DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 493

[CMS–2252–P]

RIN 0938–A034

Medicare, Medicaid, and Clinical Laboratory Improvement Amendments of 1988 (CLIA) Program; Cytology Proficiency Testing (PT)

AGENCIES: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would amend the Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations for cytology proficiency testing (PT), to reflect changes in cytology laboratory operations and practices. The proposed changes are based on recommendations received from the Clinical Laboratory Improvement Advisory Committee (CLIAC), input from the professional community, and government experience with the implementation of cytology PT. The proposed changes would amend certain definitions, lengthen the testing interval, require validation of cytology challenges before use in testing, increase the minimum number of cytology challenges per testing event, change the grading scheme, and allow flexibility to accommodate new technologies (for example, digital images, as they are implemented in cytology laboratory practice).

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on March 17, 2009.

ADDRESSES: In commenting, please refer to file code CMS–2252–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov*. Follow the instructions under the ''More Search Options'' tab.

2. *By regular mail.* You may mail written comments to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, *Attention:* CMS–2252–P, P.O. Box 8016, Baltimore, MD 21244–1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, *Attention:* CMS–2252–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original) before the close of the comment period to either of the following addresses:

a. Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey (HHH) Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by following the instructions at the end of the ''Collection of Information Requirements'' section in this document.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Nancy Anderson, CDC, (404) 498–2280. Judy Yost, CMS, (410) 786–3531.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov*. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

I. Background

A. Origin for Cytology PT

In 1987, articles in The Wall Street Journal questioned the competence of laboratories that examined Papanicolaou (Pap) smears and attributed misdiagnosed cases of cancer to ''excessive workloads of cytotechnologists, lack of quality control procedures, and poorly educated personnel.'' Walt Bogdanovich, Lax Laboratories: the Pap Test Misses Much Cervical Cancer Through Labs' Errors, The Wall Street Journal, November 2, 1987, at A:1, Column 6. Walt Bogdanovich, Physicians' Carelessness with Pap Tests is cited *in Procedure's High Failure Rate,* The Wall Street Journal. December 29, 1987, at A:17, Column 4.

Following the public outcry, Congress held hearings in both the House of Representatives and the Senate in the spring of 1988. The House of Representatives Committee on Energy and Commerce's report on the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100–578, stated ''The Committee does not intend for the Secretary to exempt analytes from proficiency testing merely because such testing is not currently available or because it is difficult to obtain consensus of the best method of proficiency testing,'' as is the case with cytology PT. *See,* H.R. Rep. No. 100–899, at p. 31 (1988), *reprinted in* 1988 U.S.C.C.A.N. 3828, 3850. The Secretary was specifically instructed to ''develop, or foster the development of, a proficiency test for cytology slides and to conduct, or require approved proficiency testing agencies to conduct, some onsite proficiency testing''. Id. at 3852. The corresponding Senate report stated that a ''* * * lack of a national proficiency testing system is of particular concern in the area of cytology * * * and that lack of a Federal proficiency testing requirement and other quality assurance standards for cytology may endanger the health of

American women.'' *See,* S. Rep. No. 561, 100th Cong., 2nd Sess. 3–4 (1988).

B. Statutory History

The CLIA amended section 353 of the Public Health Service Act (PHSA) (42 U.S.C. 263a). Among other things, CLIA established minimum standards for all clinical laboratories in the United States performing testing on human specimens for health purposes. The CLIA statute required the Secretary of the Department of Health and Human Services (HHS) to develop standards that included personnel qualifications and quality control and quality assurance procedures, and required PT as one measure of ensuring quality laboratory testing. The general laboratory PT requirements at section 353(f)(3)(A) state: ''The Secretary shall establish standards for the proficiency testing programs * * * The testing shall be conducted on a quarterly basis, except where the Secretary determines for technical and scientific reasons that a particular examination or procedure may be tested less frequently (but not less often than twice per year).'' The cytology PT requirements at section 353(f)(4)(B)(iv) vary from the general laboratory PT requirements. They require ''periodic confirmation and evaluation of the proficiency of individuals involved in screening or interpreting cytological preparations, including announced and unannounced on-site proficiency testing of such individuals, with such testing to take place, to the extent practicable, under normal working conditions.''

