

imported from abroad for the temporary exhibit without profit within the United States are of cultural significance. These objects are imported pursuant to loan agreements with the foreign lenders. I also determine that the temporary exhibition or display of the listed exhibit objects at the Metropolitan Museum of Art in New York, N.Y., beginning on or about June 6, 1990, to on or about November 4, 1990, is in the national interest.

Public Notice of this determination is ordered to be published in the **Federal Register**.

Dated: March 5, 1990.

Alberto J. Mora,
General Counsel.

[FR Doc. 90-5851 Filed 3-13-90; 8:45 am]

BILLING CODE 6230-01-M

202/485-7978, and the address is room 700, U.S. Information Agency, 301 Fourth Street, SW., Washington, DC 20547.

Culturally Significant Objects Imported for Exhibition; Determination

Notice is hereby given of the following determination: Pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985, 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978 (43 FR 13359, March 29, 1978), and Delegation Order No. 85-5 of June 27, 1985 (50 FR 27393, July 2, 1985), I hereby determine that the objects to be included in the exhibit, "From Poussin To Matisse: The Russian Taste For French Painting: A Loan Exhibition From the U.S.S.R." (see list ¹) imported from abroad for the temporary exhibition without profit within the United States are of cultural significance. These objects are imported

¹ A copy of this list may be obtained by contacting Mr. R. Wallace Stuart of the Office of the General Counsel of USIA. The telephone number is 202/485-7978, and the address is Room 700, U.S. Information Agency, 301 Fourth Street, SW., Washington, DC 20547.

pursuant to loan agreements with the foreign lenders. I also determine that the temporary exhibition or display of the listed exhibit objects at the Metropolitan Museum of Art in New York, N.Y., beginning on or about May 20, 1990, to on or about July 29, 1990, and at The Art Institute of Chicago, beginning on or about September 8, 1990 to on or about November 25, 1990, is in the national interest.

Public notice of this determination is ordered to be published in the **Federal Register**.

Dated: March 5, 1990.

Alberto J. Mora,
General Counsel.

[FR Doc. 90-5852 Filed 3-13-90; 8:45 am]

BILLING CODE 6230-01-M

Sunshine Act Meetings

Federal Register

Vol. 55, No. 50

Wednesday, March 14, 1990

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice of a Matter To Be Withdrawn From Consideration at an Agency Meeting

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given that the following matter will be withdrawn from the "discussion agenda" for consideration at the open meeting of the Board of Directors of the Federal Deposit Insurance Corporation scheduled to be held at 2:00 p.m. on Tuesday, March 13, 1990, in the Board Room on the sixth floor of the FDIC Building located at 550 17th Street NW., Washington, DC:

Memorandum re: Failing Bank Bidding Priority.

Requests for further information concerning the meeting may be directed to Mr. Hoyle L. Robinson, Executive Secretary of the Corporation, at (202) 898-3813.

Dated: March 9, 1990.
Federal Deposit Insurance Corporation.
Hoyle L. Robinson,
Executive Secretary.
[FR Doc. 90-5906 Filed 3-9-90; 5:04 pm]
BILLING CODE 6714-01-M

FEDERAL MARITIME COMMISSION

TIME AND DATE: 2:00 p.m., March 19, 1990.

PLACE: Hearing Room One, 1100 L Street, NW., Washington, DC 20573-0001.

STATUS: Part of the meeting will be open to the public, the rest of the meeting will be closed to the public.

MATTERS TO BE CONSIDERED:

Portion Open to the Public

1. Petition No. P6-89—*Motor Vehicle Manufacturers Association of the United States, Inc.—Application for Exemption of Vehicle Shipments from Portions of the Shipping Act of 1984*. Consideration of Comments.

Portion Closed to the Public

1. Docket No. 89-02—*Matson Navigation Company, Inc.: Transportation of Cargoes Between Ports and Points Outside Hawaii and Islands Within the State of Hawaii*—Consideration of the Record.

CONTACT PERSON FOR MORE

INFORMATION: Joseph C. Polking,
Secretary. (202) 523-5725.

Joseph C. Polking,
Secretary.

[FR Doc. 90-5985 Filed 3-12-90; 12:02 pm]

BILLING CODE 6730-01-M

UNITED STATES POSTAL SERVICE BOARD OF GOVERNORS

Notice of Vote To Close Meeting

At its meeting of March 5, 1990, the Board of Governors of the United States Postal Service voted unanimously to close to public observation its meeting scheduled for April 2, 1990, in Raleigh, North Carolina. The members will discuss possible strategies in collective bargaining negotiations.

The meeting is expected to be attended by the following persons:

Governors Alvarado, del Junco, Griesemer, Hall, Mackie, Nevin, Pace, Ryan and Setrakian; Postmaster General Frank, Deputy Postmaster General Coughlin, Secretary to the Board Harris, and General Counsel Hughes.

The Board determined that pursuant to section 552b(c)(3) of Title 5, United States Code, and §7.3(c) of Title 39, Code of Federal Regulations, this portion of the meeting is exempt from the open meeting requirement of the Government in the Sunshine Act [5 U.S.C. 552b(b)] because it is likely to disclose information prepared for use in connection with the negotiation of collective bargaining agreements under Chapter 12 of Title 39, United States Code, which is specifically exempted from disclosure by section 410(c)(3) of Title 39, United States Code.

In accordance with section 552b(f)(1) of title 5, United States Code, and §7.6(a) of title 39, Code of Federal Regulations, the General Counsel of the United States Postal Service has certified that in his opinion the meeting may properly be closed to public observation pursuant to section 552b(c)(3) of title 5, United States Code; section 410(c)(3) of title 39, United States Code; and § 7.3(C) of title 39, Code of the Federal Regulations.

Request for information about the meeting should be addressed to the Secretary of the Board, David F. Harris, at (202) 268-4800.

David F. Harris,
Secretary.

[FR Doc. 90-5973 Filed 3-12-90; 11:18 am]

BILLING CODE 7710-12-M

Corrections

Federal Register

Vol. 55, No. 50

Wednesday, March 14, 1990

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. MT89-7-001, et al.]

Nora Transmission Co., et al.; Natural Gas Pipeline Rate Filings

Correction

In notice document 90-3881 beginning on page 6041 in the issue of Wednesday, February 21, 1990, make the following correction:

On page 6042, in the first column, under entry 3, in the second line, "February 9, 1990." should read "February 12, 1990".

BILLING CODE 1505-01-D

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. ER90-193-000 et al.]

Northeast Utilities Service Co. et al.; Electric Rate, Small Power Production, and Interlocking Directorate Filings

Correction

In notice document 90-4347 beginning on page 6821 in the issue of Tuesday,

February 27, 1990, make the following corrections:

1. On page 6823, in the first column, under entry 11, in the second line "February 15, 1990." should read "February 14, 1990".

2. On page 6824, in the third column, under entry 23, in the second line, "February 16, 1990." should read "February 20, 1990".

BILLING CODE 1505-01-D

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. TQ90-3-38-000]

Ringwood Gathering Co.; Proposed Changes in Gas Tariff

Correction

In notice document 90-5236 appearing on page 8517 in the issue of Thursday, March 8, 1990, make the following correction:

On page 8517, in the second column, the docket number should read as set forth above.

BILLING CODE 1505-01-D

FEDERAL MARITIME COMMISSION

Agreement(s) Filed

Correction

In notice document 90-4583 beginning on page 7371 in the issue of Thursday, March 1, 1990, make the following correction:

On page 7371, in the third column, after the second paragraph, insert "Agreement No.: 224-010721-002".

BILLING CODE 1505-01-D

FEDERAL MARITIME COMMISSION

Agreement(s) Filed

Correction

In notice document 90-4587 appearing on page 7372 in the issue of Thursday, March 1, 1990, make the following correction:

In the first column, after the second paragraph, insert "Agreement No.: 224-200327".

BILLING CODE 1505-01-D

FEDERAL MARITIME COMMISSION

Agreement(s) Filed

Correction

In notice document 90-4957 appearing on page 7938 in the issue of Tuesday, March 6, 1990, make the following corrections:

1. In the second column, after the second paragraph, insert "Agreement No.: 224-200328".

2. In the third column, after the eighth line, insert "Agreement No.: 224-200295-001".

BILLING CODE 1505-01-D

Wednesday
March 14, 1990

Part II

**Department of
Health and Human
Services**

Health Care Financing Administration

42 CFR Part 74 et al.

**Medicare, Medicaid and CLIA Programs;
Revision of Laboratory Regulations; Final
Rule With Request For Comments**

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 74, 405, 416, 440, 482, 483, 488, and 493

[HSQ-146-FC]

RIN 0938-AB96

Medicare, Medicaid and CLIA Programs; Revision of the Laboratory Regulations for the Medicare, Medicaid, and Clinical Laboratories Improvement Act of 1967 Programs

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule with comment period.

SUMMARY: This rule revises regulations for laboratories regulated under the Medicare, Medicaid and Clinical Laboratories Improvement Act of 1967 (CLIA '67) programs. The revisions recodify the regulations for these programs into a new part 493 in order to simplify administration and unify the health and safety requirements for all programs as much as possible. We will now have a single set of regulations for the three programs, with an additional subpart for the licensure procedures unique to the CLIA program.

We are revising the regulations to remove outdated, obsolete and redundant requirements, make provision for new technologies and place increased reliance on outcome measures of performance.

We provide for new uniform proficiency testing standards. We have also added requirements for additional specialties, such as clinical cytogenetics.

We also implement the now and self-implementing provisions of the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88).

DATES: This rule is effective September 10, 1990, except for 42 CFR part 493, Subpart H, which will be effective on January 1, 1991, and § 483.75, which will be effective on October 1, 1990. In addition, § 405.1128 will expire on October 1, 1990.

To be considered, comments must be mailed or delivered to the appropriate address, as provided below, and must be received by 5:00 p.m. on May 14, 1990.

ADDRESSES: Mail comments to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: HSQ-146-FC, P.O. Box 26676, Baltimore, Maryland 21207.

If you prefer, you may deliver your comments to one of the following addresses:

Room 309-G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC, or
Room 132, East High Rise Building, 6325 Security Boulevard, Baltimore, Maryland.

Due to staffing and resource limitations, we cannot accept facsimile (FAX) copies of comments.

In commenting, please refer to file code HSQ-146-FC. Comments received timely will be available for public inspection as they are received, beginning approximately three weeks after publication of this document, in Room 309-G of the Department's offices at 200 Independence Ave., SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5:00 p.m. (phone: 202-245-7890).

FOR FURTHER INFORMATION CONTACT: Rhonda Whalen, (301) 966-6801.

I. Background

Multiple Laboratory Activities

Under the Medicare program, we cover diagnostic services furnished to beneficiaries by a variety of laboratories. These include a laboratory that is "hospital-based" (that is, it is located in or it is under the supervision of a hospital), located in a physician's office, or is "independent" (not hospital-based and not a rural health clinic, a group medical practice or a physician's office).

By statute, the definition of a hospital contained in Section 1861(e) of the Social Security Act (the Act) extends Medicare participation to hospital laboratories. The paragraph following section 1861(s)(11) and section 1861(s)(12) and (13) provide coverage for independent laboratory services.

Under provisions of the Clinical Laboratories Improvement Act of 1967 (CLIA '67), laboratories engaged in testing specimens in interstate commerce must meet the requirements of Section 353 of the Public Health Service Act (42 U.S.C. 263a) in order to be licensed or remain licensed for testing in interstate commerce. However, licensure under CLIA '67 to test specimens in interstate commerce should not be confused with licenses issued by the Food and Drug Administration authorizing the interstate shipment of blood and blood products.

Medicaid, under the authority of section 1902(a)(9)(C) of the Social Security Act, pays for services furnished only by laboratories that meet Medicare conditions for coverage. Because

participation in the Medicaid program is governed by Medicare rules, henceforth when we refer to Medicare we are including Medicaid.

Various State laws govern licensure requirements for laboratories engaged in intrastate commerce. There are also Federal Medicare-Medicaid requirements that laboratories must meet in terms of personnel qualifications and accuracy of test results. Under existing Federal regulations in title 42, the laboratory requirements are integrated with other requirements applicable to the provider or supplier. Thus, for example, conditions of participation for a Medicare hospital-based laboratory are found in the hospital conditions of participation in 42 CFR 482.27. Also, laboratories in skilled nursing facilities must meet the same conditions of participation as laboratories in hospitals. Regulations found at 42 CFR part 74, Clinical Laboratories, implement section 353 of the Public Health Service Act, as enacted by CLIA '67, which sets forth requirements for laboratories engaging in interstate commerce.

A CLIA laboratory and any other entity identified as a laboratory under title XVIII of the Social Security Act that wishes to receive payment for its services from Medicare or Medicaid must meet Medicare's conditions of participation or conditions for coverage of services.

A laboratory that fails to meet the Medicare conditions for coverage for a given specialty is not approved for payment of services for that specialty. The loss (termination) of approval or failure to be approved initially results in no payment from Medicare or Medicaid for the services in the failed specialty. Failure to meet CLIA requirements for a category of services or a specific test results in the loss or denial of licensure for the category of services or that test. A laboratory may fail general conditions and fail to become approved for Medicare reimbursement for any specialty; similarly, a CLIA laboratory failing to meet general requirements would not be licensed for any tests.

Federal Oversight Activities

HCFA, under an interagency agreement and a memorandum of understanding (MOU) with the Public Health Service (PHS), has administrative responsibility for both the Medicare and CLIA programs. However, PHS (for the Food and Drug Administration (FDA)) has primary responsibility for the provision of technical advice on blood bank programs, including the revision of

regulations concerning blood and blood products. HCFA and the Centers for Disease Control (CDC) further delineated responsibilities by specifying that HCFA is responsible for developing regulations that relate to Medicare and CLIA and that CDC is responsible for assisting HCFA in obtaining technical and scientific expertise.

Consolidation of Regulations

On August 5, 1988, we published a proposed rule (53 FR 29590). In the proposed rule, we proposed to consolidate all CLIA and Medicare-Medicaid laboratory requirements in a new 42 CFR part 493. We proposed to remove outdated and overly prescriptive requirements. We intended to require laboratories to comply with the health and safety standards of other Federal, State and local agencies; our decisions to approve or license laboratories would be affected by their compliance with these laws. We also proposed to add provisions requiring facilities to develop and implement their own internal quality assurance programs, and we planned also to provide for increased reliance on outcome measures by using quality control and proficiency testing data in the assessment of laboratory performance.

We proposed to recodify and revise existing laboratory regulations to accomplish several goals.

- A major goal of the proposed regulation was to have, to the extent possible, the same requirements for both CLIA and Medicare and Medicaid laboratories. To this end, we proposed to revise requirements relating to applicability of the regulations, compliance with State and local laws, personnel, proficiency testing, recordkeeping, quality control, and inspection.

- We intended to revise our personnel standards so that personnel requirements are not focused principally on qualifications but on the accurate performance of laboratory tests. We added requirements specifying that each laboratory must have a qualified individual present when testing is performed.

- We proposed to impose a new quality assurance program on all laboratories. This provision would require a laboratory to be responsible for the quality of its services yet provide the laboratory with the flexibility to evaluate the competency of its technical staff.

- We intended to update current internal quality control requirements for each specialty and subspecialty, taking into consideration current and future technological advances. We proposed to

emphasize the importance of quality control and to make failure of quality control in a specialty or subspecialty result in the loss of approval or licensure in that specialty or subspecialty.

- We intended to revise the current Medicare and CLIA proficiency testing requirements considerably. We would require every laboratory to enroll and participate successfully in an approved proficiency testing program for each specialty and subspecialty for which there is an approved program and for which the laboratory seeks or has Medicare approval or CLIA licensure. The proficiency testing programs would have to meet our requirements, including grading criteria, in order to be considered an approved program for purposes of our regulations.

- We proposed to update the licensure requirements applicable to CLIA only laboratories by eliminating overly-prescriptive requirements, such as those involved with annual license renewal.

- We proposed to require Medicare laboratories to comply with Federal laws concerning health and safety and CLIA laboratories to comply with Federal, State and local laws concerning health and safety.

II. Legislation

A. The Clinical Laboratory Improvement Amendments of 1988 (CLIA '88)

On October 31, 1988, the Congress enacted Public Law 100-578, which contains comprehensive changes to the CLIA '67 legislation by replacing section 353 of the PHS Act. The amendments apply to all laboratories, including physicians' office laboratories, that test human specimens. The law includes provisions for a self-financing certificate fee system and for recognition of accreditation programs and State licensure programs that have standards equivalent to the Federal requirements established under CLIA '88.

Historically, we have regulated laboratories by "location," rather than by the types of tests a laboratory performs. The most significant change from the historic "regulation by location" approach is the directive for us to "regulate by test," using what is commonly referred to as the "complexity model." Regulations would vary as a function of the complexity of the tests the laboratory conducts. The law contains a provision to exempt laboratories from standards enforcement and routine inspections if the tests performed are simple procedures which, as determined by

HHS, have an insignificant risk of an erroneous result.

CLIA '88 requires the development of a separate rulemaking to establish standards based on tests performed. We plan to publish proposed standards subject to public comment with final rule publication thereafter. Development of CLIA '88 standards may, of necessity, result in revisions to these regulations. Thus laboratories subject to these requirements could, under CLIA '88, be subject to lesser standards or be exempt from standards if only simple, less complex low-risk tests are performed. On the other hand, the CLIA '88 requirements may result in more stringent requirements, if the testing performed warrants more rigorous Federal oversight.

Ultimately, we plan to establish uniform laboratory requirements based on the level of testing performed that would be applicable to all laboratories.

In the development of this regulation, we attempted to assure that the standards are in conformance with CLIA '88 if at all possible. Moreover, we have included those provisions of CLIA '88 that are self-implementing and do not require prior notice and comment.

B. Omnibus Budget Reconciliation Acts of 1987 and 1989

Section 4064 of the Omnibus Budget Reconciliation Act of 1987 (OBRA '87), Pub. L. 100-203, enacted on December 22, 1987, amended the sentence following section 1861(s)(11) of the Act by requiring that physicians' offices that perform more than 5,000 tests per year must meet conditions relating to the health and safety of individuals for whom such tests were performed. The amendment applied to tests performed on or after January 1, 1990. We did not propose any regulations to implement this provision in our August 5, 1988 proposed rule but we did solicit comments concerning the applicability of the proposed standards. (We received no comments.)

On December 19, 1989, Congress enacted the Omnibus Budget Reconciliation Act of 1989 (Pub. L. 101-239). Section 6141 removed the provision requiring that, in order to be subject to the conditions relating to health and safety of individuals for whom such tests are performed, physicians' offices must perform more than 5,000 test per year. This section specifies that *all* laboratories must meet the certification requirements of CLIA '88 and became effective December 19, 1989. This final rule does not implement section 6141, which will be addressed in a

forthcoming notice of proposed rulemaking.

III. Overview of Proposed Rule, Comments and Responses, Summary of Changes to Proposed Rule and CLIA '88 Changes

General Approach

We proposed to revise the standards for all laboratories participating in Medicare or Medicaid or licensed under CLIA to provide as much uniformity as possible within these programs. There are certain limitations on the extent to which the regulations can be unified because of differences in the Medicare and CLIA statutes.

Under the Medicare program, conditions of participation or for coverage are the requirements that an entity, such as a laboratory, must meet in order to participate and have tests paid for by Medicare or Medicaid. Each condition is usually comprised of one or more standards, which enumerate activities, outcomes, or other requirements that, upon evaluation by HCFA or a State survey agency under contract with HCFA, serve as the basis for determining that a particular condition has been satisfied. If the laboratory fails to comply with any condition for coverage, we initiate an adverse action to terminate the laboratory's participation in Medicare or revoke the laboratory's licensure under CLIA. The adverse action may be taken by terminating a laboratory's participation or licensure in a specialty or subspecialty if the deficiencies are limited to particular categories of testing, or the laboratory's approval for all services may be terminated if the deficiencies are pervasive, affecting the overall services offered by the laboratory.

We proposed that the new part 493 would have ten subparts, dealing with general provisions, administration, proficiency testing, proficiency testing programs, patient test management, quality control, personnel, quality assurance, inspection, and requirements unique to CLIA laboratories and CLIA licensure procedures. The regulations affecting other facilities that have requirements for laboratory services would be modified by cross-referring them to the new regulations.

More than 1,600 commenters wrote in response to our proposal. Many comments consisted of form letters or otherwise virtually identical comments. Notwithstanding the large number of comments, many of our proposed provisions received no comments.

Readers are encouraged to consult the preamble to the August 5, 1988 proposed

rule for the rationale or explanation pertaining to final provisions of this rule not specifically explained in this preamble.

Note: In the CLIA '88 proposed rule under development we intend to include specific requirements necessary for the implementation of CLIA '88 in subparts B through F. This change necessitates our recodifying the content of proposed subparts B through J as subparts G through O. As an aid to readers, we show the final subpart letters and section numbers in parentheses after those we had proposed in the August 1988 notice of proposed rulemaking.

Subpart A—General Provisions

1. Section 493.1, Basis and scope.

Proposed Rule Overview

In a new § 493.1, Basis and scope, we proposed to indicate the sections of the laws that apply to the new part—sections 1861(e) and (j), the sentence following section 1861(s)(11), sections 1861(s)(12) and (13) and 1902 of the Social Security Act and section 353 of the Public Health Service Act. We intended for this part to apply to all independent and hospital-based laboratories, intermediate care facilities for the mentally retarded, skilled nursing facilities and ambulatory surgical centers that perform laboratory services, rural health clinics that perform tests on referral, and physicians' offices that perform any tests on referral.

Many of the commenters supported the attempt to consolidate the Medicare and CLIA requirements into one regulation.

Comments and Responses

Comment: Several commenters expressed concern that the proposed requirements would not be applicable to rural health clinics and physicians' office laboratories that do not receive tests on referral.

Response: The Omnibus Budget Reconciliation Act of 1987 required that physician office laboratories performing more than 5000 tests a year be regulated effective January 1, 1990. The Omnibus Budget Reconciliation Act of 1989 specifies that all Medicare laboratories, regardless of test volume, will be subject to CLIA '88; CLIA '88 applies to all laboratories, including rural health clinics and physicians' office laboratories. The requirements for CLIA '88 will be implemented through separate rulemaking.

Summary of Changes to Proposed Rule

In the final rule we made no changes to the section. By the dates the requirements of this rule go into effect, we expect the standards of organizations that currently accredit

laboratories under Medicare, Medicaid and CLIA '67 to meet the requirements of Section 1865 of the Social Security Act. That is, those standards should be such as to reasonably assure the Secretary that the accredited laboratories meet federal requirements. In the area of proficiency testing, if an accrediting organization does not have a proficiency testing program equivalent to that provided for in this regulation, we will direct the State survey agencies to conduct proficiency testing in the accredited facilities.

In addition, by the effective dates of this rule's requirements (i.e. by September 10, 1990 or by January 1, 1991 in the case of proficiency testing requirements), it is our intention to evaluate each accrediting organization's entire set of laboratory standards and make determinations as to whether the standards meet the requirements contained in these rules. Should we determine that we are not reasonably assured that an accrediting organization's standards do meet the federal requirements, we intend to withdraw deemed status from the accredited facilities and place them under State agency oversight.

2. Section 493.2, Definitions

It is our practice to define terms whose meanings may not be clear from their context or where we apply an interpretation that may not be commonly used. The proposed section contained definitions that are applicable to both Medicare and CLIA. We proposed to eliminate requirements of present regulations that we feel are unnecessarily prescriptive; hence, many definitions found in current §§ 405.1310 and 74.2 are no longer necessary.

Proposed Rule Overview

• Currently, "independent laboratory" is defined in § 405.1310(a). We proposed to delete the definition of "independent laboratory" from the definition section because it placed emphasis on location and ownership, conditions no longer considered relevant under the proposal. We proposed to define "laboratory" instead and to remove the exception in the present definition for laboratories maintained by physicians that accept no more than 100 specimens on referral in any category during any calendar year because our experience has not shown that the definition is effective in assuring that physician office laboratories limit testing of specimens received on referral. We intended to maintain the exception for physician office and rural health clinic laboratories that perform no tests on

referral. Under the proposed rule for CLIA '88 these rural health clinics and physician office laboratories that perform any tests on referral would be required to meet the requirements for implementing CLIA '88.

Our proposed definition of a clinical laboratory removed the word "clinical". It does not add anything to the definition and may create confusion, since we also pay for the services of independent laboratories, hospital laboratories, etc., which perform anatomic services, provided they are in compliance with the Federal health and safety standards, which are generally not considered part of clinical laboratory services.

- We also proposed minor changes to the definition of "clinical laboratory" but using the term "laboratory". We proposed to delete several terms that are redundant or unnecessary in the definition of "laboratory".

- We proposed a definition of "authorized person" as the person authorized to order and receive tests.

Under Medicare that person is a physician as defined in section 1861(r) of the Act. We would permit other individuals, including patients, to be "authorized persons" when State law and Medicaid allows. This would reduce the conflict between Federal and State law over who can order and receive tests and would defer to the States for Medicaid purposes as well as to the State where Federal funding under Medicare or Medicaid is not involved.

- We would define "challenge" and "target value," which are related to the proficiency testing requirements.

Comments and Responses

Comment: We received several comments on the definition of "laboratory." Pathologists noted that anatomic examinations are included and argued that these tests are physician services and, as such, should be exempt from these requirements. It was also pointed out that Medicare reimburses anatomic pathology services as physician services; thus, there is inequity between the Medicare approval requirements and the Medicare payment policy.

Response: In accordance with our definition of a laboratory, a physician's office laboratory would not be exempt from these requirements if tests, including anatomic services, are received on referral. Moreover, CLIA '88 specifies that a laboratory is a facility providing pathological services. Therefore, these requirements apply to anatomic pathology services.

Comment: We received several comments from proficiency testing

organizations that our definition of "target value" needed to be expanded to include the use of reference or definitive methods as well as comparative methods in establishing an analyte's target value.

Response: The definition of "target value" in this final rule reflects the addition of reference or definitive methods as well as comparative methods for the establishment of target value.

Summary of Changes to the Proposed Rule

Because we decided to maintain the current personnel requirements (see comments and responses on subpart L below), we are retaining the definition of "independent laboratory" that appears in § 405.1310(a). It will appear at 42 CFR 493.2. We eliminated the provision permitting physician office laboratories to accept on referral 100 specimens in a category per calendar year.

Since we are maintaining the current personnel requirements for independent laboratories, we are adding definitions to the independent laboratory personnel standards in subpart L. The definition section includes "subsequent to graduation", "substitution of education for experience" and "technician trainee", terms used in the independent laboratory personnel requirements. The definitions of "authorized person", "accredited laboratory", "sample" and "challenge" in the proposed rule were not changed and therefore are adopted as final.

Added to § 493.2 is a new definition of "kit" and the definition of "run". "Run" had been defined at proposed § 493.237(b)(1) (current § 493.1217), but was moved to the definition section to be consistent with other terms defined. "Kit" is used in current § 493.1209.

The definition of "referee laboratory" has been amended to allow a PT program to nominate a laboratory as a referee laboratory for HHS approval.

Also amended is the definition of "target value". Alternatives to the establishment of the mean are noted in the definition, including definitive or reference methods acceptable for use in the National Reference System by the National Committee for Clinical Laboratory Standards. When definitive or reference methods are not available, a comparative method may be used.

CLIA '88 Changes

We are adding "biological" and "biophysical" to the definition of "laboratory," to conform with CLIA '88. In the definition of accredited laboratory, we are changing the term

national accreditation organization to private non-profit organization to conform to section 353(e)(2) of CLIA '88.

Subpart B(G)—Administration

Proposed Rule Overview

As indicated earlier, material we proposed at subpart B of part 493 is being redesignated to subpart G under the same heading, Administration. For the reader's convenience we provide the citation of the proposed rule followed in parentheses by the redesignated section.

Present Medicare requirements in § 405.1311 relating to compliance with State and local laws do not include compliance with Federal laws related to health and safety nor do current requirements under CLIA. We do not believe that a laboratory should be certified if it is not in compliance with applicable Federal requirements concerning health and safety. New § 493.11 proposed to include this requirement. This revision will make these regulations consistent with the requirements for nursing homes, intermediate care facilities for the mentally retarded, hospitals and end-stage renal disease facilities.

Comments and Responses

There were no unfavorable comments on this subpart. We are adopting the content of the proposed rule as final.

Summary of Changes to the Proposed Rule

No changes were made to subpart B(G)—Administration.

Subpart C(H)—Participation in Proficiency Testing

Proposed Rule Overview

Present regulations at 42 CFR 405.1314(a) and part 74, subpart E, require laboratories to participate successfully in a proficiency testing (PT) program acceptable to the State and HHS. We proposed to expand these requirements. A new subpart C was to contain the general requirements a laboratory must meet for PT and would elevate current requirements for enrollment and successful participation to the condition level.

The proposed new PT requirements emphasized the increased importance of achieving a passing score on samples of known contents that are tested as patient samples and serve as a measure of laboratory quality.

Our proposed revisions would focus on assessing the quality of laboratory tests that are commonly performed or have results critical to the patient's health (e.g., an incorrect result has a

moderate to high risk of an error in diagnosis, treatment or death), or both. In the proposed rule we indicated that in the future we hope to include additional tests in areas such as histopathology, clinical cytogenetics and testing for drugs of abuse. We also proposed to exclude from the proposed PT program those test areas for which no performance problems are evident, such as routine urinalysis, and to continue to reevaluate the necessity for PT for other test areas in the future.

The tests and analytes we selected for challenge are representative of the laboratory's ability to perform in each specialty and subspecialty.

We proposed a specialty and subspecialty grading system as the most reasonable and appropriate mechanism to monitor quality of testing. Since our intent is to make the Medicare and CLIA programs as consistent as possible and to provide an overall assurance of quality, we proposed to require identical mechanisms of assessing PT performance for CLIA and Medicare laboratories. We proposed that the Medicare State survey agency or HCFA would make a uniform assessment of PT performance in determining the licensure and Medicare approval status of a laboratory by specialty and subspecialty. A laboratory failing the PT requirements for a testing event would have to enroll in an enhanced PT program or it would lose Medicare approval for the specialty or subspecialty. Similarly, a CLIA licensed laboratory would be notified of any PT testing event failure and would be instructed to enroll in enhanced PT or a license revocation action would be initiated.

We proposed requirements for an enhanced PT program for laboratories that failed routine PT. Laboratories with failing scores in a testing event would avoid loss of Medicare approval and/or CLIA licensure by enrolling in an enhanced PT program. The enhanced PT program would provide more samples per testing event in order to afford the laboratory more challenges to determine performance over time. In the proposed requirements, if the laboratory also fails the enhanced PT, we would initiate termination of Medicare approval or/and revocation of CLIA licensure, as applicable, for the failed specialty or subspecialty.

We did not propose enhanced PT for cytology but proposed different remedial actions that a laboratory failing PT in cytology would have to take to remain approved or licensed.

In the proposed rule, we planned to establish an evaluation system based on satisfactory participation for each

testing event of PT at approximately quarterly intervals. Under current Medicare practice we disapprove a facility if three out of four testing event scores are unsatisfactory. Currently, if a laboratory has three unsatisfactory shipments out of four, it takes over a year to initiate a termination. Under the proposed revision we could decrease this time interval to as short as two months if the laboratory did not enroll in enhanced PT. (The PT program has one month to notify us of PT results; we notify the laboratory of its loss of approval within one month.)

The proposal for revision of the PT requirements also included a provision for action against a laboratory when there is unsatisfactory performance for the same single analyte in any PT shipment or testing event or when there is unsatisfactory performance for one of two challenges for the same analyte in each of two consecutive testing events. We proposed to terminate Medicare approval of the entire specialty or subspecialty in which the failed analyte is categorized unless the laboratory requested enrollment in the enhanced PT program.

We also proposed to institute an overall PT evaluation by specialty in chemistry, immunology and microbiology. Poor performance in one subspecialty would result in the laboratory failing the specialty as well and the laboratory being unable to obtain approval for any of the other subspecialties in the same category.

Laboratory Requirements

• General

In new § 493.21, Condition: Enrollment and testing of samples, we proposed two standards: (1) If a PT program has been approved under proposed Subpart D for a specialty or subspecialty for which a laboratory seeks or has approval or licensure, a laboratory must enroll in an approved PT program for each specialty and subspecialty for which it seeks approval (Medicare or Medicaid) or licensure (CLIA); and (2) the laboratory must test or examine the PT samples in the laboratory's routine manner.

This section required the laboratory to notify HHS of the PT program it has chosen, it would be able to designate no more than one PT program per specialty (in specialties without subspecialties) or subspecialty for the purposes of meeting the PT enrollment requirements. A laboratory could change its selection of PT programs after four quarterly shipments but would have to notify HHS before any change is made. The laboratory would have to agree to allow all PT programs to release any data to

us that we need to evaluate the laboratory's performance.

Section 493.21 would contain a standard specifying how the laboratory is to test or examine the PT samples it receives from the PT program. The laboratory would have to test the PT samples with its patient specimens and by personnel who ordinarily perform the laboratory's testing; it could not perform tests in replicate unless it usually tests patient specimens in replicate; and it could not send the samples to another laboratory for analysis.

In § 493.22, Condition: Successful participation, a laboratory that does not successfully participate in PT for a given specialty and subspecialty would be able to request enrollment in an enhanced PT program within 15 days of notification of unsuccessful performance to prevent immediate termination of approval or institution of license revocation proceedings for the failed specialty or subspecialty.

In § 493.24, Reinstatement after failure to participate successfully, we proposed that a laboratory failing PT in any specialty or subspecialty that does not enroll in enhanced PT or demonstrate successful performance for three consecutive testing events of enhanced PT in that failed specialty or subspecialty would be terminated for a period of no less than six months.

We proposed to extend the successful performance period for reinstatement from the current requirement of two testing events to three testing events to assure that the laboratory demonstrates sustained improvement.

• Proficiency Testing by Specialty and Subspecialty

• General

Sections 493.31 through 493.63 proposed to contain the criteria for acceptable performance a laboratory would have to meet to participate successfully in a PT program for each specialty and subspecialty. The specialties and subspecialties named in these proposed regulations were microbiology (bacteriology, mycobacteriology, mycology, and parasitology), diagnostic immunology (syphilis serology and general immunology), chemistry (routine chemistry, endocrinology, and toxicology), hematology, pathology (including cytology for gynecologic examinations) and immunohematology.

Whenever possible, we determined a composite performance score for specialties and subspecialties. We considered a grade of 80% for an overall specialty or subspecialty of testing to be

a reasonable, achievable level of performance. In immunohematology in which even one error may have serious and immediate consequences, we required a performance level of 100% for subspecialties of testing.

Whenever changes in the regulations for PT participation are necessary, we would expedite the rulemaking process to ensure the most rapid implementation in order to have dynamic requirements to respond timely to new testing procedures and methodologies as well as refinements in performance and evaluation criteria.

Also, whenever changes are necessary, we proposed to publish a notice in the *Federal Register* before revising PT program requirements.

• Cytology

Currently, most PT programs do not test cytology services. As a result, we had less information for assessing cytology PT than we had for assessing other areas of PT. We therefore proposed three options (on-site testing, mailed shipments of specimens, and a combination) for interested parties to comment upon. All options include ranges for accuracy rates, number of challenges per testing event and number of testing events per year. We requested comments concerning which accuracy rate in each range commenters prefer (and why) as well as which PT option is preferred (and why).

We proposed to require PT in cytology only for gynecologic preparations. We proposed that Cytology: Gynecologic examinations, be a subspecialty under the specialty of pathology.

We proposed that satisfactory performance for each individual would be based on a 80 to 100 percent correct response on each PT survey. Successful performance for the laboratory, which includes all individuals engaged in slide examination, would also be based on 80 to 100 percent correct responses on each testing event. A correct response would be 95 percent consensus agreement. We were interested in receiving comments regarding instances when a graded response may be close to the consensus but not exact.

• Remedial actions for cytology (Gynecologic preparations only)

The principal purpose of any PT program is to identify areas of performance that need correction or improvement and to ensure that good performance is maintained over time. Because examination of slides in cytology involves the skill and judgment of individuals viewing slide preparations, we proposed that laboratories take remedial actions to

improve the performance of individuals who failed the cytology PT program.

We proposed remedial actions applicable to individuals who do not demonstrate satisfactory performance and penalties applicable to laboratories that fail to maintain overall successful performance in a cytology PT program. We invited comments on this proposal.

1. Remedial actions concerning individuals. We proposed that the first time an individual fails any part of a cytology PT survey, the laboratory would have to provide the individual with immediate remedial training and education in the area of the failure and a review in those areas passed. If the individual's score is 50 percent or less in each of two testing events, we would require a more stringent form of remedial action up to prohibiting the individual from reporting negative slides until the individual has been retrained and demonstrates necessary accuracy by scoring 100 percent on two consecutive PT testing events. If either two or more or ten percent or more of the individuals in a laboratory, whichever number is greater, fail any PT testing event, all individuals engaged in the examination of slides would have to undergo additional training and education in addition to that required in the personnel requirements and the laboratory would have to participate in a retrospective PT program until the laboratory achieves an overall score of 95 percent or more correct responses over three subsequent consecutive PT testing events. The 95 percent score for the laboratory represents the composite score of all individuals examining gynecologic slides in the laboratory.

2. Fiscal penalties for laboratories. We proposed that if the laboratory fails to take required remedial actions (as described above) when an individual fails the PT program or if either two or more or ten percent or more of the individuals in a laboratory, whichever number is greater, fail two or more of PT testing events, we would terminate the laboratory's Medicare approval for the subspecialty of gynecologic examinations, revoke its CLIA licensure, or both, as applicable.

Comments and Responses

Section 493.21 (§ 493.801) Condition: Enrollment and Testing of Samples

Comment: Several commenters opposed enrollment in proficiency testing programs by specialty or subspecialty designations of the subpart. They felt that there was lack of alignment between these categories and current PT programs.

Response: We cannot approve laboratories by tests performed because it is not feasible for the insurance companies that pay Medicare/Medicaid bills to program approval by test. Presently, laboratory tests are reimbursed using the Health Care Financing Administration common procedure coding system, which is based on the Physicians' Current Procedural Terminology of the American Medical Association. Each of these tests categorized by code is further categorized by specialty or subspecialty of service used as part of the survey and certification process for Medicare approval. Moreover, it would not be feasible for HHS to maintain current records of tests performed by laboratories since procedures are added or deleted on a daily, weekly, or monthly basis. Enrollment in PT by specialty and subspecialty of services is based on the current categorization of tests both for Medicare approval for payment and licensure under CLIA. Tests are selected for PT based on widespread use and appropriateness for assessment of areas of test performance. These tests are most representative of methodologies used in a specialty or subspecialty to provide proper patient care. PT organizations revise tests offered in program modules on an annual basis, and we anticipate that PT programs will provide test specimens in modules that are analogous to the type of tests required under proposed subpart D.

Comment: Numerous commenters agreed that PT samples should be tested and examined in the same manner as patient samples but thought that the requirement was not practical and was unenforceable. An even greater number of commenters noted "special handling" and attention given to PT samples currently; they stated that the more emphasis given to PT sample results, the more extraordinary treatment the samples will be given.

Response: We agree with these commenters and have added a provision under paragraph (b) of this standard requiring that the individual performing the testing or examination of PT samples attest that the samples are tested as closely as possible to patient specimens:

Section 493.22 (§ 493.803) Condition: Successful Participation

Comment: A very large number of commenters strongly objected to losing licensure for a specialty or subspecialty if a laboratory perform unsuccessfully for the challenges on a given analyte; the commenters also opposed the loss of licensure in the respective specialty if

the laboratory performed unsuccessfully in a given subspecialty.

Response: We agree with the commenters that loss or limitation of a laboratory's approval or license is a heavy penalty. However, the importance of PT in the evaluation of a laboratory's performance cannot be compromised. Throughout subparts C and D (now H and I), we intended to make the regulations more comprehensive.

