Federal Register

Friday
September 15, 1995

Part II

Department of Health and Human Services

Health Care Financing Administration

42 CFR Part 493

CLIA Program; Categorization and Certification Requirements for a New Subcategory of Moderate Complexity Testing; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Part 493

[HSQ–222–P]

RIN 0938–AG98

CLIA Program; Categorization and Certification Requirements for a New Subcategory of Moderate Complexity Testing

AGENCY: Health Care Financing Administration (HCFA) and Public Health Service (PHS), HHS.

ACTION: Proposed rule.

SUMMARY: In this proposed rule we are responding to some of the comments on categories of tests received in response to the rule published on February 28, 1992. To reduce the regulations burden on laboratories, we are proposing to revise our regulations to create a new subcategory of high quality moderate complexity procedures called accurate and precise technology (APT) tests.

DATES: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on November 14, 1995.

ADDRESSES: Mail written comments (1 original and 3 copies) to the following address: Centers for Disease Control and Prevention, Public Health Service, Department of Health and Human Services, Attention: HSQ–222–P, 4770 Buford Highway, N.E., MSF11, Atlanta, Georgia 30341–3724.

If you prefer, you may deliver your written comments (1 original and 3 copies) to one of the following addresses: Room 714–B, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HSQ–222–P. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 309–G of the Department's offices at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690–7890).

For comments that relate to information collection requirements, mail a copy of comments to: Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Allison Herron Eydt, HCFA Desk Officer.

Copies: To order copies of the **Federal Register** containing this document, send your request to: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250–7954. Specify the date of the issue requested and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 512–1800 or by faxing to (202) 512–2250. The cost for each copy is $8.00. As an alternative, you can view and photocopy the **Federal Register** document at most libraries designated as Federal Depository Libraries and at many other public and academic libraries throughout the country that receive the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Rosemary Bakes-Martin (404) 488–7655, for questions regarding the APT requirements and criteria for APT categorization; and Judy Yost, (410) 786–3531, for certificate, fee, and inspection issues.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 353 of the Public Health Service Act (42 U.S.C. 263a), as amended by the Clinical Laboratory Improvement Amendments of 1988 (CLIA), all laboratories that examine human specimens for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of, human beings, must meet certain requirements to perform the examination. In accordance with the law, regulations implementing CLIA that HHS published on February 28, 1992 (57 FR 7002) established laboratory requirements based on the complexity of the tests performed. There are currently three test categories: waived, moderate, and high complexity.

Following publication of the February 28, 1992 regulations, HHS established a Clinical Laboratory Improvement Advisory Committee (CLIAC) to advise and make recommendations on technical and scientific aspects of the regulations. The CLIAC is composed primarily of individuals involved in the provision of laboratory services, use of laboratory services, development of laboratory testing devices or methodologies, and others as approved by HHS. The CLIAC has four subcommittees: cytology; personnel; proficiency testing, quality control and quality assurance; and test categorization.

In response to publication of the February 28, 1992 regulations, we received approximately 16,000 letters from professional organizations and individuals providing around 71,000 comments.

In response to those comments, we have published three rules (in addition to this proposed rule). One of those rules responds to the comments received on the waived criteria, tests presently included in the waived category and those tests that commenters believed should be added. At our request, the CLIAC evaluated the waived category and suggested that the Centers for Disease Control and Prevention (CDC) clarify the criteria and develop a process for review of requests for waiver. We clarified the criteria for waiver and the process for requesting waived categorization and published the clarified criteria and process for requesting waiver in a proposed rule with comment on September 13, 1995 (60 FR 47534). (The other two rules appeared in the **Federal Register** on January 19, 1993 (58 FR 5215) and on April 24, 1995.

In this rule, in response to numerous comments regarding the test complexity model, we are proposing to establish a new subcategory of moderate complexity that would include high quality tests that would be subject to less stringent requirements. Establishment of this subcategory should encourage manufacturers to produce accurate, easy-to-use test systems for use by physicians and laboratories to improve test quality and enhance patient care.

II. Response to Comments Received to Previous CLIA Regulations

In this rule we address additional comments received in response to the establishment of the three testing categories. Below we have provided a general overview of the comments and our responses, followed by some additional specific comments concerning the categories of testing and our response to these comments, which includes the rationale used to develop the proposed accurate and precise technology (APT) subcategory.

Upon review of the comments, we believe that additional revision of the test categorization model is warranted. The revisions to the regulations proposed in this rule would address the commenters' concerns that many high quality tests are less complex than many of the tests currently categorized as moderate complexity, but they do not meet the criteria for waiver. The commenters feel and we agree that these tests should be subject to less stringent

requirements than those currently associated with moderate complexity tests.

In addition, we received numerous comments from professional organizations and individuals expressing concern about the burden associated with regulating laboratories based on test complexity and the criteria used to categorize tests as moderate or high complexity. Many commenters indicated that the special circumstances involved in physician offices, rural and public health clinics providing laboratory services should justify minimizing the regulatory burden on them. Some commenters believed that regulating laboratories on the basis of test complexity and the requirements applicable to moderate and high complexity tests would increase the cost of laboratory testing. Several commenters thought this regulatory burden would cause many laboratories to discontinue providing services, thereby limiting health care in underserved and rural areas. Some commenters recommended reducing some of the regulatory burden by creating a category of tests at a level between waived and moderate complexity. Other commenters suggested creating additional categories and provided examples for alternatives to the current test complexity model.

In response to these comments, the CDC developed a proposal to create a new subcategory of moderate complexity that would include simple, easy-to-use tests with proven accuracy and precision and therefore would require somewhat less stringent requirements than the requirements currently applicable to other moderate complexity tests.

During the development of the subcategory, we were especially cognizant of the concerns of the commenters who stated that there are many high quality, moderate complexity tests that might not qualify for waiver, but, on the other hand, should not be subject to the full range of requirements currently applicable to moderate complexity testing. We agree with the commenters that regulatory relief for high quality tests is appropriate. In order to justify less stringent application of the requirements, we are proposing that the tests meet rigid performance specifications and have demonstrated, through scientifically valid studies, a high level of accuracy and precision. Through this process, test systems would be evaluated to ensure they provide quality results and physicians and laboratories would have access to this categorization information to employ in test selection and determining types of laboratory services to provide.

We therefore designed a subcategory of moderate complexity testing that we proposed to call APT testing that would include high quality, less complex tests that would be unique in that the test system instructions would not only contain complete procedures for test performance, including instructions regarding the preanalytic, analytic and postanalytic phases of testing, but would also include protocols that would assist laboratories in meeting the CLIA requirements. We proposed that, in order to be considered for categorization in the APT subcategory, the producer or manufacturer of the test system would have to submit data demonstrating that the test system meets the criteria for APT categorization. In addition, the test system instructions would have to specify clearly what laboratories must do to be in compliance with the CLIA requirements. For APT testing, laboratories could rely on the manufacturer's or producer's test system instructions to meet the CLIA requirements. Since, for APT testing, compliance with the CLIA requirements would be based on laboratories following the test system instructions, we believe that random, rather than routine, inspections of laboratories having an APT certificate would be sufficient.

We discussed with the CLIAC the proposed criteria and requirements to be applicable to the new subcategory. The CLIAC supported the concept of the APT subcategory. However, the CLIAC expressed the view that the subcategory (as currently structured) would not provide the amount of regulatory relief desired by many commenters who requested revisions to the complexity model. We understand the CLIAC's concerns; however, we believe that it is essential that we reevaluate the complexity model to determine whether the regulations are effective in ensuring public access to quality laboratory services. When we established the CLIA requirements in 1992, we sought to devise a regulatory model based on the complexity of testing performed that would establish the minimum requirements necessary to ensure accurate testing. At this point, we believe there are many highly accurate, simple, easy-to-use test systems currently categorized as moderate complexity that could be eligible for less stringent requirements, and laboratories performing such testing should be provided financial and regulatory relief through a reduction in the CLIA requirements.

To obtain broad public review, we are publishing this proposed rule and encourage commenters to provide suggestions on how we might revise the CLIA requirements to ensure that they promote access to quality services and stimulate technological advances in testing. With respect to the provisions contained in this rule, we are seeking specific suggestions and recommendations concerning the criteria and process for categorizing tests in the APT subcategory, as well as comments on the appropriateness of the proposed requirements for APT testing.

III. Provisions of the Proposed Rule

Criteria for APT Categorization

In this rule, we are proposing to establish at 42 CFR 493.18 a new subcategory of moderate complexity testing designated as APT, and we are outlining the proposed criteria for determining which tests would be categorized as APT. The proposed criteria for inclusion in the APT subcategory are structurally similar to our proposed clarifications to the criteria for waived tests published on September 13, 1995.

For quantitative and qualitative tests, the similarities between the proposed criteria for APT categorization and the proposed clarifications to the criteria for waiver are as follows:

- Quantitative APT tests and quantitative waived tests would have to meet similar test characteristics and performance specifications by demonstrating, through scientifically valid studies, a high level of accuracy and precision.
- Qualitative APT tests would have to meet the same requirements for allowable error as we have proposed for qualitative waived tests.