C. Initial Efforts to Implement Cytology PT

1. Proposed Rule Implementing Cytology PT

In implementing these statutory requirements, CMS proposed cytology PT standards keyed to the individuals who perform the cytology examinations, in accordance with section 353(f)(4)(B)(iv).

On May 21, 1990, we published a proposed rule in the **Federal Register** (55 FR 20896), to establish requirements for CMS approval of PT programs including gynecologic cytology. The rule proposed that programs would be required to use 20 glass slides to test the proficiency of individuals examining Pap smears twice a year. To ensure that all individuals would be able to be tested twice each year, CMS-approved cytology PT programs would be required to provide one unannounced on-site testing event in each laboratory, and no fewer than four announced testing events in each State on an annual basis. CMS would designate the testing sites. The glass slides were to be referenced with a minimum 80 percent agreement in a scientifically defensible manner by at least five physicians certified in anatomic pathology. The diagnosis of each glass slide was to be placed into one of four categories that were based on 1988 Bethesda System terminology (that is, unsatisfactory, normal or negative (infection, reactive and reparative changes), low grade squamous cell abnormalities and high grade squamous cell abnormalities (which also included glandular cell abnormalities and non-epithelial malignant neoplasm). Test slides demonstrating premalignant and malignant lesions were to be confirmed by biopsy with an 80 percent consensus agreement of at least five physicians.

The proposed rule envisioned cytology PT programs using one grading scheme for both pathologists and cytotechnologists. This grading system was to award −1 to 2 points per challenge. The individual's score was to be calculated by adding the point values achieved for each slide, dividing it by the total points for the testing event, and multiplying it by 100. For a 100 point test, the proposed passing score was 80 percent. A rescreen of 500 slides was proposed for any individual who failed the first test event. Any cytotechnologist who failed also had to receive immediate remedial training and education.

In response to the proposed rule, we received 900 letters containing approximately 1700 comments on cytology PT participation and 470 comments on the proposed requirements for approval of cytology PT programs. The major issues identified in the comments to the cytology PT proposed rule were: Biannual testing of individuals rather than testing the laboratory; announced on-site PT versus mailed PT; content of a PT event (number of slides, test material); evaluation of pathologists and cytotechnologists in the same manner, rather than in the context of duties performed; use of the 1988 Bethesda System for reporting PT results; and remedial education and rescreening requirements following failure of a single PT event.

2. Final Rule With Comment

On February 28, 1992, we published a final rule with comment in the **Federal Register** (57 FR 7002). The provisions established in that final rule with comment are still in effect. In response to the public comments on the proposed rule, and based on the experience of State cytology PT programs, we established various requirements at 42 CFR part 493. Section 493.855 requires each laboratory to ensure that each individual examining gynecologic cytology preparations enrolls in a CMS-approved PT program by January 1, 1995, if a program is available, and, participates in at least one (announced or unannounced) PT event per year and obtains a passing score. Testing must be offered on-site at least once per year in each laboratory using a 10 glass slide test set. Individuals must score at least 90 percent to successfully complete the test. Any individual who does not score at least 90 percent on the first testing event must be retested using a 10 slide test within 45 days.

If the individual does not score at least 90 percent on the second testing event, the laboratory must provide him or her with documented remedial training in the area of failure and must ensure that all gynecologic preparations examined by this individual subsequent to the notice of failure are re-examined by someone in the laboratory who obtained at least 90 percent on the cytology PT during the current year. The individual must be retested with a 20 slide test set and score at least 90 percent in order to pass the PT event. If the individual does not score at least 90 percent on the third test, the individual must cease examining patient gynecologic slide preparations immediately upon notification of test failure and not resume examining gynecologic slides until the laboratory ensures the individual obtains at least 35 hours of documented formally structured continuing education. The individual must then be retested on a 20 slide test set and score at least 90 percent to pass the test. As provided for at 42 CFR 493.855, ''[i]f a laboratory fails to ensure that individuals are tested or those who fail a testing event are retested, or fails to take required remedial actions * * * CMS will initiate intermediate sanctions or limit the laboratory's certificate to exclude gynecologic cytology testing under CLIA, and, if applicable, suspend the laboratory's Medicare and Medicaid payments for gynecologic cytology testing in accordance with subpart R of this part.'' The individual may be retested indefinitely after a third failure, but may not resume examining gynecologic specimens until he or she scores at least 90 percent.