After evaluating comments we have retained the definition of unsuccessful performance as unsatisfactory performance in two consecutive or two of three PT events. However, we have increased the number of PT samples in the testing events for most specialties in response to suggestions from a number of commenters. Also, we have eliminated the proposed section basing the loss of the specialty of service on unsuccessful performance for a subspecialty. We do require that unacceptable performance for a given analyte or challenge result in the loss of a subspecialty of service, since approval or licensure is not granted on a test basis. However, when the final regulations are established invoking the intermediate sanction provisions of OBRA '87 and CLIA '88, we plan to include provisions for invoking an intermediate sanction for inaccurate test performance, as appropriate, as opposed to terminating approval or revoking a CLIA license for the entire subspecialty.

Section 493.23 (§ 493.805) Condition: Successful Participation Before Initial Approval of Licensure

Comment: A large number of commenters opposed the requirement of three successful PT events before initial Medicare or Medicaid approval or CLIA licensure for each specialty or subspecialty. These commenters felt that the time period required to complete three successful PT events, which they felt would represent a minimum of nine months to one year, was too long. Several commenters indicated that a new laboratory would not survive economically for this length of time.

Response: We agree with the commenters and have reduced the number of successful PT events required from three to one before initial Medicare or Medicaid approval or CLIA licensure.

Section 493.24 (§ 493.807) Reinstatement After Failure to Participate Successfully

Comment: Many commenters felt that a waiting period of not less than six months from the date of termination of Medicare approval or CLIA licensure was too long a period of time to wait for reinstatement, particularly if problems relating to the termination had been

corrected. Many commenters wanted to institute remedial action first and be allowed an opportunity to correct problems before any adverse action.

Response: We feel that laboratories should correct problems in testing immediately after notification of a PT failure, and we are requiring laboratories to document remedial action taken. Correction of the problem(s) should be demonstrated by improved performance in the next two proficiency testing events, and if not, adverse action is necessary because the problem(s) is not resolved. Following termination of Medicare approval or CLIA licensure, a laboratory need time for reflection and correction of problems relating to unsuccessful performance and the time period should be sufficient to accomplish complete rectification and also demonstrate sustained successful performance through three consecutive PT events. In view of the large numbers of commenters that attested to the "special and extraordinary handling" given PT specimens and that laboratories would fraudulently report that PT samples were tested in the same manner as patient samples, we have determined that at least one of the three PT events required for reinstatement will be conducted on-site.

Section 493.25 (§ 493.809) Condition: Enhanced Proficiency Testing

Comment: A very large number of commenters expressed strong opposition to the concept of enhanced PT as an immediate sanction. Specifics mentioned by the commenters in reference to enhanced PT were that it is too punitive, too complex and overly burdensome. Many commenters were concerned that the enrollment fee for enhanced PT would be excessively high.

Many proficiency testing program providers felt enhanced PT would be extremely difficult to administer. They anticipated that a large number of laboratories would be subject to enrollment in enhanced PT and expressed great concern about the dramatic increase in volume of PT material that they would be responsible for obtaining, validating, and distributing.

Response: We agree with the commenters that requiring enhanced PT as a separate program would be too complex, costly and burdensome. With the increased number of samples in routine PT, enhanced PT should not be necessary to identify poorly performing laboratories. Consequently, we have assimilated the increased number of samples into the routine PT program in this final rule and withdraw the proposed requirement for a separate

enhanced PT program. In accordance with CLIA '88, we are requiring that laboratories that perform unsatisfactorily on a PT event undertake training and employ the technical assistance necessary to correct the problems associated with the PT failure.

Sections 493.31 through 493.57 and 493.61 through § 493.63 (§§ 493.21–493.851, 493.55 and 493.865) Conditions and Standards For Specific Specialties and Subspecialties

Comment: Many commenters were opposed to setting the score for satisfactory performance at 80 percent and noted that the 80 percent score was higher than necessary to demonstrate satisfactory proficiency testing performance. Some took particular exception to the 100 percent score requirement in immunohematology.

Response: We consider an 80 percent score for satisfactory proficiency testing performance as a reasonable requirement. Since we are requiring five PT samples in testing, less than an 80 percent score in most specialties would mean the laboratory tested only three, or 60 percent, accurately. The require a higher score would require the laboratory to test all samples correctly.

We have revised the proposed standards, usually located at (d) of the various standards, to include the requirement that following an unsatisfactory testing event, laboratories must obtain the necessary training and assistance to correct problems associated with PT failures. In addition, we specify delaying adverse actions until laboratories demonstrate unsatisfactory performance on two consecutive testing events or two out of three consecutive testing events. We do, however, accept the views of commenters stating the overall 100 percent score in immunohematology should be amended. We agree that it is unrealistic to expect laboratories to score 100 percent in unexpected antibody detection and antibody identification; therefore, the acceptable score for both have been reduced to 80 percent. The other areas of immunohematology have not been changed in recognition of their importance.

Comment: Several commenters felt a score of "O" for failure to participate was unfair if instrumentation was not functioning during the proficiency testing event.

Response: In response to these comments, we are revising the requirement, usually located at paragraph (b) of the various standards,

to permit laboratories to submit to the inspecting agency and the PT program for consideration any situation or circumstances that prevented the laboratory from performing tests.

Comment: Many commenters noted the omission of some form of remedial action to be taken in the event of a PT failure. Suggestions made by the commenters included education, training, and technical assistance to the degree necessary to identify and rectify problems responsible for the failure.

Response: We agree with these commenters and have included a requirement, usually at paragraph (d) of the various standards, for the laboratory personally to provide or obtain the technical assistance and training necessary to correct problems associated with a proficiency testing failure. This training and technical assistance must be initiated as soon as possible after the initial failure and should allow sufficient time to correct testing problems before participation in the next testing event.

Comment: An overwhelming number of commenters expressed concerns regarding the proposed enhanced PT program. They felt that there was insufficient time to correct problems associated with an unsuccessful PT event before enhanced proficiency testing would be imposed. They vehemently opposed the provision for penalizing laboratories that failed a single analyte with the loss of an entire specialty or subspecialty.

Response: We understand the commenters' concerns; however, proficiency testing as an evaluation tool must be given the serious consideration it warrants in assessing test performance. We have deleted the section on enhanced PT in response to the concerns raised by the commenters. Instead of the proposed requirement for immediate enrollment in enhanced PT in response to an unsatisfactory testing event, we are requiring that laboratories with one unsatisfactory testing event undertake training and corrective action necessary to improve performance. As stated now, a laboratory will not be penalized for a single unsatisfactory testing event, but an adverse action will be initiated for failure of two consecutive or two out of three PT events. An adequate time period is thus being given to remedy problems causing such failures. We feel that without the opportunity to identify and correct these problems, inaccurate testing may be perpetuated.

Section 493.63 (§ 493.855) Standard: Cytology: Gynecologic Examinations

Comment: Many individuals and organizations offered suggestions on the number of times a year a PT event should be required for individuals examining gynecologic preparations. The suggestions ranged from once every five years to four times a year. The majority of the commenters favored requiring annual or semi-annual cytology PT events.

Response: CLIA '88 (Section 353(f)(3)(A) of the PHS Act) requires that proficiency testing be conducted quarterly unless HHS determines for technical and scientific reasons that a particular examination or procedure may be tested less frequently (but not less often than twice per year). In as much as cytology proficiency testing has not been conducted routinely on a national basis, the testing materials or slide preparations needed to evaluate slide examination performance currently are not readily available. It will take time for proficiency testing programs to collect the appropriate slides, evaluate and reference the slides by reportable result or diagnosis, and assemble slide sets for testing. Administering the program will require coordination between the State survey agencies and the proficiency testing program to obtain the test sets and schedule the testing events. The State agencies will have to arrange to conduct cytology proficiency testing at the time of the on-site survey. In addition, the laboratories will be responsible for insuring that all individuals are tested, requiring in some instances days off for individuals to be tested and loss of laboratory time in examining patient slides.

For all these reasons, we have decided to require cytology proficiency testing no less than twice annually, at least one of which will be on-site.

Comment: A large number of commenters favored on-site proficiency versus mailed specimens as the most ideal mechanism that would most fairly evaluate individual performance because participants would be tested in familiar surroundings using their own microscopes. Small laboratories were in favor of on-site PT for evaluating each individual as opposed to assessing the overall or collective laboratory performance through mailed PT. Several commenters suggested proficiency testing events be administered at regional testing sites where the PT could be monitored and administered to many individuals simultaneously. They also suggested that after testing the individual's performance, a review of

the PT material could be used as a continuing education tool.

Response: We agree with the commenters that on-site PT is the ideal situation and CLIA '88 mandates periodic confirmation and evaluation of the proficiency of individuals involved in examining or interpreting cytologic preparations, including announced and unannounced on-site PT. We have included in the regulations provisions for an annual, unannounced on-site PT event, as well as announced testing events conducted at regional testing centers in order to afford each individual and/or laboratory the opportunity of a testing event that will be the most convenient and the least disruptive to the laboratory.

These two testing methods ensure that each individual is tested and eliminates the potential advantage for larger laboratories to submit a collective opinion or diagnosis based on more than one individual's input to proficiency testing challenges.

We recognize the value of continuing education but have not specified any particular number or type of courses that may be beneficial to the individual or laboratory. Rather, we leave the enrollment and participation in continuing education exercises to the individuals, laboratories and professional organizations.

Comment: The majority of those who commented on passing scores recommended 80 percent as passing, although some commenters suggested passing scores in the range of 70-100 percent as alternative scores for each PT event.

Response: In as much as standards of practice for cytology are not established and uniform nomenclature for reporting cytology results has not been universally adopted, we are initially requiring a passing score of 80 percent of acceptable responses for a PT event. We and the majority of commenters believe that at this time a score of 80 percent is a reasonable and achievable level of performance. Following the evaluation over time of proficiency testing performance, higher grading criteria may be developed.

Comment: Most of the commenters were in favor of immediate remedial training and education by the laboratory after a single testing event failure. Many commenters objected to reviewing the areas in which cases were satisfactory and several commenters requested that remedial training and education only be required after failing two testing events.

Response: We agree with the commenters stating that the laboratory must provide remedial training and

education after failure in a single testing event. Cytology PT will assess an individual's performance in the examination of gynecologic material; therefore, it is critical that problems identified through PT be corrected immediately. The laboratory must provide remedial training and education in the area of failure to upgrade the performance of individuals providing diagnosis on patient specimens.

Comment: An overwhelming number of commenters objected to the proposed requirement for additional training and education of all individuals engaged in the examination of gynecologic preparations when two or more individuals or ten percent of the individuals engaged in the examination of gynecologic preparation failed a PT event.

Many commenters objected to the proposed requirement that the laboratory must participate in a retrospective PT program until the laboratory achieves 95 percent correct responses over three consecutive PT events.

Response: We agree with the commenters and are not making final the proposed requirement for remedial training and education of all individuals engaged in slide examination when one or more individuals fails. Also, we are not including in this final rule the proposed requirements for retrospective proficiency testing.

Comment: A few commenters agreed that each individual who failed a testing event should be required to achieve a score of 100 percent on two consecutive PT testing events; however, many commenters expressed the opinion that an 80 percent retest score on one PT testing event was adequate.

Response: We agree with the majority of commenters and have changed the regulations to require a passing score of at least 80 percent on a single testing event as adequate for reinstatement after failure.

Comment: The commenters offered a variety of suggestions for remedial actions for individuals failing a PT event from a 25 percent review of the case work to the permanent cessation of the examination of slides by an individual examining gynecologic slides.

Response: We have added a provision to the regulations requiring the laboratory to provide immediate remedial education and training in the failed area and re-examination of all subsequent gynecologic slides until the individual is retested and scores at least 80 percent on a testing event. For an individual examining gynecologic preparations who is not qualified as a technical supervisor and who fails a

testing event, we are requiring the re-examination of the last 500 negative gynecologic slides evaluated before the failed testing event. The re-examination must be performed by an individual who had a passing score for the last testing event. For technical supervisors who fail a testing event, we are requiring the re-examination of the last 500 gynecologic slides evaluated before the failed testing event. The re-examination must be performed by a qualified technical supervisor who achieved a passing score for the last testing event.

Comment: Many commenters agreed that the laboratory should take the responsibility for remedial action when an individual failed a testing event; however, the majority of those commenting disagreed with the termination of a laboratory's Medicare approval for gynecologic cytology testing and/or revocation of its license under CLIA for failure to take remedial actions when an individual fails a proficiency testing event.

Response: The laboratory is ultimately responsible for all patient test results reported by its employees and thus it is appropriate to terminate a laboratory's Medicare approval and/or revoke its license under CLIA if it fails to take the required remedial action.

Summary of Additions and Changes to Proposed Rule

Section 493.801 Enrollment and Testing of Samples

To the proposed requirement for testing PT samples in the same manner as patient specimens, we have added the requirement for the individual testing the PT samples to attest on the PT request form that PT samples are tested using the laboratory's routine procedures for handling and testing patient specimens. Laboratories, including those with separate locations, may not engage in discussions pertaining to PT results. Additionally, if a laboratory receives PT samples for testing from another laboratory, HHS must be advised of the receipt of the sample(s).

Section 493.803 Successful Participation

Unsuccessful participation in PT is now defined as two consecutive or two out of three unsatisfactory testing events or two consecutive or two out of three unsatisfactory scores for the same analyte.

Section 493.805 Satisfactory Participation before Initial Approval or Licensure

Laboratories must participate in one PT event and achieve a satisfactory score before initial Medicare approval or CLIA licensure.

Section 493.807 Reinstatement after Failure to Participate Successfully

Three consecutive satisfactory PT events, one of which must be on-site, are required before a laboratory is reinstated after termination of Medicare approval or revocation of CLIA licensure.

Section 493.25 Enhanced Proficiency Testing

We withdraw the proposed requirement for enhanced PT in § 493.25 but significantly increased the number of samples in a routine proficiency testing event in the final rule. This has the effect of assimilating the enhanced proficiency testing program into the routine proficiency testing events.

Sections 493.821 through 493.851 and 493.857-493.865 Proficiency Testing by Specialty and Subspecialty

The provisions of the proposed rule are adopted as final with the following exceptions/additions:

- If a laboratory fails to perform successfully for a given subspecialty, termination of CLIA licensure or disapproval of Medicare will occur only for that subspecialty. If a laboratory fails to perform successfully for a given analyte(s), termination of CLIA licensure or termination of Medicare approval will occur for the subspecialty of the failed analyte(s).

- If a laboratory fails to participate in a PT event, consideration may be given before automatic failure if the laboratory has participated in the last two PT events and notifies the PT program and inspecting agency of cessation of patient testing and the circumstance causing the non-participation.

- In § 493.861, the percentage of acceptable responses required for each analyte and each testing event for unexpected antibody detection is reduced from 100 to at least 80 percent.

Section 493.855 Cytology

Once a year, unannounced proficiency testing will be conducted on-site in each laboratory. In addition, at least four times a year, proficiency testing will be conducted on an annual basis at designated testing sites. Each individual examining slides must participate in two testing events a year.

Also, an individual must score 80 percent or higher on a PT event to achieve a satisfactory score. If an individual fails a PT event, immediate remedial training and education in the area of failure must be provided, and all subsequent gynecologic slides must be re-examined until the individual achieves at least an 80 percent score on the next testing event. At least the last 500 slides examined by an individual who failed a testing event must be re-examined by an individual who achieved a satisfactory score in the most recent PT event.

CLIA '88 Changes

1. We are including in § 493.801(b)(4) a statement to the effect that a laboratory found to have intentionally referred proficiency testing sample(s) to another laboratory for analysis will lose its approval and/or licensure for at least one year. This partially implements section 353(i)(4) of the PHS Act, as modified by CLIA '88, which, as of January 1, 1989, requires revocation of a laboratory's certificate (currently referred to as license) and which involves fines and penalties (which will be implemented later). We are including Medicare approvals as revocable, since all Medicare laboratories are subject to CLIA '88 in accordance with the Omnibus Budget Reconciliation Act of 1989.

2. In accordance with section 353(f)(3)(E) of the PHS Act (as modified by CLIA '88), we are requiring laboratories failing one PT event to investigate and correct problems causing the failure. CLIA '88 states that HHS may require training and assistance and/or enhanced proficiency testing when laboratories fail to achieve satisfactory performance. We are requiring that laboratories with one failure to institute training and assistance to remedy the problem. This was recommended by several commenters, in addition to their opposition to enhanced PT.

Subpart D(I)—Proficiency Testing Programs

Proposed Rule Overview

We proposed a new subpart D that would contain the requirements a PT program would have to meet before a laboratory could use it to meet the PT requirements of subpart C. Subpart D would indicate for each specialty and subspecialty: (a) Program content and frequency of challenge; (b) the number of challenges per quarter; and (c) how to evaluate analytes or test performance.

Basically, we proposed that programs wishing to qualify as a PT program

under the proposed regulations would have to offer a minimum of at least two challenges per quarter for each test or analyte for the subspecialty of general immunology, the specialty of hematology, and the subspecialties included in the specialties of chemistry and immunohematology; six challenges per quarter for the specialty of microbiology; five challenges per quarter for the subspecialty of syphilis serology. For the enhanced PT program, in which a laboratory failing PT would have to participate, we proposed to require six challenges per shipment for each test or analyte in the specialty of hematology and the subspecialties included in the specialties of diagnostic immunology chemistry, and immunohematology, and twelve challenges per shipment for the specialty of microbiology.

As proposed, subpart D described criteria for acceptable performance. The criteria for grading was developed through an evaluation of the current criteria in use by States and private sector programs and an evaluation of data CDC had for the performance characteristics of laboratories.

A PT program as proposed would evaluate a laboratory in a manner that reflects the scope and level of services the laboratory offers.

After the PT program has been in operation for two years we proposed to consider revisions to the program based on the performance of laboratories. We planned to solicit comments from all concerned groups regarding the need to modify the PT program requirements. Changes in the PT program might be made to incorporate new analytes, tests, or organisms of clinical significance, to delete obsolete or well-performed tests, or to improve the evaluation scheme based on new data describing actual distributions of test scores, and the relationship of test errors to physician practices and patient outcomes. We proposed that when we decided to include new challenges or evaluation criteria in future PT, we would expect these changes to be provided by approved PT programs within two years of our approval and announcement. We would review the standards for PT programs on a regular basis, make such changes as are necessary and provide notice of these changes to all affected.

The requirements for program content and number of challenges per quarter would be implemented through an expedited rulemaking process to enable us to drop or add tests in a timely manner to reflect current technologies.

• Cytology (Gynecologic examinations)

As noted above in the discussion concerning subpart C, we proposed

three options for cytology (onsite testing, mailed shipments of specimens, and a combination). For all options, we proposed one to four PT testing events per year, with five to 12 slide preparations per individual per testing event. We proposed that the type of challenges include "normals," infectious agents, benign reactive processes, pre-malignant processes, and malignant processes.

We would require the program to provide previously "referenced" slides: "positive" slides that have been confirmed by tissue biopsy and "negative" slides that have been confirmed by 95 percent consensus agreement.

Comments and Responses

Section 493.91 (§ 493.901) Approval of Proficiency Testing Programs

Comment: It was noted by a few commenters that the option for proficiency testing program providers to purchase proficiency testing material was not included in the proposed regulations.

Response: We agree with these commenters and have included this option for proficiency testing program providers. We stipulate, however, that the proficiency testing material be purchased only from manufacturers who follow the FDA Good Manufacturing Practice requirements.

Comment: One commenter felt the definition of "referee laboratory" needs to be revised to allow the proficiency testing program to choose qualified referee laboratories rather than have HHS determine referee laboratories.

Response: Although we encourage proficiency testing programs to elect referee laboratories, we retain the right to disapprove the selection.

Comment: Several commenters stated the definition of target value was overly restrictive, needed expansion with more flexibility, and that it precluded other valid methods of determining target value.

Response: We have expanded the definition of target value (see § 493.2) to include its establishment based on definitive, reference or comparative methods accepted for use in the National Reference System by the National Committee for Clinical Laboratory Standards.

Comment: Numerous commenters agreed that proficiency testing samples should be tested in the same manner as patient samples but that the requirement was unenforceable.

Response: We agree with the commenters that enforcement without

direct oversight is difficult and we address this issue more fully in the comments and response section concerning § 493.21(b) (§ 493.801(b)(1)) of proposed subpart C. In an attempt to insure that proficiency testing samples will not receive special handling, we will ask some States to conduct unannounced on-site proficiency testing in a sample of laboratories. This will provide a benchmark measurement of laboratory performance on proficiency testing and also will enable us to assess the usefulness and feasibility of on-site proficiency testing. The requirement for proficiency testing programs to include a signature block for this attestation statement is a part of the regulation designed to assure that proficiency testing samples are treated similarly to patient samples.

Comment: Several commenters suggested that proficiency testing program providers be required to make allowance for damaged or lost proficiency testing samples and to resupply such samples.

Response: We agree with the commenters and require program providers to replace lost or damaged samples. The proficiency testing participant must notify the program provider within seven days from the scheduled date of shipment to be eligible to receive a replacement sample.

Comment: Many individuals commented on the requirement that proficiency testing results be issued within thirty days from the date by which the laboratory must report proficiency testing results to the program. A few suggested a two week time period; others recommended six to eight weeks and one suggested fifteen days before the expected receipt of the next proficiency testing shipment.

Response: In view of the increased number of proficiency testing specimens stipulated in these regulations, we are extending the time period required for proficiency testing program providers to issue proficiency testing reports to laboratories. We have changed the proposed time period from thirty days to forty-five days from the date by which the laboratory must report proficiency testing results to the program.

Comment: One State noted it would be possible for a laboratory to pass the HHS approved proficiency testing program but fail proficiency testing conducted by the State. Further, the State questioned who would evaluate the State's laboratories if the State's proficiency testing program were not approved by HHS.

Response: Both the State and HCFA must make their own determinations with regard to compliance with their

respective laws and regulations. We anticipate approval of proficiency testing programs offered by both States and professional organizations. If a State's program is not approved, the laboratories within that State will be required to enroll in an HHS-approved proficiency testing program and the laboratories' performance will be monitored by HHS. The State has the option of recognizing the HHS approved proficiency testing program. In the event a State does not recognize an approved PT program, theoretically, it would be possible for a laboratory to be in compliance with the Federal proficiency testing program but not in compliance with a State program, resulting in the laboratory's loss of Medicare approval and/or CLIA licensure based on noncompliance with State requirements. Conversely, a laboratory could be in compliance with a State's proficiency testing program requirements but fail to participate successfully in an HHS-approved PT program, resulting in loss of Medicare approval and/or CLIA licensure. In such a case, the laboratory will be banned from testing Medicare/Medicaid or interstate specimens but, under State law, allowed to test intrastate patient specimens.

Section 493.96 (§ 493.907) Process For Updating Proficiency Testing Programs

Comment: A few commenters requested that well-performed tests not be deleted from PT programs to assure that acceptable PT performance is established for newly regulated laboratories.

Response: We agree with the commenters. For these final regulations, we will not delete PT for any tests specified in subpart H. However, in the future, based on PT performance review of all laboratories, we will reconsider whether to retain specific well-performed tests.

Section 493.129 (§ 493.945) Cytology: Gynecologic Examinations

Comment: A State health department requested that HHS permit laboratories to donate cytology slides to proficiency testing programs for the assembly of slide sets for proficiency testing.

Response: We have revised the record retention requirements for cytology laboratories to allow those laboratories with HHS approval for slide release to loan slides to PT programs. However, PT programs must insure that the slides will be available upon request by the donating laboratory.

Comment: Many commenters offered suggestions on the number of slide preparations to be included in each test set for a PT event. The suggestions

ranged from one slide (to insure every one was tested fairly) to 60 slide preparations per slide set.

Response: We have selected 20 slide preparations per test set as a reasonable number of challenges that may be used to evaluate an individual's performance on a variety of challenges without resulting in undue penalty for the testing event if the individual has minor problems in slide interpretation. This number is large enough to include a good representation of the types of slide preparations an individual will encounter in the examination of patient specimens.

Comment: Many commenters favored requiring participation in a proficiency testing event by each individual examining gynecologic preparations; however, they questioned whether the intent of proficiency testing was to evaluate the cytotechnologist, the pathologist or a combination of the cytotechnologist and pathologist.

A few commenters felt the examination should determine the ability of the cytotechnologist to report negatives, identify unsatisfactory slide preparations, locate and mark abnormal cells and infectious disease conditions for referral to the technical supervisor or pathologist.

A few commenters felt an individual taking the examination should be penalized for reporting a negative result when the slide preparation is a premalignant or malignant condition but not for reporting results that indicate a premalignant or malignant condition on negative slide preparations as these are reviewed by the technical supervisor or pathologist.

Response: Participation in proficiency testing is required for all individuals, cytotechnologists and pathologists, engaged in the examination of gynecologic slides. As part of their responsibilities in slide examination, cytotechnologists routinely distinguish abnormal morphology during their evaluation of patient specimens. Therefore, it is appropriate to evaluate a cytotechnologists' performance through a proficiency testing program that assesses the individual's ability to identify unsatisfactory preparations, abnormal processes and infectious agents. CLIA '88 (section 353(f)(4)(B)(iv) of the PHS Act) also requires the evaluation of the proficiency of individuals screening or interpreting cytological preparations (slides).

Comment: One professional organization recommended that unsatisfactory slide preparations be included in the proficiency testing slide set.

Response: We agree with the commenter and have added unsatisfactory slide preparations to the type of slide preparation challenges that might be included in each test set.

Comment: It was suggested that the exact type of challenges to be included in each test set not be stipulated in the regulations as this affords the individual taking the proficiency testing examination the opportunity of identifying a slide preparation by the process of elimination, which does not accurately assess the individual's ability to identify cells in each slide preparation.

Response: We agree with the suggestion and have not required that each test set include all of the different challenges.

Comment: A few commenters suggested a standard or universal nomenclature system be used for reporting results on the cytology PT examination.

Response: We agree with the commenters. In an effort to assure effective communications between the laboratory and patients' physicians, a December 1988 cytology conference was sponsored by the National Cancer Institute and resulted in consensus on a uniform reporting system for cytology known as the Bethesda System. We are specifying in § 493.945(b)(2) that the Bethesda System NIC, 1986, be used for reporting gynecologic results on proficiency testing samples. Since at the time of the August 5, 1988 rulemaking the cytology community was not in agreement on a standardized reporting system, we did not propose nomenclature for reporting cytology results on patient samples. We determined that it would not be appropriate to establish such a requirement in the final rule without the benefit of soliciting public comment. In the implementation of CLIA '88, we are considering soliciting public comment on a proposed requirement for laboratories to use the Bethesda System for reporting cytology results.

Comment: Many individuals commented on Option 1 (on-site proficiency testing), Option 2 (mailed proficiency testing), and Option 3 (combination of Options 1 and 2) and indicated preferences for glass slides, video discs, or kodachromes. Option 1, on-site proficiency testing utilizing glass slides, was preferred by the majority of those who commented on the options. Several commenters noted that the ideal system for evaluating performance was through blind proficiency testing slides.

Response: We agree with the commenters who prefer on-site proficiency testing using glass slides.

We are requiring at § 493.945(a) that proficiency testing programs use glass slides and at § 493.855 that at least one on-site PT event in cytology take place each year. This option provides a testing situation which most closely resembles the actual examination of patient samples. Although blind proficiency testing would be preferable, it is not practical or feasible on a large scale basis at this time. However, we do support an individual laboratory developing a "blind" proficiency program to evaluate individual's competency as specified in subpart M.

Summary of Changes to the Proposed Rule

Section 493.901 Approval of Proficiency Testing Programs

- PT programs may purchase PT material from manufacturers conforming with the Good Manufacturing Practices required in 21 CFR 606 and 640.
- Each PT program must provide HHS with a description of samples that it plans to include in its annual program for each specialty and subspecialty of services.
- Each PT result form must now contain an attestation statement and signature block to be completed by the individual performing the test(s).
- The PT program must have a mechanism for participants to notify the program when shipments are not received when due or are received in a condition unacceptable for testing. In addition, the PT program must have a mechanism to provide replacement specimens.

Section 498.903 Administrative Responsibilities

The PT program must issue PT result reports in an approved format on each laboratory within 45 days after the date for reporting PT results on the testing event.

Section 493.907 Process For Updating PT Testing Programs

The program updating process will not include the removal of well-performed tests but will incorporate new analytes, tests or organisms of clinical significance, delete obsolete tests and improve the evaluation scheme.

Sections 493.909-493.959 PT Programs By Specialty and Subspecialty

The notable general and specific additions and changes to specialties and subspecialties within this final rule follow.

- With the exception of immunohematology, the determination of accuracy of a laboratory's response

for each PT sample will be made by the PT program comparing the laboratory's response with the response of either 80 percent of ten or more referee laboratories or 80 percent or more of all participants. In immunohematology, the percentage used for comparison to determine the accuracy of a laboratory's response is 100 percent; the percentage for unexpected antibody detection and antibody identification is 95 percent agreement.

• We are including virology as a subspecialty of microbiology and urinalysis as a subspecialty of chemistry. (Several commenters suggested other subspecialties to be added, such as viral serology within diagnostic immunology, or drugs of abuse, erythrocyte protoporphyrins and/or blood lead in chemistry. Because these subspecialties were not proposed initially and including them would be a substantive change, we prefer to propose any such changes to everyone in a new proposed rule. We are also not prepared at this time to add or revise specialty categorization of tests because the insurance carriers responsible for payment of Medicare claims will need to reprogram to accommodate the new codes created by changes in subspecialties. Moreover, the specialty certification of all Medicare-approved laboratories would need to be reviewed and revised to reflect the addition or changes in specialties and subspecialties. However, we will consider revisions in the categorization of tests by specialty and subspecialty as part of another rulemaking to implement CLIA '88.)

• Inadvertently, we did not include in the proposed rule the current subspecialty categorization for the specialty of immunohematology. We have included in the final rule the subspecialties of immunohematology with clarification as to types of tests included.

• Individual tests have been added to some subspecialties; total protein is included under routine chemistry, and under endocrinology the additions of T_3 uptake, Triiodothyronine, free thyroxine and quantitative human chorionic gonadotropin should be noted. The specimen types (serum, plasma, or blood) for endocrinology PT samples have been expanded to include urine.

• We made adjustments to criteria for acceptable performance of specific tests; these are aspartate aminotransferase, pCO_2 , calcium, creatinine, glucose, potassium and sodium in the subspecialty of routine chemistry, lithium in the subspecialty of toxicology, and hemoglobin, leukocyte count, and

cell differentiation in the specialty of hematology.

- The number of proficiency testing samples per quarter was slightly reduced throughout microbiology, and the number of samples in all other specialties and/or subspecialties was increased. The total number of samples for each analyte per testing event has been adjusted to five throughout.

- The subspecialties of mycobacteriology, mycology and parasitology now have more concisely defined types of laboratories. We revised the types of laboratories under immunohematology, discussed more extensively under the comments and responses concerning § 493.153 (§ 493.959).

- The criteria for acceptable performance for qualitative tests in bacteriology, mycobacteriology, general immunology, routine chemistry, endocrinology, toxicology, hematology, and immunohematology have been specified.

- We have added grading formulas to all applicable specialties and subspecialties; the formulas state precisely how the program is to determine an individual analyte score for the testing event and the overall testing event score. The addition of these formulas fulfills to the extent possible the requirement of CLIA '88 (section 353(f)(3)(B) of the PHS Act) that states that the standards established by a PT program shall include uniform criteria for acceptable performance.

- In bacteriology, § 493.99(c)(4) (§ 493.911(c)(4)) the evaluation of a laboratory's performance for susceptibility testing has been made more definitive. The example used under § 493.99(c)(5) (§ 493.911(c)(5)) illustrating how a sample's score would be determined was corrected. Also, under § 493.959(c) (§ 493.153(c)), Immunohematology, the analyte ABO grouping has been clarified to exclude subgroups.

- The finalized version of cytology has more extensive inclusions:
 - Each individual's testing event will consist of 20 slides for interpretation.
 - Each individual must be tested twice annually.

- A 95 percent consensus agreement of the diagnosis must be made on PT slides that are negative, unsatisfactory, benign reactive, or infection.

- Premalignant or malignant slides used for PT must be confirmed by tissue biopsy. That biopsy must be confirmed by an 80 percent consensus agreement of at least 5 pathologists.

- The grading system has been established through a modification of the New York State grading scale. We

are requiring PT programs to establish the correct response or target diagnosis for PT slides, using the nomenclature developed at the National Cancer Institute Workshop in Bethesda, Maryland in December, 1988, and known as the Bethesda System.

We appreciate the responses of the very large number of commenters who offered their perspectives on the PT sections. The public has become more aware of laboratory quality and proficiency testing as a demonstrable indicator of the laboratory's ability to furnish accurate test results. Through the combined efforts of all involved, the requirements now in place for a proficiency testing will identify laboratories whose performance needs improvement and provides all laboratories the opportunity to demonstrate their levels of performance over time.

CLIA '88 Changes

1. Section 353(f)(3)(C) of CLIA '88 specifies that HHS shall approve PT programs offered by private nonprofit organizations or a State. This language has been added to the regulation to assure consistency between the current requirements and CLIA '88 in the evaluation of PT programs for approval.

2. The proposed rule stated in § 493.93 (§ 493.903), without specifying the purpose or frequency of the data, that the PT program must furnish HHS with additional information and data upon request. CLIA '88 (Section 353(f)(3)(C) of the PHS Act) requires us to evaluate each PT program annually; therefore, we are requiring in § 493.903 that program providers submit such information as is necessary for us to determine whether the PT program continues to meet our approval.

Subpart E(j)—Patient Test Management

Proposed Rule Overview

We proposed to establish a new subpart E and a new condition—§ 493.201, Condition—Patient test management. This condition would provide a uniform set of requirements for all laboratories (CLIA and Medicare) for test requisition and specimen submission and would more clearly define the actual records that must be kept and why they are required.

The proposed requirement was to be based on current Medicare requirements dealing with clinical laboratory management (§§ 405.1316 (e), (f) and (g)), quality control (§ 405.1317(a)(7)), and CLIA '67 laboratory requirements dealing with reports and records (§§ 74.53 and 74.54).

In the proposal, the existing requirements would be modified to allow for electronic ordering of laboratory tests to keep pace with modern technology and the advances that follow with the increasing use of computer systems. We expected these computer systems to be provided with security systems with "keys" or passwords to assure that only authorized persons can order tests. In addition, we would add to the specimen requisition requirement for cytology examinations, in § 493.201(b)(5), the provision that pertinent clinical information necessary for accurate diagnosis of cytology specimens must be provided to the laboratory, including, for Pap smear testing, an indication of whether the patient is at risk for developing cervical cancer or its precursors.

The existing requirement for retention of reports in pathology would be increased from two years to ten years because a two-year time period is insufficient to assure adequate patient tracking for cancer screening, diagnosis and followup.

The proposed standard on specimen records would indicate that the critical requirement is for the laboratory to have a system that ensures identification of the specimen being tested through all stages of testing.

The proposed rule removed the restrictive standards under Medicare that only persons authorized under the Medicare program to request or receive results could request and obtain such results even if they were not seeking Medicare payment.

The laboratory would have to determine or verify normal ranges used for reporting patient test results through validation studies required in § 493.235.

The proposed new section also would require the laboratory to make available to clients, information on factors that may affect the interpretation of test results (if they are known), including interferences, detection limits, sensitivities, specificity, accuracy, precision and validity of these test measurements. In addition, laboratories would be required to notify clients whenever changes occur in testing methodology that affect test results or interpretation of test results.

We proposed to add a requirement on test referral (standard (e)) to indicate that each laboratory performing tests either directly or on referral must have its name and other identifier on the report to the individual requesting or receiving test results so that the individual receiving the report will know

which laboratory actually performed the test.

Under the proposed requirements the laboratory must maintain a legally reproduced copy, rather than an exact duplicate as is required by current § 405.1316(g), to make these regulations consistent with other Medicare recordkeeping requirements and to allow for the use of new technologies in the storage and transmittal of data.

Comment and Responses

Section 493.201 (§ 493.1101) Condition: Patient Test Management

Comment: The majority of the commenters agreed with requirements specified for specimen collection and requiring laboratories to establish policies for specimen rejection. A few commenters questioned the need for requiring the laboratory to have such policies.

Response: Laboratory testing is dependent on the condition of the specimen to be analyzed or examined; thus, we maintain the requirement as written.

Comment: One commenter requested a provision to allow oral requests for laboratory tests, provided written authorization is obtained within forty-eight hours.

Response: We agree that oral requests for laboratory tests should be permitted provided that the laboratory subsequently obtains written authorization. However, we are requiring that the written authorization be obtained within 30 days, to ensure that one is obtained and allow a reasonable timeframe for receipt of written authorization.

Comment: Several commenters disagreed with the requirement that test requisitions must be maintained for two years.

Response: All records of testing must be maintained for two years to assure a complete record of patient testing.

Comment: Several commenters expressed concern with allowing individuals to order tests and receive test results. A few commenters were in favor of allowing this.

Response: These regulations permit individuals to order tests and receive results only when such practices are not in conflict with State and local law. In addition, only tests ordered by persons authorized by the Social Security Act to order laboratory tests will be reimbursed under Medicare.

Comment: Commenters raised the concern that omission of one or more of the items listed in paragraphs (b) (1) through (8) concerning patient or

specimen data would require them to reject a specimen.

Response: Laboratories must establish their own policies to ensure proper specimen identification, patient information, and specimen rejection criteria.

Comment: Many commenters agreed that the patient and specimen data requirements in (b) of this section would be very useful and may be pertinent to testing. However, the commenters were concerned that the laboratory would be ultimately responsible for obtaining any information omitted by the clinician.

Response: We agree with the importance of this information as outlined in this paragraph and, therefore, maintain this requirement as proposed. It is our intent that the laboratory make provisions for obtaining this information on a requisition, provide instructions for completing this requisition, and demonstrate reasonable attempts to obtain the information.

Comment: An overwhelming number of commenters expressed concern for identifying patients at risk for developing cervical cancer.

Response: We appreciate the commenters' concerns that including this type of information on specimen requisitions implies that clinicians must categorize all women either as "at risk" or "not at risk" for developing cervical cancer. To avoid this, we have eliminated this specific item requiring the identification of patients "at risk" for cervical cancer. However, we hope that physicians will provide this information in the pertinent clinical information section.

Comment: The majority of the commenters agreed with the information required under specimen records, but a few individuals felt these requirements were too specific.

Response: With the exception of the source of specimen and time of receipt of the specimen in the laboratory, all of these items are included in the current laboratory requirements and represent the minimum information that the laboratory should obtain and maintain for specimen records. Maintaining records of the source of the specimen is critical to laboratory testing, particularly in microbiology and pathology. Documenting the time of specimen receipt in the laboratory is essential in many instances to assure specimen integrity.

Comment: The majority of the commenters agreed with the requirement of maintaining cytology reports for ten years. However, several of the commenters asked why

histopathology reports should be maintained for a lesser period of time.

Response: We agree with the commenters and are specifying that all pathology reports are to be maintained for ten years.

Comment: A few commenters expressed concern that the requirement concerning reporting results within established timeframes mandated that laboratories define "turn-around times" for all tests performed.

Response: It is not our intent to establish through regulations test "turn-around times." However, the laboratory must establish and adhere to its own policies defining timeframes in which the tests it performs should be completed and reported.

Comment: Concerning our proposed requirement that legally reproduced copies of test reports must be filed in the laboratory in a manner that permits ready identification and accessibility, several of the commenters requested clarification of "legally reproduced copy", "ready identification and accessibility" and whether reports may be stored away from the laboratory premises.

Response: A legally reproduced copy of a test report is the exact duplicate of the patient test report issued to the authorized person requesting the test. If the test report was computer generated, it must be produced in the same manner as the original report, duplicating exactly all information issued to the authorized person who requested the test(s). This flexibility will allow laboratories utilizing computer systems to maintain computer records of reports, as opposed to the exact duplicate provided the computer generated report contains all information required of reports. Regarding ready identification and accessibility, our operating policy is to require that all laboratory records should be retrievable within two hours of request and permits storage of records on other premises if the two hour requirement for retrieval of records is met.

Comment: Several commenters suggested the use of the manufacturers' criteria for the laboratory's "normal" ranges.

Response: See comments and responses concerning § 493.1215 in subpart K.

