities.

(a) The technical consultant must be accessible to the laboratory to provide on-site, telephone, or electronic consultation; and

Interpretive Guidelines §493.1413(a)

Since the testing personnel usually will not have experience and training in all specialties, technical consultation is essential in identifying training needs and assuring that each individual performing testing receives regular in-service training and education. There should be documentation, such as a log book or training/discussion reports, to indicate the services provided or activities performed by the technical consultant. These activities should correlate with the responsibilities delegated to the technical consultant by the laboratory director. The technical consultant is responsible for evaluating the capabilities of the technical personnel and advising the director on proper test performance in the specialty.

D6039

§493.1413 Standard; Technical consultant responsibilities.

(b) The technical consultant is responsible for--
(b)(1) Selection of test methodology appropriate for the clinical use of the test results;

D6040

§493.1413 Standard; Technical consultant responsibilities.

(b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system;

D6041

§493.1413 Standard; Technical consultant responsibilities.

(b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered;

D6042

§493.1413 Standard; Technical consultant responsibilities.

(b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;

D6043

§493.1413 Standard; Technical consultant responsibilities.

(b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications;

D6044

§493.1413 Standard; Technical consultant responsibilities.

(b)(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly;

D6045

§493.1413 Standard; Technical consultant responsibilities.

(b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;

> *Interpretive Guidelines §493.1413(b)(7)*
> *In some instances, in-service training may be specifically related to an instrument or test, or may be very general in nature. The laboratory may establish its own format, content, and schedule or provide training on an as-needed basis. This is acceptable provided the laboratory does not have deficiencies related to test performance.*

D6046

§493.1413 Standard; Technical consultant responsibilities.

(b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to--

> *Probes §493.1413(b)(8)*
> *What mechanism is used to ensure that testing personnel are following the laboratory's policies and procedures?*
>
> *Evaluations of technical and clinical consultants' performance is located at §493.1235 - Personnel Competency Assessment Policies and §§493.1239(a)-(b),General Laboratory Systems Assessment.*

D6047

§493.1413 Standard; Technical consultant responsibilities.

(b)(8)(i) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing;

D6048

§493.1413 Standard; Technical consultant responsibilities.

(b)(8)(ii) Monitoring the recording and reporting of test results;

D6049

§493.1413 Standard; Technical consultant responsibilities.

(b)(8)(iii) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records;

D6050

§493.1413 Standard; Technical consultant responsibilities.

(b)(8)(iv) Direct observation of performance of instrument maintenance and function checks;

D6051

§493.1413 Standard; Technical consultant responsibilities.

(b)(8)(v) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and

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D6052

§493.1413 Standard; Technical consultant responsibilities.

(b)(8)(vi) Assessment of problem solving skills; and

D6053

§493.1413 Standard; Technical consultant responsibilities.

(b)(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

D6054

§493.1413 Standard; Technical consultant responsibilities.

Thereafter, evaluations must be performed at least annually

D6055

§493.1413 Standard; Technical consultant responsibilities.

unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

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.

D6059

§493.1419 Standard; Clinical consultant responsibilities.

The clinical consultant must--
(a) Be available to provide clinical consultation to the laboratory's clients;

D6060

§493.1419 Standard; Clinical consultant responsibilities.

(b) Be available to assist the laboratory's clients in ensuring that appropriate tests are ordered to meet the clinical expectations;

D6061

§493.1419 Standard; Clinical consultant responsibilities.

(c) Ensure that reports of test results include pertinent information required for specific patient interpretation; and

Probes §493.1419(c)

Has the clinical consultant reviewed the reports to ensure that test results include patient information required for specific patient interpretations?

D6062

§493.1419 Standard; Clinical consultant responsibilities.

(d) Ensure that consultation is available and communicated to the laboratory's clients on matters related to the quality of the test results reported and their interpretation concerning specific patient conditions.

D6063

§493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel.

The laboratory must have a sufficient number of individuals who meet the qualification requirements of §493.1423, to perform the functions specified in §493.1425 for the volume and complexity of tests performed.

Interpretive Guidelines §493.1421
The criteria used to determine the adequacy of the testing personnel involves evaluating testing personnel responsibilities, and ensuring that these responsibilities are specified in writing by the director, and that the responsibilities are appropriate to ensure compliance with the requirements concerning reporting and recordkeeping, quality control monitoring, quality assurance activities and proficiency testing participation. Cite this deficiency only when compliance problems are found in these areas that can be directly related to insufficient numbers of testing personnel. (Use D6028, which relates the finding of insufficient personnel to director responsibilities.)

D6064

§493.1423 Standard; Testing personnel qualifications.

Each individual performing moderate complexity testing must--
(a) Possess a current license issued by the State in which the laboratory is located, if such licensing is required; and

Interpretive Guidelines §493.1423
The laboratory director is responsible for ensuring the testing personnel have the appropriate education and experience, and receive the appropriate training for the type and complexity of testing performed. The experience required is clinical in nature. This means, examination of 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. (Use D6029).