Section 493.945 of Subpart I, ''Proficiency Testing Programs for Nonwaived Testing,'' describes requirements for CMS approval of gynecologic cytology PT programs. To be approved, each program must

provide 10 and 20 glass slide test sets that represent the four diagnostic categories (unsatisfactory, negative-benign, low grade squamous intraepithelial lesions, and high grade squamous intraepithelial lesions) as defined in § 493.945(b)(3)(ii)(A), and the test sets must be comparable to ensure equitable testing within and between PT programs. The programs are required to provide on-site testing for each individual enrolled at least once per year including announced and unannounced testing events, and must provide retesting for those individuals who fail any testing event. Technical supervisors (pathologists), who do not perform primary screening (that is, who only examine slides after they have been prescreened by a cytotechnologist) may be tested on slides that have been prescreened to locate potentially abnormal cells by a cytotechnologist who examines slides in their laboratory. There are separate scoring schemes for cytotechnologists and technical supervisors that award −5 to 10 points based on the proximity of the individual's response to the correct response. Individuals receive a maximum of 10 points for every correct response. One provision requires deducting 5 points from an individual who responds that a slide is negative when the correct response is a high grade squamous intraepithelial lesion (HSIL) or cancer (Category D). (An HSIL or cancer (Category D) lesion is one that would require immediate follow-up and treatment due to its severity including: Moderate dysplasia, severe dysplasia, or carcinoma-in-situ or a cancer.) This individual would obtain a score of less than 90 percent even if every other slide in the test set was correctly identified resulting in test failure. In this case, the individual would score 90 points for 9 correct responses and −5 points for incorrectly identifying an HSIL or cancer (Category D) as normal or benign. (The final score would be calculated by deducting 5 points from 90 points for a total of 85 points.)

3. Response to Comments to the February 28, 1992 Final Rule With Comment

Following publication of the February 28, 1992 final rule with comment, we received nearly 300 comments on the cytology PT requirements. Approximately 90 comments addressed participation in cytology PT and over 200 comments addressed the cytology PT programs. The majority of the commenters stated opposition to the cytology PT requirements, and voiced concern about the feasibility and costs associated with the development of a national glass slide PT program that included on-site testing of individuals. Some comments stated that national testing of individuals could not be achieved using glass slides. One organization suggested using media other than glass slides for testing. Other commenters were opposed to the frequency of annual testing, the 90 percent passing score, inclusion of unsatisfactory in the response categories, and grading cytotechnologists in any manner other than based on their ability to separate unsatisfactory or negative categories from those requiring review by the technical supervisor.

4. Final Rule Extending Cytology PT Enrollment Date

As of January 1, 1994, (the enrollment deadline specified in the February 28, 1992 final rule with comment), no cytology PT program had met the CLIA requirements for approval. On December 6, 1994, we published a final rule with comment (59 FR 62606) in the **Federal Register**, to allow additional time for programs to seek approval as a cytology PT provider, and to allow individuals an extension of the compliance date for enrollment in a CMS-approved cytology PT program.

The December 6, 1994 final rule with comment changed the compliance date for cytology PT enrollment from January 1, 1994 to January 1, 1995. Under that rule, enrollment was required by the compliance date if a CMS-approved program was available in the State in which the individual was employed. For individuals engaged in the examination of gynecologic cytology preparations who were employed in a State in which a CMS-approved cytology PT program was not available beginning January 1, 1995, enrollment and participation in a CMS-approved cytology PT program would be required at the point that a program became available.