Comment: Several commenters expressed concern about the requirements for the laboratory to alert the individual requesting the test of "panic" values. The commenters indicated that the requirement should be reworded to require that laboratories notify the medical personnel responsible

for the care of the patient of "panic" value results.

Response: We agree with the commenters and have added the phrase "or the individual responsible for utilizing test results" to § 493.1101(d)(5).

Comment: A few commenters objected to including information regarding the condition of specimens that do not meet the laboratory's acceptability criteria on the test report. One commenter favored the inclusion of this information. One commenter felt the final report should note when incomplete information was submitted by the clinician.

Response: The information on the test report regarding the condition of specimens that do not meet the laboratory's acceptability criteria is in the current laboratory requirements and is maintained to assure that laboratories notify the individuals ordering tests when specimens are unsatisfactory for analysis. In addition, section 353(f)(4)(B)(v) of the PHS Act, as amended by CLIA '88, requires the inclusion of this information for cytology specimens. The current laboratory requirements represent the minimum information that should be included on the patient test report. The laboratory may include any other information it finds necessary to qualify patient test results.

Comment: Many commenters expressed concerns regarding the provision of information required in § 493.1101(d)(7) to clients when the clinical impact was negligible or minor changes occurred. The commenters requested the phrase "upon request" be added to this paragraph.

Response: We have added the phrase "upon request" to this requirement in § 493.1101(d)(7).

Comment: A few commenters opposed the requirement for the interpretation of pathology cases to be performed at a laboratory that is approved and/or licensed and objected to indicating on the report form where the slide preparations are examined.

Response: A Medicare-approved laboratory may refer specimens for testing *only* to a laboratory in the same State that meets the Federal health and safety standards and is Medicare approved for the appropriate specialty or subspecialty. A CLIA licensed laboratory may refer specimens for testing *only* to a laboratory that meets Federal health and safety standards and is CLIA licensed (or exempted from CLIA licensure) for the appropriate specialty or subspecialty. The laboratory report must reflect the name and address of the laboratory performing the test.

Comment: A few commenters indicated the proposed regulations allowed in § 493.201(e) the use of Medicare approved and CLIA licensed laboratories interchangeably as reference laboratories.

Response: We agree with the commenters that this paragraph was misleading and we have reworded it to reflect that a Medicare-approved laboratory may only refer specimens to another laboratory that is a Medicare-approved laboratory within the State. Test referrals to a laboratory in another State require that the referral laboratory be licensed or exempted from license in the specialty or subspecialty in which the test is categorized. A CLIA-licensed laboratory may only refer interstate specimens to another laboratory that is CLIA-licensed (or exempt from CLIA licensure) for the appropriate specialty or subspecialty.

Comment: A few commenters asked whether nonapproved research facilities, such as Federal and State laboratories, could be used to refer esoteric tests and communicable disease specimens.

Response: Specimens may be referred to Federal and State laboratories for testing. These regulations are not currently applicable to Federal laboratories. With respect to State laboratories, if tests are performed on Medicare/Medicaid patients, and the State laboratory charges for its services, the State laboratory is subject to Medicare requirements. If a State laboratory accepts specimens in interstate commerce, it is subject to CLIA requirements for licensure.

Comment: A few commenters questioned whether interpretations of test results and consultations concerning laboratory tests were the same and under which circumstances the testing laboratory should be notified.

Response: In 42 CFR 405.556 and section 4142 of the Medicare Carriers Manual (HCFA Pub. 14-3), consultations are defined as services requested by the patient's physician, related to a test result that exceeds the clinically significant normal or expected range in view of the patient's condition, result in a written report and require the exercise of medical judgment by the consultant physician. Interpretations have not been defined in regulations or policy manuals. However, if the laboratory issues a written interpretation of a test result, the interpretation report, like the consultation report, should specify the name and address of the laboratory performing the service. If the interpretation or the consultation results in revisions of the laboratory report, the individual requesting the test and the

laboratory that performed the test should be notified.

Summary of Changes to Proposed Rule

Section 493.1101 Patient Test Management

Minimal additions have been made to this subpart and include:

- The laboratory must make available to clients written instructions for specimen labeling.
- The laboratory must assure that the requisition includes the name or identifying laboratory code number of test(s) ordered as well as patient sex, and pertinent clinical information, and age or date of birth.
- The items required and documentation necessary for a specimen identification system have been expanded.
- A legally reproduced record of preliminary laboratory reports must be preserved for at least two years after the reporting date.
- The retention time of all pathology reports is ten years from the reporting date.
- The laboratory must establish reporting procedures for imminent life-threatening results (panic values) and alert the requesting individual or the individual responsible for utilizing the test results.

Subpart F(K)—Quality Control

Proposed Rule Overview

Existing quality control requirements are in § 405.1317 and part 74, subpart C. We proposed to revise and move them to part 493 and form separate conditions. New § 493.221, Condition: General quality control, would be applicable to all the specialties and subspecialties. New § 493.241, Condition: Quality control—specialties and subspecialties, would specify that failure to meet the condition unique to a particular specialty or subspecialty would result in the loss of Medicare approval or CLIA licensure (or both) of that specialty or subspecialty.

The revision of these regulations would reflect changes in technology as well as clarify the specific requirements for each standard. The clarifications would reflect the current Medicare guidelines and would more explicitly inform the laboratories of their responsibilities under the regulations.

1. General quality control requirements: § 493.221 through § 493.240 (§ 493.1201 through § 493.1221).

The general quality control regulations in §§ 405.1317(a) and 74.20 were to be combined into one uniform condition as § 493.221. We made the

general quality control a condition to indicate its importance. We proposed to divide the requirements in current §§ 405.1317(a)(1) and 74.20(a) into several standards in new sections in order to define more clearly what the requirements are and to separate the various requirements in the current regulatory factor into several distinct and related categories so that each is equal in importance.

New § 493.221 would elaborate on what such items as "adequacy of equipment" and "test systems" consist of beyond the descriptions in the current § 405.1317(a).

We proposed to add a requirement that the laboratory specify the procedure the staff is to follow in case quality control results or patterns do not follow the expected patterns established by the laboratory. There would also be procedures for reporting patient results when test method limitations are exceeded. These are critical elements in the performance and reporting of test results and are necessary to assure that accurate and reliable results are obtained and reported. Since these factors are essential, the laboratory staff should be aware of these procedures. The quality assurance program (described in proposed § 493.451) would assure that these procedures are in place and followed.

We also proposed to require the laboratory to verify the validity of its procedures. This requirement is contained in the current regulations in § 405.1317(a)(1) but we would spell out in detail what constitutes the validation of each test method.

We also proposed to add a requirement that the laboratory have a mechanism in place to verify the accuracy and reliability of data management and reporting systems to assure that the data is accurately analyzed, processed and reported. We also would revise the regulations to indicate the importance of detecting errors in test results and reporting and promptly correcting these errors since the detection of the errors is a critical element in assuring accurate and reliable test results.

We proposed to add a requirement under the general quality control condition for the frequency of running quality control materials. The frequencies are currently indicated in § 405.1317(b). This revision would also reflect the changes in laboratory technology. We would also add provisions to these regulations to allow for lesser frequencies a changes in technology lead to improvements in test systems.

Our new requirements on equipment maintenance and function checks would indicate that the laboratory must define its own program based on the manufacturer's instructions. This is a revision from current requirements in § 405.1317(a). The laboratory would have to demonstrate that its procedures produce accurate and reliable test results. We sought comment on the appropriateness of relying on manufacturers' protocols. The new requirement would also provide for technological change. We would not specify performance characteristics but would specify that the laboratory must determine its own performance characteristics based on validation studies and must adhere to these established performance characteristics. We would require the laboratory to make the performance characteristics available upon request to individuals ordering and receiving test results. The quality assurance subpart, Subpart H, would require the laboratory to adhere to its quality assurance program and established protocols.

We proposed to define validation of methods and remedial actions and specifically indicate what is required. The requirements would match our current guidelines and would better inform the laboratories of their responsibilities.

Whenever possible we placed similar requirements in the general section that apply to more than one specialty area. In addition, because of the advent of certain new technologies, we would no longer require daily instrument verification separate from quality control checks. Rather, we would specify the basis and frequency for performing instrument checks, which correspond to our current guidelines in this area.

We also proposed to define the timeframes in which control samples must be tested with patient specimens to assure accurate results. The current requirement for including controls with each test run of patient specimens is clarified in these proposed requirements. We included alternatives to the use of two standards or two controls since these materials are not always available.

2. Specific quality control requirements: § 493.243 through § 493.315 (§ 493.1225 through 493.1285).

We proposed to transfer the contents of current § 405.1317(b), Standard; Quality control system methodologies, to this new subpart and create for each specialty a new condition and for each subspecialty a new standard. A laboratory must meet the conditions corresponding to the specialties and the

standards corresponding to the subspecialties for which it wishes to be approved or licensed. These conditions and standards appeared in proposed §§ 493.243 through 493.315. Any laboratory found out of compliance with a condition for a specialty or standard for a subspecialty would not become or remain approved or licensed for that specialty or subspecialty.

In § 493.243 we proposed to include revised microbiology requirements to indicate that the frequency of performing controls has been changed to reflect standards for current technology and state of the art developed by HCFA and CDC working with the National Committee for Clinical Laboratory Standards (NCCLS).

We also proposed to revise (in § 493.255) the syphilis serology (diagnostic immunology) requirements to reflect that CDC no longer publishes a reference manual on tests for syphilis serology. We would also add the hepatitis testing and human immunodeficiency virus test requirements for facilities performing this testing on blood and blood products used for transfusions. We would consolidate the requirements for serologic testing of the blood and blood products in this section since they relate to this area and we would not require reference laboratories performing this testing for blood banks to obtain an additional certification in immunohematology. The requirements would coincide with the PT categories being developed for these regulations.

We proposed to revise the chemistry regulations (in § 493.261) by adding requirements for three subspecialty areas: routine chemistry, endocrinology and toxicology.

The revised hematology section (proposed § 493.269) would reflect the fact that most of the requirements have been moved to the general quality control section. We would not retain current provisions for allowing an exemption from running specimens in duplicate for coagulation tests such as prothrombin time since there is no scientific evidence at this time available to justify retaining the current provisions. When criteria are available they would be published.

We proposed to revise the requirements for cytology to assure that the laboratory has a quality control program to detect errors and assure accurate diagnosis. We would specify that gynecologic preparations must be stained using the Papanicolaou stain because it is the stain of choice for demonstrating abnormal cells. We would impose requirements for staining

procedures to protect slide preparations from cross-contamination from other specimens.

We sought comments on whether we should establish workload requirements for individuals examining cytology slides. Our deliberations on establishing workload requirements resulted in consideration of several options.

One option we considered was setting a limit on the number of slides that may be reviewed by each cytotechnologist in a day. A second option we considered is setting an annual volume limit based on reasonable staffing patterns for cytology laboratories. The third option we considered specified a Federal workload limitation for cytotechnologists by placing with the technical supervisor responsibility for determining the number of slides that can be reviewed competently and accurately by each full-time cytotechnologist in an eight hour day or for part-time cytotechnologists in a lesser time period.

We proposed to revise our current requirements for rescreening of gynecologic or Pap smears interpreted to be negative from our current requirement of a ten percent random sample to either a ten percent rescreen of all negative cases screened by each cytotechnologist or a rescreen of all cases from women who are at risk for developing cervical cancer or its precursors. We specified that the laboratory must complete the rescreening before it issues final reports in order to detect and correct any false-negative results in timely manner. Also, the laboratory would not have to report Pap smear examinations immediately except in cases of viral infections in pregnant patients, dysplasia or abnormal results.

We proposed that laboratories document specified annual data to develop a statistical approach to evaluate their performance and to evaluate an individual's performance against the laboratory's overall statistics.

We proposed to specify information that must be on the laboratory report to assure that the individual ordering the cytology examination has all of the facts needed to interpret the results reported.

We proposed to increase our requirements for retention of slides and reports to assure that laboratories are able to correlate previous diagnosis with current findings.

The proposed requirements for histocompatibility testing (§ 493.277) were the same as those that already apply to Medicare laboratories but would now also apply to CLIA laboratories. We proposed to update technical requirements now in Medicare

regulations and include the explicit requirements for which HLA antigens are to be identified. We proposed not to retain certain frequency checks for the components of the serum trays found in current regulations. We also proposed to make the requirements more explicit with regard to what is required under each section of the regulation.

In proposed § 493.281 we would revise the immunohematology requirements now in § 74.24 to make them consistent with the Medicare requirements. We also cross-referred this standard to 21 CFR part 806 (with the exception of § 606.20(a) Personnel) to provide total consistency between Medicare and FDA regulations and to assure that any changes in the FDA regulations are reflected in the Medicare regulations. We also proposed to add a requirement that laboratories collecting, processing and transfusing blood and blood products meet the requirements in 21 CFR part 806 to make the Medicare regulations consistent with the FDA regulations on this subject.

We also proposed to add explicit requirements for cytogenetics testing because of the importance of this area in testing for genetic defects and the fact that the existing general quality control requirements do not adequately address this area.

It was our intent for the condition on blood banking and transfusion service to apply to all facilities in which these services are offered. Therefore, we did not propose to retain in proposed § 493.303 the hospital-specific language contained in § 482.27(d) and would move the remainder to subpart F and cross-refer all other applicable regulations to this subpart. Facilities not offering these types of services would not have to comply with these requirements. We proposed that all laboratories performing testing, processing and storage of blood and blood products comply with the FDA regulation at 21 CFR 610.53 for dating periods.

We also proposed to cross-refer the condition on bloodbanking and transfusion services to all of 21 CFR part 640 rather than just certain sections, as does § 405.1317(b)(4)(ii).

We would also include the reference in this new condition since it contains the specific FDA recordkeeping requirements for this area.

Comments and Responses

Comment: Several commenters believe that quality control requirements are too costly and detailed. Two commenters suggested eliminating subpart F in its entirety, leaving subpart H—Quality Assurance to cover these requirements.

Response: We established subpart H (now M), Quality Assurance Requirements, to assure that laboratories monitor and evaluate their individual operations. We provide flexibility to a laboratory in determining its own program for assessment but these requirements do not supersede the specific minimum requirements necessary in each area of laboratory test results outlined in subpart F (now K)—Quality Control. We are maintaining the proposed requirements in the final rule to keep the important safeguards that the quality control requirements provide to assure accurate results.

Section 493.223 (§ 493.1203), Standard: Facilities

Comment: Two commenters believe that more specificity was needed in defining "adequate" space in a facility and another commenter agreed with the section as written.

Response: It is not feasible to define the amount of space needed specifically since laboratories vary in the services provided and equipment or instrumentation utilized. In general, space is determined to be not adequate when testing is adversely affected due to space limitations.

Section 493.225 (§ 493.1205), Standard: Adequacy of Methods and Equipment

Comment: Several commenters believe that paragraphs (b) and (c) of § 493.225 concerning test methods and instrumentation should be eliminated and that a laboratory may rely entirely on a manufacturer's specifications. Two commenters agreed with these paragraphs as written.

Response: Every laboratory is ultimately responsible for establishing and supporting its basis for performing and reporting tests. Manufacturers' protocols provide excellent guidance in establishing performance characteristics and a laboratory may use these protocols to assist in establishing its own performance characteristics based on the equipment, methods, reagents and intended use of the tests for the patient population serviced. Therefore, we require each laboratory to establish its performance characteristics.

Comment: Three commenters believe that the examples of types of equipment included in § 493.255 were inappropriate and confusing.

Response: We agree with the commenters and have eliminated the examples.

Comment: Two commenters noted that paragraph (d) of § 493.225 concerning adequate reporting systems

was redundant since it was also addressed in subpart E and subpart H.

Response: We agree with the commenters and have not included this paragraph in the final rule.

Section 493.229 (§ 493.1209), Standard; Labeling of testing supplies

Comment: Concerning § 493.229, labeling of testing supplies, several commenters believe that exceptions should be considered for using reagents that have passed the expiration date, providing the reactivity of such reagents has been validated. One commenter requested the ability to use rare antisera that had passed their expiration date.

Response: We recognize that it may be appropriate to permit the use of rare antisera in certain circumstances when the reactivity of such reagents has been validated. However, for licensed biological products, product dating requirements specified in 21 CFR 610.53 must be met. Any exceptions to these product dating requirements are granted by the Food and Drug Administration in accordance with 21 CFR 610.53(d).

Comment: Several commenters believe that we should require laboratories to comply with manufacturers' specifications in regard to not "mixing" reagents from kit to kit in the use of reagents.

Response: We agree with the commenters and have added a requirement to cover kit reagents in new § 493.1209(c). This new paragraph prohibits the interchange of kit components with those of another with a different lot number unless specified by the manufacturer. A definition of "kit" has been provided and included in § 493.2 of this part.

Section 493.231 (§ 493.1211), Standard; Procedure Manual

Comment: One commenter noted the omission of test calculations when reporting patient results in § 493.231(a).

Response: We recognize this omission and have added it in paragraph (a)(9) of § 493.1211.

Comment: Several commenters believe that the supervisors rather than the director should be responsible for approving procedures and changes in procedures. One commenter noted that a requirement for annual review of procedures was omitted.

Response: As the person ultimately responsible for all services of the laboratory, the director must initially approve procedures and all changes in procedures. In view of the requirement that all changes in procedures be approved by the director, we do not believe a requirement for annual review is necessary.

Comment: Two commenters thought the retention of records of procedures for "up to two years" was not a long enough time to retain these records of procedures when the procedure was in use for longer than two years.

Response: We agree with the commenters and have specified that the procedure records are to be retained for two years after the procedure has been discontinued.

Comment: Several commenters requested to use manufacturers' package inserts as supplements to written procedures.

Response: Manufacturers' package inserts are acceptable in lieu of other written procedures, providing policies and procedures listed in § 493.1211(a) (1) through (11) are available; therefore, there has been no change to this paragraph.

Comment: Several commenters noted that documentation of corrective action when quality control results deviate from expected values or patterns was not required in this section.

Response: We agree and have added this requirement under § 493.1219, Standard; Remedial action of this subpart.

Comment: Comments were equally divided in support of and in opposition to maintaining the requirement for quality assurance policies for each laboratory procedure.

Response: The requirement for quality assurance policies allows a laboratory to establish procedures for monitoring the quality of its testing to assure that the laboratory performance is within established acceptable criteria. § 493.233 (§ 493.1213), Standard; Equipment, maintenance, and function checks.

Comment: Several commenters believed that preventive maintenance should not be performed less frequently than the manufacturer recommends. Several commenters agreed with the laboratory defining its preventive maintenance program and one commenter opposed the laboratory defining its preventive maintenance program because laboratories will not follow manufacturer's protocols and will establish inappropriate frequencies for maintenance.

Response: We agree that preventive maintenance should not be performed less frequently than the manufacturer recommends. However, a laboratory may establish more frequent maintenance, if needed.

Comment: Several commenters believed that the requirement in § 493.233(b)(1) concerning function checks mandates a complete calibration or recalibration each day of use.

Response: We have restated existing language in § 493.1213(b) to emphasize that this requirement refers to activities and checks that are performed on a daily basis to ensure that an instrument device or test system is functioning correctly and is properly calibrated but does not require a full calibration, recalibration, or calibration check unless specified by the manufacturer. It should be noted that in many cases the performance of daily quality control as specified in § 493.1217 serves as a function check, since the testing of quality control samples checks all of the operating characteristics of a test system, including instrument stability and calibrations.

Comment: Three commenters believed that required function checks should not be performed at a lesser frequency than the manufacturer recommends.

Response: This requirement allows the laboratory to use the manufacturers' recommended frequency for instrument function checks.

Comment: One commenter noted the omission of a frequency requirement for baseline or background checks on applicable equipment in § 493.233(b)(3).

Response: We acknowledge this omission and have specified checks each day of use. (This is not a change from current requirements.)

Section 493.235 (§ 493.1215), Standard; Validation of Methods

Comment: Many commenters provided recommendations on this standard. The commenters were evenly divided between a desire to maintain the requirement for laboratories to validate methods and to delete the requirement in lieu of the manufacturer's method validation.

Response: While we recognize that manufacturers provide useful information in support of method validity, the laboratory's circumstances of test performance may not mimic the manufacturer's test conditions. Each laboratory must demonstrate, within reason, its basis for performing and reporting tests.

Comment: One commenter had questions with regard to method validation versus test procedure calibration.

Response: We have clarified this misunderstanding and have made § 493.1215 compatible with calibration requirements specified in § 493.1217 (formerly § 493.237).

Comment: Many commenters expressed concern that the requirement for the laboratory to provide documentation of precision, accuracy,

sensitivity and specificity for each method was too burdensome.

Response: We understand the commenters' concern for the extent to which a laboratory must investigate and provide documentation of precision, accuracy, sensitivity and specificity. Depending on the test methodology, the manufacturers' data may specify these criteria; however, the laboratory must evaluate and verify these characteristics because the laboratory is ultimately responsible for all tests performed. We are maintaining the requirement for laboratories to establish and document their performance characteristics for test methodology.

Comment: Two commenters disagreed with the requirement in § 493.235 for defining the basis for reporting test results and the preclusion from reporting patient test results in the absence of verifying test performance characteristics.

Response: In our view it is not in the best interest of patient care nor is there scientific support for issuing test results in the absence of supportive documentation of test parameters and reporting limits.

Section 493.237 (§ 493.1217), Standard; Frequency of Quality Control

Comment: Several commenters noted that the term "run" was defined by a period of time only and should encompass qualitative testing.

Response: We agree with the commenters and are including a separate requirement at § 493.1217(e) for the frequency of testing quality control samples with qualitative tests.

Comment: One commenter requested clarification of a "procedural calibration" versus "calibration" as required in this paragraph.

Response: We acknowledge the confusion created with the word "procedural" in § 493.237(a)(1). Frequency of quality control, and have eliminated it.

Comment: One commenter requested the inclusion of "calibration verification" in § 493.237(a)(1).

Response: We agree with this commenter and have included "calibration verification" in § 493.1217(a).

Comment: Two commenters requested the deletion of the requirement in § 493.237(a)(1)(i) concerning performance of calibration or recalibration when a complete change of reagents for a procedure is introduced, while four individuals commented favorably.

Response: Any time reagents in a test system are changed, it is necessary to reestablish calibration since a complete

change in reagents can alter calibration. Therefore, we agree with the majority of the comments and have made no change to this section.

Comment: One commenter requested the deletion of the requirement for a laboratory to perform calibration or recalibration of each automated and manual method when major preventative maintenance is performed on any instrument, at § 493.237(a)(1)(ii), believing that it was included in § 493.237(a)(1)(iii), which requires calibration, calibration verification or recalibration when controls begin to reflect an unusual trend or are outside acceptable limits.

Response: There is a specific and distinct difference in each of these requirements. Major maintenance may cause variation in calibration and it is necessary to reestablish calibration before testing. Checking control values verifies only two points as opposed to calibration that gives at least a three point check. Therefore we have made no changes to this section.

Comment: Several commenters disagreed with the requirement for multiple point calibrations in § 493.237(a)(2)(i) and (ii) and recommended that the manufacturers' specifications be followed.

Response: We have provided in § 493.233(b) (now § 493.1213(b)) for the adherence to manufacturers' specifications with regard to requirements for verification of calibration of equipment and instruments each day of use. However, it is necessary for laboratories to demonstrate at least every six months that accuracy, precision, sensitivity and specificity of the test system is maintained within acceptable limits. Therefore, enhanced calibration requirements (standard curve) are necessary as outlined in paragraphs (a)(2)(i) and (ii) of § 493.1217.

Comment: Several commenters asked for clarification of "expected patient values" in § 493.237(a)(3), noting that calibrators were not available to cover the entire possible expected range of patient values. One commenter recommended that we allow for the dilution of patient specimens as part of this requirement.

Response: We agree with the commenters. The initial statement was too restrictive. In § 493.1217(a)(3) we have deleted the word "expected" from patient values and have included a provision for the dilution of patient specimens.

Comment: Several commenters noted that the term "linear range of the method" in § 493.237(a)(4)(ii) was too broad because the linear range may not

be the laboratory's range for reporting test results.

Response: We agree with commenters and have revised the terminology to more closely reflect the laboratory's reportable range.

Comment: Several commenters noted that instrument and reagent stability and operator variance were not addressed when determining the frequency of quality control.

Response: We agree with commenters and have added paragraph (b) to this section. This paragraph requires the laboratory to evaluate instrument and reagent stability and operator variance in determining the frequency of testing quality control samples in accordance with the definition of a "run" in § 493.2.

Comment: Several commenters offered suggestions when two calibrators should be required, when two controls should be required and when one calibrator and one control should be used.

Response: Although we appreciate these suggestions, we prefer that our requirements specify that each laboratory determine the frequency of quality control and the material to be used based upon its documented validation of each test procedure. This allows the laboratory maximum flexibility in determining the appropriate quality control program for each test.

Comment: One commenter noted that § 493.237(b)(3) allowed a laboratory to report test results without checking the test system with quality control specimens when calibrations and controls are not available for a specific test or instrument. The commenter also noted that this paragraph is incompatible with paragraph (b)(2)(iv) and suggested that every laboratory must have some mechanism for monitoring and evaluating test systems.

Response: We agree with the commenter and do not include the paragraph in this final rule because every laboratory must take responsibility for monitoring and evaluating its tests, as specified in a new paragraph (d)(3) of § 493.1217.

Comment: One individual requested clarification in § 493.237(c) with regard to establishing acceptable limits for unassayed controls.

Response: We agree with the commenter and provide clarification with the insertion of "over time" in what is designated as § 493.1217(f) of this final rule.

Comment: Three commenters noted that the word "microorganisms" in § 493.237(e) implied that this requirement was limited to microbiology staining reagents. One commenter

suggested we change "microorganism" to "sample of appropriate reactivity."

Response: We agree with the commenters and in § 493.1217(h) have excluded "by concurrent application to smears of microorganisms with" and have changed this language to "to ensure predictable standing characteristics."

Comment: Several commenters noted that § 493.237(d) conflicts with § 493.263, which only addressed reagents for qualitative urinalysis tests.

Response: We have revised this paragraph (now designated as (g)) to include semi-qualitative and qualitative tests with the inclusion of the language "as well as graded reactivity if applicable".

Comment: In commenting on proposed § 493.237(f) (now § 493.1217(j)) several commenters noted that for direct antigen tests it is unreasonable and unnecessary to check all phases of a system with positive control organisms.

Response: The ideal quality control system for direct antigen tests would include known positive and negative control organisms or bacterial cell suspensions in a matrix similar to patient specimens such as ready prepared dried swabs for identification of group A streptococcus. However, for viral direct antigen tests, live virus control in infected cells are not achievable. Therefore, viral antigen extracts are acceptable for monitoring viral detection phase although they do not demonstrate the leeching of antigen from cells. As more appropriate controls become available they should be employed to meet this requirement.

Reliable quality control systems for direct antigen tests are currently under review and evaluation for determination of appropriate and necessary requirements.

Comment: One commenter suggested adding "when labeled sterile" to the requirement in § 493.237(g) for checking media for sterility since all media may not be manufactured as sterile.

Response: We agree with the commenter and have included the suggested language in redesignated § 493.237(k).

Section 493.239 (§ 493.1219), Standard; Remedial Actions

Comment: One commenter requested more specificity in § 493.239 with regard to remedial actions to be taken when patient results are reported in error.

Response: We have provided additional specificity and clarification through the addition of paragraphs (c)(2) and (c)(3) to this section.

Section 493.240 (§ 493.1221), Standard; Quality Control—Records

Comment: One commenter noted that proposed § 493.240(a), which contained record-keeping requirements, was redundant and contains items already required and specified throughout this subpart.

Response: We agree with the commenter and have deleted paragraph (a) of this standard. We have also deleted paragraph (c) from this section, but add "and document" to § 493.239 (§ 493.1219), Standard; Remedial action. This eliminates the redundancy between these two standards.

Section 493.241 (§ 493.1223), Condition; Quality Control—Specialties and Subspecialties

Comment: One commenter requested a definition of the word "failure" in sentence three of § 493.241 which describes the consequences of failure to meet conditions or standards. Another commenter did not believe that a failure to meet quality control requirements should result in the loss of approval, licensure or exemption from licensure.

Response: We equate failure with noncompliance with applicable requirements. Quality controls are essential to assure accurate and reliable test results; therefore, we believe that we should not allow laboratories with quality control problems to continue to provide test results that have the potential to affect the diagnosis and treatment of patients adversely.

Comment: Several commenters expressed concern that quality control requirements were omitted in § 493.241 for specific specialty and subspecialty areas.

Response: These quality control requirements were not omitted. We call the commenters' attention to the second sentence of this paragraph, where it is stated that the laboratory must meet the general quality control requirements specified in §§ 493.221 through 493.240. These general quality control requirements are applicable to all specialties and subspecialties and are redesignated in this final rule as §§ 493.1201 through 493.1211.

Section 493.243 (§ 493.1225), Condition; Microbiology

Comment: Several commenters requested less frequency quality control requirements in microbiology in § 493.243.

Response: We have reviewed this section, which is consistent with our minimal requirements that were developed over time with the assistance and input of laboratory professionals as

well as professional organizations; therefore, we believe that currently these are appropriate for the services offered in this area. We are working with the National Committee for Clinical Laboratory Standards to review quality control frequencies in microbiology to determine appropriate quality control intervals to insure quality patient test results.

Comment: One commenter requested that laboratories be permitted in § 493.245 to report patient results when one drug—microorganism combination for reference organisms exceeded established limits.

Response: We agree with the commenter. This exception is currently authorized in the guidelines published May, 1986 in appendix C of the State Operations Manual (HCFA Pub. 7). The exception is based on adherence to The National Committee For Clinical Laboratory Standards publications and antimicrobial disc susceptibility tests and dilution antimicrobial susceptibility tests.

Comment: Several commenters requested less specificity with regard to methodology-specific requirements in § 493.245.

Response: We agree with the commenters on the specificity applied to radioisotope methods for DNA probes. Consequently, we are omitting that specificity from § 493.1227(a)(2).

Section 493.251 (§ 493.1233), Condition; Quality Control—Parasitology

Comment: One commenter noted that in § 493.251 we omitted the requirement for including a fecal control sample with parasites when performing checks on permanent stains.

Response: We agree with the commenter and have included the requirement for a fecal control sample to check staining characteristics in § 493.1233(c).

Section 493.253 (§ 493.1235), Standard; Virology

Comment: Two commenters expressed concern that proposed § 493.253 could be read in a way that, if a laboratory performs isolation and/or identification of a single virus, it would be responsible for evaluating viruses that are etiologically related.

Response: We agree with the commenters but do not believe the regulation must be changed. However, in appendix C of the State Operations Manual we will clarify the testing situations in which laboratories will need to evaluate viruses that are etiologically related.

Section 493.259 (§ 493.1241), Standard; General Immunology

Comment: Two commenters noted that § 493.259(d) as written implies that transfusion facilities would have to repeat HIV and hepatitis tests that were already performed on the blood or blood products.

Response: We agree with the commenters. It was not our intent to require retesting if testing was performed in an appropriately approved and/or licensed facility. We have changed this paragraph to be consistent with the Food and Drug Administration terminology, which provides that HIV and hepatitis tests can be referred to a laboratory that is approved and/or licensed to perform HIV and hepatitis tests.

Section 493.261 (§ 493.1243), Condition: Chemistry.

Comment: One commenter expressed concern that these requirements for chemistry quality control do not apply to CLIA-exempt laboratories.

Response: Once final regulations are established to implement all the provisions of CLIA '88, we will be evaluating those formerly CLIA-exempt laboratories engaged in low volume testing. The granting of exemptions under CLIA '88 will be based on HHS' determination that the tests the laboratory performs are simple, accurate, and safe procedures that pose no reasonable risk of harm to patients if performed incorrectly.

Section 493.263 (§ 493.1245), Standard: Routine Chemistry

Comment: Several commenters requested specific requirements in § 493.263 for blood gas analyses and deletion of the requirement to include a calibrator or control each time patients are tested for blood gases.

Response: We specify requirements for blood gases with the addition of (a) through (c) of this standard and have specified when a calibrator or control must be included. We also include provisions for automated instrumentation. These requirements are based on the guidelines of the National Committee For Clinical Laboratory Standards.

Comment: Many commenters requested that urinalysis be removed from the routine chemistry standard and made a separate subspecialty.

Response: We have removed urinalysis from the routine chemistry standard; it now appears alone in § 493.1251.

Section 493.269 (§ 493.1253), Condition: Hematology

Comment: Many commenters objected to the requirement for running automated coagulation tests in duplicate and one commenter suggested that control frequency should be based on each group of patients tested at the same time.

Response: We agree with the commenters and have revised this section. Requirements for coagulation have been separated out from other hematology tests for purposes of clarification and we have added a requirement to include two levels of control each time a change in reagents occurs. Section 493.1253(c) requires duplicate testing only for manual coagulation tests.

Section 493.270 (§ 493.1255), Condition: Pathology

Comment: Two commenters noted the absence of a subspecialty for dermatopathology and one commenter questioned the inclusion of oral pathology as a separate subspecialty.

Response: Dermatopathology is included within the subspecialty of histopathology and oral pathology has been a separate subspecialty since 1974 because testing in this area is specialized and requires special expertise for technical supervision. While we did not propose to add specialties or subspecialties in the proposed rule, we will consider revising the subspecialties and specialties when issuing proposed rules to implement changes made by CLIA '88.

Section 493.271 (§ 493.1257), Standard: Cytology

Comment: Many comments were received regarding the requirement that all gynecologic smears be stained by a Papanicolaou staining method. The commenters were equally divided on the advisability of restricting the requirement to a Papanicolaou staining method and to the use of other methods such as DNA probes, H&E stain and special stains.

Response: At present, a Papanicolaou stain is the best stain for gynecologic slide preparations, affording better differentiation in the cytoplasm of cells; therefore, until better staining methods are developed, we support a Papanicolaou technique as the stain of choice for routine cytodiagnosis of gynecologic smears. Other staining methods may be used as adjuncts, but not as a replacement for a Papanicolaou staining procedure.

Comment: Many individuals favored the separate staining of cytologic

specimens to prevent cross-contamination. A few commenters objected to separate staining of cytologic specimens and the filtering or discarding of the stains after processing non-gynecologic specimens.

Response: We have clarified which cytologic specimens must be processed separately from other specimens and how staining solutions must be handled to avoid cross-contamination.

Comment: A few commenters noted that the proposed regulations did not address the rejection of unsatisfactory smears.

Response: On the basis of these comments and the provision of CLIA '88 (section 353(f)(4)(B)(v) of the PHS Act) that requires that no cytological diagnosis be reported on unsatisfactory smears, we are amending our rule at § 493.1257(a)(4) to require that diagnostic interpretation not be reported on unsatisfactory smears.

Comment: Many comments were received from professional organizations, pathologists, cytotechnologists and other health care professionals in regard to the number of slides each individual may examine in a particular time period. A daily workload figure (option I) was favored by the majority of the commenters with a range of 80-100 slides per person per 24 hour period as the most frequently suggested workload limit. Many of the commenters agreed that the daily workload figure should be prorated for part-time workers.

The majority of pathologists recommended that the technical supervisor should establish workload limits as opposed to the establishment of a Federal standard for workload. Alternatively, cytotechnologists noted that the current regulations permit each laboratory and/or technical supervisor to determine individual workload limits, which has resulted in the present situation of individuals examining an excessive number of slides and incorrectly reporting negative results on unsatisfactory smears or smears with infectious agents or premalignant or malignant conditions. Some individuals noted the workload limit should not include quality control slides; others felt that any established workload limits would of necessity have to include every type of slide examined.

Many individuals opposed a workload limit of 30 slides for nongynecological specimens and suggested that the workload limit for nongynecological material should be based on the type of specimen, including both gynecological and nongynecological specimens. A few individuals noted that a workload limit

should be established for the examination of previously unevaluated cytological slides by all individuals including pathologists.

Response: After evaluating these comments and in accordance with CLIA '88 (section 353(f)(4)(B) (i) and (ii) of the PHS Act), which is effective January 1, 1990, we have established a workload limit specifying the maximum number of slides that any individual may examine in a 24 hour period. This workload limit is established for an individual using standard microscopic technique without any device or instrument that assists in locating or identifying cells. As technology is developed to expedite and improve the process of evaluating cytology slides, we will review the requirements to determine the appropriate workload limits. The maximum number of slides to be examined in 24 hours is 120 slides, which includes all slides evaluated, including all initial examinations, quality control and quality assurance activities, evaluation of proficiency testing specimens and nongynecological slide evaluations. The 120 slide limit represents an absolute maximum number; however, a laboratory may not automatically use the 120 slide limit for each individual. In each laboratory, the technical supervisor must evaluate each individual's performance and establish the individual's workload limit based on performance. We recognize that all individuals do not possess the same capabilities with respect to slide examinations and that every laboratory's caseload is different with respect to degree of difficulty in interpretation and to numbers and types of gynecological and nongynecological preparations processed. Therefore, we are specifying that laboratories must evaluate their own operation and determine appropriate workloads that do not exceed 120 slides per 24 hours for each individual, including the technical supervisor in cytology when he or she performs initial gynecological interpretations and/or participates in the 10 percent rescreen of cases interpreted to be negative for premalignant or malignant changes.

In addition, we are aware that populations and clients change, resulting in different types of cases to be evaluated and an individual's ability to examine a certain number of slides accurately may be altered, resulting in lower or higher workload limits. Thus, we have specified that workload limits for individuals are to be reassessed monthly. As part of the workload limit determination, we are changing the proposed requirement to include all

slides examined and have not established a separate workload limit for nongynecological preparations. Moreover, we agree with the workload limit most frequently suggested by the commenters of 80 slides for initial evaluations and maintain that any other slides examined in the 24 hour period must be related to quality assurance, quality control and proficiency testing activities.

We are aware that some individuals may devote much of their time to the rescreening of previously examined slides. For these individuals, a workload limit not to exceed 120 slides for a 24 hour period must be established by the technical supervisor to include all slides examined with any combination of evaluated and unevaluated slides, provided the number of unevaluated slides does not exceed two-thirds of the established workload limits.

In response to the commenters that notified us that cytotechnologists frequently examine slides on a part-time basis, we have prorated the number of slides that an individual may examine in less than eight hours. We have added a provision to assure that no individual will examine the maximum number of slides in less than six hours to assure that an individual's entire workload will not be conducted in a shorter time period.

The workload limit is applicable to all individuals examining cytology slides, including technical supervisors. However, the workload limit for technical supervisors includes only those gynecologic or nongynecologic slides initially examined and reviews of benign slides previously evaluated by another individual. Previously examined premalignant and malignant gynecologic slide preparations as defined in § 493.1275(a)(1), previously examined nongynecologic preparations, and tissue pathology slides examined by the technical supervisor are not included in the workload limit for technical supervisors.

Based on section 353(f)(4)(B)(ii) of the PHS Act as modified by CLIA '88, we have established a requirement that laboratories maintain a record of the number of cytology slides screened during each 24 hour period by each individual who examines cytology slides and that laboratories have documentation of the number of hours during each 24 hour period devoted to screening cytology slides by each individual.

Comment: Many commenters agreed with the confirmation of the review of all gynecologic smears interpreted to be in the premalignant or malignant

category as defined in § 493.1275(a)(1) and review of all nongynecologic cytologic preparations by the technical supervisor. However, one individual thought review of gynecologic smears interpreted to be in the premalignant or malignant category by a cytology supervisor with five years experience was adequate. Several commenters approved of the use of electronic signatures.

Response: We agree with the majority of the commenters that gynecologic smears interpreted to be in the premalignant or malignant category must be reviewed by a technical supervisor and that the report must be signed or reflect an electronic signature authorized by the technical supervisor to document the review. Therefore, we have not changed the rule as proposed.

Comment: Two-thirds of the individuals commenting on the provision for documenting and evaluating each individual's slide examination performance agreed with this requirement.

Response: We agree with the majority of the commenters on the importance of documenting and evaluating each individual's slide examination and performance and, therefore, we have not changed the rule as proposed.

