(3) The clinic's or center's health care policies.

(c) The purpose of the evaluation is to determine whether:

(1) The utilization of services was appropriate;

(2) The established policies were followed; and

(3) Any changes are needed.

(d) The clinic or center staff considers the findings of the evaluation and takes corrective action if necessary.

[57 FR 24984, June 12, 1992]

PART 493—LABORATORY REQUIREMENTS

Subpart A—General Provisions

Subpart B—Certificate of Waiver

Subpart C—Registration Certificate, Certificate for Provider–performed Microscopy Procedures, and Certificate of Compliance

Subpart D—Certificate of Accreditation

Subpart E—Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program

Subpart F—General Administration

Subpart L [Reserved]

Subpart M—Personnel for Moderate Complexity (Including the Subcategory) and High Complexity Testing

Subparts N–O [Reserved]

Subpart P—Quality Assurance for Moderate Complexity (Including the Subcategory) or High Complexity Testing, or Any Combination of These Tests

Subpart Q—Inspection

Subpart R—Enforcement Procedures

Subpart S [Reserved]

Subpart T—Consultations

AUTHORITY: Sec. 353 of the Public Health Service Act, secs. 1102, 1861(e), the sentence following sections 1861(s)(11) through 1861(s)(16) of the Social Security Act (42 U.S.C. 263a, 1302, 1395x(e), the sentence following 1395x(s)(11) through 1395x(s)(16)).

SOURCE: 55 FR 9576, Mar. 14, 1990, unless otherwise noted.

Subpart A—General Provisions

SOURCE: 57 FR 7139, Feb. 28, 1992, unless otherwise noted.

§ 493.1 Basis and scope.

This part sets forth the conditions that all laboratories must meet to be certified to perform testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). It implements sections 1861 (e) and (j), the sentence following section 1861(s)(13), and 1902(a)(9) of the Social Security Act, and section 353 of the Public Health Service Act. This part applies to all laboratories as defined under ''laboratory'' in §493.2 of this part. This part also applies to laboratories seeking payment under the Medicare and Medicaid programs. The requirements are the same for Medicare approval as for CLIA certification.

§ 493.2 Definitions.

As used in this part, unless the context indicates otherwise—

Accredited institution means a school or program which—

(a) Admits as regular student only persons having a certificate of graduation from a school providing secondary education, or the recognized equivalent of such certificate;

(b) Is legally authorized within the State to provide a program of education beyond secondary education;

(c) Provides an educational program for which it awards a bachelor's degree or provides not less than a 2-year program which is acceptable toward such a degree, or provides an educational program for which it awards a master's or doctoral degree;

(d) Is accredited by a nationally recognized accrediting agency or association.

This definition includes any foreign institution of higher education that HHS or its designee determines meets substantially equivalent requirements.

Accredited laboratory means a laboratory that has voluntarily applied for and been accredited by a private, nonprofit accreditation organization approved by HCFA in accordance with this part;

Adverse action means the imposition of a principal or alternative sanction by HCFA.

ALJ stands for Administrative Law Judge.

Alternative sanctions means sanctions that may be imposed in lieu of or in addition to principal sanctions. The term is synonymous with ''intermediate sanctions'' as used in section 1846 of the Act.

Analyte means a substance or constituent for which the laboratory conducts testing.

Approved accreditation organization for laboratories means a private, nonprofit accreditation organization that has formally applied for and received HCFA's approval based on the organization's compliance with this part.

Approved State laboratory program means a licensure or other regulatory program for laboratories in a State, the requirements of which are imposed under State law, and the State laboratory program has received HCFA approval based on the State's compliance with this part.

Authorized person means an individual authorized under State law to order tests or receive test results, or both.

Challenge means, for quantitative tests, an assessment of the amount of substance or analyte present or measured in a sample. For qualitative tests, a challenge means the determination of the presence or the absence of an analyte, organism, or substance in a sample.

CLIA means the Clinical Laboratory Improvement Amendments of 1988.

CLIA certificate means any of the following types of certificates issued by HCFA or its agent:

(1) *Certificate of compliance* means a certificate issued to a laboratory after an inspection that finds the laboratory to be in compliance with all applicable condition level requirements, or reissued before the expiration date, pending an appeal, in accordance with §493.49, when an inspection has found the laboratory to be out of compliance with one or more condition level requirements.

(2) *Certificate for provider-performed microscopy (PPM) procedures* means a certificate issued or reissued before the

expiration date, pending an appeal, in accordance with §493.47, to a laboratory in which a physician, midlevel practitioner or dentist performs no tests other than PPM procedures and, if desired, waived tests listed in §493.15(c).

(3) *Certificate of accreditation* means a certificate issued on the basis of the laboratory's accreditation by an accreditation organization approved by HCFA (indicating that the laboratory is deemed to meet applicable CLIA requirements) or reissued before the expiration date, pending an appeal, in accordance with §493.61, when a validation or complaint survey has found the laboratory to be noncompliant with one or more CLIA conditions.

(4) *Certificate of registration or registration certificate* means a certificate issued or reissued before the expiration date, pending an appeal, in accordance with §493.45, that enables the entity to conduct moderate or high complexity laboratory testing or both until the entity is determined to be in compliance through a survey by HCFA or its agent; or in accordance with §493.57 to an entity that is accredited by an approved accreditation organization.

(5) *Certificate of waiver* means a certificate issued or reissued before the expiration date, pending an appeal, in accordance with §493.37, to a laboratory to perform only the waived tests listed at §493.15(c).

CLIA-exempt laboratory means a laboratory that has been licensed or approved by a State where HCFA has determined that the State has enacted laws relating to laboratory requirements that are equal to or more stringent than CLIA requirements and the State licensure program has been approved by HCFA in accordance with subpart E of this part.

Condition level deficiency means noncompliance with one or more condition level requirements.

Condition level requirements means any of the requirements identified as ''conditions'' in subparts G through Q of this part.

Credible allegation of compliance means a statement or documentation that—

(1) Is made by a representative of a laboratory that has a history of having maintained a commitment to compliance and of taking corrective action when required;

(2) Is realistic in terms of its being possible to accomplish the required corrective action between the date of the exit conference and the date of the allegation; and

(3) Indicates that the problem has been resolved.

Dentist means a doctor of dental medicine or doctor of dental surgery licensed by the State to practice dentistry within the State in which the laboratory is located.

Equivalency means that an accreditation organization's or a State laboratory program's requirements, taken as a whole, are equal to or more stringent than the CLIA requirements established by HCFA, taken as whole. It is acceptable for an accreditation organization's or State laboratory program's requirements to be organized differently or otherwise vary from the CLIA requirements, as long as (1) all of the requirements taken as a whole would provide at least the same protection as the CLIA requirements taken as a whole; and (2) a finding of noncompliance with respect to CLIA requirements taken as a whole would be matched by a finding of noncompliance with the accreditation or State requirements taken as a whole.

HCFA agent means an entity with which HCFA arranges to inspect laboratories and assess laboratory activities against CLIA requirements and may be a State survey agency, a private, nonprofit organization other than an approved accreditation organization, a component of HHS, or any other governmental component HCFA approves for this purpose. In those instances where all of the laboratories in a State are exempt from CLIA requirements, based on the approval of a State's exemption request, the State survey agency is not the HCFA agent.

HHS means the Department of Health and Human Services, or its designee.

Immediate jeopardy means a situation in which immediate corrective action is necessary because the laboratory's noncompliance with one or more condition level requirements has already caused, is causing, or is likely to cause, at any time, serious injury or harm, or

death, to individuals served by the laboratory or to the health or safety of the general public. This term is synonymous with imminent and serious risk to human health and significant hazard to the public health.

Intentional violation means knowing and willful noncompliance with any CLIA condition.

Kit means all components of a test that are packaged together.

Laboratory means a facility for the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body. Facilities only collecting or preparing specimens (or both) or only serving as a mailing service and not performing testing are not considered laboratories.

Midlevel practitioner means a nurse midwife, nurse practitioner, or physician assistant, licensed by the State within which the individual practices, if such licensing is required in the State in which the laboratory is located.

Operator means the individual or group of individuals who oversee all facets of the operation of a laboratory and who bear primary responsibility for the safety and reliability of the results of all specimen testing performed in that laboratory. The term includes—

(1) A director of the laboratory if he or she meets the stated criteria; and

(2) The members of the board of directors and the officers of a laboratory that is a small corporation under subchapter S of the Internal Revenue Code.

Owner means any person who owns any interest in a laboratory except for an interest in a laboratory whose stock and/or securities are publicly traded. (That is e.g., the purchase of shares of stock or securities on the New York Stock Exchange in a corporation owning a laboratory would not make a person an owner for the purpose of this regulation.)

Party means a laboratory affected by any of the enforcement procedures set forth in this subpart, by HCFA or the OIG, as appropriate.

Performance characteristic means a property of a test that is used to describe its quality, e.g., accuracy, precision, analytical sensitivity, analytical specificity, reportable range, reference range, etc.

Performance specification means a value or range of values for a performance characteristic, established or verified by the laboratory, that is used to describe the quality of patient test results.

Physician means an individual with a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine degree who is licensed by the State to practice medicine, osteopathy, or podiatry within the State in which the laboratory is located.

Principal sanction means the suspension, limitation, or revocation of any type of CLIA certificate or the cancellation of the laboratory's approval to receive Medicare payment for its services.

Prospective laboratory means a laboratory that is operating under a registration certificate or is seeking any of the three other types of CLIA certificates.

Rate of disparity means the percentage of sample validation inspections for a specific accreditation organization or State where HCFA, the State survey agency or other HCFA agent finds noncompliance with one or more condition level requirements but no comparable deficiencies were cited by the accreditation organization or the State, and it is reasonable to conclude that the deficiencies were present at the time of the most recent accreditation organization or State licensure inspection.

EXAMPLE: Assume the State survey agency, HCFA or other HCFA agent performs 200 sample validation inspections for laboratories accredited by a single accreditation organization or licensed in an exempt State during a validation review period and finds that 60 of the 200 laboratories had one or more condition level requirements out of compliance. HCFA reviews the validation and accreditation organization's or State's

inspections of the validated laboratories and determines that the State or accreditation organization found comparable deficiencies in 22 of the 60 laboratories and it is reasonable to conclude that deficiencies were present in the remaining 38 laboratories at the time of the accreditation organization's or State's inspection. Thirty-eight divided by 200 equals a 19 percent rate of disparity.

Referee laboratory means a laboratory currently in compliance with applicable CLIA requirements, that has had a record of satisfactory proficiency testing performance for all testing events for at least one year for a specific test, analyte, subspecialty, or specialty and has been designated by an HHS approved proficiency testing program as a referee laboratory for analyzing proficiency testing specimens for the purpose of determining the correct response for the specimens in a testing event for that specific test, analyte, subspecialty, or specialty.

Reference range means the range of test values expected for a designated population of individuals, e.g., 95 percent of individuals that are presumed to be healthy (or normal).

Sample in proficiency testing means the material contained in a vial, on a slide, or other unit that contains material to be tested by proficiency testing program participants. When possible, samples are of human origin.

State includes, for purposes of this part, each of the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands and a political subdivision of a State where the State, acting pursuant to State law, has expressly delegated powers to the political subdivision sufficient to authorize the political subdivision to act for the State in enforcing requirements equal to or more stringent than CLIA requirements.

State licensure means the issuance of a license to, or the approval of, a laboratory by a State laboratory program as meeting standards for licensing or approval established under State law.

State licensure program means a State laboratory licensure or approval program.

State survey agency means the State health agency or other appropriate State or local agency that has an agreement under section 1864 of the Social Security Act and is used by HCFA to perform surveys and inspections.

Substantial allegation of noncompliance means a complaint from any of a variety of sources (including complaints submitted in person, by telephone, through written correspondence, or in newspaper or magazine articles) that, if substantiated, would have an impact on the health and safety of the general public or of individuals served by a laboratory and raises doubts as to a laboratory's compliance with any condition level requirement.

Target value for quantitative tests means either the mean of all participant responses after removal of outliers (those responses greater than 3 standard deviations from the original mean) or the mean established by definitive or reference methods acceptable for use in the National Reference System for the Clinical Laboratory (NRSCL) by the National Committee for the Clinical Laboratory Standards (NCCLS). In instances where definitive or reference methods are not available or a specific method's results demonstrate bias that is not observed with actual patient specimens, as determined by a defensible scientific protocol, a comparative method or a method group (''peer'' group) may be used. If the method group is less than 10 participants, ''target value'' means the overall mean after outlier removal (as defined above) unless acceptable scientific reasons are available to indicate that such an evaluation is not appropriate.

Unsatisfactory proficiency testing performance means failure to attain the minimum satisfactory score for an analyte, test, subspecialty, or specialty for a testing event.

Unsuccessful participation in proficiency testing means any of the following:

(1) Unsatisfactory performance for the same analyte in two consecutive or two out of three testing events.

(2) Repeated unsatisfactory overall testing event scores for two consecutive or two out of three testing events for the same specialty or subspecialty.

(3) An unsatisfactory testing event score for those subspecialties not graded by analyte (that is, bacteriology, mycobacteriology, virology,

parasitology, mycology, blood compatibility, immunohematology, or syphilis serology) for the same subspecialty for two consecutive or two out of three testing events.

(4) Failure of a laboratory performing gynecologic cytology to meet the standard at § 493.855.

Unsuccessful proficiency testing performance means a failure to attain the minimum satisfactory score for an analyte, test, subspecialty, or specialty for two consecutive or two of three consecutive testing events.

Validation review period means the one year time period during which HCFA conducts validation inspections and evaluates the results of the most recent surveys performed by an accreditation organization or State laboratory program.

[57 FR 7139, Feb. 28, 1992, as amended at 57 FR 7236, Feb. 28, 1992; 57 FR 34013, July 31, 1992; 57 FR 35761, Aug. 11, 1992; 58 FR 5220, Jan. 19, 1993; 58 FR 48323, Sept. 15, 1993; 60 FR 20043, Apr. 24, 1995; 63 FR 26732, May 14, 1998]

§ 493.3 Applicability.

(a) *Basic rule.* Except as specified in paragraph (b) of this section, a laboratory will be cited as out of compliance with section 353 of the Public Health Service Act unless it—

(1) Has a current, unrevoked or unsuspended certificate of waiver, registration certificate, certificate of compliance, certificate for PPM procedures, or certificate of accreditation issued by HHS applicable to the category of examinations or procedures performed by the laboratory; or

(2) Is CLIA–exempt.

(b) *Exception.* These rules do not apply to components or functions of—

(1) Any facility or component of a facility that only performs testing for forensic purposes;

(2) Research laboratories that test human specimens but do not report patient specific results for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of individual patients; or

(3) Laboratories certified by the National Institutes on Drug Abuse (NIDA), in which drug testing is performed which meets NIDA guidelines and regulations. However, all other testing conducted by a NIDA-certified laboratory is subject to this rule.

(c) *Federal laboratories.* Laboratories under the jurisdiction of an agency of the Federal Government are subject to the rules of this part, except that the Secretary may modify the application of such requirements as appropriate.

[57 FR 7139, Feb. 28, 1992, as amended at 58 FR 5221, Jan. 19, 1993; 60 FR 20043, Apr. 24, 1995]

§ 493.5 Categories of tests by complexity.

(a) Laboratory tests are categorized as one of the following:

(1) Waived tests.

(2) Tests of moderate complexity, including the subcategory of PPM procedures.

(3) Tests of high complexity.

(b) A laboratory may perform only waived tests, only tests of moderate complexity, only PPM procedures, only tests of high complexity or any combination of these tests.

(c) Each laboratory must be either CLIA-exempt or possess one of the following CLIA certificates, as defined in § 493.2:

(1) Certificate of registration or registration certificate.

(2) Certificate of waiver.

(3) Certificate for PPM procedures.

(4) Certificate of compliance.

(5) Certificate of accreditation.

[60 FR 20043, Apr. 24, 1995]

§ 493.15 Laboratories performing waived tests.

(a) *Requirement.* Tests for certificate of waiver must meet the descriptive criteria specified in paragraph (b) of this section.

(b) *Criteria.* Test systems are simple laboratory examinations and procedures which—

(1) Are cleared by FDA for home use;

(2) Employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible; or

(3) Pose no reasonable risk of harm to the patient if the test is performed incorrectly.

(c) *Certificate of waiver tests.* A laboratory may qualify for a certificate of waiver under section 353 of the PHS

Act if it restricts the tests that it performs to one or more of the following tests or examinations (or additional tests added to this list as provided under paragraph (d) of this section) and no others:

(1) Dipstick or Tablet Reagent Urinalysis (non-automated) for the following:

(i) Bilirubin;

(ii) Glucose;

(iii) Hemoglobin;

(iv) Ketone;

(v) Leukocytes;

(vi) Nitrite;

(vii) pH;

(viii) Protein;

(ix) Specific gravity; and

(x) Urobilinogen.

(2) Fecal occult blood;

(3) Ovulation tests—visual color comparison tests for human luteinizing hormone;

(4) Urine pregnancy tests—visual color comparison tests;

(5) Erythrocyte sedimentation rate—non-automated;

(6) Hemoglobin—copper sulfate—non-automated;

(7) Blood glucose by glucose monitoring devices cleared by the FDA specifically for home use;

(8) Spun microhematocrit; and

(9) Hemoglobin by single analyte instruments with self-contained or component features to perform specimen/reagent interaction, providing direct measurement and readout.

(d) *Revisions to criteria for test categorization and the list of waived tests.* HHS will determine whether a laboratory test meets the criteria listed under paragraph (b) of this section for a waived test. Revisions to the list of waived tests approved by HHS will be published in the FEDERAL REGISTER in a notice with opportunity for comment.

(e) Laboratories eligible for a certificate of waiver must—

(1) Follow manufacturers' instructions for performing the test; and

(2) Meet the requirements in subpart B, Certificate of Waiver, of this part.

[57 FR 7139, Feb. 28, 1992, as amended at 58 FR 5221, Jan. 19, 1993]

§ 493.17 Test categorization.

(a) *Categorization by criteria.* Notices will be published in the FEDERAL REGISTER which list each specific test system, assay, and examination categorized by complexity. Using the seven criteria specified in this paragraph for categorizing tests of moderate or high complexity, each specific laboratory test system, assay, and examination will be graded for level of complexity by assigning scores of 1, 2, or 3 within each criteria. The score of ''1'' indicates the lowest level of complexity, and the score of ''3'' indicates the highest level. These scores will be totaled. Test systems, assays or examinations receiving scores of 12 or less will be categorized as moderate complexity, while those receiving scores above 12 will be categorized as high complexity.

NOTE: A score of ''2'' will be assigned to a criteria heading when the characteristics for a particular test are intermediate between the descriptions listed for scores of ''1'' and ''3.''

(1) *Knowledge.*

(i) *Score 1.* (A) Minimal scientific and technical knowledge is required to perform the test; and

(B) Knowledge required to perform the test may be obtained through on-the-job instruction.

(ii) *Score 3.* Specialized scientific and technical knowledge is essential to perform preanalytic, analytic or postanalytic phases of the testing.

(2) *Training and experience.*

(i) *Score 1.* (A) Minimal training is required for preanalytic, analytic and postanalytic phases of the testing process; and

(B) Limited experience is required to perform the test.

(ii) *Score 3.* (A) Specialized training is essential to perform the preanalytic, analytic or postanalytic testing process; or

(B) Substantial experience may be necessary for analytic test performance.

(3) *Reagents and materials preparation.*

(i) *Score 1.* (A) Reagents and materials are generally stable and reliable; and

(B) Reagents and materials are prepackaged, or premeasured, or require

no special handling, precautions or storage conditions.

(ii) *Score 3.* (A) Reagents and materials may be labile and may require special handling to assure reliability; or

(B) Reagents and materials preparation may include manual steps such as gravimetric or volumetric measurements.

(4) *Characteristics of operational steps.* (i) *Score 1.* Operational steps are either automatically executed (such as pipetting, temperature monitoring, or timing of steps), or are easily controlled.

(ii) *Score 3.* Operational steps in the testing process require close monitoring or control, and may require special specimen preparation, precise temperature control or timing of procedural steps, accurate pipetting, or extensive calculations.

(5) *Calibration, quality control, and proficiency testing materials.*

(i) *Score 1.* (A) Calibration materials are stable and readily available;

(B) Quality control materials are stable and readily available; and

(C) External proficiency testing materials, when available, are stable.

(ii) *Score 3.* (A) Calibration materials, if available, may be labile;

(B) Quality control materials may be labile, or not available; or

(C) External proficiency testing materials, if available, may be labile.

(6) *Test system troubleshooting and equipment maintenance.*

(i) *Score 1.* (A) Test system troubleshooting is automatic or self-correcting, or clearly described or requires minimal judgment; and

(B) Equipment maintenance is provided by the manufacturer, is seldom needed, or can easily be performed.

(ii) *Score 3.* (A) Troubleshooting is not automatic and requires decision-making and direct intervention to resolve most problems; or

(B) Maintenance requires special knowledge, skills, and abilities.

(7) *Interpretation and judgment.* (i) *Score 1.* (A) Minimal interpretation and judgment are required to perform preanalytic, analytic and postanalytic processes; and

(B) Resolution of problems requires limited independent interpretation and judgment; and

(ii) *Score 3.* (A) Extensive independent interpretation and judgment are required to perform the preanalytic, analytic or postanalytic processes; and

(B) Resolution of problems requires extensive interpretation and judgment.

(b) *Revisions to the criteria for categorization.* The Clinical Laboratory Improvement Advisory Committee, as defined in subpart T of this part, will conduct reviews upon request of HHS and recommend to HHS revisions to the criteria for categorization of tests.

(c) *Process for device/test categorization utilizing the scoring system under § 493.17(a).* (1)(i) For new commercial test systems, assays, or examinations, the manufacturer, as part of its 510(k) and PMA application to FDA, will submit supporting data for device/test categorization. FDA will determine the complexity category, notify the manufacturers directly, and will simultaneously inform both HCFA and CDC of the device/test category. FDA will consult with CDC concerning test categorization in the following three situations:

(A) When categorizing previously uncategorized new technology;

(B) When FDA determines it to be necessary in cases involving a request for a change in categorization; and

(C) If a manufacturer requests review of a categorization decision by FDA in accordance with 21 CFR 10.75.

(ii) Test categorization will be effective as of the notification to the applicant.

(2) For test systems, assays, or examinations not commercially available, a laboratory or professional group may submit a written request for categorization to PHS. These requests will be forwarded to CDC for evaluation; CDC will determine complexity category and notify the applicant, HCFA, and FDA of the categorization decision. In the case of request for a change of category or for previously uncategorized new technology, PHS will receive the request application and forward it to CDC for categorization.

(3) A request for recategorization will be accepted for review if it is based on

new information not previously submitted in a request for categorization or recategorization by the same applicant and will not be considered more frequently than once per year.

(4) If a laboratory test system, assay or examination does not appear on the lists of tests in the FEDERAL REGISTER notices, it is considered to be a test of high complexity until PHS, upon request, reviews the matter and notifies the applicant of its decision. Test categorization is effective as of the notification to the applicant.

(5) PHS will publish revisions periodically to the list of moderate and high complexity tests in the FEDERAL REGISTER in a notice with opportunity for comment.

[57 FR 7139, Feb. 28, 1992, as amended at 58 FR 5222, Jan. 19, 1993]

§ 493.19 Provider-performed microscopy (PPM) procedures.

(a) *Requirement.* To be categorized as a PPM procedure, the procedure must meet the criteria specified in paragraph (b) of this section.

(b) *Criteria.* Procedures must meet the following specifications:

(1) The examination must be personally performed by one of the following practitioners:

(i) 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 an employee.

(ii) A midlevel practitioner, under the supervision of a physician or in independent practice only if authorized by the State, during the patient's visit on a specimen obtained from his or her own patient or from a patient of a clinic, group medical practice, or other health care provider of which the midlevel practitioner is a member or an employee.

(iii) 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.

(2) The procedure must be categorized as moderately complex.

(3) The primary instrument for performing the test is the microscope, limited to bright-field or phase-contrast microscopy.

(4) The specimen is labile or delay in performing the test could compromise the accuracy of the test result.

(5) Control materials are not available to monitor the entire testing process.

(6) Limited specimen handling or processing is required.

(c) *Provider-performed microscopy (PPM) examinations.* A laboratory may qualify to perform tests under this section if it restricts PPM examinations to one or more of the following procedures (or additional procedures added to this list as provided under paragraph (d) of this section), waived tests and no others:

(1) All direct wet mount preparations for the presence or absence of bacteria, fungi, parasites, and human cellular elements.

(2) All potassium hydroxide (KOH) preparations.

(3) Pinworm examinations.

(4) Fern tests.

(5) Post-coital direct, qualitative examinations of vaginal or cervical mucous.

(6) Urine sediment examinations.

(7) Nasal smears for granulocytes.

(8) Fecal leukocyte examinations.

(9) Qualitative semen analysis (limited to the presence or absence of sperm and detection of motility).

(d) *Revisions to criteria and the list of PPM procedures.*

(1) The CLIAC conducts reviews upon HHS' request and recommends to HHS revisions to the criteria for categorization of procedures.

(2) HHS determines whether a laboratory procedure meets the criteria listed under paragraph (b) of this section for a PPM procedure. Revisions to the list of PPM procedures proposed by HHS are published in the FEDERAL REGISTER as a notice with an opportunity for public comment.

(e) *Laboratory requirements.* Laboratories eligible to perform PPM examinations must—

(1) Meet the applicable requirements in subpart C or subpart D, and subparts F, H, J, K, M, and P of this part.

(2) Be subject to inspection as specified under subpart Q of this part.

[60 FR 20044, Apr. 24, 1995]

§ 493.20 Laboratories performing tests of moderate complexity.

(a) A laboratory may qualify for a certificate to perform tests of moderate complexity provided that it restricts its test performance to waived tests or examinations and one or more tests or examinations meeting criteria for tests of moderate complexity including the subcategory of PPM procedures.

(b) A laboratory that performs tests or examinations of moderate complexity must meet the applicable requirements in subpart C or subpart D, and subparts F, H, J, K, M, P, and Q of this part. Under a registration certificate or certificate of compliance, laboratories also performing PPM procedures must meet the inspection requirements at § 493.1777.

(c) If the laboratory also performs waived tests, compliance with subparts H, J, K, M, and P of this part is not applicable to the waived tests. However, the laboratory must comply with the requirements in §§ 493.15(e) and 493.1775.

[60 FR 20044, Apr. 24, 1995]

§ 493.25 Laboratories performing tests of high complexity.

(a) A laboratory must obtain a certificate for tests of high complexity if it performs one or more tests that meet the criteria for tests of high complexity as specified in § 493.17(a).

(b) A laboratory performing one or more tests of high complexity must meet the applicable requirements of subpart C or subpart D, and subparts F, H, J, K, M, P, and Q of this part.

(c) If the laboratory also performs tests of moderate complexity, the applicable requirements of subparts H, J, K, M, P, and Q of this part must be met. Under a registration certificate or certificate of compliance, PPM procedures must meet the inspection requirements at § 493.1777.

(d) If the laboratory also performs waived tests, the requirements of subparts H, J, K, M, and P are not applicable to the waived tests. However, the laboratory must comply with the requirements in §§ 493.15(e) and 493.1775.

[57 FR 7139, Feb. 28, 1992, as amended at 60 FR 20044, Apr. 24, 1995]

Subpart B—Certificate of Waiver

SOURCE: 57 FR 7142, Feb. 28, 1992, unless otherwise noted.

§ 493.35 Application for a certificate of waiver.

(a) *Filing of application.* Except as specified in paragraph (b) of this section, a laboratory performing only one or more waived tests listed in § 493.15 must file a separate application for each laboratory location.

(b) *Exceptions.* (1) Laboratories that are not at a fixed location, that is, laboratories that move from testing site to testing site, such as mobile units providing laboratory testing, health screening fairs, or other temporary testing locations may be covered under the certificate of the designated primary site or home base, using its address.

(2) Not-for-profit or Federal, State, or local government laboratories that engage in limited (not more than a combination of 15 moderately complex or waived tests per certificate) public health testing may file a single application.

(3) Laboratories within a hospital that are located at contiguous buildings on the same campus and under common direction may file a single application or multiple applications for the laboratory sites within the same physical location or street address.

(c) *Application format and contents.* The application must—

(1) Be made to HHS or its designee on a form or forms prescribed by HHS;

(2) Be signed by an owner, or by an authorized representative of the laboratory who attests that the laboratory will be operated in accordance with requirements established by the Secretary under section 353 of the PHS Act; and

(3) Describe the characteristics of the laboratory operation and the examinations and other test procedures performed by the laboratory including—

(i) The name and the total number of test procedures and examinations performed annually (excluding tests the laboratory may run for quality control, quality assurance or proficiency testing purposes;

(ii) The methodologies for each laboratory test procedure or examination performed, or both; and

(iii) The qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory examinations and test procedures.

(d) *Access requirements.* Laboratories that perform one or more waived tests listed in § 493.15(c) and no other tests must meet the following conditions:

(1) Make records available and submit reports to HHS as HHS may reasonably require to determine compliance with this section and § 493.15(e);

(2) Agree to permit announced and unannounced inspections by HHS in accordance with subpart Q of this part under the following circumstances:

(i) When HHS has substantive reason to believe that the laboratory is being operated in a manner that constitutes an imminent and serious risk to human health.

(ii) To evaluate complaints from the public.

(iii) On a random basis to determine whether the laboratory is performing tests not listed in § 493.15.

(iv) To collect information regarding the appropriateness of waiver of tests listed in § 493.15.

(e) *Denial of application.* If HHS determines that the application for a certificate of waiver is to be denied, HHS will—

(1) Provide the laboratory with a written statement of the grounds on which the denial is based and an opportunity for appeal, in accordance with the procedures set forth in subpart R of this part;

(2) Notify a laboratory that has its application for a certificate of waiver denied that it cannot operate as a laboratory under the PHS Act unless the denial is overturned at the conclusion of the administrative appeals process provided by subpart R; and

(3) Notify the laboratory that it is not eligible for payment under the Medicare and Medicaid programs.

[57 FR 7142, Feb. 28, 1992, as amended at 58 FR 5222, Jan. 19, 1993; 60 FR 20044, Apr. 24, 1995]

§ 493.37 Requirements for a certificate of waiver.

(a) HHS will issue a certificate of waiver to a laboratory only if the laboratory meets the requirements of § 493.35.

(b) Laboratories issued a certificate of waiver—

(1) Are subject to the requirements of this subpart and § 493.15(e) of subpart A of this part; and

(2) Must permit announced or unannounced inspections by HHS in accordance with subpart Q of this part.

(c) Laboratories must remit the certificate of waiver fee specified in subpart F of this part.

(d) In accordance with subpart R of this part, HHS will suspend or revoke or limit a laboratory's certificate of waiver for failure to comply with the requirements of this subpart. In addition, failure to meet the requirements of this subpart will result in suspension or denial of payments under Medicare and Medicaid in accordance with subpart R of this part.

(e)(1) A certificate of waiver issued under this subpart is valid for no more than 2 years. In the event of a noncompliance determination resulting in HHS action to revoke, suspend, or limit the laboratory's certificate of waiver, HHS will provide the laboratory with a statement of grounds on which the determination of non-compliance is based and offer an opportunity for appeal as provided in subpart R of this part.

(2) If the laboratory requests a hearing within the time specified by HHS, it retains its certificate of waiver or reissued certificate of waiver until a decision is made by an administrative law judge, as specified in subpart R of this part, except when HHS finds that conditions at the laboratory pose an imminent and serious risk to human health.

(3) For laboratories receiving payment from the Medicare or Medicaid program, such payments will be suspended on the effective date specified in the notice to the laboratory of a non-compliance determination even if there has been no appeals decision issued.

(f) A laboratory seeking to renew its certificate of waiver must—

(1) Complete the renewal application prescribed by HHS and return it to HHS not less than 9 months nor more than 1 year before the expiration of the certificate; and

(2) Meet the requirements of §§ 493.35 and 493.37.

(g) A laboratory with a certificate of waiver that wishes to perform examinations or tests not listed in the waiver test category must meet the requirements set forth in subpart C or subpart D of this part, as applicable.

[57 FR 7142, Feb. 28, 1992, as amended at 58 FR 5222, Jan. 19, 1993; 60 FR 20045, Apr. 24, 1995]

§ 493.39 Notification requirements for laboratories issued a certificate of waiver.

Laboratories performing one or more tests listed in § 493.15 and no others must notify HHS or its designee—

(a) Before performing and reporting results for any test or examination that is not specified under § 493.15 for which the laboratory does not have the appropriate certificate as required in subpart C or subpart D of this part, as applicable; and

(b) Within 30 days of any change(s) in—

(1) Ownership;

(2) Name;

(3) Location; or

(4) Director.

[57 FR 7142, Feb. 28, 1992, as amended at 60 FR 20045, Apr. 24, 1995]

Subpart C—Registration Certificate, Certificate for Provider-performed Microscopy Procedures, and Certificate of Compliance

SOURCE: 57 FR 7143, Feb. 28, 1992, unless otherwise noted.

§ 493.43 Application for registration certificate, certificate for provider-performed microscopy (PPM) procedures, and certificate of compliance.

(a) *Filing of application.* Except as specified in paragraph (b) of this section, all laboratories performing tests of moderate complexity (including the subcategory) or high complexity, or any combination of these tests, must file a separate application for each laboratory location.

(b) *Exceptions.* (1) Laboratories that are not at a fixed location, that is, laboratories that move from testing site to testing site, such as mobile units providing laboratory testing, health screening fairs, or other temporary testing locations may be covered under the certificate of the designated primary site or home base, using its address.

(2) Not-for-profit or Federal, State, or local government laboratories that engage in limited (not more than a combination of 15 moderately complex or waived tests per certificate) public health testing may file a single application.

(3) Laboratories within a hospital that are located at contiguous buildings on the same campus and under common direction may file a single application or multiple applications for the laboratory sites within the same physical location or street address.

(c) *Application format and contents.* The application must—(1) Be made to HHS or its designee on a form or forms prescribed by HHS;

(2) Be signed by an owner, or by an authorized representative of the laboratory who attests that the laboratory will be operated in accordance with the requirements established by the Secretary under section 353 of the Public Health Service Act; and

(3) Describe the characteristics of the laboratory operation and the examinations and other test procedures performed by the laboratory including—

(i) The name and total number of test procedures and examinations performed annually (excluding waived tests or tests for quality control, quality assurance or proficiency testing purposes);

(ii) The methodologies for each laboratory test procedure or examination performed, or both;

(iii) The qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the examinations and test procedures.