The proposed criteria for inclusion in the APT subcategory would differ from the proposed criteria for waiver in that:

- Waived tests must be fail-safe with no operator intervention, whereas APT test protocols could allow some operator intervention to investigate questionable results and to resolve test system failures.
- Waived qualitative tests are limited to reagent impregnated devices (such as dipsticks), whereas qualitative APT tests would not be limited to any specific type of technology. [It is important to clarify what is meant by qualitative tests in this regulation. Qualitative tests are test methods that provide two categorical responses (e.g., positive/negative or presence/absence). For these types of tests, the concentration of the analyte is defined as being above or below a certain discrimination zone that

defines negativity or positivity.] On the other hand, test methods that give results by defining specific absorbance values at which tests will be considered positive are essentially quantitative tests in that they directly depend on defined concentrations of the analyte producing the discrete absorbance value. In this regulation, we are proposing to consider the latter as quantitative tests.

- Waived tests may use only direct unprocessed specimens, have direct readout of results and require no invasive troubleshooting or electronic or mechanical maintenance. However, APT tests could have simple noncalculated conversions and some troubleshooting and maintenance performed by the analyst.
- Instructions for performance of waived tests must be written at no higher than a seventh grade reading level and include a description of the analytic skills required to perform the test. APT test instructions would have no such requirements, since personnel performing APT testing would, at a minimum, have to have a high school diploma, or equivalent, and relevant training.
- Quantitative waived tests may have a certain amount of random error but they must be shown to be essentially free of systematic error, whereas quantitative APT tests would be allowed a minimal amount of error that may be either random or systematic, or both.

Review Process

Also at § 493.18, we are proposing the process for approving tests for the APT subcategory. We are proposing that requests for placement of tests in this subcategory be in conformance with the proposed submission process outlined in this regulation. The data submitted for evaluation would have to meet specific criteria related to operational characteristics, ease of use, and test performance. The test system's instructions will be reviewed by PHS to ensure that laboratories can rely on these instructions to assist them in meeting the regulations in subparts J, K and P when performing APT testing.

Submission Requirements

Under the proposed rule, the manufacturer or test system producer would have to determine which procedures in the preanalytic, analytic and postanalytic phases of testing are essential to ensure accurate test results. These procedures would be identified in the submission to PHS as mandatory procedures for the laboratory to follow. In addition, the manufacturer or test system producer would have to include protocols to assist laboratories in meeting the CLIA requirements. The test system instructions should remind laboratories to enroll in an HHS-approved proficiency testing program, if applicable.

Since many manufacturers are currently providing this type of assistance to laboratories, often in the form of complete protocols containing instructional materials that cover all aspects of the regulations and, in addition, examples of suggested forms to use to document monitoring activities, we believe that the APT subcategory merely strengthens and confirms that interaction between the producer of the test system and the laboratory user. Formalizing this relationship and making it uniform for all manufacturers and producers of these test systems should reduce the regulatory burden on laboratories, while providing an effective mechanism for laboratories to achieve regulatory compliance with the CLIA requirements.

We encourage individuals to submit their comments and suggestions on how we might improve the APT categorization criteria or process and revise the regulations to incorporate these changes. Following review of comments received in response to this notice, we will make the necessary revisions to the APT requirements, including the criteria for APT categorization and the process for reviewing requests for APT categorization of test systems.

After a final rule responding to the comments received to this proposed rule is published establishing the APT subcategory, requests for APT categorization may be submitted for review. Once a test system review has been completed, the manufacturer or producer would be notified of the APT categorization decision, whether denied or granted. APT categorization would be effective on the date of notification to the applicant. Any test categorized as APT also would be published in the **Federal Register** as a notice with an opportunity for public comment. (As with all comments received on test categorization, our responses to the comments received on APT categorization will be included in a subsequent **Federal Register** notice.) Once we receive comments on the **Federal Register** notice, we reserve the right to reevaluate and recategorize the test based upon those comments.

Administration

We are proposing to make conforming changes to subpart F (General Administration) to accommodate the addition of the new certificate for APT tests. Laboratories that qualify for a certificate of APT tests would have to pay a fee for the issuance of a certificate. Each laboratory would be assessed a fee representing the certificate fee and a fee for the costs of the random inspections. The certificate fee would be based on the fee schedule (which is based on the test volume and scope of specialties tested) in effect. This fee would represent the APT laboratory's share of the general cost to HHS of administering the laboratory certification program. This would include, but would not be limited to, the cost of issuing the certificate, the cost of collecting fees, the administrative costs of determining which tests would qualify for inclusion in the APT test category, and the administrative costs associated with processing and evaluating laboratory applications. The fee for random inspection would represent the cost to HHS of conducting random inspections of approximately five percent of the laboratories issued a certificate for APT tests to assess compliance with the applicable requirements of 42 CFR part 493. Random inspection costs would be shared by all laboratories issued a certificate for APT tests.

If, in the case of a laboratory subject to a random inspection, it is determined that a follow-up survey is necessary because of identified deficiencies, HHS would assess that laboratory an additional fee to cover the cost of the follow-up survey activities. The fee would be based on the actual resources and time necessary to perform the follow-up visits. Failure of a laboratory to pay any assessed costs would result in HHS revoking the laboratory's certificate.

Patient Test Management

We are proposing to add a new § 493.1102 to subpart J (patient test management) to include the new patient test management requirements that would be applicable to APT testing. These requirements would be less burdensome to the laboratory than the requirements currently applicable to other moderate complexity testing because the manufacturer's or producer's PHS-approved test system instructions would specify what laboratories must do to comply with the CLIA patient test management requirements. There would be two requirements in this new standard. The two requirements would be that the laboratory must: (a) have available and follow the patient test management procedures specified in the PHS-approved instructions; and (b) maintain records documenting compliance with

the patient test management requirements for two years.

Quality Control

In subpart K (quality control), we propose to recodify the current § 493.1204 as § 493.1206 and add a new § 493.1204 to accommodate the quality control provisions resulting from the proposed addition of the new subcategory of APT tests. Since the PHS-approved test system instructions for APT procedures would include instructions for meeting the CLIA requirements, the laboratory quality control requirements for APT testing would be less stringent than for other moderate complexity tests. We are proposing that, before reporting patient test results, laboratories, at a minimum, use the PHS-approved test system instructions for verifying the test system's performance specifications. The laboratory may include, as appropriate, expanded or additional protocols for verifying the test system's performance specifications. As with other procedures of moderate complexity, quality control activities for APT tests would have to be documented and the records retained for two years, except immunohematology records, which must be maintained for a period of no less than five years. We would stress that laboratories must not modify the test system's PHS-approved test performance instructions, since any modification would result in the test no longer being categorized as APT. Any modified procedure would become an uncategorized test and would be considered high complexity until categorized by PHS.

Personnel

The personnel requirements for APT testing would be located at § 493.1371 through § 493.1387. APT personnel requirements would be somewhat less stringent than for other moderate complexity testing because APT tests would have been reviewed to ensure that they meet the criteria for simple, reliable, accurate and precise tests. The personnel requirements for this subcategory would not include a technical consultant because manufacturers or producers of APT tests would develop maintenance protocols, calibration and control procedures, remedial action policies and criteria for reporting and interpreting test results, which would fulfill most of the technical consultant's responsibilities. The remaining technical consultant responsibilities (e.g., employee evaluations) would be performed by the laboratory director.

For APT tests, we would require laboratories to have a qualified director, clinical consultant and testing personnel. The qualifications required for director and clinical consultant would be the same as for moderate complexity testing, while the testing personnel training requirements would be modified slightly from the training required for other moderate complexity testing because the test system manufacturer or producer would be providing specific instructions on test system performance, including reagent stability and storage and quality control. The responsibility requirements for each level of personnel within the APT subcategory would be somewhat less stringent in accordance with the laboratory's reliance on the manufacturer or producer of the test system to provide detailed test instructions, protocols for meeting the regulatory requirements, performance specifications and information regarding test results and interpretation.

Quality Assurance

We are proposing to add a new § 493.1702 to the quality assurance requirements located in subpart P to include the proposed requirements applicable to APT testing. These requirements would be less burdensome than the requirements currently applicable to other moderate complexity testing, since the PHS-approved test system instructions would assist the laboratory in meeting the quality assurance requirements. Like § 493.1102 in subpart J (patient test management), there would be two requirements in § 493.1702. To meet the quality assurance requirements in subpart P, we are proposing that: (a) laboratories must have available and follow procedures specified in the test system's PHS-approved instructions to meet the quality assurance requirements; and (b) laboratories must document and maintain records of quality assurance activities for two years.

Inspections

We are proposing to establish a new § 493.1778 specifying that laboratories with a certificate for APT tests are subject to announced or unannounced inspections on a random basis to assess compliance with the applicable requirements of part 493, to evaluate compliance when indicated by unsuccessful participation in proficiency testing and complaints, and to collect information for determining the appropriateness of tests categorized as APT. We are proposing to require random, rather than routine, inspections for a laboratory having an APT certificate since the laboratory would be required only to follow the PHS-approved instructions to meet the CLIA requirements for APT testing. During a random inspection, as with any inspection of other test complexity categories, not all test systems would be reviewed. A few test systems would be randomly selected and assessed for compliance. We would also clarify in this section that if the same laboratory is performing provider-performed microscopy procedures, those tests may also be assessed for compliance with all applicable requirements specific to that subcategory of testing during the random inspection.