Each individual must have documentation of training applicable to the types and complexity of testing performed. This training should be such that the individual can demonstrate that he/she has the skills required for proper performance of preanalytic, analytic, and postanalytic phases of testing. For example, if the individual performs a rapid Strep test, he/she should be able to demonstrate the skills for:

- *Proper specimen handling prior to testing, e.g., assuring the specimen is properly labeled and received and tested within appropriate timeframes, the swab is received at the proper temperature, and the ampule on the swab containing transport media is broken;*
- *Proper test performance according to the laboratory's policies and manufacturer's instructions, e.g., using reagents that are not outdated, are at the proper temperature, and of the same lot number, accurate timing of all steps in the procedure, proper performance of quality control procedures; and*
- *Proper reporting of patient test results in accordance with the laboratory's policies, e.g., notifying the person authorized to receive test results of a positive result, not reporting the test result if quality control fails.*

Training may include, but is not limited to, attendance at:

- *Seminars given by experts in the field, e.g., a lecture about antibiotic resistance given by the infection control officer of a local hospital;*
- *On-site or off-site instrument trainings given by a manufacturer, e.g., a week-long training course given at the manufacturer's headquarters, or training by a manufacturer's technical representative on an instrument purchased by a laboratory;*
- *Technical training sessions, workshops, or conferences given by a professional laboratory organization, e.g., CAP, ASMT, AACC, and ASCT;*
- *Technical education classes or specialty courses that include hands-on test performance, e.g., parasitology, bacteriology, cytology, given by CDC, a State Health Department, or professional laboratory organizations;*
- *A formal laboratory training program; or*
- *Inservices offered by a local hospital laboratory staff, pathologist, or medical technologist to a physician's office personnel.*

Documentation may consist of, but is not limited to, letters from training programs or employers, attestation statements by the laboratory director, a log sheet initialed by the attendees indicating attendance at a training session/inservice, certificates from organizations providing the training session, workshop, conference, specialty course.

D6065

§493.1423 Standard; Testing personnel qualifications.

(b) Meet one of the following requirements:
(b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or

Interpretive Guidelines §493.1423(b)(1)
See §493.2 for the definition of and guidance for accredited institution.

(b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or
(b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or

Interpretive Guidelines §493.1423(b)(3)

Equate similar military courses with different titles. Evaluate the course length and content to assure that it provides effective training for testing personnel. Refer to A Guide to the Evaluation of Educational Experience in the Armed Services, American Council on Education, Washington, D.C.

(b)(4)(i) Have earned a high school diploma or equivalent; and

Interpretive Guidelines §493.1423(b)(4)
Personnel qualifying under this requirement must have a high school diploma or GED.

Probes §1493.1423(b)(4)
How does the laboratory assure that personnel receiving orientation and training have the necessary skills for properly performing assigned responsibilities?

D6066

§493.1423 Standard; Testing personnel qualifications.

(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens.

D6067

§493.1423 Standard; Testing personnel qualifications.

Such training must ensure that the individual has--
(b)(4)(ii)(A) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens;
(b)(4)(ii)(B) The skills required for implementing all standard laboratory procedures;
(b)(4)(ii)(C) The skills required for performing each test method and for proper instrument use;
(b)(4)(ii)(D) The skills required for performing preventive maintenance, troubleshooting and calibration procedures related to each test performed;
(b)(4)(ii)(E) A working knowledge of reagent stability and storage;
(b)(4)(ii)(F) The skills required to implement the quality control policies and procedures of the laboratory;
(b)(4)(ii)(G) An awareness of the factors that influence test results; and
(b)(4)(ii)(H) The skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results.

D6068

§493.1425 Standard; Testing personnel responsibilities.

The testing personnel are responsible for specimen processing, test performance, and for reporting test results.

D6069

§493.1425 Standard; Testing personnel responsibilities.

(a) Each individual performs only those moderate complexity tests that are authorized by the laboratory director and require a degree of skill commensurate with the individual's education, training or experience, and technical abilities.

D6070

§493.1425 Standard; Testing personnel responsibilities.

(b) Each individual performing moderate complexity testing must--
(b)(1) Follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results;

D6071

§493.1425 Standard; Testing personnel responsibilities.

(b)(2) Maintain records that demonstrate that proficiency testing samples are tested in the same manner as patient samples;

D6072

§493.1425 Standard; Testing personnel responsibilities.

(b)(3) Adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed;

D6073

§493.1425 Standard; Testing personnel responsibilities.

(b)(4) Follow the laboratory's established corrective action policies and procedures whenever test systems are not within the laboratory's established acceptable levels of performance;

D6074

§493.1425 Standard; Testing personnel responsibilities.

(b)(5) Be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the technical consultant, clinical consultant or director; and

Interpretive Guidelines §493.1425(b)(5)
If, during the survey, testing personnel demonstrate an inability to identify a problem that adversely affects a patient test result, cite D6029 under director responsibilities.

Some examples of problems that may adversely affect patient test results may include, but are not limited to:

- *A pleural fluid that is mislabeled and, therefore, is processed as a urine culture;*
- *Performing a potassium on a hemolyzed sample; or*
- *Tests are incubated at 37°C when the manufacturer's instructions require 25°Cincubation.*

D6075

§493.1425 Standard; Testing personnel responsibilities.

(b)(6) Document all corrective actions taken when test systems deviate from the laboratory's established performance specifications.

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.

Interpretive Guidelines §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.

Interpretive Guidelines §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

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 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.*

(b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

D6080

§493.1445 Standard; Laboratory director responsibilities.

(c) The laboratory director must be accessible to the laboratory to provide onsite, telephone or electronic consultation as needed.

D6081

§493.1445 Standard; Laboratory director responsibilities.

(d) Each individual may direct no more than five laboratories.

Interpretive Guidelines §493.1445(d)
An individual may serve as a director of 5 nonwaived certified laboratories. However, an individual may serve as technical consultant, clinical consultant or technical supervisor for any number of laboratories.

D6082

§493.1445 Standard; Laboratory director responsibilities.

(e) The laboratory director must--
(e)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

§493.1445(e) Guidelines:
If the director cannot practically provide personal, on-site supervision, it must be demonstrated that the director:

- *Provides direction and consultation electronically or by telephone, as necessary; or*
- *Delegates to qualified personnel specific responsibilities as provided in the regulations.*

The laboratory director may reapportion to a technical supervisor, in writing, the responsibilities in: §§493.1445(e)(3), (4), (5), (6), (7), (12), (13), and (14).