(d) *Access and reporting requirements.* All laboratories must make records available and submit reports to HHS as

HHS may reasonably require to determine compliance with this section.

[57 FR 7143, Feb. 28, 1992, as amended at 58 FR 5222, Jan. 19, 1993; 58 FR 39155, July 22, 1993; 60 FR 20045, Apr. 24, 1995]

§ 493.45 Requirements for a registration certificate.

Laboratories performing only waived tests, PPM procedures, or any combination of these tests, are not required to obtain a registration certificate.

(a) A registration certificate is required—(1) Initially for all laboratories performing test procedures of moderate complexity (other than the subcategory of PPM procedures) or high complexity, or both; and

(2) For all laboratories that have been issued a certificate of waiver or certificate for PPM procedures that intend to perform tests of moderate or high complexity, or both, in addition to those tests listed in §493.15(c) or specified as PPM procedures.

(b) HHS will issue a registration certificate if the laboratory—

(1) Complies with the requirements of §493.43;

(2) Agrees to notify HHS or its designee within 30 days of any changes in ownership, name, location, director or technical supervisor (laboratories performing high complexity testing only);

(3) Agrees to treat proficiency testing samples in the same manner as it treats patient specimens; and

(4) Remits the fee for the registration certificate, as specified in subpart F of this part.

(c) Prior to the expiration of the registration certificate, a laboratory must—

(1) Remit the certificate fee specified in subpart F of this part;

(2) Be inspected by HHS as specified in subpart Q of this part; and

(3) Demonstrate compliance with the applicable requirements of this subpart and subparts H, J, K, M, P, and Q of this part.

(d) In accordance with subpart R of this part, HHS will initiate suspension or revocation of a laboratory's registration certificate and will deny the laboratory's application for a certificate of compliance for failure to comply with the requirements set forth in this subpart. HHS may also impose certain alternative sanctions. In addition, failure to meet the requirements of this subpart will result in suspension of payments under Medicare and Medicaid as specified in subpart R of this part.

(e) A registration certificate is—

(1) Valid for a period of no more than two years or until such time as an inspection to determine program compliance can be conducted, whichever is shorter; and

(2) Not renewable; however, the registration certificate may be reissued if compliance has not been determined by HHS prior to the expiration date of the registration certificate.

(f) In the event of a noncompliance determination resulting in an HHS denial of a laboratory's certificate of compliance application, HHS will provide the laboratory with a statement of grounds on which the noncompliance determination is based and offer an opportunity for appeal as provided in subpart R.

(g) If the laboratory requests a hearing within the time specified by HHS, it retains its registration certificate or reissued registration certificate until a decision is made by an administrative law judge as provided in subpart R of this part, except when HHS finds that conditions at the laboratory pose an imminent and serious risk to human health.

(h) For laboratories receiving payment from the Medicare or Medicaid program, such payments will be suspended on the effective date specified in the notice to the laboratory of denial of the certificate application even if there has been no appeals decision issued.

[57 FR 7143, Feb. 28, 1992, as amended at 58 FR 5223, Jan. 19, 1993; 60 FR 20045, Apr. 24, 1995]

§ 493.47 Requirements for a certificate for provider-performed microscopy (PPM) procedures.

(a) A certificate for PPM procedures is required—

(1) Initially for all laboratories performing test procedures specified as PPM procedures; and

(2) For all certificate of waiver laboratories that intend to perform only

test procedures specified as PPM procedures in addition to those tests listed in § 493.15(c).

(b) HHS will issue a certificate for PPM procedures if the laboratory—

(1) Complies with the requirements of § 493.43; and

(2) Remits the fee for the certificate, as specified in subpart F of this part.

(c) Laboratories issued a certificate for PPM procedures are subject to—

(1) The notification requirements of § 493.53;

(2) The applicable requirements of this subpart and subparts H, J, K, M, and P of this part; and

(3) Inspection only under the circumstances specified under § 493.1776, but are not routinely inspected to determine compliance with the requirements specified in paragraphs (c) (1) and (2) of this section.

(d) In accordance with subpart R of this part, HHS will initiate suspension, limitation, or revocation of a laboratory's certificate for PPM procedures for failure to comply with the applicable requirements set forth in this subpart. HHS may also impose certain alternative sanctions. In addition, failure to meet the requirements of this subpart may result in suspension of all or part of payments under Medicare and Medicaid, as specified in subpart R of this part.

(e) A certificate for PPM procedures is valid for a period of no more than 2 years.

[58 FR 5223, Jan. 19, 1993, as amended at 60 FR 20045, Apr. 24, 1995]

§ 493.49 Requirements for a certificate of compliance.

A certificate of compliance may include any combination of tests categorized as high complexity or moderate complexity or listed in § 493.15(c) as waived tests. Moderate complexity tests may include those specified as PPM procedures.

(a) HHS will issue a certificate of compliance to a laboratory only if the laboratory—

(1) Meets the requirements of §§ 493.43 and 493.45;

(2) Remits the certificate fee specified in subpart F of this part; and

(3) Meets the applicable requirements of this subpart and subparts H, J, K, M, P, and Q of this part.

(b) Laboratories issued a certificate of compliance—

(1) Are subject to the notification requirements of § 493.51; and

(2) Must permit announced or unannounced inspections by HHS in accordance with subpart Q of this part—

(i) To determine compliance with the applicable requirements of this part;

(ii) To evaluate complaints;

(iii) When HHS has substantive reason to believe that tests are being performed, or the laboratory is being operated in a manner that constitutes an imminent and serious risk to human health; and

(iv) To collect information regarding the appropriateness of tests listed in § 493.15 or tests categorized as moderate complexity (including the subcategory) or high complexity.

(c) Failure to comply with the requirements of this subpart will result in—

(1) Suspension, revocation or limitation of a laboratory's certificate of compliance in accordance with subpart R of this part; and

(2) Suspension or denial of payments under Medicare and Medicaid in accordance with subpart R of this part.

(d) A certificate of compliance issued under this subpart is valid for no more than 2 years.

(e) In the event of a noncompliance determination resulting in an HHS action to revoke, suspend or limit the laboratory's certificate of compliance, HHS will—

(1) Provide the laboratory with a statement of grounds on which the determination of noncompliance is based; and

(2) Offer an opportunity for appeal as provided in subpart R of this part. If the laboratory requests a hearing within 60 days of the notice of sanction, it retains its certificate of compliance or reissued certificate of compliance until a decision is made by an administrative law judge (ALJ) as provided in subpart R of this part, except when HHS finds that conditions at the laboratory pose an imminent and serious risk to human health or when the criteria at § 493.1840(a) (4) and (5) are met.

(f) For laboratories receiving payment from the Medicare or Medicaid program, such payments will be suspended on the effective date specified in the notice to the laboratory of a noncompliance determination even if there has been no appeals decision issued.

(g) A laboratory seeking to renew its certificate of compliance must—

(1) Complete and return the renewal application to HHS 9 to 12 months prior to the expiration of the certificate of compliance; and

(2) Meet the requirements of § 493.43 and paragraphs (a)(2) and (b)(2) of this section.

(h) If HHS determines that the application for the renewal of a certificate of compliance must be denied or limited, HHS will notify the laboratory in writing of the—

(1) Basis for denial of the application; and

(2) Opportunity for appeal as provided in subpart R of this part.

(i) If the laboratory requests a hearing within the time period specified by HHS, the laboratory retains its certificate of compliance or reissued certificate of compliance until a decision is made by an ALJ as provided in subpart R, except when HHS finds that conditions at the laboratory pose an imminent and serious risk to human health.

(j) For laboratories receiving payment from the Medicare or Medicaid program, such payments will be suspended on the effective date specified in the notice to the laboratory of nonrenewal of the certificate of compliance even if there has been no appeals decision issued.

[60 FR 20045, Apr. 24, 1995]

§ 493.51 Notification requirements for laboratories issued a certificate of compliance.

Laboratories issued a certificate of compliance must meet the following conditions:

(a) Notify HHS or its designee within 30 days of any change in—

(1) Ownership;

(2) Name;

(3) Location;

(4) Director; or

(5) Technical supervisor (laboratories performing high complexity only).

(b) Notify HHS no later than 6 months after performing any test or examination within a specialty or subspecialty area that is not included on the laboratory's certificate of compliance, so that compliance with requirements can be determined.

(c) Notify HHS no later than 6 months after any deletions or changes in test methodologies for any test or examination included in a specialty or subspecialty, or both, for which the laboratory has been issued a certificate of compliance.

[57 FR 7143, Feb. 28, 1992, as amended at 60 FR 20046, Apr. 24, 1995]

§ 493.53 Notification requirements for laboratories issued a certificate for provider-performed microscopy (PPM) procedures.

Laboratories issued a certificate for PPM procedures must notify HHS or its designee—

(a) Before performing and reporting results for any test of moderate or high complexity, or both, in addition to tests specified as PPM procedures or any test or examination that is not specified under § 493.15(c), for which it does not have a registration certificate as required in subpart C or subpart D, as applicable, of this part; and

(b) Within 30 days of any change in—

(1) Ownership;

(2) Name;

(3) Location; or

(4) Director.

[58 FR 5224, Jan. 19, 1993, as amended at 60 FR 20046, Apr. 24, 1995]

Subpart D—Certificate of Accreditation

SOURCE: 57 FR 7144, Feb. 28, 1992, unless otherwise noted.

§ 493.55 Application for registration certificate and certificate of accreditation.

(a) *Filing of application.* A laboratory may be issued a certificate of accreditation in lieu of the applicable certificate specified in subpart B or subpart C of this part provided the laboratory—

(1) Meets the standards of a private non-profit accreditation program approved by HHS in accordance with subpart E; and

(2) Files a separate application for each location, except as specified in paragraph (b) of this section.

(b) *Exceptions.* (1) Laboratories that are not at fixed locations, that is, laboratories that move from testing site to testing site, such as mobile units providing laboratory testing, health screening fairs, or other temporary testing locations may be covered under the certificate of the designated primary site or home base, using its address.

(2) Not-for-profit or Federal, State, or local government laboratories that engage in limited (not more than a combination of 15 moderately complex or waived tests per certificate) public health testing may file a single application.

(3) Laboratories within a hospital that are located at contiguous buildings on the same campus and under common direction may file a single application or multiple applications for the laboratory sites within the same physical location or street address.

(c) *Application format and contents.* The application must—(1) Be made to HHS on a form or forms prescribed by HHS;

(2) Be signed by an owner or authorized representative of the laboratory who attests that the laboratory will be operated in accordance with the requirements established by the Secretary under section 353 of the Public Health Service Act; and

(3) Describe the characteristics of the laboratory operation and the examinations and other test procedures performed by the laboratory including—

(i) The name and total number of tests and examinations performed annually (excluding waived tests and tests for quality control, quality assurance or proficiency testing purposes);

(ii) The methodologies for each laboratory test procedure or examination performed, or both; and

(iii) The qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory examinations and test procedures.

(d) *Access and reporting requirements.* All laboratories must make records available and submit reports to HHS as HHS may reasonably require to determine compliance with this section.

[57 FR 7144, Feb. 28, 1992, as amended at 58 FR 5224, Jan. 19, 1993; 58 FR 39155, July 22, 1993; 60 FR 20046, Apr. 24, 1995]

§ 493.57 Requirements for a registration certificate.

A registration certificate is required for all laboratories seeking a certificate of accreditation, unless the laboratory holds a valid certificate of compliance issued by HHS.

(a) HHS will issue a registration certificate if the laboratory—

(1) Complies with the requirements of § 493.55;

(2) Agrees to notify HHS within 30 days of any changes in ownership, name, location, director, or supervisor (laboratories performing high complexity testing only);

(3) Agrees to treat proficiency testing samples in the same manner as it treats patient specimens; and

(4) Remits the fee for the registration certificate specified in subpart F of this part.

(b)(1) The laboratory must provide HHS with proof of accreditation by an approved accreditation program—

(i) Within 11 months of issuance of the registration certificate; or

(ii) Prior to the expiration of the certificate of compliance.

(2) If such proof of accreditation is not supplied within this timeframe, the laboratory must meet, or continue to meet, the requirements of § 493.49.

(c) In accordance with subpart R of this part, HHS will initiate suspension, revocation, or limitation of a laboratory's registration certificate and will deny the laboratory's application for a certificate of accreditation for failure to comply with the requirements set forth in this subpart. In addition, failure to meet the requirements of this subpart will result in suspension or denial of payments under Medicare and Medicaid as specified in subpart R of this part.

(d) A registration certificate is valid for a period of no more than 2 years.

However, it may be reissued if the laboratory is subject to subpart C of this part, as specified in §493.57(b)(2) and compliance has not been determined by HHS before the expiration date of the registration certificate.

(e) In the event that the laboratory does not meet the requirements of this subpart, HHS will—

(1) Deny a laboratory's request for certificate of accreditation;

(2) Notify the laboratory if it must meet the requirements for a certificate as defined in subpart C of this part;

(3) Provide the laboratory with a statement of grounds on which the application denial is based;

(4) Offer an opportunity for appeal on the application denial as provided in subpart R of this part. If the laboratory requests a hearing within the time specified by HHS, the laboratory will retain its registration certificate or reissued registration certificate until a decision is made by an administrative law judge as provided in subpart R, unless HHS finds that conditions at the laboratory pose an imminent and serious risk to human health; and

(5) For those laboratories receiving payment from the Medicare or Medicaid program, such payments will be suspended on the effective date specified in the notice to the laboratory of denial of the request even if there has been no appeals decision issued.

[57 FR 7144, Feb. 28, 1992, as amended at 60 FR 20046, Apr. 24, 1995]

§493.61 Requirements for a certificate of accreditation.

(a) HHS will issue a certificate of accreditation to a laboratory if the laboratory—

(1) Meets the requirements of §493.57 or, if applicable, §493.49 of subpart C of this part; and

(2) Remits the certificate of accreditation fee specified in subpart F of this part.

(b) Laboratories issued a certificate of accreditation must—

(1) Treat proficiency testing samples in the same manner as patient samples;

(2) Meet the requirements of §493.63;

(3) Comply with the requirements of the approved accreditation program;

(4) Permit random sample validation and complaint inspections as required in subpart Q of this part;

(5) Permit HHS to monitor the correction of any deficiencies found through the inspections specified in paragraph (b)(4) of this section;

(6) Authorize the accreditation program to release to HHS the laboratory's inspection findings whenever HHS conducts random sample or complaint inspections; and

(7) Authorize its accreditation program to submit to HHS the results of the laboratory's proficiency testing.

(c) A laboratory failing to meet the requirements of this section—

(1) Will no longer meet the requirements of this part by virtue of its accreditation in an approved accreditation program;

(2) Will be subject to full determination of compliance by HHS;

(3) May be subject to suspension, revocation or limitation of the laboratory's certificate of accreditation or certain alternative sanctions; and

(4) May be subject to suspension of payments under Medicare and Medicaid as specified in subpart R.

(d) A certificate of accreditation issued under this subpart is valid for no more than 2 years. In the event of a non-compliance determination as a result of a random sample validation or complaint inspection, a laboratory will be subject to a full review by HHS in accordance with §488.11 of this chapter.

(e) Failure to meet the applicable requirements of part 493, will result in an action by HHS to suspend, revoke or limit the certificate of accreditation. HHS will—

(1) Provide the laboratory with a statement of grounds on which the determination of noncompliance is based;

(2) Notify the laboratory if it is eligible to apply for a certificate as defined in subpart C of this part; and

(3) Offer an opportunity for appeal as provided in subpart R of this part.

(f) If the laboratory requests a hearing within the time frame specified by HHS—

(1) It retains its certificate of accreditation or reissued certificate of accreditation until a decision is made by an administrative law judge as provided in subpart R of this part, unless

HHS finds that conditions at the laboratory pose an imminent and serious risk to human health; and

(2) For those laboratories receiving payments from the Medicare or Medicaid program, such payments will be suspended on the effective date specified in the notice to the laboratory even if there has been no appeals decision issued.

(g) In the event the accreditation organization's approval is removed by HHS, the laboratory will be subject to the applicable requirements of subpart C of this part or §493.57.

(h) A laboratory seeking to renew its certificate of accreditation must—

(1) Complete and return the renewal application to HHS 9 to 12 months prior to the expiration of the certificate of accreditation;

(2) Meet the requirements of this subpart; and

(3) Submit the certificate of accreditation fee specified in subpart F of this part.

(i) If HHS determines that the renewal application for a certificate of accreditation is to be denied or limited, HHS will notify the laboratory in writing of—

(1) The basis for denial of the application;

(2) Whether the laboratory is eligible for a certificate as defined in subpart C of this part;

(3) The opportunity for appeal on HHS's action to deny the renewal application for certificate of accreditation as provided in subpart R of this part. If the laboratory requests a hearing within the time frame specified by HHS, it retains its certificate of accreditation or reissued certificate of accreditation until a decision is made by an administrative law judge as provided in subpart R of this part, unless HHS finds that conditions at the laboratory pose an imminent and serious risk to human health; and

(4) Suspension of payments under Medicare or Medicaid for those laboratories receiving payments under the Medicare or Medicaid programs.

[57 FR 7144, Feb. 28, 1992, as amended at 58 FR 5224, Jan. 19, 1993]

§493.63 Notification requirements for laboratories issued a certificate of accreditation.

Laboratories issued a certificate of accreditation must:

(a) Notify HHS and the approved accreditation program within 30 days of any changes in—

(1) Ownership;

(2) Name;

(3) Location; or

(4) Director.

(b) Notify the approved accreditation program no later than 6 months after performing any test or examination within a specialty or subspecialty area that is not included in the laboratory's accreditation, so that the accreditation organization can determine compliance and a new certificate of accreditation can be issued.

(c) Notify the accreditation program no later than 6 months after of any deletions or changes in test methodologies for any test or examination included in a specialty or subspecialty, or both, for which the laboratory has been issued a certificate of accreditation.

Subpart E—Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program

SOURCE: 63 FR 26732, May 14, 1998, unless otherwise noted.

§493.551 General requirements for laboratories.

(a) *Applicability.* HCFA may deem a laboratory to meet all applicable CLIA program requirements through accreditation by a private nonprofit accreditation program (that is, grant deemed status), or may exempt from CLIA program requirements all State licensed or approved laboratories in a State that has a State licensure program established by law, if the following conditions are met:

(1) The requirements of the accreditation organization or State licensure program are equal to, or more stringent than, the CLIA condition-level requirements specified in this part, and

the laboratory would meet the condition-level requirements if it were inspected against these requirements.

(2) The accreditation program or the State licensure program meets the requirements of this subpart and is approved by HCFA.

(3) The laboratory authorizes the approved accreditation organization or State licensure program to release to HCFA all records and information required and permits inspections as outlined in this part.

(b) *Meeting CLIA requirements by accreditation.* A laboratory seeking to meet CLIA requirements through accreditation by an approved accreditation organization must do the following:

(1) Obtain a certificate of accreditation as required in subpart D of this part.

(2) Pay the applicable fees as required in subpart F of this part.

(3) Meet the proficiency testing (PT) requirements in subpart H of this part.

(4) Authorize its PT organization to furnish to its accreditation organization the results of the laboratory's participation in an approved PT program for the purpose of monitoring the laboratory's PT and for making the annual PT results, along with explanatory information required to interpret the PT results, available on a reasonable basis, upon request of any person. A laboratory that refuses to authorize release of its PT results is no longer deemed to meet the condition-level requirements and is subject to a full review by HCFA, in accordance with subpart Q of this part, and may be subject to the suspension or revocation of its certificate of accreditation under § 493.1840.

(5) Authorize its accreditation organization to release to HCFA or a HCFA agent the laboratory's PT results that constitute unsuccessful participation in an approved PT program, in accordance with the definition of ''unsuccessful participation in an approved PT program,'' as specified in § 493.2 of this part, when the laboratory has failed to achieve successful participation in an approved PT program.

(6) Authorize its accreditation organization to release to HCFA a notification of the actions taken by the organization as a result of the unsuccessful participation in a PT program within 30 days of the initiation of the action. Based on this notification, HCFA may take an adverse action against a laboratory that fails to participate successfully in an approved PT program.

(c) *Withdrawal of laboratory accreditation.* After an accreditation organization has withdrawn or revoked its accreditation of a laboratory, the laboratory retains its certificate of accreditation for 45 days after the laboratory receives notice of the withdrawal or revocation of the accreditation, or the effective date of any action taken by HCFA, whichever is earlier.

§ 493.553 Approval process (application and reapplication) for accreditation organizations and State licensure programs.

(a) *Information required.* An accreditation organization that applies or reapplies to HCFA for deeming authority, or a State licensure program that applies or reapplies to HCFA for exemption from CLIA program requirements of licensed or approved laboratories within the State, must provide the following information:

(1) A detailed comparison of the individual accreditation, or licensure or approval requirements with the comparable condition-level requirements; that is, a crosswalk.

(2) A detailed description of the inspection process, including the following:

(i) Frequency of inspections.

(ii) Copies of inspection forms.

(iii) Instructions and guidelines.

(iv) A description of the review and decision-making process of inspections.

(v) A statement concerning whether inspections are announced or unannounced.

(vi) A description of the steps taken to monitor the correction of deficiencies.

(3) A description of the process for monitoring PT performance, including action to be taken in response to unsuccessful participation in a HCFA-approved PT program.

(4) Procedures for responding to and for the investigation of complaints against its laboratories.

(5) A list of all its current laboratories and the expiration date of their

accreditation or licensure, as applicable.

(6) Procedures for making PT information available (under State confidentiality and disclosure requirements, if applicable) including explanatory information required to interpret PT results, on a reasonable basis, upon request of any person.

(b) *HCFA action on an application or reapplication.* If HCFA receives an application or reapplication from an accreditation organization, or State licensure program, HCFA takes the following actions:

(1) HCFA determines if additional information is necessary to make a determination for approval or denial of the application and notifies the accreditation organization or State to afford it an opportunity to provide the additional information.

(2) HCFA may visit the accreditation organization or State licensure program offices to review and verify the policies and procedures represented in its application and other information, including, but not limited to, review and examination of documents and interviews with staff.

(3) HCFA notifies the accreditation organization or State licensure program indicating whether HCFA approves or denies the request for deeming authority or exemption, respectively, and the rationale for any denial.

(c) *Duration of approval.* HCFA approval may not exceed 6 years.

(d) *Withdrawal of application.* The accreditation organization or State licensure program may withdraw its application at any time before official notification, specified at §493.553(b)(3).

§493.555 Federal review of laboratory requirements.

HCFA's review of an accreditation organization or State licensure program includes, but is not limited to, an evaluation of the following:

(a) Whether the organization's or State's requirements for laboratories are equal to, or more stringent than, the condition-level requirements for laboratories.

(b) The organization's or State's inspection process to determine the comparability of the full inspection and complaint inspection procedures and requirements to those of HCFA, including, but not limited to, inspection frequency and the ability to investigate and respond to complaints against its laboratories.

(c) The organization's or State's agreement with HCFA that requires it to do the following:

(1) Notify HCFA within 30 days of the action taken, of any laboratory that has—

(i) Had its accreditation or licensure suspended, withdrawn, revoked, or limited;

(ii) In any way been sanctioned; or

(iii) Had any adverse action taken against it.

(2) Notify HCFA within 10 days of any deficiency identified in an accredited or CLIA-exempt laboratory if the deficiency poses an immediate jeopardy to the laboratory's patients or a hazard to the general public.

(3) Notify HCFA, within 30 days, of all newly—

(i) Accredited laboratories (or laboratories whose areas of specialty/subspecialty testing have changed); or

(ii) Licensed laboratories, including the specialty/subspecialty areas of testing.

(4) Notify each accredited or licensed laboratory within 10 days of HCFA's withdrawal of the organization's deeming authority or State's exemption.

(5) Provide HCFA with inspection schedules, as requested, for validation purposes.

§493.557 Additional submission requirements.

(a) *Specific requirements for accreditation organizations.* In addition to the information specified in §§493.553 and 493.555, as part of the approval and review process, an accreditation organization applying or reapplying for deeming authority must also provide the following:

(1) The specialty or subspecialty areas for which the organization is requesting deeming authority and its mechanism for monitoring compliance with all requirements equivalent to condition-level requirements within the scope of the specialty or subspecialty areas.

(2) A description of the organization's data management and analysis system

with respect to its inspection and accreditation decisions, including the kinds of routine reports and tables generated by the systems.

(3) Detailed information concerning the inspection process, including, but not limited to the following:

(i) The size and composition of individual accreditation inspection teams.

(ii) Qualifications, education, and experience requirements that inspectors must meet.

(iii) The content and frequency of training provided to inspection personnel, including the ability of the organization to provide continuing education and training to inspectors.

(4) Procedures for removal or withdrawal of accreditation status for laboratories that fail to meet the organization's standards.

(5) A proposed agreement between HCFA and the accreditation organization with respect to the notification requirements specified in § 493.555(c).

(6) Procedures for monitoring laboratories found to be out of compliance with its requirements. (These monitoring procedures must be used only when the accreditation organization identifies noncompliance. If noncompliance is identified through validation inspections, HCFA or a HCFA agent monitors corrections, as authorized at § 493.565(d)).

(7) A demonstration of its ability to provide HCFA with electronic data and reports in compatible code, including the crosswalk specified in § 493.553(a)(1), that are necessary for effective validation and assessment of the organization's inspection process.

(8) A demonstration of its ability to provide HCFA with electronic data, in compatible code, related to the adverse actions resulting from PT results constituting unsuccessful participation in PT programs as well as data related to the PT failures, within 30 days of the initiation of adverse action.

(9) A demonstration of its ability to provide HCFA with electronic data, in compatible code, for all accredited laboratories, including the area of specialty or subspecialty.

(10) Information defining the adequacy of numbers of staff and other resources.

(11) Information defining the organization's ability to provide adequate funding for performing required inspections.

(12) Any facility-specific data, upon request by HCFA, which includes, but is not limited to, the following:

(i) PT results that constitute unsuccessful participation in a HCFA-approved PT program.

(ii) Notification of the adverse actions or corrective actions imposed by the accreditation organization as a result of unsuccessful PT participation.

(13) An agreement to provide written notification to HCFA at least 30 days in advance of the effective date of any proposed change in its requirements.

(14) An agreement to disclose any laboratory's PT results upon reasonable request by any person.

(b) *Specific requirements for a State licensure program.* In addition to requirements in §§ 493.553 and 493.555, as part of the approval and review process, when a State licensure program applies or reapplies for exemption from the CLIA program, the State must do the following:

(1) Demonstrate to HCFA that it has enforcement authority and administrative structures and resources adequate to enforce its laboratory requirements.

(2) Permit HCFA or a HCFA agent to inspect laboratories in the State.

(3) Require laboratories in the State to submit to inspections by HCFA or a HCFA agent as a condition of licensure or approval.

(4) Agree to pay the cost of the validation program administered in that State as specified in §§ 493.645(a) and 493.646(b).

(5) Take appropriate enforcement action against laboratories found by HCFA not to be in compliance with requirements equivalent to CLIA requirements.

(6) Submit for Medicare and Medicaid payment purposes, a list of the specialties and subspecialties of tests performed by each laboratory.

(7) Submit a written presentation that demonstrates the agency's ability to furnish HCFA with electronic data in compatible code, including the crosswalk specified in § 493.553(a)(1).

(8) Submit a statement acknowledging that the State will notify HCFA

through electronic transmission of the following:

(i) Any laboratory that has had its licensure or approval revoked or withdrawn or has been in any way sanctioned by the State within 30 days of taking the action.

(ii) Changes in licensure or inspection requirements.

(iii) Changes in specialties or subspecialties under which any licensed laboratory in the State performs testing.

(9) Provide information for the review of the State's enforcement procedures for laboratories found to be out of compliance with the State's requirements.

(10) Submit information that demonstrates the ability of the State to provide HCFA with the following:

(i) Electronic data and reports in compatible code with the adverse or corrective actions resulting from PT results that constitute unsuccessful participation in PT programs.

(ii) Other data that HCFA determines are necessary for validation and assessment of the State's inspection process requirements.

(11) Agree to provide HCFA with written notification of any changes in its licensure/approval and inspection requirements.

(12) Agree to disclose any laboratory's PT results in accordance with a State's confidentiality requirements.

(13) Agree to take the appropriate enforcement action against laboratories found by HCFA not to be in compliance with requirements comparable to condition-level requirements and report these enforcement actions to HCFA.

(14) If approved, reapply to HCFA every 2 years to renew its exempt status and to renew its agreement to pay the cost of the HCFA-administered validation program in that State.

§ 493.559 Publication of approval of deeming authority or CLIA exemption.

(a) *Notice of deeming authority or exemption.* HCFA publishes a notice in the FEDERAL REGISTER when it grants deeming authority to an accreditation organization or exemption to a State licensure program.

(b) *Contents of notice.* The notice includes the following:

(1) The name of the accreditation organization or State licensure program.

(2) For an accreditation organization:

(i) The specific specialty or subspecialty areas for which it is granted deeming authority.

(ii) A description of how the accreditation organization provides reasonable assurance to HCFA that a laboratory accredited by the organization meets CLIA requirements equivalent to those in this part and would meet CLIA requirements if the laboratory had not been granted deemed status, but had been inspected against condition-level requirements.

(3) For a State licensure program, a description of how the laboratory requirements of the State are equal to, or more stringent than, those specified in this part.

(4) The basis for granting deeming authority or exemption.

(5) The term of approval, not to exceed 6 years.

§ 493.561 Denial of application or reapplication.

(a) *Reconsideration of denial.* (1) If HCFA denies a request for approval, an accreditation organization or State licensure program may request, within 60 days of the notification of denial, that HCFA reconsider its original application or application for renewal, in accordance with part 488, subpart D.

(2) If the accreditation organization or State licensure program requests a reconsideration of HCFA's determination to deny its request for approval or reapproval, it may not submit a new application until HCFA issues a final reconsideration determination.

(b) *Resubmittal of a request for approval— accreditation organization.* An accreditation organization may resubmit a request for approval if a final reconsideration determination is not pending and the accreditation program meets the following conditions:

(1) It has revised its accreditation program to address the rationale for denial of its previous request.

(2) It demonstrates that it can provide reasonable assurance that its accredited facilities meet condition-level requirements.

(3) It resubmits the application in its entirety.

(c) *Resubmittal of request for approval—State licensure program.* The State licensure program may resubmit a request for approval if a final reconsideration determination is not pending and it has taken the necessary action to address the rationale for any previous denial.

§ 493.563 Validation inspections—Basis and focus.

(a) *Basis for validation inspection*—(1) *Laboratory with a certificate of accreditation.* (i) HCFA or a HCFA agent may conduct an inspection of an accredited laboratory that has been issued a certificate of accreditation on a representative sample basis or in response to a substantial allegation of noncompliance.

(ii) HCFA uses the results of these inspections to validate the accreditation organization's accreditation process.

(2) *Laboratory in a State with an approved State licensure program.* (i) HCFA or a HCFA agent may conduct an inspection of any laboratory in a State with an approved State licensure program on a representative sample basis or in response to a substantial allegation of noncompliance.

(ii) The results of these inspections are used to validate the appropriateness of the exemption of that State's licensed or approved laboratories from CLIA program requirements.

(b) *Validation inspection conducted on a representative sample basis.* (1) If HCFA or a HCFA agent conducts a validation inspection on a representative sample basis, the inspection is comprehensive, addressing all condition-level requirements, or it may be focused on a specific condition-level requirement.

(2) The number of laboratories sampled is sufficient to allow a reasonable estimate of the performance of the accreditation organization or State.

(c) *Validation inspection conducted in response to a substantial allegation of noncompliance.* (1) If HCFA or a HCFA agent conducts a validation inspection in response to a substantial allegation of noncompliance, the inspection focuses on any condition-level requirement that HCFA determines to be related to the allegation.

(2) If HCFA or a HCFA agent substantiates a deficiency and determines that the laboratory is out of compliance with any condition-level requirement, HCFA or a HCFA agent conducts a full CLIA inspection.

(d) *Inspection of operations and offices.* As part of the validation review process, HCFA may conduct an onsite inspection of the operations and offices to verify the following:

(1) The accreditation organization's representations and to assess the accreditation organization's compliance with its own policies and procedures.

(2) The State's representations and to assess the State's compliance with its own policies and procedures, including verification of State enforcement actions taken on the basis of validation inspections performed by HCFA or a HCFA agent.

(e) *Onsite inspection of an accreditation organization.* An onsite inspection of an accreditation organization may include, but is not limited to, the following:

(1) A review of documents.

(2) An audit of meetings concerning the accreditation process.

(3) Evaluation of accreditation inspection results and the accreditation decision-making process.

(4) Interviews with the accreditation organization's staff.

(f) *Onsite inspection of a State licensure program.* An onsite inspection of a State licensure program office may include, but is not limited to, the following:

(1) A review of documents.

(2) An audit of meetings concerning the licensure or approval process.

(3) Evaluation of State inspection results and the licensure or approval decision-making process.

(4) Interviews with State employees.

§ 493.565 Selection for validation inspection—laboratory responsibilities.

A laboratory selected for a validation inspection must do the following:

(a) Authorize its accreditation organization or State licensure program, as applicable, to release to HCFA or a HCFA agent, on a confidential basis, a copy of the laboratory's most recent

full, and any subsequent partial inspection.

(b) Authorize HCFA or a HCFA agent to conduct a validation inspection.

(c) Provide HCFA or a HCFA agent with access to all facilities, equipment, materials, records, and information that HCFA or a HCFA agent determines have a bearing on whether the laboratory is being operated in accordance with the requirements of this part, and permit HCFA or a HCFA agent to copy material or require the laboratory to submit material.

(d) If the laboratory possesses a valid certificate of accreditation, authorize HCFA or a HCFA agent to monitor the correction of any deficiencies found through the validation inspection.

§ 493.567 Refusal to cooperate with validation inspection.

(a) *Laboratory with a certificate of accreditation.* (1) A laboratory with a certificate of accreditation that refuses to cooperate with a validation inspection by failing to comply with the requirements in § 493.565—

(i) Is subject to full review by HCFA or a HCFA agent, in accordance with this part; and

(ii) May be subject to suspension, revocation, or limitation of its certificate of accreditation under this part.