Additionally, we would revise the introductory paragraph to § 493.1777, which currently contains the condition concerning inspection of laboratories requesting or issued a certificate of compliance, to clarify the inspection requirements for a laboratory with a certificate of compliance when the laboratory also performs APT procedures. Specifically, for laboratories that perform APT procedures and have a certificate of compliance, APT procedures may be included in the sample of moderate complexity tests inspected during the laboratory's routine, biennial inspections.

Summary of Changes to the Regulations

We are proposing to add or change the following sections to incorporate requirements applicable to APT tests:

- Section 493.18, Accurate and precise technology (APT) tests.
- Section 493.21, Laboratories performing accurate and precise technology (APT) tests.
- Section 493.48, Requirements for a certificate for accurate and precise technology (APT) tests.
- Section 493.1102, Patient test management requirements for accurate and precise technology (APT) tests.
- In subpart K, we are proposing to add the new quality control requirements applicable to APT testing at § 493.1204 and move the facilities requirements (without change) currently located at § 493.1204 to a new § 493.1206.
- To subpart M, we are proposing to add nine new sections to include the personnel requirements for laboratories performing APT testing. At § 493.1371, we are proposing to add the condition requirements for director, and at §§ 493.1373 and 493.1375, respectively, we plan to include the qualification and responsibility requirements for director. The condition level requirements for clinical consultant would be located at § 493.1377, with clinical consultant qualifications to be specified under

§ 493.1379 and responsibilities to be included under § 493.1381. The testing personnel condition requirements would be at § 493.1383, with testing personnel qualifications at § 493.1385 and responsibilities to be included at § 493.1387.

- Section 493.1702, Quality assurance requirements for accurate and precise technology (APT) tests.
- Section 493.1778, Inspection of laboratories issued a certificate for accurate and precise technology (APT) tests.

We are proposing to make conforming technical changes to the following sections and headings: §§ 493.2; 493.3(a)(1); 493.5 (a)(2), (b) and (c)(4); 493.20 (a) and (b); 493.25(c); the headings for subpart C and 493.43; 493.43(a); 493.45 introductory paragraph and (a); 493.49; 493.51 heading, introductory paragraph and paragraphs (b) and (c) and new (d); 493.53(a); 493.602; 493.638 (a) and (b); 493.639(b); 493.643(a); 493.645 heading and new paragraph (c) and paragraph (d) (redesignated from paragraph (c)); subpart H; 493.803(a); 493.807 heading; subheading preceding 493.821; subpart I heading; subpart J heading; 493.1101 heading and introductory paragraph; subpart K heading; 493.1201 heading, revision to paragraph (a) and (b) and addition of new paragraph (c); 493.1202(c); 493.1203; part M heading; 493.1351; subpart P heading; 493.1777 introductory paragraph; 493.1814(b)(3); 493.1834 (b) and (f)(2)(iii); and 493.1836 (c)(2) and (c)(3); and 493.2001.

In addition, we are deleting the words ''of this part'' wherever they follow a specific section number in regulations text appearing in this **Federal Register** document to conform with rules of the Office of the Federal Register.

IV. Response to Comments

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, if we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Collection of Information Requirements

The proposed rule contains information collections that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1980. The title, description, and respondent description of the information collection requirements are shown below with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

§ 493.18: This section outlines the criteria a manufacturer must follow in order to have its moderate complexity test categorized as an ''Accuracy and Precise Technology'' (APT) test. These include but are not limited to test system characteristics, instructions, field studies and evaluation of data.

§§ 493.43, 493.45, 493.48, 493.49, 493.51, 493.53: Sections 493.43 through 493.53 are currently approved under OMB approval number 0938–0612 with an expiration date of February 28, 1998. The information is gathered on form number HCFA-R–26. These sections outline the requirements for a laboratory to follow to submit application forms for CLIA certification. The requirements include laboratory notification to HHS of changes to the types of tests performed or changes in ownership, name location or director.

Section 493.48 is a new section added to reflect the addition of the new certificate category for laboratories performing tests categorized as accurate and precise technology testing (APT).

§§ 493.1101 and 493.1102: Sections 493.1101 through 493.1111 are currently approved under OMB approval number 0938–0612 with an expiration date of February 28, 1998. This section concerns patient test management for laboratories performing tests of moderate and high complexity that implement the CLIA statutory mandate for laboratories to meet requirements relating to the proper collection, transportation, and storage of specimens and the reporting of results. Section 493.1102 is a new section added to reflect the addition of the new subcategory for tests categorized as accurate and precise technology testing (APT).

§§ 493.1201, 493.1202 and 493.1204: Sections 493.1201 and 493.1202 are currently approved under OMB approval number 0938–0612 with an expiration date of February 28, 1998. These sections set forth the general quality control standards for monitoring and evaluating the quality of the testing process to assure accurate and reliable patient test results and reports as required under CLIA. Section 493.1204 is a new section required to reflect the addition of the new subcategory for accurate and precise technology testing (APT).

§ 493.1702: Sections 493.1701 through 493.1721 are currently approved under OMB approval number 0938–0612 with an expiration date of February 28, 1998. Section 493.1702 is a new section developed to address specific requirements that relate to quality assurance for a laboratory performing APT testing. Specifically it requires a laboratory to have available and follow the PHS-approved instructions and supplements (where appropriate) and maintain records documenting compliance for a 2-year period.

§§ 493.1777 and 493.1778: Sections 493.1725 through 493.1780 are currently approved under OMB approval number 0938–0612 with an expiration date of February 28, 1998. Section 493.1777 concerns the inspections of laboratories. The burden associated with inspections consists of retrieving the records and documentation requested by the inspector, participating in the entrance and exit interviews, responding to the statement of deficiencies that may result from the inspection and documenting any corrective actions taken that are appropriate to the plan of correction for the deficiencies cited. Section 493.1778 is a new section developed to address the inspection requirements as they apply to laboratories with an APT certificate. This section sets forth the policy of random inspections for laboratories with an APT certificate.

When OMB approves those provisions not currently approved we will publish a notice in the **Federal Register** to that affect.

Description of Respondents

§ 493.18: Small businesses or organizations, businesses or other for profit, non-profit institutions, who manufacture laboratory tests.

§§ 493.43, 493.45, 493.48, 493.49, 493.51, 493.53; 493.1101 and 493.1102; 493.1201, 493.1202 and 493.1204; 493.1702; 493.1777 and 493.1778: Small businesses or organizations, businesses or other for profit, non-profit institutions, state and local governments, federal agencies.

ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN

CFR sections	Annual number of responses	Annual frequency	Average burden per response (hours)	Annual burden hours
493.18	50	1	336	16,800
493.43, 493.45, 493.48, 493.49, 493.51, 493.53	28,700	1	.25	7,175
493.1101, 493.1102	82,000	1	.5	41,000
493.1201, 493.1202 and 493.1204	82,000	1	12	984,000
493.1702	24,600(a)	1	42	1,033,200
493.1777 and 493.1778	1,230(a)	1	4	4,920

(a) Assuming 30% of 82,000 non-waived laboratories become APT.

The agency has submitted a copy of the proposed rule to OMB for its review of these information collections. Interested persons are invited to send comments regarding this burden estimate or any other aspect of these collections of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden. Comments should be sent to HCFA, OFHR, MPAS, C2–26–17, 7500 Security Boulevard, Baltimore, Maryland 21244–1850 and to the OMB official whose name appears in the **ADDRESSES** section of this preamble.

VI. Regulatory Impact Statement

We generally prepare a 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 rule would not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, all laboratories and manufacturers of laboratory test systems are considered to be small entities. Individuals and States are not included in the definition of a small entity.

Also, section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 50 beds.

This proposed rule would modify CLIA regulations published February 28, 1992 by establishing a new subcategory of moderate complexity testing, accurate and precise technology (APT) tests. There are approximately 157,000 entities enrolled under CLIA that could be affected by this rule; however, the significance of the effect would vary depending on the volume and complexity of tests performed. While we cannot estimate the number of entities that may make changes in their laboratory testing practices, we believe the modifications to the CLIA program would be beneficial to the affected entities and would be well received, since they are being proposed in response to comments requesting revisions to the test complexity categories.

In proposing this new subcategory, we acknowledge the unique aspects of the many tests with proven accuracy and precision that may not qualify for waiver, but should not be subject to all of the requirements applicable to moderate complexity testing, including routine inspection. To this end, this proposed rule would establish less stringent requirements, including less frequent (random) inspections and fewer personnel requirements, for laboratories providing tests categorized as APT. We expect no clinically meaningful decrease in test accuracy, or patient health, from this proposal. Furthermore, to the extent that it encourages cost-effective testing more than the present CLIA rules, and increases the amount of such testing in settings that might otherwise eschew testing, it is likely to improve patient health. In addition, this proposed rule would reduce the financial burden for some laboratories by enabling them to provide an expanded test menu without incurring the higher costs associated with a certificate of compliance.