5. Litigation Regarding the February 28, 1992 Regulations

On January 14, 1993, the Consumer Federation of America and Public Citizen filed a lawsuit in the United States District Court for the District of Columbia (the Court), challenging the HHS implementation of CLIA (*Consumer Federation of American and Public Citizen* v. *HHS,* 906 F. Supp., 657 (D. D.C. 1995), reversed in part and remanded in part). Among other things, plaintiffs argued that the cytology PT regulations violated the statutory mandate for cytology PT to ''* * * take place, to the extent practicable, under normal working conditions, * * *'' The plaintiffs' suit indicated that the February 28, 1992 final rule with comment limited cytotechnologists to examining no more than 100 slides in a 24 hour period, and that they must be allowed at least 8 hours to complete the examination of 100 slides. These provisions result in an average rate of review of 12.5 slides per hour. However, with respect to PT, the February 28, 1992 final rule with comment included a lower slide examination rate of 5 slides per hour (the 10 slide test was to be completed within 2 hours and the 20 slide test was allotted 4 hours).

On August 29, 1995, the Court ruled that the regulations did not strictly conform to the statutory mandate. The Court ordered HHS to engage in expedited rulemaking (within 90 days of its order), to publish a proposed rule in the **Federal Register** requesting public comment on the PT regulations for cytology personnel in light of 42 U.S.C. 263a(f)(4)(B)(iv) (providing that individuals should be tested, to the extent practicable, under normal working conditions). The existing regulations were to remain in effect pending the issuance of a final rule as specified by the Court.

In accordance with the Court's order, on November 30, 1995, we published a proposed rule in the **Federal Register** (60 FR 61509). The rule proposed changing the provisions that authorized the examination of cytology PT slides at a rate of 5 slides per hour to a rate of 12.5 slides per hour. In order to achieve this PT workload rate, the rule proposed changing the cytology PT 10 slide test's duration from 2 hours to 45 minutes per testing event. The rule also proposed to limit the time for a 20 slide retest to 90 minutes instead of 4 hours. The proposed rule stated that there might be other options for complying with the statutory mandate (providing that individuals should be tested, to the extent practicable, under normal working conditions), and specifically requested comments on options.

We received approximately 760 comments in response to the proposed rule from cytotechnologists, pathologists, professional organizations, and other members of the public. Nearly 100 percent of the comments stated opposition to the proposed rate change. Commenters stated that PT differs from the working conditions associated with the examination of patient specimens; therefore, the time frame for a PT examination should not be equated to an individual's workload rate. Reasons cited for opposing the proposed PT workload rate change included the following:

• Cytology PT requires screening a higher number of abnormal slides than is routinely seen in the patient workload.
• The individual's workload limit is a maximum rate and not a target rate.
• The staining of PT slides may vary from the laboratories' patient slides.
• The individual screening rates differ.
• The reporting format for PT results is different from the laboratory format.
• There is more stress associated with PT.

Approximately 350 comments were received in response to the proposed rule's request for comments on expanding the CLIA provisions to permit the use of computer-based proficiency testing (CBPT) as an alternative to glass slide proficiency testing (GSPT). While a number of the comments indicated that individuals were apprehensive about a CBPT program, many commenters stated that a national GSPT program was not feasible and provided suggestions for implementing a CBPT program.

HHS appealed the District Court's ruling and sought to re-establish the cytology PT testing time frame established in the February 28, 1992 final rule with comment. In a decision dated May 21, 1996, the United States Court of Appeals for the District of Columbia reversed and remanded those aspects of the District Court's ruling. It provided that HHS could either offer an adequate explanation for the original cytology PT rule and reinstate that rule or issue a final rule in response to the comments received on the November 30, 1995 proposed rule (60 FR 61509) (*Consumer Federation of America and Public Citizen* v. *Department of Health and Human Services*, 83 F.3d 1497, 1506–07 (D.C. Cir. 1996)).