(2) A laboratory with a certificate of accreditation is again deemed to meet the condition-level requirements by virtue of its accreditation when the following conditions exist:

(i) The laboratory withdraws any prior refusal to authorize its accreditation organization to release a copy of the laboratory's current accreditation inspection, PT results, or notification of any adverse actions resulting from PT failure.

(ii) The laboratory withdraws any prior refusal to allow a validation inspection.

(iii) HCFA finds that the laboratory meets all the condition-level requirements.

(b) *CLIA-exempt laboratory.* If a CLIA-exempt laboratory fails to comply with the requirements specified in § 493.565, HCFA notifies the State of the laboratory's failure to meet the requirements.

§ 493.569 Consequences of a finding of noncompliance as a result of a validation inspection.

(a) *Laboratory with a certificate of accreditation.* If a validation inspection results in a finding that the accredited laboratory is out of compliance with one or more condition-level requirements, the laboratory is subject to—

(1) The same requirements and survey and enforcement processes applied to laboratories that are not accredited and that are found out of compliance following an inspection under this part; and

(2) Full review by HCFA, in accordance with this part; that is, the laboratory is subject to the principal and alternative sanctions in § 493.1806.

(b) *CLIA-exempt laboratory.* If a validation inspection results in a finding that a CLIA-exempt laboratory is out of compliance with one or more condition-level requirements, HCFA directs the State to take appropriate enforcement action.

§ 493.571 Disclosure of accreditation, State and HCFA validation inspection results.

(a) *Accreditation organization inspection results.* HCFA may disclose accreditation organization inspection results to the public only if the results are related to an enforcement action taken by the Secretary.

(b) *State inspection results.* Disclosure of State inspection results is the responsibility of the approved State licensure program, in accordance with State law.

(c) *HCFA validation inspection results.* HCFA may disclose the results of all validation inspections conducted by HCFA or its agent.

§ 493.573 Continuing Federal oversight of private nonprofit accreditation organizations and approved State licensure programs.

(a) *Comparability review.* In addition to the initial review for determining equivalency of specified organization or State requirements to the comparable condition-level requirements, HCFA reviews the equivalency of requirements in the following cases:

(1) When HCFA promulgates new condition-level requirements.

(2) When HCFA identifies an accreditation organization or a State licensure program whose requirements are no longer equal to, or more stringent than, condition-level requirements.

(3) When an accreditation organization or State licensure program adopts new requirements.

(4) When an accreditation organization or State licensure program adopts changes to its inspection process, as required by §493.575(b)(1), as applicable.

(5) Every 6 years, or sooner if HCFA determines an earlier review is required.

(b) *Validation review*. Following the end of a validation review period, HCFA evaluates the validation inspection results for each approved accreditation organization and State licensure program.

(c) *Reapplication procedures.* (1) Every 6 years, or sooner, as determined by HCFA, an approved accreditation organization must reapply for continued approval of deeming authority and a State licensure program must reapply for continued approval of a CLIA exemption. HCFA provides notice of the materials that must be submitted as part of the reapplication procedure.

(2) An accreditation organization or State licensure program that does not meet the requirements of this subpart, as determined through a comparability or validation review, must furnish HCFA, upon request, with the reapplication materials HCFA requests. HCFA establishes a deadline by which the materials must be submitted.

(d) *Notice.* (1) HCFA provides written notice, as appropriate, to the following:

(i) An accreditation organization indicating that its approval may be in jeopardy if a comparability or validation review reveals that it is not meeting the requirements of this subpart and HCFA is initiating a review of the accreditation organization's deeming authority.

(ii) A State licensure program indicating that its CLIA exemption may be in jeopardy if a comparability or validation review reveals that it is not meeting the requirements of this subpart and that a review is being initiated of the CLIA exemption of the State's laboratories.

(2) The notice contains the following information:

(i) A statement of the discrepancies that were found as well as other related documentation.

(ii) An explanation of HCFA's review process on which the final determination is based and a description of the possible actions, as specified in §493.575, that HCFA may impose based on the findings from the comparability or validation review.

(iii) A description of the procedures available if the accreditation organization or State licensure program, as applicable, desires an opportunity to explain or justify the findings made during the comparability or validation review.

(iv) The reapplication materials that the accreditation organization or State licensure program must submit and the deadline for that submission.

§493.575 Removal of deeming authority or CLIA exemption and final determination review.

(a) *HCFA review*. HCFA conducts a review of the following:

(1) A deeming authority review of an accreditation organization's program if the comparability or validation review produces findings, as described at §493.573. HCFA reviews, as appropriate, the criteria described in §§493.555 and 493.557(a) to reevaluate whether the accreditation organization continues to meet all these criteria.

(2) An exemption review of a State's licensure program if the comparability or validation review produces findings, as described at §493.573. HCFA reviews, as appropriate, the criteria described in §§493.555 and 493.557(b) to reevaluate whether the licensure program continues to meet all these criteria.

(3) A review of an accreditation organization or State licensure program, at HCFA's discretion, if validation review findings, irrespective of the rate of disparity, indicate widespread or systematic problems in the organization's accreditation or State's licensure process that provide evidence that the requirements, taken as a whole, are no longer equivalent to CLIA requirements, taken as a whole.

(4) A review of the accreditation organization or State licensure program

whenever validation inspection results indicate a rate of disparity of 20 percent or more between the findings of the organization or State and those of HCFA or a HCFA agent for the following periods:

(i) One year for accreditation organizations.

(ii) Two years for State licensure programs.

(b) *HCFA action after review.* Following the review, HCFA may take the following action:

(1) If HCFA determines that the accreditation organization or State has failed to adopt requirements equal to, or more stringent than, CLIA requirements, HCFA may give a conditional approval for a probationary period of its deeming authority to an organization 30 days following the date of HCFA's determination, or exempt status to a State within 30 days of HCFA's determination, both not to exceed 1 year, to afford the organization or State an opportunity to adopt equal or more stringent requirements.

(2) If HCFA determines that there are widespread or systematic problems in the organization's or State's inspection process, HCFA may give conditional approval during a probationary period, not to exceed 1 year, effective 30 days following the date of the determination.

(c) *Final determination.* HCFA makes a final determination as to whether the organization or State continues to meet the criteria described in this subpart and issues a notice that includes the reasons for the determination to the organization or State within 60 days after the end of any probationary period. This determination is based on an evaluation of any of the following:

(1) The most recent validation inspection and review findings. To continue to be approved, the organization or State must meet the criteria of this subpart.

(2) Facility-specific data, as well as other related information.

(3) The organization's or State's inspection procedures, surveyors' qualifications, ongoing education, training, and composition of inspection teams.

(4) The organization's accreditation requirements, or the State's licensure or approval requirements.

(d) *Date of withdrawal of approval.* HCFA may withdraw its approval of the accreditation organization or State licensure program, effective 30 days from the date of written notice to the organization or State of this proposed action, if improvements acceptable to HCFA have not been made during the probationary period.

(e) *Continuation of validation inspections.* The existence of any validation review, probationary status, or any other action, such as a deeming authority review, by HCFA does not affect or limit the conduct of any validation inspection.

(f) *Federal Register notice.* HCFA publishes a notice in the FEDERAL REGISTER containing a justification for removing the deeming authority from an accreditation organization, or the CLIA-exempt status of a State licensure program.

(g) *Withdrawal of approval-effect on laboratory status*—(1) *Accredited laboratory.* After HCFA withdraws approval of an accreditation organization's deeming authority, the certificate of accreditation of each affected laboratory continues in effect for 60 days after it receives notification of the withdrawal of approval.

(2) *CLIA-exempt laboratory.* After HCFA withdraws approval of a State licensure program, the exempt status of each licensed or approved laboratory in the State continues in effect for 60 days after a laboratory receives notification from the State of the withdrawal of HCFA's approval of the program.

(3) *Extension.* After HCFA withdraws approval of an accreditation organization or State licensure program, HCFA may extend the period for an additional 60 days for a laboratory if it determines that the laboratory submitted an application for accreditation to an approved accreditation organization or an application for the appropriate certificate to HCFA or a HCFA agent before the initial 60-day period ends.

(h) *Immediate jeopardy to patients.* (1) If at any time HCFA determines that the continued approval of deeming authority of any accreditation organization poses immediate jeopardy to the patients of the laboratories accredited

by the organization, or continued approval otherwise constitutes a significant hazard to the public health, HCFA may immediately withdraw the approval of deeming authority for that accreditation organization.

(2) If at any time HCFA determines that the continued approval of a State licensure program poses immediate jeopardy to the patients of the laboratories in that State, or continued approval otherwise constitutes a significant hazard to the public health, HCFA may immediately withdraw the approval of that State licensure program.

(i) *Failure to pay fees.* HCFA withdraws the approval of a State licensure program if the State fails to pay the applicable fees, as specified in §§ 493.645(a) and 493.646(b).

(j) *State refusal to take enforcement action.* (1) HCFA may withdraw approval of a State licensure program if the State refuses to take enforcement action against a laboratory in that State when HCFA determines it to be necessary.

(2) A laboratory that is in a State in which HCFA has withdrawn program approval is subject to the same requirements and survey and enforcement processes that are applied to a laboratory that is not exempt from CLIA requirements.

(k) *Request for reconsideration.* Any accreditation organization or State that is dissatisfied with a determination to withdraw approval of its deeming authority or remove approval of its State licensure program, as applicable, may request that HCFA reconsider the determination, in accordance with subpart D of part 488.

Subpart F—General Administration

SOURCE: 57 FR 7138 and 7213, Feb. 28, 1992, unless otherwise noted.

§ 493.602 Scope of subpart.

This subpart sets forth the methodology for determining the amount of the fees for issuing the appropriate certificate, and for determining compliance with the applicable standards of the Public Health Service Act (the PHS Act) and the Federal validation of accredited laboratories and of CLIA-exempt laboratories.

[60 FR 20047, Apr. 24, 1995]

§ 493.606 Applicability of subpart.

The rules of this subpart are applicable to those laboratories specified in § 493.3.

[58 FR 5212, Jan. 19, 1993]

§ 493.638 Certificate fees.

(a) *Basic rule.* Laboratories must pay a fee for the issuance of a registration certificate, certificate for PPM procedures, certificate of waiver, certificate of accreditation, or a certificate of compliance, as applicable. Laboratories must also pay a fee to reapply for a certificate for PPM procedures, certificate of waiver, certificate of accreditation, or a certificate of compliance. The total of fees collected by HHS under the laboratory program must be sufficient to cover the general costs of administering the laboratory certification program under section 353 of the PHS Act.

(1) For registration certificates and certificates of compliance, the costs include issuing the certificates, collecting the fees, evaluating and monitoring proficiency testing programs, evaluating which procedures, tests or examinations meet the criteria for inclusion in the appropriate complexity category, and implementing section 353 of the PHS Act.

(2) For a certificate of waiver, the costs include issuing the certificate, collecting the fees, determining if a certificate of waiver should be issued, evaluating which tests qualify for inclusion in the waived category, and other direct administrative costs.

(3) For a certificate for PPM procedures, the costs include issuing the certificate, collecting the fees, determining if a certificate for PPM procedures should be issued, evaluating which procedures meet the criteria for inclusion in the subcategory of PPM procedures, and other direct administrative costs.

(4) For a certificate of accreditation, the costs include issuing the certificate, collecting the fees, evaluating the programs of accrediting bodies, and other direct administrative costs.

(b) *Fee amount.* The fee amount is set annually by HHS on a calendar year basis and is based on the category of test complexity, or on the category of test complexity and schedules or ranges of annual laboratory test volume (excluding waived tests and tests performed for quality control, quality assurance, and proficiency testing purposes) and specialties tested, with the amounts of the fees in each schedule being a function of the costs for all aspects of general administration of CLIA as set forth in §493.649 (b) and (c). This fee is assessed and payable at least biennially. The methodology used to determine the amount of the fee is found in §493.649. The amount of the fee applicable to the issuance of the registration certificate or the issuance or renewal of the certificate for PPM procedures, certificate of waiver, certificate of accreditation, or certificate of compliance is the amount in effect at the time the application is received. Upon receipt of an application for a certificate, HHS or its designee notifies the laboratory of the amount of the required fee for the requested certificate.

[60 FR 20047, Apr. 24, 1995]

§493.639 Fee for revised certificate.

(a) If, after a laboratory is issued a registration certificate, it changes its name or location, the laboratory must pay a fee to cover the cost of issuing a revised registration certificate. The fee for the revised registration certificate is based on the cost to issue the revised certificate to the laboratory.

(b) A laboratory must pay a fee to cover the cost of issuing a revised certificate in any of the following circumstances:

(1) The fee for issuing an appropriate revised certificate is based on the cost to issue the revised certificate to the laboratory as follows:

(i) If a laboratory with a certificate of waiver wishes to perform tests in addition to those listed in §493.15(c) as waived tests, it must, as set forth in §493.638, pay an additional fee for the appropriate certificate to cover the additional testing.

(ii) If a laboratory with a certificate for PPM procedures wishes to perform tests in addition to those specified as PPM procedures or listed in §493.15(c) as waived tests, it must, as set forth in §493.638, pay an additional fee for the appropriate certificate to cover the additional testing.

(2) A laboratory must pay a fee to cover the cost of issuing a revised certificate when—

(i) A laboratory changes its name, location, or its director; or

(ii) A laboratory deletes services or wishes to add services and requests that its certificate be changed. (An additional fee is also required under §493.643(d) if it is necessary to determine compliance with additional requirements.)

[57 FR 7213, Feb. 28, 1992, as amended at 60 FR 20047, Apr, 24, 1995]

§493.643 Fee for determination of program compliance.

(a) *Fee requirement.* In addition to the fee required under §493.638, a laboratory subject to routine inspections must pay a fee to cover the cost of determining program compliance. Laboratories issued a certificate for PPM procedures, certificate of waiver, or a certificate of accreditation are not subject to this fee for routine inspections.

(b) *Costs included in the fee.* Included in the fee for determining program compliance is the cost of evaluating qualifications of personnel; monitoring proficiency testing; conducting onsite inspections; documenting deficiencies; evaluating laboratories' plans to correct deficiencies; and necessary administrative costs. HHS sets the fee amounts annually on a calendar year basis. Laboratories are inspected biennially; therefore, fees are assessed and payable biennially. If additional expenses are incurred to conduct follow up visits to verify correction of deficiencies, to impose sanctions, and/or for surveyor preparation for and attendance at ALJ hearings, HHS assesses an additional fee to include these costs. The additional fee is based on the actual resources and time necessary to perform the activities.

(c) *Classification of laboratories that require inspection for purpose of determining amount of fee.* (1) There are ten classifications (schedules) of laboratories for the purpose of determining the fee amount a laboratory is assessed. Each laboratory is placed into

one of the ten following schedules based on the laboratory's scope and volume of testing (excluding tests performed for quality control, quality assurance, and proficiency testing purposes).

(i) (A) *Schedule A Low Volume.* The laboratory performs not more than 2,000 laboratory tests annually.

(B) *Schedule A.* The laboratory performs tests in no more than 3 specialties of service with a total annual volume of more than 2,000 but not more than 10,000 laboratory tests.

(ii) *Schedule B.* The laboratory performs tests in at least 4 specialties of service with a total annual volume of not more than 10,000 laboratory tests.

(iii) *Schedule C.* The laboratory performs tests in no more 3 specialties of service with a total annual volume of more than 10,000 but not more than 25,000 laboratory tests.

(iv) *Schedule D.* The laboratory performs tests in at least 4 specialties with a total annual volume of more than 10,000 but not more than 25,000 laboratory tests.

(v) *Schedule E.* The laboratory performs more than 25,000 but not more than 50,000 laboratory tests annually.

(vi) *Schedule F.* The laboratory performs more than 50,000 but not more than 75,000 laboratory tests annually.

(vii) *Schedule G.* The laboratory performs more than 75,000 but not more than 100,000 laboratory tests annually.

(viii) *Schedule H.* The laboratory performs more than 100,000 but not more than 500,000 laboratory tests annually.

(ix) *Schedule I.* The laboratory performs more than 500,000 but not more than 1,000,000 laboratory tests annually.

(x) *Schedule J.* The laboratory performs more than 1,000,000 laboratory tests annually.

(2) For purposes of determining a laboratory's classification under this section, a test is a procedure or examination for a single analyte. (Tests performed for quality control, quality assurance, and proficiency testing are excluded from the laboratory's total annual volume). Each profile (that is, group of tests) is counted as the number of separate procedures or examinations; for example, a chemistry profile consisting of 18 tests is counted as 18 separate procedures or tests.

(3) For purposes of determining a laboratory's classification under this section, the specialties and subspecialties of service for inclusion are:

(i) The specialty of Microbiology, which includes one or more of the following subspecialties:

(A) Bacteriology.

(B) Mycobacteriology.

(C) Mycology.

(D) Parasitology.

(E) Virology.

(ii) The specialty of Serology, which includes one or more of the following subspecialties:

(A) Syphilis Serology.

(B) General immunology

(iii) The specialty of Chemistry, which includes one or more of the following subspecialties:

(A) Routine chemistry.

(B) Endocrinology.

(C) Toxicology.

(D) Urinalysis.

(iv) The specialty of Hematology.

(v) The specialty of Immunohematology, which includes one or more of the following subspecialties:

(A) ABO grouping and Rh typing.

(B) Unexpected antibody detection.

(C) Compatibility testing.

(D) Unexpected antibody identification.

(vi) The specialty of Pathology, which includes the following subspecialties:

(A) Cytology.

(B) Histopathology.

(C) Oral pathology.

(vii) The specialty of Radiobioassay.

(viii) The specialty of Histocompatibility.

(ix) The specialty of Cytogenetics.

(d) *Additional fees.* (1) If after a certificate of compliance is issued, a laboratory adds services and requests that its certificate be upgraded, the laboratory must pay an additional fee if, in order to determine compliance with additional requirements, it is necessary to conduct an inspection, evaluate personnel, or monitor proficiency testing performance. The additional fee is based on the actual resources and time necessary to perform the activities.

HHS revokes the laboratory's certificate for failure to pay the compliance determination fee.

(2) If it is necessary to conduct a complaint investigation, impose sanctions, or conduct a hearing, HHS assesses the laboratory holding a certificate of compliance a fee to cover the cost of these activities. If a complaint investigation results in a complaint being unsubstantiated, or if an HHS adverse action is overturned at the conclusion of the administrative appeals process, the government's costs of these activities are not imposed upon the laboratory. Costs for these activities are based on the actual resources and time necessary to perform the activities and are not assessed until after the laboratory concedes the existence of deficiencies or an ALJ rules in favor of HHS. HHS revokes the laboratory's certificate of compliance for failure to pay the assessed costs.

[57 FR 7138 and 7213, Feb. 28, 1992, as amended at 60 FR 20047, Apr. 24, 1995]

§ 493.645 Additional fee(s) applicable to approved State laboratory programs and laboratories issued a certificate of accreditation, certificate of waiver, or certificate for PPM procedures.

(a) *Approved State laboratory programs.* State laboratory programs approved by HHS are assessed a fee for the following:

(1) Costs of Federal inspections of laboratories in that State (that is, CLIA-exempt laboratories) to verify that standards are being enforced in an appropriate manner.

(2) Costs incurred for investigations of complaints against the State's CLIA-exempt laboratories if the complaint is substantiated.

(3) Costs of the State's prorata share of general overhead to develop and implement CLIA.

(b) *Accredited laboratories.* (1) In addition to the certificate fee, a laboratory that is issued a certificate of accreditation is also assessed a fee to cover the cost of evaluating individual laboratories to determine overall whether an accreditation organization's standards and inspection policies are equivalent to the Federal program. All accredited laboratories share in the cost of these inspections. These costs are the same as those that are incurred when inspecting nonaccredited laboratories.

(2) If a laboratory issued a certificate of accreditation has been inspected and followup visits are necessary because of identified deficiencies, HHS assesses the laboratory a fee to cover the cost of these visits. The fee is based on the actual resources and time necessary to perform the followup visits. HHS revokes the laboratory's certificate of accreditation for failure to pay the assessed fee.

(c) If, in the case of a laboratory that has been issued a certificate of accreditation, certificate of waiver, or certificate for PPM procedures, it is necessary to conduct a complaint investigation, impose sanctions, or conduct a hearing, HHS assesses that laboratory a fee to cover the cost of these activities. Costs are based on the actual resources and time necessary to perform the activities and are not assessed until after the laboratory concedes the existence of deficiencies or an ALJ rules in favor of HHS. HHS revokes the laboratory's certificate for failure to pay the assessed costs. If a complaint investigation results in a complaint being unsubstantiated, or if an HHS adverse action is overturned at the conclusion of the administrative appeals process, the costs of these activities are not imposed upon the laboratory.

[60 FR 20047, Apr. 24, 1995]

§ 493.646 Payment of fees.

(a) Except for CLIA-exempt laboratories, all laboratories are notified in writing by HHS or its designee of the appropriate fee(s) and instructions for submitting the fee(s), including the due date for payment and where to make payment. The appropriate certificate is not issued until the applicable fees have been paid.

(b) For State-exempt laboratories, HHS estimates the cost of conducting validation surveys within the State for a 2-year period. HHS or its designee notifies the State by mail of the appropriate fees, including the due date for payment and the address of the United States Department of Treasury designated commercial bank to which payment must be made. In addition, if complaint investigations are conducted

in laboratories within these States and are substantiated, HHS bills the State(s) the costs of the complaint investigations.

[57 FR 7138 and 7213, Feb. 28, 1992, as amended at 60 FR 20048, Apr. 24, 1995]

§ 493.649 Methodology for determining fee amount.

(a) *General rule.* The amount of the fee in each schedule for compliance determination inspections is based on the average hourly rate (which includes the costs to perform the required activities and necessary administration costs) multiplied by the average number of hours required or, if activities are performed by more than one of the entities listed in paragraph (b) of this section, the sum of the products of the applicable hourly rates multiplied by the average number of hours required by the entity to perform the activity. The fee for issuance of the registration certificate or certificate of compliance is based on the laboratory's scope and volume of testing.

(b) *Determining average hourly rates used in fee schedules.* Three different entities perform activities related to the issuance or reissuance of any certificate. HHS determines the average hourly rates for the activities of each of these entities.

(1) *State survey agencies.* The following costs are included in determining an average hourly rate for the activities performed by State survey agencies:

(i) The costs incurred by the State survey agencies in evaluating personnel qualifications and monitoring each laboratory's participation in an approved proficiency testing program. The cost of onsite inspections and monitoring activities is the hourly rate derived as a result of an annual budget negotiation process with each State. The hourly rate encompasses salary costs (as determined by each State's civil service pay scale) and fringe benefit costs to support the required number of State inspectors, management and direct support staff.

(ii) Travel costs necessary to comply with each State's administrative requirements and other direct costs such as equipment, printing, and supplies. These costs are established based on historical State requirements.

(iii) Indirect costs as negotiated by HHS.

(2) *Federal agencies.* The hourly rate for activities performed by Federal agencies is the most recent average hourly cost to HHS to staff and support a full time equivalent employee. Included in this cost are salary and fringe benefit costs, necessary administrative costs, such as printing, training, postage, express mail, supplies, equipment, computer system and building service charges associated with support services provided by organizational components such as a computer center, and any other oversight activities necessary to support the program.

(3) *HHS contractors.* The hourly rate for activities performed by HHS contractors is the average hourly rate established for contractor assistance based on an independent government cost estimate for the required workload. This rate includes the cost of contractor support to provide proficiency testing programs to laboratories that do not participate in an approved proficiency testing program, provide specialized assistance in the evaluation of laboratory performance in an approved proficiency testing program, perform assessments of cytology testing laboratories, conduct special studies, bill and collect fees, issue certificates, establish accounting, monitoring and reporting systems, and assist with necessary surveyor training.

(c) *Determining number of hours.* The average number of hours used to determine the overall fee in each schedule is HHS's estimate, based on historical experience, of the average time needed by each entity to perform the activities for which it is responsible.

[57 FR 7138 and 7213, Feb. 28, 1992, as amended at 60 FR 20048, Apr. 24, 1995]

Subpart G [Reserved]

Subpart H—Participation in Proficiency Testing for Laboratories Performing Tests of Moderate Complexity (Including the Subcategory), High Complexity, or Any Combination of These Tests

SOURCE: 57 FR 7146, Feb. 28, 1992, unless otherwise noted.

§ 493.801 Condition: Enrollment and testing of samples.

Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.

(a) *Standard; Enrollment.* The laboratory must—

(1) Notify HHS of the approved program or programs in which it chooses to participate to meet proficiency testing requirements of this subpart.

(2)(i) Designate the program(s) to be used for each specialty, subspecialty, and analyte or test to determine compliance with this subpart if the laboratory participates in more than one proficiency testing program approved by HCFA; and

(ii) For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with § 493.1709.

(3) For each specialty, subspecialty and analyte or test, participate in one approved proficiency testing program or programs, for one year before designating a different program and must notify HCFA before any change in designation; and

(4) Authorize the proficiency testing program to release to HHS all data required to—

(i) Determine the laboratory's compliance with this subpart; and

(ii) Make PT results available to the public as required in section 353(f)(3)(F) of the Public Health Service Act.

(b) *Standard; Testing of proficiency testing samples.* The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens.

(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods. The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.

(2) The laboratory must test samples the same number of times that it routinely tests patient samples.

(3) Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications pertaining to the results of proficiency testing sample(s) until after the date by which the laboratory must report proficiency testing results to the program for the testing event in which the samples were sent. Laboratories with multiple testing sites or separate locations must not participate in any communications or discussions across sites/locations concerning proficiency testing sample results until after the date by which the laboratory must report proficiency testing results to the program.

(4) The laboratory must not send PT samples or portions of samples to another laboratory for any analysis which it is certified to perform in its own laboratory. Any laboratory that HCFA determines intentionally referred its proficiency testing samples to another laboratory for analysis will have its certification revoked for at least one year. Any laboratory that receives proficiency testing samples from another laboratory for testing must

notify HCFA of the receipt of those samples.

(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event.

(6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.

[57 FR 7146, Feb. 28, 1992, as amended at 58 FR 5228, Jan. 19, 1993]

§ 493.803 Condition: Successful participation.

(a) Each laboratory performing tests of moderate complexity (including the subcategory) and/or high complexity must successfully participate in a proficiency testing program approved by HCFA, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA.

(b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, HCFA imposes sanctions, as specified in subpart R of this part.

(c) If a laboratory fails to perform successfully in a HCFA-approved proficiency testing program, for the initial unsuccessful performance, HCFA may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists:

(1) There is immediate jeopardy to patient health and safety.

(2) The laboratory fails to provide HCFA or a HCFA agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance.

(3) The laboratory has a poor compliance history.

[57 FR 7146, Feb. 28, 1992, as amended at 60 FR 20048, Apr. 24, 1995; 63 FR 26737, May 14, 1998]

§ 493.807 Condition: Reinstatement of laboratories performing tests of moderate complexity (including the subcategory), high complexity, or any combination of these tests, after failure to participate successfully.

(a) If a laboratory's certificate is suspended or limited or its Medicare or Medicaid approval is cancelled or its Medicare or Medicaid payments are suspended because it fails to participate successfully in proficiency testing for one or more specialties, subspecialties, analyte or test, or voluntarily withdraws its certification under CLIA for the failed specialty, subspecialty, or analyte, the laboratory must then demonstrate sustained satisfactory performance on two consecutive proficiency testing events, one of which may be on site, before HCFA will consider it for reinstatement for certification and Medicare or Medicaid approval in that specialty, subspecialty, analyte or test.

(b) The cancellation period for Medicare and Medicaid approval or period for suspension of Medicare or Medicaid payments or suspension or limitation of certification under CLIA for the failed specialty, subspecialty, or analyte or test is for a period of not less than six months from the date of cancellation, limitation or suspension of the CLIA certificate.

[58 FR 5228, Jan. 19, 1993, as amended at 60 FR 20048, Apr. 24, 1995]

PROFICIENCY TESTING BY SPECIALTY AND SUBSPECIALTY FOR LABORATORIES PERFORMING TESTS OF MODERATE COMPLEXITY (INCLUDING THE SUBCATEGORY), HIGH COMPLEXITY, OR ANY COMBINATION OF THESE TESTS

§ 493.821 Condition: Microbiology.

The specialty of microbiology includes, for purposes of proficiency testing, the subspecialties of bacteriology, mycobacteriology, mycology, parasitology and virology.

§ 493.823 Standard; Bacteriology.

(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) Remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.825 Standard; Mycobacteriology.

(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) Remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.827 Standard; Mycology.

(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) Remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.829 Standard; Parasitology.

(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) Remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.831 Standard; Virology.

(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame

for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unsatisfactory testing events, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.833 Condition: Diagnostic immunology.

The specialty of diagnostic immunology includes for purposes of proficiency testing the subspecialties of syphilis serology and general immunology.

§ 493.835 Standard; Syphilis serology.

(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame

for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unacceptable testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.837 Standard; General immunology.

(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame

for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.839 Condition: Chemistry.

The specialty of chemistry includes for the purposes of proficiency testing the subspecialties of routine chemistry, endocrinology, and toxicology.

§ 493.841 Standard; Routine chemistry.

(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.843 Standard; Endocrinology.

(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.845 Standard; Toxicology.

(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.849 Condition: Hematology.

The specialty of hematology, for the purpose of proficiency testing, is not

subdivided into subspecialties of testing.

§ 493.851 Standard; Hematology.

(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.

(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.853 Condition: Pathology.

The specialty of pathology includes, for purposes of proficiency testing, the subspecialty of cytology limited to gynecologic examinations.

§ 493.855 Standard; Cytology: gynecologic examinations.

To participate successfully in a cytology proficiency testing program for gynecologic examinations (Pap smears), the laboratory must meet the requirements of paragraphs (a) through (c) of this section.

(a) The laboratory must ensure that each individual engaged in the examination of gynecologic preparations is enrolled in a proficiency testing program approved by HCFA by January 1, 1995, if available in the State in which he or she is employed. The laboratory must ensure that each individual is tested at least once per year and obtains a passing score. To ensure this annual testing of individuals, an announced or unannounced testing event will be conducted on-site in each laboratory at least once each year. Laboratories will be notified of the time of each announced on-site testing event at least 30 days prior to each event. Additional testing events will be conducted as necessary in each State or region for the purpose of testing individuals who miss the on-site testing event and for retesting individuals as described in paragraph (b) of this section.

(b) The laboratory must ensure that each individual participates in an annual testing event that involves the examination of a 10-slide test set as described in § 493.945. Individuals who fail this testing event are retested with another 10-slide test set as described in paragraphs (b)(1) and (b)(2) of this section. Individuals who fail this second test are subsequently retested with a 20-slide test set as described in paragraphs (b)(2) and (b)(3) of this section. Individuals are given not more than 2 hours to complete a 10-slide test and not more than 4 hours to complete a 20-

slide test. Unexcused failure to appear by an individual for a retest will result in test failure with resulting remediation and limitations on slide examinations as specified in (b)(1), (b)(2), and (b)(3) of this section.

(1) An individual is determined to have failed the annual testing event if he or she scores less than 90 percent on a 10-slide test set. For an individual who fails an annual proficiency testing event, the laboratory must schedule a retesting event which must take place not more than 45 days after receipt of the notification of failure.

(2) An individual is determined to have failed the second testing event if he or she scores less than 90 percent on a 10-slide test set. For an individual who fails a second testing event, the laboratory must provide him or her with documented, remedial training and education in the area of failure, and must assure that all gynecologic slides evaluated subsequent to the notice of failure are reexamined until the individual is again retested with a 20-slide test set and scores at least 90 percent. Reexamination of slides must be documented.

(3) An individual is determined to have failed the third testing event if he or she scores less than 90 percent on a 20-slide test set. An individual who fails the third testing event must cease examining gynecologic slide preparations immediately upon notification of test failure and may not resume examining gynecologic slides until the laboratory assures that the individual obtains at least 35 hours of documented, formally structured, continuing education in diagnostic cytopathology that focuses on the examination of gynecologic preparations, and until he or she is retested with a 20-slide test set and scores at least 90 percent.

(c) If a laboratory fails to ensure that individuals are tested or those who fail a testing event are retested, or fails to take required remedial actions as described in paragraphs (b)(1), (b)(2) or (b)(3) of this section, HCFA will initiate intermediate sanctions or limit the laboratory's certificate to exclude gynecologic cytology testing under CLIA, and, if applicable, suspend the laboratory's Medicare and Medicaid payments for gynecologic cytology testing in accordance with subpart R of this part.

[57 FR 7146, Feb. 28, 1992, as amended at 58 FR 5228, Jan. 19, 1993; 59 FR 62609, Dec. 6, 1994]

§ 493.857 Condition: Immunohematology.

The specialty of immunohematology includes four subspecialties for the purposes of proficiency testing: ABO group and D (Rho) typing; unexpected antibody detection; compatibility testing; and antibody identification.

§ 493.859 Standard; ABO group and D (Rho) typing.

(a) Failure to attain a score of at least 100 percent of acceptable responses for each analyte or test in each testing event is unsatisfactory analyte performance for the testing event.

(b) Failure to attain an overall testing event score of at least 100 percent is unsatisfactory performance.

(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(e)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unacceptable analyte or unsatisfactory testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(f) Failure to achieve satisfactory performance for the same analyte in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

(g) Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.861 Standard; Unexpected antibody detection.

(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unsatisfactory testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(e) Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.863 Standard; Compatibility testing.

(a) Failure to attain an overall testing event score of at least 100 percent is unsatisfactory performance.

(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unsatisfactory testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(e) Failure to achieve an overall testing event score of satisfactory for two

consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.865 Standard; Antibody identification.

(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unsatisfactory testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(e) Failure to identify the same antibody in two consecutive or two out of three consecutive testing events is unsuccessful performance.

(f) Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

Subpart I—Proficiency Testing Programs for Tests of Moderate Complexity (Including the Subcategory), High Complexity, or Any Combination of These Tests

SOURCE: 57 FR 7151, Feb. 28, 1992, unless otherwise noted.

§ 493.901 Approval of proficiency testing programs.