The changes proposed in this regulation may affect a laboratory's test menu and choice of certificate. Laboratories holding a certificate of compliance that change to a certificate for APT would experience a decrease in compliance costs and the number of surveys, since APT laboratories would not be subject to routine inspections and the associated fees. The laboratories that would realize the greatest benefit from these savings would most likely be physician office laboratories and public health laboratories. Laboratories, specifically many physician offices and other limited service laboratories, expanding from a certificate of waiver or PPM to a certificate for APT would be able to enhance the range of laboratory services available to patients, while their costs (including certification fees and costs inherent in meeting applicable requirements such as personnel and quality control), would remain less than the costs of obtaining a certificate of compliance. The availability of a CLIA certificate that allows an expanded test menu at less cost also may encourage new entities to begin providing services, thereby increasing physician and patient access to health care, particularly in underserved and rural areas.

This proposed rule may affect some manufacturers of laboratory tests who would be required to submit specific information and data demonstrating that their test meets the criteria for APT categorization. We estimate that approximately 500 test systems may qualify for this subcategory. These test systems are predominantly small automated instruments or ''desktop'' analyzers. Manufacturers of any test system approved by PHS in the APT subcategory also must provide laboratories with complete instructions, which include protocols to assist laboratories in meeting the CLIA requirements. However, many manufacturers are currently providing this type of information and assistance to laboratories in the form of instructional materials and protocols. Because laboratories would not be required to develop their own operational policies and quality control protocols, a wider variety of laboratories might decide to offer APT testing.

Therefore, we anticipate that categorization as an APT test would result in increased sales and distribution for the manufacturers.

As indicated above, we believe that the creation of the subcategory of APT and subsequent decrease in the regulatory and financial burden for laboratories performing APT tests would benefit patients, laboratories, and manufacturers. However, we are unable to quantify these likely long run effects because they depend on market decisions, research results, and technological change that cannot be predicted.

Regardless, we believe that for the most part these effects would involve relatively small savings of a few hundred or a few thousand dollars a year for each laboratory, mainly due to reduced inspection fees or QC costs. In the aggregate these savings would be substantial, because they are shared by thousands of laboratories. However, few if any entities are likely to achieve very substantial savings.

This proposed rule would establish the process for categorizing moderate complexity tests into a new subcategory of moderate complexity testing and would also establish a new type of certificate. Proper realignment of the fee schedule, if necessary, would follow implementation of this rule.

For these reasons, we are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined, and the Secretary certifies, that this proposed rule would not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals. We do request comments, however, on possible improvements in these proposed regulations to achieve even greater savings to affected entities and will consider them carefully in formulating the final rule.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 493

Grant programs-health, Health facilities, Laboratories, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR part 493 would be amended as set forth below:

PART 493—LABORATORY REQUIREMENTS

1. The authority citation continues to read as follows:

Authority: Sec. 353 of the Public Health Service Act, secs. 1102, 1861(e), the sentence following 1861(s)(11), 1861(s)(12), 1861(s)(13), 1861(s)(14), 1861(s)(15), and 1861(s)(16) of the Social Security Act (42 U.S.C. 263a, 1302, 1395x(e), the sentence following 1395x(s)(11), 1395x(s)(12), 1395x(s)(13), 1395x(s)(14), 1395x(s)(15), and 1395x(s)(16)).

2. In Section 493.2, in the definition of ''CLIA certificate'' the introductory text is republished and paragraph (6) is added to read as follows:

§ 493.2 Definitions.

* * * * *

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

* * * * *

(6) *Certificate for accurate and precise technology (APT) tests* means a certificate issued or reissued before the expiration date, pending an appeal in accordance with § 493.48, to a laboratory that only performs tests approved by PHS as APT tests and, if desired, tests specified as PPM procedures, tests approved by PHS as waived tests, or both.

* * * * *

3. In § 493.3, the introductory text of paragraph (a) is republished and paragraph (a)(1) is revised to read as follows:

§ 493.3 Applicability.

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

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

* * * * *

4. Section 493.5 is revised to read as follows:

§ 493.5 Categories of tests by complexity.

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

(1) Waived tests.

(2) Tests of moderate complexity, including the subcategories of moderate complexity, which are limited to the following tests and procedures:

(i) PPM procedures.

(ii) APT tests.

(3) Tests of high complexity.

(b) A laboratory has the option of performing only waived tests, only tests of moderate complexity, only PPM procedures, only APT tests, only tests of high complexity, or any combination.

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

(1) Registration certificate.

(2) Certificate of waiver.

(3) Certificate for PPM procedures.

(4) Certificate for APT tests.

(5) Certificate of compliance.

(6) Certificate of accreditation.

5. A new § 493.18 is added to read as follows:

§ 493.18 Accurate and precise technology (APT) tests.

(a) *Requirement.* To be included in the APT subcategory, the test system must be categorized as moderate complexity using the criteria in § 493.17 and it must meet the descriptive criteria specified in paragraph (b) of this section.

(b) *Criteria.* (1) For quantitative tests, methods must be easy to use, accurate, and precise as evidenced by the following items:

(i) Test systems that have the following characteristics:

(A) Are fully automated (no operator intervention during the analytic phase).

(B) Provide direct readout of results or simple noncalculated conversions.

(ii) Test system instructions that address the following items:

(A) Requirements for specimen collection, handling, storage and preservation.

(B) Reportable range for patient results.

(C) Reference range (normal values) and suggested panic values (values requiring immediate medical intervention).

(D) Units of measurement used for reporting patient results.

(E) Step-by-step protocols that include, as appropriate, the following items:

(*1*) Instrument or test system operation and test performance instructions.

(*2*) Test system maintenance procedures.

(*3*) Preparation and storage of reagents, calibrators, controls, or other materials used in testing.

(*4*) Control procedures including the type of materials, suggested concentrations, and frequency of assay.

(*5*) Calibration procedures including the number and type of materials and frequency of assay.

(*6*) Acceptable ranges for any control or calibration material included with the test system.

(*7*) Action to be taken when calibration or control results do not meet the acceptable range of values.

(*8*) Methods for converting test system values to reportable results.

(*9*) Description of course of action to be taken when the test system becomes inoperable.

(*10*) Any limitations to methodologies such as interfering substances.

(*11*) A written protocol for reporting patient test results.

(iii) Field studies that meet the following requirements:

(A) Demonstrate that the manufacturer's or producer's written instructions are the only protocols required to perform the test accurately and reliably.

(B) Demonstrate that individuals with no formal laboratory training can correctly perform the test.

(iv) Data from field studies that meet the following requirements:

(A) Are generated from protocols that address the points described in paragraph (b)(1)(iii) of this section.

(B) Are adequate to produce measures of performance that are both statistically valid and defensible (estimates must support valid confidence limits for all statistical parameters).

(C) Evaluate performance at all medical decision points and relevant upper and lower limits of the reportable range using at least three concentrations of the analyte being tested.

(D) Evaluate among-operator imprecision using test results of all study participants.

(E) Evaluate within-site imprecision using test results generated at each site by an adequate number of participants to produce measures of performance that are statistically valid and defensible. Testing must be performed at a minimum of three independent study sites.

(F) Evaluate among-site imprecision at an adequate number of sites to produce measures of performance that are statistically valid and defensible using results generated by study participants on aliquots of a single testing material.

(v) Method accuracy studies demonstrating little or no systematic error when—

(A) Using reference materials assayed by study participants that produce data that show there is little or no statistically significant difference between the test results and the value of the reference materials.

(B) Using patient samples instead of reference materials, demonstrating there is little or no introduction of error in patient test results due to the effects of the sample matrix.

(C) Adding or simulating common interfering substances known to affect the analyte in patient samples, demonstrating that there is little or no introduction of error due to the presence of these substances.

(vi) Demonstration that the total amount of error, which includes all components contributing to imprecision and inaccuracy as defined by studies described in paragraphs (b)(1)(iv)(D) through (b)(1)(iv)(F) and (b)(1)(v)(A) through (b)(1)(v)(C) of this section, is less than one fourth of the reference range for the analyte divided by the mean of the reference interval.

(2) For qualitative tests, methods must be easy to use, accurate, and precise as evidenced by the following items:

(i) Test systems that meet the following requirements:

(A) Contain steps that are limited in number and complexity, are self-contained and are packaged as a complete system.

(B) Have a qualitative endpoint that requires no interpretation beyond discerning agglutination patterns, color comparisons, or other easily interpreted reactions.

(ii) Test system instructions that address the following items:

(A) Requirements for specimen collection, handling, storage and preservation.

(B) Reportable range for patient results.

(C) Reference range (normal values).

(D) Step-by-step protocols that include, as appropriate, the following items:

(*1*) Test performance instructions.

(*2*) Preparation and storage of reagents, calibrators, controls, or other materials used in testing.

(*3*) Control procedures including the type of materials and frequency of assay.

(*4*) Calibration procedures including the number and type of materials and frequency of assay.

(*5*) Acceptable ranges for any control or calibration material included with the test system.

(*6*) Action to be taken when calibration or control results do not meet acceptable range of values.

(*7*) The correct interpretation of test reactions or endpoints.

(*8*) Description of course of action to be taken when test reactions or endpoints cannot be determined.

(*9*) Any limitations to methodologies.