Comment: The majority of the commenters supported the concept of reexamining gynecologic cases that are interpreted to be normal or negative for malignant or premalignant conditions and that are from patients who are identified as "high risk" but many of the commenters expressed concern regarding the identification of a patient as "high risk". Many commenters indicated that clinicians would not identify their patients in this manner. Laboratories that screen mostly high risk patients expressed concern over the requirement of rescreening a large portion of their patients. Several commenters indicated the laboratory should have the option of selecting a random 10 percent of cases interpreted as normal and negative or reviewing those cases from patients identified as "high risk" and interpreted as normal or negative. Several individuals suggested a reexamination of a percentage of the patients identified as "high risk" as opposed to all "high risk" patients. Several individuals requested we delete the phrase "a high probability of developing cervical cancer" as defined in § 493.201(b)(5)(iii) and substitute "a postabnormal slide or a history of an abnormality".

Response: We understand the commenters' concern in obtaining the information to identify patients as

having a high probability of developing cervical cancer, but insofar as the clinicians and laboratories cooperate in obtaining this information, the laboratory must implement a system of focused reexamination on this patient population. We agree with the commenters' suggestion that we not require the reexamination of all "high risk" patients and have revised the quality control requirements at § 493.1257 to reflect a reexamination of 10 percent of the cases reported as normal and negative, which must include some cases from patients if identified as "high risk." Therefore, we are retaining the requirement at § 493.1101(b)(8) that the laboratory's requisition includes, if available, information indicating whether the patient is at risk for developing cervical cancer or its precursors.

Comment: Many commenters supported the requirement for re-screening at least 10 percent of the normal and negative gynecologic cases examined by each cytotechnologist should be reviewed by a second cytotechnologist or the technical supervisor. A few commenters suggested the use of a sliding scale for determining the precise number of cases for rescreening and a few individuals suggested the cases should be reviewed by a supervisor with five years' experience or by a cytotechnologist with a minimum of three years of experience.

Response: We agree with the majority of the commenters that for each individual examining slides at least 10 percent of the gynecologic slides interpreted to be normal and negative must be reexamined by a second person or the technical supervisor in cytology. We have provided the laboratory with the flexibility of determining the qualifications and experience required of the person who performs the reexamination of the slides.

Comment: Many commenters support the comparison of clinical information with cytology reports, the comparison of the cytology report with the histology report and the determination of the cause of any discrepancies; however, it was suggested that the laboratory should demonstrate that it has made an effort to obtain the histologic information.

Many commenters agreed with the review of prior cytologic specimens for each premalignant and malignant cytology result; however, they requested that the regulations be modified to require only a review of the prior normal and negative gynecologic specimens for the previous two to five years. Many pathologists objected to documenting the statistical data required in

§ 493.271(c)(4), especially error rates, unsatisfactory specimens and complaints; however, most cytotechnologists were in favor of this requirement. A few commenters noted that documentation of unsatisfactory specimens and complaints was covered in other areas. A large number of commenters were evenly divided on the requirement to evaluate each individual's case reviews against the laboratory's overall statistical values.

Response: The regulations at § 493.1257(d)(2) now require the comparison clinical information with cytology reports and the comparison of the cytology report with the histology report and the determination of the cause of any discrepancies. The regulations (§ 493.1257(d)(3)) now require that only normal and negative gynecologic specimens within the last 5 years, if available in the laboratory, be reviewed for those patients with a currently premalignant or malignant cytology result. These requirements were predicated on the premise that these records and specimens are available in the laboratory (either on-site or in storage) and biopsy-confirmed cases of cervical cancer will be available through the State health department registry.

We have added the qualifier "number of" before gynecologic cases where premalignant or malignant cytology and available histology are discrepant and before gynecologic cases where any routine rescreen of a normal or negative specimen results in a reclassification as premalignant or malignant. In addition, we have changed the term "rates" to "cases" in response to the comments that the actual number of cancers in the population is unknown. In response to the commenters we have deleted the reference to documenting complaints in this section, as it is covered in § 493.1501. In view of the CLIA '88 requirement for periodic confirmation and evaluation of the proficiency of individuals involved in screening or interpreting cytological preparation, we are maintaining the requirement for documenting the evaluation of each individual's case reviews compared with the laboratory's overall statistics.

Comment: With a few exceptions, most commenters were in favor of the requirements concerning the cytology laboratory report. A few commenters noted the absence of a requirement for uniform terminology, classification and reporting system.

Response: We agree that specifying nomenclature for reporting cervical cytology results would improve reporting practices by ensuring uniformity and would support the efforts

of the National Cancer Institute in the development of the Bethesda System (previously discussed). In the development of rules to implement CLIA '88, we will consider proposing for public comment a regulation that would require laboratories to report cervical cytology results using uniform nomenclature, such as the Bethesda System. It should be noted that CLIA '88 (Section 353(f)(4)(B)(v) of the PHS Act, effective January 1, 1990) mandates the addition of the requirement that appears in § 493.1257(e)(6) specifying notification to referring physicians if specimens and/or smears are unsatisfactory for diagnostic interpretation.

Comment: Many commenters agreed that corrected reports issued by the laboratory must indicate the basis for the correction. A few felt this was not necessary and should not appear on the corrected report.

Response: We agree with the majority of these commenters and have required the basis for a corrected report to be indicated on that report.

Comment: Many of the commenters agreed with the slide retention times required by the regulations; however, several commenters suggested lesser retention times be required because of the storage expense and the extremely rare requests for retrieval of slides. Several commenters suggested revisions in the regulations to require longer retention times.

Response: We believe that all premalignant and malignant preparations should be retained for 10 years, and that normal, negative, and unsatisfactory slide preparations should be retained for five years.

The quality control regulations specified in proposed § 493.271 define these time periods for slide retention. These are minimum quality control requirements and are essential to provide accessibility of previous abnormal slides for review with subsequent biopsied specimens. This is but one facet of a broad spectrum quality control program we feel is needed to assure accurate results for proper patient care and management.

We also believe the availability of previous slide preparations is critical as a reference point for future slide interpretations and potential diagnoses. We feel the laboratory's inconvenience related to slide storage is far outweighed by the potential benefit to the patient of having previous slide history retrievable for diagnostic reference and tracking patient treatment.

We allow laboratories the flexibility to retain slide preparations for longer

time periods if they feel this will aid in the provision of better patient care.

Section 493.273 (§ 493.1259), Standard: Histopathology

Comment: In commenting on § 493.273, several commenters believed that patient slide preparation and specimen blocks should be maintained for up to twenty years and one commenter requested that remnants of tissue specimens be maintained for one week after reporting.

Response: We are retaining the requirement that laboratories retain patient slide preparations at least ten years from the date of examination and specimen blocks for two years from the date of examination. In addition, a laboratory must be in compliance with State and local laws where such laws mandate a longer retention time. These requirements are intended to be a minimum and laboratories are not precluded from retaining slides and blocks for a longer time period. Although we do not object to increasing the retention of tissue remnants to one week after reporting, we prefer not to change the requirement based on only one comment. However, if other comments are received indicating that this revision should be made, we will consider this for future changes to the regulations.

Comment: One commenter requested a requirement for electronic signature authorization to be included in § 493.273 (now § 493.1259) (histopathology) to provide continuity with § 493.271(b) (1) and (2).

Response: We agree with the commenter and have added paragraph (d) to this standard to show that computer generated reports must reflect a signature by a qualified individual.

Comment: One commenter noted that there is a variety of recognized systems of disease nomenclature for reporting tissue pathology results and requested the deletion of proposed § 493.273(d), which requires the laboratory to use acceptable terminology of a recognized system of disease nomenclature in reporting results.

Response: The current requirement provides flexibility for the laboratory to choose a recognized system for reporting tissue pathology. In the proposed regulations to implement CLIA '88 we will accept recommendations from commenters on the appropriateness of establishing a disease nomenclature for reporting histopathology results.

Comment: Many commenters disagreed with the requirement to report cervical cancer cases to a registry in § 493.273(e) and requested its deletion

since a specific cancer registry was not specified. Commenters noted that some States do not have a cancer registry and other commenters noted that some States have several registries. Many of the commenters felt that reporting to a cancer registry was the responsibility of the clinician and not the laboratory. Commenters also questioned the reporting of cervical cancer as opposed to other types of cancer.

Response: We agree with the commenters that many States have not established a single cancer registry and some States do not have a cancer registry; therefore, we have revised the standard to require laboratories to report cervical cancer cases to the State health department. This requirement is established to assist laboratories in tracking and obtaining results of follow-up biopsies from the client physicians who submit Pap smears. Many physicians send cytology smears to one laboratory, but many submit a follow-up biopsy to another laboratory. Moreover, patients themselves may often change doctors or move to another community and thus become lost to laboratory follow-up.

Since laboratories are required in § 493.1257 to make various correlations between cytology and histology reports, this regulation will enhance a laboratory's capacity to make timely correlations, to identify false negative and false positive cases, and to make statistical evaluations of performance based on outcome measures. A central repository containing laboratory reported biopsies will provide a mechanism by which all laboratories could practice better quality control as well as comply with the standards. The gynecologic Pap smear is the most effective, non-invasive screening tool currently available for the early detection of asymptomatic malignant and premalignant cervical lesions and this requirement provides the critical link required for public health prevention and control of cervical cancer.

Section 493.275 (§ 493.1263), Condition: Radiobioassay

Comment: One commenter requested the deletion of the condition on radiobioassay and suggested its inclusion with routine chemistry or endocrinology.

Response: This is a separate condition because it addresses in vivo testing, instead of in vitro testing.

Section 493.277 (§ 493.1265), Condition: Histocompatibility

Comment: Three commenters recommended the deletion of the word

"cells" from the requirement at § 493.277(a)(10) concerning typing of potential transplant recipient cells, indicating that the inclusion of the word implies that the laboratory must type "all cells of the transplant recipients".

Response: We agree with the commenters and have eliminated the word "cells".

Comment: Three commenters noted that there are many HLA specificities currently known for which reagents are unavailable or extremely difficult to obtain.

Response: We agree with the commenters and have modified § 493.1265(a)(15) to add "for which reagents are readily available".

Comment: Three commenters noted that screening is performed on recipient serum and that typing of living or cadaver donors may not coincide with receipt of a serum specimen from the recipient.

Response: The requirement has been reworded to provide clarity and accuracy by specifying that potential transplant recipient sera are screened for antibody content at the time of the recipients' initial HLA typing, and, thereafter, at monthly intervals or following a sensitizing event.

Comment: Three commenters questioned the wording of our proposed requirement concerning compatibility testing for cellularly-defined antigens. Commenters further stated that mixed lymphocyte culture (MLC) tests are only necessary for bone marrow transplants.

Response: We have changed this requirement now at § 493.1265(a)(20) to clarify the various techniques, including but not limited to the MLC test, that must be used when a laboratory performs compatibility testing for cellularly-defined antigens.

Comment: Three commenters noted that all histocompatibility laboratories may not directly perform ABO blood grouping and Rh typing. Commenters further noted that, as stated, this requirement applied to recipients but not donors.

Response: We agree with the commenters and have restated this requirement as suggested.

Comment: Three commenters noted that ABO grouping was not performed to purify cells but that ABO agglutinins were utilized.

Response: We have reworded this requirement to provide the clarification needed as noted by the commenters.

Comment: One commenter suggested that histocompatibility laboratories participate in a proficiency testing program rather than a cell exchange program.

Response: At this time we have not defined requirements for proficiency testing programs with respect to histocompatibility. This is an area of testing in which we may develop the necessary criteria for approval of proficiency at a later date.

Comment: Three commenters noted that mixed lymphocyte cultures are necessary for bone marrow transplantation.

Response: We agree with the commenters and have established a separate requirement (§ 493.1265(b)(2)) for laboratories performing histocompatibility testing for bone marrow transplantation.

Comment: Three commenters noted that there is currently no conclusive evidence to support the necessity of pre-transplant crossmatches in transplantation of non-renal organs if the recipient is non-sensitized. Also, it was noted that donor organs remain viable for a very short time and the crossmatch may not be completed before transplantation.

Response: We agree with the commenters and have added a new requirement (§ 493.1265(b)(3)), with regard to presensitized recipients only, to address requirements for laboratories performing histocompatibility testing for non-renal solid organ transplantation.

Comment: One commenter suggested that requirements for laboratories that perform HLA typing for disease associated studies be extended to those laboratories that perform HLA typing for parentage testing.

Response: We agree and have added parentage testing to this requirement.

Comment: Three commenters noted that histocompatibility laboratories do not typically perform HIV tests and suggested restating this requirement for those laboratories that perform HIV tests for organ transplantation.

Response: This requirement was not meant to address only those laboratories that routinely perform HIV tests but rather to require that all laboratories that test organs for transplantation tests the donor for HIV reactivity.

Section 493.279 (§ 493.1261), Condition: Clinical Cytogenetics

Comment: Two commenters noted that routine sex determination is no longer conducted by X and Y chromatin counts in most laboratories. One commenter suggested confirmatory testing be performed on all atypical results since this analysis is not state-of-the-art technology.

Response: We have restated this requirement and have included a

requirement in § 493.1267(a) for confirmatory testing.

Section 493.301 (§ 493.1271), Condition: Transfusion Services and Blood Banking

Comment: One commenter requested a definition of "readily available" in § 493.301, which requires a facility that provides services for blood and blood product transfusions have blood and blood products "readily available".

Response: We have deleted the term "readily available" and substituted language specifying that blood and blood-products must be available to meet the needs of the physicians responsible for the diagnosis, management and treatment of patients.

Section 493.303 (§ 493.1273), Standard: Immuno-hematological Collection, Processing, Dating Periods, and Distribution of Blood and Blood Products

Comment: One commenter noted that there were multiple sections in the regulations that address immuno-hematology and blood bank and requested these requirements be deleted and/or condensed.

Response: This codification represents a dramatic condensation of regulations from the Food and Drug Administration, which includes 21 CFR Part 606 (excluding 21 CFR 606.20(a)), 21 CFR 610.53, and 21 CFR Part 640, Interstate Licensure and Medicare. We do not believe it is possible to codify the requirements in fewer places than we proposed, or to delete requirements, because of differing requirements for blood services in different types of facilities.

Summary of Changes to the Proposed Rule

Section 493.1203 Facilities

We have added a requirement for laboratories to maintain adequate ventilation for the performance of tests and the reporting of test results.

Section 493.1205 Adequacy of Methods and Equipment

Deleted from § 493.225 (now § 493.1205) is the requirement for laboratories to determine test methodology by considering factors such as utilizing the appropriate test system to achieve the performance characteristics specified by the laboratory, and to assure a statistically valid number of counts to provide accurate and reliable test results for systems such as particle counters, radioactive counters, spectrophotometers, and other equipment for which this is a critical

variable. We moved this requirement, excluding a statistically valid number of counts for spectrophotometers, to § 493.1215, Validation of methods.

Section 493.1207 Temperature and Humidity Monitoring

We have added "tissue" to the list of items that must be maintained at a controlled temperature and humidity.

Section 493.1209 Labeling of Testing Supplies

We have added to this section a requirement that laboratories must not interchange components of a kit with reagents of another kit with a different lot number unless otherwise specified by the manufacturer.

Section 493.1211 Procedure Manual

The laboratory must now include in the procedure manual instructions for adequate slide preparation and calculations.

Section 493.1213 Equipment Maintenance and Function Checks

- We have added a requirement that the laboratory must document its preventive maintenance and function checks on equipment.

- Each day of use, baseline and background checks of instruments and equipment must be within acceptable limits. We are adding to the section a requirement that these checks must be completed before patient testing is initiated.

Section 493.1217 Frequency of Quality Control

- We have added a requirement that the laboratory is to follow the manufacturer's recommendations for quality control or to determine the frequency of testing quality control samples based on the evaluation of instrument and reagent stability and operator variance, but in no event can quality control be performed less than each day of use;

- We have moved the term "microorganism controls" from the requirement for checking staining characteristics in order to provide a broader application of the requirement.

- With reference to the number of calibrators required to calibrate, re-calibrate, or verify calibration of non-linear procedures, we have added a provision allowing the laboratory to follow the manufacturer's specifications if more than five points and a zero are required by the manufacturer or the laboratory must document the validity of using fewer calibration points than required by the manufacturer, but no

less than 5 points and a zero may be used at least every six months to verify calibration.

- The requirement for quality control of fluorescent stains has been moved from the specialty of microbiology to the general quality control section applicable to all specialties, where appropriate;

- We have clarified that the control organisms used to check direct antigen detection procedures must evaluate all testing phases, including extraction and reaction, if appropriate;

- The requirement for checking media sterility has been qualified to require sterility checks only of the media that is labeled as sterile;

- We have added a requirement that laboratories must test control samples in the same manner as patient specimens.

Section 493.1219 Remedial Actions

- We have revised this section to require the laboratory to notify the individual responsible for utilizing the test results (rather than the individual ordering the test) when specimens cannot be analyzed within the laboratory's timeframe for testing.

- The requirement to maintain records of remedial actions taken when a testing system problem or problems occur that prevent the laboratory from analyzing specimens in its established timeframes has been moved from § 493.240, Quality control records to § 493.1219, Remedial action.

- We now require the laboratory to issue any corrected or amended laboratory report promptly to the authorized person who ordered the test.

- We also now require the laboratory to maintain copies of the original report as well as any corrected or amended report for a two year period.

Section 493.1221 Quality Control—Records

- Laboratories are now required to maintain immunohematology records for a period of five years as specified by the FDA in 21 CFR Part 606, Subpart I.

- The "list" of records laboratories must maintain (under § 493.240, now § 493.1221) has been removed, since maintenance of these records is specified under each standard.

Quality Control—Specialties and Subspecialties

Section 493.1227 Bacteriology

The frequency for including quality control specimens with DNA probe tests has been changed from each time of use to each day of use.

Section 493.1229 Mycobacteriology

We have added the requirement for fluorochrome acid-fast stains to be checked each day of use for positive and negative reactivity.

Sections 493.1227, 493.1231 Bacteriology and Mycology

Under the subspecialties of bacteriology and mycology we have added to the requirement stating that quality control results for susceptibility tests must be within established limits "before reporting patient results".

Section 493.1233 Parasitology

We have added a new stipulation that a fecal sample control must be used that demonstrates staining characteristics.

Section 493.1239 Syphilis Serology

Facilities manufacturing blood and blood products for transfusion or laboratories performing syphilis serology tests on referral from these manufacturing facilities are now required to meet the syphilis serology testing requirements of 21 FR 640.5(a).

Section 493.1241 General Immunology

The regulations now require facilities manufacturing blood and blood products for transfusion, or referral laboratories for these facilities, to meet the HIV testing requirements of 21 CFR 610.45 and the hepatitis testing requirements of 21 CFR 610.40.

Section 493.1251 Urinalysis

This new subspecialty of chemistry has been added at § 493.1251.

Section 493.1253 Hematology

- We are now requiring that only manual coagulation tests be run in duplicate.

- Each individual performing manual coagulation tests must test two levels of controls before testing patient specimens. This is an addition to the proposed requirements.

- Also added to coagulation quality control is the requirement that laboratories include two levels of controls each time a change of reagents occurs for all manual and automated coagulation tests.

Section 493.1257 Cytology

- All references to "abnormal" and "positive" slides have been changed to "pre-malignant" and "malignant" and references to "negative" cases have been changed to "normal and negative" or "normal or negative".

- We have added a requirement that laboratories must retain unsatisfactory slides for five years.

- We have clarified that the maximum number of slides to be examined in 24 hours for each individual refers to examination of slide preparations by nonautomated microscopic techniques. If technology is developed that improves the process of slide evaluation, HHS will evaluate the equipment to determine whether a workload limit needs to be established through proposed revisions to these regulations.

- We have added an option to allow laboratories to loan slides to an approved PT program in lieu of maintaining the slide preparations for the storage time required by these regulations if authorization is obtained from HHS.

- We are clarifying that, before staining body cavity fluids, the laboratory must assess their potential for cross-contamination of other non-gynecologic specimens. Body cavity fluids found to have a probability for cross-contamination must be stained separately and the stains filtered between staining batches of slides.

Section 493.1259 Histopathology

- Added to this section is an option for technical supervisors to use electronic signatures on computer generated reports.

- We have clarified that laboratories must report results of all biopsy confirmed cases of cervical cancer to the State health department for the State in which the laboratory is located instead of to a cancer registry.

Section 493.1265 Histocompatibility

- We are clarifying that reagents for typing recipients and donors must be adequate to define all major and International Workshop HLA—A, B, and DR specificities for which reagents are readily available.

- We also clarify that the laboratory must screen recipient serum for pre-formed antibodies at the time of the recipient's initial HLA typing and at monthly intervals thereafter and following sensitizing events.

- Added to compatibility testing for cellularly defined antigens is a requirement for laboratories to utilize techniques such as the mixed lymphocyte culture (MLC) test, homozygous typing cells or DNA analyses.

- We have revised this section to require donor and recipient ABO and Rh₀(D) group to be performed in accordance with § 493.1269 of this subpart.

- We added a requirement for the specificity of the ABO reagents to be

verified with control cells if the laboratory utilized ABO agglutinins to remove erythrocytes during lymphocyte isolation.

- We revised this section to require that all laboratories performing histocompatibility testing for bone marrow transplantation must meet all of the histocompatibility testing requirements, including the performance of MLC.

- Results of a final crossmatch must be available before nonrenal solid organ transplantation when the recipient has demonstrated pre-sensitization by prior serum screening. This is an added requirement.

- Laboratories that perform HLA typing for parentage testing must now meet all of the requirements under the histocompatibility section, except the performance of MLC.

Section 493.1267 Clinical Cytogenetics

- Confirmatory testing for all atypical results is now required when the determination of sex is performed by "X" and "Y" chromatin counts.

- We have clarified that the laboratory report must include:

- the summary of the observation;
- the interpretation of the observation;
- the number of cells counted and evaluated; and
- the use of appropriate nomenclature.

Section 493.1269 Immunohematology

Laboratories must now employ a control system capable of detecting false positive Rh₀(D) test results if required by the manufacturer.

Section 493.1271 Transfusion Services and Bloodbanking

- We have clarified that facilities providing transfusion services and bloodbanking must be under the technical supervision of a physician who qualifies under Subpart L as a technical supervisor in Immunohematology, transfusion services.

- The proposed requirement for transfusion facilities has been reworded to specify that blood products are available to meet the needs of physicians responsible for diagnosis, management, and treatment of patients.

Section 493.1273 Immunohematological Collection, Processing, Dating Periods and Distribution of Blood Products

- The standard has been amended to include collection, dating periods, and distribution of blood and blood products, while excluding testing and storage from this standard.

- We have included provisions for the labeling of blood and blood products in conformance with the FDA regulations in 21 CFR Part 606, Subpart G.

- The requirement for a technical supervisor has been withdrawn.

Section 493.1275 Standard Facilities

- Blood storage facilities are now required to ensure that storage conditions, including temperature, are maintained to avoid deterioration.

CLIA '88 Changes

Section 353(f)(4)(A) of the PHS Act mandates us to establish standards for cytology services designed to assure consistent performance by laboratories of valid and reliable cytology services. The specific changes made to the proposed requirements to accommodate CLIA '88 are listed below. They reflect changes that are either self-implementing or represent a logical outgrowth of the proposed rule based on the comments we received.

1. Provisions of CLIA '88 (section 353(f)(4)(B)(i) of the PHS Act) require the Secretary to determine the maximum number of cytology slides that an individual may screen in a 24-hour period. We have added to this subpart on quality control in § 493.1257(b) (1) and (2) our determination of the number of cytological slides an individual may interpret and the related recordkeeping requirements.

2. CLIA '88 (section 353(f)(4)(B)(ii)) also requires records of the number of slides interpreted by an individual in 24 hours and documentation of the number of hours devoted to the examination of slides.

We require in § 493.1257(b)(2) that the laboratory maintain a record of the number of slides examined by each individual during each 24-hour period and the number of hours each individual spends examining slides in the 24-hour period.

3. Section 353(f)(4)(B)(iii) (I), (II) and (III) of the PHS Act as amended by CLIA '88 requires us to establish standards that include criteria for requiring rescreening of cytologic preparations, such as (a) random rescreening of specimens determined to be benign, (b) focused rescreening of the preparations in high risk groups, and (c) for each abnormal cytologic result, rescreening of all prior cytologic specimens for the patient, if available in the laboratory (either on-site or in storage). They reinforce our proposed requirements at § 493.271(c)(1) (i) and (ii) and (3) (now § 493.1257(d)(1) (i) and (ii) and (3)).

4. In §§ 493.271(b)(3) (now § 493.1257(c)(3)) and 493.451(f) (now § 493.1501(h)), we had proposed periodic

evaluation of the performance of the individuals involved in screening cytological preparations through rescreening of previously examined cytologic preparations. CLIA '88 also requires laboratories to conduct rescreening of cytological preparations (section 353(f)(4)(B)(iii) of the PHS Act). These requirements will assure increased accuracy in slide examination and more careful slide evaluation by the individual responsible for reviewing slides. Each individual must be apprised of his or her slide examination performance in order to improve or maintain quality test reports.

5. CLIA '88 specifically mandates, at section 353(f)(4)(B)(v) of the PHS Act, the laboratory's responsibility for establishing procedures for detecting inadequately prepared cytology slides, assuring that no cytologic diagnosis is rendered on inadequately prepared slides and notifying the referring physicians of unsatisfactory slides. We have specified in § 493.1211(a)(2) that laboratories must establish the criteria for evaluating whether a slide is satisfactory and these criteria must be written and accessible to each individual interpreting cytology smears to assure consistent and repeatable decisions are made in rejecting and accepting slides for examinations. In § 493.1257(a)(4), we have included a provision for assuring that no cytological diagnosis is rendered on an inadequately prepared slide. In § 493.1257(e)(6), we include a requirement that the laboratory must notify referring physicians of any patient specimen that is received in the laboratory in an unsatisfactory condition making diagnostic interpretation inappropriate.

6. Section 353(f)(4)(B)(vii) of the PHS Act as amended by CLIA '88 requires us to have requirements for the retention of cytology slides by laboratories for each period of time as we consider appropriate. Our proposed regulations at § 493.271 (f) and (g) required normal slides to be retained for 5 years and abnormal ones for 10 years; this final rule at § 493.1257 (g) and (h) adopts the same requirements with changes in the term "normal" to "normal and negative" or "normal or negative" and "abnormal" is changed to "pre-malignant and malignant".

Subpart G—Personnel Standards

Overview of Proposed Rule

The current Medicare independent laboratory regulations (§§ 405.1312, 405.1313, 405.1314(b) and 405.1315), and CLIA personnel standards (§§ 74.30 and

74.31) contain detailed education and experience requirements for individuals at the director, technical supervisor, general supervisor, technologist and technician level (CLIA does not have a technician level requirement). The Medicare conditions of participation for hospitals (42 CFR part 482) and conditions of participation for skilled nursing facilities (42 CFR Part 483) have specific requirements only for the laboratory director, who has responsibility for determining the qualifications of the supervisory personnel and the individuals performing the tests at the bench. These latter regulations provide the director with the maximum flexibility in the selection and utilization of personnel.

In the proposed rule we planned to establish the same personnel requirements for all laboratories that participate in Medicare and Medicaid or are licensed under CLIA. We proposed personnel standards for director, supervisor and cytotechnologist with technical supervision qualifications specified for blood bank, pathology, cytogenetics and histocompatibility services. Our decision to set standards for these categories of personnel was based partially on the model for the current hospital standards, which specify qualifications only for a laboratory director and allow the director to determine the qualifications of other laboratory personnel. However, we strengthened the hospital and nursing home personnel standards with the addition of requirements for supervisors and cytotechnologists.

The proposed rule contained the provision required by section 9339(d) of the Omnibus Budget Reconciliation Act of 1986 to accept for Medicare purposes individuals that meet State licensure requirements for laboratory directors. This provision specifies that if a State provides licensing or other standards with respect to the operation of laboratories (including those in hospitals) in the State and establishes qualifications under which an individual may direct a laboratory, title XVIII of the Act may not be construed as authorizing the Secretary of HHS to require other qualifications; this provision was effective January 1, 1987.

We would also include a provision to enable individuals who qualify as laboratory directors under current regulations to continue to qualify as such.

The proposed rule contained a provision to allow for the recognition of private sector certification programs for director level personnel as an alternative mechanism for qualification as currently contained in §§ 74.30 and

405.1312. This provision reduces the need for the program to evaluate the credentials of individuals who have already been evaluated by a private sector organization approved by HHS and provides recognition for many of the programs in existence.

We believed that it was important to retain technical supervisor qualifications for some specialty and subspecialty testing areas currently contained in the regulations. Therefore, we proposed qualifications for individuals providing technical supervision of tests in the area of pathology, which includes histopathology, including skin pathology, cytology and oral pathology. We also proposed to retain requirements for a technical supervisor in transfusion and blood banking services, as well as histocompatibility. In addition, we proposed requirements for technical supervisor of cytogenetics.

Since the laboratory director may not always be present when testing is performed, we specified personnel requirements for supervisors to assure that at least one individual with supervisor qualifications would oversee the processing, testing or examination of specimens and the reporting of patient test results.

We proposed qualifications for cytotechnologists because currently the testing is solely dependent on individual judgment and interpretation. Also, the risk factors associated with errors in slide examination or misdiagnosis are obvious and can be linked to individual expertise based on education and training. In addition, generally agreed upon personnel credentials have been established and represent agreement by the various cytology professional organizations.

We proposed to eliminate in independent laboratories the personnel requirements for technologists and technicians for the following reasons:

- It is necessary to emphasize responsibility of the director for assuring the quality of the services of the laboratory and to allow the director the maximum flexibility to choose the personnel required to achieve this goal;

- Changes in technology make it difficult to develop detailed specific standards and revise them as needed to cover the wide variety of instruments, methodology and test systems currently performed and to be performed in the future in laboratories; and

- It is more reliable to depend on outcome measures such as quality control, proficiency testing and quality assurance programs, rather than detailed personnel standards, as

mechanisms to assure the quality of testing.

- Although it is generally believed that degreed individuals are better prepared to assume technical responsibilities to assure quality, there is limited evidence available to correlate the degree level of education achieved by an individual with the quality of the test results produced.

There have been several studies on the relationship between personnel standards and quality of testing, including one commissioned by the Office of the Assistant Secretary for Planning and Evaluation of the Office of the Secretary of the Department of Health and Human Services, but definitive data correlating the relationship of specific standards to quality of testing does not exist. The available studies have been applied only to limited areas. Although evidence exists of some improvements in performance as a function of personnel credentials, these studies are limited in scope, and they are not all based on the same assessment techniques. They also do not indicate that inaccurate or medically unacceptable results were produced by any particular type of level of individual.

Our requirements in the proposed rule applicable to the personnel levels below the director and supervisor would provide for maximum flexibility for the director in choosing the laboratory staff, except for cytology in which specific personnel qualifications would be required to assure the quality of cytology results. The individuals employed in laboratories would still have to meet State standards, if any exist. This would place responsibility with the States to set specific criteria for personnel to meet local needs. The director would have to ensure that the personnel have the necessary training, experience, and continuing education and that they receive continuous evaluation and monitoring of performance levels as well as meet any State licensure requirements. The proposed personnel requirements would allow the flexibility to utilize the various private-sector credentialing programs, State licensure programs, and private-sector examinations as a guide in selecting individuals for employment purposes.

In proposed § 493.405 we specified the laboratory director responsibilities and emphasized the duties required of the laboratory director. The laboratory director would have the overall responsibility for the quality of testing performed by the laboratory and would be responsible for establishing and

maintaining a quality assurance program and establishing performance characteristics for the test systems employed by the laboratory. The director would also be responsible for providing evidence that the laboratory can maintain these performance levels: the director would assess factors such as staff performance, quality control results, proficiency testing results, validation of test procedures and methodologies, and assure that the laboratory corrects all problems before reporting test results. In addition, if errors are detected after results are reported, the director would be responsible for providing the necessary corrected information to the individual requesting or utilizing the test results.

We proposed in § 493.407 that a qualified supervisor be on the premises whenever routine testing is performed. In proposed § 493.411, we specified that laboratory supervisors would be responsible for supervision of laboratory personnel, test performance and test reporting.

In § 493.417, we proposed that cytotechnologists would be responsible for documenting the gynecologic and non-gynecologic cases examined and for recording slide interpretation results for each gynecologic and non-gynecologic cases reviewed.

Comments and Responses

Overview—of the 1,600 total comments received, an overwhelming majority expressed opinions regarding the proposed personnel standards. Almost 85 percent of these comments disagreed with what many perceived as diminished requirements for education, training, experience and/or credentials for technical personnel. Retention of existing personnel standards was requested by the majority of commenters. Some commenters, aware of existing personnel requirements for hospitals before the August 5th proposal, opposed the increased requirements for hospital laboratory personnel. Others requested the same personnel requirements for hospitals and independent laboratories. Some respondents stated that only independent laboratories should be regulated; however, several commenters expressed a collective desire to regulate hospitals, independent and physicians' office laboratories using the same standards for personnel.

Overview of Comments by Level of Technical Personnel

Director

With respect to laboratory director qualifications, commenters expressed

disagreement with the following provisions of the proposed rule:

- Recognizing State licensure requirements for director if the State standards were less stringent than the Federal requirements. (It should be noted that this proposed regulation is required by law—the Omnibus Budget Reconciliation Act of 1987);
- Allowing individuals to qualify that did not have an M.D., D.O., or doctoral level degree;
- Permitting individuals to qualify as directors under the "grandfather" provisions without imposing additional requirements, although a few commenters supported the "grandfather" provisions as written;
- Qualifying individuals who were not board certified pathologists;
- Using the HHS examination to qualify laboratory directors;
- Recognizing certification boards as a means of qualifying individuals; however, a few commenters supported HHS recognition of professional organizations' certification programs.

Many commenters disagreed with the proposed laboratory directors' responsibilities with respect to allowing the director to determine personnel qualifications of the laboratory staff and making the director responsible for the non-scientific management of the laboratory.

Commenters suggested or agreed with the following:

- Retaining present Medicare regulations for qualification of the laboratory director;
- Using the laboratory director qualifications specified in § 483.460 (ICF/MR regulations);
- Allowing non-doctoral degree level directors such as those holding degree as masters of science or medical technology;
- Requiring pathologist, cytopathologist, M.D., D.O., and Ph.D level directors;
- Requiring more experience for directors who are not pathologists or cytopathologists.

Technical Supervision

The majority of the commenters who expressed an opinion on the requirements for technical supervision requested that we reinstate requirements for a technical supervisor in all the specialty areas of the laboratory. Several commenters suggested that we require more pertinent laboratory experience for the technical supervisor, especially in the subspecialty of cytology. Many commenters objected to the experience and training requirements proposed for the technical supervisor in the

specialties of histocompatibility and clinical cytogenetics. A large number of pathologists requested that we qualify pathologists as technical supervisors in histocompatibility and clinical cytogenetics or allow those pathologists whose laboratories currently perform histocompatibility and/or clinical cytogenetics testing to "grandfather" as technical supervisors in their respective specialty(ies) of testing. On the other hand, several individuals agreed with the proposed technical supervisor requirements for these areas.

Several commenters, having reviewed the proposed qualifications for the technical supervisor in clinical cytogenetics, requested the deletion of the requirement for experience in immunology and substitution of experience in clinical genetics in its place.

There were a few respondents who objected to requiring a technical supervisor in histopathology, dermatopathology and oral pathology.

Several comments were received requesting the retention of existing standards for technical supervisor and a few requested that we allow medical technologists to qualify as technical supervisors for all specialty areas.

General Supervisor

Opposition to the proposed requirements for general supervisor are summarized below.

- The majority of individuals commenting on the requirements for general supervisor disagreed with the proposed reduction to the number of years' experience required, with many qualifying their opinion by requesting a limit to the number of technologists and technicians these general supervisors should be allowed to supervise. Many other commenters stated the general supervisor should be experienced in the areas they supervise.

• Several commenters objected to general supervisor requirements of any type, and several more opposed requirements for general supervisors in hospitals, small laboratories and in rural hospitals.

• Many commenters were in opposition to the educational requirement of a bachelor's degree, especially for hospital laboratories.

• Many statements of opposition were received referring to the proposed provision requiring the general supervisor to be on-site during the laboratory's regularly scheduled hours of operation. Some felt the availability of the general supervisor by telephone was sufficient for the laboratory and staff's needs. A few thought a general

supervisor was needed in the work shifts during which "stat" tests are performed, because of the critical nature of such testing.

- Several commenters were opposed to allowing a medical technologist to qualify as a general supervisor in cytology.

- Other commenters requested an HHS examination be given to quality individuals as a general supervisor.

- A few commenters were opposed to requiring a medical technologist as a general supervisor in blood gas laboratories.

Technologist

An overwhelming number of commenters objected to the absence of personnel standards for technologists and technicians. Many commenters requested that we retain or increase the present personnel standards for Medicare certified laboratories. Many comments were received noting the need for personnel standards at the bench level for microbiology, hematology and blood banking because of the judgment calls involved in these specialty areas and the ramifications to patients' health when test errors occur.

Several commenters requested that we recognize certification by professional organizations as a qualification requirement for technologists. Many others stated that a bachelor's degree should be required to qualify as a technologist; however, several other commenters believed a bachelor's degree was not necessary and experience should be substitutable for education, especially for laboratories in rural areas or in financially burdened situations.

Several commenters agreed with the deletion of qualification requirements for branch level personnel but recommended the addition of language requiring appropriate education, training and experience to perform assigned duties properly.

A few commenters suggested we retain the present personnel standards in testing areas that are subjective in nature and require evaluation skills or a knowledge of quality control principles and practice or that educational requirements be established based on test complexity.

The comments we received concerning the elimination of personnel requirements for technologists and technicians in independent laboratories were overwhelmingly from individuals employed in hospitals who were against the elimination of the bench level personnel requirements.

We reached two conclusions based on our review of comments. First,

individuals who work in other settings, such as nursing homes, and who would be subject to the same requirements as individuals currently in an independent laboratory setting, did not comment even though they would also have been affected by the new requirements.

Second, approximately 1,000 commenters from hospitals expressed the view that the elimination of personnel requirements for technologists and technicians would weaken hospital laboratory personnel requirements even though they did not realize the hospital's regulations currently contain no such requirements. At present, the personnel requirements for hospitals specify only that the hospital must have a qualified laboratory director, and the director need not be present when testing is performed. In our proposed rule, we were attempting to strengthen the personnel requirements in nursing homes and hospitals by adding a requirement for supervision. We believed that each laboratory, including those in hospitals and nursing homes, should employ at least one individual with laboratory credentials who would be on the premises when testing is performed. We are pointing out these observations because when we again propose personnel requirements to implement CLIA '88, we urge affected individuals from all work settings to comment.

Cytotechnologist

Although the majority of individuals' comments on cytology personnel standards were in favor of the proposed requirement for cytotechnologists, the following recommendations were offered:

- Require a bachelor's degree to meet the education qualifications;
- Recognize professional organizations' certification programs;
- Develop performance standards to credential cytotechnologists based on capabilities and competency; and
- Establish a "grandfather" provision for individuals not meeting current qualification requirements for cytotechnologist that would qualify persons engaged in the examination of cytologic preparations who have been under the supervision of a pathologist from 1985 to the present.

A few commenters opposed requiring a cytotechnologist for the examination of all cytologic preparations, stating that cytotechnologists could be reserved for examining difficult or questionable slides, re-screening of slides for quality control purposes and for the provision of supervision.

A few commenters suggested we recognize two levels of cytotechnologist: those with a Bachelor's degree and one year experience who would perform all routine screening and provide supervision, and those individuals with two-year associate degrees and six months of training, who would be limited to screening gynecologic preparations only.

Many commenters objected to the responsibilities for cytotechnologists, which would require daily records of the number of gynecologic and non-gynecologic cases examined and the slide interpretation results, but several respondents agreed with these cytotechnologist responsibilities.

Summary of Changes to Proposed Rule Or Changes to The Current Personnel Regulations

We have decided to retain existing personnel standards in the final rule because CLIA '88 specifies that laboratory personnel qualifications should be established based on tests performed, and we intend to develop personnel standards to implement CLIA '88 in a separate rulemaking. As a result, we are not adopting the proposed changes that would make laboratory personnel requirements uniform from one type of facility to another, with three exceptions discussed below.