The laboratory director may reapportion to a clinical consultant, in writing, the responsibilities in: §§493.1445(e)(8) and (9).

The only responsibilities that may be delegated to the general supervisor are listed at §§493.1463(b)(1)-(4).

D6083

§493.1445 Standard; Laboratory director responsibilities.

(e)(2) Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed and

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D6084

§493.1445 Standard; Laboratory director responsibilities.

and provide a safe environment in which employees are protected from physical, chemical, and biological hazards;

Interpretive Guidelines §493.1445(e)(2)
OSHA/EPA issues cannot be cited using these requirements. If immediate jeopardy exists, inform the director immediately.

If you observe or obtain information regarding potential safety violations not applicable under CLIA, notify the appropriate State or local authority. Consult with the Regional Office (RO) for notification to other Federal agencies such as the Occupational Safety and Health Administration (OSHA) www.osha.gov, Environmental Protection Agency

(EPA) www.epa.gov, or Nuclear Regulatory Commission (NRC). The appropriate Federal, State or local authority, if warranted, will investigate and, if necessary, conduct an on-site visit.

D6085

§493.1445 Standard; Laboratory director responsibilities.

(e)(3) Ensure that--
(e)(3)(i) The test methodologies selected have the capability of providing the quality of results required for patient care;

D6086

§493.1445 Standard; Laboratory director responsibilities.

(e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and

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D6087

§493.1445 Standard; Laboratory director responsibilities.

(e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results;

D6088

§493.1445 Standard; Laboratory director responsibilities.

(e)(4) Ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed and that--

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D6089

§493.1445 Standard; Laboratory director responsibilities.

(e)(4)(i) The proficiency testing samples are tested as required under subpart H of this part;

D6090

§493.1445 Standard; Laboratory director responsibilities.

(e)(4)(ii) The results are returned within the timeframes established by the proficiency testing program;

D6091

§493.1445 Standard; Laboratory director responsibilities.

(e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; and

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D6092

§493.1445 Standard; Laboratory director responsibilities.

(e)(4)(iv) An approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory;

D6093

§493.1445 Standard; Laboratory director responsibilities.

(e)(5) Ensure that the quality control and

D6094

§493.1445 Standard; Laboratory director responsibilities.

quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

D6095

§493.1445 Standard; Laboratory director responsibilities.

(e)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;

D6096

§493.1445 Standard; Laboratory director responsibilities.

(e)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified, and

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D6097

§493.1445 Standard; Laboratory director responsibilities.

that patient test results are reported only when the system is functioning properly;

D6098

§493.1445 Standard; Laboratory director responsibilities.

(e)(8) Ensure that reports of test results include pertinent information required for interpretation;

D6099

§493.1445 Standard; Laboratory director responsibilities.

(e)(9) Ensure that consultation is available to the laboratory's clients on matters relating to the quality of the test results reported and their interpretation concerning specific patient conditions;

D6100

§493.1445 Standard; Laboratory director responsibilities.

(e)(10) Ensure that a general supervisor provides on-site supervision of high complexity test performance by testing personnel qualified under §493.1489(b)(4);

D6101

§493.1445 Standard; Laboratory director responsibilities.

(e)(11) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart;

D6102

§493.1445 Standard; Laboratory director responsibilities.

(e)(12) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results;

D6103

§493.1445 Standard; Laboratory director responsibilities.

(e)(13) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

D6106

§493.1445 Standard; Laboratory director responsibilities.

(e)(14) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and

D6107

§493.1445 Standard; Laboratory director responsibilities.

(e)(15) Specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

Interpretive Guidelines §493.1445(e)(15)
The director must assign, in writing, the duties/responsibilities to each person involved in all phases of the testing process. The list of assigned duties must be current.

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

Interpretive Guidelines §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

Interpretive Guidelines §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

Interpretive Guidelines §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

Interpretive Guidelines §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

Interpretive Guidelines §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

Interpretive Guidelines §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

Interpretive Guidelines §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

Interpretive Guidelines §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

Interpretive Guidelines §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

Interpretive Guidelines §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

Interpretive Guidelines §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

Interpretive Guidelines §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;

Interpretive Guidelines §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

Interpretive Guidelines §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

Interpretive Guidelines §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.

D6113

§493.1451 Standard: Technical supervisor responsibilities.

(a) The technical supervisor must be accessible to the laboratory to provide on-site, telephone, or electronic consultation; and

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D6114

§493.1451 Standard: Technical supervisor responsibilities.

(b) The technical supervisor is responsible for--
(b)(1) Selection of the test methodology that is appropriate for the clinical use of the test results;

D6115

§493.1451 Standard: Technical supervisor responsibilities.

(b)(2) Verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system;

D6116

§493.1451 Standard: Technical supervisor responsibilities.

(b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered;

D6117

§493.1451 Standard: Technical supervisor responsibilities.

(b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;

D6118

§493.1451 Standard: Technical supervisor responsibilities.

(b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications;

D6119

§493.1451 Standard: Technical supervisor responsibilities.

(b)(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly;

D6120

§493.1451 Standard: Technical supervisor responsibilities.
(b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;

> *Interpretive Guidelines §493.1451(b)(7)*
> *In some instances, in-service training may be specifically related to an instrument or test, or may be very general in nature. The laboratory may establish its own format, content, and schedule or provide training on an as-needed basis. This is acceptable provided the laboratory does not have deficiencies related to test performance.*

(b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

> *Probes §493.1451(b)(8)*
> *What mechanism is used to ensure that testing personnel are following the laboratory's policies and procedures? When approved by the director, these policies and procedures may include manufacturer's instructions.*

D6121

§493.1451 Standard: Technical supervisor responsibilities.