(iii) Field studies that meet the following requirements:

(A) Demonstrate that the manufacturer's or producer's written instructions are the only protocols required to perform the test accurately and reliably.

(B) Demonstrate that individuals with no formal laboratory training can correctly perform the test.

(iv) Data from field studies that meet the following requirements:

(A) Are generated from protocols that address the points described in paragraph (b)(2)(iii) of this section.

(B) Are adequate to produce measures of performance that are both statistically valid and defensible.

(C) Confirm that study participants are able to read and interpret test endpoints with the same precision as laboratory professionals.

(D) Confirm that the performance of study participants is essentially the same as laboratory professionals when testing samples at or near the cutoff and at sufficient distance above and below the cutoff to confirm precision at all analytical decision points.

(E) Demonstrate minimal among-operator imprecision using results of all study participants.

(F) Demonstrate minimal within-site imprecision using test results generated at each site by an adequate number of participants to produce measures of performance that are statistically valid and defensible. Testing must be performed at a minimum of three independent study sites.

(G) Using results generated by study participants, demonstrate minimal among-site imprecision at an adequate number of sites to produce measures of performance that are statistically valid and defensible.

(v) Method accuracy studies demonstrating that there is no statistically significant difference between observed values and expected values at the cutoff point when—

(A) The test values are compared to a quantitative result such as the value of a reference material or the presence or absence of a particular biologic component;

(B) Confirming that there are no significant equivocal test results on either side of the cutoff;

(C) Comparing results between study participants and laboratory professionals on samples with values at the cutoff;

(D) The test is performed on patient samples instead of reference materials, confirming there is no introduction of error due to sample matrix; and

(E) Samples contain substances that commonly cause interference confirming there is no introduction of error because of these substances.

(c) *Provisions for inclusion of tests in the APT subcategory*—(1) *Process for requesting APT categorization.*

(i) Requests for APT categorization must be submitted to PHS.

(ii) PHS reviews requests for APT categorization that meet the criteria specified in paragraph (b) of this section and the submission requirements under paragraph (c)(2) of this section.

(iii) The CLIAC, as specified in subpart T of this part, conducts reviews upon the request of HHS and makes recommendations to HHS concerning APT test categorization.

(iv) Any change or modification to an APT test system by the manufacturer or producer that could affect the accuracy or reliability of that test must be resubmitted to PHS for evaluation and review. Until this review is completed and categorization status is determined, the modified test is considered uncategorized and, in accordance with § 493.17(c)(4), is considered high complexity.

(v) A request for reconsideration of a test denied APT categorization is accepted for review if the request is based on information not previously submitted.

(2) *Submission requirements.*

(i) Requests for APT categorization must meet the criteria described in paragraph (b) of this section. In the event that a request does not include complete information, the request is not reviewed and the manufacturer or producer of the test system is notified.

(ii) Data collection protocols and data submitted must be complete and data submitted must be statistically valid and meet the criteria described under paragraph (b) of this section.

(iii) Test system instructions must be complete and must include, as applicable, the items defined in paragraph (b)(1)(ii) of this section for quantitative tests and under paragraph (b)(2)(ii) of this section for qualitative tests. In addition, test system instructions must include the following statements:

(A) ''Any modification by the laboratory to the PHS-approved test system instructions will result in the test no longer meeting the requirements for APT categorization. Modified tests are considered high complexity and are subject to all applicable CLIA requirements contained in 42 CFR part 493.''

(B) ''The laboratory must notify the producer of this test system of any performance, perceived or validated, that does not meet the performance specifications as outlined in these instructions.'' The name, address and phone number(s) of the producer's contact person(s) must follow this statement.

(C) If applicable: ''Laboratories performing accurate and precise technology (APT) tests are subject to the proficiency testing (PT) requirements under 42 CFR part 493, subpart H of this part. The laboratory must enroll and successfully participate in an HHS-approved PT program.''

(iv) Patient test management protocols must be complete and include sufficient information to assist laboratories in meeting each of the requirements in subpart J of this part. These protocols must meet the following requirements:

(A) Clearly specify the instructions that must be followed by the laboratory to ensure proper specimen handling and accurate test result reporting and assist laboratories in meeting the requirements of subpart J of this part, including the following requirements listed in paragraphs (c)(2)(iv)(A)(*1*) through (c)(2)(iv)(A)(*4*) and (c)(2)(iv)(B) of this section, as applicable:

(*1*) Section 493.1103(a), procedures for specimen submission and handling, including protocols for preparation of patients, specimen collection, preservation, and conditions for specimen transport.

(*2*) Section 493.1105(f), any test requisition information that is relevant and necessary to a specific test to assure accurate testing and reporting of results.

(*3*) Sections 493.1107(c) and 493.1109(c), test records and test report information related to the criteria for specimen acceptability.

(*4*) Section 493.1109, test report information including the following information:

(*i*) Section 493.1109(d), pertinent ''reference'' or ''normal'' ranges.

(*ii*) Section 493.1109(f), any imminent life-threatening laboratory results or panic values.

(*iii*) Section 493.1109(g), the test methodology employed and any information that may affect the interpretation of test results.

(B) Provide information (for example, written instructions, instructional materials or samples of forms for documentation of activities performed) that laboratories may follow or supplement, in accordance with the test system's PHS-approved instructions, in meeting the requirements in subpart J of this part.

(v) Quality control instructions must include the following items:

(A) Protocols for documentation of all control and calibration results, any remedial action to be taken, and the appropriate record retention requirements as described at § 493.1221.

(B) Protocols for documentation of equipment maintenance performance and the appropriate record retention requirements as described at § 493.1221.

(C) Safety precaution instructions that cover any physical hazard or biohazardous material, including the proper handling and disposal of testing materials.

(D) Protocols for developing written procedures for the following activities:

(*1*) Determining specimen acceptability.

(*2*) Reporting patient test results, including suggested panic values, if applicable.

(*3*) The course of action to be taken in the event that a test system becomes inoperable.

(*4*) Referral of samples, as specified in § 493.1111, including procedures for specimen submission and handling as described in § 493.1103.

(E) Verification of method performance specifications and verification that the reference range is appropriate for the laboratory's patient population.

(vi) Quality assurance protocols must be complete and include sufficient information to assist laboratories in meeting each of the requirements in subpart P of this part. These protocols must meet the following requirements:

(A) Clearly specify the instructions that must be followed by the laboratory in establishing a comprehensive quality assurance program for monitoring and evaluating the overall quality of the total testing process (preanalytic, analytic, and postanalytic) and identifying and correcting problems based on the results of the evaluation to assure the accurate, reliable and prompt reporting of patient results and assist laboratories in meeting the requirements of subpart P of this part listed in paragraphs (c)(2)(vi)(A)(*1*) through (c)(2)(vi)(A)(*4*) and (c)(2)(vi)(B) of this section, and, as applicable, meet the requirements of the following sections:

(*1*) Section 493.1703, Patient test management assessment, including the following requirements:

(*i*) The criteria established for patient preparation, specimen collection, preservation and transportation.

(*ii*) The completeness and relevance of the information solicited on the laboratory's test requisition.

(*iii*) The use and appropriateness of the criteria established for specimen rejection.

(*iv*) The completeness, usefulness and accuracy of the test report information necessary for the interpretation or utilization of test results.

(*2*) Section 493.1705, Quality control assessment, including a mechanism to assess the effectiveness of the corrective actions taken in the following situations:

(*i*) Problems identified during the evaluation of calibration and control data for the test method.

(*ii*) Problems identified during the evaluation of patient test values for the purpose of ensuring the appropriateness of the reference range of the test method.

(*3*) Section 493.1709, Comparison of test results, including procedures for evaluating and defining the relationship between test results using different methodologies, instruments, or testing sites.

(*4*) Section 493.1711, Relationship of patient information to patient results, including procedures for identifying and evaluating patient test results that appear inconsistent with any relevant criteria specified in § 493.1711.

(B) Provide information (for example, written instructions, instructional materials, or samples of forms for documentation of activities performed) that laboratories may follow or supplement, in accordance with the test system's PHS-approved instructions, in meeting the requirements in subpart P of this part.

(3) *Notification of decision.*

(i) PHS determines whether a laboratory test meets the criteria listed under paragraph (b) of this section for an APT test.

(ii) PHS notifies the applicant of APT categorization, whether denied or granted.

(iii) APT categorization is effective as of the date of notification to the applicant.

(iv) PHS publishes additions and revisions periodically to tests categorized as APT in the **Federal Register** in a notice with opportunity for public comment. PHS reserves the right to reevaluate and recategorize a test based upon the comments it receives in response to the **Federal Register** notice.

6. In § 493.20, paragraphs (a) and (b) are revised to read as follows:

§ 493.20 Laboratories performing tests of moderate complexity.

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

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

* * * * *

7. A new § 493.21 is added to read as follows:

§ 493.21 Laboratories performing accurate and precise technology (APT) tests.

(a) A laboratory may qualify for a certificate to perform APT tests if it performs tests categorized by PHS as APT tests and no other procedures, except those specified as PPM procedures or those approved by PHS as waived tests.