We have added requirements for technical supervisors in clinical cytogenetics. We proposed that the individual have a doctor of science degree or be a physician, and have 4 years of experience in immunology or genetics. In response to the recommendations, we are requiring experience solely in genetics, two years of which must be in clinical cytogenetics. This requirement will apply to cytogenetics technical supervisors in any setting (e.g. hospital, SNF).

Current hospital regulations do not delineate technical supervisor requirements in cytology, although current independent laboratories have such a rule. We are adopting as proposed the current independent laboratory requirement for technical supervisor in cytology to permit individuals qualified in independent laboratories as a cytology technical supervisor to function in that category in the hospital setting.

The final rule also includes the proposed provision implementing OBRA '87 at § 493.1403(a)(3), 493.1407(a)(3), and 493.1415(b)(6) that allows a person qualified under State law to direct the laboratory; however, we have slightly modified the proposed revision to follow

the statute more closely. The statute (section 9339(c)(1) of Pub. L. 99-509) clearly expects a director to meet the requirements of the State in which he or she is directing a laboratory. Our proposal may have implied that a director could qualify to be a director by meeting the requirements of any State.

We want the public to understand that since CLIA '88 requires HHS to set personnel requirements as a function of test complexity rather than location or type of laboratory, we will soon propose an approach to regulating personnel qualifications could be very different from the approach used in this final rule. We will urge commenters to assist us in the formulation of a regulatory scheme that is test-complexity based, rather than location/type of laboratory based. We cannot state whether the regulations implementing CLIA '88 will or will not be similar to the personnel requirements as written in this rule.

It is our intention that all of the personnel requirements for the various types of facilities be in part 493, subpart L. To assist in this organization, we are codifying the content of paragraphs and sections concerning personnel requirements found in various parts and subparts of title 42 in new subpart L.

In § 493.2, as discussed earlier, we define "independent laboratory". It reads substantively the same as current § 405.1310(a), except that we have deleted the provision allowing a physician office laboratory to accept 100 specimens per category in a calendar year from other physicians.

The independent laboratory personnel regulations in this rule at § 493.1413 reflect the current structure of § 405.1312, Condition: Laboratory director, which includes standards for laboratory director qualifications and responsibilities in the same condition. The requirements for technical personnel currently located in § 405.1315, specify standards for qualifications and responsibilities in the same condition; we have made no changes in these requirements, which appear in § 493.1431, Condition: Independent laboratories; Technical personnel, and the standards in §§ 493.1433 and 493.1435, which concern technologists' qualifications and responsibilities.

Revisions to the current regulations for general and technical supervision located at § 405.1313 and 405.1314 are necessary because § 405.1313, Condition—clinical laboratory; Supervision, contains the responsibilities for both types of supervisors and § 405.1314, Condition—Clinical laboratory, specifies requirements for proficiency testing

participation. This rule will revise the current regulations to reflect a separate condition at § 493.1419 for technical supervision with standards for qualifications and responsibilities at §§ 493.1421 and 493.1423, respectively. The condition at § 493.1425 will contain the condition for general supervisor with the standard of § 493.1427 specifying the qualifications for a general supervisor and the standard of § 493.1429 listing the general supervisor responsibilities. Throughout subpart L, we will include the requirement for personnel to have a current State license, if such licensing exists. The requirement for personnel to be appropriately licensed by the State will also appear under subpart B, Compliance with Federal, State and Local Laws. We are adding this requirement to subpart L to unify all personnel requirements in one area.

We are maintaining the requirement at § 493.1439 for cytotechnologists to document cases examined to facilitate the requirement for evaluation of cytotechnologists' performance by the technical supervisor.

Section 493.1403, Hospital personnel, contains the current content of § 482.27(c) (1) and (2) with the addition of personnel requirements for technical supervision of histocompatibility (§ 493.1403(b)(5)), clinical cytogenetics at § 493.1403(b)(6) and cytology at § 493.1403(b) (proposed § 493.403), Standard: Laboratory director qualifications, paragraph (b).

Section 493.1407, ICF/MR laboratory services, contains the current content of § 483.460, Condition of participation: Health care services, paragraph (n)(2)(ii)(A)—(D), which concern the personnel requirements for ICF/MR laboratories.

CLIA '88 Changes

No changes were made because of CLIA '88 to subpart G(L), Personnel Standards.

Subpart H (M)—Quality Assurance

Proposed Rule Overview

In § 493.451 (now § 493.1501) we proposed to add a quality assurance condition for both the Medicare and CLIA laboratories to require the laboratories to establish and follow protocols that assess the effectiveness of their operations. The condition would require the laboratory to establish procedures for monitoring the quality of its testing and staff performance and to assure that the laboratory's performance is within established acceptable criteria. This section would add an additional level of quality control and place the burden on the laboratory to accept

responsibility for monitoring its own performance as an adjunct to the checks placed on the facility by the regulatory agency. The laboratory would utilize its quality control and proficiency data and regular staff performance evaluations to monitor and assure the quality of testing and reporting.

The responsibility for establishing and implementing a quality assurance program would be placed on the laboratory director; it would serve as an additional outcome measurement of quality and would assure accurate and reliable test performance and reporting.

The director would also have the responsibility for having a program in place to monitor and control various health and safety hazards from a variety of biological, chemical, environmental and radiological materials or factors, which may affect testing as well as patient and worker safety. This requirement would place responsibility on the laboratory director for setting up and implementing an appropriate program, which would include assuring compliance with the existing Federal, State, and local laws.

As part of the quality assurance initiative, we would also encourage laboratories to enroll in PT programs for analytes other than those included in the current grading scheme. For the subspecialty of cytology, laboratories would be able to insert "blind samples" into their workload or exchange slides with another laboratory for retrospective screening and comparison.

We requested comments on alternate mechanisms of quality assurance that can be used in a Federal regulatory program. We solicited specific suggestions for changes in quality assurance requirements and data to support these changes.

Comments and Responses

Comment: Several commenters believe that this subpart is repetitious of subparts C and F; they are unclear of the differences and distinctions between quality assurance and the requirements specified in proficiency testing and quality control. On the other hand, many commenters believe that this subpart was the essential component of the regulations and should form the basis for all regulatory requirements.

Response: As noted in the original preamble we have added a quality assurance condition for both the Medicare and CLIA laboratories to establish and follow protocols that assess the effectiveness of their operations. The new condition requires the laboratory to establish procedures for monitoring the quality of its testing

and staff performance and to assure that the laboratory's performance is within established acceptable criteria. This section adds an additional level of quality control and places the burden on the laboratory to accept responsibility for monitoring its own performance as an adjunct to the checks placed on the facility by the requirements of Medicare or CLIA programs, or both. The laboratory utilizes its quality control and PT data and regular staff performance evaluations to monitor and assure the quality of testing and reporting.

Comment: One commenter noted that quality controls are no longer included with each group or batch of patient specimens but may be extended to a maximum frequency of twenty-four hours.

The commenter asked that clarification be provided to address the point at which patient test results should be evaluated for accuracy when a quality control failure has been identified.

Response: We agree with this commenter and have included a requirement under standard (c) of § 493.1501 of this subpart to clarify that all patient test results analyzed before a failure in quality control must be evaluated for accuracy and reliability.

Comment: Two commenters noted the absence of the evaluation of patient test results in these requirements.

Response: We agree with the commenters and have added standard (f) to § 493.1501 to require evaluation of patient test results when the results appear inconsistent with clinically relevant criteria such as the patient's age, sex, diagnosis or pertinent clinical data, distribution of patient test results, and relationship with other test parameters.

Comment: Comments were evenly divided in support of and in opposition to the requirement for assessing the performance and competency of employees. Some commenters believe that this function is best left to the laboratory's discretion and that Federal requirements should not be established to regulate this activity. Other commenters were vigorous in their support of this requirement, and some commenters suggested that continuing education units (CEUs) be considered in lieu of this requirement.

Response: We believe that it is essential for each laboratory to assess the competency of employees performing laboratory analysis to assure quality test results. CEUs may be used as an adjunct to this requirement but may not be used in lieu of these requirements because these courses are

not equivalent to semester hours acceptable by a college or university as courses toward a degree. Continuing education courses are lectures or practical "hands on" instruction sessions to provide individuals with technical updates but generally are not in-depth courses that require testing or assessment of comprehension or competency.

Comment: A few commenters indicated that the requirement of using blind proficiency test samples for evaluating employees may cause problems and create false files.

Response: The use of blind proficiency test samples as a mechanism to evaluate employees is one of several options provided to the laboratory as a means of meeting this requirement. Laboratories that anticipate difficulties in using blind proficiency samples may use another option to evaluate employees.

Comment: Several commenters requested more specificity as to the types of complaints that should be investigated by the laboratory.

Response: We have provided flexibility in this requirement by specifying that although all complaints must be documented the laboratory must establish its policies and procedures for which complaints will be investigated and the extent of the investigation.

Summary of Changes to Proposed Rule

Section 493.1501 Quality Assurance

- When a quality control failure occurs, the results of all patient specimens analyzed in the same run before the unacceptable quality control result must be evaluated for accuracy and reliability before release.
- The laboratory must have and use a procedure to evaluate the clinical relationship of each test result that appears inconsistent as it pertains to:
 - patient age
 - patient sex
 - diagnosis and/or clinical data
 - result distribution
 - other test parameters
- The laboratory must have an established program for providing orientation and in service training to employees to improve performances when problems relating to their competency to perform testing (as specified by the laboratory) are identified.
- The laboratory must document problems identified during quality assurance reviews.
- Complaints and problems reported to the laboratory must be documented and, if necessary, investigated; in

addition, where appropriate, corrective actions must be instituted and documented.

CLIA '88 Changes

Subpart M, Quality Assurance, includes no self-implementing provisions of CLIA '88. Any changes necessitated by CLIA '88 will be implemented through separate rulemaking.

Subpart I(N)—Inspection

Proposed Rule Overview

We proposed to add a condition on inspection of the laboratories, § 493.501, which specifies the requirements a laboratory must meet for inspections and record retention and availability.

Under this proposal, we would require the laboratory to demonstrate satisfactory performance on quality control and PT before inspection or approval.

The proposed § 493.501 allowed us to inspect a laboratory during any hours of operation or business and stated that HHS has the right of access to all records required to make a determination of a facility's status. The proposed rule required that the laboratory make these records available to us within a reasonable period of time during the course of the inspection.

The regulations would extend our authority to require the laboratory to test either patient specimens or proficiency testing materials in the laboratory during the inspection to allow us to determine the competency of the personnel and ability of the laboratory to perform tests.

In addition to the subpart C (now subpart H) requirement for participation in a mailed PT program, we considered the development of a methodology for evaluating laboratory performance through onsite PT to enhance the survey process. As stated in our proposal, we plan to select in 1990 a limited number of States in which a random sampling of laboratories would be chosen for the State survey agencies to conduct unannounced onsite PT surveys to compare laboratory performance of on-site PT with performance on mailed PT and to evaluate the feasibility of this type of PT.

In addition, under the proposed requirements, DHHS would be able to reinspect the laboratories at such frequencies as are necessary to determine compliance or continued compliance with the regulations. We proposed to indicate that denial of access could result in revocation or denial of licensure, termination, or

denial of initial approval under Medicare.

Under this proposal the laboratory would also be required to notify us of changes in ownership, direction, location or services so that we can determine the status of the laboratory and its ability to provide reliable and accurate test results. These provisions would not add new requirements but would serve to clarify and unify the existing Medicare and CLIA requirements.

The proposed § 493.501 did not include a number of the requirements in § 405.1909. (Section § 405.1909 was redesignated as § 488.52 and modified on June 17, 1988, 53 FR 23100. For purposes of accurately repeating the proposed rule in this preamble, we retain references to § 405.1909 as codified in the Code of Federal Regulations, revised as of October 1, 1987.) What constitutes a laboratory test (in § 405.1909(a)) was not retained. The provisions relating to specialties and subspecialties for licensure and approval would be relocated in Subpart F, Quality Control, redesignated in these regulations as Subpart K. The content of § 405.1909(b) would be deleted since the date to which it refers has expired. The content of § 405.1909(c), the requirements for successful participation in proficiency testing, were revised and moved to subparts on participation in proficiency testing and proficiency testing programs.

In addition, the specific requirement in § 405.1909(c) for on-site PT would be revised in the subpart on proficiency testing programs. The proposed requirements on proficiency testing would clarify the conditions for successful and unsuccessful performance, and subpart I (now subpart N) would specify that HHS may perform whatever follow-up and inspections are required to determine a laboratory's compliance with the standards.

Comments and Responses

Comment: Many commenters objected to unannounced inspections without a specific cause. Other commenters suggested on-site inspections only with a specific cause.

Response: With the exception of hospitals, it is our policy to conduct unannounced inspections for all health care providers and suppliers, laboratories included. It is imperative that a laboratory be evaluated during its routine operation so that we have access to the daily services provided. Inspections are not necessarily conducted for the convenience of either the laboratory or the survey agency but

rather serve as a mechanism to assess the quality of services routinely provided by the laboratory for use in the diagnosis and treatment of patients.

Comment: Many commenters objected to the use of on-site proficiency test samples, believing that this is disruptive to the operations of the laboratory.

Response: It is not our intent to disrupt the laboratory's operation. Every effort will be made to accommodate the laboratory's responsibility to meet patient care needs.

Comment: An overwhelming number of commenters noted that evaluating a laboratory's performance on the basis of mailed proficiency testing is not valid as the samples are not treated in the same manner as patient specimens in that they are given special treatment in the analysis process. In addition, New York State advocates on-site proficiency testing in addition to mailed proficiency testing to verify laboratory performance and bases its endorsement of this requirement on twenty years of experience in conducting on-site proficiency testing.

Response: It is our view, which was reinforced by the commenters, that on-site proficiency testing is one of the most meaningful mechanisms to evaluate a laboratory's true performance. This provides an assessment of the entire testing system process from receipt of specimens through result reporting. In 1990, on a pilot basis in a limited number of states, we plan to assess laboratory performance of on-site proficiency testing.

Comment: One individual noted the omission of the requirement to notify HHS of changes in supervisory staff and recommended that it be included.

Response: We agree with the commenter in view of the fact that supervisors are required to be present on the laboratory premises when testing is performed. We have included "supervisors" in the list of changes of which we must be notified in § 493.501(d), redesignated as § 493.1601(d).

Comment: Many commenters objected to the one year requirement specified in § 493.501(e) with regard to successful participation in an approved proficiency testing program before inspection for approval in Medicare or licensure under CLIA '67. In addition, commenters requested a mechanism for provisional approval and/or licensure to allow them to operate in this time period.

Response: We have changed the requirement for successful participation in an approved proficiency testing program, from "up to one year before inspection", to require successful

participation for one testing event before inspection, approval or licensure can take place. We agree that one year is too long, because of financial considerations for those laboratories with a significant number of Medicare or Medicaid clients. This revision lessens the need for the provisional approval or licensing, which we cannot provide since we must determine a laboratory's compliance with the regulations before allowing it to perform tests for Medicare and Medicaid beneficiaries.

Comment: Many commenters expressed concern with regard to maintaining the integrity of on-site proficiency testing samples.

Response: We agree with the commenters that specimen integrity of all proficiency test specimens must be assured before any grading criteria can be applied. We will evaluate each proficiency testing program's criteria for on-site sample integrity during the annual review of each provider's PT program.

Summary of Changes to Proposed Rule

Section 493.1601 Inspection

- Unless otherwise specified in this part, approval of a laboratory may be denied for a period of at least one year for violation of any of the requirements of this part or by the Social Security Act, subject to the appeal rights specified in part 498 of this chapter.

- Upon request from HHS or its designee, the laboratory must provide all information and data needed to determine the laboratory's compliance with the requirements.

- The laboratory must notify HHS or its designee within 30 days of the effective date of all changes in supervisors.

- A laboratory applying for Medicare/Medicaid approval and/or CLIA licensure (or letter of exemption) must successfully participate in an approved PT program for one testing event for each specialty or subspecialty for which it seeks approval and/or licensure. The results of the PT event must be submitted to HHS or its designee before inspection.

CLIA '88 Changes

Section 353(g)(1) of the PHS Act, as amended by CLIA '88, permits us to conduct unannounced inspections. This reinforces our current policy and our statement in the proposed rule (§ 493.501) and we repeat that position in this final rule at § 493.1601.

Subpart J (O)—CLIA-Only Requirements

Proposed Rule Overview

We proposed to place requirements applicable only to laboratories engaged in interstate commerce in Subpart J. For example, the CLIA requirements concerning recognition of accreditation programs are different from those for Medicare laboratories due to differences in the two statutes; CLIA allows HHS more flexibility on the type and scope of information that can be requested.

We also proposed to make several modifications in the licensure procedures for laboratories under CLIA. Specifically, we proposed to revise the regulations to indicate that: (1) Licenses will be issued or revoked by specialty and subspecialty rather than by individual test procedures in order to achieve uniformity between programs; (2) we are placing increased reliance on overall outcome measures; and (3) only certain tests are subject to PT, because not all tests are currently included in PT programs.

We also proposed to revise the exemption applicable to certain physician office laboratories that examine specimens on referral so that we would grant exemptions in cases only in which the total number of tests performed annually is 100 or fewer rather than granting exemptions for each specialty or subspecialty in which 100 tests or fewer are performed. (It should be noted that we could not eliminate the test limit since the CLIA statute in effect at the time of our proposal required us to provide a low test volume. CLIA '88 amends this provision so that, effective January 1, 1990, a waiver may be granted to laboratories that perform tests that are determined by HHS to be simple, accurate tests which pose no reasonable risk of harm to patients if performed incorrectly. Our interpretation of this provision will be proposed in a separate Federal Register document.) We proposed to specify that HHS may determine that certain categories or types of tests pose a hazard to public health if performed incorrectly; therefore, no exemption will be granted in these cases.

We also proposed adding a provision (§ 493.704) that would allow us to issue a notice that a license can continue in effect for another year, rather than reissuing the formal license every year. This would meet the intent of the statute and still permit annual renewal without inordinate paperwork when no changes in licensure status have occurred.

Comments and Responses

Comment: In reference to § 493.701 (§ 493.1701), Basis and scope, one commenter requested that laboratories performing tests solely for the purpose of insurance policy eligibility should be subject to the same regulations as laboratories doing comparable testing.

Response: At this time, laboratories performing tests for the purpose of insurance policy eligibility are not subject to the regulations, provided that the results of such testing are not used for clinical, medical intervention. However, under CLIA '88, such testing could be subject to Federal regulations.

Comment: With respect to § 493.704 (§ 493.1704), Licensure application and issuance, a few commenters noted different termination periods in the proposed regulations; the six month termination period in the participation in proficiency testing, proposed § 493.24, Reinstatement after failure to participate successfully, differed from the one year termination period in proposed § 493.704(b)(4) in CLIA requirements.

Response: In subpart C of the proposed rule, we specified a six month termination period whereas in subpart J we indicated that, for laboratories that have had a license revoked in whole or in part, HHS would not consider a licensure application until one year after the effective date of termination unless the laboratory submits good cause for a waiver of the one year period. For laboratories whose licensure revocation was based on unsuccessful proficiency testing performance, we intended for the "good cause" provision to allow reinstatement after six months, if successful performance is achieved on 3 consecutive proficiency testing events. We have clarified § 493.1704(b)(4) to reflect our intent.

Comment: One commenter requested a definition of a physician's office laboratory.

Response: The applicability of these regulations is clearly specified in the basis and scope section and does not include physician's office laboratories; therefore, we have not provided a definition of the term "physician's office laboratory."

Comment: Referencing § 493.710 (§ 493.1710), a few commenters requested that the College of American Pathologists' letter of exemption be extended to include Medicare approved laboratories as well as CLIA licensed laboratories.

Response: Currently, there is a statutory provision in CLIA '67 recognizing the laboratory accreditation program of the College of American Pathologists (CAP). CAP has requested

recognition of its laboratory accreditation program under the Social Security Act for Medicare laboratories. However, we could not act on the CAP request because we were in the process of revising our laboratory standards. We are not accepting requests for recognition of accreditation programs until we fully implement CLIA '88 because some additional changes may be made in the Medicare-Medicaid requirements as well as the standards of CLIA '88. Following establishment of the CLIA '88 standards enforcement program, we will establish requirements for recognition of State licensure and professional organizations' accreditation programs. Moreover, although CAP is currently recognized under CLIA '87, it will be necessary to re-evaluate CAP's program in terms of the new standards implemented under CLIA '88.

Summary of Changes to Proposed Rule

In § 493.704(b)(2), now § 493.1704(b)(2), we added the requirement for laboratories to notify HHS within 30 days of changes in ownership, location, name, director(s), supervisor(s), and/or deletion of specialties or subspecialties of service. Current regulations in Part 74 require laboratories to notify HHS within 10 days of a change in ownership and 30 days of a change in director or supervisor. In the proposed rule, we specified that HHS would issue a revised license when changes occurred but omitted the timeframe for laboratories to notify HHS of changes and failed to specify the changes in a laboratory operation that would affect licensure status.

We revised § 493.704(b)(4) (now § 493.1704(b)(4)) to be consistent with requirements in subpart H for reinstatement of the failure to participate successfully.

CLIA '88 Changes

No changes were made in this subpart. The entire subpart will be deleted when CLIA '88 is fully implemented because it will no longer be applicable. It should be noted that although we proposed to establish standards similar to the current CLIA '67 requirements for recognition of accreditation and State licensure programs (that is, a laboratory accredited or licensed by one of these programs is deemed to meet Medicare conditions of coverage), the broader implications of CLIA '88 have caused us to place a moratorium on recognition of private sector and State programs until the CLIA '88 standards are implemented. We feel this approach will be less

disruptive than evaluating programs under the revised standards and performing another evaluation when the CLIA '88 regulations are finalized. Therefore, under these regulations, the College of American Pathologists Laboratory Accreditation Program and the New York State licensure program will continue to be recognized for accrediting laboratories subject to CLIA '87. However, all programs, including New York State and College of American Pathologists programs, will have to be evaluated following the establishment of CLIA '88 standards.

IV. Other Revisions Affecting Laboratories

- We proposed to revise § 405.1909 (redesignated June 17, 1988 (53 FR 23100), as § 488.52). Special requirements applicable to independent laboratories, to delete the current paragraphs (b) through (d), as the comparable content would be in part 493, and to add a definition of "independent laboratory." We also proposed to revise the last sentence in paragraph (a), which currently indicates that diagnostic tests performed by an attending or consulting physician are physician's services rather than clinical laboratory services so that laboratory services furnished by physicians are paid for on a fee schedule basis. (See the discussion concerning § 405.1909, second column, page 29605 of the proposed rule for a fuller explanation).

- We proposed to revise the definitions found in current 42 CFR 405.2102, to clarify that histocompatibility testing determines compatibility between a potential organ donor and recipient and not between a donor organ and a recipient.

- We also proposed to revise current § 405.2171(d), Condition: Minimal service requirements for a renal transplantation center, to cross-refer it to the new unified regulations for clinical laboratories, including histocompatibility testing for renal transplantation centers. However, we would retain the requirement concerning 24-hour availability of services (§ 405.2171(d)(1)) as it would not apply to other laboratories.

- We proposed to revise current 42 CFR 416.49, Condition for coverage—Laboratory and radiological services, to require laboratories in ambulatory surgical centers to comply with the conditions of coverage of laboratory services in new part 493 except for urinalyses, hemoglobins, and hematocrits performed within a few days before, or on, the day of surgery.

We received several comments from individuals questioning the rationale for

not regulating ambulatory surgical centers that perform hemoglobin and hematocrit tests and urinalysis. Ambulatory surgical centers, as well as other entities, performing laboratory services, will be subject to CLIA '88. Our rulemaking to implement CLIA '88 will include ambulatory surgical centers and that rule will specify which tests can be considered under the waiver provision of CLIA '88.

- Our proposed revisions to § 482.27 (the condition of participation concerning hospital-based laboratories) only deleted personnel requirements that would be in the new part and cross-referred to part 493 for requirements a hospital-based laboratory must meet. We intended to retain the requirements currently in § 482.27(a)(1) and (2) as they would continue to apply only to hospital-based laboratories. In this final rule, we transfer to § 493.1403 (rather than delete) the personnel requirements in § 482.27(a)(3) (ii), (iii) and (iv), and (c) through (f).

Summary of Changes to Proposed Rule

Except for the comments mentioned above, there were no other comments on these proposals. Therefore, except for a number of technical changes (to bring the coding up to date), we are adopting them as final.

CLIA '88 Changes

There were no self-implementing CLIA '88 changes affecting the regulations sections discussed as "Other Revisions" in section IV.

V. Regulatory Impact Analysis

A. Introduction

Executive Order 12291 (E. O. 12291) requires us to prepare and publish a final regulatory impact analysis for any proposed regulation that meets one of the E. O. criteria for a "major rule"; that is, that will be likely to result in:—

- An annual effect on the economy of \$100 million or more;
- A major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or,
- Significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

In addition, we generally prepare a final regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612), unless the Secretary certifies that a final regulation will not

have a significant economic impact on a substantial number of small entities. For purposes of the RFA, we consider all hospital-based and independent laboratories as small entities. For purposes of this regulation, physician laboratories that perform any tests on referral from other physicians also are small entities. Individuals and states are not included in the definition of a small entity.

In addition, section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis for any final rule that may have a significant impact on the operations of a substantial number of small rural hospitals. Such an analysis must conform to the provisions of section 604 of the RFA. For purposes of Section 1102(b) of the Act, we define a small rural hospital as a hospital which is located outside a metropolitan statistical area and has fewer than 50 beds.

We do not believe that the provisions of this regulation constitute a major rule. However, because we expect that this regulation could have a significant impact on some laboratories, may affect some personnel employed by laboratories, and may have an effect on some States regarding State requirements, licensure and certification of laboratories, we have performed the following analysis voluntarily.

B. Anticipated Effects

1. Affected Entities

There are approximately 12,000 Federally regulated laboratories located in hospitals and independent settings. These facilities range from large medical centers and corporate-operated independent laboratories to small, independent laboratories and physician's office laboratories.

Although not small entities, we expect States to be affected by some additional administrative burden because they may have to adapt or establish a methodology for assessment of PT requirements and ensure compliance with these requirements. States may have to make more recommendations for termination of Medicare approval if the PT standards are not met.

We expect entities providing PT programs to be affected because of program changes that may be necessary in order to meet the criteria for an approved PT program and additional documentation required to perform in the Federal program.

2. Cost/Savings

We expect our standards to be achievable by the majority of

laboratories although some may have to incur costs to achieve the required compliance with PT standards. Depending upon the actual costs in upgrading a specific lab to meet PT standards, the charges of that laboratory for its services may rise to offset the costs of improvements. However, we believe that in an area with sufficient competition, including that from physicians' office laboratories, the charges for services will remain stable. Therefore, since charge increases are unlikely, we assume that laboratories will seek to minimize cost increases through increased efficiencies. The regulation provides increased flexibility over existing regulations to permit different approaches to achieving efficiencies.

This final regulation will expand Medicare coverage from physicians' office laboratories receiving 100 or more referrals to those laboratories receiving any test on referrals. This change may create a slight increase in the number of laboratories requiring Medicare approval.

We expect that some physicians' office laboratories will seek Medicare approval and thus comply with Medicare requirements to be reimbursed for referral tests. We also expect that those physician office laboratories that may incur a substantial increase in costs to meet these requirements may increase their charges or may elect to stop doing tests on referral.

There may also be additional increases in the purchase of automated laboratory equipment and computers by laboratories attempting to achieve satisfactory performance in proficiency testing.

3. Proficiency Testing Effects

This regulation establishes consistent PT requirements based on data from professional organizations that operate PT programs. We will require specific minimum PT passing scores for each specialty and subspecialty. Currently, passing levels for PT are set by each State and the levels vary. We expect the PT standards to enable us to identify and take consistent action against Medicare and CLIA laboratories whose PT performances are below the range of acceptability achieved by the vast majority of laboratories. A laboratory's poor PT performance would result in a denial of Medicare or Medicaid payment for a failed specialty or subspecialty of testing or in revocation of CLIA licensure.

Even though we lack definitive data, we do not expect this regulation to affect most laboratories adversely because most laboratories already

participate in PT, both for their own benefit and because Medicare requires it. However, laboratories in States with less rigorous proficiency testing program standards than we will require would be the most likely to be adversely affected. We also expect the number of tests for which payment is denied by the Medicare and Medicaid programs for payment purposes to increase for those laboratories that do not improve to our designated performance level. This will occur as a result of the laboratory's approval being terminated for unsuccessful PT performance, which means that laboratories will not be paid for tests categorized in the terminated specialty or subspecialty of services.

Some laboratories may incur greater costs to achieve compliance with the required PT standards than others because of the costs that would be incurred to improve their quality control activities and quality assurance programs.

If a laboratory's PT performance is determined to be unsuccessful, payment will not be made for tests in the failed specialty or subspecialty. We expect the number of laboratories not receiving payment to increase. However, we also expect the quality of laboratory services to improve as a result of implementation of these standards.

At present, Medicare and CLIA laboratories are not required to participate in PT programs for cytology, because no such program has been established. This final regulation will establish national standards for cytology proficiency testing. This may mean additional expense for those laboratories that have to participate in a cytology PT program for the first time or incur additional costs in order to perform successfully in the cytology PT program.

4. Quality Control/Quality Assurance

This final regulation includes an update of quality control requirements to account for changes in technology and instrumentation that have occurred in the laboratory field since 1974. Laboratories would be required to implement their own quality assurance programs that they would be expected to follow. As a result of this regulation, laboratory directors will be required to assess laboratory performance and staff competency.

We expect this regulation to improve laboratory testing in terms of the quality of the end result or outcome while removing many of the process requirements that current regulations specify to achieve that outcome. The laboratory would have more discretion over what type of internal controls,

methodology, and equipment (such as computerized rather than manual equipment) are necessary to ensure that the required quality control standards are met.

5. Personnel Standards

The final regulation makes no change in current personnel requirements related to qualifications of individuals. However, we have specified that laboratories must evaluate the competency of employees on an ongoing basis. The additional requirement for laboratories to assess personnel performance should reduce laboratory testing errors and improve the quality of test results.

6. Conclusion

We believe that these changes will result in clearer, more uniformly applied criteria for determining acceptability of laboratory performance. We expect some laboratories to incur costs to upgrade their performance. We expect these costs to be somewhat offset by savings from removal of detailed process requirements. Overall benefits, in terms of consistent laboratory requirements and improved quality will increase benefits to patients and will more than offset the costs of upgrading and improvements.

We conclude, based on the analysis above, that the final rule is not a major rule under Executive Order 12291. Although some laboratories will be adversely affected, we believe that benefits to society will outweigh the adverse effects. We expect most laboratories not to incur substantial costs to comply with our conditions. The Secretary certifies that this final regulation will not have a significant impact on the operations of a substantial number of small rural hospitals.

VI. Paperwork Reduction Act

Sections 493.701, 493.801, 493.823, 493.825, 493.827, 493.829, 493.831, 493.833, 493.835, 493.837, 493.841, 493.843, 493.845, 493.847, 493.851, 493.859, 493.861, 493.863, 493.865, 493.901, 493.903, 493.911, 493.913, 493.915, 493.917, 493.919, 493.923, 493.925, 493.931, 493.933, 493.937, 493.939, 493.941, 493.945, 493.959, 493.1101, 493.1209, 493.1211, 493.1213, 493.1215, 493.1217, 493.1219, 493.1221, 493.1223, 493.1235, 493.1257, 493.1259, 493.1265, 493.1267, 493.1277, 493.1285, 493.1429, 493.1501, 493.1601, 493.1704, 493.1708, 493.1710 of this rule contain information collection requirements subject to the Paperwork Reduction Act. These sections are being revised and recodified into a new part in order to simplify and unify the health

and safety requirements, with a single set of regulations for the three programs. Reporting burden for these collections of information is estimated to vary from 0 minutes up to 4 hours per response. A notice will be published in the Federal Register when approval is obtained. Organizations and individuals desiring to submit comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, may submit them to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

VII. Response to Comments

Because of the impact these regulations will have on clinical laboratories and because of the Department's continuing regulatory responsibilities, we are interested in receiving additional comments on this final rule. We will accept these comments for 60 days after the date of publication.

Because of the large number of items of correspondence we normally receive on a Final Rule with comment, we are not able to acknowledge or respond to them individually. However, we will consider all comments that we receive by the date and time specified in the "DATES" section of this preamble, and, if we proceed with a final rule, we will respond to the comments in the preamble of that rule.

VIII. List of Subjects

42 CFR Part 74

Administrative practice and procedure, Health, Laboratories, Reporting and recordkeeping requirements.

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Nursing homes, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 416

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 440

Grant programs—health, Medicaid.

42 CFR Part 462

Hospitals, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 483

Grant programs—health, Health facilities, Health professions, Health records, Medicaid, Nursing homes, Nutrition, Reporting and recordkeeping requirements, Safety.

42 CFR Part 468

Health facilities, Survey and certification, Forms and guidelines.

42 CFR Part 493

Laboratories, Medicare, Medicaid, Health facilities, Reporting and recordkeeping requirements.

Title 42 of the Code of Federal Regulations is amended, as set forth below:

CHAPTER I—PUBLIC HEALTH SERVICE, DEPARTMENT OF HEALTH AND HUMAN SERVICES

PART 74—CLINICAL LABORATORIES

I. Chapter I is amended by removing part 74 and reserving it.

PART 74—[Reserved]

CHAPTER IV—HEALTH CARE FINANCING ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

II. Chapter IV is amended as set forth below:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

A. Part 405 is amended as follows:

Subpart E—Criteria for Determination of Reasonable Charges; Reimbursement for Services of Hospital Interns, Residents, and Supervising Physicians

1. Subpart E is amended as follows:

a. The authority citation for subpart E continues to read as follows:

Authority: Secs. 1102, 1814(b), 1832, 1833(a), 1842 (b) and (h), 1861 (b) and (v), 1862(a)(14), 1866(a), 1871, 1881, 1886, 1887, and 1889 of the Social Security Act as amended (42 U.S.C. 1302, 1395f(b), 1395k, 1395l(a), 1395u (b) and (h), 1395x (b) and (v), 1395y(a)(14), 1395cc(a), 1395hh, 1395rr, 1395ww, 1395xx, and 1395zz).

§ 405.556 [Amended]

b. In paragraph (c) of § 405.556, the cross-reference to § 405.1310(a) is changed to § 438.52.

2. Subpart K is amended as follows:

a. The authority citation for subpart K continues to read as follows:

Authority: Secs. 1102, 1814, 1832, 1833, 1861, 1863, 1865, 1886, 1871 of the Social Security Act; 42 U.S.C. 1302, 1395f, 1395k, 1395l, 1395x, 1395z, 1395bb, 1395cc, 1395hh.

b. Section 405.1128 is revised to read as follows:

§ 405.1128 Condition of participation—laboratory and radiologic services.

The skilled nursing facility has provision for promptly obtaining required laboratory, x-ray, and other diagnostic services.

(a) *Standard: Provision for services.*

(1) If the skilled nursing facility furnishes its own x-ray services, it must meet the applicable conditions established for certification of hospitals in § 482.26 of this chapter. If the facility does not provide x-ray services, it makes arrangements to obtain these services from a physician's office, a participating hospital or skilled nursing facility, or a portable x-ray supplier.

(2) If the skilled nursing facility furnishes its own laboratory services, it must meet the applicable conditions established for certification of hospitals and for approval of laboratories found in §§ 482.27 and part 493 of this chapter, respectively. If the facility does not provide laboratory services, it makes arrangements to obtain these services from a participating hospital or skilled nursing facility, or a laboratory meeting the requirements of part 493 of this chapter.

(3) All x-ray and laboratory services are provided only on the orders of the attending physician, who is notified promptly of the findings. The facility assists the patient, if necessary, in arranging for transportation to and from the source of service. Signed and dated reports of a clinical laboratory, x-ray, and other diagnostic services are filed with the patient's medical record.

(b) *Standard: Blood and blood products.* Blood handling and storage facilities are safe, adequate, and properly supervised. If the facility provides for maintaining and transfusing blood and blood products, it meets the conditions established in §§ 493.301 through 493.315 of this chapter. If the facility does not provide its own facilities but does provide transfusion services alone, it meets at least the requirements of §§ 493.305, 493.307, 493.309, and 493.315 of this chapter.

Subpart M—[Reserved]

3. Subpart M (consisting of §§ 405.1310 through 405.1317) is removed and reserved and the table of contents is amended to reflect this change.

Subpart U—Conditions for Coverage of Suppliers of End-Stage Renal Disease (ESRD) Services

4. Part 405, subpart U is amended as follows:

a. The authority citation for subpart U continues to read as follows:

Authority: Secs. 1102, 1861, 1862(a), 1871, 1874, and 1881 of the Social Security Act (42 U.S.C. 1302, 1395x, 1395y(a), 1395hh, 1395kk, and 1395rr).

b. The definition of histocompatibility testing in § 405.2102 is revised to read as follows:

§ 405.2102 Definitions.

Histocompatibility testing. Laboratory test procedures which determine compatibility between a potential organ donor and a potential organ transplant recipient.

c. Paragraph (b) of 405.2163 is revised to read as follows:

§ 405.2163 Condition: Minimal service requirements for a renal dialysis facility or renal dialysis center.

(b) *Standard: Laboratory services.* The dialysis facility makes available laboratory services (other than the specialty of tissue pathology and histocompatibility testing), to meet the needs of the ESRD patient. Laboratory services are performed by a laboratory that meets the requirements of part 493 of this chapter.

d. Paragraph (d) of § 405.2171 is revised to read as follows:

§ 405.2171 Condition: Minimal services requirements for a renal transplantation center.

(1) (d) *Standard: laboratory services.* The Renal Transplantation Center makes available, directly or under arrangements, laboratory services to meet the needs of ESRD patients. Laboratory services are performed in a laboratory facility approved in accordance with part 493 of this chapter to participate in the Medicare program and, for histocompatibility testing purposes, also meets §§ 493.1201 through 493.1221, 493.1237, 493.1265, 493.1269 and 493.1421(j) of this chapter and, when services are furnished in the subspecialty of histopathology, §§ 493.1421(g) and 493.1259 of this chapter.

(2) Laboratory services for cross-matching of recipient serum and donor lymphocytes for preformed antibodies by an acceptable technique are available on a 24-hour emergency basis.

PART 416—AMBULATORY SURGICAL SERVICES

B. Part 416 is amended as follows:

1. The authority citation for part 416 continues to read as follows:

Authority: Secs. 1102, 1832(a)(2), 1833, 1863 and 1864 of the Social Security Act (42 U.S.C. 1302, 1395k(a)(2), 1395l, 1395z and 1395aa).

Subpart B—Ambulatory Surgical Centers: Coverage and Benefits

2. Section 416.49 is revised to read as follows:

§ 416.49 Condition for coverage—Laboratory and radiologic services.

The ASC must have procedures for obtaining routine and emergency laboratory services from a laboratory meeting requirements of part 493 of this chapter. The ASC must have procedures for obtaining radiologic services from a Medicare-approved facility to meet the needs of patients. The laboratory offering the services must be a laboratory approved in accordance with part 493 of this chapter.

PART 440—SERVICES: GENERAL PROVISIONS

C. Part 440 as amended as follows:

1. The authority citation for part 440 continues to read as follows:

Authority: 42 U.S.C. 1302.

Subpart A—Definitions

2. Section 440.30(a) is revised to read as follows:

§ 440.30 Other laboratory and X-ray services.

"Other laboratory and X-ray services" means professional and technical laboratory and radiological services—

(a) Ordered and provided by or under the direction of a physician or other licensed practitioner of the healing arts within the scope of his practice as defined by State law or ordered and billed by a physician but provided by an independent laboratory as defined in § 488.52 of this chapter.

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

D. Part 482 is amended as follows:

1. The authority citation continues to read as follows:

Authority: Secs. 1102, 1814(a)(6), 1861 (e), (f), (k), (r), (v)(1)(G), and (z), 1864, 1871, 1883, 1886, 1902(a)(30), and 1905(a) of the Social Security Act (42 U.S.C. 1302, 1395f(a)(6), 1395x (e), (f), (k), (r), (v)(1)(G), and (z), 1395aa, 1395hh, 1395tt, 1395ww, 1396a(a)(30), and 1396d(a)).