In order for a proficiency testing program to receive HHS approval, the program must be offered by a private nonprofit organization or a Federal or State agency, or entity acting as a designated agent for the State. An organization, Federal, or State program seeking approval or reapproval for its program for the next calendar year must submit an application providing the required information by July 1 of the current year. The organization, Federal, or State program must provide technical assistance to laboratories seeking to qualify under the program, and must, for each specialty, subspecialty, and analyte or test for which it provides testing—

(a) Assure the quality of test samples, appropriately evaluate and score the testing results, and identify performance problems in a timely manner;

(b) Demonstrate to HHS that it has—

(1) The technical ability required to—

(i) Prepare or purchase samples from manufacturers who prepare the samples in conformance with the appropriate good manufacturing practices required in 21 CFR parts 606, 640, and 820; and

(ii) Distribute the samples, using rigorous quality control to assure that samples mimic actual patient specimens when possible and that samples are homogeneous, except for specific subspecialties such as cytology, and will be stable within the time frame for analysis by proficiency testing participants;

(2) A scientifically defensible process for determining the correct result for each challenge offered by the program;

(3) A program of sufficient annual challenge and with the frequency specified in §§ 493.909 through 493.959 to establish that a laboratory has met minimum performance requirements;

(4) The resources needed to provide Statewide or nationwide reports to regulatory agencies on individual's performance for gynecologic cytology and on individual laboratory performance on testing events, cumulative reports and scores for each laboratory or individual, and reports of specific laboratory failures using grading criteria acceptable to HHS. These reports must be provided to HHS on a timely basis when requested;

(5) Provisions to include on each proficiency testing program report form used by the laboratory to record testing event results, an attestation statement that proficiency testing samples were tested in the same manner as patient specimens with a signature block to be completed by the individual performing the test as well as by the laboratory director;

(6) A mechanism for notifying participants of the PT shipping schedule and for participants to notify the proficiency testing program within three days of the expected date of receipt of the shipment that samples have not arrived or are unacceptable for testing. The program must have provisions for replacement of samples that are lost in transit or are received in a condition that is unacceptable for testing; and

(7) A process to resolve technical, administrative, and scientific problems about program operations;

(c) Meet the specific criteria for proficiency testing programs listed by specialty, subspecialty, and analyte or test contained in §§ 493.901 through 493.959 for initial approval and thereafter provide HHS, on an annual basis, with the information necessary to assure that the proficiency testing program meets the criteria required for approval; and

(d) Comply with all applicable packaging, shipment, and notification requirements of 42 CFR part 72.

[57 FR 7151, Feb. 28, 1992, as amended at 58 FR 5228, Jan. 19, 1993]

§ 493.903 Administrative responsibilities.

The proficiency testing program must—

(a)(1) Provide HHS or its designees and participating laboratories with an electronic or a hard copy, or both, of reports of proficiency testing results and all scores for each laboratory's performance in a format as required by and approved by HCFA for each CLIA-certified specialty, subspecialty, and analyte or test within 60 days after the date by which the laboratory must report proficiency testing results to the proficiency testing program.

(2) Provide HHS with reports of PT results and scores of individual performance in cytology and provide copies of reports to participating individuals, and to all laboratories that employ the individuals, within *15* working days of the testing event;

(b) Furnish to HHS cumulative reports on an individual laboratory's performance and aggregate data on CLIA-certified laboratories for the purpose of establishing a system to make the proficiency testing program's results available, on a reasonable basis, upon request of any person, and include such explanatory information as may be appropriate to assist in the interpretation of the proficiency testing program's results;

(c) Provide HHS with additional information and data upon request and submit such information necessary for HHS to conduct an annual evaluation to determine whether the proficiency testing program continues to meet the requirements of §§ 493.901 through 493.959;

(d) Maintain records of laboratories' performance for a period of five years or such time as may be necessary for any legal proceedings; and

(e) Provide HHS with an annual report and, if needed, an interim report which identifies any previously unrecognized sources of variability in kits, instruments, methods, or PT samples, which adversely affect the programs' ability to evaluate laboratory performance.

[57 FR 7151, Feb. 28, 1992, as amended at 58 FR 5228, Jan. 19, 1993]

§ 493.905 Nonapproved proficiency testing programs.

If a proficiency testing program is determined by HHS to fail to meet any criteria contained in §§ 493.901 through 493.959 for approval of the proficiency testing program, HCFA will notify the program and the program must notify all laboratories enrolled of the nonapproval and the reasons for nonapproval within 30 days of the notification.

PROFICIENCY TESTING PROGRAMS BY SPECIALTY AND SUBSPECIALTY

§ 493.909 Microbiology.

The subspecialties under the specialty of microbiology for which a program may offer proficiency testing are bacteriology, mycobacteriology, mycology, parasitology and virology. Specific criteria for these subspecialties are found at §§ 493.911 through 493.919.

§ 493.911 Bacteriology.

(a) *Types of services offered by laboratories.* In bacteriology, for proficiency testing purposes, there are five types of laboratories:

(1) Those that interpret Gram stains or perform primary inoculation, or both; and refer cultures to another laboratory appropriately certified for the subspecialty of bacteriology for identification;

(2) Those that use direct antigen techniques to detect an organism and may also interpret Gram stains or perform primary inoculation, or perform any combination of these;

(3) Those that, in addition to interpreting Gram stains, performing primary inoculations, and using direct antigen tests, also isolate and identify aerobic bacteria from throat, urine, cervical, or urethral discharge specimens to the genus level and may also perform antimicrobial susceptibility tests on selected isolated microorganisms;

(4) Those that perform the services in paragraph (a)(3) of this section and also isolate and identify aerobic bacteria from any source to the species level and may also perform antimicrobial susceptibility tests; and

(5) Those that perform the services in paragraph (a)(4) of this section and also isolate and identify anaerobic bacteria from any source.

(b) *Program content and frequency of challenge.* To be approved for proficiency testing for bacteriology, the annual program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The samples may be provided to the laboratory through mailed shipments or, at HHS' option, may be provided to HHS or its designee for onsite testing. For the types of laboratories specified in paragraph (a) of this section, an annual program must include samples that contain organisms that are representative of the six major groups of bacteria: anaerobes, Enterobacteriaceae, gram-positive bacilli, gram-positive cocci, gram-negative cocci, and miscellaneous gram-negative bacteria, as appropriate. The specific organisms included in the samples may vary from year to year. The annual program must include samples for bacterial antigen detection, bacterial isolation and identification, Gram stain, and antimicrobial susceptibility testing.

(1) An approved program must furnish HHS with a description of samples that it plans to include in its annual program no later than six months before each calendar year. At least 50 percent of the samples must be mixtures of the principal organism and appropriate normal flora. The program must include other important emerging pathogens (as determined by HHS) and either organisms commonly occurring in patient specimens or opportunistic pathogens. The program must include the following two types of samples; each type of sample must meet the 50 percent mixed culture criterion:

(i) Samples that require laboratories to report only organisms that the testing laboratory considers to be a principal pathogen that is clearly responsible for a described illness (excluding immuno-compromised patients). The program determines the reportable isolates, including antimicrobial susceptibility for any designated isolate; and

(ii) Samples that require laboratories to report all organisms present. Samples must contain multiple organisms frequently found in specimens such as

urine, blood, abscesses, and aspirates where multiple isolates are clearly significant or where specimens are derived from immuno-compromised patients. The program determines the reportable isolates.

(2) An approved program may vary over time. For example, the types of organisms that might be included in an approved program over time are—

Anaerobes:
- *Bacteroides fragilis group*
- *Clostridium perfringens*
- *Peptostreptococcus anaerobius*

Enterobacteriaceae
- *Citrobacter freundii*
- *Enterobacter aerogenes*
- *Escherichia coli*
- *Klebsiella pneumoniae*
- *Proteus mirabilis*
- *Salmonella typhimurium*
- *Serratia marcescens*
- *Shigella sonnei*
- *Yersinia enterocolitica*

Gram-positive bacilli:
- *Listeria monocytogenes*
- *Corynebacterium species CDC Group JK*

Gram-positive cocci:
- *Staphylococcus aureus*
- *Streptococcus Group A*
- *Streptococcus Group B*
- *Streptococcus Group D (S. bovis and enterococcus)*
- *Streptococcus pneumoniae*

Gram-negative cocci:
- *Branhamella catarrhalis*
- *Neisseria gonorrhoeae*
- *Neisseria meningitidis*

Miscellaneous Gram-negative bacteria:
- *Campylobacter jejuni*
- *Haemophilis influenza, Type B*
- *Pseudomonas aeruginosa*

(3) For antimicrobial susceptibility testing, the program must provide at least one sample per testing event that includes gram-positive or gram-negative strains that have a predetermined pattern of sensitivity or resistance to the common antimicrobial agents.

(c) *Evaluation of a laboratory's performance.* HHS approves only those programs that assess the accuracy of a laboratory's responses in accordance with paragraphs (c) (1) through (7) of this section.

(1) The program determines staining characteristics to be interpreted by Gram stain. The program determines the reportable bacteria to be detected by direct antigen techniques or isolation. To determine the accuracy of a laboratory's response for Gram stain interpretation, direct antigen detection, identification, or antimicrobial susceptibility testing, the program must compare the laboratory's response for each sample with the response which reflects agreement of either 90 percent of ten or more referee laboratories or 90 percent or more of all participating laboratories.

(2) To evaluate a laboratory's response for a particular sample, the program must determine a laboratory's type of service in accordance with paragraph (a) of this section. A laboratory must isolate and identify the organisms to the same extent it performs these procedures on patient specimens. A laboratory's performance will be evaluated on the basis of its final answer, for example, a laboratory specified in paragraph (a)(3) of this section will be evaluated on the basis of the average of its scores for paragraphs (c)(3) through (c)(6) as determined in paragraph (c)(7) of this section.

(3) Since laboratories may incorrectly report the presence of organisms in addition to the correctly identified principal organism(s), the grading system must provide a means of deducting credit for additional erroneous organisms that are reported. Therefore, the total number of correct responses for organism isolation and identification submitted by the laboratory divided by the number of organisms present plus the number of incorrect organisms reported by the laboratory must be multiplied by 100 to establish a score for each sample in each testing event. For example, if a sample contained one principal organism and the laboratory reported it correctly but reported the presence of an additional organism, which was not considered reportable, the sample grade would be $1/(1+1)\times 100=50$ percent.

(4) For antimicrobial susceptibility testing, a laboratory must indicate which drugs are routinely included in its test panel when testing patient samples. A laboratory's performance will be evaluated for only those antibiotics for which service is offered. A correct response for each antibiotic will be determined as described in §§ 493.911(c) (1) using criteria such as

the guidelines established by the National Committee for Clinical Laboratory Standards. Grading is based on the number of correct susceptibility responses reported by the laboratory divided by the actual number of correct susceptibility responses determined by the program, multiplied by 100. For example, if a laboratory offers susceptibility testing for *Enterobacteriaceae* using amikacin, cephalothin, and tobramycin, and the organism in the proficiency testing sample is an *Enterobacteriaceae,* and the laboratory reports correct responses for two of three antimicrobial agents, the laboratory's grade would be 2/3×100=67 percent.

(5) The performance criterion for qualitative antigen tests is the presence or absence of the bacterial antigen. The score for antigen tests is the number of correct responses divided by the number of samples to be tested for the antigen, multiplied by 100.

(6) The performance criteria for Gram stain is staining reaction, i.e., gram positive or gram negative. The score for Gram stain is the number of correct responses divided by the number of challenges to be tested, multiplied by 100.

(7) The score for a testing event in bacteriology is the average of the scores determined under paragraphs (c)(3) through (c)(6) of this section kbased on the type of service offered by the laboratory.

[57 FR 7151, Feb. 28, 1992, as amended at 58 FR 5228, Jan. 19, 1993]

§ 493.913 Mycobacteriology.

(a) *Types of services offered by laboratories.* In mycobacteriology, there are five types of laboratories for proficiency testing purposes:

(1) Those that interpret acid-fast stains and refer specimen to another laboratory appropriately certified in the subspecialty of mycobacteriology;

(2) Those that interpret acid-fast stains, perform primary inoculation, and refer cultures to another laboratory appropriately certified in the subspecialty of mycobacteriology for identification;

(3) Those that interpret acid-fast stains, isolate and perform identification and/or antimycobacterial susceptibility of *Mycobacterium tuberculosis,* but refer other mycobacteria species to another laboratory appropriately certified in the subspecialty of mycobacteriology for identification and/or susceptibility tests;

(4) Those that interpret acid-fast stains, isolate and identify all mycobacteria to the extent required for correct clinical diagnosis, but refer antimycobacterial susceptibility tests to another laboratory appropriately certified in the subspecialty of mycobacteriology; and

(5) Those that interpret acid-fast stains, isolate and identify all mycobacteria to the extent required for correct clinical diagnosis, and perform antimycobacterial susceptibility tests on the organisms isolated.

(b) *Program content and frequency of challenge.* To be approved for proficiency testing for mycobacteriology, the annual program must provide a minimum of five samples per testing event. There must be at least two testing events per year. The samples may be provided through mailed shipments or, at HHS' option, provided to HHS or its designee for on-site testing events. For types of laboratories specified in paragraphs (a)(1) and (a) (3) through (5) of this section, an annual program must include samples that contain species that are representative of the 5 major groups (complexes) of mycobacteria encountered in human specimens. The specific mycobacteria included in the samples may vary from year to year.

(1) An approved program must furnish HHS and its agents with a description of samples that it plans to include in its annual program no later than six months before each calendar year. At least 50 percent of the samples must be mixtures of the principal mycobacteria and appropriate normal flora. The program must include mycobacteria commonly occurring in patient specimens and other important emerging mycobacteria (as determined by HHS). The program determines the reportable isolates and correct responses for antimycobacterial susceptibility for any designated isolate.

(2) An approved program may vary over time. For example, the types of

mycobacteria that might be included in an approved program over time are—

TB
Mycobacterium tuberculosis
Mycobacterium bovis
Group I
Mycobacterium kansasii
Group II
Mycobacterium szulgai
Group III
Mycobacterium avium-intracellulare
Mycobacterium terrae
Group IV
Mycobacterium fortuitum

(3) For antimycobacterial susceptibility testing, the program must provide at least one sample per testing event that includes mycobacterium tuberculosis that has a predetermined pattern of sensitivity or resistance to the common antimycobacterial agents.

(4) For laboratories specified in paragraphs (a)(1) and (a)(2), the program must provide at least five samples per testing event that includes challenges that are acid-fast and challenges which do not contain acid-fast organisms.

(c) *Evaluation of a laboratory's performance.* HHS approves only those programs that assess the accuracy of a laboratory's response in accordance with paragraphs (c)(1) through (6) of this section.

(1) The program determines the reportable mycobacteria to be detected by acid-fast stain, for isolation and identification, and for antimycobacterial susceptibility. To determine the accuracy of a laboratory's response, the program must compare the laboratory's response for each sample with the response that reflects agreement of either 90 percent of ten or more referee laboratories or 90 percent or more of all participating laboratories.

(2) To evaluate a laboratory's response for a particular sample, the program must determine a laboratory's type of service in accordance with paragraph (a) of this section. A laboratory must interpret acid-fast stains and isolate and identify the organisms to the same extent it performs these procedures on patient specimens. A laboratory's performance will be evaluated on the basis of the average of its scores as determined in paragraph (c)(6) of this section.

(3) Since laboratories may incorrectly report the presence of organisms in addition to the correctly identified principal organism(s), the grading system must provide a means of deducting credit for additional erroneous organisms reported. Therefore, the total number of correct responses submitted by the laboratory divided by the number of organisms present plus the number of incorrect organisms reported by the laboratory must be multiplied by 100 to establish a score for each sample in each testing event. For example, if a sample contained one principal organism and the laboratory reported it correctly but reported the presence of an additional organism, which was not present, the sample grade would be

$1/(1+1)\times 100=50$ percent

(4) For antimycobacterial susceptibility testing, a laboratory must indicate which drugs are routinely included in its test panel when testing patient samples. A laboratory's performance will be evaluated for only those antibiotics for which susceptibility testing is routinely performed on patient specimens. A correct response for each antibiotic will be determined as described in § 493.913(c)(1). Grading is based on the number of correct susceptibility responses reported by the laboratory divided by the actual number of correct susceptibility responses as determined by the program, multiplied by 100. For example, if a laboratory offers susceptibility testing using three antimycobacterial agents and the laboratory reports correct response for two of the three antimycobacterial agents, the laboratory's grade would be $\frac{2}{3}\times 100=67$ percent.

(5) The performance criterion for qualitative tests is the presence or absence of acid-fast organisms. The score for acid-fast organism detection is the number of correct responses divided by the number of samples to be tested, multiplied by 100.

(6) The score for a testing event in mycobacteriology is the average of the scores determined under paragraphs (c)(3) through (c)(5) of this section

based on the type of service offered by the laboratory.

[57 FR 7151, Feb. 28, 1992, as amended at 58 FR 5228, Jan. 19, 1993]

§ 493.915 Mycology.

(a) *Types of services offered by laboratories.* In mycology, there are four types of laboratories for proficiency testing purposes that may perform different levels of service for yeasts, dimorphic fungi, dermatophytes, and aerobic actinomycetes:

(1) Those that isolate and identify only yeasts and/or dermatophytes to the genus level;

(2) Those that isolate and identify yeasts and/or dermatophytes to the species level;

(3) Those that isolate and perform identification of all organisms to the genus level; and

(4) Those that isolate and perform identification of all organisms to the species level.

(b) *Program content and frequency of challenge.* To be approved for proficiency testing for mycology, the annual program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The samples may be provided through mailed shipments or, at HHS' option, may be provided to HHS or its designee for on-site testing. An annual program must include samples that contain organisms that are representative of five major groups of fungi: Yeast or yeast-like fungi; dimorphic fungi; dematiaceous fungi; dermatophytes; and saprophytes, including opportunistic fungi. The specific fungi included in the samples may vary from year to year.

(1) An approved program must, before each calendar year, furnish HHS with a description of samples that it plans to include in its annual program no later than six months before each calendar year. At least 50 percent of the samples must be mixtures of the principal organism and appropriate normal background flora. Other important emerging pathogens (as determined by HHS) and organisms commonly occurring in patient specimens must be included periodically in the program.

(2) An approved program may vary over time. As an example, the types of organisms that might be included in an approved program over time are—

Candida albicans
Candida (other species)
Cryptococcus neoformans
Sporothrix schenckii
Exophiala jeanselmei
Fonsecaea pedrosoi
Microsporum sp.
Acremonium sp.
Trichophyton sp.
Aspergillus fumigatus
Nocardia sp.
Blastomyces dermatitidis[1]
Zygomycetes sp.

NOTE:[1] Provided as a nonviable sample.

(c) *Evaluation of a laboratory's performance.* HHS approves only those programs that assess the accuracy of a laboratory's response, in accordance with paragraphs (c)(1) through (5) of this section.

(1) The program determines the reportable organisms. To determine the accuracy of a laboratory's response, the program must compare the laboratory's response for each sample with the response that reflects agreement of either 90 percent of ten or more referee laboratories or 90 percent or more of all participating laboratories.

(2) To evaluate a laboratory's response for a particular sample, the program must determine a laboratory's type of service in accordance with paragraph (a) of this section. A laboratory must isolate and identify the organisms to the same extent it performs these procedures on patient specimens.

(3) Since laboratories may incorrectly report the presence of organisms in addition to the correctly identified principal organism(s), the grading system must deduct credit for additional erroneous organisms reported. Therefore, the total number of correct responses submitted by the laboratory divided by the number of organisms present plus the number of incorrect organisms reported by the laboratory must be multiplied by 100 to establish a score for each sample in each shipment or testing event. For example, if a sample contained one principal organism and the laboratory reported it correctly but reported the presence of an additional organism, which was not

present, the sample grade would be 1/(1+1)x100=50 percent.

(4) The score for the antigen tests is the number of correct responses divided by the number of samples to be tested for the antigen, multiplied by 100.

(5) The score for a testing event is the average of the sample scores as determined under paragraph (c)(3) or (c)(4), or both, of this section.

[57 FR 7151, Feb. 28, 1992, as amended at 58 FR 5228, Jan. 19, 1993]

§ 493.917 Parasitology.

(a) *Types of services offered by laboratories.* In parasitology there are two types of laboratories for proficiency testing purposes—

(1) Those that determine the presence or absence of parasites by direct observation (wet mount) and/or pinworm preparations and, if necessary, refer specimens to another laboratory appropriately certified in the subspecialty of parasitology for identification;

(2) Those that identify parasites using concentration preparations and/or permanent stains.

(b) *Program content and frequency of challenge.* To be approved for proficiency testing in parasitology, a program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The samples may be provided through mailed shipments or, at HHS's option, may be provided to HHS or its designee for on-site testing. An annual program must include samples that contain parasites that are commonly encountered in the United States as well as those recently introduced into the United States. Other important emerging pathogens (as determined by HHS) and parasites commonly occurring in patient specimens must be included periodically in the program.

(1) An approved program must, before each calendar year furnish HHS with a description of samples that it plans to include in its annual program no later than six months before each calendar year. Samples must include both formalinized specimens and PVA (polyvinyl alcohol) fixed specimens as well as blood smears, as appropriate for a particular parasite and stage of the parasite. The majority of samples must contain protozoa or helminths or a combination of parasites. Some samples must be devoid of parasites.

(2) An approved program may vary over time. As an example, the types of parasites that might be included in an approved program over time are—

Enterobius vermicularis
Entamoeba histolytica
Entamoeba coli
Giardia lamblia
Endolimax nana
Dientamoeba fragilis
Iodamoeba butschli
Chilomastix mesnili
Hookworm
Ascaris lumbricoides
Strongyloides stercoralis
Trichuris trichiura
Diphyllobothrium latum
Cryptosporidium sp.
Plasmodium falciparum

(3) For laboratories specified in paragraph (a)(1) of this section, the program must provide at least five samples per testing event that include challenges which contain parasites and challenges that are devoid of parasites.

(c) *Evaluation of a laboratory's performance.* HHS approves only those programs that assess the accuracy of a laboratory's responses in accordance with paragraphs (c)(1) through (6) of this section.

(1) The program must determine the reportable parasites. It may elect to establish a minimum number of parasites to be identified in samples before they are reported. Parasites found in rare numbers by referee laboratories are not considered in scoring a laboratory's performance; such findings are neutral. To determine the accuracy of a laboratory's response, the program must compare the laboratory's response with the response that reflects agreement of either 90 percent of ten or more referee laboratories or 90 percent or more of all participating laboratories.

(2) To evaluate a laboratory's response for a particular sample, the program must determine a laboratory's type of service in accordance with paragraph (a) of this section. A laboratory must determine the presence or absence of a parasite(s) or concentrate and identify the parasites to the same extent it performs these procedures on patient specimens.

(3) Since laboratories may incorrectly report the presence of parasites in addition to the correctly identified principal parasite(s), the grading system must deduct credit for these additional erroneous parasites reported and not found in rare numbers by the program's referencing process. Therefore, the total number of correct responses submitted by the laboratory divided by the number of parasites present plus the number of incorrect parasites reported by the laboratory must be multiplied by 100 to establish a score for each sample in each testing event. For example, if a sample contained one principal parasite and the laboratory reported it correctly but reported the presence of an additional parasite, which was not present, the sample grade would be

$1/(1+1)\times100=50$ percent.

(4) The criterion for acceptable performance for qualitative parasitology examinations is presence or absence of a parasite(s).

(5) The score for parasitology is the number of correct responses divided by the number of samples to be tested, multiplied by 100.

(6) The score for a testing event is the average of the sample scores as determined under paragraphs (c)(3) through (c)(5) of this section.

§ 493.919 Virology.

(a) *Types of services offered by laboratories.* In virology, there are two types of laboratories for proficiency testing purposes—

(1) Those that only perform tests that directly detect viral antigens or structures, either in cells derived from infected tissues or free in fluid specimens; and

(2) Those that are able to isolate and identify viruses and use direct antigen techniques.

(b) *Program content and frequency of challenge.* To be approved for proficiency testing in virology, a program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The samples may be provided to the laboratory through mailed shipments or, at HHS's option, may be provided to HHS or its designee for on-site testing. An annual program must include viral species that are the more commonly identified viruses. The specific organisms found in the samples may vary from year to year. The annual program must include samples for viral antigen detection and viral isolation and identification.

(1) An approved program must furnish HHS with a description of samples that it plans to include in its annual program no later than six months before each calendar year. The program must include other important emerging viruses (as determined by HHS) and viruses commonly occurring in patient specimens.

(2) An approved program may vary over time. For example, the types of viruses that might be included in an approved program over time are the more commonly identified viruses such as Herpes simplex, respiratory syncytial virus, adenoviruses, enteroviruses, and cytomegaloviruses.

(c) *Evaluation of laboratory's performance.* HHS approves only those programs that assess the accuracy of a laboratory's response in accordance with paragraphs (c)(1) through (5) of this section.

(1) The program determines the reportable viruses to be detected by direct antigen techniques or isolated by laboratories that perform viral isolation procedures. To determine the accuracy of a laboratory's response, the program must compare the laboratory's response for each sample with the response that reflects agreement of either 90 percent of ten or more referee laboratories or 90 percent or more of all participating laboratories.

(2) To evaluate a laboratory's response for a particular sample, the program must determine a laboratory's type of service in accordance with paragraph (a) of this section. A laboratory must isolate and identify the viruses to the same extent it performs these procedures on patient specimens.

(3) Since laboratories may incorrectly report the presence of viruses in addition to the correctly identified principal virus, the grading system must provide a means of deducting credit for additional erroneous viruses reported. Therefore, the total number of correct responses determined by

virus culture techniques submitted by the laboratory divided by the number of viruses present plus the number of incorrect viruses reported by the laboratory must be multiplied by 100 to establish a score for each sample in each testing event. For example, if a sample contained one principal virus and the laboratory reported it correctly but reported the presence of an additional virus, which was not present, the sample grade would be 1/(1+1)×100=50 percent.

(4) The performance criterion for qualitative antigen tests is presence or absence of the viral antigen. The score for the antigen tests is the number of correct responses divided by the number of samples to be tested for the antigen, multiplied by 100.

(5) The score for a testing event is the average of the sample scores as determined under paragraph (c)(3) and (c)(4) of this section.

§ 493.921 Diagnostic immunology.

The subspecialties under the specialty of immunology for which a program may offer proficiency testing are syphilis serology and general immunology. Specific criteria for these subspecialties are found at §§ 493.923 and 493.927.

§ 493.923 Syphilis serology.

(a) *Program content and frequency of challenge.* To be approved for proficiency testing in syphilis serology, a program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The samples may be provided through mailed shipments or, at HHS' option, may be provided to HHS or its designee for on-site testing. An annual program must include samples that cover the full range of reactivity from highly reactive to non-reactive.

(b) *Evaluation of test performance.* HHS approves only those programs that assess the accuracy of a laboratory's responses in accordance with paragraphs (b)(1) through (4) of this section.

(1) To determine the accuracy of a laboratory's response for qualitative and quantitative syphilis tests, the program must compare the laboratory's response with the response that reflects agreement of either 90 percent of ten or more referee laboratories or 90 percent or more of all participating laboratories. The proficiency testing program must indicate the minimum concentration, by method, that will be considered as indicating a positive response. The score for a sample in syphilis serology is the average of scores determined under paragraphs (b)(2) and (b)(3) of this section.

(2) For quantitative syphilis tests, the program must determine the correct response for each method by the distance of the response from the target value. After the target value has been established for each response, the appropriateness of the response must be determined by using fixed criteria. The criterion for acceptable performance for quantitative syphilis serology tests is the target value ± 1 dilution.

(3) The criterion for acceptable performance for qualitative syphilis serology tests is reactive or nonreactive.

(4) To determine the overall testing event score, the number of correct responses must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for all challenges}}{\text{Total number of all challenges}} \times 100 = \text{Testing event score}$$

[57 FR 7151, Feb. 28, 1992, as amended at 58 FR 5229, Jan. 19, 1993]

§ 493.927 General immunology.

(a) *Program content and frequency of challenge.* To be approved for proficiency testing for immunology, the annual program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The annual program must provide samples that cover the full range of reactivity from highly reactive to nonreactive. The samples may be provided through mailed shipments or, at HHS' option, may be provided to HHS or its designee for on-site testing.

(b) *Challenges per testing event.* The minimum number of challenges per

testing event the program must provide for each analyte or test procedure is five. Analytes or tests for which laboratory performance is to be evaluated include:

Analyte or Test Procedure

Alpha-l antitrypsin
Alpha-fetoprotein (tumor marker)
Antinuclear antibody
Antistreptolysin O
Anti-human immunodeficiency virus (HIV)
Complement C3
Complement C4
Hepatitis markers (HBsAg, anti-HBc, HBeAg)
IgA
IgG
IgE
IgM
Infectious mononucleosis
Rheumatoid factor
Rubella

(c) *Evaluation of a laboratory's analyte or test performance.* HHS approves only those programs that assess the accuracy of a laboratory's responses in accordance with paragraphs (c)(1) through (5) of this section.

(1) To determine the accuracy of a laboratory's response for quantitative and qualitative immunology tests or analytes, the program must compare the laboratory's response for each analyte with the response that reflects agreement of either 90 percent of ten or more referee laboratories or 90 percent or more of all participating laboratories. The proficiency testing program must indicate the minimum concentration that will be considered as indicating a positive response. The score for a sample in general immunology is either the score determined under paragraph (c)(2) or (3) of this section.

(2) For quantitative immunology analytes or tests, the program must determine the correct response for each analyte by the distance of the response from the target value. After the target value has been established for each response, the appropriateness of the response must be determined by using either fixed criteria or the number of standard deviations (SDs) the response differs from the target value.

Criteria for Acceptable Performance

The criteria for acceptable performance are—

Analyte or test	Criteria for acceptable performance
Alpha-1 antitrypsin	Target value ±3 SD.
Alpha-fetoprotein (tumor marker).	Target value ±3 SD.
Antinuclear antibody	Target value +/−2 dilutions or positive or negative.
Antistreptolysin O	Target value +/−2 dilution or positive or negative.
Anti-Human Immunodeficiency virus.	Reactive or nonreactive.
Complement C3	Target value ±3 SD.
Complement C4	Target value ±3 SD.
Hepatitis (HBsAg, anti-HBc, HBeAg).	Reactive (positive) or nonreactive (negative).
IgA	Target value ±3 SD.
IgE	Target value ±3 SD.
IgG	Target value +/−25%.
IgM	Target value ±3 SD.
Infectious mononucleosis	Target value +/−2 dilutions or positive or negative.
Rheumatoid factor	Target value +/−2 dilutions or positive or negative.
Rubella	Target value +/−2 dilutions or immune or nonimmune or positive or negative.

(3) The criterion for acceptable performance for qualitative general immunology tests is positive or negative.

(4) To determine the analyte testing event score, the number of acceptable analyte responses must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for the analyte}}{\text{Total number of challenges for the analyte}} \times 100 = \text{Analyte score for the testing event}$$

(5) To determine the overall testing event score, the number of correct responses for all analytes must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for all challenges}}{\text{Total number of all challenges}} \times 100 = \text{Testing event score}$$

[57 FR 7151, Feb. 28, 1992, as amended at 58 FR 5229, Jan. 19, 1993]

§ 493.929 Chemistry.

The subspecialties under the specialty of chemistry for which a proficiency testing program may offer proficiency testing are routine chemistry, endocrinology, and toxicology. Specific criteria for these subspecialties are listed in §§ 493.931 through 493.939.

§ 493.931 Routine chemistry.

(a) *Program content and frequency of challenge.* To be approved for proficiency testing for routine chemistry, a program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The annual program must provide samples that cover the clinically relevant range of values that would be expected in patient specimens. The specimens may be provided through mailed shipments or, at HHS' option, may be provided to HHS or its designee for on-site testing.

(b) *Challenges per testing event.* The minimum number of challenges per testing event a program must provide for each analyte or test procedure listed below is five serum, plasma or blood samples.

Analyte or Test Procedure

Alanine aminotransferase (ALT/SGPT)
Albumin
Alkaline phosphatase
Amylase
Aspartate aminotransferase (AST/SGOT)
Bilirubin, total
Blood gas (pH, pO2, and pCO2)
Calcium, total
Chloride
Cholesterol, total
Cholesterol, high density lipoprotein
Creatine kinase
Creatine kinase, isoenzymes
Creatinine
Glucose (Excluding measurements on devices cleared by FDA for home use)
Iron, total
Lactate dehydrogenase (LDH)
LDH isoenzymes
Magnesium
Potassium
Sodium
Total Protein
Triglycerides
Urea Nitrogen
Uric Acid

(c) *Evaluation of a laboratory's analyte or test performance.* HHS approves only those programs that assess the accuracy of a laboratory's responses in accordance with paragraphs (c)(1) through (5) of this section.

(1) To determine the accuracy of a laboratory's response for qualitative and quantitative chemistry tests or analytes, the program must compare the laboratory's response for each analyte with the response that reflects agreement of either 90 percent of ten or more referee laboratories or 90 percent or more of all participating laboratories. The score for a sample in routine chemistry is either the score determined under paragraph (c)(2) or (3) of this section.

(2) For quantitative chemistry tests or analytes, the program must determine the correct response for each analyte by the distance of the response from the target value. After the target value has been established for each response, the appropriateness of the response must be determined by using either fixed criteria based on the percentage difference from the target value or the number of standard deviations (SDs) the response differs from the target value.

Criteria for Acceptable Performance

The criteria for acceptable performance are—

Analyte or test	Criteria for acceptable performance
Alanine aminotransferase (ALT/SGPT).	Target value ±20%.
Albumin	Target value ±10%.
Alkaline phosphatase	Target value ±30%.
Amylase	Target value ±30%.
Aspartate aminotransferase (AST/SGOT).	Target value ±20%.
Bilirubin, total	Target value ±0.4 mg/dL or ±20% (greater).
Blood gas pO2	Target value ±3 SD.
pCO2	Target value ±5 mm Hg or +/−8% (greater).
pH	Target value ±0.04.
Calcium, total	Target value ±1.0 mg/dL.
Chloride	Target value ±5%.
Cholesterol, total	Target value ±10%.
Cholesterol, high density lipoprotein.	Target value ±30%.
Creatine kinase	Target value ±30%.
Creatine kinase isoenzymes	MB elevated (presence or absence) or Target value ±3SD.
Creatinine	Target value ±0.3 mg/dL or ±15% (greater).