The procedures for evaluation of the competency of the staff must include, but are not limited to--
(b)(8)(i) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing;

D6122

§493.1451 Standard: Technical supervisor responsibilities.

(b)(8)(ii) Monitoring the recording and reporting of test results;

D6123

§493.1451 Standard: Technical supervisor responsibilities.

(b)(8)(iii) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records;

D6124

§493.1451 Standard: Technical supervisor responsibilities.

(b)(8)(iv) Direct observation of performance of instrument maintenance and function checks;

D6125

§493.1451 Standard: Technical supervisor responsibilities.

(b)(8)(v) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and

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D6126

§493.1451 Standard: Technical supervisor responsibilities.

(b)(8)(vi) Assessment of problem solving skills; and

D6127

§493.1451 Standard: Technical supervisor responsibilities.

(b)(9) Evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.

D6128

§493.1451 Standard: Technical supervisor responsibilities.

Thereafter, evaluations must be performed at least annually

D6129

§493.1451 Standard: Technical supervisor responsibilities.

unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.
(c) In cytology, the technical supervisor or the individual qualified under §493.1449(k)(2)--
(c)(1) May perform the duties of the cytology general supervisor and the cytotechnologist, as specified in §§493.1471 and 493.1485, respectively;

D6130

§493.1451 Standard: Technical supervisor responsibilities.

(c)(2) Must establish the workload limit for each individual examining slides;
(c)(3) Must reassess the workload limit for each individual examining slides at least every 6 months and adjust as necessary;

D6131

§493.1451 Standard: Technical supervisor responsibilities.

(c)(4) Must perform the functions specified in §493.1274(d) and (e);

D6132

§493.1451 Standard: Technical supervisor responsibilities.

(c)(5) Must ensure that each individual examining gynecologic preparations participates in an HHS approved cytology proficiency testing program, as specified in §493.945 and achieves a passing score, as specified in §493.855; and

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D6133

§493.1451 Standard: Technical supervisor responsibilities.

(c)(6) If responsible for screening cytology slide preparations, must document the number of cytology slides screened in 24 hours and the number of hours devoted during each 24-hour period to screening cytology slides.

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.

D6137

§493.1457 Standard; Clinical consultant responsibilities.

The clinical consultant must--
(a) Be available to provide consultation to the laboratory's clients;

D6138

§493.1457 Standard; Clinical consultant responsibilities.

(b) Be available to assist the laboratory's clients in ensuring that appropriate tests are ordered to meet the clinical expectations;

D6139

§493.1457 Standard; Clinical consultant responsibilities.

(c) Ensure that reports of test results include pertinent information required for specific patient interpretation; and

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D6140

§493.1457 Standard; Clinical consultant responsibilities.

(d) Ensure that consultation is available and communicated to the laboratory's clients on matters related to the quality of the test results reported and their interpretation concerning specific patient conditions.

D6141

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

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

Interpretive Guidelines §493.1459
The Condition of general supervisor is not met when the general supervisor:

- *Position is not filled;*
- *Is not qualified; or*

- *Does not fulfill the general supervisor responsibilities.*

D6142

§493.1461 Standard; General supervisor qualifications.

The laboratory must have one or more general supervisors who, under the direction of the laboratory director and supervision of the technical supervisor, provides day-to-day supervision of testing personnel and reporting of test results. In the absence of the director and technical supervisor, the general supervisor must be responsible for the proper performance of all laboratory procedures and reporting of test results.

Interpretive Guidelines §493.1461
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.

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 and experience is equivalent to 2080 hours and could extend over more than one 12 calendar-month period.

If all testing personnel have associate degrees, but none meet the training or experience requirement for general supervisor, the duties of the general supervisor must be fulfilled by an appropriately qualified individual. This individual need not be on-site at all times.

D6143

§493.1461 Standard: General supervisor qualifications.

(a) The general supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and
(b) The general supervisor must be qualified as a--
(b)(1) Laboratory director under §493.1443; or
(b)(2) Technical supervisor under §493.1449.
(c) If the requirements of paragraph (b)(1) or paragraph (b)(2) of this section are not met, the individual functioning as the general supervisor must--
(c)(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; and

Interpretive Guidelines §493.1461(c)(1)(i)
See §493.2 for the definition of and guidance for accredited institutions.

(c)(1)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing; or
(c)(2)(i) Qualify as testing personnel under §493.1489(b)(2); and
(c)(2)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing; or

(c)(3)(i) Except as specified in paragraph (3)(ii) of this section, have previously qualified as a general supervisor under §493.1462 on or before February 28, 1992.
(c)(3)(ii) Exception. An individual who achieved a satisfactory grade in a proficiency examination for technologist given by HHS between March 1, 1986 and December 31, 1987, qualifies as a general supervisor if he or she meets the requirements of §493.1462 on or before January 1, 1994."
(c)(4) On or before September 1, 1992, have served as a general supervisor of high complexity testing and as of April 24, 1995--
(c)(4)(i) Meet one of the following requirements:
(c)(4)(i)(A) Have graduated from a medical laboratory or clinical laboratory training program approved or accredited by the Accrediting Bureau of Health Education Schools (ABHES), the Commission on Allied Health Education Accreditation (CAHEA), or other organization approved by HHS.
(c)(4)(i)(B) Be a high school graduate or equivalent and have successfully completed an official U.S. military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician).
(c)(4)(ii) Have at least 2 years of clinical laboratory training, or experience, or both, in high complexity testing; or
(c)(5) On or before September 1, 1992, have served as a general supervisor of high complexity testing and--
(c)(5)(i) Be a high school graduate or equivalent; and
(c)(5)(ii) Have had at least 10 years of laboratory training or experience, or both, in high complexity testing, including at least 6 years of supervisory experience between September 1, 1982 and September 1, 1992.
(d) For blood gas analysis, the individual providing general supervision must--
(d)(1) Be qualified under §§493.1461(b)(1) or (2), or 493.1461(c); or
(d)(2)(i) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and
(d)(2)(ii) Have at least one year of laboratory training or experience, or both, in blood gas analysis; or
(d)(3)(i) Have earned an associate degree related to pulmonary function from an accredited institution; and