Subpart C—Basic Hospital Functions

2. Section 482.27 is revised as follows

§ 482.27 Condition of participation: Laboratory services.

(a) *General.* The hospital must maintain, or have available, adequate laboratory services to meet the needs of its patients. The hospital must ensure that all laboratory services provided to its patients are performed in a facility certified in accordance with part 493 of this chapter.

(b) *Standard: Adequacy of laboratory services.* The hospital must have laboratory services available, either directly or through a contractual agreement with a laboratory, that meets the requirements of part 493 of this chapter.

(1) Emergency laboratory services must be available 24 hours a day.

(2) A written description of services provided must be available to the medical staff.

(3) The laboratory must make provision for proper receipt and reporting of tissue specimens.

(4) The medical staff and a pathologist must determine which tissue specimens require a macroscopic (gross) examination and which require both macroscopic and microscopic examinations.

PART 483—CONDITIONS OF PARTICIPATION AND REQUIREMENTS FOR LONG TERM CARE FACILITIES

E. Part 483 is amended as follows:

1. The authority citation for part 483 continues to read as follows:

Authority: Sec. 1102, 1819(a)-(d), 1861 (j) and (l), 1863, 1871, 1902(a)(28), 1905(a) and (c), and 1919 (a)-(d) of the Social Security Act (42 U.S.C. 1302, 1395(i)(3) (a)-(d), 1395x (j) and (l), 1395hh, 1396a(a)(28), and 1396d(c) and 1396f (a)-(d)), unless otherwise noted.

Subpart B—Requirements for Long Term Care Facilities

2. Section 483.75(l) is revised to read as follows:

§ 483.75 Level A requirement: Administration.

(l) *Level B requirement: Laboratory services.* (1) The facility must provide or obtain clinical laboratory services to meet the needs of its residents. The facility is responsible for the quality and timeliness of the services.

(i) If the facility provides its own laboratory services, the services must meet the applicable conditions for coverage of the services furnished by laboratories specified in part 493 of this chapter;

(ii) If the facility provides blood bank and transfusion services, it must meet

the requirements for laboratories specified in part 493 of this chapter.

(iii) If the laboratory chooses to refer specimens for testing to another laboratory, the referral laboratory must be approved or licensed to test specimens in the appropriate specialties and/or subspecialties of service in accordance with part 493 of this chapter.

(iv) If the facility does not provide laboratory services on site, it must have an agreement to obtain these services only from a laboratory that meets the requirements of part 493 of this chapter.

(2) The facility must—

(i) Provide or obtain laboratory services only when ordered by the attending physicians;

(ii) Promptly notify the attending physician of the findings;

(iii) Assist the resident in making transportation arrangements to and from the source of service, if the resident needs assistance.

(iv) File in the resident's clinical record signed and dated reports of laboratory services.

Subpart D—Conditions of Participation for Intermediate Care Facilities for the Mentally Retarded

3. Section 483.460(n) is revised to read as follows:

§ 483.60 Condition of participation: Health care services.

(n) *Standard: Laboratory services.* (1) For purposes of this section, "laboratory" means an entity for the biological, biophysical, immunohematological microbiological, serological, chemical, hematological, 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 the assessment of the health of human beings.

(2) If a facility chooses to provide laboratory services, the laboratory must meet the requirements specified in part 493 of this chapter.

(3) If the laboratory chooses to refer specimens for testing to another laboratory, the referral laboratory must meet the requirements of part 493 of this chapter.

PART 488—[AMENDED]

F. Part 488 is amended as follows:

1. The authority citation for part 488 continues to read as follows:

Authority: Secs. 1102, 1814, 1861, 1365, 1866, 1871, 1880, 1881 and 1883 of the Social Security Act (42 U.S.C. 1302, 1395f, 1395x, 1395bb, 1395cc, 1395hh, 1395qq, 1395rr and 1395tt).

2. Section 488.52 is revised to read as follows:

§ 488.52 Special requirements applicable to independent laboratories.

(a) The services of a qualified independent laboratory for which reimbursement may be made under the supplementary medical insurance program "relate only to diagnostic tests performed in an independent laboratory. Diagnostic laboratory tests for purposes of section 1861(s) (13) and (14) of the Act and for purposes of subparts A, B and C of this part shall include only those clinical and anatomical pathology diagnostic tests and procedures included in specialties and subspecialties listed in § 493.2 under "laboratory". Such diagnostic tests performed by out-of-hospital physicians whose primary practice is directly attending patients and/or consultation (i.e., furnishing an attending physician with an opinion about a patient's condition or diagnosis), even though conducted partly through diagnostic procedures, are not considered services of an independent laboratory except when they are done on referral.

(b) For purposes of this section, an independent laboratory is a facility meeting the requirements of part 493 of this chapter and maintained for the purpose of performing laboratory testing. An independent laboratory is not a facility that is controlled, managed or supervised by a hospital as defined by section 1861(e) of the Act, a hospital's organized medical staff, or the attending or consulting physician's office.

F. A new part 493 is added as follows:

PART 493—LABORATORY REQUIREMENTS

Subpart A—General Provisions

Sec.

493.1 Basis and scope.

493.2 Definitions.

Subpart B-F [Reserved]

Subpart G—Administration

493.701 Condition: Compliance with Federal, State and local laws.

Subpart H—Participation in Proficiency Testing

493.801 Condition: Enrollment and testing of samples.

493.803 Condition: Successful participation.

493.805 Condition: Satisfactory participation before initial approval or licensure.

493.807 Condition: Reinstatement after failure to participate successfully.

Proficiency Testing by Specialty and Subspecialty

493.821 Condition: Microbiology.

493.823 Standard: Bacteriology.

493.825 Standard: Mycobacteriology.

493.827 Standard: Mycology.

493.829 Standard: Parasitology.

493.831 Standard: Virology.

493.833 Condition: Diagnostic immunology.

493.835 Standard: Syphilis serology.

493.837 Standard: General immunology.

493.839 Condition: Chemistry.

493.841 Standard: Routine chemistry.

493.843 Standard: Endocrinology.

493.845 Standard: Toxicology.

493.847 Standard: Urinalysis.

493.849 Condition: Hematology.

493.851 Standard: Hematology.

493.853 Condition: Pathology.

493.855 Standard: Cytology: Gynecologic examinations.

493.857 Condition: Immunohematology.

493.859 Standard: ABO blood group and Rh₀ (D) group.

493.861 Standard: Unexpected antibody detection.

493.863 Standard: Compatibility testing.

493.865 Standard: Antibody identification.

Subpart I—Proficiency Testing Programs

493.901 Approval of proficiency testing programs.

493.903 Administrative responsibilities.

493.905 Disapproved proficiency testing programs.

493.907 Process for updating proficiency testing programs.

Proficiency Testing Programs by Specialty and Subspecialty

493.909 Microbiology.

493.911 Bacteriology.

493.913 Mycobacteriology.

493.915 Mycology.

493.917 Parasitology.

493.919 Virology.

493.921 Diagnostic immunology.

493.923 Syphilis serology.

493.927 General immunology.

493.929 Chemistry.

493.931 Routine chemistry.

493.933 Endocrinology.

493.937 Toxicology.

493.939 Urinalysis.

493.941 Hematology (including routine hematology and coagulation).

493.945 Cytology: Gynecologic examinations.

493.959 Immunohematology.

Subpart J—Patient Test Management

493.1101 Condition: Patient test management

Subpart K—Quality Control

493.1201 Condition: General quality control.

493.1203 Standard: Facilities.

493.1205 Standard: Adequacy of methods and equipment.

493.1207 Standard: Temperature and humidity monitoring.

493.1209 Standard: Labeling of testing supplies.

493.1211 Standard: Procedure manual.

493.1213 Standard: Equipment maintenance and function checks.

493.1215 Standard: Validation of methods.

- 493.1217 Standard; Frequency of quality control.
- 493.1219 Standard; Remedial actions.
- 493.1221 Standard; Quality control—records.
- 493.1223 Condition: Quality control—specialties and subspecialties.
- 493.1225 Condition: Microbiology.
- 493.1227 Standard; Bacteriology.
- 493.1229 Standard; Mycobacteriology.
- 493.1231 Standard; Mycology.
- 493.1233 Standard; Parasitology.
- 493.1235 Standard; Virology.
- 493.1237 Condition: Diagnostic immunology.
- 493.1239 Standard; Syphilis serology.
- 493.1241 Standard; General immunology.
- 493.1243 Condition: Chemistry.
- 493.1245 Standard; Routine chemistry.
- 493.1247 Standard; Endocrinology.
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- 493.1251 Standard; Urinalysis.
- 493.1253 Condition: Hematology.
- 493.1255 Condition: Pathology.
- 493.1257 Standard; Cytology.
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- 493.1263 Condition: Radiobiology.
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- 493.1701 Basis and scope.

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- 493.1706 Revocation, suspension and limitation of licenses and letters of exemption; notice

- 493.1708 Approval of accreditation and State licensure programs; notice.

- 493.1710 Letter of exemption.

Authority: Secs. 1102, 1861(e), the sentence following 1861(s)(11), 1861(s)(12) and 1861(s)(13) of the Social Security Act and sec. 353 of the Public Health Service Act (42 U.S.C. 263a, 1302, the sentence following sec. 1395x(s)(11), and sec. 1395x(s) (12) and (13).)

Subpart A—General Provisions

§ 493.1 Basis and scope.

This part sets forth the conditions that laboratories must meet in order for their tests to be approved for coverage under the Medicare and Medicaid programs and in order for laboratories to be licensed under CLIA to perform testing on specimens received in interstate commerce. It implements sections 1861(e) and (j), the sentence following section 1861(s)(13), sections 1861(s) (14) and (15), and 1902 of the Social Security Act, and section 353 of the Public Health Service Act. This part applies to: Laboratories located in physicians' offices (including group medical practices) that perform any tests on referred specimens; hospitals meeting at least the requirements specified in section 1861(e) of the Act to qualify for emergency hospital services under section 1814 of the Act; skilled nursing facilities; intermediate care facilities for the mentally retarded; rural health clinics that perform tests on referral; ambulatory surgical centers except as provided in § 416.49 of this chapter; end-stage renal disease facilities except with respect to the services prescribed in § 405.2163 of this chapter; and

independent laboratories, as defined in § 488.52 of this chapter. It does not apply to laboratories operated by a rural health clinic, HMO, or physician's office exclusively for its own patients.

§ 493.2 Definitions.

As used in this part—

Accredited laboratory means a laboratory (including a laboratory in a hospital) accredited by, with respect to hospitals, the Joint Commission on the Accreditation of Healthcare Organizations or the American Osteopathic Association and, with respect to interstate licensed laboratories, the Laboratory Accreditation Program of the College of American Pathologists, or any other private non-profit organization that has been approved by HHS as provided in section 353 of the Public Health Service Act.

Authorized person means a person authorized under section 1861(r) of the Act to order and to receive test results. With respect to tests performed on individuals not receiving or seeking Medicare reimbursement, an authorized person is an individual not excluded under State law or by Medicaid.

Challenge means, for quantitative tests, an assessment of the amount of substance or analyte present 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 Laboratories Improvement Act of 1967.

Independent laboratory. An independent laboratory performing diagnostic tests means one which is independent both of the attending or consulting physician's office and of a hospital which meets at least the requirements specified in section 1861(e) of the Act to qualify for payment for emergency hospital services under section 1814(d) of the Act. A laboratory which is located in a hospital which meets at least the requirements specified in section 1861(e) of the Act to qualify for payment for emergency hospital services under section 1814(d) of the Act or, if outside the hospital, is operated under the supervision of the hospital or its organized medical staff, and serves the hospital's patients, is not an independent laboratory. Services furnished by out-of-hospital laboratories under the direction of a physician, such as a pathologist, are considered to be subject to the conditions where the physician holds himself and the facilities of his office out to other

physicians as being available for the performance of diagnostic tests. A laboratory maintained by a physician for performing diagnostic tests for his own patients is exempt from the conditions unless such laboratory accepts any laboratory tests on referral.

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 screening procedures to determine the presence or absence of various substances or organisms in the body. Facilities only collecting specimens or only serving as a mailing service and not performing testing are not considered laboratories.

Kit is all components of a test which are packaged together.

Referee laboratory means a laboratory that has had a record of satisfactory performance for all testing events for at least one year in a specific test specialty or subspecialty and has been nominated by an approved proficiency testing program and approved by HHS as a referee laboratory for that specialty or subspecialty.

Run means an interval within which the accuracy and precision of a testing system is expected to be stable but must not exceed a period of 24 hours and must not be less frequent than the manufacturer's specification for including controls and calibrators.

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.

Target value means either the mean of all 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 by the National Committee for Clinical Laboratory Standards. In instances where definitive or reference methods are not available, a comparative method may be used. If the method group is less than 20 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.

Subparts B-F [Reserved]

Subpart G—Administration

§ 493.701 Condition: Compliance with Federal, State and local laws.

The laboratory must be in compliance with all applicable Federal, State and local laws.

(a) **Standard; Federal laws.** The laboratory must be in compliance with applicable Federal laws related to the health and safety of individuals whose specimens are submitted to it for testing.

(b) **Standard; State licensure.** The laboratory must be (1) licensed if State or applicable local law requires licensure; or (2) approved as meeting standards for licensing established by the agency of the State or locality responsible for licensing laboratories.

(c) **Standard; licensed staff.** All personnel, including those individuals who collect specimens, must be licensed or meet other applicable standards that are required by State and local laws.

(d) **Standard; fire safety.** The laboratory must comply with State and local laws related to fire safety.

(e) **Standard; environment and health.** The laboratory must comply with Federal, State and local laws relating to the storage, handling and disposal of chemical, biological and radioactive materials.

Subpart H—Participation in Proficiency Testing

§ 493.801 Condition: Enrollment and testing of samples.

A laboratory must enroll in a proficiency testing program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in such a program for each of the specialties and subspecialties for which it seeks or has approval for Medicare or Medicaid participation or for licensure under CLIA. The laboratory must test the samples in the same manner as patients' specimens.

(a) **Standard; Enrollment.** The laboratory must notify HHS of the approved program or programs in which it chooses to participate to meet proficiency testing requirements of this subpart. The laboratory must—

(1) Designate the program to be used for each specialty and subspecialty to determine compliance with this subpart if the laboratory participates in more than one proficiency testing program approved by HHS;

(2) For each specialty and subspecialty, participate in one approved proficiency testing program for four quarters before designating a

different program and must notify HHS before any change in designation; and

(3) Authorize the proficiency testing program to release to HHS all data required by HHS to determine the laboratory's compliance with this subpart.

(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 must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.

(2) The laboratory may not test the samples with greater frequency of testing than it routinely tests patient samples.

(3) A laboratory that performs tests on proficiency testing samples may not engage in any interlaboratory communications pertaining to the results of proficiency testing sample(s). Laboratories with multiple testing sites or separate locations may not engage in any communications or discussions across sites/locations concerning proficiency testing results.

(4) The laboratory must not send the samples or portions of samples to another laboratory for analysis. Any laboratory that HHS determines intentionally referred its proficiency testing samples to another laboratory for analysis will have its approval and/or license revoked for at least one year. Any laboratory that receives proficiency testing samples from another laboratory for testing must notify HHS 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 and 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, for a minimum of two years from the date of the proficiency testing event.

§ 493.803 Condition: Successful participation.

(a) Each laboratory must successfully participate in a proficiency testing program approved by HHS, if applicable, as described in subpart I of

this part for each specialty and subspecialty in which the laboratory seeks Medicare approval or licensure under CLIA.

(b) If the laboratory fails to participate successfully in proficiency testing for a given specialty or subspecialty, as defined in this section, the laboratory's Medicare approval or licensure under CLIA, or both, will be terminated, revoked, suspended or limited for the specialty or subspecialty.

(c) If the laboratory fails to perform successfully for the challenges on a given analyte or test procedure, as defined in this section, the laboratory's Medicare approval or licensure under CLIA, or both, for the specialty or subspecialty in which the analyte is categorized¹ will be terminated, revoked, suspended or limited.

§ 493.805 Condition: Satisfactory participation before initial approval or licensure.

Laboratories must satisfactorily participate in one proficiency testing event for each specialty and subspecialty before initial Medicare approval or CLIA licensure of the specialty or subspecialty.

§ 493.807 Condition: Reinstatement after failure to participate successfully.

(a) If a laboratory fails to participate successfully in one or more specialties or subspecialties, or voluntarily withdraws its participation from Medicare or Medicaid or its licensure under CLIA for the failed specialty or subspecialty, the laboratory's participation or licensure for the applicable specialty or subspecialty will be terminated. The laboratory must then demonstrate sustained successful performance on three consecutive proficiency testing events, at least one of which will be on-site proficiency testing, before HHS will consider it for reinstatement in the specialty or subspecialty.

(b) The termination period for Medicare participation or period for revocation of licensure under CLIA for the failed specialty or subspecialty is for a period of not less than six months from the date of termination or revocation.

Proficiency Testing by Specialty and Subspecialty

§ 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 timeframe allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the timeframe 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 timeframe specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(d) For any unsatisfactory testing event, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. All remedial action taken must be documented and 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.

§ 493.825 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 timeframe allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the timeframe 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 timeframe specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(d) For any unsatisfactory testing event, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. All remedial action taken must be documented and 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.

§ 493.827 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 timeframe allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the timeframe 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 timeframe specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(d) For any unsatisfactory testing event, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. All remedial action taken must be documented and 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.

§ 493.829 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 timeframe allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the timeframe 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 timeframe specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(d) For any unsatisfactory testing event, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. All remedial action taken must be documented and 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.

§ 493.831 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 timeframe allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the timeframe 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 timeframe specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(d) For any unsatisfactory testing event, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. All remedial action taken must be documented and 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.

§ 493.833 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 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 timeframe allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the timeframe 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 timeframe specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(e) For any unsatisfactory analyte performance or testing event, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct

problems associated with a proficiency testing failure. All remedial action taken must be documented and 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(s) 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.

§ 493.837 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 timeframe allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the timeframe 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 timeframe specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(e) For any unsatisfactory analyte performance or testing event, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. All remedial action taken must be documented and 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(s) 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.

§ 493.839 Condition: Chemistry.

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

§ 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 timeframe allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the timeframe 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 timeframe specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(e) For any unsatisfactory analyte performance or testing event, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. All remedial action taken must be documented and 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(s) 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.

§ 493.843 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 timeframe allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the timeframe 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 timeframe specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(e) For any unsatisfactory analyte performance or testing event, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. All remedial action taken must be documented and 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(s) 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.

§ 493.845 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 timeframe allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the timeframe 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 timeframe specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(e) For any unsatisfactory analyte performance or testing event, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. All remedial action taken must be documented and 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(s) 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.

§ 493.847 Standard; Urinalysis.

(a) Failure to attain 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 timeframe allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the timeframe 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 timeframe specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(e) For any unsatisfactory analyte performance or testing event, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. All remedial action taken must be documented and 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(s) 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.

§ 493.849 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 timeframe allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the timeframe 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 timeframe specified by the program is unsatisfactory

performance and results in a score of 0 for the testing event.

(e) For any unsatisfactory analyte performance or testing event, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. All remedial action taken must be documented and 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.

§ 493.853 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 require each individual engaged in the examination of gynecologic preparations to be tested twice per year. To insure this biannual examination, once a year one unannounced testing event will be conducted on-site in each laboratory and no less than four announced testing events will be conducted annually in each State. HHS will designate the testing sites.

(b) An individual is determined to have failed a testing event if he or she scores less than 80 percent on a test set. For any individual who fails a proficiency testing event, the laboratory must provide him or her with immediate remedial training and education in the area of failure, document the training and education provided, and assure that all subsequent gynecologic slides are reexamined until the individual is retested and scores at least 80 percent on the next testing event. If the individual who failed the testing event is not qualified as a technical supervisor in cytology under § 493.1421(a), 493.1421(f), or 493.1403(b)(1), at least the last 500 negative slides examined by the individual before the failed testing event must be reexamined. The reexamination

must be performed by an individual who achieved a score of at least 80 percent on the most recent proficiency testing event. When a technical supervisor in cytology qualified under § 493.1421(a), 493.1421(f), or 493.1403(b)(1) fails a proficiency testing event, at least the last 500 slides examined by the individual before the failed testing event must be reexamined. The reexamination must be performed by an individual who qualifies under § 493.1421(a), 493.1421(f), or 493.1403(b)(1) and achieved a score of at least 80 percent on the most recent testing event.

(c) If a laboratory fails to take required remedial actions as described in paragraph (b) of this section when one or more individuals fails a testing event, HHS will terminate the laboratory's Medicare approval for gynecologic cytology testing or revoke its licensure under CLIA, or both if applicable.

§ 493.857 Condition: Immunohematology.

The specialty of immunohematology includes four subspecialties for the purposes of proficiency testing: ABO group and Rh₀ (D) group; unexpected antibody detection; compatibility testing; and antibody identification.

§ 493.859 Standard: ABO group and Rh₀ (D) group.

(a) Failure to attain a score of at least 100 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 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 timeframe allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the timeframe 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 timeframe specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(e) For any unsatisfactory analyte performance or testing event, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. All remedial action taken must be documented and 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(s) 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 timeframe allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the timeframe 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 timeframe specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(d) For any unsatisfactory analyte performance or testing event, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. All remedial action taken must be documented and 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 timeframe allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the timeframe 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 timeframe specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(d) For any unsatisfactory testing event, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. All remedial action taken must be documented and 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 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 timeframe allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the timeframe 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 timeframe specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(e) For any unsatisfactory analyte performance or testing event, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. All remedial action taken must be documented and 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(s) 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.

Subpart I—Proficiency Testing Programs

§ 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 and must, for each specialty and subspecialty for which it provides testing—

(a) Assure the quality of test samples, appropriately evaluate the testing results, and identify performance problems in a timely manner; and

(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 and 640; and

(ii) Distribute the samples, using rigorous quality control to assure that samples mimic actual patient specimens when possible and that samples are homogeneous 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 frequency 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 laboratory performance on testing events, cumulative reports about laboratory performance, and reports of specific laboratory failures using grading criteria acceptable to HHS. These reports must be provided to HHS on a timely basis;

(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; and

(6) A mechanism for participants to notify the proficiency testing program within seven days from the scheduled date of 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.

(c) Meet the specific criteria for proficiency testing programs listed by specialty and subspecialty of services contained in §§ 493.901-493.959 for initial approval and thereafter provide HHS, on an annual basis, with a description of program content and grading criteria.

§ 493.903 Administrative responsibilities.

The proficiency testing program must—

(a) Issue reports in a format approved by HHS on each laboratory's performances for the individual Medicare, Medicaid or CLIA-licensed specialty or subspecialty of service within 45 days after the date by which the laboratory must report proficiency testing results to the proficiency testing program. Copies of these laboratory reports must be sent to the State survey agency at the same time reports are sent to the laboratory;

(b) Furnish to HHS cumulative reports on an individual laboratory's performance and aggregate data on Medicare approved and CLIA-licensed laboratories;

(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 §§ 493.901-493.959; and

(d) Maintain records of Medicare-approved and CLIA-licensed laboratories' performance for a period of

five years or such time as may be necessary for any legal proceedings.

§ 493.905 Disapproved proficiency testing programs.

If a proficiency testing program is determined by HHS to fail to meet the criteria contained in §§ 493.901-493.959 for approval of the proficiency testing program, HHS will notify the program and all laboratories that are Medicare-approved or CLIA-licensed of the nonapproval and the reasons for nonapproval.

§ 493.907 Process for updating proficiency testing programs.

HHS reviews the requirements for proficiency testing on a regular basis and considers revisions to the program based on the performance of laboratories. It will change requirements after soliciting comments from concerned groups regarding the need to modify the criteria for an approved proficiency testing program. Changes in the program may be made to incorporate new analytes, tests, or organisms of clinical significance, to delete obsolete tests, to consider deleting well-performed tests, or to improve the evaluation scheme. When HHS decides to include new challenges or evaluation criteria in future proficiency testing, it will notify all proficiency testing programs of the necessary changes in proficiency testing and require these changes to be provided by approved proficiency testing programs within two years of the notice of change.

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 three types of laboratories:

(1) Those that interpret Gram stains, use direct antigen techniques to detect an organism, perform primary inoculation, or perform any combination of these;

(2) Those that—

(i) May use direct antigen techniques to detect an organism or isolate aerobic and anaerobic bacteria from mixed bacterial populations; and

(ii) Interpret Gram stains and perform limited identification, perform

antimicrobial susceptibility tests on selected microorganisms isolated, or both; and

(3) Those that—

(i) Interpret Gram stains and are able to identify aerobic and anaerobic bacteria from mixed bacterial populations to both genus and species in most patient specimens and perform antimicrobial susceptibility tests on the microorganisms isolated; and

(ii) May use direct antigen techniques to detect an organism.

(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 four testing events per year. The samples may be provided to the laboratory through mailed shipments or, at HHS' option, may be provided to HHS for on-site 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 antigens detection and bacterial isolation and identification.

(1) An approved program must, prior to each calendar year, furnish HHS with a description of samples that it plans to include in its annual program. 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 two types of samples and 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 significant pathogen that is clearly responsible for a described illness (excluding immunocompromised patients). The program determines the reportable isolates, including antimicrobial susceptibility for any designated isolate.

(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 immunocompromised 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 overtime are—

Anaerobes:

Bacteroides fragilis group
Clostridium perfringens
Peptostreptococcus anaerobius

Enterobacteriaceae:

Klebsiella pneumoniae
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
Haemophilus influenza, Type B

(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 predictable 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 subparagraphs (1) through (6) of this paragraph.

(1) The program determines the morphologic and 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 organism identification or antimicrobial susceptibility testing, the program must compare the laboratory's response for each sample with the response which reflects agreement of either 80 percent of ten or more referee laboratories or 80 percent or more of all participating laboratories. Sample scores must be averaged to determine the score for the testing event.

(2) 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 or erroneous Gram stain interpretations that are reported. Therefore, the total number of correct responses for Gram stain interpretations, direct antigen and organism isolation and detection techniques, 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.

(3) 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.

(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 paragraph (c)(1) of this section using criteria based on a consensus document such as the standards 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 $2/3 \times 100 = 67$ percent.

(5) The score for a sample in bacteriology is the score determined under paragraph (c)(2) of this section for detection and identification of organisms or, if the laboratory also performs antimicrobial susceptibility testing for the organism, the score determined by dividing the total number of correct organisms a laboratory

identified plus the number of correct antimicrobial agent responses by the number of possible organisms plus the number of additional erroneous organisms reported plus the actual number of correct susceptibility responses (see paragraph (c)(4) of this section) multiplied by 100 to establish a score for each sample in each testing event. For example, if a sample contained three reportable organisms and a laboratory reported all three correctly, but reported one additional organism, which was not present, and reported correct results for two of three antimicrobial agents tested, its score for the sample would be:

$$(3+2)/(3+1+3) \times 100 = 71 \text{ percent.}$$

(6) The performance criterion for qualitative antigen tests is the presence or absence of the bacterial antigen. The performance criterion for Gram stain in Gram positive or negative.

§ 493.913 Mycobacteriology.

(a) **Types of services offered by laboratories.** In mycobacteriology, there are three types of laboratories for proficiency testing purposes:

(1) Those that interpret acid-fast stains or interpret acid-fast stains and refer cultures to another laboratory for identification;

(2) 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 for identification and/or susceptibility tests; and

(3) 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, or 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.

(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 for on-site testing. For types of laboratories specified in paragraph (a) (2) and (3) of this section, an annual program must include samples that contain species that are representative of the five 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, before each calendar year, furnish HHS with a description of samples that it plans to include in its annual program. 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—

Tuberculosis

Mycobacterium tuberculosis

Mycobacterium bovis

Group I

Mycobacterium kansasii

Group II

Mycobacterium szulgai

Group III

Mycobacterium avium—intracellular

Group IV

Mycobacterium terrae

Group V

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 predictable pattern of sensitivity or resistance to the common antimycobacterial agents.

(4) For laboratories specified in paragraph (a)(1), the program must provide at least five samples per testing event that include challenges that are acid-fast and challenges that 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 paragraph (c) (1) through (6) of this section.

(1) The program determines the reportable mycobacteria to be detected by acid-fast stain and for isolation and identification. 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 80 percent of ten or more referee laboratories or 80 percent or more of all participating laboratories. Sample scores must be averaged to determine the score for the testing event.

(2) 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.

(3) 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.

(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 paragraph (c)(1) of this section. 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 the correct response for two of the three antimycobacterial agents, the laboratory's grade would be $2/3 \times 100 = 67$ percent.

(5) The score for a sample in mycobacteriology is the score determined under (2) for detection and identification of organisms. If the laboratory also performs antimycobacterial susceptibility testing, the score is determined by dividing the total number of correct organisms a laboratory identified plus the number of correct antimycobacterial agent responses as determined by the program by the number of possible organisms plus the number of additional erroneous organisms reported plus the actual number of correct susceptibility

responses multiplied by 100. For example, if a sample contained one principal organism and a laboratory reported it correctly, and reported correct results for two of three antimycobacterial agents tested, its score for the sample would be:

$$(1+2)/(1+3) \times 100 = 75 \text{ percent.}$$

(6) The performance criterion for qualitative tests is the presence or absence of acid-fast organisms.

§ 493.915 Mycology.

(a) *Types of services offered by laboratories.* In mycology, there are two 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 perform identification to the genus level; and

(2) Those that isolate and perform identification of 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 four testing events per year. The samples may be provided through mailed shipments or, at HHS' option, may be provided to HHS 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. At least 50% 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 jeikei

Fonsecaea pedrosoi

Acremonium sp.

Trichophyton sp.

Aspergillus fumigatus
Nocardia sp.
*Blastomyces dermatitidis*¹
Zygomycetes sp.

(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 (3) 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 80 percent of ten or more referee laboratories or 80 percent or more of all participating laboratories. Sample scores must be averaged to determine the score for the testing event.

(2) 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 $1/(1+1) \times 100 = 50$ percent.

(3) 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.

§ 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 are able to determine the presence of parasites by direct observation (wet mount) and refer them to another laboratory for identification; and

(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 four testing events per year. The samples may be provided through mailed shipments or, at HHS' option, may be provided to HHS 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 must calendar year, furnish HHS with a description of samples that it plans to include in its annual program. 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—

Entamoeba histolytica
Entamoeba coli
Giardia lamblia
Endolimax nana
Dientamoeba fragilis
Iodamoeba butschlii
Chilomastix mesnili
 Hookworm
Ascaris lumbricoides
Strongyloides stercoralis
Trichuris trichiura
Enterobius vermicularis
Diphyllobothrium latum
Cryptosporidium sp.
Plasmodium falciparum

(3) For laboratories specified in paragraph (a)(1), the program must provide at least five samples per testing event that include challenges that 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 (3) of this paragraph.

(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 or if the program has assured itself that the samples that were distributed were homogeneous, it could rely on the following method of determining 80%

consensus. 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 80% of ten or more referee laboratories or 80% or more of all participating laboratories. Sample scores must be averaged to determine the score for the testing event.

(2) 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. 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 $1/(1+1) \times 100 = 50$ percent.

(3) 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.

(4) The criterion for acceptable performance for qualitative parasitology is presence or absence of a parasite(s).

§ 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 four testing events per year. The samples may be provided to the laboratory through mailed shipments or, at HHS option, may be provided to HHS 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

¹ Provided as a nonviable sample.

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, prior to each calendar year, furnish HHS with a description of samples that it plans to include in its annual program. 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 (4) 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 80 percent of ten or more referee laboratories or 80 percent or more of all participating laboratories. Each sample score must be averaged to determine the testing event score.

(2) 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 $1/(1+1) \times 100 = 50$ percent.

(3) 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.

(4) The performance criterion for qualitative antigen tests is presence or absence of the viral antigen.

§ 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 four testing events per year. The samples may be provided through mailed shipments or, at HHS' option, may be provided to HHS for on-site testing. An annual program must include samples that cover the full range of reactivity from highly reactive to non-reactive.

(b) *Challenges per quarter.* The minimum number of challenges per testing event a program must offer for syphilis serology is five.

(c) *Evaluation of 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 response for qualitative and quantitative syphilis tests, the program must compare the laboratory's response for each analyte with the response that reflects agreement of either 80 percent of ten or more referee laboratories or 80 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 syphilis serology is either the score determined under paragraphs (c) (2) or (3) of this section.

(2) For quantitative syphilis 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 the response differs from the target value. 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 positive or negative.

(4) To determine the overall testing event score, the number of correct responses for all analytes must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for all analytes}}{\text{Total number of all analytes}} \times 100 = \text{Testing event score}$$

§ 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 four testing events 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 for on-site testing.

(b) *Challenges per quarter.* The minimum number of challenges per testing event the program must provide for each analyte or test procedure is five.

Analyte or test procedure

Alpha-1 antitrypsin
Alpha-fetoprotein
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 response 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 80 percent of ten or more referee laboratories or 80 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.....	Target value ± 3 SD.
Antinuclear antibody.....	Target value ± 1 dilution or (pos. or neg.).
Antistreptolysin O.....	Target value ± 1 dilution or (pos. or neg.).
Anti-Human.....	Reactive or nonreactive.
Immunodeficiency Virus	
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 ± 3 SD.
IgM.....	Target value ± 3 SD.
Infectious mononucleosis.	Target value ± 1 dilution or (pos. or neg.).
Rheumatoid factor.....	Target value ± 1 dilution or (pos. or neg.).
Rubella.....	Target value ± 1 dilution or (pos. or neg.).

(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:

$$\frac{\text{Number of acceptable responses for the analyte}}{\text{Total number of analyte samples}} \times 100 = \text{Analyte score for the testing event}$$

(5) To determine the overall testing event score, the number of correct responses for all analytes must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for all analytes}}{\text{Total number of all analytes}} \times 100 = \text{Testing score event}$$

§ 493.929 Chemistry.

The subspecialties under the specialty of chemistry for which a proficiency testing program may offer proficiency testing are routine chemistry, endocrinology, toxicology, and urinalysis. 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 chemistry, a program must provide a minimum of five samples per testing event. There must be four testing events 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 for on-site testing.

(b) *Challenges per quarter.* 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

Alanine aminotransferase (ALT/SGPT)
Albumin
Alkaline phosphatase
Amylase
Aspartate aminotransferase (AST/SGOT)
Bilirubin, total
Blood gas pH, pO₂, pCO₂
Calcium, total
Chloride
Cholesterol, total
Cholesterol, high density lipoprotein
Creatine kinase
Creatine kinase, isoenzymes
Creatinine
Glucose
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 80 percent of ten or more referee laboratories or 80 percent or more of all participating laboratories. The score for a sample in routine chemistry is the score determined under either 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 (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 $\pm 20\%$
Albumin.....	Target value $\pm 10\%$
Alkaline phosphatase.....	Target value ± 3 SD
Amylase.....	Target value ± 3 SD
Aspartate aminotransferase (AST/SGOT).	Target value $\pm 20\%$
Bilirubin, total.....	Target value ± 0.3 mg/dL or $\pm 20\%$ (greater)
Blood gas pO ₂	Target value ± 3 SD
Blood gas pCO ₂	Target value ± 5 mm Hg or $\pm 8\%$ (greater)
Blood gas pH.....	Target value ± 0.04
Calcium, total.....	Target value ± 1.0 mg/dL
Chloride.....	Target value $\pm 5\%$
Cholesterol, total.....	Target value $\pm 10\%$
Cholesterol, high density lipoprotein.	Target value ± 3 SD
Creatine kinase.....	Target value ± 3 SD
Creatine kinase isoenzymes.	MB elevated (+ or -) or Target value ± 3 SD
Creatinine.....	Target value ± 0.3 mg/dL or $\pm 15\%$ (greater)
Glucose.....	Target value ± 6 mg/dl or $\pm 10\%$ (greater)
Iron, total.....	Target value $\pm 20\%$
Lactate dehydrogenase (LDH).	Target value $\pm 20\%$
LDH isoenzymes.....	LDH1/LDH2 (+ or -) or Target value ± 3 SD
Magnesium.....	Target value $\pm 25\%$
Potassium.....	Target value ± 0.5 mmol/L

Analyte or test	Criteria for acceptable performance
Sodium.....	Target value ± 4 mmol/L
Total Protein.....	Target value $\pm 10\%$
Triglycerides.....	Target value ± 3 SD
Urea Nitrogen.....	Target value ± 2 mg/dL or $\pm 9\%$ (greater)
Uric Acid.....	Target value $\pm 17\%$

(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:

$$\frac{\text{Number of acceptable responses for the analyte}}{\text{Total number of analyte samples}} \times 100 = \text{Analyte score for the testing event}$$

(5) To determine the overall testing event score, the number of correct responses for all analytes must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for all analytes}}{\text{Total number of all analytes}} \times 100 = \text{Testing score event}$$

§ 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 four testing events 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 for on-site testing.

(b) *Challenges per quarter.* 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
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 80 percent of ten or more referee laboratories or 80 percent or more of all participating laboratories. The score for a sample in endocrinology is the score determined under either paragraph (c) (2) or (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 (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 $\pm 25\%$.
Free Thyroxine.....	Target value ± 3 SD.
Human Chorionic Gonadotropin.....	Target value ± 3 SD or (positive or negative).
T ₃ Uptake.....	Target value ± 3 SD by method.
Triiodothyronine.....	Target value ± 3 SD.
Thyroid-stimulating hormone.....	Target value ± 3 SD.
Thyroxine.....	Target value ± 3 SD.

(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:

$$\frac{\text{Number of acceptable responses for the analyte}}{\text{Total number of analyte samples}} \times 100 = \text{Analyte score for the testing event}$$

(5) To determine the overall testing event score, the number of correct

responses for all analytes must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for all analytes}}{\text{Total number of all analytes}} \times 100 = \text{Testing score event}$$

§ 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 four testing events 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 for on-site testing.

(b) *Challenges per quarter.* 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)
Blood lead
Carbamazepine
Digoxin
Ethosuximide
Gentamicin
Lithium
Phenobarbital
Phenytoin
Primidone
Procainamide (and metabolite)
Quinidine
Theophylline
Valproic 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 responses for quantitative and qualitative toxicology tests or analytes, the program must compare the laboratory's response for each analyte with the response that reflects agreement of either 80 percent of ten or more referee laboratories or 80 percent or more of all participating laboratories. The score for a sample in toxicology is the score determined under either paragraph (2) or (3).

(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 (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
Alcohol, blood.....	Target value $\pm 25\%$.
Blood lead.....	Target value $\pm 15\%$ or ± 6 mcg/dL (greater).
Carbamazepine.....	Target value $\pm 25\%$.
Digoxin.....	Target value $\pm 20\%$ or ± 0.2 ng/mL (greater).
Ethosuximide.....	Target value $\pm 20\%$.
Gentamicin.....	Target value $\pm 25\%$.
Lithium.....	Target value ± 0.2 mmol/L or $\pm 20\%$ (greater).
Phenobarbital.....	Target value $\pm 20\%$.
Phenytoin.....	Target value $\pm 25\%$.
Primidone.....	Target value $\pm 25\%$.
Procainamide (and metabolite).....	Target value $\pm 25\%$.
Quinidine.....	Target value $\pm 25\%$.
Theophylline.....	Target value $\pm 25\%$.
Valproic Acid.....	Target value $\pm 25\%$.

(3) The criterion for acceptable performance for qualitative toxicology 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:

$$\frac{\text{Number of acceptable responses for the analyte}}{\text{Total number of analyte samples}} \times 100 = \text{Analyte score for the testing event}$$

(5) To determine the overall testing event score, the number of correct responses for all analytes must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for all analytes}}{\text{Total number of all analytes}} \times 100 = \text{Testing score event}$$

§ 493.939 Urinalysis.

(a) *Program content and frequency of challenge.* To be approved for proficiency testing for urinalysis, a program must provide a minimum of five samples per testing event. There must be four testing events 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 for on-site testing.

(b) *Challenges per quarter.* The minimum number of challenges per testing event a program must provide for each analyte or test procedure is five.