Analyte or test	Criteria for acceptable performance
Glucose (excluding glucose performed on monitoring devices cleared by FDA for home use.	Target value ±6 mg/dl or ±10% (greater).
Iron, total	Target value ±20%.
Lactate dehydrogenase (LDH).	Target value ±20%.
LDH isoenzymes	LDH1/LDH2 (+ or −) or Target value ± 30%.
Magnesium	Target value ±25%.
Potassium	Target value ±0.5 mmol/L.
Sodium	Target value ±4 mmol/L.
Total Protein	Target value ±10%.
Triglycerides	Target value ±25%.
Urea nitrogen	Target value ±2 mg/dL or ±9% (greater).
Uric acid	Target value ±17%.

(3) The criterion for acceptable performance for qualitative routine chemistry tests is positive or negative.

(4) To determine the analyte testing event score, the number of acceptable analyte responses must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for the analyte}}{\text{Total number of challenges for the analyte}} \times 100 = \text{Analyte score for the testing event}$$

(5) To determine the overall testing event score, the number of correct responses for all analytes must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for all challenges}}{\text{Total number of all challenges}} \times 100 = \text{Testing event score}$$

§ 493.933 Endocrinology.

(a) *Program content and frequency of challenge.* To be approved for proficiency testing for endocrinology, a program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The annual program must provide samples that cover the clinically relevant range of values that would be expected in patient specimens. The samples may be provided through mailed shipments or, at HHS' option, may be provided to HHS or its designee for on-site testing.

(b) *Challenges per testing event.* The minimum number of challenges per testing event a program must provide for each analyte or test procedure is five serum, plasma, blood, or urine samples.

Analyte or Test
Cortisol
Free Thyroxine
Human Chorionic gonadotropin (excluding urine pregnancy tests done by visual color comparison categorized as waived tests)
T3 Uptake
Triiodothyronine
Thyroid-stimulating hormone
Thyroxine

(c) *Evaluation of a laboratory's analyte or test performance.* HHS approves only those programs that assess the accuracy of a laboratory's responses in accordance with paragraphs (c)(1) through (5) of this section.

(1) To determine the accuracy of a laboratory's response for qualitative and quantitative endocrinology tests or analytes, a program must compare the laboratory's response for each analyte with the response that reflects agreement of either 90 percent of ten or more referee laboratories or 90 percent or more of all participating laboratories. The score for a sample in endocrinology is either the score determined under paragraph (c)(2) or (c)(3) of this section.

(2) For quantitative endocrinology tests or analytes, the program must determine the correct response for each analyte by the distance of the response from the target value. After the target value has been established for each response, the appropriateness of the response must be determined by using either fixed criteria based on the percentage difference from the target value or the number of standard deviations (SDs) the response differs from the target value.

Criteria for Acceptable Performance

The criteria for acceptable performance are—

Analyte or test	Criteria for acceptable performance
Cortisol	Target value +/−25%.
Free Thyroxine	Target value +/−3 SD.

Analyte or test	Criteria for acceptable performance
Human Chorionic Gonadotropin (excluding urine pregnancy tests done by visual color comparison categorized as waived tests).	Target value +/−3 SD positive or negative.
T3 Uptake	Target value +/−3 SD.
Triiodothyronine	Target value +/−3 SD.
Thyroid-stimulating hormone	Target value +/−3 SD.
Thyroxine	Target value +/−20% or 1.0 mcg/dL (greater).

(3) The criterion for acceptable performance for qualitative endocrinology tests is positive or negative.

(4) To determine the analyte testing event score, the number of acceptable analyte responses must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for the analyte}}{\text{Total number of challenges for the analyte}} \times 100 = \text{Analyte score for the testing event}$$

(5) To determine the overall testing event score, the number of correct responses for all analytes must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for all challenges}}{\text{Total number of all challenges}} \times 100 = \text{Testing event score}$$

[57 FR 7151, Feb. 28, 1992, as amended at 58 FR 5229, Jan. 19, 1993]

§ 493.937 Toxicology.

(a) *Program content and frequency of challenge.* To be approved for proficiency testing for toxicology, the annual program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The annual program must provide samples that cover the clinically relevant range of values that would be expected in specimens of patients on drug therapy and that cover the level of clinical significance for the particular drug. The samples may be provided through mailed shipments or, at HHS' option, may be provided to HHS or its designee for on-site testing.

(b) *Challenges per testing event.* The minimum number of challenges per testing event a program must provide for each analyte or test procedure is five serum, plasma, or blood samples.

Analyte or Test Procedure

Alcohol (blood)	Phenytoin
Blood lead	Primidone
Carbamazepine	Procainamide (and metabolite)
Digoxin	Quinidine
Ethosuximide	Theophylline
Gentamicin	Tobramycin
Lithium	Valproic Acid
Phenobarbital	

(c) *Evaluation of a laboratory's analyte or test performance.* HHS approves only those programs that assess the accuracy of a laboratory's responses in accordance with paragraphs (c)(1) through (4) of this section.

(1) To determine the accuracy of a laboratory's responses for quantitative toxicology tests or analytes, the program must compare the laboratory's response for each analyte with the response that reflects agreement of either 90 percent of ten or more referee laboratories or 90 percent or more of all participating laboratories. The score for a sample in toxicology is the score determined under paragraph (c)(2) of this section.

(2) For quantitative toxicology tests or analytes, the program must determine the correct response for each analyte by the distance of the response from the target value. After the target value has been established for each response, the appropriateness of the response must be determined by using fixed criteria based on the percentage difference from the target value

Criteria for Acceptable Performance

The criteria for acceptable performance are:

Analyte or test	Criteria for acceptable performance
Alcohol, blood	Target Value ± 25%.
Blood lead	Target Value ±10% or 4 mcg/dL (greater).
Carbamazepine	Target Value ± 25%.
Digoxin	Target Value ± 20% or ± 0.2 ng/mL (greater).
Ethosuximide	Target Value ± 20%.
Gentamicin	Target Value ± 25%.
Lithium	Target Value ± 0.3 mmol/L or ± 20% (greater).

Analyte or test	Criteria for acceptable performance
Phenobarbital	Target Value ± 20%
Phenytoin	Target Value ± 25%.
Primidone	Target Value ± 25%.
Procainamide (and metabolite).	Target Value ± 25%.
Quinidine	Target Value ± 25%.
Tobramycin	Target Value ± 25%.
Theophylline	Target Value ± 25%.
Valproic Acid	Target Value ± 25%.

(3) To determine the analyte testing event score, the number of acceptable analyte responses must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for the analyte}}{\text{Total number of challenges for the analyte}} \times 100 = \text{Analyte score for the testing event}$$

(4) To determine the overall testing event score, the number of correct responses for all analytes must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for all challenges}}{\text{Total number of all challenges}} \times 100 = \text{Testing event score}$$

[57 FR 7151, Feb. 28, 1992, as amended at 58 FR 5229, Jan. 19, 1993]

§ 493.941 Hematology (including routine hematology and coagulation).

(a) *Program content and frequency of challenge.* To be approved for proficiency testing for hematology, a program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The annual program must provide samples that cover the full range of values that would be expected in patient specimens. The samples may be provided through mailed shipments or, at HHS' option, may be provided to HHS and or its designee for on-site testing.

(b) *Challenges per testing event.* The minimum number of challenges per testing event a program must provide for each analyte or test procedure is five.

Analyte or Test Procedure
Cell identification or white blood cell differential
Erythrocyte count
Hematocrit (excluding spun microhematocrit)
Hemoglobin
Leukocyte count
Platelet count
Fibrinogen
Partial thromboplastin time
Prothrombin time

(1) An approved program for cell identification may vary over time. The types of cells that might be included in an approved program over time are—

Neutrophilic granulocytes
Eosinophilic granulocytes
Basophilic granulocytes
Lymphocytes
Monocytes
Major red and white blood cell abnormalities
Immature red and white blood cells

(2) White blood cell differentials should be limited to the percentage distribution of cellular elements listed above.

(c) *Evaluation of a laboratory's analyte or test performance.* HHS approves only those programs that assess the accuracy of a laboratory's responses in accordance with paragraphs (c) (1) through (5) of this section.

(1) To determine the accuracy of a laboratory's responses for qualitative and quantitative hematology tests or analytes, the program must compare the laboratory's response for each analyte with the response that reflects agreement of either 90 percent of ten or more referee laboratories or 90 percent or more of all participating laboratories. The score for a sample in hematology is either the score determined under paragraph (c) (2) or (3) of this section.

(2) For quantitative hematology tests or analytes, the program must determine the correct response for each analyte by the distance of the response from the target value. After the target value has been established for each response, the appropriateness of the response is determined using either fixed criteria based on the percentage difference from the target value or the number of standard deviations (SDs) the response differs from the target value.

Criteria for Acceptable Performance

The criteria for acceptable performance are:

Analyte or test	Criteria for acceptable performance
Cell identification	90% or greater consensus on identification.
White blood cell differential	Target +/− 3SD based on the percentage of different types of white blood cells in the samples.
Erythrocyte count	Target +/−6%.
Hematocrit (Excluding spun hematocrits).	Target +/−6%.
Hemoglobin	Target +/−7%.
Leukocyte count	Target +/−15%.
Platelet count	Target +/−25%.
Fibrinogen	Target +/− 20%.
Partial thromboplastin time	Target +/−15%.
Prothrombin time	Target +/−15%.

(3) The criterion for acceptable performance for the qualitative hematology test is correct cell identification.

(4) To determine the analyte testing event score, the number of acceptable analyte responses must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for the analyte}}{\text{Total number of challenges for the analyte}} \times 100 = \text{Analyte score for the testing event}$$

(5) To determine the overall testing event score, the number of correct responses for all analytes must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for all challenges}}{\text{Total number of all challenges}} \times 100 = \text{Testing event score}$$

[57 FR 7151, Feb. 28, 1992, as amended at 58 FR 5229, Jan. 19, 1993]

§ 493.945 Cytology; gynecologic examinations.

(a) *Program content and frequency of challenge.* (1) To be approved for proficiency testing for gynecologic examinations (Pap smears) in cytology, a program must provide test sets composed of 10- and 20-glass slides. Proficiency testing programs may obtain slides for test sets from cytology laboratories, provided the slides have been retained by the laboratory for the required period specified in § 493.1257. If slide preparations are still subject to retention by the laboratory, they may be loaned to a proficiency testing program if the program provides the laboratory with documentation of the loan of the slides and ensures that slides loaned to it are retrievable upon request. Each test set must include at least one slide representing each of the response categories described in paragraph (b)(3)(ii)(A) of this section, and test sets should be comparable so that equitable testing is achieved within and between proficiency testing providers.

(2) To be approved for proficiency testing in gynecologic cytology, a program must provide announced and unannounced on-site testing for each individual at least once per year and must provide an initial retesting event for each individual within 45 days after notification of test failure and subsequent retesting events within 45 days after completion of remedial action described in § 493.855.

(b) *Evaluation of an individual's performance.* HHS approves only those programs that assess the accuracy of each individual's responses on both 10- and 20-slide test sets in which the slides have been referenced as specified in paragraph (b)(1) of this section.

(1) To determine the accuracy of an individual's response on a particular challenge (slide), the program must compare the individual's response for each slide preparation with the response that reflects the predetermined consensus agreement or confirmation on the diagnostic category, as described in the table in paragraph (b)(3)(ii)(A) of this section. For all slide preparations, a 100% consensus agreement among a minimum of three physicians certified in anatomic pathology is required. In addition, for premalignant and malignant slide preparations, confirmation by tissue biopsy is required either by comparison of the reported biopsy results or reevaluation of biopsy slide material by a physician certified in anatomic pathology.

(2) An individual qualified as a technical supervisor under § 493.1449 (b) or

(k) who routinely interprets gynecologic slide preparations only after they have been examined by a cytotechnologist can either be tested using a test set that has been screened by a cytotechnologist in the same laboratory or using a test set that has not been screened. A technical supervisor who screens and interprets slide preparations that have not been previously examined must be tested using a test set that has not been previously screened.

(3) The criteria for acceptable performance are determined by using the scoring system in paragraphs (b)(3) (i) and (ii) of this section.

(i) Each slide set must contain 10 or 20 slides with point values established for each slide preparation based on the significance of the relationship of the interpretation of the slide to a clinical condition and whether the participant in the testing event is a cytotechnologist qualified under §§ 493.1469 or 493.1483 or functioning as a technical supervisor in cytology qualified under § 493.1449 (b) or (k) of this part.

(ii) The scoring system rewards or penalizes the participants in proportion to the distance of their answers from the correct response or target diagnosis and the penalty or reward is weighted in proportion to the severity of the lesion.

(A) The four response categories for reporting proficiency testing results and their descriptions are as follows:

Category	Description
A	Unsatisfactory for diagnosis due to: (1) Scant cellularity. (2) Air drying. (3) Obscuring material (blood, inflammatory cells, or lubricant).
B	Normal or Benign Changes—includes: (1) Normal, negative or within normal limits. (2) Infection other than Human Papillomavirus (HPV) (e.g., *Trichomonas vaginalis*, changes or morphology consistent with *Candida* spp., *Actinomyces* spp. or *Herpes simplex* virus). (3) Reactive and reparative changes (e.g., inflammation, effects of chemotherapy or radiation).
C	Low Grade Squamous Intraepithelial Lesion—includes: (1) Cellular changes associated with HPV. (2) Mild dysplasia/CIN–1.
D	High Grade Lesion and Carcinoma—includes: (1) High grade squamous intraepithelial lesions which include moderate dysplasia/CIN–2 and severe dysplasia/carcinoma in-situ/CIN–3. (2) Squamous cell carcinoma. (3) Adenocarcinoma and other malignant neoplasms.

(B) In accordance with the criteria for the scoring system, the charts in paragraphs (b)(3)(ii)(C) and (D) of this section, for technical supervisors and cytotechnologists, respectively, provide a maximum of 10 points for a correct response and a maximum of minus five (−5) points for an incorrect response on a 10-slide test set. For example, if the correct response on a slide is ''high grade squamous intraepithelial lesion'' (category ''D'' on the scoring system chart) and an examinee calls it ''normal or negative'' (category ''B'' on the scoring system chart), then the examinee's point value on that slide is calculated as minus five (−5). Each slide is scored individually in the same manner. The individual's score for the testing event is determined by adding the point value achieved for each slide preparation, dividing by the total points for the testing event and multiplying by 100.

(C) Criteria for scoring system for a 10-slide test set. (See table at (b)(3)(ii)(A) of this section for a description of the response categories.) For technical supervisors qualified under § 493.1449(b) or (k):

Examinee's response:	A	B	C	D
Correct response category:				
A	10	0	0	0
B	5	10	0	0
C	5	0	10	5
D	0	5	5	10

(D) Criteria for scoring system for a 10-slide test set. (See table at paragraph (b)(3)(ii)(A) of this section for a description of the response categories.) For cytotechnologists qualified under §§ 493.1469 or 493.1483:

Examinee's response:	A	B	C	D
Correct response category:				
A	10	0	5	5
B	5	10	5	5
C	5	0	10	10
D	0	−5	10	10

(E) In accordance with the criteria for the scoring system, the charts in paragraphs (b)(3)(ii)(F) and (G) of this section, for technical supervisors and cytotechnologists, respectively, provide maximums of 5 points for a correct response and minus ten (−10) points for an incorrect response on a 20-slide test set.

(F) Criteria for scoring system for a 20-slide test set. (See table at paragraph (b)(3)(ii)(A) of this section for a description of the response categories.) For technical supervisors qualified under § 493.1449(b) or (k):

Examinee's response:	A	B	C	D
Correct response category:				
A	5	0	0	0
B	2.5	5	0	0
C	2.5	0	5	2.5
D	0	−10	2.5	5

(G) Criteria for scoring system for a 20-slide test set. (See table at (b)(3)(ii)(A) of this section for a description of the response categories.) For cytotechnologists qualified under §§ 493.1469 or 493.1483:

Examinee's response:	A	B	C	D
Correct response category:				
A	5	0	2.5	2.5
B	2.5	5	2.5	2.5
C	2.5	0	5	5
D	0	−10	5	5

[57 FR 7151, Feb. 28, 1992, as amended at 58 FR 5229, Jan. 19, 1993]

§ 493.959 Immunohematology.

(a) *Types of services offered by laboratories.* In immunohematology, there are four types of laboratories for proficiency testing purposes—

(1) Those that perform ABO group and/or D (Rho) typing;

(2) Those that perform ABO group and/or D (Rho) typing, and unexpected antibody detection;

(3) Those that in addition to paragraph (a)(2) of this section perform compatibility testing; and

(4) Those that perform in addition to paragraph (a)(3) of this section antibody identification.

(b) *Program content and frequency of challenge.* To be approved for proficiency testing for immunohematology, a program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The annual program must provide samples that cover the full range of interpretation that would be expected in patient specimens. The samples may be provided through mailed shipments or, at HHS' option, may be provided to HHS or its designee for on-site testing.

(c) *Challenges per testing event.* The minimum number of challenges per testing event a program must provide for each analyte or test procedure is five.

Analyte or Test Procedure

ABO group (excluding subgroups)
D (Rho) typing
Unexpected antibody detection
Compatibility testing
Antibody identification

(d) *Evaluation of a laboratory's analyte or test performance.* HHS approves only those programs that assess the accuracy of a laboratory's response in accordance with paragraphs (d)(1) through (5) of this section.

(1) To determine the accuracy of a laboratory's response, a program must compare the laboratory's response for each analyte with the response that reflects agreement of either 100 percent of ten or more referee laboratories or 95 percent or more of all participating laboratories except for unexpected antibody detection and antibody identification. To determine the accuracy of a laboratory's response for unexpected antibody detection and antibody identification, a program must compare the laboratory's response for each analyte with the response that reflects agreement of either 95 percent of ten or more referee laboratories or 95 percent or more of all participating laboratories. The score for a sample in immunohematology is either the score determined under paragraph (d)(2) or (3) of this section.

(2) *Criteria for acceptable performance.* The criteria for acceptable performance are—

Analyte or test	Criteria for acceptable performance
ABO group	100% accuracy.
D (Rho) typing	100% accuracy.
Unexpected antibody detection	80% accuracy.
Compatibility testing	100% accuracy.
Antibody identification	80% accuracy.

(3) The criterion for acceptable performance for qualitative immunohematology tests is positive or negative.

(4) To determine the analyte testing event score, the number of acceptable analyte responses must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for the analyte} \times 100 = \text{Analyte score for the testing event}}{\text{Total number of challenges for the analyte}}$$

(5) To determine the overall testing event score, the number of correct responses for all analytes must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for all challenges} \times 100 = \text{Testing event score}}{\text{Total number of all challenges}}$$

Subpart J—Patient Test Management for Moderate Complexity (Including the Subcategory), High Complexity, or Any Combination of These Tests

SOURCE: 57 FR 7162, Feb, 28, 1992, unless otherwise noted.

§ 493.1101 Condition: Patient test management; moderate complexity (including the subcategory), or high complexity testing, or any combination of these tests.

Each laboratory performing moderate complexity (including the subcategory) or high complexity testing, or any combination of these tests, must employ and maintain a system that provides for proper patient preparation; proper specimen collection, identification, preservation, transportation, and processing; and accurate result reporting. This system must assure optimum patient specimen integrity and positive identification throughout the preanalytic (pre-testing), analytic (testing), and postanalytic (post-testing) processes and must meet the standards as they apply to the testing performed.

[60 FR 20048, Apr. 24, 1995]

§ 493.1103 Standard; Procedures for specimen submission and handling.

(a) The laboratory must have available and follow written policies and procedures for each of the following, if applicable: Methods used for the preparation of patients; specimen collection; specimen labeling; specimen preservation; conditions for specimen transportation; and specimen processing. Such policies and procedures must assure positive identification and optimum integrity of the patient specimens from the time the specimen(s) are collected until testing has been completed and the results reported.

(b) If the laboratory accepts referral specimens, written instructions must be available to clients and must include, as appropriate, the information specified in paragraph (a) of this section.

(c) Oral explanation of instructions to patients for specimen collection, including patient preparation, may be used as a supplement to written instructions where applicable.

[57 FR 7162, Feb. 28, 1992, as amended at 58 FR 5229, Jan. 19, 1993]

§ 493.1105 Standard; Test requisition.

The laboratory must perform tests only at the written or electronic request of an authorized person. Oral requests for laboratory tests are permitted only if the laboratory subsequently requests written authorization for testing within 30 days. The laboratory must maintain the written authorization or documentation of efforts made to obtain a written authorization. Records of test requisitions or test authorizations must be retained for a minimum of two years. The patient's chart or medical record, if used as the test requisition, must be retained for a minimum of two years and

must be available to the laboratory at the time of testing and available to HHS upon request. The laboratory must assure that the requisition or test authorization includes—

(a) The patient's name or other unique identifier;

(b) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for utilizing the test results or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminent life threatening laboratory results or panic values;

(c) The test(s) to be performed;

(d) The date of specimen collection;

(e) For Pap smears, the patient's last menstrual period, age or date of birth, and indication of whether the patient had a previous abnormal report, treatment or biopsy; and

(f) Any additional information relevant and necessary to a specific test to assure accurate and timely testing and reporting of results.

[57 FR 7162, Feb. 28, 1992, as amended at 58 FR 5229, Jan. 19, 1993]

§493.1107 Standard; Test records.

The laboratory must maintain a record system to ensure reliable identification of patient specimens as they are processed and tested to assure that accurate test results are reported. These records must identify the personnel performing the testing procedure. Records of patient testing, including, if applicable, instrument printouts, must be retained for at least two years. Immunohematology records and transfusion records must be retained for no less than five years in accordance with 21 CFR part 606, subpart I. In addition, records of blood and blood product testing must be maintained for a period not less than five years after processing records have been completed, or six months after the latest expiration date, whichever is the later date, in accordance with 21 CFR 606.160(d). The record system must provide documentation of information specified in §493.1105 (a) through (f) and include—

(a) The patient identification number, accession number, or other unique identification of the specimen;

(b) The date and time of specimen receipt into the laboratory;

(c) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability; and

(d) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s), which are necessary to assure proper identification and accurate reporting of patient test results.

[57 FR 7162, Feb. 28, 1992, as amended at 58 FR 5229, Jan. 19, 1993]

§493.1109 Standard; Test report.

The laboratory report must be sent promptly to the authorized person, the individual responsible for using the test results or laboratory that initially requested the test. The original report or an exact duplicate of each test report, including final and preliminary report, must be retained by the testing laboratory for a period of at least two years after the date of reporting. Immunohematology reports and transfusion records must be retained by the laboratory for a period of no less than five years in accordance with 21 CFR part 606, subpart I. In addition, records of blood and blood product testing must be maintained for a period not less than five years after processing records have been completed, or six months after the latest expiration date, whichever is the later date, in accordance with 21 CFR 606.160(d). For pathology, test reports must be retained for a period of at least ten years after the date of reporting. This information may be maintained as part of the patient's chart or medical record which must be readily available to the laboratory and to HHS upon request.

(a) The laboratory must have adequate systems in place to report results in a timely, accurate, reliable and confidential manner, and, ensure patient confidentiality throughout those parts of the total testing process that are under the laboratory's control.

(b) The test report must indicate the name and address of the laboratory location at which the test was performed, the test performed, the test result and, if applicable, the units of measurement.

(c) The laboratory must indicate on the test report any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

(d) Pertinent ''reference'' or ''normal'' ranges, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests or the individual responsible for utilizing the test results.

(e) The results or transcripts of laboratory tests or examinations must be released only to authorized persons or the individual responsible for utilizing the test results.

(f) The laboratory must develop and follow written procedures for reporting imminent life-threatening laboratory results or panic values. In addition, the laboratory must immediately alert the individual or entity requesting the test or the individual responsible for utilizing the test results when any test result indicates an imminent life-threatening condition.

(g) The laboratory must, upon request, make available to clients a list of test methods employed by the laboratory and, in accordance with §493.1213, as applicable, the performance specifications of each method used to test patient specimens. In addition, information that may affect the interpretation of test results, such as test interferences, must be provided upon request. Pertinent updates on testing information must be provided to clients whenever changes occur that affect the test results or interpretation of test results.

(h) The original report or exact duplicates of test reports must be maintained by the laboratory in a manner that permits ready identification and timely accessibility.

[57 FR 7162, Feb. 28, 1992, as amended at 58 FR 5229, Jan. 19, 1993]

§493.1111 Standard; Referral of specimens.

A laboratory must refer specimens for testing only to a laboratory possessing a valid certificate authorizing the performance of testing in the specialty or subspecialty of service for the level of complexity in which the referred test is categorized.

(a) The referring laboratory must not revise results or information directly related to the interpretation of results provided by the testing laboratory.

(b) The referring laboratory may permit each testing laboratory to send the test result directly to the authorized person who initially requested the test. The referring laboratory must retain or be able to produce an exact duplicate of each testing laboratory's report.

(c) The authorized person who orders a test or procedure must be notified by the referring laboratory of the name and address of each laboratory location at which a test was performed.

Subpart K—Quality Control for Tests of Moderate Complexity (Including the Subcategory), High Complexity, or Any Combination of These Tests

SOURCE: 57 FR 7163, Feb. 28, 1992, unless otherwise noted.

§493.1201 Condition: General quality control; moderate complexity (including the subcategory) or high complexity testing, or any combination of these tests.

(a) *Applicability of subpart K of this part.* Subpart K is divided into two sections, general quality control and quality control for specialties and subspecialties. The quality control requirements are specified in §§493.1201 through 493.1285 unless—

(1) An alternative procedure specified in the manufacturer's protocol has been cleared by the Food and Drug Administration (FDA) as meeting certain CLIA requirements for general quality control and specialty/subspecialty quality control, and the manufacturer's instructions contain the following statement,

Unless this device is modified by a laboratory, the laboratory's compliance with these quality control instructions will satisfy the applicable requirements of 42 CFR 493.1203(b).

or

(2) HHS approves an equivalent procedure that is specified in Appendix C of the State Operations Manual (HCFA Pub. 7).

(b) The laboratory must establish and follow written quality control procedures for monitoring and evaluating the quality of the analytical testing process of each method to assure the accuracy and reliability of patient test results and reports. The laboratory must meet the applicable standards in §§493.1202 through 493.1221 of this subpart, unless an alternative procedure specified in the manufacturer's protocol has been cleared by the Food and Drug Administration (FDA) as meeting certain CLIA requirements for quality control or HHS approves an equivalent procedure specified in appendix C of the State Operations Manual (HCFA Pub. 7). HCFA Pub. 7 is available from the Technical Information Service, U.S. Department of Commerce, 5825 Port Royal Road, Springfield, VA 22161, telephone number (703) 487–4630.

[58 FR 5230, Jan. 19, 1993, as amended at 60 FR 20048, Apr. 24, 1995]

§493.1202 Standard; Moderate or high complexity testing, or both: Effective from September 1, 1992 to December 31, 2000.

(a) For each test of high complexity performed, the laboratory must meet all applicable standards of this subpart.

(b) For each test of moderate complexity performed using a standardized method, or method developed in-house, a device not subject to clearance by the FDA (including any commercially distributed instrument, kit or test system subject to the Food, Drug and Cosmetic Act marketed prior to the Medical Device Amendments, Public Law 94–295, enacted on May 28, 1976, and those identified in 21 CFR parts 862, 864, and 866 as exempt from FDA premarket review), or using an instrument, kit or test system cleared by the FDA through the premarket notification (510(k)) or premarket approval (PMA) process for in-vitro diagnostic use but modified by the laboratory, the laboratory must meet all applicable standards of this subpart.

(c) For all other tests of moderate complexity performed using an instrument, kit or test system cleared by the FDA through the premarket notification (510(k)) or premarket approval (PMA) process for in-vitro diagnostic use, the laboratory must—(1) Follow the manufacturer's instructions for instrument or test system operation and test performance;

(2) Have a procedure manual describing the processes for testing and reporting patient test results;

(3) Perform and document calibration procedures or check calibration at least once every six months;

(4) Perform and document control procedures using at least two levels of control materials each day of testing;

(5) Perform and document applicable specialty and subspecialty control procedures as specified under §493.1223;

(6) Perform and document that remedial action has been taken when problems or errors are identified as specified in §493.1219; and

(7) Maintain records of all quality control activities for two years. Quality control records for immunohematology and blood and blood products must be maintained as specified in §493.1221.

[57 FR 7163, Feb. 28, 1992, as amended at 58 FR 5230, Jan. 19, 1993]

§493.1203 Standard; Moderate or high complexity testing, or both: Effective beginning December 31, 2000.

For each moderate or high complexity test performed, the laboratory will be in compliance with this section if it:

(a) Meets all applicable quality control requirements specified in this subpart when using a standardized method, a method developed in-house, a device not subject to clearance by the FDA (including any commercially distributed instrument, kit or test system subject to the Food, Drug and Cosmetic Act marketed prior to the Medical Device Amendments, Public Law 94–295, enacted on May 28, 1976, and those identified in 21 CFR parts 862, 864, and 866 as exempt from FDA premarket review), a manufacturer's product modified by the laboratory, or a device (instrument, kit or test system) not cleared by the FDA as meeting certain CLIA quality control requirements; or

(b) Follows manufacturer's instructions when using a device (instrument,

kit, or test system) cleared by the FDA as meeting the CLIA requirements for quality control located at §§ 493.1215, 493.1217, and 493.1223, and applicable parts of §§ 493.1205, 493.1211 and 493.1218. In addition, the laboratory must comply with the requirements of §§ 493.1204, 493.1213, 493.1219, and 493.1221 and those parts of §§ 493.1205, 493.1211, and 493.1218 that are unique to the laboratory facility and cannot be met by following manufacturer's instructions.

[58 FR 5230, Jan. 19, 1993]

§ 493.1204 Standard; Facilities.

The laboratory must provide the space and environmental conditions necessary for conducting the services offered.

(a) The laboratory must be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of testing, including the preanalytic (pre-testing), analytic (testing), and postanalytic (post-testing), as appropriate.

(b) Safety precautions must be established, posted, and observed to ensure protection from physical, chemical, biochemical and electrical hazards and biohazardous materials.

[57 FR 7163, Feb. 28, 1992, as amended at 58 FR 5230, Jan. 19, 1993]

§ 493.1205 Standard; Test methods, equipment, instrumentation, reagents, materials, and supplies.

The laboratory must utilize test methods, equipment, instrumentation, reagents, materials, and supplies that provide accurate and reliable test results and test reports.

(a) Test methodologies and equipment must be selected and testing performed in a manner that provides test results within the laboratory's stated performance specifications for each test method as determined under § 493.1213.

(b) The laboratory must have appropriate and sufficient equipment, instruments, reagents, materials, and supplies for the type and volume of testing performed and for the maintenance of quality during the preanalytic, analytic, and postanalytic phases of testing.

(c) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, and accurate and reliable test system operation and test result reporting.

(1) These conditions include, if applicable—

(i) Water quality;

(ii) Temperature;

(iii) Humidity; and

(iv) Protection of equipment and instrumentation from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

(2) Remedial actions taken to correct conditions that fail to meet the criteria specified in paragraph (c)(1) of this section must be documented.

(d) Reagents, solutions, culture media, control materials, calibration materials and other supplies, as appropriate, must be labeled to indicate—

(1) Identity and, when significant, titer, strength or concentration;

(2) Recommended storage requirements;

(3) Preparation and expiration date; and

(4) Other pertinent information required for proper use.

(e) Reagents, solutions, culture media, control materials, calibration materials and other supplies must be prepared, stored, and handled in a manner to ensure that—

(1) Reagents, solutions, culture media, controls, calibration materials and other supplies are not used when they have exceeded their expiration date, have deteriorated or are of substandard quality. The laboratory must comply with the FDA product dating requirements of 21 CFR 610.53 for blood products and other biologicals, and labeling requirements, as cited in 21 CFR 809.10 for all other in vitro diagnostics. Any exception to the product dating requirements in 21 CFR 610.53 will be granted by the FDA in the form of an amendment of the product license, in accordance with 21 CFR 610.53(d). All exceptions must be documented by the laboratory; and

(2) Components of reagent kits of different lot numbers are not interchanged unless otherwise specified by the manufacturer.

[57 FR 7163, Feb. 28, 1992, as amended at 58 FR 5230, Jan. 19, 1993]

§493.1211 Standard; Procedure manual.

(a) A written procedure manual for the performance of all analytical methods used by the laboratory must be readily available and followed by laboratory personnel. Textbooks may be used as supplements to these written descriptions but may not be used in lieu of the laboratory's written procedures for testing or examining specimens.

(b) The procedure manual must include, when applicable to the test procedure:

(1) Requirements for specimen collection and processing, and criteria for specimen rejection;

(2) Procedures for microscopic examinations, including the detection of inadequately prepared slides;

(3) Step-by-step performance of the procedure, including test calculations and interpretation of results;

(4) Preparation of slides, solutions, calibrators, controls, reagents, stains and other materials used in testing;

(5) Calibration and calibration verification procedures;

(6) The reportable range for patient test results as established or verified in §493.1213;

(7) Control procedures;

(8) Remedial action to be taken when calibration or control results fail to meet the laboratory's criteria for acceptability;

(9) Limitations in methodologies, including interfering substances;

(10) Reference range (normal values);

(11) Imminent life-threatening laboratory results or ''panic values'';

(12) Pertinent literature references;

(13) Appropriate criteria for specimen storage and preservation to ensure specimen integrity until testing is completed;

(14) The laboratory's system for reporting patient results including, when appropriate, the protocol for reporting panic values;

(15) Description of the course of action to be taken in the event that a test system becomes inoperable; and

(16) Criteria for the referral of specimens including procedures for specimen submission and handling as described in §493.1103.

(c) Manufacturers' package inserts or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(13) of this section. Any of the items under paragraphs (b)(1) through (b)(13) of this section not provided by the manufacturer must be provided by the laboratory.

(d) Procedures must be approved, signed, and dated by the director.

(e) Procedures must be re-approved, signed and dated if the directorship of the laboratory changes.

(f) Each change in a procedure must be approved, signed, and dated by the current director of the laboratory.

(g) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance. These records must be retained for two years after a procedure has been discontinued.

§493.1213 Standard; Establishment and verification of method performance specifications.

Prior to reporting patient test results, the laboratory must verify or establish, for each method, the performance specifications for the following performance characteristics: accuracy; precision; analytical sensitivity and specificity, if applicable; the reportable range of patient test results; the reference range(s) (normal values); and any other applicable performance characteristic.