(b) Laboratories performing APT tests must meet the following requirements:

(1) Follow each test system's PHS-approved instructions for performing the test; and

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

(c) If the laboratory also performs PPM procedures, the laboratory must meet the applicable requirements in subparts H, J, K, M, P, and Q of this part.

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

8. In § 493.25, paragraph (c) is revised to read as follows:

§ 493.25 Laboratories performing tests of high complexity.

* * * * *

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

* * * * *

9. The heading of subpart C is revised to read as follows:

Subpart C—Registration Certificate, Certificate for Provider-Performed Microscopy Procedures, Certificate for Accurate and Precise Technology Tests, and Certificate of Compliance

10. In § 493.43, the section heading and paragraph (a) are revised to read as follows:

§ 493.43 Application for registration certificate, certificate for provider-performed microscopy (PPM) procedures, certificate for accurate and precise technology (APT) tests, and certificate of compliance.

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

* * * * *

11. In § 493.45, the introductory paragraph is revised, the introductory text of paragraph (a) is republished, and paragraphs (a)(1) and (a)(2) are revised to read as follows:

§ 493.45 Requirements for a registration certificate.

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

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

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

* * * * *

12. A new § 493.48 is added to read as follows:

§ 493.48 Requirements for a certificate for accurate and precise technology (APT) tests.

(a) A certificate for APT tests is required for all laboratories that intend to perform only the following tests:

(1) Tests that have been categorized by PHS as APT tests.

(2) APT tests in addition to waived tests or PPM procedures.

(3) APT tests, waived tests and PPM procedures.

(b) HHS issues a certificate for APT tests if the laboratory meets the following requirements:

(1) Complies with the requirements of § 493.43 for applying for a certificate.

(2) Agrees to treat proficiency testing samples in the same manner as it treats patient specimens.

(3) Agrees to be inspected by HHS as specified in § 493.1778.

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

(c) A laboratory issued a certificate for APT tests is subject to the following requirements:

(1) The notification requirements of § 493.51.

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

(d) A laboratory requesting a certificate for APT tests that also

performs PPM procedures is subject to the following requirements:

(1) Ensuring that PPM procedures are performed only by individuals meeting the personnel requirements of subpart M of this part.

(2) Undergoing random inspections as specified in § 493.1778.

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

(f) A certificate for APT tests is valid for a period of no more than 2 years. A laboratory must follow the procedures established by HHS for renewal of this certificate.

13. Section 493.49 is amended by revising the introductory text and paragraphs (a) and (b) to read as follows:

§ 493.49 Requirements for a certificate of compliance.

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

(a) HHS issues a certificate of compliance to a laboratory only if the laboratory meets the following requirements:

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

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

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

(b) A laboratory issued a certificate of compliance must meet the following requirements:

(1) Meets the notification requirements of § 493.51.

(2) Permits announced or unannounced inspections by HHS in accordance with subpart Q of this part for the following reasons:

(i) Routine determination of compliance with the applicable requirements of this part.

(ii) Evaluation of complaints.

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

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

* * * * *

14. Section 493.51 is revised to read as follows:

§ 493.51 Notification requirements for laboratories issued a certificate for accurate and precise technology (APT) tests or a certificate of compliance.

Laboratories issued a certificate for APT tests or a certificate of compliance must meet the following requirements:

(a) Notify HHS or its designee within 30 days of any change in any of the following items:

(1) Ownership.

(2) Name.

(3) Location.

(4) Director.

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

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

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

(d) Notify HHS before performing and reporting results for tests not included under the certificate for APT tests (which are tests other than waived tests, PPM procedures, and APT tests) unless the laboratory has been issued a registration certificate as required in subpart C or subpart D of this part, as applicable.

15. Section 493.53 is amended by revising the introductory text and paragraph (a) to read as follows:

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

Laboratories issued a certificate for PPM procedures must notify HHS or its designee in the following situations:

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

* * * * *

16. In § 493.638, introductory paragraph (a) is revised, paragraph (a)(4) is redesignated as (a)(5), new paragraph (a)(4) is added, and paragraph (b) is revised to read as follows:

§ 493.638 Certificate fees.

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

* * * * *

(4) For a certificate for APT tests, the costs include issuing the certificate, collecting the fees, determining if a certificate for APT tests should be issued, evaluating which test systems qualify for inclusion in the subcategory of APT tests, and other direct administrative costs.

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

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

the time the application is received. Upon receipt of an application for a certificate, HHS or its designee notifies the laboratory of the amount of the required fee for the requested certificate.

17. In § 493.639, paragraphs (b) introductory text and (b)(1) are revised to read as follows:

§ 493.639 Fee for revised certificate.

* * * * *

(b) A laboratory must pay a fee to cover the cost of issuing a revised certificate in any of the circumstances specified in paragraphs (b)(1) and (b)(2) of this section.

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

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

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

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

* * * * *

18. In § 493.643, paragraph (a) is revised to read as follows:

§ 493.643 Fee for determination of program compliance.

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

* * * * *

19. In section 493.645, the heading is revised, paragraph (c) is redesignated as (d) and revised, and a new paragraph (c) is added:

§ 493.645 Additional fee(s) applicable to approved State laboratory programs and laboratories issued certain certificates.

* * * * *

(c) *Laboratories with a certificate for APT tests.*

(1) In addition to the certificate fee, a laboratory requesting a certificate for APT tests is also assessed a fee representing the cost to HHS of random inspections to determine compliance with CLIA requirements. All laboratories issued a certificate for APT tests will share in the cost of these inspections.

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

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

20. The heading of subpart H is revised to read as follows:

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

21. Section 493.803(a) is revised to read as follows:

§ 493.803 Condition: Successful participation.

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

* * * * *

22. The heading of § 493.807 is revised to read as follows:

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

* * * * *

23. The undesignated center heading immediately preceding § 493.821 is revised to read as follows:

Proficiency Testing by Specialty and Subspecialty for Laboratories Performing Tests of Moderate Complexity (Including the Subcategories), High Complexity, or Any Combination of These Tests

24. The heading to subpart I is revised to read as follows:

Subpart I—Proficiency Testing Programs for Tests of Moderate Complexity (Including the Subcategories), High Complexity, or any Combination of These Tests

25. The heading to subpart J is revised to read as follows:

Subpart J—Patient Test Management for Moderate Complexity (Including the Subcategories), High Complexity, or any Combination of These Tests

26. Section 493.1101 is revised to read as follows:

§ 493.1101 Condition: Patient test management; moderate complexity (including the subcategories), high complexity testing, or any combination of these tests.

Each laboratory performing moderate complexity (including the subcategories) or high complexity testing, or any combination of these tests, must employ and maintain a system that provides for proper patient preparation; proper specimen collection, identification, preservation, transportation, and processing; and accurate result reporting. This system must assure optimum patient specimen integrity and positive identification throughout the preanalytic (pre-testing), analytic (testing), and postanalytic (post-testing) processes and must meet the standards as they apply to the testing performed.

27. A new § 493.1102 is added to read as follows:

§ 493.1102 Standard; Patient test management requirements for accurate and precise technology (APT) tests.

For each APT test performed, the laboratory must meet all applicable patient test management requirements specified in §§ 493.1103 through 493.1111. The laboratory meets these requirements by doing both of the following activities:

(a) Having available and following the test system's PHS-approved instructions and, as appropriate, any supplements to the procedures established by the laboratory in accordance with the test system's PHS-approved instructions.

(b) Maintaining all records documenting compliance with paragraph (a) of this section for 2 years.

28. The heading to subpart K is revised to read as follows:

Subpart K—Quality Control for Tests of Moderate Complexity (Including the Subcategories), High Complexity, or any Combination of These Tests

29. Section 493.1201 is amended by revising paragraph (a) introductory text and paragraph (b) and by adding paragraph (c) to read as follows:

§ 493.1201 Condition: General quality control; Moderate complexity (including the subcategories) or high complexity testing, or any combination of these tests.

(a) *General.* Subpart K of this part is divided into two sections, general quality control and quality control for specialties and subspecialties. The quality control requirements are specified in §§ 493.1201 through 493.1285 unless—

* * * * *

(b) *Applicability of subpart K to moderate complexity (excluding APT tests) and high complexity tests.* The laboratory must establish and follow written quality control procedures for monitoring and evaluating the quality of the analytical testing process of each method to assure the accuracy and reliability of patient test results and reports. The laboratory must meet the applicable general quality control standards in §§ 493.1202 through 493.1221, unless an alternative procedure specified in the manufacturer's protocol has been cleared by the Food and Drug Administration (FDA) as meeting certain CLIA requirements for quality control or HHS approves an equivalent procedure specified in appendix C of the State Operations Manual (HCFA Pub. 7). HCFA Pub. 7 is available from the National Technical Information Service, U.S. Department of Commerce, 5825 Port Royal Road, Springfield, VA 22161, telephone number (703) 487–4630.

(c) *Applicability of subpart K to APT testing.* The laboratory must follow each test system's PHS-approved written instructions for monitoring and evaluating the quality of the analytical testing process to assure the accuracy and reliability of patient test results and reports. For each APT test, the laboratory must meet the quality control requirements of § 493.1204.

