

(c) The laboratory must document all postanalytic systems quality assessment activities.

[68 FR 3703, Jan. 24, 2003; 68 FR 50724, Aug. 22, 2003]

### Subpart L [Reserved]

### Subpart M—Personnel for Nonwaived Testing

SOURCE: 57 FR 7172, Feb. 28, 1992, unless otherwise noted.

#### § 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.

[60 FR 20049, Apr. 24, 1995]

#### LABORATORIES PERFORMING PROVIDER-PERFORMED MICROSCOPY (PPM) PROCEDURES

SOURCE: 60 FR 20049, Apr. 24, 1995, unless otherwise noted.

#### § 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.

#### § 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.

#### § 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:

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

(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.

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

#### § 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—

(a) Direct no more than five laboratories; and

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

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

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

[57 FR 7172, Feb. 28, 1992, as amended at 68 FR 3713, Jan. 24, 2003; 68 FR 50724, Aug. 22, 2003]

#### § 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.

#### § 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:

**§ 493.1365**

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

(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.

(3) Be a dentist as defined in § 493.2 of this part.

**§ 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:

(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.

(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.

(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

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

**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.

**42 CFR Ch. IV (10–1–23 Edition)**

**§ 493.1405 Standard; Laboratory director qualifications.**

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

(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—

(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

(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

(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

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

(A) At least one year directing or supervising non-waived laboratory testing; or

(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

(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

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

(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