Analyte or test procedure

pH
Bilirubin
Glucose
Hemoglobin
Ketones
Protein

(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 urinalysis tests or analytes, the program must compare the laboratory's response for each analyte with the response that reflects agreement of either 80 percent of ten or more referee laboratories or 80 percent or more of all participating laboratories. The score for a sample in urinalysis is the score determined under either paragraph (c) (2) or (3).

(2) For quantitative urinalysis tests or analytes, the program must determine the correct response for the analyte by the distance of the response from the target value. After the target value has been established, the appropriateness of the response must be determined using the fixed criteria.

Criteria for acceptable performance. The criteria for acceptable performance are:

Analyte or test	Criteria for acceptable performance
pH.....	Target value ± 0.5 .
Bilirubin.....	Positive or negative.
Glucose.....	Positive or negative.
Hemoglobin.....	Positive or negative.
Ketones.....	Positive or negative.
Protein.....	Positive or negative.

(3) The criterion for acceptable performance for qualitative urinalysis 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:

$$\frac{\text{Number of acceptable responses for the analyte}}{\text{Total number of analyte samples}} \times 100 = \text{Analyte score for the testing event}$$

(5) To determine the overall testing event score, the number of correct responses for all analytes must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for all analytes}}{\text{Total number of all analytes}} \times 100 = \text{Testing score event}$$

§ 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 four testing events 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 for on-site testing.

(b) *Challenges per quarter.* 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
White cell differential
Erythrocyte count
Hematocrit
Hemoglobin
Leukocyte count
Platelet count
Fibrinogen
Partial thromboplastin time
Prothrombin time

(1) An approved program for cell identification may vary over time. For example, 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 cell differentiation 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 80 percent of ten or more referee laboratories or 80 percent or more of all participating laboratories. The score for a sample in hematology is the score determined under either 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 (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	80% or greater consensus on identification.
White cell differentiation	Target ± 3 SD based on the percentage of different types of white cells in the samples.
Erythrocyte count	Target ± 3 SD or $\pm 6\%$ (lesser).
Hematocrit	Target ± 3 SD or $\pm 6\%$ (lesser).
Hemoglobin	Target ± 3 SD or $\pm 7\%$ (lesser).
Leukocyte count	Target ± 3 SD or $\pm 15\%$ (lesser).
Platelet count	Target ± 3 SD or $\pm 25\%$ (lesser).
Fibrinogen	Target ± 3 SD.
Partial thromboplastin time	Target ± 3 SD or $\pm 15\%$ (greater).
Prothrombin time	Target ± 3 SD or $\pm 15\%$ (greater).

(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:

$$\frac{\text{Number of acceptable responses for the analyte}}{\text{Total number of analyte samples}} \times 100 = \text{Analyte score for the testing event}$$

(5) To determine the overall testing event score, the number of correct responses for all analytes must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for all analytes}}{\text{Total number of all analytes}} \times 100 = \text{Testing score event}$$

§ 493.945 Cytology: Gynecologic examinations.

(a) *Program content and frequency of challenge.* To be approved for proficiency testing for gynecologic examinations (Pap smears) in cytology, a program must provide 20 glass slide preparations per test set. Proficiency testing programs may obtain slides for test sets from cytology laboratories, provided the slides have been maintained by the laboratory for the required periods specified in § 493.1257 or the proficiency testing program must ensure that slides loaned to it are retrievable upon request, if necessary. Each test set should include slides representing some but not necessarily all of the following: unsatisfactory preparations; normal challenges; infectious agents; and benign reactive processes, premalignant processes, and malignant processes.

(b) *Evaluation of an individual's performance.* HHS approves only those programs that assess the accuracy of each individual's responses on a 20 slide test set in which the slides have been referenced in a scientifically defensible manner.

(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 consensus agreement or confirmation. For slide preparations that are normal, unsatisfactory, benign reactive processes or contain infection agents, a 95 percent consensus agreement is required. For premalignant or malignant slide preparations, confirmation by tissue biopsy is required. An 80 percent consensus agreement of at least five pathologists is also required on tissue biopsies that confirm the premalignant or malignant cytology slides used in proficiency testing events.

(2) The criteria for acceptable performance are determined by using the scoring system in paragraphs (b)(2)(i) and (ii) of this section.

(i) Each slide set must contain 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. Total points for slide set must be established by the proficiency testing program and need not be 100.

(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 of reward is weighted in proportion to the severity of the lesion.

(A) In accordance with the criteria for scoring system chart in paragraph (b)(2)(ii)(B) of this section, a maximum of 2 points is awarded for a correct response and a minimum of minus one (-1) point is assessed for misinterpretation of malignant and premalignant smears. For example, if the correct response on a slide is "squamous abnormality, high grade" (category "D" on the scoring system chart) and an examinee calls it "normal/negative" (category "B" on the scoring system chart), then the examinee's point value on that slide is calculated as minus one (-1). 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, divided by the total points for the testing event and multiplied by 100. For example, if a testing event has a total point score of 40 and an individual has a point score of 32, the individual's testing event score is $32/40 \times 100 = 80$ percent.

(B) Criteria for scoring system.

Response categories (Bethesda system description in § 493.958 of this subpart)	A	B	C	D
A Unsatisfactory	2	0	0	0
B Normal/Negative Infection Reactive and Preparative Changes	0	2	1	0
C Squamous cell abnormalities (low grade)	-1	-1	2	1
D Squamous Cell abnormalities (high grade). Glandular cell abnormalities. Non-epithelial malignant neoplasm	-1	-1	1	2

§ 493.958 Cytopathology testing results.

The format and terminology for reporting cytopathology proficiency testing results is taken from the 1988 Bethesda System for Reporting Cervical/Vaginal Cytologic Diagnoses.

including a statement on adequacy of the specimen, a general categorization of the diagnosis and the descriptive diagnosis as follows:

(a) *Statement on specimen adequacy.*

- (1) Satisfactory for interpretation;
- (2) Less than optimal;
- (3) Unsatisfactory.

(b) *Explanation for "less than optimal/unsatisfactory samples":*

- (1) Scant cellularity;
- (2) Poor fixation or preservation;
- (3) Presence of foreign material (e.g., lubricant);
- (4) Partially or completely obscuring inflammation;
- (5) Partially or completely obscuring blood;
- (6) Excessive cytolysis or autolysis;
- (7) No endocervical component in a premenopausal woman who has a cervix;
- (8) Not representative of the anatomic site;
- (9) Other.

(c) *General categorization.*

- (1) Within normal limits;
- (2) Other.
- (i) See descriptive diagnosis.
- (ii) Further action recommended.
- (d) *Descriptive diagnoses.*

(1) *Infection.*

(i) *Fungal.*

(A) Fungal organisms morphologically consistent with *Candida species*;

(B) Other.

(ii) *Bacterial.*

(A) Microorganisms morphologically consistent with *Gardnerella species*;

(B) Microorganisms morphologically consistent with *Actinomyces species*;

(C) Cellular changes suggestive of *Chlamydia species* infection, subject to confirmatory studies;

(D) Other.

(iii) *Protozoan.*

(A) *Trichomonas vaginalis*;

(B) Other.

(iv) *Viral.*

(A) Cellular changes associated with cytomegalovirus;

(B) Cellular changes associated with herpes simplex virus;

(C) Other.

Note: For human papillomavirus (HPV), refer to Epithelial cell abnormalities, squamous cell, in paragraph (d)(3)(i) of this section.

(v) *Other.*

(2) *Reactive and reparative changes.*

(i) *Inflammation—*

- (A) Associated cellular changes;
- (B) Follicular cervicitis.

(ii) *Miscellaneous (as related to patient history)—*

- (A) Effects of therapy;
- (B) Ionizing radiation;
- (C) Chemotherapy;

(D) Effects of mechanical devices (e.g., intrauterine contraceptive device);

(E) Effects of non-steroidal estrogen exposure (e.g., diethylstilbestrol);

(F) *Other.*

(3) *Epithelial cell abnormalities.*

(i) *Squamous cell.*

(A) Atypical squamous cells of undetermined significance (recommended follow-up and/or type of further investigation; specify).

(B) Squamous intraepithelial lesion (SIL) (comment on presence of cellular changes associated with HPV if applicable)—

(1) Low-grade squamous

intraepithelial lesion, encompassing—

(i) Cellular changes associated with HPV;

(ii) Mild (slight) dysplasia/cervical intraepithelial neoplasia grade 1 (CIN 1).

(2) High-grade squamous

intraepithelial lesion, encompassing—

(i) Moderate dysplasia/CIN 2;

(ii) Severe dysplasia/CIN 3;

(iii) Carcinoma in situ/CIN 3.

(C) Squamous cell carcinoma

(i) *Glandular cell.*

(A) Presence of endometrial cells in one of the following circumstances—

(1) Out-of-phase in a menstruating woman

(2) In a postmenopausal woman;

(3) No menstrual history available.

(B) Atypical glandular cells of

undetermined significance (recommended follow-up and/or type of further investigation; specify)

(1) Endometrial;

(2) Endocervical;

(3) Not otherwise specified.

(C) Adenocarcinoma

(1) Specify probable site of origin:

endocervical, endometrial, extrauterine;

(2) Not otherwise specified.

(D) Other epithelial malignant

neoplasm: specify.

(iv) *Non-epithelial malignant*

neoplasm: specify.

§ 493.959 Immuno-hematology.

(a) *Types of services offered by laboratories.* In immuno-hematology, there are four types of laboratories for proficiency testing purposes—

(1) Those that perform ABO group and/or Rh₀ (D) group;

(2) Those that perform ABO group and/or Rh₀ (D) group and unexpected antibody detection;

(3) Those that perform ABO group and/or Rh₀ (D) group, unexpected antibody detection, and compatibility testing; and;

(4) Those that perform ABO group and/or Rh₀ (D) group, unexpected antibody detection, compatibility testing, and antibody identification.

(b) *Program content and frequency of challenge.* To be approved for

proficiency testing for immuno-hematology, a program must provide a minimum of five samples per testing event. There must be four testing events 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 for on-site testing.

(c) *Challenges per quarter.* 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)

Rh₀ (D) group

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 (c)(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 unexpected antibody detection and antibody identification 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 immuno-hematology is the score determined under either paragraph (2) or (3).

(2) *Criteria for acceptable performance.* The criteria for acceptable performance are—

Analyte or test	Criteria for acceptable performance
ABO group.....	100% accuracy.
Rh ₀ (D) group.....	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:

$$\frac{\text{Number of acceptable responses for the analyte}}{\text{Total number of analyte samples}} \times 100 = \text{Analyte score for the testing event}$$

(5) To determine the overall testing event score, the number of correct responses for all analytes must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for all analytes}}{\text{Total number of all analytes}} \times 100 = \text{Testing score event}$$

Subpart J—Patient Test Management

§ 493.1101 Condition: Patient test management.

The laboratory must maintain and employ a system that provides for proper receipt and processing of patient specimens and accurate reporting of patient test results and that meets the standards in paragraphs (a) through (e) of this section.

(a) *Standard; Procedures for specimen submission.* The laboratory must have available and follow written policies and procedures regarding collection, labeling, preservation or fixation, including conditions for proper transportation and processing or preparation of specimens that, when followed, will assure the optimum condition of patient specimens for testing. The laboratory must make available to clients written instructions for specimen collection, labeling, handling, preservation or fixation, processing or preparation and conditions necessary for transportation to ensure that specimens submitted are received in a condition acceptable for testing.

(b) *Standard; Specimen 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 obtains written authorization for testing within 30 days of the request. Records of test requisitions must be maintained for at least two years. The laboratory must assure that the requisition includes—

- (1) The patient's name or other method of specimen identification to assure accurate reporting of results;
- (2) The name or other suitable identifier of the authorized person who ordered the test or the name of the laboratory submitting the specimen;
- (3) The date of specimen collection;
- (4) The time of specimen collection, when pertinent to testing;
- (5) The source of specimen, if pertinent, and name or identifying laboratory code number of test(s) ordered;
- (6) Patient sex and age or date of birth;
- (7) Pertinent clinical information; and
- (8) For Pap smears, the last menstrual period and indication of whether the patient had a previous abnormal report, treatment or biopsy and, if available, information indicating whether the patient is at risk for developing cervical cancer or its precursors.

(c) *Standard; Specimen records.* The laboratory must maintain a system to ensure reliable specimen identification, and must document each step in processing, testing, and reporting patient specimens to assure accurate test results are reported. Records of patient testing must be maintained for at least two years. All immunohematology records must be maintained for a period of five years. This system must provide documentation of information specified in (b)(1) through (b)(8) of this section and—

- (1) The accession number or other identification of the specimen;
- (2) The date and time of specimen receipt into the laboratory;
- (3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability; and
- (4) The records and dates of performance of each step in patient testing leading to and including the final report to assure proper identification and reliable reporting of test results.

(d) *Standard; Test report.* The laboratory report must be sent promptly to the authorized person or laboratory that initially requested the test. A legally reproduced record of each test result, including preliminary reports, must be preserved by the testing laboratory for a period of at least two years after the date of reporting. Immunohematology reports must be maintained for a period of five years. For pathology, test reports must be maintained at least ten years after the date of reporting.

(1) The laboratory must have adequate systems in place to report results in a timely, accurate and reliable manner and in a way that ensures

confidentiality according to the laboratory's procedures.

(2) The legally reproduced copies of test reports must be filed in the laboratory in a manner that permits ready identification and accessibility.

(3) The results or transcripts of laboratory tests or examinations must be released only to authorized persons.

(4) Pertinent "normal" ranges, as determined by the laboratory performing the tests, must be available to the authorized person who ordered or who utilizes the test results.

(5) The laboratory must establish special reporting procedures for imminent life-threatening laboratory results or panic values. In addition, the laboratory must immediately alert the individual requesting the test or the individual responsible for utilizing test results when any test result indicates an imminent life-threatening condition.

(6) 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.

(7) The laboratory must upon request make available to clients a list of test methods employed by the laboratory and a basis for the listed "normal" ranges. In addition, information that may affect the interpretation of test results, such as test interferences, if known, and performance claims including, where applicable, detection limits, sensitivity, specificity, accuracy, precision and validity of test measurement and other pertinent test characteristics must be provided upon request. Updates on testing information must be provided to clients whenever changes occur that affect the test results or interpretation of test results.

(8) The test report must include the name and address of each laboratory location at which each test was performed.

(e) *Standard; Referral of specimens.* A Medicare laboratory may refer specimens for testing only to a laboratory that is Medicare-approved for the appropriate specialty or subspecialty. If tests are sent to a laboratory in another State, the referral laboratory must have a CLIA license applicable to the specialty or subspecialty of services requested. A CLIA licensed laboratory may refer specimens for testing only to a laboratory that is CLIA licensed (or exempted from CLIA licensure) for the appropriate specialty or subspecialty.

(1) 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.

(2) If the referring laboratory interprets or revises in any way the test results provided by the testing laboratory, the referring laboratory must notify the authorized person who requested the test or examination and the testing laboratory. The referring laboratory must maintain a legally reproduced copy of such interpretations, alterations or revisions and of the notice to the client and testing laboratory.

(3) 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 maintain a legally reproduced copy of each testing laboratory's report.

Subpart K—Quality Control

§ 493.1201 Condition: General quality control.

(a) Quality control requirements are specified in this subpart unless HHS approves a lesser frequency in Appendix C of the State Operations Manual (HCFA Pub. 7).

(b) The laboratory must impose and practice quality control procedures that provide and assure accurate, reliable and valid test results and reports and that meet the standards in §§ 493.1203 through 493.1221 of this subpart.

§ 493.1203 Standard; Facilities.

The laboratory must be constructed, arranged and maintained to ensure adequate space, ventilation, facilities and essential utilities for the performance and reporting of tests.

§ 493.1205 Standard; Adequacy of methods and equipment.

The laboratory must employ methodologies and equipment that provide accurate and reliable test results and reports.

(a) The laboratory must have appropriate and sufficient equipment and instruments for the type and volume of testing performed.

(b) The equipment and instrumentation used must be capable of providing test results within the laboratory's stated performance characteristics. These performance characteristics include detection limits, precision, accuracy, specificity, and sensitivity as well as freedom from interferences and related test variables.

(c) Test procedures, examinations, or both, must be performed in a manner that provides test results within the laboratory's stated performance characteristics for its test method, including precision, accuracy, sensitivity, specificity, and detection

limits as well as freedom from interference and related test variables.

§ 493.1207 Standard; Temperature and humidity monitoring.

Temperature and humidity must be maintained and monitored within a defined acceptable range to assure—

- (a) Proper storage of specimens, tissue, reagents and supplies; and
- (b) Accurate and reliable test performance and reporting.

§ 493.1209 Standard; Labeling of testing supplies.

(a) Reagents, solutions, culture media, controls, calibrators and other materials must be labeled to indicate—

- (1) Identity and, when significant, titer, strength or concentration;
- (2) Recommended storage requirements;

- (3) Preparation or expiration date; and
- (4) Other pertinent information.

(b) The laboratory may not use materials that have exceeded their expiration date, are of substandard reactivity, or have deteriorated. The laboratory must comply with the Food and Drug Administration licensed product dating requirements of 21 CFR 610.53. Any exceptions to these product dating requirements will be granted by the Food and Drug Administration in accordance with 21 CFR 610.53(d).

(c) Components of each kit of reagents may not be interchanged with other kit reagents of different lot numbers unless otherwise specified by the manufacturer.

§ 493.1211 Standard; Procedure manual.

(a) Personnel examining specimens and performing related procedures within a specialty or subspecialty must have available in the testing area complete written instructions and descriptions related to the current analytical methods or procedures used by personnel concerning:

- (1) Specimen requirements and processing;
- (2) Microscopic examination, including criteria for detecting inadequately prepared slides;
- (3) Preparation of slides, solutions, reagents, materials, and stains;
- (4) Calibration;
- (5) Quality control;
- (6) Quality assurance;
- (7) Limitations in methodologies;
- (8) Actions to be followed when quality control results deviate from expected values or patterns;
- (9) Reporting patient results, including test calculations;
- (10) Pertinent literature references; and

(11) Alternative methods for performing tests or storing the test specimens in the event that a test system becomes inoperable.

(b) Procedures must be initially approved, signed and dated by the current director of the laboratory.

(c) Each change in a procedure must be approved, signed and dated by the current director of the laboratory.

(d) The laboratory must maintain copies of each procedure it uses and the length of time the procedure was in use. These records must be maintained for two years after a procedure has been discontinued.

(e) 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.

§ 493.1213 Standard; Equipment maintenance and function checks.

The laboratory establishes and employs policies and procedures for—

(a) The proper maintenance of equipment, instruments and test systems by—

(1) Defining its preventive maintenance program for each instrument and piece of equipment based on the manufacturer's instructions. A laboratory must document that preventative maintenance has occurred with at least the frequency recommended by the manufacturer. If the manufacturer does not specify a frequency, the laboratory must document the validity of its preventive maintenance program; and

(2) Documenting the performance of its preventive maintenance program.

(b) Performing and documenting function checks on equipment, including but not limited to spectrophotometers, radioactive counters, particle counters, automated analyzers, centrifuges, densitometers and data processors to assure proper performance and accurate and reliable test results by—

(1) Rechecking, calibrating or recalibrating each instrument, device or test system at least once each day of use or more frequently, as specified by the manufacturer;

(2) Performing the function checks with at least the frequency specified by the manufacturer. The laboratory must establish performance criteria for each test or procedure if the manufacturer of the test system or equipment has not specified the type of maintenance and function checks to perform; and

(3) Performing all necessary baseline or background checks each day of use on radioactive counters, particle counters, refractometers,

spectrophotometers and other equipment requiring such measurements. Background or baseline checks must be performed and be within acceptable limits before patient testing.

§ 493.1215 Standard; Validation of methods.

The laboratory must have a written protocol and documentation for the validation of each method that verifies that the method produces test results within the laboratory's stated performance characteristics. Method validation must be performed before a test procedure is placed into routine use; thereafter, each method must be checked through calibration requirements specified in § 493.1217 of this subpart.

(a) The linear reportable range of each quantitative method, if applicable, must be established.

(b) In the case of qualitative and screening tests, the laboratory must determine and document the basis for specifying reportable results as positive, negative, or degree of reactivity. The laboratory must follow these established limits in reporting test results.

(c) A method used by the laboratory must be validated before it is used and documentation of the validation must be available for the period during which the procedure is used by the laboratory or for two years, whichever is longer.

(d) The laboratory must have documentation of the level of precision, accuracy, sensitivity, and specificity that the laboratory claims for each method in use and for which it reports results.

(e) The laboratory must maintain documentation verifying that test systems perform according to the laboratory's specifications. This documentation must be available to the authorized persons ordering or receiving test results.

(f) The laboratory must establish its reference range for each method before reporting patient test results.

(g) The laboratory may not report patient test results if it does not have data to verify the specified test performance characteristics and reporting limits.

§ 493.1217 Standard; Frequency of quality control.

The laboratory must perform quality control at the frequencies specified in this section unless another frequency is specified in §§ 493.1223 through 493.1285 of this subpart or HHS approves a lesser frequency in Appendix C of the State Operations Manual (HCFA Pub. 7).

(a) The laboratory must establish and document a schedule for calibration,

recalibration or calibration verification of each automated and manual method.

(1) The laboratory must perform calibration, calibration verification or recalibration of each automated and manual procedure at least once every six months, or more frequently if specified by the manufacturer, using a complete range of calibrators and, in addition, when any of the following occur:

(i) A complete change of reagents for a procedure is introduced. If all of the reagents for a test are packaged together, the laboratory is not required to recalibrate for each package of reagents, provided the reagents are received in the same shipment and contain the same lot number;

(ii) There is major preventive maintenance or replacement of critical parts, such as an excimer lamp;

(iii) Controls begin to reflect an unusual trend or are outside of acceptable limits;

(iv) The manufacturer's recommendations specify more frequent recalibration; or

(v) The laboratory's established schedule requires more frequent recalibration.

(2) The number of calibrators the laboratory uses to calibrate, recalibrate, or verify calibration varies by method—

(i) For methods in which a linear relationship exists between concentration and direct instrument reading, at least three points and a zero or minimum value are required; and

(ii) For methods in which a nonlinear relationship exists between concentration and direct instrument readings, at least five points and a zero or minimum value are required unless the manufacturer specifies more points for calibration. If the manufacturer specifies more than five points of calibration and a zero, the laboratory must follow the manufacturer's recommendation or document the validity of performing procedural calibration using fewer, but not less than five, points.

(3) The calibrators must cover the entire range of patient values, with dilution as necessary, to be reported for the test procedures.

(4) For patient values above the maximum calibration point or below the minimum calibration point—

(i) The laboratory must report the patient results as greater than the upper limit or less than the lower limit or an equivalent designation; or

(ii) For patient results greater than the upper limit, the laboratory must dilute the sample and the diluted sample must fall within the laboratory's reportable range for the method. If a dilution

method is employed, the laboratory must be able to provide evidence that the dilution process can yield accurate, reliable and valid test results.

(b) For each procedure, the laboratory must evaluate instrument and reagent stability and operator variance in determining the frequency of testing quality control samples in accordance with each run as defined in § 493.2 of this part.

(c) For quantitative tests, the laboratory must include two calibrator samples, one calibrator sample and one control sample, or two control samples in each run of unknown samples when these reference samples are available.

(d) The laboratory must use the calibrator samples, the control samples, or combination thereof, and monitor both the abnormal and normal range of reportable patient values.

(1) If calibrators are not used, two controls of different concentrations must be used;

(2) If controls are not used, two calibrators of different concentrations must be used. Two separate dilutions from a stock calibrator must be prepared or a calibrator and a sample spiked with a calibrator must be used;

(3) If calibrators and controls are not available, the laboratory must have a mechanism to assure the quality, accuracy and precision of the test results.

(e) For qualitative tests, the laboratory must include a positive and negative control with each run of specimens.

(f) The laboratory must determine its statistical limits (e.g., mean and standard deviation) for each lot number of controls through repetitive testing. The laboratory may use the assayed control limits established by the manufacturer, provided the limits are verified by the laboratory and the manufacturer's limits correspond to the methodology and instrumentation employed by the laboratory. Acceptable limits for unassayed materials must be established over time by the laboratory through concurrent testing with a control material having previously determined ranges.

(g) Initially, the laboratory must check each batch or shipment of reagents, discs, stains, antisera and identification systems (systems using two or more substrates and antigen detection systems) when prepared or opened for positive and negative reactivity, as well as graded reactivity if applicable.

(h) Each day of use (unless otherwise specified in this subpart), the laboratory must test staining materials for intended reactivity to ensure predictable staining characteristics.

(i) The laboratory must check positive and negative reactivity each time of use for fluorescent stains.

(j) Each day of use, the laboratory must test direct antigen detection systems using positive and negative control organisms that evaluate all phases of the system including the extraction and reaction phases, if appropriate.

(k) The laboratory must check each batch or shipment of media for sterility when labeled sterile, ability to support growth and, as appropriate, selectivity/inhibition, biochemical response or both. The laboratory may use a commercial manufacturer's quality control checks of media if the laboratory has documentation to verify that the manufacturer has used the quality assurance practices that have been approved by HHS in Appendix C of the State Operations Manual (HCFA Pub. 7). 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. A batch of media (solid, semi-solid, or liquid)—

(1) Consists of all tubes, plates, or containers of the same medium prepared at the same time and in the same laboratory; or

(2) 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.

(l) Quality control samples must be tested in the same manner as patient specimens.

(m) Patient results may not be reported unless control results meet the laboratory's quality control criteria.

§ 493.1219 Standard; Remedial actions.

The laboratory must establish and employ policies and procedures and document actions taken when—

(a) Test systems do not meet the laboratory's established criteria as determined in § 493.1215, including—

(1) Quality control results that are outside of acceptable limits;

(2) Equipment or methodologies that perform outside of established operating parameters or specifications; and

(3) Test results that are outside of the laboratory's reportable range, established on the basis of maximum and minimum calibration values;

(b) It cannot test samples within specified times that it has established. The laboratory must establish and follow criteria for referring or for storing

specimens. The laboratory must notify the individual responsible for utilizing test results if the laboratory cannot test a specimen within the laboratory's established timeframe for testing specimens;

(c) It detects errors in the reported patient results. The laboratory must promptly—

(1) Notify the authorized person ordering or individual utilizing the test results of reporting errors;

(2) Issue corrected reports to the authorized person ordering the test; and

(3) Maintain copies of the original report as well as the corrected report for two years;

(d) It does not report test results within its established time frames; and

(e) Proficiency test results are unacceptable or unsatisfactory.

§ 493.1221 Standard; Quality control—records.

(a) The laboratory must document all quality control activities specified in §§ 493.1203 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 five years as specified in 21 CFR Part 606, Subpart I.

(b) The laboratory must maintain records of each step in the processing and testing of quality control samples to assure that the quality control samples are tested in the same manner as patient samples.

§ 493.1223 Condition: Quality control—specialties and subspecialties.

The laboratory must establish and follow policies and procedures for an acceptable quality control program that include verification and assessment of accuracy, measurement of precision and detection of error for all analyses and procedures performed by the laboratory. In addition to the general requirements specified in §§ 493.1201 through 493.1221 of this subpart, the laboratory must meet the applicable requirements of §§ 493.1225 through 493.1285 for each specialty and subspecialty for which the laboratory is licensed (CLIA and/or approved (Medicare and Medicaid).

Failure to meet any of the applicable conditions in §§ 493.1225 through 493.1285 will result in noncompliance with and in the loss of approval, licensure, or exemption from licensure for the entire specialty to which the condition applies; failure to meet any of the standards in §§ 493.1227 through 493.1285 will result in the loss of approval, licensure or exemption from licensure for the subspecialty to which the standard applies.

§ 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 approved (Medicare and Medicaid) and/or licensed (CLIA) under the speciality of microbiology.

§ 493.1227 Standard; 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) and (b) of this section.

(a) The laboratory must check positive and negative reactivity with control organisms—

(1) Each day of use for catalase, coagulase, oxidase reagents and DNA probes;

(2) Each week of use for Gram and acid-fast stains, bacitracin, optochin, ONPG, X, V, and XV discs or strips; and

(3) Each month of use for antisera.

(b) 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, unless the laboratory can establish precision and accuracy to be within the limits established by HHS in Appendix C of the State Operations Manual (HCFA Pub. 7).

§ 493.1229 Standard; 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.

(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 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 day of use.

(c) The laboratory must check each week of use acid-fast stains 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 control strain of *Mycobacterium tuberculosis*.

§ 493.1231 Standard; 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 (c) of this section.

(a) Each day of use, the laboratory must check the nitrate reagent with a peptone control.

(b) Each week of use, the laboratory must check acid-fast stains for positive and negative reactivity.

(c) 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 control results must be met prior to reporting patient results.

§ 493.1233 Standard; 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.

(a) The laboratory must have available a reference collection of slides, photographs or gross specimens for identification of parasites available and use it in the laboratory for appropriate comparison with diagnostic specimens.

(b) The laboratory must use a 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 Standard; 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.

(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 employ uninoculated cells or cell substrate controls 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 approved (Medicare and Medicaid) and/or licensed (CLIA) under the specialty of diagnostic immunology.

§ 493.1239 Standard; 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.

(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 unless otherwise specified by HHS in Appendix C of the State Operations Manual (HCFA Pub. 7).

(c) The laboratory must employ controls for all test components to ensure reactivity and uniform dosages.

(d) The laboratory may not report test results unless the predetermined reactivity pattern 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 Standard; 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.

(a) 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 unless otherwise

specified by HHS in Appendix C of the State Operations Manual (HCFA Pub. 7).

(b) The laboratory must employ controls for all test components (antigens, complement, erythrocyte indicator systems, etc.) to ensure reactivity and uniform dosages.

(c) The laboratory may not report test results unless the predetermined reactivity pattern 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 493.1251 of this subpart for the subspecialties for which it is approved (Medicare and Medicaid) and/or licensed (CLIA) under the specialty of chemistry.

§ 493.1245 Standard; 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. In addition, for blood gas analyses, the laboratory must—

(a) Calibrate, recalibrate or verify calibration each eight hours using two calibrators;

(b) Test control materials each eight hours of testing; and

(c) Include a calibrator or control each time patients are tested unless automated instrumentation internally verifies calibration at least every thirty minutes.

§ 493.1247 Standard; 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.

§ 493.1249 Standard; 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.

§ 493.1251 Standard; Urinalysis.

(a) To meet the quality control requirements for urinalysis, the laboratory must comply with the applicable requirements in §§ 493.1201 through 493.1221; and

(b) For urinalysis qualitative or screening tests, the laboratory must include a positive control each day of testing to check the reactivity of each constituent for which qualitative test results are reported.

§ 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 (c) of this section.

(a) For hematology tests excluding coagulation, the laboratory must include two levels of control each eight hours of operation except for manual cell counts, in which one level of control is required for each eight hours of operation.

(b) For all coagulation tests the laboratory must include two levels of control each eight hours of operation and each time a change in reagents occurs.

(c) For manual coagulation tests—

(1) Each individual performing tests must test two levels of controls before testing patient samples; and

(2) Patient and control specimens must be tested in duplicate.

§ 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 approved (Medicare and Medicaid) and/or licensed (CLIA) under the specialty of pathology.

§ 493.1257 Standard: 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 (i) of this section.

(a) The laboratory must assure that—

(1) All gynecologic smears are stained using a Papanicolaou staining method;

(2) Staining solutions must be filtered or changed between the staining of gynecologic specimen batches and nongynecologic specimen batches;

(3) Before routine staining, all body cavity fluids are assessed for their potential to cross-contaminate other non-gynecological specimens. Those specimens found to have a high potential for cross-contamination must be stained separately from other nongynecological specimens and the stains filtered between batches; and

(4) Diagnostic interpretations are not reported on unsatisfactory smears.

(b) The laboratory is responsible for insuring that—

(1) Each individual engaged in the evaluation of cytology preparations by nonautomated microscopic techniques examines no more than 120 slides, which include both gynecologic and nongynecologic preparations, in a 24 hour period. Of the slide limit established by the technical supervisor for each individual in accordance with paragraph (c)(4) of this section, no more than two-thirds (up to a maximum of 80) of the unevaluated slides may be examined; the remaining slides that may be examined must be for quality control and quality assurance or proficiency testing purposes. Previously examined premalignant or malignant gynecologic cases defined in paragraph (c)(1), previously examined non-gynecologic cytology preparations, and tissue pathology slides examined by a person qualified under § 493.1421 (a) or (f) or § 493.1403(b)(1) are not included in the 120 slide limit for the technical supervisor.

(2) Records are maintained of the number of slides examined by each individual during each 24 hour period and the number of hours each individual spends examining slides in the 24 hour period.

(i) The maximum number of 120 slides described in paragraph (b)(1) may be examined in no less than 6 hours.

(ii) For the purposes of establishing workload limits for individuals examining slides on a part-time basis, a period of 8 hours must be used to prorate the number of slides that may be examined. Use the formula—

$$\frac{\text{No. of hours} \times 120}{8}$$

8

to determine maximum slide volume to be examined. No more than two-thirds of the slides examined by individuals on a part-time basis may be unevaluated slides; the remaining slide preparations must be for quality control and quality assurance or proficiency testing purposes only.

(c) The individual providing technical supervision of cytology must assure that—

(1) All gynecological smears interpreted to be in the premalignant (dysplasia, cervical intraepithelial neoplasia or any squamous intraepithelial lesions including human papillomavirus associated changes) or malignant category are confirmed by the technical supervisor in cytology. The report must be signed to reflect the review or, if a computer report is

generated, it must reflect an electronic signature authorized by the technical supervisor in cytology.

(2) All nongynecological cytological 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, it must reflect an electronic signature authorized by the technical supervisor.

(3) Provision is made for documenting and evaluating the slide examination performance of each individual not qualified under § 493.1421 (a) or (f) or § 493.1403(b)(1), including performance evaluation through the re-examination of normal and negative cases and feedback on the premalignant or malignant cases as defined in paragraph (c)(1) of this section referred to the technical supervisor in cytology.

(4) A maximum number of slides, not to exceed 120 slides, to be examined in 24 hours or in the period spent examining slides is established by the technical supervisor for each individual examining slide preparations by non-automated microscopic technique.

(i) The workload limit must be documented for each individual and established in accordance with the individual's capability based on the quality assurance evaluations required in § 493.1501 of this subpart.

(ii) Records are available to document that each individual's workload limit is reassessed monthly and adjusted when necessary.

(d) The laboratory must establish and follow a program designed to detect errors in the performance of cytological examinations and the reporting of results.

(1) The laboratory must establish a program that includes a review of slides examined by each individual not qualified under § 493.1421 (a) or (f) or § 493.1403(b)(1); records of initial examinations and rescreening results must be available. The review must be completed before reporting patient results and must meet the requirements of subparagraph (1)(i) and (1)(ii) of this paragraph.

(i) At least ten percent of all gynecologic cases interpreted to be negative for premalignant or malignant conditions as defined in paragraph (c)(1) of this section must be re-examined by another individual authorized by the laboratory to examine cytologic preparation; and

(ii) Gynecologic cases that are interpreted to be negative for premalignant or malignant conditions as defined in paragraph (c)(1) of this section and that are from patients who

are identified as having a high probability of developing cervical cancer, as referred to in § 493.1101(b)(8), must be included in the ten percent of cases to be re-examined by an individual authorized by the laboratory to examine cytologic preparations.

(2) The laboratory must compare clinical information with cytology reports and must compare all premalignant and malignant (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) or available through the State health department registry, and determine the causes of any discrepancies.

(3) The laboratory must review all normal or negative gynecologic specimens, within the last five years, if available in the laboratory (either on-site or in storage), for each patient with a current premalignant or malignant (as defined in paragraph (c)(1) of this section) gynecologic result.

(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 patients reported by diagnosis, 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 a reclassification as premalignant or malignant as defined in paragraph (c)(1) of this section, and the number of gynecologic cases for which histology results were unavailable to compare with premalignant or malignant cytology cases as defined in paragraph (c)(1) of this section. The laboratory must also document the number of unsatisfactory specimens submitted by each physician or laboratory.

(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 smears that are unsatisfactory for diagnostic interpretation;

(2) Contain narrative descriptions for any premalignant or malignant results;

(3) Include the presence of endometrial cells if endometrial cells are present out of cycle;

(4) Indicate evidence of viral infection if present;

(5) Contain appropriate provisions for follow-up recommendations; and

(6) Notify physicians if specimens and/or smears are unsatisfactory for examination.

(f) Corrected reports issued by the laboratory must indicate the basis for correction.

(g) The laboratory must retain all normal, negative and unsatisfactory slide preparations for five years from the date of examination.

(h) The laboratory must retain all premalignant and malignant as defined in paragraph (c)(1) of this section slide preparations for ten years from the date of examination.

(i) Slides may be loaned to approved proficiency testing programs, as specified in subparts H and I of this part in lieu of maintaining slides for the time periods specified in §§ 493.1257(g) and 493.1257(h) of this section, only if authorized by HHS.

§ 493.1259 Standard; 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 (f) of this section.

(a) A control slide of known reactivity must be included with each slide or group of slides for differential or special stain. 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 fixative solution until the portions submitted for microscopic examination have been examined and a diagnosis made by an individual qualified under § 493.1421(g)(1), 493.1421(g)(2) or 493.1403(b)(2) of this part. In addition, an individual who meets the requirements of § 493.1421(g)(1), 493.1421(g)(2), 493.1421(g)(3), or 493.1403(b)(3), may examine and provide reports for specimens for skin pathology; an individual meeting the requirements of § 493.1421(a), 493.1421(h) or § 493.1403(b)(4) 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 this 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.

(f) The laboratory must report results of all biopsy-confirmed cases of cervical cancer to the State health department for the State in which the laboratory is located.

§ 493.1261 Standard; 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.

§ 493.1263 Condition; Radiobiology.

To meet quality control requirements for radiobiology, the laboratory must meet the specific requirements of §§ 493.1201 through 493.1221 of this subpart.

§ 493.1265 Condition; Histocompatibility.

In addition to meeting the 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, if applicable, the laboratory must comply with the applicable requirements in paragraphs (a) through (d) of this section.

(a) For renal allotransplantation the laboratory must meet the requirements of paragraphs (a)(1) through (a)(24) of this section.

(1) The laboratory must have available and follow criteria for selecting appropriate patient serum samples for crossmatching;

(2) The laboratory must have available results of final crossmatches before an organ or tissue is transplanted;

(3) The laboratory must have available and follow criteria for the technique used in crossmatching;

(4) The laboratory must have available and follow criteria for preparation of donor lymphocytes for crossmatching;

(5) The laboratory must have available and follow criteria for reporting crossmatch results;

(6) The laboratory must have available serum specimens for all potential transplant recipients at initial typing, for periodic screening, for pretransplantation crossmatch and following sensitizing events, such as transfusion and transplant loss;

(7) 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) Be well-organized with all specimens properly identified and easily retrievable;
- (8) The laboratory's reagent typing sera inventory (applicable only to locally constructed trays) must indicate source, bleeding date and identification number, and volume remaining;
- (9) The laboratory must properly label and store cells, complement, buffer, dyes, etc.;
- (10) The laboratory must HLA type all potential transplant recipients;
- (11) The laboratory must type cells from organ donors referred to the laboratory;
- (12) The laboratory must have available and follow criteria for the preparation of lymphocytes for HLA-A, B and DR typing;
- (13) The laboratory must have available and follow criteria for selecting typing reagents, whether locally or commercially prepared;
- (14) The laboratory must have available and follow criteria for the assignment of HLA antigens;
- (15) The laboratory's reagents for typing recipients and donors must be adequate to define all major and International Workshop HLA-A, B and DR specificities for which reagents are readily available;
- (16) The laboratory must include positive and negative controls on each tray;
- (17) The laboratory must have a written policy that it follows that establishes when antigen redefinition and retyping are required;
- (18) The laboratory must screen recipient sera for preformed antibodies with a suitable lymphocyte panel that assures that—
 - (i) Potential transplant recipient sera are screened for HLA-A and B antibody content at the time of the recipient's initial HLA typing; and
 - (ii) Screening must be performed on samples collected at monthly intervals thereafter and following sensitizing events;
- (19) The laboratory must use a suitable cell panel for screening patient sera (antibody screen), a screen that contains all the major HLA specificities and common splits—
 - (i) If the laboratory does not use commercial panels, it must maintain a list of individuals for fresh panel bleeding; and
 - (ii) If the laboratory uses frozen panels, there must be a suitable storage system.
- (20) Compatibility testing for cellularly-defined antigens must utilize

techniques such as the mixed lymphocyte culture test, homozygous typing cells or DNA analysis;

(21) If the laboratory reports the recipient's and/or donor's ABO blood group and Rh₀(D) group, the testing must be performed in accordance with § 493.1269 of this subpart;

(22) If the laboratory utilizes ABO agglutinins to remove red blood cells during lymphocyte isolation, the specificity of the ABO reagents must be verified with control cells;

(23) The laboratory must, at least once each month, give each individual performing tests a previously tested specimen as an unknown to verify his or her ability to reproduce test results. The laboratory must maintain records of the results for each individual; and

(24) 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)(1) For laboratories performing histocompatibility testing only for transfusions and other nonrenal transplantation, excluding bone marrow, the laboratory must meet all the requirements specified in this section except for the performance of mixed lymphocyte cultures.