30. In § 493.1202, the introductory text of paragraph (c) is revised to read as follows:

§ 493.1202 Standard; Moderate or high complexity testing, or both: Effective from September 1, 1992 to September 1, 1996.

* * * * *

(c) For all other tests of moderate complexity, excluding the subcategory of APT testing, performed using an instrument, kit, or test system cleared by the FDA through premarket notification (510(k)) or the premarket approval (PMA) process for in-vitro diagnostic use, the laboratory must—

* * * * *

31. Section 493.1203 is amended by revising the introductory text to read as follows:

§ 493.1203 Standard; Moderate complexity (excluding accurate and precise technology (APT) tests) or high complexity testing or both: Effective September 1, 1996.

For each moderate complexity (excluding APT tests) or high complexity test performed, the laboratory is in compliance with this section if it—

* * * * *

§ 493.1204 [Redesignated as § 493.1206]

32. Section 493.1204 is redesignated as § 493.1206.

33. New § 493.1204 is added to read as follows:

§ 493.1204 Standard; Quality control requirements for accurate and precise technology (APT) tests.

For each APT test performed, the laboratory is in compliance with this subpart if it meets all applicable quality control requirements in this section. The laboratory must meet the following requirements:

(a) Have available and follow each test system's PHS-approved written instructions, which include the following protocols:

(1) Safety precautions.

(2) Protocols for instrument or test system operation and test performance, including maintenance and function checks.

(3) Calibration procedures.

(4) Quality control procedures defined by the manufacturer or producer of the test system, which include running at least two levels of control each day of testing to monitor all steps in the testing process, including the extraction phase if applicable, unless one of the following circumstances applies:

(i) The test system's PHS-approved instructions specify other than two levels of control.

(ii) The procedure cannot be controlled by conventional procedures and an alternative means of controlling the system has been approved by PHS.

(5) Remedial action procedures.

(b) Ensure that it meets the following requirements:

(1) It has available and follows written procedures, based on each test system's PHS-approved instructions, as applicable, for the following procedures:

(i) Determining specimen acceptability.

(ii) Reporting patient test results, including panic values (values requiring immediate medical intervention).

(iii) Course of action to be taken in the event that a test system becomes inoperable.

(iv) Referral of samples as specified in § 493.1111, including procedures for specimen submission and handling, as described in § 493.1103.

(2) The written procedures, whether provided by the manufacturer, the test system producer, or the laboratory, are approved, signed and dated by the current director of the laboratory.

(3) Any change to a procedure by the manufacturer or producer of a test system is approved by PHS and signed and dated by the laboratory director for use by laboratory personnel.

(4) Any change to a laboratory's protocol designed to meet the requirements is approved, signed and dated by the laboratory director.

(5) A copy of each procedure with the dates of initial use and discontinuance is retained for 2 years after a procedure has been discontinued.

(c) Before reporting patient results, using at least the test system's PHS-approved written instructions, verify that it can obtain performance specifications for accuracy, precision and reportable range of patient results that meet those established by the manufacturer or producer of the test system. The laboratory must also ensure that the laboratory's patient population is included in the reference range specified in the PHS-approved instructions.

(d) Document all remedial actions taken—

(1) In accordance with the test system's PHS-approved written instructions; and

(2) When errors in the reported patient test results are detected. In such a case, the laboratory must perform the following procedures:

(i) Promptly notify the authorized person ordering the test or individual using the test results of report errors.

(ii) Issue corrected reports promptly to the authorized person ordering the test or the individual using the test results.

(iii) Maintain exact duplicates of the original erroneous report as well as the corrected report for 2 years.

(e) Document and maintain records of all quality control activities specified in this section and retain records for at least 2 years or longer as specified by the manufacturer or producer of the test system in accordance with § 493.1221.

(f) Promptly report any inaccurate or imprecise method performance, whether perceived or validated, to the manufacturer or producer of the test system and, if the problem is not rectified, to PHS.

(g) Ensure that no modification is made in the test system's PHS-approved written instructions. Any changes made to the test system will result in the test system no longer meeting the requirements for categorization in the APT category. Modified tests are considered high complexity and are subject to the applicable CLIA quality control requirements contained in subpart K of this part, as well as all other applicable requirements for high complexity testing.

34. The heading to subpart M is revised to read as follows:

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

35. Section 493.1351 is revised to read as follows:

§ 493.1351 General.

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

36. Following § 493.1365, a new undesignated center heading and new §§ 493.1371 through 493.1387 are added to read as follows:

Laboratories Performing Accurate and Precise Technology (APT) Tests

Sec.

Laboratories Performing Accurate and Precise Technology (APT) Tests

§ 493.1371 Condition: Laboratories performing APT tests; Laboratory director.

The laboratory must have a director who meets the qualification requirements of § 493.1373 and provides overall management and direction in accordance with § 493.1375.

§ 493.1373 Standard; Laboratory director qualifications.

The laboratory director must be qualified to manage and direct the laboratory personnel and the performance of APT tests and must be eligible to be an operator of a laboratory within the requirements of subpart R of this part and meet the requirements of § 493.1405, which contain laboratory director qualifications for moderate complexity testing.

§ 493.1375 Standard; Laboratory director responsibilities.

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform APT tests in accordance with each test system's PHS-approved instructions, and record and report test results promptly, accurately, and proficiently, and for assuring compliance with applicable regulations.

(a) The laboratory director, if qualified, may perform the duties of the clinical consultant and testing personnel or may delegate these responsibilities to personnel meeting the qualification requirements of §§ 493.1379 and 493.1385, respectively.

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

(c) No individual may direct more than five laboratories.

(d) The laboratory director must meet the following requirements:

(1) Ensure that testing systems selected for each of the tests performed in the laboratory are appropriate for the clinical use of the test results.

(2) Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed and provide a safe environment in which employees are protected from physical, chemical, and biological hazards.

(3) Ensure that the following requirements are met:

(i) Before reporting patient results, using at least the test system's PHS-approved verification procedure, the laboratory can obtain or verify performance specifications for accuracy, precision and reportable range of patient results that meet those established by the manufacturer or producer of the test system and can ensure that the reference range specified by the manufacturer or producer of the test system is appropriate for the laboratory's patient populations.

(ii) Testing personnel are following test analyses and quality control procedures in accordance with each test system's PHS-approved instructions.

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

testing performed and that the laboratory meets the following requirements:

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

(ii) The results are returned within the time frames established by the proficiency testing program.

(iii) All proficiency testing reports received are reviewed to evaluate the laboratory's performance and to identify any problems that require corrective action.

(iv) An approved corrective action plan is followed and documented when any proficiency testing results are found to be unacceptable or unsatisfactory.

(5) Ensure that a quality assurance program is established and maintained to assure the quality of laboratory services provided.

(6) Ensure that all necessary remedial actions are taken and documented and that patient results are reported only when the test system is functioning properly.

(7) Ensure that the producer or manufacturer of the test system is notified when the test system does not meet the performance specifications as outlined in the test system's PHS-approved instructions and, if the problem is not rectified, notify PHS.

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

(9) Ensure that consultation is available to the laboratory's clients on matters relating to the results of APT tests reported and their interpretation concerning specific patient conditions, including any relevant information provided in the test system's PHS-approved instructions.

(10) Employ a sufficient number of testing personnel with the appropriate education and either experience or training to perform tests and report test results in accordance with the personnel responsibilities described in this subpart.

(11) Ensure that, before they test patient samples, testing personnel receive the appropriate training for the services offered and have demonstrated that they can perform all testing operations, in accordance with each test system's PHS-approved instructions, to provide and report accurate results.

(12) Ensure that policies and procedures are established for evaluating and documenting the performance of testing personnel responsible for APT testing to ensure that they are competent and maintain their competency to handle specimens, perform test procedures, report test results promptly and proficiently, and, whenever necessary, identify needs for remedial training or continuing education to improve testing skills. The director must ensure that evaluations are conducted at least semiannually during the first year the individual tests patient specimens and that, thereafter, the evaluations are performed at least annually unless test methodology or instrumentation changes, in which case, before reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. The evaluation of the competency of testing personnel must include at least one or more of the following, but is not limited to the following procedures:

(i) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, and testing.

(ii) Monitoring the recording and reporting of test results.

(iii) Review of work sheets, quality control records, proficiency testing results, and preventive maintenance records.

(iv) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples.

(13) Ensure that an approved procedure manual is available to all testing personnel.

(14) Specify, in writing, the responsibilities and duties of each person engaged in the performance of APT testing that identifies which examinations and procedures each individual is authorized to perform.

§ 493.1377 Condition: Laboratories performing APT testing; clinical consultant.

The laboratory must have a clinical consultant who meets the qualification requirements of § 493.1379 and provides clinical consultation in accordance with § 493.1381.

§ 493.1379 Standard; Clinical consultant qualifications.

The clinical consultant must be qualified to consult with and furnish opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must meet the requirements of § 493.1417, Clinical consultant qualifications for moderate complexity testing.

§ 493.1381 Standard; Clinical consultant responsibilities.

The clinical consultant provides consultation regarding the appropriateness of the testing ordered and interpretation of test results. The clinical consultant must meet the following requirements:

(a) Be available to provide clinical consultation to the laboratory's clients.