On March 17, 2000, we published a notice in the **Federal Register** (65 FR 14510) withdrawing the November 30, 1995 proposed rule, providing further explanation of the rationale behind the 1992 cytology PT provisions and reinstating the time frame for PT contained in the February 28, 1992 final rule with comment. The rationale provided further explanation for the original cytology PT rule provisions on test duration as required by the Court. It documented that the time provided for testing represented as reasonable an approximation of normal working conditions is possible under the circumstances. In the supplementary statement, HHS noted that the February 28, 1992 final rule with comment stipulated time frame for cytology PT of 5 slides per hour was based on the time frame used by the cytology PT program developed by the State of Maryland. CMS concluded that this time frame would provide for equitable testing on a national scale allowing individuals sufficient time to complete the test at their normal pace, without unduly restricting or extending the time for examination. This conclusion was reached even though a cytotechnologist who reviews the maximum number of slides per day would screen approximately 12.5 slides per hour. In the supplementary statement, HHS provided the following reasons for this conclusion: (1) A workload of 100 slides is the maximum allowed and not all cytology personnel examine 100 slides each day; (2) PT includes a higher ratio of abnormal to normal slides and should appropriately take longer to review; and (3) PT may include slides with different staining characteristics and test result forms that could be unfamiliar to the cytology personnel and require extra time for reporting results. HHS determined that the 2 hours to examine a 10 slide PT test set and 4 hours to examine a 20 slide PT retest used by the Maryland program were appropriate and took into account differences between examination of slides during normal workdays and during PT.

D. Implementing Cytology PT

1. Request for Proposal

No PT programs requested CMS approval in time for the regulatory deadline of July 1st of each calendar year for nationwide cytology PT testing. In an effort to obtain the 26,000 referenced Pap smears estimated to be needed to provide for a national cytology PT program, the CDC issued a Request for Proposal (RFP) in March 1993, for a contractor to undertake procurement of the glass slides for use in administering the program. Although CDC did not receive any proposals in response to the RFP, they did receive comments from cytology organizations and individuals that echoed the comments previously received in response to the final regulations. The commenters stated that conducting a national GSPT program with on-site testing of individuals was logistically and financially infeasible, due to the expense associated with collecting the requisite number of high-quality glass slides representing appropriate diagnostic categories, and the time that would be needed to assemble, reference, and maintain the collection of slides.

2. 1993 Symposium

In November 1993, the CDC and CMS cosponsored a cytology symposium with the Cytology Education Consortium, (which at that time was composed of the American Society for Clinical Pathology (ASCP), the American Society of Cytology (ASC), the American Society for Cytotechnology (ASCT)), and the College of American Pathologists (CAP), to consider possible alternatives to a national cytology PT program using glass slides. A number of approaches were discussed, including state-administered glass slide programs, mailed glass slide programs, and programs that use photographic image representations (that is, color transparencies, color plates, or digitized computer images) of glass slide specimens instead of glass slides. It was determined that the most promising strategy would be to develop a variety of cytology PT programs to accomplish the mandate specified in Section 353(f)(4)(B)(iv) of the PHS Act—''* * * proficiency testing of such individuals, with such testing to take place, to the extent practicable, under normal working conditions, * * *.''

3. Clinical Laboratory Improvement Advisory Committee (CLIAC) Recommendations

The Secretary of HHS is authorized by the Public Health Service Act to establish advisory committees. The Clinical Laboratory Improvement Advisory Committee (CLIAC) was established on February 19, 1992 to provide scientific and technical advice to HHS. CLIAC membership consists of subject matter experts in laboratory medicine, pathology, public health, clinical practice, as well as a consumer representative and a liaison from private industry. Ex officio members represent the HHS agencies that administer the CLIA Program. On December 13, 1993, a CLIAC cytology subcommittee met to review alternative approaches to cytology PT. This meeting was suggested during the 1993 symposium to provide recommendations for consideration by CLIAC. The CLIAC met on December 14 through 15, 1993 to consider the recommendations of the cytology subcommittee. After deliberation, the committee endorsed those recommendations. The CLIAC recommended: (1) That research studies be conducted to define outcomes and evaluate the effectiveness of both glass slide and alternative cytology PT programs; (2) that regulatory revisions be promulgated, as needed, to permit approval of alternative programs; and (3) that statutory changes be pursued to allow cytology PT requirements, like PT requirements for other specialties and subspecialties, to be applied to the laboratory as a whole rather than to individuals. The CLIAC also encouraged

professional organizations and States to develop appropriate programs to meet the February 28, 1992 final rule with comment requirements and make PT available for cytology personnel. The formal proceedings of this CLIAC meeting can be found at the following Web site: *http://www.cdc.gov/cliac/*.