> *Interpretive Guidelines §493.1461(d)(3)(i)*
> *NOTE: Many blood gas systems are categorized as moderate complexity tests; therefore, only moderate complexity personnel requirements are applicable. To determine which tests are categorized as waived or nonwaived (i.e., moderate or high complexity tests), refer to the "Specific List For Categorization of Laboratory Test Systems, Assays, and Examinations by Complexity" [www.fda.gov/cdrh/clia/index.html]. Test systems, assays, and examinations not yet classified are considered high complexity.*

(d)(3)(ii) Have at least two years of training or experience, or both in blood gas analysis.
(e) The general supervisor requirement is met in histopathology, oral pathology, dermatopathology, and ophthalmic pathology because all tests and examinations, must be performed:
(e)(1) In histopathology, by an individual who is qualified as a technical supervisor under §§493.1449(b) or 493.1449(l)(1);
(e)(2) In dermatopathology, by an individual who is qualified as a technical supervisor under §§493.1449(b) or 493.1449(l) or (2);
(e)(3) In ophthalmic pathology, by an individual who is qualified as a technical supervisor under §§493.1449(b) or 493.1449(1)(3); and
(e)(4) In oral pathology, by an individual who is qualified as a technical supervisor under §§493.1449(b) or 493.1449(m).

Interpretive Guidelines §493.1461(e)
In the case of gross examinations, the technical supervisor may delegate to individuals qualified under §493.1489 the responsibility for the physical examination/description, including color, weight, measurement and other characteristics of the tissue; or other mechanical procedures for which a specific written protocol has been developed.

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

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

To qualify as a general supervisor under §493.1461(c)(3), an individual must have met or could have met the following qualifications as they were in effect on or before February 28, 1992.
(a) Each supervisor possesses a current license as a laboratory supervisor issued by the State, if such licensing exists; and
(b) The laboratory supervisor--
(b)(1) Who qualifies as a laboratory director under §493.1406(b)(1), (2), (4), or (5) is also qualified as a general supervisor; therefore, depending upon the size and functions of the laboratory, the laboratory director may also serve as the laboratory supervisor; or
(b)(2)(i) Is a physician or has earned a doctoral degree from an accredited institution with a major in one of the chemical, physical, or biological sciences; and
(b)(2)(ii) Subsequent to graduation, has had at least 2 years of experience in one of the laboratory specialties in a laboratory; or
(b)(3)(i) Holds a master's degree from an accredited institution with a major in one of the chemical, physical, or biological sciences; and
(b)(3)(ii) Subsequent to graduation has had at least 4 years of pertinent full-time laboratory experience of which not less than 2 years have been spent working in the designated specialty in a laboratory; or
(b)(4)(i) Is qualified as a laboratory technologist under §493.1491; and
(b)(4)(ii) After qualifying as a laboratory technologist, has had at least 6 years of pertinent full-time laboratory experience of which not less than 2 years have been spent working in the designated laboratory specialty in a laboratory; or
(b)(5) With respect to individuals first qualifying before July 1, 1971, has had at least 15 years of pertinent full-time laboratory experience before January 1, 1968; this required experience may be met by the substitution of education for experience.

D6144

§493.1463 Standard; General supervisor responsibilities.

The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results.

Interpretive Guidelines §493.1463
Interview several testing personnel to elicit information about the duties they perform and the degree of supervision they receive.

D6145

§493.1463 Standard; General supervisor responsibilities.

(a) The general supervisor--(a)(1) Must be accessible to testing personnel at all times testing is performed to provide on-site, telephone or electronic consultation to resolve technical problems in accordance with policies and procedures established either by the laboratory director or technical supervisor;

D6146

§493.1463 Standard; General supervisor responsibilities.

(a)(2) Is responsible for providing day-to-day supervision of high complexity test performance by a testing personnel qualified under §493.1489;

D6147

§493.1463 Standard; General supervisor responsibilities.

(a)(3) Except as specified in paragraph (c) of this section, must be onsite to provide direct supervision when high complexity testing is performed by any individuals qualified under §493.1489(b)(5); and

D6148

§493.1463 Standard; General supervisor responsibilities.

(a)(4) Is responsible for monitoring test analyses and specimen examinations to ensure that acceptable levels of analytic performance are maintained.

D6149

§493.1463 Standard; General supervisor responsibilities.

(b) The director or technical supervisor may delegate to the general supervisor the responsibility for--
(b)(1) Assuring that all remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications;

D6150

§493.1463 Standard; General supervisor responsibilities.

(b)(2) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is properly functioning;

D6151

§493.1463 Standard; General supervisor responsibilities.

(b)(3) Providing orientation to all testing personnel; and
(b)(4) Annually evaluating and documenting the performance of all testing personnel.

D6152

§493.1463 Standard; General supervisor responsibilities.

(c) Exception. For individuals qualified under §493.1489(b)(5), who were performing high complexity testing on or before January 19, 1993, the requirements of paragraph (a)(3) of this section are not effective, provided that all high complexity testing performed by the individual in the absence of a general supervisor is reviewed within 24 hours by a general supervisor qualified under §493.1461.

D6153

§493.1467 Condition: Laboratories performing high complexity testing; cytology general supervisor.