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

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

(d) Ensure that consultation is available and communicated to the laboratory's clients on matters related to the results of APT tests reported and their interpretation concerning specific patient conditions, including any relevant information provided in the test system's PHS-approved instructions.

§ 493.1383 Condition: Laboratories performing APT testing; testing personnel.

The laboratory must have a sufficient number of individuals who meet the qualification requirements of § 493.1385 to perform the functions specified in § 493.1387 for the volume of tests performed.

§ 493.1385 Standard; Testing personnel qualifications.

Each individual performing APT testing must meet the following requirements:

(a) Possess a current license issued by the State in which the laboratory is located, if such licensing is required.

(b) Meet one of the following requirements:

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

(2) Have earned an associate degree in a chemical, physical, or biological science, or in medical laboratory technology from an accredited institution.

(3) Be a high school graduate or equivalent and have successfully completed an official U.S. military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician).

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

(ii) Have documentation of training appropriate for the APT testing performed before analyzing patient

specimens. This training must ensure that the individual has the following skills and knowledge:

(A) The skills required for proper specimen collection, including patient preparation (if applicable), labeling, handling, preservation, transportation and storage of specimens.

(B) The skills required for performing each test method and control procedure and for proper instrument use.

(C) The skills required for performing preventive maintenance, troubleshooting and calibration procedures related to each test performed.

(D) An awareness of the factors that influence test results.

§ 493.1387 Standard; Testing personnel responsibilities.

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

(a) Each individual performs only those APT tests that they are authorized by the laboratory director to perform.

(b) Each individual performing APT testing must meet the following requirements:

(1) Follow each test system's PHS-approved written instructions and, as applicable, the laboratory's written policies and procedures for specimen submission and handling and for reporting and maintaining records of patient test results.

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

(3) Adhere to each test system's PHS-approved written instructions for quality control procedures, including the documentation of all quality control activities, remedial actions, instrument and procedural calibrations, and maintenance performed.

(4) Be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the director.

(5) Notify the director of any test system performance that does not meet the performance specifications as outlined in the test system's PHS-approved instructions.

37. The heading to subpart P is revised to read as follows:

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

§ 493.1701 [Amended]

38. Section 493.1701 is amended by revising the word ''subcategory'' to read ''subcategories'' wherever it appears in the heading and text.

39. A new § 493.1702 is added to read as follows:

§ 493.1702 Standard; Quality Assurance for accurate and precise technology (APT) tests.

For each APT test performed, the laboratory must meet all applicable quality assurance requirements specified in §§ 493.1703 through 493.1721. The laboratory meets these requirements by doing both of the following activities:

(a) Having available and following the test system's PHS-approved instructions and, as appropriate, any supplements to the procedures established by the laboratory in accordance with the test system's PHS-approved instructions.

(b) Maintaining all records documenting compliance with paragraph (a) of this section for 2 years.

40. In § 493.1777 the introductory text is revised to read as follows:

§ 493.1777 Condition: Inspection of laboratories requesting or issued a certificate of compliance.

Laboratories requesting a certificate of compliance must permit an inspection to assess compliance with part 493 of this chapter. All testing conducted, including testing in the subcategories of APT tests or PPM procedures, may be included in the laboratory's routine or complaint inspection. APT tests and PPM procedures are assessed for compliance with only the applicable requirements specific to those subcategories of testing.

* * * * *

41. A new § 493.1778 is added to read as follows:

§ 493.1778 Condition: Inspection of laboratories issued a certificate for accurate and precise technology (APT) tests.

(a) HHS or its designee may conduct announced or unannounced inspections of any laboratory issued a certificate for APT tests at any time during its hours of operation for the following purposes:

(1) Assess compliance with the following circumstances, as applicable:

(i) On a random basis.

(ii) Following a laboratory's demonstration of unsuccessful participation in proficiency testing for analytes specified in subpart I of this part.

(iii) To evaluate complaints from the public.

(2) Determine whether testing is being performed or the laboratory is being operated in a manner that does not constitute an imminent and serious risk to public health.

(3) Collect information to determine the appropriateness of tests categorized as APT tests according to the criteria listed at § 493.18.

(4) Determine whether the laboratory is performing tests in addition to tests categorized as APT tests according to the criteria listed at § 493.18, specified as PPM procedures, or tests approved by PHS as waived tests that are not included on the laboratory's certificate.

(b) The laboratory may be required as part of this inspection to perform or authorize the following activities:

(1) Test samples (including proficiency testing samples) or perform procedures as HHS or its designee requires.

(2) Allow HHS or its designee to interview all employees of the laboratory concerning the laboratory's compliance with the applicable requirements as noted in paragraph (d) of this section.

(3) Permit employees to be observed performing tests (including proficiency testing specimens), data analysis and reporting.

(4) Permit HHS or its designee access to all areas of the facility, including the following areas:

(i) Specimen procurement and processing areas.

(ii) Storage facilities for specimens, reagents, supplies, records, and reports.

(iii) Testing and reporting areas.

(5) Provide copies to HHS or its designee of all records and data required under this part.

(c) The laboratory must have all records and data accessible and retrievable within a reasonable time frame during the inspection.

(d) Applicable requirements for the purpose of this section are located in subparts C, H, J, K, M, and P of this part and § 493.21.

(e) The laboratory must provide upon reasonable request all information and data needed by HHS or its designee to make a determination of compliance with the applicable requirements.

(f) HHS or its designee may reinspect a laboratory at any time necessary to assess the laboratory's compliance with the applicable requirements.

(g) Failure to permit an inspection under this section will result in the suspension of Medicare and Medicaid payments to the laboratory or

termination of the laboratory's participation in Medicare and Medicaid for payment, and suspension of, or action to revoke, the laboratory's CLIA certificate in accordance with subpart R of this part.

42. In § 493.1814, the text of the introductory text of paragraph (b) is republished and paragraph (b)(3) is revised to read as follows:

§ 493.1814 Action when deficiencies are at the condition level but do not pose immediate jeopardy.

* * * * *

(b) *Failure to correct condition level deficiencies.* If HCFA imposes alternative sanctions for condition level deficiencies that do not pose immediate jeopardy and the laboratory does not correct the condition level deficiencies within 12 months after the last day of inspection, HCFA—

* * * * *

(3) May impose (or continue, if already imposed) any alternative sanctions that do not pertain to Medicare payments. (Sanctions imposed under the authority of section 353 of the PHS Act may continue for more than 12 months from the last date of inspection, while a hearing on the proposed suspension, limitation, or revocation of the certificate of compliance, registration certificate, certificate of accreditation, certificate for APT tests, or certificate for PPM procedures is pending.)

* * * * *

43. In § 493.1834, the heading and introductory text of paragraph (f)(2) are republished and paragraphs (b) and (f)(2)(iii) are revised to read as follows:

§ 493.1834 Civil money penalty.

* * * * *

(b) *Scope.* This section sets forth the procedures that HCFA follows to impose a civil money penalty in lieu of, or in addition to, suspending, limiting, or revoking the certificate of compliance, registration certificate, certificate of accreditation, certificate for APT tests, or certificate for PPM procedures of a laboratory that is found to have condition level deficiencies.

* * * * *

(f) *Accrual and duration of penalty.*

* * *

(2) *Duration of penalty.* The civil money penalty continues to accrue until the earliest of the following occurs:

* * * * *

(iii) HCFA suspends, limits, or revokes the laboratory's certificate of compliance, registration certificate, certificate of accreditation, certificate for APT tests, or certificate for PPM procedures.

* * * * *

44. In § 493.1836, the heading of paragraph (c) is republished and paragraphs (c)(2) and (c)(3) are revised to read as follows:

§ 493.1836 State onsite monitoring.

* * * * *

(c) *Duration and sanction.* * * *

(2) If the laboratory does not correct all deficiencies within 12 months, and a revisit indicates that deficiencies remain, HCFA cancels the laboratory's approval for Medicare payment for its services and notifies the laboratory of its intent to suspend, limit, or revoke the laboratory's certificate of compliance, registration certificate, certificate of accreditation, certificate for APT tests, or certificate for PPM procedures.

(3) If the laboratory still does not correct its deficiencies, the Medicare sanction continues until the suspension, limitation, or revocation of the laboratory's certificate of compliance, registration certificate, certificate of accreditation, certificate for APT tests, or certificate for PPM procedures is effective.

45. In § 493.2001, the introductory text of paragraph (e) is republished and paragraph (e)(1) is revised to read as follows:

§ 493.2001 Establishment and function of the Clinical Laboratory Improvement Advisory Committee.

* * * * *

(e) The Clinical Laboratory Improvement Advisory Committee or subcommittee at the request of HHS will review and make recommendations concerning—

(1) Criteria for categorizing tests and examinations of moderate complexity (including the subcategories) and high complexity;

* * * * *

Authority: Sec. 353 of the Public Health Service Act (42 U.S.C. 263a)

Dated: May 25, 1995.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

Dated: May 26, 1995.

Philip R. Lee,

Assistant Secretary for Health.

Dated: June 5, 1995.

Donna E. Shalala,

Secretary.

[FR Doc. 95–22861 Filed 9–14–95; 8:45 am]

BILLING CODE 4120–01–P