(a) The provisions of this section are not retroactive. Laboratories are not required to verify or establish performance specifications for any test method of moderate or high complexity in use prior to September 1, 1992.

(b)(1) Each laboratory that introduces a new procedure for patient testing using a device (instrument, kit, or test system) cleared by the FDA as meeting certain CLIA requirements for quality control, must demonstrate that, prior to reporting patient test results, it can obtain the performance specifications for accuracy, precision,

and reportable range of patient test results, comparable to those established by the manufacturer. The laboratory must also verify that the manufacturer's reference range is appropriate for the laboratory's patient population.

(2) Each laboratory that introduces a new method or device as specified in either §493.1202(a) or (b), or §493.1203(a), must, prior to reporting patient test results—

(i) Verify or establish for each method the performance specifications for the following performance characteristics, as applicable:

(A) Accuracy;

(B) Precision;

(C) Analytical sensitivity;

(D) Analytical specificity to include interfering substances;

(E) Reportable range of patient test results;

(F) Reference range(s); and

(G) Any other performance characteristic required for test performance.

(ii) Based upon the performance specifications verified or established in accordance with paragraph (b)(2)(i) of this section, establish calibration and control procedures for patient testing as required under §§493.1217 and 493.1218.

(c) The laboratory must have documentation of the verification or establishment of all applicable test performance specifications.

[57 FR 7163, Feb. 28, 1992, as amended at 58 FR 5230, Jan. 19, 1993]

§493.1215 Standard; Equipment maintenance and function checks.

The laboratory must perform equipment maintenance and function checks that include electronic, mechanical and operational checks necessary for the proper test performance and test result reporting of equipment, instruments and test systems, to assure accurate and reliable test results and reports.

(a) *Maintenance of equipment, instruments, and test systems.* (1) For manufacturers' equipment, instruments or test systems cleared by the FDA as meeting certain CLIA requirements for quality control, the laboratory must—

(i) Perform maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer; and

(ii) Document all maintenance performed.

(2) For methods or devices, as specified in either §493.1202(a) or (b) or §493.1203(a), the laboratory must—

(i) Establish a maintenance protocol that ensures equipment, instrument, and test system performance necessary for accurate and reliable test results and test result reporting;

(ii) Perform maintenance with at least the frequency specified in paragraph (a)(2)(i) of this section; and

(iii) Document all maintenance performed.

(b) *Function checks of equipment, instruments, and test systems.* (1) For manufacturers' equipment, instruments, or test systems cleared by the FDA as meeting certain CLIA requirements for quality control, the laboratory must—

(i) Perform function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer; and

(ii) Document all function checks performed.

(2) For methods or devices, as specified in either §493.1202 (a) or (b) or §493.1203(a), the laboratory must—

(i) Define a function check protocol that ensures equipment, instrument, and test system performance necessary for accurate and reliable test results and test result reporting;

(ii) Perform function checks including background or baseline checks specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted; and

(iii) Document all function checks performed.

[57 FR 7163, Feb. 28, 1992, as amended at 58 FR 5231, Jan. 19, 1993; 58 FR 39155, July 22, 1993]

§493.1217 Standard; Calibration and calibration verification procedures.

Calibration and calibration verification procedures are required to substantiate the continued accuracy of the test method throughout the laboratory's reportable range for patient test rests. Calibration is the process of testing and adjusting an instrument, kit,

or test system to provide a known relationship between the measurement response and the value of the substance that is being measured by the test procedure. Calibration verification is the assaying of calibration materials in the same manner as patient samples to confirm that the calibration of the instrument, kit, or test system has remained stable throughout the laboratory's reportable range for patient test results. The reportable range of patient test results is the range of test result values over which the laboratory can establish or verify the accuracy of the instrument, kit or test system measurement response. Calibration and calibration verification must be performed and documented as required in this section unless otherwise specified in §§493.1223 through 493.1285.

(a) For laboratory test procedures that are performed using instruments, kits, or test systems that have been cleared by the FDA as meeting certain CLIA requirements for quality control, the laboratory must, at a minimum, follow the manufacturer's instructions for calibration and calibration verification procedures using calibration materials specified by the manufacturer.

(b) For each method or device, as specified in either §493.1202 (a) or (b) or §493.1203(a), the laboratory must—

(1) Perform calibration procedures—

(i) At a minimum, in accordance with manufacturer's instructions, if provided, using calibration materials provided or specified, as appropriate, and with at least the frequency recommended by the manufacturer; and

(ii) In accordance with criteria established by the laboratory, as required under §493.1213(b)(2)(i)—

(A) Including the number, type and concentration of calibration materials, acceptable limits for calibration, and the frequency of calibration; and

(B) Using calibration materials appropriate for the methodology and, if possible, traceable to a reference method or reference material of known value; and

(iii) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification; and

(2) Perform calibration verification procedures—

(i) In accordance with the manufacturer's calibration verification instructions when they meet or exceed the requirements specified in paragraph (b)(2)(ii) of this section; or

(ii) In accordance with criteria established by the laboratory—

(A) Including the number, type, and concentration of calibration materials, acceptable limits for calibration verification and frequency of calibration verification;

(B) Using calibration materials appropriate for—

(*1*) The methodology and, if possible, traceable to a reference method or reference material of known value; and

(*2*) Verifying the laboratory's established reportable range of patient test results, which must include at least a minimal (or zero) value, a mid-point value, and a maximum value at the upper limit of that range; and

(C) At least once every six months and whenever any of the following occur:

(*1*) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes;

NOTE: If reagents are obtained from a manufacturer and all of the reagents for a test are packaged together, the laboratory is not required to perform calibration verification for each package of reagents, provided the packages of reagents are received in the same shipment and contain the same lot number.

(*2*) There is major preventive maintenance or replacement of critical parts that may influence test performance;

(*3*) Controls reflect an unusual trend or shift or are outside of the laboratory's acceptable limits and other means of assessing and correcting unacceptable control values have failed to identify and correct the problem; or

(*4*) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification than specified in paragraphs

(b)(2)(ii)(C) (*1*), (*2*), or (*3*) of this section; and

(3) Document all calibration and calibration verification procedures performed.

[58 FR 5231, Jan. 19, 1993]

§ 493.1218 Standard; Control procedures.

Control procedures are performed on a routine basis to monitor the stability of the method or test system; control and calibration materials provide a means to indirectly assess the accuracy and precision of patient test results. Control procedures must be performed as defined in this section unless otherwise specified in §§ 493.1223 through 493.1285 of this subpart.

(a) For each device cleared by the FDA as meeting certain CLIA requirements for quality control, the laboratory must, at a minimum, follow the manufacturer's instructions for control procedures. In addition, the laboratory must meet the requirements under paragraphs (c) through (e) of this section and, as applicable, paragraph (f) of this section.

(b) For each device, as specified in either § 493.1202 (a) or (b) or § 493.1203(a), the laboratory must evaluate instrument and reagent stability and operator variance in determining the number, type, and frequency of testing calibration or control materials and establish criteria for acceptability used to monitor test performance during a run of patient specimen(s). A run is an interval within which the accuracy and precision of a testing system is expected to be stable, but cannot be greater than 24 hours or less than the frequency recommended by the manufacturer. For each procedure, the laboratory must monitor test performance using calibration materials or control materials or a combination thereof.

(1) For qualitative tests, the laboratory must include a positive and negative control with each run of patient specimens.

(2) For quantitative tests, the laboratory must include at least two samples of different concentrations of either calibration materials, control materials, or a combination thereof with the frequency determined in § 493.1218(b), but not less frequently than once each run of patient specimens.

(3) For electrophoretic determinations—

(i) At least one control sample must be used in each electrophoretic cell; and

(ii) The control sample must contain fractions representative of those routinely reported in patient specimens.

(4) Each day of use, the laboratory must evaluate the detection phase of direct antigen systems using an appropriate positive and negative control material (organism or antigen extract). When direct antigen systems include an extraction phase, the system must be checked each day of use using a positive organism.

(5) If calibration materials and control materials are not available, the laboratory must have an alternative mechanism to assure the validity of patient test results.

(c) Control samples must be tested in the same manner as patient specimens.

(d) When calibration or control materials are used, statistical parameters (e.g., mean and standard deviation) for each lot number of calibration material and each lot of control material must be determined through repetitive testing.

(1) The stated values of an assayed control material may be used as the target values provided the stated values correspond to the methodology and instrumentation employed by the laboratory and are verified by the laboratory.

(2) Statistical parameters for unassayed materials must be established over time by the laboratory through concurrent testing with calibration materials or control materials having previously determined statistical parameters.

(e) Control results must meet the laboratory's criteria for acceptability prior to reporting patient test results.

(f) *Reagent and supply checks.* (1) The laboratory must check each batch or shipment of reagents, discs, stains, antisera and identification systems (systems using two or more substrates) when prepared or opened for positive and negative reactivity, as well as graded reactivity if applicable.

(2) Each day of use (unless otherwise specified in this subpart), the laboratory must test staining materials for intended reactivity to ensure predictable staining characteristics.

(3) The laboratory must check fluorescent stains for positive and negative reactivity each time of use (unless otherwise specified in this subpart).

(4) The laboratory must check each batch or shipment of media for sterility, if it is intended to be sterile, and sterility is required for testing. Media must also be checked for its ability to support growth, and as appropriate, selectivity/inhibition and/or biochemical response. The laboratory may use manufacturer's control checks of media provided the manufacturer's product insert specifies that the manufacturer's quality control checks meet the National Committee for Clinical Laboratory Standards (NCCLS) for media quality control. The laboratory must document that the physical characteristics of the media are not compromised and report any deterioration in the media to the manufacturer. The laboratory must follow the manufacturer's specifications for using the media and be responsible for the test results.

NOTE: A batch of media (solid, semi-solid, or liquid) consists of all tubes, plates, or containers of the same medium prepared at the same time and in the same laboratory; or, if received from an outside source or commercial supplier, consists of all of the plates, tubes or containers of the same medium that have the same lot numbers and are received in a single shipment.

[57 FR 7163, Feb. 28, 1992, as amended at 58 FR 5232, Jan. 19, 1993]

§493.1219 Standard; Remedial actions.

Remedial action policies and procedures must be established by the laboratory and applied as necessary to maintain the laboratory's operation for testing patient specimens in a manner that assures accurate and reliable patient test results and reports. The laboratory must document all remedial actions taken when—

(a) Test systems do not meet the laboratory's established performance specifications, as determined in §493.1213 of this section, which include but are not limited to—

(1) Equipment or methodologies that perform outside of established operating parameters or performance specifications;

(2) Patient test values that are outside of the laboratory's reportable range of patient test results; and

(3) The determination that the laboratory's reference range for a test procedure is inappropriate for the laboratory's patient population.

(b) Results of control and calibration materials fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run or since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected and the laboratory must take the remedial action necessary to ensure the reporting of accurate and reliable patient test results;

(c) The laboratory cannot report patient test results within its established time frames. The laboratory must determine, based on the urgency of the patient test(s) requested, the need to notify the appropriate individual of the delayed testing; and

(d) Errors in the reported patient test results are detected. The laboratory must—

(1) Promptly notify the authorized person ordering or individual utilizing the test results of reporting errors;

(2) Issue corrected reports promptly to the authorized person ordering the test or the individual utilizing the test results; and

(3) Maintain exact duplicates of the original report as well as the corrected report for two years.

§493.1221 Standard; Quality control records.

The laboratory must document and maintain records of all quality control activities specified in §§493.1202 through 493.1285 of this subpart and retain records for at least two years. Immunohematology quality control records must be maintained for a period of no less than five years. In addition, quality control records for blood and blood products must be maintained for a period not less than five years after processing records have been

completed, or six months after the latest expiration date, whichever is the later date, in accordance with 21 CFR 606.160(d).

§ 493.1223 Condition: Quality control—specialties and subspecialties for tests of moderate or high complexity, or both.

The laboratory must establish and follow written quality control procedures for monitoring and evaluating the quality of the analytical testing process of each method to assure the accuracy and reliability of patient test results and reports. Except as specified in § 493.1202(c), the laboratory must meet the applicable general requirements specified in §§ 493.1201 through 493.1221. In addition, the laboratory must meet the applicable requirements of §§ 493.1225 through 493.1285 unless an alternative procedure specified in the manufacturer's protocol has been cleared by the Food and Drug Administration (FDA) as meeting certain CLIA requirements for quality control or HCFA approves an equivalent procedure specified in appendix C of the State Operations Manual (HCFA Pub. 7). Failure to meet any of the applicable conditions in §§ 493.1225 through 493.1285 will result in intermediate sanctions, loss of Medicare or Medicaid approval, and/or revocation of CLIA certification for the entire specialty or subspecialty to which the condition applies, in accordance with subpart R of this part.

[58 FR 5232, Jan. 19, 1993]

§ 493.1225 Condition: Microbiology.

The laboratory must meet the applicable quality control requirements in §§ 493.1201 through 493.1221 and in §§ 493.1227 through 493.1235 of this subpart for the subspecialties for which it is certified under the specialty of microbiology.

§ 493.1227 Condition: Bacteriology.

To meet the quality control requirements for bacteriology, the laboratory must comply with the applicable requirements in §§ 493.1201 through 493.1221 and with paragraphs (a) through (c) of this section. All quality control activities must be documented.

(a) The laboratory must check positive and negative reactivity with control organisms—

(1) Each day of use for catalase, coagulase, beta-lactamase, and oxidase reagents and DNA probes;

(2) Each week of use for Gram and acid-fast stains, bacitracin, optochin, ONPG, X, and V discs or strips; and

(3) Each month of use for antisera.

(b) Each week of use, the laboratory must check XV discs or strips with a positive control organism.

(c) For antimicrobial susceptibility tests, the laboratory must check each new batch of media and each lot of antimicrobial discs before, or concurrent with, initial use, using approved reference organisms.

(1) The laboratory's zone sizes or minimum inhibitory concentration for reference organisms must be within established limits before reporting patient results.

(2) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure.

§ 493.1229 Condition: Mycobacteriology.

To meet the quality control requirements for mycobacteriology, the laboratory must comply with the applicable requirements in §§ 493.1201 through 493.1221 of this subpart and with paragraphs (a) through (d) of this section. All quality control activities must be documented.

(a) Each day of use, the laboratory must check the iron uptake test with at least one acid-fast organism that produces a positive reaction and with an organism that produces a negative reaction and check all other reagents or test procedures used for mycobacteria identification with at least one acid-fast organism that produces a positive reaction.

(b) The laboratory must check fluorochrome acid-fast stains for positive and negative reactivity each week of use.

(c) The laboratory must check acid-fast stains each week of use with an acid-fast organism that produces a positive reaction.

(d) For susceptibility tests performed on *Mycobacterium tuberculosis* isolates,

the laboratory must check the procedure each week of use with a strain of *Mycobacterium tuberculosis* susceptible to all antimycobacterial agents tested.

§ 493.1231 Condition: Mycology.

To meet the quality control requirements for mycology, the laboratory must comply with the applicable requirements in §§ 493.1201 through 493.1221 of this subpart and with paragraphs (a) through (d) of this section. All quality control activities must be documented.

(a) Each day of use, the laboratory using the auxanographic medium for nitrate assimilation must check the nitrate reagent with a peptone control.

(b) Each week of use, the laboratory must check all reagents used with biochemical tests and other test procedures for mycological identification with an organism that produces a positive reaction.

(c) Each week of use, the laboratory must check acid-fast stains for positive and negative reactivity.

(d) For susceptibility tests, the laboratory must test each drug each day of use with at least one control strain that is susceptible to the drug. The laboratory must establish control limits. Criteria for acceptable control results must be met prior to reporting patient results.

§ 493.1233 Condition: Parasitology.

To meet the quality control requirements for parasitology, the laboratory must comply with the applicable requirements of §§ 493.1201 through 493.1221 of this subpart and with paragraphs (a) through (c) of this section. All quality control activities must be documented.

(a) The laboratory must have available a reference collection of slides or photographs, and, if available, gross specimens for identification of parasites and use these references in the laboratory for appropriate comparison with diagnostic specimens.

(b) The laboratory must calibrate and use the calibrated ocular micrometer for determining the size of ova and parasites, if size is a critical parameter.

(c) Each month of use, the laboratory must check permanent stains using a fecal sample control that will demonstrate staining characteristics.

§ 493.1235 Condition: Virology.

To meet the quality control requirements for virology, the laboratory must comply with the applicable requirements in §§ 493.1201 through 493.1221 of this subpart and with paragraphs (a) through (c) of this section. All quality control activities must be documented.

(a) The laboratory must have available host systems for the isolation of viruses and test methods for the identification of viruses that cover the entire range of viruses that are etiologically related to clinical diseases for which services are offered.

(b) The laboratory must maintain records that reflect the systems used and the reactions observed.

(c) In tests for the identification of viruses, the laboratory must simultaneously culture uninoculated cells or cell substrate controls as a negative control to detect erroneous identification results.

§ 493.1237 Condition: Diagnostic immunology.

The laboratory must meet the applicable quality control requirements in §§ 493.1201 through 493.1221 and §§ 493.1239 through 493.1241 of this subpart for the subspecialties for which it is certified under the specialty of diagnostic immunology.

§ 493.1239 Condition: Syphilis serology.

To meet the quality control requirements for syphilis serology, the laboratory must comply with the applicable requirements in §§ 493.1201 through 493.1221 of this subpart and with paragraphs (a) through (e) of this section. All quality control activities must be documented.

(a) For laboratories performing syphilis testing, the equipment, glassware, reagents, controls, and techniques for tests for syphilis must conform to manufacturers' specifications.

(b) The laboratory must run serologic tests on patient specimens concurrently with a positive serum control of known titer or controls of graded reactivity plus a negative control.

(c) The laboratory must employ positive and negative controls that evaluate all phases of the test system to ensure reactivity and uniform dosages.

(d) The laboratory may not report test results unless the predetermined reactivity pattern of the controls is observed.

(e) All facilities manufacturing blood and blood products for transfusion or serving as referral laboratories for these facilities must meet the syphilis serology testing requirements of 21 CFR 640.5(a).

§ 493.1241 Condition: General immunology.

To meet the quality control requirements for general immunology, the laboratory must comply with the applicable requirements in §§ 493.1201 through 493.1221 of this subpart and with paragraphs (a) through (d) of this section. All quality control activities must be documented.

(a) The laboratory must run serologic tests on patient specimens concurrently with a positive serum control of known titer or controls of graded reactivity, if applicable, plus a negative control.

(b) The laboratory must employ controls that evaluate all phases of the test system (antigens, complement, erythrocyte indicator systems, etc.) to ensure reactivity and uniform dosages when positive and negative controls alone are not sufficient.

(c) The laboratory may not report test results unless the predetermined reactivity pattern of the controls is observed.

(d) All facilities manufacturing blood and blood products for transfusion or serving as referral laboratories for these facilities must meet—

(1) The HIV testing requirements of 21 CFR 610.45; and

(2) Hepatitis testing requirements of 21 CFR 610.40.

§ 493.1243 Condition: Chemistry.

The laboratory must meet the applicable quality control requirements in §§ 493.1201 through 493.1221 and §§ 493.1245 through 493.1249 of this subpart for the subspecialties for which it is certified under the specialty of chemistry.

§ 493.1245 Condition: Routine chemistry.

To meet the quality control requirements for routine chemistry, the laboratory must comply with the applicable requirements in §§ 493.1201 through 493.1221. All quality control activities must be documented. In addition, for blood gas analyses, the laboratory must—

(a) Calibrate or verify calibration according to the manufacturer's specifications and with at least the frequency recommended by the manufacturer;

(b) Test one sample of control material each eight hours of testing;

(c) Use a combination of calibrators and control materials that include both low and high values on each day of testing; and

(d) Include one sample of calibration material or control material each time patients are tested unless automated instrumentation internally verifies calibration at least every thirty minutes.

§ 493.1247 Condition: Endocrinology.

To meet the quality control requirements for endocrinology, the laboratory must comply with the applicable requirements contained in §§ 493.1201 through 493.1221 of this subpart. All quality control activities must be documented.

§ 493.1249 Condition: Toxicology.

To meet the quality control requirements for toxicology, the laboratory must comply with the applicable requirements in §§ 493.1201 through 493.1221 of this subpart. All quality control activities must be documented. In addition, for drug abuse screening using thin layer chromatography—

(a) Each plate must be spotted with at least one sample of calibration material containing all drug groups identified by thin layer chromatography which the laboratory reports; and

(b) At least one control sample must be included in each chamber, and the control sample must be processed through each step of patient testing, including extraction procedures.

§493.1251 Condition: Urinalysis.

Except for those tests categorized as waived, to meet the quality control requirements for urinalysis, the laboratory must comply with the applicable requirements in §§493.1201 through 493.1221.

[58 FR 5232, Jan. 19, 1993]

§493.1253 Condition: Hematology.

To meet the quality control requirements for hematology, the laboratory must comply with the applicable requirements in §§493.1201 through 493.1221 of this subpart and with paragraphs (a) through (d) of this section. All quality control activities must be documented.

(a) Cell counts performed manually using a hemocytometer must be tested in duplicate. One control is required for each eight hours of operation.

(b) For non-manual hematology testing systems, excluding coagulation, the laboratory must include two levels of controls each eight hours of operation.

(c) For all non-manual coagulation testing systems, the laboratory must include two levels of control each eight hours of operation and each time a change in reagents occurs.

(d) For manual coagulation tests—

(1) Each individual performing tests must test two levels of controls before testing patient samples and each time a change in reagents occurs; and

(2) Patient and control specimens must be tested in duplicate.

[57 FR 7163, Feb. 28, 1992, as amended at 58 FR 5232, Jan. 19, 1993]

§493.1255 Condition: Pathology.

The laboratory must meet the applicable quality control requirements in §§493.1201 through 493.1221 and §§493.1257 through 493.1261 of this subpart for the subspecialties for which it is certified under the specialty of pathology. All quality control activities must be documented.

§493.1257 Condition: Cytology.

To meet the quality control requirements for cytology, the laboratory must comply with the applicable requirements in §§493.1201 through 493.1221 of this subpart and paragraphs (a) through (g) of this section.

(a) The laboratory must assure that—

(1) All gynecologic smears are stained using a Papanicolaou or modified Papanicolaou staining method;

(2) Effective measures are taken to prevent cross-contamination between gynecologic and nongynecologic specimens during the staining process;

(3) Nongynecologic specimens that have a high potential for cross-contamination are stained separately from other nongynecologic specimens, and the stains are filtered or changed following staining;

(4) Diagnostic interpretations are not reported on unsatisfactory smears; and

(5) All cytology slide preparations are evaluated on the premises of a laboratory certified to conduct testing in the subspecialty of cytology.

(b) The laboratory is responsible for ensuring that—

(1) Each individual engaged in the evaluation of cytology preparations by nonautomated microscopic technique examines no more than 100 slides (one patient per slide, gynecologic or nongynecologic, or both) in a 24 hour period, irrespective of the site or laboratory. This limit represents an absolute maximum number of slides and is not to be employed as a performance target for each individual. Previously examined negative, reactive, reparative, atypical, premalignant or malignant gynecologic cases as defined in paragraph (c)(1) of this section, previously examined nongynecologic cytology preparations, and tissues patholoty slides examined by a technical supervisor qualified under §493.1449 (b) or (k) are not included in the 100 slide limit. (For this section, all references to technical supervisor refer to individuals qualified under §§493.1449 (b) and (k).);

(2) For purposes of workload calculations, each slide preparation (gynecologic and nongynecologic) made using automated, semi-automated, or other liquid-based slide preparatory techniques which result in cell dispersion over one-half or less of the total available slide area and which is examined by nonautomated microscopic technique counts as one-half slide.

(3) Records are maintained of the total number of slides examined by

each individual during each 24 hour period, irrespective of the site or laboratory, and the number of hours each individual spends examining slides in the 24 hour period;

(i) The maximum number of 100 slides described in paragraph (b)(1) of this section is examined in no less than an 8 hour workday;

(ii) For the purposes of establishing workload limits for individuals examining slides by nonautomated microscopic technique on other than an 8 hour workday basis (includes full-time employees with duties other than slide examination and part-time employees), a period of 8 hours must be used to prorate the number of slides that may be examined. Use the formula—

$$\frac{\text{No. of hours examining slides} \times 100}{8}$$

to determine maximum slide volume to be examined.

(c) The individual qualified under §§ 493.1449 (b) or (k) who provides technical supervision of cytology must ensure that—

(1) All gynecologic smears interpreted to be showing reactive or reparative changes, atypical squamous or glandular cells of undetermined significance, or to be in the premalignant (dysplasia, cervical intraepithelial neoplasia or all squamous intraepithelial lesions including human papillomavirus-associated changes) or malignant category are confirmed by a technical supervisor in cytology. The report must be signed to reflect the review or, if a computer report is generated with signature, it must reflect an electronic signature authorized by the technical supervisor in cytology;

(2) All nongynecologic cytologic preparations are reviewed by the technical supervisor in cytology. The report must be signed to reflect technical supervisory review or, if a computer report is generated with signature, it must reflect an electronic signature authorized by the technical supervisor;

(3) The slide examination performance of each cytotechnologist is evaluated and documented, including performance evaluation through the re-examination of normal and negative cases and feedback on the reactive, reparative, atypical, malignant or premalignant cases as defined in paragraph (c)(1) of this section; and

(4) A maximum number of slides, not to exceed the maximum workload limit described in paragraph (b) of this section is established by the technical supervisor for each individual examining slide preparations by nonautomated microscopic technique.

(i) The actual workload limit must be documented for each individual and established in accordance with the individual's capability based on the performance evaluation as described in paragraph (c)(3) of this section.

(ii) Records are available to document that each individual's workload limit is reassessed at least every 6 months and adjusted when necessary.

(d) The laboratory must establish and follow a program designed to detect errors in the performance of cytologic examinations and the reporting of results.

(1) The laboratory must establish a program that includes a review of slides from at least 10 percent of the gynecologic cases interpreted to be negative for reactive, reparative, atypical, premalignant or malignant conditions as defined in paragraph (c)(1) of this section that are examined by each individual not qualified under §§ 493.1449 (b) or (k). This review must be done by a technical supervisor in cytology, a cytology general supervisor qualified under § 493.1469, or a cytotechnologist qualified under § 493.1483 who has the experience specified in § 493.1469(b)(2).

(i) The review must include negative cases selected at random from the total caseload and from patients or groups of patients that are identified as having a high probability of developing cervical cancer, based on available patient information;

(ii) Records of initial examinations and rescreening results must be available; and

(iii) The review must be completed before reporting patient results on those cases selected.

(2) The laboratory must compare clinical information, when available, with cytology reports and must compare all malignant and premalignant

(as defined in paragraph (c)(1) of this section) gynecology reports with the histopathology report, if available in the laboratory (either on-site or in storage), and determine the causes of any discrepancies.

(3) For each patient with a current high grade intraepithelial lesion or above (moderate dysplasia or CIN–2 or above), the laboratory must review all normal or negative gynecologic specimens received within the previous five years, if available in the laboratory (either on-site or in storage). If significant discrepancies are found that would affect patient care, the laboratory must notify the patient's physician and issue an amended report.

(4) The laboratory must establish and document an annual statistical evaluation of the number of cytology cases examined, number of specimens processed by specimen type, volume of patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation), number of gynecologic cases where cytology and available histology are discrepant, the number of gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as malignant or premalignant, as defined in paragraph (c)(1) of the section, and the number of gynecologic cases for which histology results were unavailable to compare with malignant or premalignant cytology cases as defined in paragraph (c)(1) of this section.

(5) The laboratory must evaluate the case reviews of each individual examining slides against the laboratory's overall statistical values, document any discrepancies, including reasons for the deviation, and document corrective action, if appropriate.

(e) The laboratory report must—

(1) Clearly distinguish specimens or smears, or both, that are unsatisfactory for diagnostic interpretation; and

(2) Contain narrative descriptive nomenclature for all results.

(f) Corrected reports issued by the laboratory must indicate the basis for correction.

(g) The laboratory must retain all slide preparations for five years from the date of examination, or slides may be loaned to proficiency testing programs, in lieu of maintaining them for this time period, provided the laboratory receives written acknowledgment of the receipt of slides by the proficiency testing program and maintains the acknowledgment to document the loan of such slides. Documentation for slides loaned or referred for purposes other than proficiency testing must also be maintained. All slides must be retrievable upon request.

[57 FR 7163, Feb. 28, 1992, as amended at 58 FR 5232, Jan. 19, 1993; 58 FR 39155, July 22, 1993]

§493.1259 Condition: Histopathology.

To meet the quality control requirements for histopathology, a laboratory must comply with the applicable requirements in §§493.1201 through 493.1221 of this subpart and paragraphs (a) through (e) of this section. All quality control activities must be documented.

(a) A control slide of known reactivity must be included with each slide or group of slides for differential or special stains. Reaction(s) of the control slide with each special stain must be documented.

(b) The laboratory must retain stained slides at least ten years from the date of examination and retain specimen blocks at least two years from the date of examination.

(c) The laboratory must retain remnants of tissue specimens in a manner that assures proper preservation of the tissue specimens until the portions submitted for microscopic examination have been examined and a diagnosis made by an individual qualified under §§493.1449(b) or 493.1449(l)(1) of this part. In addition, an individual who meets the requirements of §§493.1449(b), 493.1449(l)(1) or 493.1449(l)(2), may examine and provide reports for specimens for skin pathology; an individual meeting the requirements of §§493.1449(b) or 493.1449(l)(3) may examine and provide reports for ophthalmic pathology; an individual meeting the requirements of §§493.1449(b) or 493.1449(m) may examine and provide reports for oral pathology specimens.

(d) All tissue pathology reports must be signed by an individual qualified as specified in paragraph (c) of the section. If a computer report is generated

with an electronic signature, it must be authorized by the individual qualified as specified in paragraph (c) of this section.

(e) The laboratory must utilize acceptable terminology of a recognized system of disease nomenclature in reporting results.

§ 493.1261 Condition: Oral pathology.

To meet the quality control requirements for oral pathology, the laboratory must comply with the applicable requirements in §§ 493.1201 through 493.1221 and § 493.1259 of this subpart. All quality control activities must be documented.

§ 493.1263 Condition: Radiobioassay.

To meet quality control requirements for radiobioassay, the laboratory must comply with the applicable requirements of §§ 493.1201 through 493.1221 of this subpart. All quality control activities must be documented.

§ 493.1265 Condition: Histocompatibility.

In addition to meeting the applicable requirements for general quality control in §§ 493.1201 through 493.1221, for quality control for general immunology in § 493.1241 of this subpart and for immunohematology in § 493.1269 of this subpart, the laboratory must comply with the applicable requirements in paragraphs (a) through (d) of this section. All quality control activities must be documented.

(a) For renal allotransplantation, the laboratory must meet the following requirements:

(1) The laboratory must have available and follow criteria for—

(i) Selecting appropriate patient serum samples for crossmatching;

(ii) The technique used in crossmatching;

(iii) Preparation of donor lymphocytes for crossmatching; and

(iv) Reporting crossmatch results;

(2) The laboratory must—

(i) Have available results of final crossmatches before an organ or tissue is transplanted; and

(ii) Make a reasonable attempt and document efforts to have available serum specimens for all potential transplant recipients at initial typing, for periodic screening, for pre-transplantation crossmatch and following sensitizing events, such as transfusion and transplant loss;

(3) The laboratory's storage and maintenance of both recipient sera and reagents must—

(i) Be at an acceptable temperature range for sera and components;

(ii) Use a temperature alarm system and have an emergency plan for alternate storage; and

(iii) Ensure that all specimens are properly identified and easily retrievable;

(4) The laboratory's reagent typing sera inventory (applicable only to locally constructed trays) must indicate source, bleeding date and identification number, and volume remaining;

(5) The laboratory must properly label and store cells, complement, buffer, dyes, etc.;

(6) The laboratory must—

(i) HLA type all potential transplant recipients;

(ii) Type cells from organ donors referred to the laboratory; and

(iii) Have available and follow a policy that establishes when antigen redefinition and retyping are required;

(7) The laboratory must have available and follow criteria for—

(i) The preparation of lymphocytes for HLA–A, B and DR typing;

(ii) Selecting typing reagents, whether locally or commercially prepared;

(iii) The assignment of HLA antigens; and

(iv) Assuring that reagents used for typing recipients and donors are adequate to define all major and International Workshop HLA–A,B and DR specificities for which reagents are readily available;

(8) The laboratory must—

(i) Screen potential transplant recipient sera for preformed HLA–A and B antibodies with a suitable lymphocyte panel on sera collected;

(A) At the time of the recipient's initial HLA typing; and

(B) Thereafter, following sensitizing events and upon request; and

(ii) Use a suitable cell panel for screening patient sera (antibody screen), a screen that contains all the major HLA specificities and common splits—

(A) If the laboratory does not use commercial panels, it must maintain a list of individuals for fresh panel bleeding; and

(B) If the laboratory uses frozen panels, it must have a suitable storage system;

(9) The laboratory must check—

(i) Each typing tray using—

(A) Positive control sera;

(B) Negative control sera; and

(C) Positive controls for specific cell types when applicable (i.e., T cells, B cells, and monocytes); and

(ii) Each compatibility test (i.e. mixed lymphocyte cultures, homozygous typing cells or DNA analysis) and typing for disease-associated antigens using controls to monitor the test components and each phase of the test system to ensure an acceptable performance level;

(10) Compatibility testing for cellularly-defined antigens must utilize techniques such as the mixed lymphocyte culture test, homozygous typing cells or DNA analysis;

(11) If the laboratory reports the recipient's or donor's, or both, ABO blood group and D(Rho) typing, the testing must be performed in accordance with §493.1269 of this subpart;

(12) If the laboratory utilizes immunologic reagents (such as antibodies or complement) to remove contaminating cells during the isolation of lymphocytes or lymphocyte subsets, the efficacy of the methods must be verified with appropriate quality control procedures;

(13) At least once each month, the laboratory must have each individual performing tests evaluate a previously tested specimen as an unknown to verify his or her ability to reproduce test results. Records of the results for each individual must be maintained; and

(14) The laboratory must participate in at least one national or regional cell exchange program, if available, or develop an exchange system with another laboratory in order to validate interlaboratory reproducibility.