(2) For laboratories performing histocompatibility testing for bone marrow transplantation, the laboratory must meet all the requirements specified in this section including the performance of mixed lymphocyte cultures.

(3) For laboratories performing histocompatibility testing for 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.

(c) Laboratories performing HLA typing for disease-associated studies, or parentage testing must meet all the requirements specified in this section except for the performance of mixed lymphocyte cultures.

(d) For laboratories performing tests for organ transplantation, the laboratory must assure the donor is tested for HIV reactivity using the same protocols as required under § 493.1241 of this part for the transfusion of blood and blood products, unless the organ recipient (or an individual authorized to act on his or her behalf) waives the tests because of medical circumstances.

§ 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.

(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 document the 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 adequate 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.

(a) The laboratory must perform ABO group and Rh₀(D) group, unexpected antibody detection, antibody identification and compatibility testing in accordance with 21 CFR part 606 (with the exception of 21 CFR 606.20a, Personnel) and 21 CFR 640 et seq.

(b) The laboratory must perform ABO group by testing unknown red cells with anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be testing with known A₁ and B red cells.

(c) The laboratory must determine the Rh₀(D) group by testing unknown red cells with anti-D (anti-Rh₀) 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 Rh₀ 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 L for technical supervision in immunohematology, transfusion services. The facility must ensure that there are facilities for procurement, safekeeping and transfusion of blood and blood products and that blood products are 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 of this subpart.

§ 493.1273 Standard; Immunohematological collection, processing, dating periods, labeling and distribution of blood and blood products.

In addition to the requirements in 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 be Medicare-approved.

(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.

§ 493.1275 Standard; Blood storage facilities.

If blood is stored or maintained for transfusion, the facility must ensure 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, RH₀ (D) group, unexpected antibody detection, compatibility testing in accordance with § 493.1269 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.

§ 493.1281 Standard; Storage facilities.

The blood storage facilities must have an adequate temperature alarm system that is regularly inspected.

§ 493.1283 Standard; Retention 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 its own facility 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 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—Personnel**§ 493.1401 General.**

This subpart consists of the requirements that the personnel of various types of providers and suppliers must meet.

§ 493.1402 Definitions.

For purposes of this subpart, the following definitions apply:

Subsequent to graduation. The phrase "subsequent to graduation" means laboratory training and experience acquired after receipt of the degree specified. However, for purposes of § 493.1415 or 493.1427, experience as a technologist in a laboratory, which was gained prior to acquiring such degree, may be substituted on an equivalency basis of 1.5 years of such experience for every 1 year of postdegree training and experience; and experience as a general supervisor in an approved clinical laboratory, which was gained prior to acquiring such degree, may be substituted on a 1-for-1 basis.

Substitution of education for experience. The phrase "substitution of education for experience," applies only to §§ 493.1427(b)(6), 493.1433(b)(5), and 493.1441(b)(5) and means that a minimum of 30 semester hours of credit from an approved school of medical

technology, or toward a bachelor's degree from an accredited institution with a chemical, physical, or biological science as his major subject is considered equivalent to 2 years of experience. Additional education is equated at the rate of 15 semester hours of credit for 1 year of experience.

Technician trainee. The term "technician trainee" means a high school graduate or equivalent who is gaining the required 2 years of clinical laboratory on-the-job experience to qualify as a technician, and is participating in a structured training program approved by the State agency designed to provide the trainee with a broad range of laboratory procedures of progressive technical difficulty.

Hospital-Based Laboratories**§ 493.1403 Hospital personnel.**

As part of meeting the condition of participation at § 482.27 of this chapter, a hospital's laboratory must provide personnel to direct and conduct the laboratory services.

(a) The laboratory director must be technically qualified to supervise the laboratory personnel and test performance.

(1) The director must be a pathologist or other doctor of medicine or osteopathy with training and experience in clinical laboratory services;

(2) A laboratory specialist with a doctoral degree in physical, chemical or biological sciences, and training and experience in clinical laboratory services; or

(3) Qualifies under State law to direct a laboratory in the State in which the laboratory is located.

(b) If the laboratory performs services in any of following testing areas, specific qualifications are required for the individual providing technical supervision.

(1) Cytology—In the case of tests in cytology, the individual is a physician who—

(i) Is certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology;

(ii) Is certified by the American Society of Cytology to practice cytopathology;

(iii) Possesses qualifications that are equivalent to those required for certification by the Boards specified in paragraph (b)(1)(i) of this section; or

(iv) Possesses qualifications that are equivalent to those required for certification specified in (b)(1)(ii) of this section.

(2) Histopathology—In the case of tests limited to histopathology, the individual is a physician who meets the requirements of paragraph (b)(1)(i) or (b)(1)(iii) of this section.

(3) Dermatopathology—In the case of tests in dermatopathology, the individual—

(i) Is a physician who meets the requirements of paragraph (b)(1)(i) or (b)(1)(iii) of this section.

(ii) Is certified in dermatopathology by the American Board of Dermatology, the American Osteopathic Board of Dermatology, the American Board of Pathology, or the American Osteopathic Board of Pathology; or

(iii) Possesses qualifications that are equivalent to those required for certification by the Boards specified in paragraph (b)(3)(ii) of this section.

(4) Oral pathology—In the case of tests in oral pathology, the individual—

(i) Is a physician who meets the requirements of paragraph (b)(1)(i) or (b)(1)(iii) of this section;

(ii) Is certified in oral pathology by the American Board of Oral Pathology; or

(iii) Possesses qualifications that are equivalent to those required for certification by the Board specified in paragraph (b)(4)(ii) of this section.

(5) Histocompatibility—In the case of tests in histocompatibility, the individual—

(i) Holds an earned doctoral degree in a biological science or is a physician; and

(ii) Subsequent to graduation, has had four years of experience in immunology, two of which have been in histocompatibility testing.

(6) Clinical cytogenetics—In the case of tests in clinical cytogenetics, the individual—

(i) Holds an earned doctoral degree in a biological science or is a physician; and

(ii) Has had four years of experience in genetics, two of which have been in clinical cytogenetics.

(7) Transfusion services and blood banking—The individual is a pathologist or other doctor of medicine or osteopathy with training and experience in transfusion services.

(c) The laboratory director must—

(1) Provide technical supervision of the laboratory services; and

(2) Assure that tests, examinations, and procedures are properly performed, recorded, and reported.

(d) The laboratory director must ensure that the staff—

(1) Has appropriate education, experience, and training to perform and report laboratory tests promptly and proficiently;

(2) Is sufficient in number for the scope and complexity of the services provided; and

(3) Receives in-service training appropriate to the type and complexity of the laboratory services offered.

(4) The laboratory technologists must be technically competent to perform test procedures and report test results promptly and proficiently.

SNF Laboratories

§ 493.1405 Skilled nursing facility laboratory personnel.

As part of meeting the condition of participation for laboratory services (see § 405.1128 of this chapter), a skilled nursing facility's laboratory personnel must meet the same requirements as hospital laboratory personnel must meet in § 493.1403 (a) through (d) of this subpart.

ICF/MR Laboratories

§ 493.1407 ICF/MR laboratory services.

If a facility chooses to provide laboratory services, its personnel must meet the following requirements—

(a) The laboratory director must be technically qualified to supervise the laboratory personnel and test performance and must meet licensing or other qualification standards established by the State with respect to directors of clinical laboratories. For those States that do not have licensure or qualification requirements pertaining to directors of laboratories, the director must be either—

(1) A pathologist or other doctor of medicine or osteopathy with training and experience in laboratory services; or

(2) A laboratory specialist with a doctoral degree in physical, chemical or biological sciences, and training and experience in laboratory services; or

(3) Qualified under State law to direct a laboratory in the State in which the laboratory is located.

(b) The laboratory director must provide adequate technical supervision of the laboratory services and assure that tests, examinations and procedures are properly performed, recorded and reported.

(c) The laboratory director must ensure that the staff—

(1) Has appropriate education, experience, and training to perform and report laboratory tests promptly and proficiently;

(2) Is sufficient in number for the scope and complexity of the services provided; and

(3) Receives in-service training appropriate to the type and complexity of the laboratory services offered; and

(4) Is technically competent to perform test procedures and report test results promptly and proficiently.

Independent Laboratories

§ 493.1413 Condition—Independent laboratories; laboratory director.

The laboratory must have a director who meets the requirements of § 493.1415 of this subpart and provides overall management and direction in accordance with § 493.1417 of this subpart.

§ 493.1415 Standard; Laboratory director, qualifications.

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 fulltime 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, 1968 required by State law for a laboratory director license. An exception to the July 1, 1971, qualifying date in paragraph (b)(5) of this section was made provided that the individual requested qualification approval by October 21, 1975 and had been employed in a laboratory for at least 3 years of the 5 years preceding the date of submission of his qualifications.

§ 493.1417 Standard; Laboratory director responsibilities.

The laboratory director must be responsible for the overall management of the laboratory personnel, for the performance of test procedures and reporting of test results and for assuring compliance with the applicable regulations.

(a) The laboratory director must assure that technical supervision is provided by individuals as required under § 493.1419 of this subpart.

(b) The laboratory director must—

(1) Assure that tests, examinations and procedures are properly performed, recorded and reported;

(2) Assure that the laboratory maintains an ongoing quality assurance program;

(3) Assure that when tests are being performed there is a general supervisor on the premises who meets the qualifications of § 493.1417 of this subpart; and

(4) Assure compliance with the applicable regulations.

(c) The laboratory director must ensure that the staff—

(1) Has the appropriate education, experience and training to perform and report laboratory tests promptly and proficiently;

(2) Is sufficient in number for the scope and complexity of the services provided;

(3) Receives regular in-service training appropriate for the type and complexity of the laboratory services offered; and

(4) Maintains competency to perform test procedures and report test results promptly and proficiently.

§ 493.1419 Condition: Independent laboratories; technical supervision.

For each specialty or subspecialty of services performed, the laboratory must have an individual who is qualified under § 493.1421 of this subpart to provide technical supervision in accordance with § 493.1423 of this subpart.

§ 493.1421 Standard; Technical supervisor qualifications.

Specific qualifications are required for the individual providing technical supervision for each of the specialties and subspecialties in which the laboratory performs tests or procedures.

(a) The laboratory may perform anatomical and clinical laboratory procedures and tests in all specialties and subspecialties of services except histocompatibility and clinical cytogenetics services provided the technical supervisor is a physician and—

(1) Is certified in both anatomical and clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or

(2) Possesses qualifications that are equivalent to those required for certification.

(b) If the requirements of paragraph (a) of this section are not met and the laboratory performs tests in the specialty of microbiology, including the subspecialties of bacteriology, mycobacteriology, mycology, parasitology, and virology, the testing

must be performed under the supervision of an individual who—

(1) Is a physician and—

(i) Is certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or

(ii) Possesses qualifications that are equivalent to those required for certification by one of the Boards specified in subparagraph (1)(i) of this paragraph; or

(2)(i) Holds an earned doctoral or master's degree in microbiology from an accredited institution or is a physician, and

(ii) Subsequent to graduation has had at least 4 years of experience in clinical microbiology.

(c) If the requirements of paragraph (a) of this section are not met and the laboratory performs tests in the specialty of diagnostic immunology, the testing must be performed under the supervision of an individual who—

(1) Is a physician and—

(i) Is certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or

(ii) Possesses qualifications that are equivalent to those required for certification by one of the Boards specified in subparagraph (1)(i) of this paragraph; or

(2)(i) Holds an earned doctoral or master's degree in biology, chemistry, immunology, or microbiology from an accredited institution or is a physician, and

(ii) Subsequent to graduation has had at least 4 years of experience in immunology.

(d) If the requirements of paragraph (a) of this section are not met and the laboratory performs tests in the specialty of chemistry, the testing must be performed under the supervision of an individual who—

(1) Is a physician and—

(i) Is certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or

(ii) Possesses qualifications that are equivalent to those required for certification by one of the Boards specified in subparagraph (1)(i) of this paragraph; or

(2)(i) Holds an earned doctoral or master's degree in chemistry from an accredited institution or is a physician, and

(ii) Subsequent to graduation has had at least 4 years of experience in clinical chemistry.

(e) If the requirements of paragraph (a) of this section are not met and the

laboratory performs tests in the specialty of hematology, the testing must be performed under the supervision of an individual who—

(1) Is a physician and—
(i) Is certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or

(ii) Possesses qualifications that are equivalent to those required for certification by one of the Boards specified in subparagraph (1)(i) of this paragraph; or

(2)(i) Holds a master's or a bachelor's degree in biology, immunology, microbiology, or chemistry, or medical technology from an accredited institution, and

(ii) Subsequent to graduation has had at least 4 years of experience in hematology.

(f) If the requirements of paragraph (a) of this section are not met and the laboratory performs tests in the subspecialty of cytology, the testing must be performed under the supervision of a physician who—

(1) Is certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology;

(2) Is certified by the American Society of Cytology to practice cytopathology; or

(3) Possesses qualifications that are equivalent to those required for certification specified in (f)(1) or (f)(2) of this section.

(g) If the laboratory performs tests in the subspecialty of histopathology, the testing must be performed under the supervision of an individual who—

(1) Meets the requirements of paragraph (a) of this section;

(2) Is a physician and—

(i) Is certified in anatomical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or

(ii) Possesses qualifications that are equivalent to those required for certification by one of the Boards specified in subparagraph (1)(i) of this paragraph; or

(3) For tests in dermatopathology, the individual—

(i) Meets the requirements of paragraph (a) of this section;

(ii) Is a physician and is certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology;

(iii) Is certified in dermatology by the American Board of Dermatology or the American Osteopathic Board of Dermatology; or

(iv) Possesses qualifications that are equivalent to those required for

certification by one of the Boards specified in subparagraph (3)(ii) or (iii) of this paragraph.

(h) If the requirements of paragraph (a) of this section are not met and the laboratory performs tests in the subspecialty of oral pathology, the testing must be performed under the supervision of an individual who—

(1) Is a physician and—

(i) Is certified in anatomical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or

(ii) Possesses qualifications that are equivalent to those required for certification by one of the Boards specified in subparagraph (1)(i) of this paragraph; or

(2)(i) Is certified in oral pathology by the American Board of Oral Pathology; or

(ii) Possesses qualifications that are equivalent to those required for certification.

(i) If the requirements of paragraph (a) of this section are not met and the laboratory performs tests in the specialty of radiobiology, the testing must be performed under the supervision of an individual who—

(1) Is a physician and—

(i) Is certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or

(ii) Possesses qualifications that are equivalent to those required for certification by one of the boards specified in paragraph (1)(i) of this paragraph; or

(2)(i) Holds an earned doctoral, master's, or bachelor's degree in chemistry, physics, biology, or medical technology from an accredited institution or is a physician and

(ii) Subsequent to graduation has had at least 4 years of experience in radiobiology.

(j) If the laboratory performs tests in the specialty of histocompatibility, the testing must be performed under the supervision of an individual who—

(1) Holds an earned doctoral degree in a biological science or is a physician, and

(2) Subsequent to graduation has had 4 years of experience in immunology, 2 of which have been in histocompatibility testing.

(k) If the laboratory performs tests in the specialty of clinical cytogenetics, the testing must be performed under the supervision of an individual who—

(1) Holds an earned doctoral degree in a biological science or is a physician, and

(2) Has had four years of experience in genetics, two of which have been in clinical cytogenetics.

(l) If the requirements of paragraph (a) of this section are not met and the laboratory performs tests in the specialty of immunohematology, the testing must be performed under the supervision of an individual who—

(1) Is a physician and—

(i) Is certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or

(ii) Possesses qualifications that are equivalent to those required for certification by one of the Boards specified in subparagraph (1)(i) of this paragraph; or

(2) Is a physician with at least 2 years of experience in immunohematology subsequent to graduation; or

(3) Within the specialty of immunohematology, the laboratory performs tests in the subspecialties of ABO group and Rh, (D) group, unexpected antibody detection, antibody identification, and titrating only, the supervisor holds a master's or bachelor's degree in biology, immunology, microbiology, chemistry, or medical technology from an accredited institution and subsequent to graduation has had at least 4 years of experience in immunohematology.

(m) A laboratory whose director qualifies as a director under § 493.1415(b)(5)(iv) is qualified as a technical supervisor in the laboratory specialties in which the director achieved a satisfactory grade in the examination conducted or sponsored by the Public Health Service. Further, a director who achieved a satisfactory grade in chemistry or blood grouping and Rh. group, or both, is deemed to meet the requirements of paragraphs (i), (1)(2), or both, of this section.

(n) If the laboratory has a director who qualifies under § 493.1415(b)(5)(iii) of this subpart, the laboratory may perform tests in the specialty of microbiology, if the director has a bachelor's degree in a biological science and subsequent to graduation has had at least 6 years of experience in microbiology;

(o) If the laboratory has a director who qualifies under § 493.1415(b)(5)(iii) of this subpart, the laboratory may perform tests in the specialty of hematology, if the director has a bachelor's degree in biology, immunology, or microbiology from an accredited institution and subsequent to graduation has had at least 6 years of laboratory experience of which at least 4 years of experience are in hematology;

(p) If the laboratory has a director who qualifies under § 493.1415(b)(5)(iii) of this subpart, the laboratory may perform tests in the specialty of diagnostic immunology, if the director has a bachelor's degree in biology, chemistry, immunology, or microbiology and subsequent to graduation has had at least 6 years of experience in immunology;

(q) If the laboratory has a director who qualifies under § 493.1415(b)(5)(iii) of this subpart, the laboratory may perform tests in the specialty of radioassay, if the director has a bachelor's degree in a chemical, physical, or biological science and subsequent to graduation has had at least 6 years of laboratory experience at least 1 year of which is in radioassay;

(r) If the laboratory has a director who qualifies under § 493.1415(b)(5)(iii) of this subpart the laboratory may perform ABO blood grouping and Rh₀(D) group, unexpected antibody detection, antibody identification, and titrating, if the director has a bachelor's degree in biology, immunology, or microbiology from an accredited institution and subsequent to graduation has had at least 6 years of laboratory experience of which at least 4 years of experience are in immunohematology;

(s) If the laboratory has a director who qualifies under § 493.1415(b)(5)(iii) of this subpart, the laboratory may perform tests in the specialty of chemistry, if the director has a bachelor's degree in a chemical science or its equivalent and subsequent to graduation has had at least 6 years of experience in clinical chemistry;

(t) If the laboratory has a director who qualifies under § 493.1415(b)(5)(iii) of this subpart, the laboratory may perform tests referred to in paragraphs (n) through (s) of this section, if the director has a bachelor's degree in medical technology and after graduation has had at least the designated years of specialized experience.

§ 493.1423 Standard; Technical supervisor responsibilities.

The technical supervisor spends an adequate amount of time in the laboratory to supervise the technical performance of the staff in the specialty for which the technical supervisor is responsible and is readily available for personal or telephone consultation.

§ 493.1425 Condition: Independent laboratories; general supervisor.

The laboratory must have one or more general supervisors who are qualified under § 493.1427 of this subpart to provide general supervision in

accordance with § 493.1429 of this subpart.

§ 493.1427 Standard; General supervisor qualification.

The laboratory has one or more supervisors who, under the direction of the laboratory director, supervise technical personnel and reporting of test results, perform tests requiring special scientific skills, and, in the absence of the director and technical supervisor, are held responsible for the proper performance of all laboratory procedures.

(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 § 493.1415(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.

(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.

(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 four 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.

(4)(i) Is qualified as a laboratory technologist under § 493.1433(b) (1), (2), (3), (4) or (6) of this subpart; 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.

(5) With respect to the specialty of diagnostic cytology, qualifies as a supervisory cytotechnologist because he or she—

(i) Is qualified as a cytotechnologist under § 493.1437; and

(ii) Has had 4 years of full-time experience as cytotechnologist in a laboratory directed or supervised by a pathologist or other physician recognized as a specialist in diagnostic cytology within the preceding 10 years;

(6) 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.

§ 493.1429 Standard; General supervisor responsibilities.

The general supervisor, under the direction of the laboratory director and the technical supervision of the technical supervisor, supervises laboratory personnel, test performance, and test reporting.

(a) A general supervisor is on the laboratory premises during all hours in which tests are being performed.

(b) The general supervisor in cytology must be on the premises when nonsupervisory cytotechnologists examine cytologic preparations unless a technical supervisor who qualifies under § 493.1421 (a) or (f) of this subpart is present.

(c) When emergencies arise outside regularly scheduled hours of duty, an individual who qualifies as a general supervisor is not required to be on the premises, provided that the technologist performing tests is qualified to perform such tests, the supervisor who is responsible for the results of the work reviews them during the next duty period, and a record is maintained to reflect the actual review.

§ 493.1431 Condition: Independent laboratories; technical personnel.

The laboratory has a sufficient number of properly qualified technical personnel for the volume and diversity of tests performed.

§ 493.1433 Standard; Technologist qualifications.

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;

(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;

(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;

(4) Have successfully completed 3 years (90 semester hours or equivalent) in an accredited college or university with the following distribution of courses—

(i) *For those whose training was completed before September 15, 1963.* At least 24 semester hours in chemistry and biology courses of which—

(A) At least 6 semester hours were in inorganic chemistry and at least 3 semester hours were in other chemistry courses; and

(B) At least 12 semester hours in biology courses pertinent to the medical sciences; or

(ii) *For those whose training was completed after September 14, 1963.*

(A) 16 semester hours in chemistry courses that included at least 6 semester hours in inorganic chemistry and that are acceptable toward a major in chemistry;

(B) 16 semester hours in biology courses that are pertinent to the medical sciences and are acceptable toward a major in the biological sciences; and

(C) 3 semester hours of mathematics; and

(iii) 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.

§ 493.1435 Standard; Technologist duties.

The laboratory must—

(a) Employ a sufficient number of laboratory technologists, cytotechnologists, or both, to perform proficiently under general supervision the laboratory tests that require the exercise of independent judgment; and

(b) Ensure that—

(1) The laboratory technologists perform tests requiring the exercise of independent judgment and responsibility with minimal supervision by the director or supervisors only in those specialties or subspecialties in

which the laboratory technologists are qualified by education, training, and experience;

(2) For specialties in which the laboratory technologist is not qualified by education, training, or experience, tests are performed only under the direct supervision of the laboratory supervisor or qualified technologist;

(3) Laboratory technologists are sufficient in number to supervise the work of technicians and technician trainees adequately; and

(4) An individual qualified as a cytotechnologist solely under § 493.1437 of this subpart may supervise technicians and trainees only in the specialty of cytology.

§ 493.1437 Standard; Cytotechnologist qualifications.

Each laboratory cytotechnologist—

(a) Possesses a current license as a cytotechnologist issued by the State, if such licensing exists; and

(b)(1) Has successfully completed 2 years in an accredited college or university with at least 12 semester hours in science, 8 hours of which are in biology, and

(i) Has had 12 months of training in a school of cytotechnology accredited by an accrediting agency approved by the HHS; or

(ii) Has received 6 months of formal training in a school of cytotechnology accredited by an accrediting agency approved by the Secretary and 6 months of full time experience in cytotechnology in a laboratory acceptable to the pathologist who directed the formal 6 months of training;

(2) Before January 1, 1969, had:

(i) Been graduated from high school;

(ii) Completed 6 months of training in cytotechnology in a laboratory directed by a pathologist or other physician recognized as a specialist in cytology; and

(iii) Completed 2 years of full-time supervised experience in cytotechnology; or

(3) Achieves a satisfactory grade in a proficiency examination approved by HHS and designed to qualify persons as cytotechnologists.

§ 493.1439 Standard; Cytotechnologist responsibilities

The cytotechnologist must—

(a) Document the gynecologic and non-gynecologic cases examined; and

(b) Record slide interpretation results of each gynecologic and nongynecologic case reviewed.

§ 493.1441 Standard; Technician qualifications.

Each laboratory technician—

(a) Possesses a current license as a technician, issued by the State if such licensing exists; and

(b)(1) Has successfully completed 60 semester hours of academic credit including chemistry and biology as well as a structured curriculum in medical laboratory techniques at an accredited institution or has an associate degree based on a course of study including those subjects from an accredited institution;

(2) Is a high school graduate or equivalent and has completed at least 1 year in a technician training program in a school accredited by an accrediting agency approved by HHS;

(3) Is a high school graduate or equivalent and has 2 years of pertinent full-time laboratory experience as a technician trainee in a laboratory;

(4) Is a high school graduate or equivalent and has successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and has held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician);

(5) With respect to a technician not meeting the training and experience requirements defined in paragraph (b) (1), (2), (3), or (4) of this section—

(i) Was performing the duties of a clinical laboratory technician any time between July 1, 1961, and January 1, 1968, and

(ii) Has had at least 5 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. However, after December 31, 1977, initial certification as a technician must be in accordance with paragraph (b) (1), (2), (3), or (4) of this section.

§ 493.1443 Standard; Technician duties.

The laboratory must—

(a) Employ a sufficient number of technicians to meet the workload demands of the laboratory;

(b) Ensure that—

(1) Technicians perform laboratory procedures only under the direct supervision of a technologist;

(2) Each technician performs only those laboratory procedures that require a degree of skill commensurate with the technician's education, training, and technical abilities and involve limited exercise of independent judgment;

(3) No laboratory technician performs procedures in the absence of a qualified

laboratory technologist, supervisor, or director; and

(4) A technician trainee performs only repetitive procedures that require a minimal exercise of independent judgment and that he or she performs these procedures only when a qualified supervisor or technologist is in the immediate bench area.

Subpart M—Quality Assurance

§ 493.1501 Condition: Quality assurance.

The laboratory must establish and follow policies and procedures for an ongoing quality assurance program designed to monitor and evaluate quality; identify and correct problems; assure the accurate, reliable and prompt reporting of test results; assure the adequacy and competency of the staff; and the laboratory's quality assurance program must meet the standards in paragraphs (a) through (l) of this section.

(a) *Standard.* The laboratory must have an ongoing system under which it monitors and evaluates quality control and proficiency testing data for the purpose of substantiating that all tests performed and reported by the laboratory conform to the laboratory's specified performance criteria. These criteria include: precision, accuracy, detection limits, interferences, linearity, sensitivity, specificity, validity and adequacy.

(b) *Standard.* The laboratory must have a mechanism for assuring the accurate and timely reporting of test results. Reporting times must be within the acceptable time periods established by the laboratory.

(c) *Standard.* The laboratory must have a mechanism for assuring that—

(1) All quality control data are reviewed;

(2) Patient test results are not reported when control values are outside the acceptable range established by the laboratory;

(3) All patient test results analyzed in the same test run before a failure in quality control or since the last acceptable quality control must be reevaluated before reporting to determine that the patient values are accurate and reliable; and

(4) Actions are taken to correct the problems that led to the unsatisfactory quality control results and the corrective actions are documented.

(d) *Standard.* The laboratory must have a mechanism for assuring that corrective action is taken and is documented on all unacceptable or unsatisfactory proficiency testing results.

(e) *Standard.* The laboratory must have a mechanism to assure that

specimens are not tested when they do not meet the laboratory's established criteria for acceptability and that the authorized person ordering the test is notified of the condition of specimens not meeting the laboratory's criteria for a satisfactory specimen suitable for testing or any limitations on the reliability of the test results.

(f) *Standard.* The laboratory must have a mechanism to identify and evaluate patient test results that appear inconsistent with clinically relevant criteria such as—

(1) Patient's age;

(2) Sex;

(3) Diagnosis or pertinent clinical data;

(4) Distribution of patient test results; and

(5) Relationship with other test parameters.

(g) The laboratory must have a system in place to document problems that occur related to breakdowns in communication between the laboratory and the authorized individual who orders or receives the results of test procedures or examinations. Records of the corrective action taken to minimize or resolve the problems must be available.

(h) *Standard.* The laboratory must have policies and procedures for an ongoing program to assure that employees are competent and maintain their competency to perform their duties as specified by the laboratory. Policies and procedures may include direct observation of routine patient test performance as well as analysis of unknowns, monitoring the reporting of test results, or other activities identified by the laboratory. The laboratory must have an established program for providing orientation and in service training to employees to improve performance when problems are identified. The laboratory must evaluate employee performance by—

(1) Retesting of previously analyzed specimens, internal blind proficiency test samples, or external proficiency test samples (that have already been reported to approved proficiency testing programs) to assess the performance levels of each staff member responsible for performing and/or supervising testing; or

(2) Enrolling in external proficiency testing programs to the extent that there are programs available to cover all analyses performed, to assess an individual's laboratory performance. (The proficiency test samples are in addition to those required in Subpart H of this part.) For cytology, the laboratory may insert into the workload slides from previously reported cases as blind

samples or may arrange to exchange cases with another laboratory for the purpose of rescanning slides and comparing results.

(i) *Standard.* 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 necessary corrective actions to prevent recurrences.

(j) *Standard.* The laboratory must evaluate all data analysis and test reporting systems to assure that the systems perform according to specifications and provide accurate and reliable reporting, transmittal, storage and retrieval of data.

(k) *Standard.* The laboratory must establish and follow policies and procedures to assure that all complaints and problems reported to the laboratory are documented. If necessary, these complaints are investigated and, where appropriate, corrective actions are instituted and documented.

(l) *Standard.* The laboratory must maintain records of its quality assurance program, document all corrective actions taken to remedy problems it has identified and make records of corrective action available to HHS or its designee.

Subpart N—Inspection

§ 493.1601 Condition: Inspection.

HHS or its designees may conduct an unannounced inspection of any laboratory at any time during its hours of operation. Unless otherwise specified in this part, HHS may deny approval to a laboratory for a period of at least one year for violation of any of the requirements of this part or of the Social Security Act, subject to the appeal rights specified in Part 498 of this chapter.

(a) *Standard.* The laboratory may be required, as part of this inspection, to—

(1) Test samples (including proficiency testing samples) or perform procedures as HHS requires;

(2) Allow an interview of any employee of the laboratory;

(3) Allow employees to be observed performing tests (including proficiency testing specimens provided by the inspection team), data analysis and reporting; and

(4) Provide copies to HHS or its designee of all records and data it requires.

(b) *Standard.* All records and data must be readily accessible and retrievable within a reasonable time frame during the course of the inspection. All records must be

available for at least two years unless other time frames are specified in this part or HHS specifies a different interval in Appendix C of the State Operations Manual (HCFA Pub. 7).

(c) *Standard.* The laboratory must provide upon request all information and data needed by HHS or its designee to make a determination of the laboratory's compliance with the requirements.

(d) *Standard.* The laboratory must notify HHS or its designee within 30 days of the effective date of all changes in directors, supervisors, ownership and control, location, specialties and subspecialties of service offered, and hours of operation.

(e)(1) *Standard.* A laboratory applying for Medicare/Medicaid approval or CLIA licensure (or letter of exemption), or both, must successfully participate in an approved proficiency testing program for one testing event for each specialty and subspecialty for which Medicare or Medicaid approval or CLIA licensure (or letter of exemption) is requested. The laboratory must submit the results of the testing to HHS or its designee before inspection, approval or licensure of the facility can take place.

(2) An approved or licensed laboratory must successfully participate in one proficiency testing event for each additional specialty or subspecialty of service for which approval or licensure is requested. The laboratory must submit the results of the testing to HHS or its designee before inspection, approval or licensure of service can take place.

(f) *Standard.* HHS or its designee may reinspect a laboratory at any time necessary to evaluate the ability of the laboratory to provide accurate and reliable test results.

Subpart O—CLIA Requirements

§ 493.1701 Basis and scope.

(a) This subpart applies to laboratories engaged in the laboratory examination of, or other laboratory procedures relating to, human specimens solicited or accepted in interstate commerce, directly or indirectly, for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment, or the assessment of the health, of human beings. All screening procedures are included as well as quantitative testing of specimens for the presence or absence of any substance, pathogen or other analytes.

(b) This subpart does not apply to—

(1) Any laboratory that performs 100 or fewer tests during any calendar year; however, the laboratory must—

(i) Hold an unrevoked or unsuspended letter of exemption for low volume from HHS;

(ii) Provide information to HHS upon request, permit inspections, and make records available as required by § 493.1601 of this part for licensed laboratories; and

(iii) Perform testing that HHS has determined poses no significant threat to public health;

(2) Any laboratory operated by a licensed physician, osteopath, dentist, or podiatrist, or group of these individuals in any combination who performs laboratory tests or procedures solely as an adjunct to the treatment of the practitioner's or practitioners' own patients;

(3) Any laboratory performing tests or other procedures solely for the purpose of determining whether to write an insurance contract or determine eligibility or continued eligibility for insurance payments; and

(4) Any laboratory exempted under section 353(1) of the Public Health Service Act.

§ 493.1702 Definitions.

As used in this subpart—
Act means the Public Health Service Act, as amended, 42 U.S.C. 201, et seq., also known as the Clinical Laboratories Improvement Act of 1967 (CLIA).

§ 493.1704 Licensure application and issuance.

(a) *Licensure application.* (1) An application for the issuance or renewal of a license must be made for each laboratory location by the owner, director or authorized representative of the laboratory on the form or forms prescribed by HHS.

(2) The application for renewal of a license may not be submitted less than 30 days nor more than 60 days before the expiration date of the license.

(b) *Licensure issuance or renewal.* (1) As a part of the review of the application for issuance or renewal of licensure, HHS may require the laboratory to furnish additional information needed to consider the application. HHS also reviews the results of an onsite inspection of the laboratory's premises, performance in proficiency testing and compliance with this part. If HHS determines that the laboratory complies with the standards and other requirements of CLIA and provides consistent performance of accurate and reliable test procedures and services, HHS issues an initial or a renewal license with respect to one or more specialties or subspecialties as specified in §§ 493.1225 through 493.1269 of this part.

(2) HHS issues initial or renewal licenses for a period of at least one year. If no changes occur that affect the licensure status of the laboratory, HHS notifies the laboratory of its continued approval for at least another year. The laboratory must notify HHS within 30 days of any change in ownership, location, name, director(s), or supervisor(s), and/or of any deletion of specialties or subspecialties of service. The laboratory must notify HHS of all additions of specialties or subspecialties of service and no interstate testing may be reported until the laboratory is licensed for the appropriate specialty or subspecialties of service. HHS issues revised licenses reflecting any changes in the laboratory's status.

(3) If HHS does not issue or renew a license (in whole or in part), HHS gives the laboratory reasonable notice and issues a statement of grounds on which it proposes not to issue or renew the license or any part of it. The laboratory is also given an opportunity to request a hearing in accordance with the provisions of part 498 of this chapter.

(4) If a laboratory applies for licensure in any specialty or subspecialty for which a license has been revoked or application for a license has been denied by HHS, licensure for that specialty or subspecialty will not be approved until at least one year elapses from the effective date of the adverse action. HHS may waive this one year period if the laboratory submits good cause for the waiver, such as satisfactory performance on three consecutive proficiency testing events, one of which is on-site proficiency testing, in no less than six months following the termination action. A laboratory that requests reinstatement after this one year period must provide assurance that it complies with this subpart.

(c) *Exception.* These standards for issuance and renewal of licenses do not apply to accredited laboratories if—

(1) HHS determines that the standards applied by an accrediting organization are equal to or more stringent than the requirements of CLIA and of these regulations;

(2) The accrediting organization assures that its standards are met by the laboratory;

(3) The accrediting organization and accredited laboratories make available to HHS all records and information required by these regulations and permit inspections as required by HHS.

(4) The laboratory holds an unrevoked and unsuspended letter of exemption issued in accordance with § 493.1710 of this subpart.

§ 493.1706 Revocation, suspension, and limitation of licenses and letters of exemption; notice.

(a) A laboratory license or letter of exemption may be revoked, suspended or limited whenever HHS, after reasonable notice and opportunity for a hearing to the owner or director of the laboratory as provided in part 498 of this chapter, finds—

(1) In the case of a license, that the owner, director or any employee of the laboratory has committed any of the actions specified in section 353 (e) of the Act or has not met the requirements of this part; or

(2) In the case of a letter of exemption, that the laboratory is no longer eligible for its letter of exemption.

(b) Any notice issued under paragraph (a) of this section will contain a statement of the proposed action and of the grounds upon which HHS proposes to act.

(c) If HHS proposes to suspend a license or letter of exemption the notice will state—

(1) The period of such proposed suspension or the action required to end the suspension; and

(2) That the license or letter of exemption will be revoked if the appropriate remedial action is not taken within the suspension period.

(d) If HHS proposes to revoke or limit a license or letter of exemption, the notice will state the specialty or subspecialty with respect to which the license or letter of exemption will no longer apply.

§ 493.1708 Approval of accreditation and State licensure programs; notice.

(a) Approval of accreditation and State licensure programs is based on HHS' determination that these programs have requirements at least as stringent as those contained in CLIA. HHS, in making this evaluation, considers each program's standards, standards

enforcement and survey procedures related to: quality control; maintenance of records; equipment and facilities; qualifications of personnel; proficiency testing; program administration related to renewal of accreditation; frequency and comprehensiveness of onsite inspections; and maintenance and availability of data and records related to accredited laboratories.

(b) In filing an application for approval, the accrediting organization or State must initially provide all information and data HHS determines necessary to determine if a program can be approved and thereafter must provide all information needed by HHS to determine a program's continued approval. The accrediting organization or State licensure program must—

(1) Provide information regarding the accreditation or licensure, specialties or subspecialties for which accreditation or licensure is applicable at a frequency required by HHS; and

(2) Notify HHS within five days of any changes in accreditation or licensure.

(c) HHS may require an accrediting organization or State licensure program to sign a written agreement specifying the terms of approval.

(d) If HHS determines at any time that the accrediting organization's or State licensure program's requirements are no longer at least as stringent as the Act's requirements, HHS will notify the accrediting organization or State licensure program and provide a reasonable period of time for revision. If the organization or State licensure program does not provide satisfactory evidence on a timely basis of its continued acceptability, HHS will notify the accrediting organization or State licensure program of the basis for revoking approval. The notice will state that the provisions of section 353 of the Act and 42 CFR part 493 requiring licensure will apply to all its accredited or licensed laboratories effective 30

days after the date the notice is received. HHS will also notify each laboratory affected by this determination that its exemption from CLIA licensure is not in effect 30 days after the date the notice is received by the accreditation organization or State licensure program.

§ 493.1710 Letter of exemption.

(a) HHS may issue a letter of exemption to a laboratory provided that—

(1) The laboratory owner or authorized representative of the laboratory signs an agreement to permit inspections as required by HHS and makes available records and other information HHS requires; and

(2) The laboratory submits an application form provided by HHS that certifies that the laboratory is accredited or licensed by an approved organization or State licensure program and specifies the specialties and subspecialties for which the laboratory is accredited or licensed and the date or dates of accreditation or licensure.

(b) If a laboratory fails to comply with the requirements of this part, the laboratory will no longer be eligible for a letter of exemption and is subject to the revocation and suspension procedures described in § 493.1706 of this subpart.

(Catalog of Federal Domestic Programs No. 13.714—Medical Assistance Program; No. 13.773, Medicare—Hospital Insurance Program; No. 13.774, Medicare—Supplementary Medical Insurance Program)

Dated: February 8, 1990.

Gail R. Wilensky,
Administrator, Health Care Financing
Administration.

Approved: March 1, 1990.

Louis W. Sullivan,
Secretary.

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