For the subspecialty of cytology, the laboratory must have a general supervisor who meets the qualification requirements of §493.1469 of this subpart, and provides supervision in accordance with §493.1471 of this subpart.

Interpretive Guideline §493.1467
The Condition of cytology general supervisor is not met when the cytology general supervisor:

- *Position is not filled;*
- *Is not qualified; or*
- *Does not fulfill the cytology general supervisor responsibilities.*

D6155

§493.1469 Standard; Cytology general supervisor qualifications.

The cytology general supervisor must be qualified to supervise cytology services. The general supervisor in cytology must possess a current license issued by the State in which the laboratory is located, if such licensing is required, and must--
(a) Be qualified as a technical supervisor under §493.1449 (b) or (k); or
(b)(1) Be qualified as a cytotechnologist under §493.1483; and
(b)(2) Have at least 3 years of full-time (2,080 hours per year) experience as a cytotechnologist within the preceding 10 years.

Interpretive Guidelines §493.1469(b)(2)
In addition to screening slides in a laboratory, the 3 years of full-time experience as a cytotechnologist can be fulfilled if the individual has been:

- *Teaching in schools of cytotechnology;*
- *Teaching cytotechnology for residency programs in academic institutions; or*
- *Participating in research directly related to cytotechnology, which includes screening slides, library research, and documentation.*

D6156

§493.1471 Standard; Cytology general supervisor responsibilities.

The technical supervisor of cytology may perform the duties of the cytology general supervisor or delegate the responsibilities to an individual qualified under §493.1469.

D6157

§493.1471 Standard; Cytology general supervisor responsibilities.

(a) The cytology general supervisor is responsible for the day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results.

D6158

§493.1471 Standard; Cytology general supervisor responsibilities.

(b) The cytology general supervisor must--
(b)(1) Be accessible to provide on-site, telephone, or electronic consultation to resolve technical problems in accordance with policies and procedures established by the technical supervisor of cytology;

D6159

§493.1471 Standard; Cytology general supervisor responsibilities.

(b)(2) Document the slide interpretation results of each gynecologic and nongynecologic cytology case he or she examined or reviewed (as specified under §493.1274(c));

D6160

§493.1471 Standard; Cytology general supervisor responsibilities.

(b)(3) For each 24-hour period, document the total number of slides he or she examined or reviewed in the laboratory as well as the total number of slides examined or reviewed in any other laboratory or for any other employer; and

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D6161

§493.1471 Standard; Cytology general supervisor responsibilities.

(b)(4) Document the number of hours spent examining slides in each 24-hour period.

D6162

§493.1481 Condition: Laboratories performing high complexity testing; cytotechnologist.

For the subspecialty of cytology, the laboratory must have a sufficient number of cytotechnologists who meet the qualifications specified in §493.1483 to perform the functions specified in §493.1485.

D6163

§493.1483 Standard; Cytotechnologist qualifications.

Each person examining cytology slide preparations must meet the qualifications of §493.1449 (b) or (k), or--

D6164

§493.1483 Standard; Cytotechnologist qualifications.

(a) Possess a current license as a cytotechnologist issued by the State in which the laboratory is located, if such licensing is required; and
(b) Meet one of the following requirements:
(b)(1) Have graduated from a school of cytotechnology accredited by the Committee on Allied Health Education and Accreditation or other organization approved by HHS; or
(b)(2) Be certified in cytotechnology by a certifying agency approved by HHS; or
(b)(3) Before September 1, 1992--
(b)(3)(i) Have successfully completed 2 years in an accredited institution with at least 12 semester hours in science, 8 hours of which are in biology; and
(b)(3)(i)(A) Have had 12 months of training in a school of cytotechnology accredited by an accrediting agency approved by HHS; or

> *Interpretive Guideline §493.1483(b)(3)(i)(A)*
> *"A school of cytotechnology accredited by an accrediting agency approved by HHS" means a school or program approved by one of the accrediting agencies described in Subpart A of the Guidelines. (See §493.2)*

(b)(3)(i)(B) Have received 6 months of formal training in a school of cytotechnology accredited by an accrediting agency approved by HHS and 6 months of full-time experience in cytotechnology in a laboratory acceptable to the pathologist who directed the formal 6 months of training; or
(b)(3)(ii) Have achieved a satisfactory grade to qualify as a cytotechnologist in a proficiency examination approved by HHS and designed to qualify persons as cytotechnologists; or
(b)(4) Before September 1, 1994, have full-time experience of at least 2 years or equivalent within the preceding 5 years examining slide preparations under the supervision of a physician qualified under §493.1449(b) or (k)(1), and before January 1, 1969, must have--
(b)(4)(i) Graduated from high school;
(b)(4)(ii) Completed 6 months of training in cytotechnology in a laboratory directed by a pathologist or other physician providing cytology services; and
(b)(4)(iii) Completed 2 years of full-time supervised experience in cytotechnology; or
(b)(5)(i) On or before September 1, 1994, have full-time experience of at least 2 years or equivalent examining cytology slide preparations within the preceding 5 years in the United States under the supervision of a physician qualified under §493.1449(b) or (k)(1); and
(b)(5)(ii) On or before September 1, 1995, have met the requirements in either paragraph (b)(1) or (2) of this section.

D6165

§493.1485 Standard; Cytotechnologist responsibilities.

The cytotechnologist is responsible for documenting--

(a) The slide interpretation results of each gynecologic and nongynecologic cytology case he or she examined or reviewed (as specified in §493.1274(c));

D6166

§493.1485 Standard; Cytotechnologist responsibilities.

(b) For each 24-hour period, the total number of slides examined or reviewed in the laboratory as well as the total number of slides examined or reviewed in any other laboratory or for any other employer; and

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D6167

§493.1485 Standard; Cytotechnologist responsibilities.