(b) If the laboratory performs histocompatibility testing for—

(1) Transfusions and other non-renal transplantation, excluding bone marrow and living transplants, all the requirements specified in this section, as applicable, except for the performance of mixed lymphocyte cultures, must be met;

(2) Bone marrow transplantation, all the requirements specified in this section, including the performance of mixed lymphocyte cultures or other augmented testing to evaluate class II compatibility, must be met; and

(3) Non-renal solid organ transplantation, the results of final crossmatches must be available before transplantation when the recipient has demonstrated presensitization by prior serum screening except for emergency situations. The laboratory must document the circumstances, if known, under which emergency transplants are performed, and records must reflect any information concerning the transplant provided to the laboratory by the patient's physician.

(c) Laboratories performing HLA typing for disease-associated studies must meet all the requirements specified in this section except for the performance of mixed lymphocyte cultures, antibody screening and crossmatching.

(d) For laboratories performing organ donor HIV testing the requirements of §493.1241 of this subpart for the transfusion of blood and blood products must be met.

[57 FR 7163, Feb. 28, 1992, as amended at 58 FR 5233, Jan. 19, 1993]

§493.1267 Condition: Clinical cytogenetics.

To meet the quality control requirements for clinical cytogenetics, the laboratory must comply with the applicable requirements of §§493.1201 through 493.1221 of this subpart and with paragraphs (a) through (d) of this section. All quality control activities must be documented.

(a) When determination of sex is performed by X and Y chromatin counts, these counts must be based on an examination of an adequate number of cells. Confirmatory testing such as full chromosome analysis must be performed for all atypical results.

(b) The laboratory must have records that reflect the media used and document the reactions observed, number of cells counted, the number of cells

karyotyped, the number of chromosomes counted for each metaphase spread, and the quality of the banding; that the resolution is sufficient to support the reported results; and that an adequate number of karyotypes are prepared for each patient.

(c) The laboratory also must have policies and procedures for assuring an accurate and reliable patient sample identification during the process of accessioning, cell preparation, photographing or other image reproduction technique, and photographic printing, and storage and reporting of results or photographs.

(d) The laboratory report must include the summary and interpretation of the observations and number of cells counted and analyzed and the use of appropriate nomenclature.

§ 493.1269 Condition: Immunohematology.

To meet the quality control requirements for immunohematology, the laboratory must comply with the applicable requirements in §§ 493.1201 through 493.1221 of this subpart and with paragraphs (a) through (d) of this section. All quality control activities must be documented.

(a) The laboratory must perform ABO group and D(Rho) typing, unexpected antibody detection, antibody identification and compatibility testing in accordance with manufacturer's instructions, if provided, and as applicable, with 21 CFR part 606 (with the exception of 21 CFR 606.20a, Personnel) and 21 CFR part 640 *et seq*.

(b) The laboratory must perform ABO group by concurrently testing unknown red cells with anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells.

(c) The laboratory must determine the D(Rho) type by testing unknown red cells with anti-D (anti-Rho) blood grouping reagent.

(d) If required in the manufacturer's package insert for anti-D reagents, the laboratory must employ a control system capable of detecting false positive D(Rho) test results.

§ 493.1271 Condition: Transfusion services and bloodbanking.

If a facility provides services for the transfusion of blood and blood products, the facility must be under the adequate control and technical supervision of the pathologist or other doctor of medicine or osteopathy meeting the qualifications in subpart M for technical supervision in immunohematology. The facility must ensure that there are facilities for procurement, safekeeping and transfusion of blood and blood products and that blood and blood products must be available to meet the needs of the physicians responsible for the diagnosis, management, and treatment of patients. The facility meets this condition by complying with the standards in §§ 493.1273 through 493.1285.

[58 FR 5233, Jan. 19, 1993]

§ 493.1273 Standard; Immunohematological collection, processing, dating periods, labeling and distribution of blood and blood products.

In addition to the requirements in paragraphs (a) through (d) of this section, the facility must also meet the applicable quality control requirements in §§ 493.1201 through 493.1221 of this part.

(a) Blood and blood product collection, processing and distribution must comply with 21 CFR part 640 and 21 CFR part 606, and the testing laboratory must meet the applicable requirements of part 493.

(b) Dating periods for blood and blood products must conform to 21 CFR 610.53.

(c) Labeling of blood and blood products must conform to 21 CFR part 606, subpart G.

(d) Policies to ensure positive identification of a blood or blood product recipient must be established, documented, and followed.

§ 493.1275 Standard; Blood and blood products storage facilities.

(a) The blood and blood products must be stored under appropriate conditions, which include an adequate temperature alarm system that is regularly inspected.

(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period; and

(2) Inspections of the alarm system must be documented.

(b) If blood is stored or maintained for transfusion outside of a monitored refrigerator, the facility must ensure and document that storage conditions, including temperature, are appropriate to prevent deterioration of the blood or blood product.

§493.1277 Standard; Arrangement for services.

In the case of services provided outside the blood bank, the facility must have an agreement reviewed and approved by the director that governs the procurement, transfer and availability of blood and blood products.

§493.1279 Standard; Provision of testing.

There must be provision for prompt ABO blood group, D(Rho) type, unexpected antibody detection and compatibility testing in accordance with §493.1269 of this subpart and for laboratory investigation of transfusion reactions, either through the facility or under arrangement with an approved facility on a continuous basis, under the supervision of a pathologist or other doctor of medicine or osteopathy meeting the qualifications of §§493.1449(b) or 493.1449(q).

§493.1283 Standard; Retention of samples of transfused blood.

According to the facility's established procedures, samples of each unit of transfused blood must be retained for further testing in the event of reactions. The facility must promptly dispose of blood not retained for further testing that has passed its expiration date.

§493.1285 Standard; Investigation of transfusion reactions.

The facility, according to its established procedures, must promptly investigate all transfusion reactions occurring in all facilities for which it has investigational responsibility and make recommendations to the medical staff regarding improvements in transfusion procedures. The facility must document that all necessary remedial actions are taken to prevent future recurrences of transfusion reactions and that all policies and procedures are reviewed to assure that they are adequate to ensure the safety of individuals being transfused within the facility.

Subpart L [Reserved]

Subpart M—Personnel for Moderate Complexity (Including the Subcategory) and High Complexity 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, M, and P of this part.

§ 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:

(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.

§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

(ii) Have had at least one year experience directing or supervising non-waived laboratory testing;

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

(ii) Have at least one year of laboratory training or experience, or both in non-waived testing; and

(iii) In addition, have at least one year of supervisory laboratory experience in non-waived testing; or

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

(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing; and

(iii) In addition, have at least 2 years of supervisory laboratory experience in non-waived testing;

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

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

[57 FR 7172, Feb. 28, 1992, as amended at 58 FR 5233, Jan. 19, 1993]

§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:

(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;

(2) Be a physician who:

(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

(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

(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

(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;

(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;

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

(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

(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;

(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:

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

(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;

(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

(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

(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.

[58 FR 5233, Jan. 19, 1993]

§ 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.

(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.

(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.

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

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

(e) The laboratory director must—

(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;

(2) Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed and provide a safe environment in which employees are protected from physical, chemical, and biological hazards;

(3) Ensure that—

(i) The test methodologies selected have the capability of providing the quality of results required for patient care;

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

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

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

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

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

(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

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

(5) Ensure that the quality control and quality assurance programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

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

(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, and that patient test results are reported only when the system is functioning properly;

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

(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;

(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;

(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;

(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;

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

(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.

§ 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.

§ 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.

(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—

(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 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

(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

(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

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

(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.

[57 FR 7172, Feb. 28, 1992, as amended at 58 FR 5234, Jan. 19, 1993]

§ 493.1413 Standard; Technical consultant responsibilities.

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

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

(b) The technical consultant is responsible for—

(1) Selection of test methodology appropriate for the clinical use of the test results;

(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;

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

(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;

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

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

(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;

(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—

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

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

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

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

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

(vi) Assessment of problem solving skills; and

(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. Thereafter, evaluations must be performed at least annually 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.

§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.

§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.

[57 FR 7172, Feb. 28, 1992, as amended at 58 FR 5234, Jan. 19, 1993]

§ 493.1419 Standard; Clinical consultant responsibilities.

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

(a) Be available to provide clinical consultation to the laboratory's clients;

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

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

(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.

§ 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.

§ 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

(b) Meet one of the following requirements:

(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

(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or

(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

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

(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. Such training must ensure that the individual has—

(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) The skills required for implementing all standard laboratory procedures;

(C) The skills required for performing each test method and for proper instrument use;

(D) The skills required for performing preventive maintenance, troubleshooting and calibration procedures related to each test performed;

(E) A working knowledge of reagent stability and storage;

(F) The skills required to implement the quality control policies and procedures of the laboratory;

(G) An awareness of the factors that influence test results; and

(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.

[57 FR 7172, Feb. 28, 1992, as amended at 58 FR 5234, Jan. 19, 1993]

§ 493.1425 Standard; Testing personnel responsibilities.

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

(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.

(b) Each individual performing moderate complexity testing must—

(1) Follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results;

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

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

(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;

(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

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

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.

§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.

(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) 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

(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

(ii) Have at least 2 years of experience directing or supervising high complexity testing; 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, the American Board of Medical Laboratory Immunology or other board deemed comparable by HHS; or

(ii) Until December 31, 2000, must have at least—

(A) Two years of laboratory training or experience, or both;

(B) Two years of experience directing or supervising high complexity testing; and

(C) On December 31, 2000, individuals must meet the qualifications specified in paragraph (b)(3)(i) of this section;

(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

(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

(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.

[57 FR 7172, Feb. 28, 1992, as amended at 58 FR 5234, Jan. 19, 1993; 59 FR 62609, Dec. 6, 1994; 62 FR 25858, May 12, 1997; 63 FR 55034, Oct. 14, 1998]

§ 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.

(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.

(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.

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

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

(e) The laboratory director must—

(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;

(2) Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed and provide a safe environment in which employees are protected from physical, chemical, and biological hazards;

(3) Ensure that—

(i) The test methodologies selected have the capability of providing the quality of results required for patient care;

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

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

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

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

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

(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

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

(5) Ensure that the quality control and quality assurance programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

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

(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified, and that patient test results are reported only when the system is functioning properly;

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

(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;

(10) Ensure that a general supervisor provides on-site supervision of high complexity test performance by testing

personnel qualified under §493.1489(b)(4);

(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;

(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;

(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;

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

(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.

§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.

§493.1449 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.

(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—

(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

(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.

(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—

(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 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

(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 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

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

(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

(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

(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

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

(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—

(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 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

(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

(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

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

(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

(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

(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

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

(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—

(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 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

(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 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

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

(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

(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

(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

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

(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—

(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

(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

(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 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;

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

(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

(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

(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

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

(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—

(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 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

(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 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

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

(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

(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

(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

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

(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—

(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

(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

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

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

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

(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

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

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

(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—

(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 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

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

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

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

(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

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

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

(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—

(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

(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

(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 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

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

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

(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

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

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

(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—

(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

(ii) Meet one of the following requirements—

(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

(B) Be certified by the American Society of Cytology to practice cytopathology or possess qualifications

that are equivalent to those required for such certification;

(2) An individual qualified under § 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 § 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—

(1) Meet one of the following requirements:

(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

(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;

(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.

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

(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—

(B) Meet one of the following requirements:

(*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

(*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

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

(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.

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

(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—

(B) Must meet one of the following requirements:

(*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

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

(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:

(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—

(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

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

(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—

(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

(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

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

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

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

(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

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

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

(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—

(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

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

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

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

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

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

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

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

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

(*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—

(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

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

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

(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—

(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

(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

(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 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.

[57 FR 7172, Feb. 28, 1992, as amended at 58 FR 5234, Jan. 19, 1993]

§ 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.

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

(b) The technical supervisor is responsible for—

(1) Selection of the test methodology that is appropriate for the clinical use of the test results;

(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;

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

(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;

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

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

(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;

(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—

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

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

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

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

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

(vi) Assessment of problem solving skills; and

(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. Thereafter, evaluations must be performed at least annually 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)—

(1) May perform the duties of the cytology general supervisor and the cytotechnologist, as specified in §§493.1471 and 493.1485, respectively;

(2) Must establish the workload limit for each individual examining slides;

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

(4) Must perform the functions specified in §493.1257(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

(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.

[57 FR 7172, Feb. 28, 1992, as amended at 58 FR 5235, Jan. 19, 1993]

§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.

§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.

[57 FR 7172, Feb. 28, 1992, as amended at 58 FR 5235, Jan. 19, 1993]

§493.1457 Standard; Clinical consultant responsibilities.

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

(a) Be available to provide consultation to the laboratory's clients;

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

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

(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.

§ 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.

§ 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.

(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—

(1) Laboratory director under § 493.1443; or

(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—

(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

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing; or

(2)(i) Qualify as testing personnel under § 493.1489(b)(2); and

(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing; or

(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.

(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.''

(4) On or before September 1, 1992, have served as a general supervisor of high complexity testing and as of April 24, 1995—

(i) Meet one of the following requirements:

(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.

(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).

(ii) Have at least 2 years of clinical laboratory training, or experience, or both, in high complexity testing; or

(5) On or before September 1, 1992, have served as a general supervisor of high complexity testing and—

(i) Be a high school graduate or equivalent; and

(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—

(1) Be qualified under §§ 493.1461(b) (1) or (2), or 493.1461(c); or

(2)(i) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and

(ii) Have at least one year of laboratory training or experience, or both, in blood gas analysis; or

(3)(i) Have earned an associate degree related to pulmonary function from an accredited institution; and

(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:

(1) In histopathology, by an individual who is qualified as a technical supervisor under §§493.1449(b) or 493.1449(l)(1);

(2) In dermatopathology, by an individual who is qualified as a technical supervisor under §§493.1449(b) or 493.1449(l) or (2);

(3) In ophthalmic pathology, by an individual who is qualified as a technical supervisor under §§493.1449(b) or 493.1449(1)(3); and

(4) In oral pathology, by an individual who is qualified as a technical supervisor under §§493.1449(b) or 493.1449(m).

[57 FR 7172, Feb. 28, 1992, as amended at 58 FR 5235, Jan. 19, 1993; 58 FR 39155, July 22, 1993; 60 FR 20049, Apr. 24, 1995]

§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—

(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

(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

(ii) Subsequent to graduation, has had at least 2 years of experience in one of the laboratory specialties in a laboratory; or

(3)(i) Holds a master's degree from an accredited institution with a major in one of the chemical, physical, or biological sciences; and

(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

(4)(i) Is qualified as a laboratory technologist under §493.1491; and

(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

(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.

[58 FR 39155, July 22, 1993]

§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.

(a) The general supervisor—(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;

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

(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

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

(b) The director or technical supervisor may delegate to the general supervisor the responsibility for—

(1) Assuring that all remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications;

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

(3) Providing orientation to all testing personnel; and

(4) Annually evaluating and documenting the performance of all testing personnel.

(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.

[57 FR 7172, Feb. 28, 1992, as amended at 58 FR 5235, Jan. 19, 1993; 60 FR 20050, Apr. 24, 1995]

§ 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.

§ 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

(2) Have at least 3 years of full-time (2,080 hours per year) experience as a cytotechnologist within the preceding 10 years.

§ 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.

(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.

(b) The cytology general supervisor must—

(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;

(2) Document the slide interpretation results of each gynecologic and nongynecologic cytology case he or she examined or reviewed (as specified under § 493.1257(d));

(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

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

§ 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.

§ 493.1483 Standard: Cytotechnologist qualifications.

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

(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:

(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

(2) Be certified in cytotechnology by a certifying agency approved by HHS; or

(3) Before September 1, 1992—

(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

(A) Have had 12 months of training in a school of cytotechnology accredited by an accrediting agency approved by HHS; or

(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

(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

(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—

(i) Graduated from high school;

(ii) Completed 6 months of training in cytotechnology in a laboratory directed by a pathologist or other physician providing cytology services; and

(iii) Completed 2 years of full-time supervised experience in cytotechnology; or

(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

(ii) On or before September 1, 1995, have met the requirements in either paragraph (b)(1) or (2) of this section.

[57 FR 7172, Feb. 28, 1992, as amended at 59 FR 685, Jan. 6, 1994]

§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 §493.1257(d));

(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

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

§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.

§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

(b) Meet one of the following requirements:

(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;

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

(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes—

(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either—

(*1*) 24 semester hours of medical laboratory technology courses; or

(*2*) 24 semester hours of science courses that include—

(*i*) Six semester hours of chemistry;

(*ii*) Six semester hours of biology; and

(*iii*) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and

(B) Have laboratory training that includes either of the following:

(*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.)

(*2*) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing.

(3) Have previously qualified or could have qualified as a technologist under §493.1491 on or before February 28, 1992;

(4) On or before April 24, 1995 be a high school graduate or equivalent and have either—

(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or

(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);

(5)(i) Until September 1, 1997—

(A) Have earned a high school diploma or equivalent; and

(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has—

(*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;

(*2*) The skills required for implementing all standard laboratory procedures;

(*3*) The skills required for performing each test method and for proper instrument use;

(*4*) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed;

(*5*) A working knowledge of reagent stability and storage;

(*6*) The skills required to implement the quality control policies and procedures of the laboratory;

(*7*) An awareness of the factors that influence test results; and

(*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

(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;

(6) For blood gas analysis—

(i) Be qualified under §493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5);

(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or

(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or

(7) For histopathology, meet the qualifications of §493.1449 (b) or (l) to perform tissue examinations.

[57 FR 7172, Feb. 28, 1992, as amended at 58 FR 5236, Jan. 19, 1993; 58 FR 39155, July 22, 1993; 60 FR 20050, Apr. 24, 1995]

§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

(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

(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

(4)(i) Have successfully completed 3 years (90 semester hours or equivalent) in an accredited college or university with the following distribution of courses—

(A) *For those whose training was completed before September 15, 1963.* At least 24 semester hours in chemistry and biology courses of which—

(*1*) At least 6 semester hours were in inorganic chemistry and at least 3 semester hours were in other chemistry courses; and

(*2*) At least 12 semester hours in biology courses pertinent to the medical sciences; or

(B) *For those whose training was completed after September 14, 1963.*

(*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;

(*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

(*3*) 3 semester hours of mathematics; and

(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

(5) With respect to individuals first qualifying before July 1, 1971, the technologist—

(i) Was performing the duties of a laboratory technologist at any time between July 1, 1961, and January 1, 1968, and

(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

(6) Achieves a satisfactory grade in a proficiency examination approved by HHS.

[58 FR 39155, July 22, 1993]

§493.1495 Standard; Testing personnel responsibilities.

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

(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.

(b) Each individual performing high complexity testing must—

(1) Follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results;

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

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

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

(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;

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

(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.

(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.

[57 FR 7172, Feb. 28, 1992, as amended at 58 FR 5236, Jan. 19, 1993; 60 FR 20050, Apr. 24, 1995]

Subparts N–O [Reserved]

Subpart P—Quality Assurance for Moderate Complexity (Including the Subcategory) or High Complexity Testing, or Any Combination of These Tests

SOURCE: 57 FR 7183, Feb. 28, 1992, unless otherwise noted.

§ 493.1701 Condition: Quality assurance; moderate complexity (including the subcategory) or high complexity testing, or any combination of these tests.

Each laboratory performing moderate complexity (including the subcategory) or high complexity testing, or any combination of these tests, must establish and follow written policies and procedures for a comprehensive quality assurance program that is designed to monitor and evaluate the ongoing and overall quality of the total testing process (preanalytic, analytic, postanalytic). The laboratory's quality assurance program must evaluate the effectiveness of its policies and procedures; identify and correct problems; assure the accurate, reliable and prompt reporting of test results; and assure the adequacy and competency of the staff. As necessary, the laboratory must revise policies and procedures based upon the results of those evaluations. The laboratory must meet the standards as they apply to the services offered, complexity of testing performed and test results reported, and the unique practices of each testing entity. All quality assurance activities must be documented.

[60 FR 20050, Apr. 24, 1995]

§ 493.1703 Standard; Patient test management assessment.

The laboratory must have an ongoing mechanism for monitoring and evaluating the systems required under subpart J, Patient Test Management. The laboratory must monitor, evaluate, and revise, if necessary, based on the results of its evaluations, the following:

(a) The criteria established for patient preparation, specimen collection, labeling, preservation and transportation;

(b) The information solicited and obtained on the laboratory's test requisition for its completeness, relevance, and necessity for the testing of patient specimens;

(c) The use and appropriateness of the criteria established for specimen rejection;

(d) The completeness, usefulness, and accuracy of the test report information necessary for the interpretation or utilization of test results;

(e) The timely reporting of test results based on testing priorities (STAT, routine, etc.); and

(f) The accuracy and reliability of test reporting systems, appropriate storage of records and retrieval of test results.

§ 493.1705 Standard; Quality control assessment.

The laboratory must have an ongoing mechanism to evaluate the corrective actions taken under § 493.1219, Remedial actions. Ineffective policies and procedures must be revised based on the outcome of the evaluation. The mechanism must evaluate and review the effectiveness of corrective actions taken for—

(a) Problems identified during the evaluation of calibration and control data for each test method;

(b) Problems identified during the evaluation of patient test values for the purpose of verifying the reference range of a test method; and

(c) Errors detected in reported results.

§493.1707 Standard; Proficiency testing assessment.

Under subpart H of this part, Proficiency Testing, the corrective actions taken for any unacceptable, unsatisfactory, or unsuccessful proficiency testing result(s) must be evaluated for effectiveness.

§493.1709 Standard; Comparison of test results.

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites.

(b) If a laboratory performs tests that are not included under subpart I of this part, Proficiency Testing Programs, the laboratory must have a system for verifying the accuracy of its test results at least twice a year.

[58 FR 5236, Jan. 19, 1993]

§493.1711 Standard; Relationship of patient information to patient test results.

For internal quality assurance, the laboratory must have a mechanism to identify and evaluate patient test results that appear inconsistent with relevant criteria such as—

(a) Patient age;

(b) Sex;

(c) Diagnosis or pertinent clinical data, when provided;

(d) Distribution of patient test results when available; and

(e) Relationship with other test parameters, when available within the laboratory.

§493.1713 Standard; Personnel assessment.

The laboratory must have an ongoing mechanism to evaluate the effectiveness of its policies and procedures for assuring employee competence and, if applicable, consultant competence.

§493.1715 Standard; Communications.

The laboratory must have a system in place to document problems that occur as a result of breakdowns in communication between the laboratory and the authorized individual who orders or receives the results of test procedures or examinations. Corrective actions must be taken, as necessary, to resolve the problems and minimize communication breakdowns.

[58 FR 5236, Jan. 19, 1993]

§493.1717 Standard; Complaint investigations.

The laboratory must have a system in place to assure that all complaints and problems reported to the laboratory are documented. Investigations of complaints must be made, when appropriate, and, as necessary, corrective actions are instituted.

§493.1719 Standard; Quality assurance review with staff.

The laboratory must have a mechanism for documenting and assessing problems identified during quality assurance reviews and discussing them with the staff. The laboratory must take corrective actions that are necessary to prevent recurrences.

§493.1721 Standard; Quality assurance records.

The laboratory must maintain documentation of all quality assurance activities including problems identified and corrective actions taken. All quality assurance records must be available to HHS and maintained for a period of 2 years.

[58 FR 5236, Jan. 19, 1993]

Subpart Q—Inspection

SOURCE: 57 FR 7184, Feb. 28, 1992, unless otherwise noted.

§ 493.1771 Condition: Inspection requirements applicable to all CLIA-certified and CLIA-exempt laboratories.

(a) Each laboratory issued a CLIA certificate must meet the requirements in § 493.1773 and the specific requirements for its certificate type, as specified in §§ 493.1775 through 493.1780.

(b) All CLIA-exempt laboratories must comply with the inspection requirements in §§ 493.1773 and 493.1780, when applicable.

[63 FR 26737, May 14, 1998]

§ 493.1773 Standard: Basic inspection requirements for all laboratories issued a CLIA certificate and CLIA-exempt laboratories.

(a) A laboratory issued a certificate must permit HCFA or a HCFA agent to conduct an inspection to assess the laboratory's compliance with the requirements of this part. A CLIA-exempt laboratory and a laboratory that requests, or is issued a certificate of accreditation, must permit HCFA or a HCFA agent to conduct validation and complaint inspections.

(b) *General requirements.* As part of the inspection process, HCFA or a HCFA agent may require the laboratory to do the following:

(1) Test samples, including proficiency testing samples, or perform procedures.

(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part.

(3) Permit laboratory personnel to be observed performing all phases of the total testing process (preanalytic, analytic, and postanalytic).

(4) Permit HCFA or a HCFA agent access to all areas encompassed under the certificate including, but not limited to, the following:

(i) Specimen procurement and processing areas.

(ii) Storage facilities for specimens, reagents, supplies, records, and reports.

(iii) Testing and reporting areas.

(5) Provide HCFA or a HCFA agent with copies or exact duplicates of all records and data it requires.

(c) *Accessible records and data.* A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection.

(d) *Requirement to provide information and data.* A laboratory must provide, upon request, all information and data needed by HCFA or a HCFA agent to make a determination of the laboratory's compliance with the applicable requirements of this part.

(e) *Reinspection.* HCFA or a HCFA agent may reinspect a laboratory at any time to evaluate the ability of the laboratory to provide accurate and reliable test results.

(f) *Complaint inspection.* HCFA or a HCFA agent may conduct an inspection when there are complaints alleging noncompliance with any of the requirements of this part.

(g) *Failure to permit an inspection or reinspection.* Failure to permit HCFA or a HCFA agent to conduct an inspection or reinspection results in the suspension or cancellation of the laboratory's participation in Medicare and Medicaid for payment, and suspension or limitation of, or action to revoke the laboratory's CLIA certificate, in accordance with subpart R of this part.

[63 FR 26737, May 14, 1998; 63 FR 32699, June 15, 1998]

§ 493.1775 Standard: Inspection of laboratories issued a certificate of waiver or a certificate for provider-performed microscopy procedures.

(a) A laboratory that has been issued a certificate of waiver or a certificate for provider-performed microscopy procedures is not subject to biennial inspections.

(b) If necessary, HCFA or a HCFA agent may conduct an inspection of a laboratory issued a certificate of waiver or a certificate for provider-performed microscopy procedures at any time during the laboratory's hours of operation to do the following:

(1) Determine if the laboratory is operated and testing is performed in a manner that does not constitute an imminent and serious risk to public health.

(2) Evaluate a complaint from the public.

(3) Determine whether the laboratory is performing tests beyond the scope of the certificate held by the laboratory.

(4) Collect information regarding the appropriateness of tests specified as waived tests or provider-performed microscopy procedures.

(c) The laboratory must comply with the basic inspection requirements of §493.1773.

[63 FR 26737, May 14, 1998]

§493.1777 Standard: Inspection of laboratories that have requested or have been issued a certificate of compliance.

(a) *Initial inspection.* (1) A laboratory issued a registration certificate must permit an initial inspection to assess the laboratory's compliance with the requirements of this part before HCFA issues a certificate of compliance.

(2) The inspection may occur at any time during the laboratory's hours of operation.

(b) *Subsequent inspections.* (1) HCFA or a HCFA agent may conduct subsequent inspections on a biennial basis or with such other frequency as HCFA determines to be necessary to ensure compliance with the requirements of this part.

(2) HCFA bases the nature of subsequent inspections on the laboratory's compliance history.

(c) *Provider-performed microscopy procedures.* The inspection sample for review may include testing in the subcategory of provider-performed microscopy procedures.

(d) *Compliance with basic inspection requirements.* The laboratory must comply with the basic inspection requirements of §493.1773.

[63 FR 26738, May 14, 1998]

§493.1780 Standard: Inspection of CLIA-exempt laboratories or laboratories requesting or issued a certificate of accreditation.

(a) *Validation inspection.* HCFA or a HCFA agent may conduct a validation inspection of any accredited or CLIA-exempt laboratory at any time during its hours of operation.

(b) *Complaint inspection.* HCFA or a HCFA agent may conduct a complaint inspection of a CLIA-exempt laboratory or a laboratory requesting or issued a certificate of accreditation at any time during its hours of operation upon receiving a complaint applicable to the requirements of this part.

(c) *Noncompliance determination.* If a validation or complaint inspection results in a finding that the laboratory is not in compliance with one or more condition-level requirements, the following actions occur:

(1) A laboratory issued a certificate of accreditation is subject to a full review by HCFA, in accordance with subpart E of this part and §488.11 of this chapter.

(2) A CLIA-exempt laboratory is subject to appropriate enforcement actions under the approved State licensure program.

(d) *Compliance with basic inspection requirements.* CLIA-exempt laboratories and laboratories requesting or issued a certificate of accreditation must comply with the basic inspection requirements in §493.1773.

[63 FR 26738, May 14, 1998]

Subpart R—Enforcement Procedures

SOURCE: 57 FR 7237, Feb. 28, 1992, unless otherwise noted.

§493.1800 Basis and scope.

(a) *Statutory basis.* (1) Section 1846 of the Act—

(i) Provides for intermediate sanctions that may be imposed on laboratories that perform clinical diagnostic tests on human specimens when those laboratories are found to be out of compliance with one or more of the conditions for Medicare coverage of their services; and

(ii) Requires the Secretary to develop and implement a range of such sanctions, including four that are specified in the statute.

(2) The Clinical Laboratories Improvement Act of 1967 (section 353 of the Public Health Service Act) as amended by CLIA '88—

(i) Establishes requirements for all laboratories that perform clinical diagnostic tests on human specimens;

(ii) Requires a Federal certification scheme to be applied to all such laboratories; and

(iii) Grants the Secretary broad enforcement authority, including—

(A) Use of intermediate sanctions;

(B) Suspension, limitation, or revocation of the certificate of a laboratory that is out of compliance with one or more requirements for a certificate; and

(C) Civil suit to enjoin any laboratory activity that constitutes a significant hazard to the public health.

(3) Section 353 also—

(i) Provides for imprisonment or fine for any person convicted of intentional violation of CLIA requirements;

(ii) Specifies the administrative hearing and judicial review rights of a laboratory that is sanctioned under CLIA; and

(iii) Requires the Secretary to publish annually a list of all laboratories that have been sanctioned during the preceding year.

(b) *Scope and applicability.* This subpart sets forth—

(1) The policies and procedures that HCFA follows to enforce the requirements applicable to laboratories under CLIA and under section 1846 of the Act; and

(2) The appeal rights of laboratories on which HCFA imposes sanctions.

§ 493.1804 General considerations.

(a) *Purpose.* The enforcement mechanisms set forth in this subpart have the following purposes:

(1) To protect all individuals served by laboratories against substandard testing of specimens.

(2) To safeguard the general public against health and safety hazards that might result from laboratory activities.

(3) To motivate laboratories to comply with CLIA requirements so that they can provide accurate and reliable test results.

(b) *Basis for decision to impose sanctions.* (1) HCFA's decision to impose sanctions is based on one or more of the following:

(i) Deficiencies found by HCFA or its agents in the conduct of inspections to certify or validate compliance with Federal requirements, or through review of materials submitted by the laboratory (e.g., personnel qualifications).

(ii) Unsuccessful participation in proficiency testing.

(2) HCFA imposes one or more of the alternative or principal sanctions specified in §§ 493.1806 and 493.1807 when HCFA or HCFA's agent finds that a laboratory has condition-level deficiencies.

(c) *Imposition of alternative sanctions.* (1) HCFA may impose alternative sanctions in lieu of, or in addition to principal sanctions, (HCFA does not impose alternative sanctions on laboratories that have certificates of waiver because those laboratories are not inspected for compliance with condition-level requirements.)

(2) HCFA may impose alternative sanctions other than a civil money penalty after the laboratory has had an opportunity to respond, but before the hearing specified in § 493.1844.

(d) *Choice of sanction: Factors considered.* HCFA bases its choice of sanction or sanctions on consideration of one or more factors that include, but are not limited to, the following, as assessed by the State or by HCFA, or its agents:

(1) Whether the deficiencies pose immediate jeopardy.

(2) The nature, incidence, severity, and duration of the deficiencies or noncompliance.

(3) Whether the same condition level deficiencies have been identified repeatedly.

(4) The accuracy and extent of laboratory records (e.g., of remedial action) in regard to the noncompliance, and their availability to the State, to other HCFA agents, and to HCFA.

(5) The relationship of one deficiency or group of deficiencies to other deficiencies.

(6) The overall compliance history of the laboratory including but not limited to any period of noncompliance that occurred between certifications of compliance.

(7) The corrective and long-term compliance outcomes that HCFA hopes to achieve through application of the sanction.

(8) Whether the laboratory has made any progress toward improvement following a reasonable opportunity to correct deficiencies.

(9) Any recommendation by the State agency as to which sanction would be appropriate.

(e) *Number of alternative sanctions.* HCFA may impose a separate sanction for each condition level deficiency or a single sanction for all condition level deficiencies that are interrelated and subject to correction by a single course of action.

(f) *Appeal rights.* The appeal rights of laboratories dissatisfied with the imposition of a sanction are set forth in §493.1844.

[57 FR 7237, Feb. 28, 1992; 57 FR 35761, Aug. 11, 1992, as amended at 60 FR 20051, Apr. 24, 1995]

§493.1806 Available sanctions: All laboratories.

(a) *Applicability.* HCFA may impose one or more of the sanctions specified in this section on a laboratory that is out of compliance with one or more CLIA conditions.

(b) *Principal sanction.* HCFA may impose any of the three principal CLIA sanctions, which are suspension, limitation, or revocation of any type of CLIA certificate.

(c) *Alternative sanctions.* HCFA may impose one or more of the following alternative sanctions in lieu of or in addition to imposing a principal sanction, except on a laboratory that has a certificate of waiver.

(1) Directed plan of correction, as set forth at §493.1832.

(2) State onsite monitoring as set forth at §493.1836.

(3) Civil money penalty, as set forth at §493.1834.

(d) *Civil suit.* HCFA may bring suit in the appropriate U.S. District Court to enjoin continuation of any activity of any laboratory (including a CLIA-exempt laboratory that has been found with deficiencies during a validation survey), if HCFA has reason to believe that continuation of the activity would constitute a significant hazard to the public health.

(e) *Criminal sanctions.* Under section 353(1) of the PHS Act, an individual who is convicted of intentionally violating any CLIA requirement may be imprisoned or fined.