(c) The number of hours spent examining slides in each 24-hour period.

D6168

§493.1487 Condition: Laboratories performing high complexity testing; testing personnel.

The laboratory has a sufficient number of individuals who meet the qualification requirements of §493.1489 of this subpart to perform the functions specified in §493.1495 of this subpart for the volume and complexity of testing performed.

Interpretive Guidelines §493.1487
The criteria used to determine the adequacy of the testing personnel involves evaluating testing personnel responsibilities, ensuring that these responsibilities are specified by the director in writing and are appropriate to ensure compliance with the reporting and recordkeeping requirements, quality control monitoring, quality assessment activities, and proficiency testing participation. Cite this deficiency only when problems are found in areas that can be directly related to insufficient numbers of testing personnel. (Use D6101 to relate the finding to insufficient personnel to director responsibilities.)

D6170

§493.1489 Standard; Testing personnel qualifications.

Each individual performing high complexity testing must--
(a) Possess a current license issued by the State in which the laboratory is located, if such licensing is required; and

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D6171

§493.1489 Standard; Testing personnel qualifications.

(b) Meet one of the following requirements:
(b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution;

Interpretive Guidelines §493.1489(b)(1)
See §493.2 for the definition of and guidance for accredited institutions.

(b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or--

Interpretive Guidelines §493.1489(b)(2)
"An associate degree in a laboratory science" is interpreted to mean an associate degree in a chemical or biological science.

(b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes--
(b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either--
(b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or
(b)(2)(ii)(A)(2) 24 semester hours of science courses that include--
(b)(2)(ii)(A)(2)(i) Six semester hours of chemistry;
(b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and
(b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and
(b)(2)(ii)(B) Have laboratory training that includes either of the following:
(b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.)
(b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing.
(b)(3) Have previously qualified or could have qualified as a technologist under §493.1491 on or before February 28, 1992;
(b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either--
(b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or
(b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician);
(b)(5)(i) Until September 1, 1997--
(b)(5)(i)(A) Have earned a high school diploma or equivalent; and
(b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has--
(b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens;
(b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures;
(b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use;
(b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed;
(b)(5)(i)(B)(5) A working knowledge of reagent stability and storage;
(b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory;
(b)(5)(i)(B)(7) An awareness of the factors that influence test results; and
(b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and
(b)(5)(ii) As of September 1, 1997, be qualified under §493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995;

Interpretive Guidelines §493.1489(b)(5)(ii)
The laboratory director is responsible for ensuring that testing personnel have the appropriate education and experience, and receive the appropriate training for the type and complexity of testing performed. The experience required is clinical in nature. This means examination of 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. (Use D6102.)

Each individual must have documentation of training applicable to the types and complexity of testing performed. This training should be such that the individual can demonstrate that he/she has the skills required for proper performance of preanalytic, analytic, and postanalytic phases of testing. For example, if the individual performs a manual differential, he/she should be able to demonstrate the skills for:

- *Proper specimen handling prior to testing, e.g., assuring the specimen is properly drawn, if appropriate, properly labeled, the blood film is made within appropriate timeframes and is one-cell layer thick and without cell distortion;*
- *Proper test performance according to the laboratory's policies and manufacturer's instructions, e.g., using stains that are not outdated, that lack contamination and precipitation, following staining procedures, including staining order and timing and allowing slide to air dry, identification of cells and interpretation of smear to be consistent with blood count, diagnosis, treatment; and*
- *Proper reporting of patient test results in accordance with the laboratory's policies, e.g., notifying the person authorized to receive test results of a panic value, not reporting the test result if inconsistent with blood count and noting an explanation, such as "platelet clumping."*

Training may include, but is not limited to, attendance at:

- *Seminars given by experts in the field, e.g., a lecture about antibiotic resistance given by the infection control officer of a local hospital;*
- *On-site or off-site instrument trainings given by a manufacturer, e.g., a week-long training course given at the manufacturer's headquarters, or training by a manufacturer's technical representative on an instrument purchased by a laboratory;*
- *Technical training sessions, workshops, or conferences given by a professional laboratory organization, e.g., CAP, ASMT, AACC, and ASCT;*
- *Technical education classes or specialty courses that include hands-on test performance, e.g., parasitology, bacteriology, cytology, given by CDC, a State Health Department, or professional laboratory organizations;*
- *A formal laboratory training program; or*
- *In-services offered by a local hospital laboratory staff, pathologist, or medical technologist to a physician's office personnel.*

Documentation may consist of, but is not limited to, letters from training programs or employers, attestation statements by the laboratory director, a log sheet initialed by the attendees indicating attendance at a training session/in-service, certificates from organizations providing the training session, workshop, conference, or specialty course.

(b)(6) For blood gas analysis--

Interpretive Guidelines §493.1489(b)(6)
This requirement applies only to performance of blood gas analysis procedures which are categorized as high complexity.

NOTE: *Some blood gas systems are categorized as moderate complexity tests. Therefore, only moderate complexity personnel requirements are applicable to them. To determine which tests are categorized as waived or nonwaived (i.e., moderate or high complexity tests), refer to the "Specific List For Categorization of Laboratory Test Systems, Assays, and Examinations by Complexity" [www.fda.gov/cdrh/clia/index.html]. Test systems, assays, and examinations not yet classified are considered high complexity.*

(b)(6)(i) Be qualified under §493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5);
(b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or
(b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or
(b)(7) For histopathology, meet the qualifications of §493.1449 (b) or (l) to perform tissue examinations.

Interpretive Guidelines §493.1489(b)(7)
In the case of gross examinations, the technical supervisor may delegate to individuals qualified under §493.1489 the responsibility for the physical examination/description, including color, weight, measurement and other characteristics of the tissue; or other mechanical procedures for which a specific written protocol has been developed. The technical supervisor is ultimately responsible for the diagnosis related to the gross examination and must sign the examination report. The technical supervisor is not required to provide direct onsite supervision but is responsible for the accuracy of all test results reported. All physical examinations/descriptions of tissue including color, weight, measurement and other characteristics of the tissue; or other mechanical procedures performed in the absence of the technical supervisor by individuals qualified under §493.1489 should be reviewed within 24 hours by the technical supervisor. All microscopic tissue examinations must be performed by individuals qualified under §493.1449(b), (l) or (m), as appropriate.

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§493.1491 Technologist qualifications on or before February 28, 1992.

In order to qualify as high complexity testing personnel under §493.1489(b)(3), the individual must have met or could have met the following qualifications for technologist as they were in effect on or before February 28, 1992. Each technologist must--
(a) Possess a current license as a laboratory technologist issued by the State, if such licensing exists; and
(b)(1) Have earned a bachelor's degree in medical technology from an accredited university; or
(b)(2) Have successfully completed 3 years of academic study (a minimum of 90 semester hours or equivalent) in an accredited college or university, which met the specific requirements for entrance into a school of medical technology accredited by an accrediting agency approved by the Secretary, and has successfully completed a course of training of at least 12 months in such a school; or
(b)(3) Have earned a bachelor's degree in one of the chemical, physical, or biological sciences and, in addition, has at least 1 year of pertinent full-time laboratory experience or training, or both, in the specialty or subspecialty in which the individual performs tests; or
(b)(4)(i) Have successfully completed 3 years (90 semester hours or equivalent) in an accredited college or university with the following distribution of courses--
(b)(4)(i)(A) For those whose training was completed before September 15, 1963. At least 24 semester hours in chemistry and biology courses of which--
(b)(4)(i)(A)(1) At least 6 semester hours were in inorganic chemistry and at least 3 semester hours were in other chemistry courses; and

(b)(4)(i)(A)(2) At least 12 semester hours in biology courses pertinent to the medical sciences; or
(b)(4)(i)(B) For those whose training was completed after September 14, 1963.
(b)(4)(i)(B)(1) 16 semester hours in chemistry courses that included at least 6 semester hours in inorganic chemistry and that are acceptable toward a major in chemistry;
(b)(4)(i)(B)(2) 16 semester hours in biology courses that are pertinent to the medical sciences and are acceptable toward a major in the biological sciences; and
(b)(4)(i)(B)(3) 3 semester hours of mathematics; and
(b)(4)(ii) Has experience, training, or both, covering several fields of medical laboratory work of at least 1 year and of such quality as to provide him or her with education and training in medical technology equivalent to that described in paragraphs (b)(1) and (2) of this section; or
(b)(5) With respect to individuals first qualifying before July 1, 1971, the technologist--
(b)(5)(i) Was performing the duties of a laboratory technologist at any time between July 1, 1961, and January 1, 1968, and
(b)(5)(ii) Has had at least 10 years of pertinent laboratory experience prior to January 1, 1968. (This required experience may be met by the substitution of education for experience); or
(b)(6) Achieves a satisfactory grade in a proficiency examination approved by HHS.

D6173

§493.1495 Standard; Testing personnel responsibilities.

The testing personnel are responsible for specimen processing, test performance and for reporting test results.

D6174

§493.1495 Standard; Testing personnel responsibilities.

(a) Each individual performs only those high complexity tests that are authorized by the laboratory director and require a degree of skill commensurate with the individual's education, training or experience, and technical abilities.

D6175

§493.1495 Standard; Testing personnel responsibilities.

(b) Each individual performing high complexity testing must--
(b)(1) Follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results;

D6176

§493.1495 Standard; Testing personnel responsibilities.

(b)(2) Maintain records that demonstrate that proficiency testing samples are tested in the same manner as patient specimens;

D6177

§493.1495 Standard; Testing personnel responsibilities.

(b)(3) Adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed;

D6178

§493.1495 Standard; Testing personnel responsibilities.

(b)(4) Follow the laboratory's established policies and procedures whenever test systems are not within the laboratory's established acceptable levels of performance;

D6179

§493.1495 Standard; Testing personnel responsibilities.

(b)(5) Be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the general supervisor, technical supervisor, clinical consultant, or director;

> *Interpretive Guidelines §493.1495(b)(5) Guidelines:*
> *If, during the survey, testing personnel demonstrate an inability to identify a problem that adversely affects a patient test result, cite 493.1445(e)(12) under the director responsibilities.*
>
> *Some examples of problems that may adversely affect patient test results may include:*
> - *A pleural fluid that is mislabeled as a urine specimen and, therefore, is cultured as a urine culture;*
> - *Performing a potassium on a hemolyzed sample; or*
> - *Tests are incubated at 37°C when the manufacturer's instructions require 25°C incubation.*

D6181

§493.1495 Standard; Testing personnel responsibilities.

(b)(6) Document all corrective actions taken when test systems deviate from the laboratory's established performance specifications; and

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D6182

§493.1495 Standard; Testing personnel responsibilities.

(b)(7) Except as specified in paragraph (c) of this section, if qualified under §493.1489(b)(5), perform high complexity testing only under the onsite, direct supervision of a general supervisor qualified under §493.1461.

D6183

§493.1495 Standard; Testing personnel responsibilities.

(c) Exception. For individuals qualified under §493.1489(b)(5), who were performing high complexity testing on or before January 19, 1993, the requirements of paragraph (b)(7) of this section are not effective, provided that all high complexity testing performed by the

individual in the absence of a general supervisor is reviewed within 24 hours by a general supervisor qualified under §493.1461.