[57 FR 7237, Feb. 28, 1992, as amended at 58 FR 5237, Jan. 19, 1993]

§493.1807 Additional sanctions: Laboratories that participate in Medicare.

The following additional sanctions are available for laboratories that are out of compliance with one or more CLIA conditions and that have approval to receive Medicare payment for their services.

(a) *Principal sanction.* Cancellation of the laboratory's approval to receive Medicare payment for its services.

(b) *Alternative sanctions.* (1) Suspension of payment for tests in one or more specific specialties or subspecialties, performed on or after the effective date of sanction.

(2) Suspension of payment for all tests in all specialties and subspecialties performed on or after the effective date of sanction.

§493.1808 Adverse action on any type of CLIA certificate: Effect on Medicare approval.

(a) *Suspension or revocation of any type of CLIA certificate.* When HCFA suspends or revokes any type of CLIA certificate, HCFA concurrently cancels the laboratory's approval to receive Medicare payment for its services.

(b) *Limitation of any type of CLIA certificate.* When HCFA limits any type of CLIA certificate, HCFA concurrently limits Medicare approval to only those specialties or subspecialties that are authorized by the laboratory's limited certificate.

§493.1809 Limitation on Medicaid payment.

As provided in section 1902(a)(9)(C) of the Act, payment for laboratory services may be made under the State plan only if those services are furnished by a laboratory that has a CLIA certificate or is licensed by a State whose licensure program has been approved by the Secretary under this part.

[57 FR 7237, Feb. 28, 1992; 57 FR 35761, Aug. 11, 1992]

§493.1810 Imposition and lifting of alternative sanctions.

(a) *Notice of noncompliance and of proposed sanction: Content.* If HCFA or its agency identifies condition level noncompliance in a laboratory, HCFA or

its agent gives the laboratory written notice of the following:

(1) The condition level noncompliance that it has identified.

(2) The sanction or sanctions that HCFA or its agent proposes to impose against the laboratory.

(3) The rationale for the proposed sanction or sanctions.

(4) The projected effective date and duration of the proposed sanction or sanctions.

(5) The authority for the proposed sanction or sanctions.

(6) The time allowed (at least 10 days) for the laboratory to respond to the notice.

(b) *Opportunity to respond.* During the period specified in paragraph (a)(6) of this section, the laboratory may submit to HCFA or its agent written evidence or other information against the imposition of the proposed sanction or sanctions.

(c) *Notice of imposition of sanction*—(1) *Content.* HCFA gives the laboratory written notice that acknowledges any evidence or information received from the laboratory and specifies the following:

(i) The sanction or sanctions to be imposed against the laboratory.

(ii) The authority and rationale for the imposing sanction or sanctions.

(iii) The effective date and duration of sanction.

(2) *Timing.* (i) If HCFA or its agent determines that the deficiencies pose immediate jeopardy, HCFA provides notice at least 5 days before the effective date of sanction.

(ii) If HCFA or its agent determines that the deficiencies do not pose immediate jeopardy, HCFA provides notice at least 15 days before the effective date of the sanction.

(d) *Duration of alternative sanctions.* An alternative sanction continues until the earlier of the following occurs:

(1) The laboratory corrects all condition level deficiencies.

(2) HCFA's suspension, limitation, or revocation of the laboratory's CLIA certificate becomes effective.

(e) *Lifting of alternative sanctions*—(1) *General rule.* Alternative sanctions are not lifted until a laboratory's compliance with all condition level requirements is verified.

(2) *Credible allegation of compliance.* When a sanctioned laboratory submits a credible allegation of compliance, HCFA's agent determines whether—

(i) It can certify compliance on the basis of the evidence presented by the laboratory in its allegation; or

(ii) It must revisit to verify whether the laboratory has, in fact, achieved compliance.

(3) *Compliance achieved before the date of revisit.* If during a revisit, the laboratory presents credible evidence (as determined by HCFA or its agent) that it achieved compliance before the date of revisit, sanctions are lifted as of that earlier date.

§ 493.1812 Action when deficiencies pose immediate jeopardy.

If a laboratory's deficiencies pose immediate jeopardy, the following rules apply:

(a) HCFA requires the laboratory to take immediate action to remove the jeopardy and may impose one or more alternative sanctions to help bring the laboratory into compliance.

(b) If the findings of a revisit indicate that a laboratory has not eliminated the jeopardy, HCFA suspends or limits the laboratory's CLIA certificate no earlier than 5 days after the date of notice of suspension or limitation. HCFA may later revoke the certificate.

(c) In addition, if HCFA has reason to believe that the continuation of any activity by any laboratory (either the entire laboratory operation or any specialty or subspecialty of testing) would constitute a significant hazard to the public health, HCFA may bring suit and seek a temporary injunction or restraining order against continuation of that activity by the laboratory, regardless of the type of CLIA certificate the laboratory has and of whether it is State-exempt.

§ 493.1814 Action when deficiencies are at the condition level but do not pose immediate jeopardy.

If a laboratory has condition level deficiencies that do not pose immediate jeopardy, the following rules apply:

(a) *Initial action.* (1) HCFA may cancel the laboratory's approval to receive Medicare payment for its services.

(2) HCFA may suspend, limit, or revoke the laboratory's CLIA certificate.

(3) If HCFA does not impose a principal sanction under paragraph (a)(1) or (a)(2) of this section, it imposes one or more alternative sanctions. In the case of unsuccessful participation in proficiency testing, HCFA may impose the training and technical assistance requirement set forth at §493.1838 in lieu of, or in addition to, one or more alternative sanctions.

(b) *Failure to correct condition level deficiencies.* If HCFA imposes alternative sanctions for condition level deficiencies that do not pose immediate jeopardy, and the laboratory does not correct the condition level deficiencies within 12 months after the last day of inspection, HCFA—

(1) Cancels the laboratory's approval to receive Medicare payment for its services, and discontinues the Medicare payment sanctions as of the day cancellation is effective.

(2) Following a revisit which indicates that the laboratory has not corrected its condition level deficiencies, notifies the laboratory that it proposes to suspend, limit, or revoke the certificate, as specified in §493.1816(b), and the laboratory's right to hearing; and

(3) May impose (or continue, if already imposed) any alternative sanctions that do not pertain to Medicare payments. (Sanctions imposed under the authority of section 353 of the PHS Act may continue for more than 12 months from the last date of inspection, while a hearing on the proposed suspension, limitation, or revocation of the certificate of compliance, registration certificate, certificate of accreditation, or certificate for PPM procedures is pending.)

(c) *Action after hearing.* If a hearing decision upholds a proposed suspension, limitation, or revocation of a laboratory's CLIA certificate, HCFA discontinues any alternative sanctions as of the day it makes the suspension, limitation, or revocation effective.

[57 FR 7237, Feb. 28, 1992, as amended at 60 FR 20051, Apr. 24, 1995]

§493.1816 Action when deficiencies are not at the condition level.

If a laboratory has deficiencies, that are not at the condition level, the following rules apply:

(a) *Initial action.* The laboratory must submit a plan of correction that is acceptable to HCFA in content and time frames.

(b) *Failure to correct deficiencies.* If, on revisit, it is found that the laboratory has not corrected the deficiencies within 12 months after the last day of inspection, the following rules apply:

(1) HCFA cancels the laboratory's approval to receive Medicare payment for its services.

(2) HCFA notifies the laboratory of its intent to suspend, limit, or revoke the laboratory's CLIA certificate and of the laboratory's right to a hearing.

§493.1820 Ensuring timely correction of deficiencies.

(a) *Timing of visits.* HCFA, the State survey agency or other HCFA agent may visit the laboratory at any time to evaluate progress, and at the end of the period to determine whether all corrections have been made.

(b) *Deficiencies corrected before a visit.* If during a visit, a laboratory produces credible evidence that it achieved compliance before the visit, the sanctions are lifted as of that earlier date.

(c) *Failure to correct deficiencies.* If during a visit it is found that the laboratory has not corrected its deficiencies, HCFA may propose to suspend, limit, or revoke the laboratory's CLIA certificate.

(d) *Additional time for correcting lower level deficiencies* not at the condition level. If at the end of the plan of correction period all condition level deficiencies have been corrected, and there are deficiencies, that are not at the condition level, HCFA may request a revised plan of correction. The revised plan may not extend beyond 12 months from the last day of the inspection that originally identified the cited deficiencies.

(e) *Persistence of deficiencies.* If at the end of the period covered by the plan of correction, the laboratory still has deficiencies, the rules of §§493.1814 and 493.1816 apply.

§ 493.1826 Suspension of part of Medicare payments.

(a) *Application.* (1) HCFA may impose this sanction if a laboratory—

(i) Is found to have condition level deficiencies with respect to one or more specialties or subspecialties of tests; and

(ii) Agrees (in return for not having its Medicare approval cancelled immediately) not to charge Medicare beneficiaries or their private insurance carriers for the services for which Medicare payment is suspended.

(2) HCFA suspends Medicare payment for those specialities or subspecialties of tests for which the laboratory is out of compliance with Federal requirements.

(b) *Procedures.* Before imposing this sanction, HCFA provides notice of sanction and opportunity to respond in accordance with § 493.1810.

(c) *Duration and effect of sanction.* This sanction continues until the laboratory corrects the condition level deficiencies or HCFA cancels the laboratory's approval to receive Medicare payment for its services, but in no event longer than 12 months.

(1) If the laboratory corrects all condition level deficiencies, HCFA resumes Medicare payment effective for all services furnished on or after the date the deficiencies are corrected.

(2) [Reserved]

[57 FR 7237, Feb. 28, 1992; 57 FR 35761, Aug. 11, 1992]

§ 493.1828 Suspension of all Medicare payments.

(a) *Application.* (1) HCFA may suspend payment for all Medicare-approved laboratory services when the laboratory has condition level deficiencies.

(2) HCFA suspends payment for all Medicare covered laboratory services when the following conditions are met:

(i) Either—

(A) The laboratory has not corrected its condition level deficiencies included in the plan of correction within 3 months from the last date of inspection; or

(B) The laboratory has been found to have the same condition level deficiencies during three consecutive inspections; and

(ii) The laboratory has chosen (in return for not having its Medicare approval immediately cancelled), to not charge Medicare beneficiaries or their private insurance carriers for services for which Medicare payment is suspended.

(3) HCFA suspends payment for services furnished on and after the effective date of sanction.

(b) *Procedures.* Before imposing this sanction, HCFA provides notice of sanction and opportunity to respond in accordance with § 493.1810.

(c) *Duration and effect of sanction.* (1) Suspension of payment continues until all condition level deficiencies are corrected, but never beyond twelve months.

(2) If all the deficiencies are not corrected by the end of the 12 month period, HCFA cancels the laboratory's approval to receive Medicare payment for its services.

§ 493.1832 Directed plan of correction and directed portion of a plan of correction.

(a) *Application.* HCFA may impose a directed plan of correction as an alternative sanction for any laboratory that has condition level deficiencies. If HCFA does not impose a directed plan of correction as an alternative sanction for a laboratory that has condition level deficiencies, it at least imposes a directed portion of a plan of correction when it imposes any of the following alternative sanctions:

(1) State onsite monitoring.

(2) Civil money penalty.

(3) Suspension of all or part of Medicare payments.

(b) *Procedures*—(1) *Directed plan of correction.* When imposing this sanction, HCFA—

(i) Gives the laboratory prior notice of the sanction and opportunity to respond in accordance with § 493.1810;

(ii) Directs the laboratory to take specific corrective action within specific time frames in order to achieve compliance; and

(iii) May direct the laboratory to submit the names of laboratory clients for notification purposes, as specified in paragraph (b)(3) of this section.

(2) *Directed portion of a plan of correction.* HCFA may decide to notify clients

of a sanctioned laboratory, because of the seriousness of the noncompliance (e.g., the existence of immediate jeopardy) or for other reasons. When imposing this sanction, HCFA takes the following steps—

(i) Directs the laboratory to submit to HCFA, the State survey agency, or other HCFA agent, within 10 calendar days after the notice of the alternative sanction, a list of names and addresses of all physicians, providers, suppliers, and other clients who have used some or all of the services of the laboratory since the last certification inspection or within any other timeframe specified by HCFA.

(ii) Within 30 calendar days of receipt of the information, may send to each laboratory client, via the State survey agency, a notice containing the name and address of the laboratory, the nature of the laboratory's noncompliance, and the kind and effective date of the alternative sanction.

(iii) Sends to each laboratory client, via the State survey agency, notice of the recission of an adverse action within 30 days of the rescission.

(3) *Notice of imposition of a principal sanction following the imposition of an alternative sanction.* If HCFA imposes a principal sanction following the imposition of an alternative sanction, and for which HCFA has already obtained a list of laboratory clients, HCFA may use that list to notify the clients of the imposition of the principal sanction.

(c) *Duration of a directed plan of correction.* If HCFA imposes a directed plan of correction, and on revisit it is found that the laboratory has not corrected the deficiencies within 12 months from the last day of inspection, the following rules apply:

(1) HCFA cancels the laboratory's approval for Medicare payment of its services, and notifies the laboratory of HCFA's intent to suspend, limit, or revoke the laboratory's CLIA certificate.

(2) The directed plan of correction continues in effect until the day suspension, limitation, or revocation of the laboratory's CLIA certificate.

§493.1834 Civil money penalty.

(a) *Statutory basis.* Sections 1846 of the Act and 353(h)(2)(B) of the PHS Act authorize the Secretary to impose civil money penalties on laboratories. Section 1846(b)(3) of the Act specifically provides that incrementally more severe fines may be imposed for repeated or uncorrected deficiencies.

(b) *Scope.* This section sets forth the procedures that HCFA follows to impose a civil money penalty in lieu of, or in addition to, suspending, limiting, or revoking the certificate of compliance, registration certificate, certificate of accreditation, or certificate for PPM procedures of a laboratory that is found to have condition level deficiencies.

(c) *Basis for imposing a civil money penalty.* HCFA may impose a civil money penalty against any laboratory determined to have condition level deficiencies regardless of whether those deficiencies pose immediate jeopardy.

(d) *Amount of penalty*—(1) *Factors considered.* In determining the amount of the penalty, HCFA takes into account the following factors:

(i) The nature, scope, severity, and duration of the noncompliance.

(ii) Whether the same condition level deficiencies have been identified during three consecutive inspections.

(iii) The laboratory's overall compliance history including but not limited to any period of noncompliance that occurred between certifications of compliance.

(iv) The laboratory's intent or reason for noncompliance.

(v) The accuracy and extent of laboratory records and their availability to HCFA, the State survey agency, or other HCFA agent.

(2) *Range of penalty amount.*

(i) For a condition level deficiency that poses immediate jeopardy, the range is $3,050–$10,000 per day of noncompliance or per violation.

(ii) For a condition level deficiency that does not pose immediate jeopardy, the range is $50–$3,000 per day of noncompliance or per violation.

(3) *Decreased penalty amounts.* If the immediate jeopardy is removed, but the deficiency continues, HCFA shifts the penalty amount to the lower range.

(4) *Increased penalty amounts.* HCFA may, before the hearing, propose to increase the penalty amount for a laboratory that has deficiencies which, after imposition of a lower level penalty

amount, become sufficiently serious to pose immediate jeopardy.

(e) *Procedures for imposition of civil money penalty*—(1) *Notice of intent.* (i) HCFA sends the laboratory written notice, of HCFA's intent to impose a civil money penalty.

(ii) The notice includes the following information:

(A) The statutory basis for the penalty.

(B) The proposed daily or per violation amount of the penalty.

(C) The factors (as described in paragraph (d)(1) of this section) that HCFA considered.

(D) The opportunity for responding to the notice in accordance with § 493.1810(c).

(E) A specific statement regarding the laboratory's appeal rights.

(2) *Appeal rights.* (i) The laboratory has 60 days from the date of receipt of the notice of intent to impose a civil money penalty to request a hearing in accordance with § 493.1844(g).

(ii) If the laboratory requests a hearing, all other pertinent provisions of § 493.1844 apply.

(iii) If the laboratory does not request a hearing, HCFA may reduce the proposed penalty amount by 35 percent.

(f) *Accrual and duration of penalty*—(1) *Accrual of penalty.* The civil money penalty begins accruing as follows:

(i) 5 days after notice of intent if there is immediate jeopardy.

(ii) 15 days after notice of intent if there is not immediate jeopardy.

(2) *Duration of penalty.* The civil money penalty continues to accrue until the earliest of the following occurs:

(i) The laboratory's compliance with condition level requirements is verified on the basis of the evidence presented by the laboratory in its credible allegation of compliance or at the time or revisit.

(ii) Based on credible evidence presented by the laboratory at the time of revisit, HCFA determines that compliance was achieved before the revisit. (In this situation, the money penalty stops accruing as of the date of compliance.)

(iii) HCFA suspends, limits, or revokes the laboratory's certificate of compliance, registration certificate, certificate of accreditation, or certificate for PPM procedures.

(g) *Computation and notice of total penalty amount*—(1) *Computation.* HCFA computes the total penalty amount after the laboratory's compliance is verified or HCFA suspends, limits, or revokes the laboratory's CLIA certificate but in no event before—

(i) The 60 day period for requesting a hearing has expired without a request or the laboratory has explicitly waived its right to a hearing; or

(ii) Following a hearing requested by the laboratory, the ALJ issues a decision that upholds imposition of the penalty.

(2) *Notice of penalty amount and due date of penalty.* The notice includes the following information:

(i) Daily or per violation penalty amount.

(ii) Number of days or violations for which the penalty is imposed.

(iii) Total penalty amount.

(iv) Due date for payment of the penalty.

(h) *Due date for payment of penalty.* (1) Payment of a civil money penalty is due 15 days from the date of the notice specified in paragraph (g)(2) of this section.

(2) HCFA may approve a plan for a laboratory to pay a civil money penalty, plus interest, over a period of up to one year from the original due date.

(i) *Collection and settlement*—(1) *Collection of penalty amounts.* (i) The determined penalty amount may be deducted from any sums then or later owing by the United States to the laboratory subject to the penalty.

(ii) Interest accrues on the unpaid balance of the penalty, beginning on the due date. Interest is computed at the rate specified in § 405.378(d) of this chapter.

(2) *Settlement.* HCFA has authority to settle any case at any time before the ALJ issues a hearing decision.

[57 FR 7237, Feb. 28, 1992, as amended at 60 FR 20051, Apr. 24, 1995; 61 FR 63749, Dec. 2, 1996]

§ 493.1836 State onsite monitoring.

(a) *Application.* (1) HCFA may require continuous or intermittent monitoring of a plan of correction by the State

survey agency to ensure that the laboratory makes the improvements necessary to bring it into compliance with the condition level requirements. (The State monitor does not have management authority, that is, cannot hire or fire staff, obligate funds, or otherwise dictate how the laboratory operates. The monitor's responsibility is to oversee whether corrections are made.)

(2) The laboratory must pay the costs of onsite monitoring by the State survey agency.

(i) The costs are computed by multiplying the number of hours of onsite monitoring in the laboratory by the hourly rate negotiated by HCFA and the State.

(ii) The hourly rate includes salary, fringe benefits, travel, and other direct and indirect costs approved by HCFA.

(b) *Procedures.* Before imposing this sanction, HCFA provides notice of sanction and opportunity to respond in accordance with §493.1810.

(c) *Duration of sanction.* (1) If HCFA imposes onsite monitoring, the sanction continues until HCFA determines that the laboratory has the capability to ensure compliance with all condition level requirements.

(2) If the laboratory does not correct all deficiencies within 12 months, and a revisit indicates that deficiencies remain, HCFA cancels the laboratory's approval for Medicare payment for its services and notifies the laboratory of its intent to suspend, limit, or revoke the laboratory's certificate of compliance, registration certificate, certificate of accreditation, or certificate for PPM procedures.

(3) If the laboratory still does not correct its deficiencies, the Medicare sanction continues until the suspension, limitation, or revocation of the laboratory's certificate of compliance, registration certificate, certificate of accreditation, or certificate for PPM procedures is effective.

[57 FR 7237, Feb. 28, 1992, as amended at 60 FR 20051, Apr. 24, 1995]

§493.1838 Training and technical assistance for unsuccessful participation in proficiency testing.

If a laboratory's participation in proficiency testing is unsuccessful, HCFA may require the laboratory to undertake training of its personnel, or to obtain necessary technical assistance, or both, in order to meet the requirements of the proficiency testing program. This requirement is separate from the principal and alternative sanctions set forth in §§493.1806 and 493.1807.

§493.1840 Suspension, limitation, or revocation of any type of CLIA certificate.

(a) *Adverse action based on actions of the laboratory's owner, operator or employees.* HCFA may initiate adverse action to suspend, limit or revoke any CLIA certificate if HCFA finds that a laboratory's owner or operator or one of its employees has—

(1) Been guilty of misrepresentation in obtaining a CLIA certificate;

(2) Performed, or represented the laboratory as entitled to perform, a laboratory examination or other procedure that is not within a category of laboratory examinations or other procedures authorized by its CLIA certificate;

(3) Failed to comply with the certificate requirements and performance standards;

(4) Failed to comply with reasonable requests by HCFA for any information or work on materials that HCFA concludes is necessary to determine the laboratory's continued eligibility for its CLIA certificate or continued compliance with performance standards set by HCFA;

(5) Refused a reasonable request by HCFA or its agent for permission to inspect the laboratory and its operation and pertinent records during the hours that the laboratory is in operation;

(6) Violated or aided and abetted in the violation of any provisions of CLIA and its implementing regulations;

(7) Failed to comply with an alternative sanction imposed under this subpart; or

(8) Within the preceding two-year period, owned or operated a laboratory that had its CLIA certificate revoked. (This provision applies only to the owner or operator, not to all of the laboratory's employees.)

(b) *Adverse action based on improper referrals in proficiency testing.* If HCFA determines that a laboratory has intentionally referred its proficiency testing samples to another laboratory for analysis, HCFA revokes the laboratory's CLIA certificate for at least one year, and may also impose a civil money penalty.

(c) *Adverse action based on exclusion from Medicare.* If the OIG excludes a laboratory from participation in Medicare, HCFA suspends the laboratory's CLIA certificate for the period during which the laboratory is excluded.

(d) *Procedures for suspension or limitation*—(1) *Basic rule.* Except as provided in paragraph (d)(2) of this section, HCFA does not suspend or limit a CLIA certificate until after an ALJ hearing decision (as provided in §493.1844) that upholds suspension or limitation.

(2) *Exceptions.* HCFA may suspend or limit a CLIA certificate before the ALJ hearing in any of the following circumstances:

(i) The laboratory's deficiencies pose immediate jeopardy.

(ii) The laboratory has refused a reasonable request for information or work on materials.

(iii) The laboratory has refused permission for HCFA or a HCFA agent to inspect the laboratory or its operation.

(e) *Procedures for revocation.* (1) HCFA does not revoke any type of CLIA certificate until after an ALJ hearing that upholds revocation.

(2) HCFA may revoke a CLIA certificate after the hearing decision even if it had not previously suspended or limited that certificate.

(f) *Notice to the OIG.* HCFA notifies the OIG of any violations under paragraphs (a)(1), (a)(2), (a)(6), and (b) of this section within 30 days of the determination of the violation.

§493.1842 Cancellation of Medicare approval.

(a) *Basis for cancellation.* (1) HCFA always cancels a laboratory's approval to receive Medicare payment for its services if HCFA suspends or revokes the laboratory's CLIA certificate.

(2) HCFA may cancel the laboratory's approval under any of the following circumstances:

(i) The laboratory is out of compliance with a condition level requirement.

(ii) The laboratory fails to submit a plan of correction satisfactory to HCFA.

(iii) The laboratory fails to correct all its deficiencies within the time frames specified in the plan of correction.

(b) *Notice and opportunity to respond.* Before canceling a laboratory's approval to receive Medicare payment for its services, HCFA gives the laboratory—

(1) Written notice of the rationale for, effective date, and effect of, cancellation;

(2) Opportunity to submit written evidence or other information against cancellation of the laboratory's approval.

This sanction may be imposed before the hearing that may be requested by a laboratory, in accordance with the appeals procedures set forth in §493.1844.

(c) *Effect of cancellation.* Cancellation of Medicare approval terminates any Medicare payment sanctions regardless of the time frames originally specified.

§493.1844 Appeals procedures.

(a) *General rules.* (1) The provisions of this section apply to all laboratories and prospective laboratories that are dissatisfied with any initial determination under paragraph (b) of this section.

(2) Hearings are conducted in accordance with procedures set forth in subpart D of part 498 of this chapter, except that the authority to conduct hearings and issue decisions may be exercised by ALJs assigned to, or detailed to, the Departmental Appeals Board.

(3) Any party dissatisfied with a hearing decision is entitled to request review of the decision as specified in subpart E of part 498 of this chapter, except that the authority to review the decision may be exercised by the Departmental Appeals Board.

(4) When more than one of the actions specified in paragraph (b) of this section are carried out concurrently, the laboratory has a right to only one hearing on all matters at issue.

(b) *Actions that are initial determinations.* The following actions are initial determinations and therefore are subject to appeal in accordance with this section:

(1) The suspension, limitation, or revocation of the laboratory's CLIA certificate by HCFA because of noncompliance with CLIA requirements.

(2) The denial of a CLIA certificate.

(3) The imposition of alternative sanctions under this subpart (but not the determination as to which alternative sanction or sanctions to impose).

(4) The denial or cancellation of the laboratory's approval to receive Medicare payment for its services.

(c) *Actions that are not initial determinations.* Actions that are not listed in paragraph (b) of this section are not initial determinations and therefore are not subject to appeal under this section. They include, but are not necessarily limited to, the following:

(1) The finding that a laboratory accredited by a HCFA-approved accreditation organization is no longer deemed to meet the conditions set forth in subparts H, J, K, M, P, and Q of this part. However, the suspension, limitation or revocation of a certificate of accreditation is an initial determination and is appealable.

(2) The finding that a laboratory determined to be in compliance with condition-level requirements but has deficiencies that are not at the condition level.

(3) The determination not to reinstate a suspended CLIA certificate because the reason for the suspension has not been removed or there is insufficient assurance that the reason will not recur.

(4) The determination as to which alternative sanction or sanctions to impose, including the amount of a civil money penalty to impose per day or per violation.

(5) The denial of approval for Medicare payment for the services of a laboratory that does not have in effect a valid CLIA certificate.

(6) The determination that a laboratory's deficiencies pose immediate jeopardy.

(7) The amount of the civil money penalty assessed per day or for each violation of Federal requirements.

(d) *Effect of pending appeals*—(1) *Alternative sanctions.* The effective date of an alternative sanction (other than a civil money penalty) is not delayed because the laboratory has appealed and the hearing or the hearing decision is pending.

(2) *Suspension, limitation, or revocation of a laboratory's CLIA certificate*—(i) *General rule.* Except as provided in paragraph (d)(2)(ii) of this section, suspension, limitation, or revocation of a CLIA certificate is not effective until after a hearing decision by an ALJ is issued.

(ii) *Exceptions.* (A) If HCFA determines that conditions at a laboratory pose immediate jeopardy, the effective date of the suspension or limitation of a CLIA certificate is not delayed because the laboratory has appealed and the hearing or the hearing decision is pending.

(B) HCFA may suspend or limit a laboratory's CLIA certificate before an ALJ hearing or hearing decision if the laboratory has refused a reasonable request for information (including but not limited to billing information), or for work on materials, or has refused permission for HCFA or a HCFA agent to inspect the laboratory or its operation.

(3) *Cancellation of Medicare approval.* The effective date of the cancellation of a laboratory's approval to receive Medicare payment for its services is not delayed because the laboratory has appealed and the hearing or hearing decision is pending.

(4) *Effect of ALJ decision.* (i) An ALJ decision is final unless, as provided in paragraph (a)(3) of this section, one of the parties requests review by the Departmental Appeals Board within 60 days, and the Board reviews the case and issues a revised decision.

(ii) If an ALJ decision upholds a suspension imposed because of immediate jeopardy, that suspension becomes a revocation.

(e) *Appeal rights for prospective laboratories*—(1) *Reconsideration.* Any prospective laboratory dissatisfied with a denial of a CLIA certificate, or of approval for Medicare payment for its

services, may initiate the appeals process by requesting reconsideration in accordance with §§ 498.22 through 498.25 of this chapter.

(2) *Notice of reopening.* If HCFA reopens an initial or reconsidered determination, HCFA gives the prospective laboratory notice of the revised determination in accordance with § 498.32 of this chapter.

(3) *ALJ hearing.* Any prospective laboratory dissatisfied with a reconsidered determination under paragraph (e)(1) of this section or a revised reconsidered determination under § 498.30 of this chapter is entitled to a hearing before an ALJ, as specified in paragraph (a)(2) of this section.

(4) *Review of ALJ hearing decisions.* Any prospective laboratory that is dissatisfied with an ALJ's hearing decision or dismissal of a request for hearing may file a written request for review by the Departmental Appeals Board as provided in paragraph (a)(3) of this section.

(f) *Appeal rights of laboratories*—(1) *ALJ hearing.* Any laboratory dissatisfied with the suspension, limitation, or revocation of its CLIA certificate, with the imposition of an alternative sanction under this subpart, or with cancellation of the approval to receive Medicare payment for its services, is entitled to a hearing before an ALJ as specified in paragraph (a)(2) of this section and has 60 days from the notice of sanction to request a hearing.

(2) *Review of ALJ hearing decisions.* Any laboratory that is dissatisfied with an ALJ's hearing decision or dismissal of a request for hearing may file a written request for review by the Departmental Appeals Board, as provided in paragraph (a)(3) of this section.

(3) *Judicial review.* Any laboratory dissatisfied with the decision to impose a civil money penalty or to suspend, limit, or revoke its CLIA certificate may, within 60 days after the decision becomes final, file with the U.S. Court of Appeals of the circuit in which the laboratory has its principal place of business, a petition for judicial review.

(g) *Notice of adverse action.* (1) If HCFA suspends, limits, or revokes a laboratory's CLIA certificate or cancels the approval to receive Medicare payment for its services, HCFA gives notice to the laboratory, and may give notice to physicians, providers, suppliers, and other laboratory clients, according to the procedures set forth at § 493.1832. In addition, HCFA notifies the general public each time one of these principal sanctions is imposed.

(2) The notice to the laboratory—

(i) Sets forth the reasons for the adverse action, the effective date and effect of that action, and the appeal rights if any; and

(ii) When the certificate is limited, specifies the specialties or subspecialties of tests that the laboratory is no longer authorized to perform, and that are no longer covered under Medicare.

(3) The notice to other entities includes the same information except the information about the laboratory's appeal rights.

(h) *Effective date of adverse action.* (1) When the laboratory's deficiencies pose immediate jeopardy, the effective date of the adverse action is at least 5 days after the date of the notice.

(2) When HCFA determines that the laboratory's deficiencies do not pose immediate jeopardy, the effective date of the adverse action is at least 15 days after the date of the notice.

[57 FR 7237, Feb. 28, 1992; 57 FR 35761, Aug. 11, 1992]

§ 493.1846 Civil action.

If HCFA has reason to believe that continuation of the activities of any laboratory, including a State-exempt laboratory, would constitute a significant hazard to the public health, HCFA may bring suit in a U.S. District Court to enjoin continuation of the specific activity that is causing the hazard or to enjoin the continued operation of the laboratory if HCFA deems it necessary. Upon proper showing, the court shall issue a temporary injunction or restraining order without bond against continuation of the activity.

§ 493.1850 Laboratory registry.

(a) Once a year HCFA makes available to physicians and to the general public specific information (including information provided to HCFA by the OIG) that is useful in evaluating the performance of laboratories, including the following:

(1) A list of laboratories that have been convicted, under Federal or State laws relating to fraud and abuse, false billing, or kickbacks.

(2) A list of laboratories that have had their CLIA certificates suspended, limited, or revoked, and the reason for the adverse actions.

(3) A list of persons who have been convicted of violating CLIA requirements, as specified in section 353(1) of the PHS Act, together with the circumstances of each case and the penalties imposed.

(4) A list of laboratories on which alternative sanctions have been imposed, showing—

(i) The effective date of the sanctions;

(ii) The reasons for imposing them;

(iii) Any corrective action taken by the laboratory; and

(iv) If the laboratory has achieved compliance, the verified date of compliance.

(5) A list of laboratories whose accreditation has been withdrawn or revoked and the reasons for the withdrawal or revocation.

(6) All appeals and hearing decisions.

(7) A list of laboratories against which HCFA has brought suit under § 493.1846 and the reasons for those actions.

(8) A list of laboratories that have been excluded from participation in Medicare or Medicaid and the reasons for the exclusion.

(b) The laboratory registry is compiled for the calendar year preceding the date the information is made available and includes appropriate explanatory information to aid in the interpretation of the data. It also contains corrections of any erroneous statements or information that appeared in the previous registry.

Subpart S [Reserved]

Subpart T—Consultations

SOURCE: 57 FR 7185, Feb. 28, 1992, unless otherwise noted.

§ 493.2001 Establishment and function of the Clinical Laboratory Improvement Advisory Committee.

(a) HHS will establish a Clinical Laboratory Improvement Advisory Committee to advise and make recommendations on technical and scientific aspects of the provisions of this part 493.

(b) The Clinical Laboratory Improvement Advisory Committee will be comprised of individuals involved in the provision of laboratory services, utilization of laboratory services, development of laboratory testing or methodology, and others as approved by HHS.

(c) HHS will designate specialized subcommittees as necessary.

(d) The Clinical Laboratory Improvement Advisory Committee or any designated subcommittees will meet as needed, but not less than once each year.

(e) The Clinical Laboratory Improvement Advisory Committee or subcommittee, at the request of HHS, will review and make recommendations concerning:

(1) Criteria for categorizing tests and examinations of moderate complexity (including the subcategory) and high complexity;

(2) Determination of waived tests;

(3) Personnel standards;

(4) Patient test management, quality control, quality assurance standards;

(5) Proficiency testing standards;

(6) Applicability to the standards of new technology; and

(7) Other issues relevant to part 493, if requested by HHS.

(f) HHS will be responsible for providing the data and information, as necessary, to the members of the Clinical Laboratory Improvement Advisory Committee.

[57 FR 7185, Feb. 28, 1992, as amended at 58 FR 5237, Jan. 19, 1993; 60 FR 20051, Apr. 24, 1995]

PART 494 [RESERVED]