4. Cooperative Agreements to Explore Computer-Based PT

In September 1994, CDC awarded three 1-year cooperative agreements to promote the development of CBPT programs and to evaluate the acceptability of these programs by cytology personnel. These awards were made to the ASCP, New England Medical Center, and Thomas Jefferson University. The three CBPT prototypes were pilot tested at the 1995 spring meetings of ASCP/CAP and the ASCT. More individuals indicated that they preferred the CBPT (68 percent) over GSPT. However, respondents indicated that the three cooperative agreements' CBPT programs did not include a mechanism to fully evaluate locator skills. (Locator skills are those skills necessary to find the abnormal cells on gynecologic cytology preparations.) The three CBPT prototypes were presented to CLIAC in March 1996. The CLIAC stated that the prototypes were adequate to test identification skills, but encouraged CDC to continue development of a prototype that would test locator skills.

5. CDC Computer-Based Prototype, CytoView™

The recommendations from the cooperative agreement pilot evaluations were incorporated into the CBPT prototype developed by CDC, named CytoView™. A full description of this prototype was published in Acta Cytologica. *See*, Taylor R.N., Gagnon M.C., Lange J.V., Lee T.L., Draut R., Kujawski E.: *CytoView™*: *A Prototype Computer Image-Based Papanicolaou Smear Proficiency Test*, 43 Acta Cytologica 1045–1051 (1999). The first CytoView™ prototype was developed in October 1996 and demonstrated to CLIAC in January 1997.

6. Evaluation of PT as a Measure of Workplace Performance

In January 1995, CDC awarded a 2 year contract to Analytical Sciences Incorporated, to compare the actual work performance of cytology personnel with their PT performance. For each individual, the contractor rescreened 500 previously reported cases to determine a score for individual work performance. The work performance score was then compared to two methods of PT: (1) A GSPT administered by the contractor; and (2) the CytoView™ prototype CBPT administered by the CDC. The study, based on a sample of 85 participants consisting of cytotechnologists (73) and pathologists (12) across the U.S. who performed primary screening (that is, examined slides without the assistance of a prescreening cytotechnologist), was completed in the spring of 1997.

The results of the study were published in the American Journal of Clinical Pathology [Keenlyside R., Collins C.L., Hancock J.S., *et al.: Do Proficiency Test Results Correlate with the Work Performance of Screeners Who Screen Papanicolaou Smears?* (112) American Journal of Clinical Pathology. 769–776 (1999)]. The authors reported a moderate correlation (that is, unlikely to be a chance finding) between performance scores on the 500 slide rescreen and both the GSPT and CBPT. The research model had several limitations including: comparing a 10 slide test to the rescreen of 500 slides; for a few individuals all four diagnostic categories were not present in the 500 slide rescreen; glass slides used in the GSPT and images used in the CBPT were not field validated; and the 42,500 slides rescreened by the 85 participants were not referenced by 3 pathologists.

Study participants were asked to evaluate CytoView™ after completion of the CBPT. While 64 percent of the responses stated that the CBPT was an acceptable alternative, 68 percent favored GSPT. Negative comments about CytoView™ included: The program was slow; the operating system was bulky; an optimal focal plane was not always available; and it did not test the workplace performance of the majority of pathologists, since they were required to screen the entire image.

7. CytoView™ II Development

CytoView™ II was developed in June 1999 by the CDC based on comments received from the CytoView™ evaluation questionnaire. CytoView™ II operates from a laptop computer, displaying images at a faster speed with a fluid focusing mechanism that more closely simulates the microscope and provides an instant display of the field of view at a higher magnification with a single mouse click. An additional feature allows tandem screening by a cytotechnologist or pathologist team. The cytotechnologist marks (dots) areas of the slide and can write comments for the pathologist to review. The pathologist may then review only the marks, the entire slide, or a combination of the two features. The CytoView™ II prototype was demonstrated at the 1999 fall meetings of the ASCP/CAP and ASC.

CDC trademarked the name CytoView™ and in November 2000 a patent was issued on MicroScreen, the software used to capture the interactive images used by CytoView™.

8. Comparison of Glass Slide Testing to Computer-Based Testing

In July 2002, CDC completed a study with the Maryland Cytology Proficiency Testing Program (MCPTP) comparing PT in gynecological cytology using glass slides to virtual slides using the CytoView™ II prototype. To compare performance, a total of 111 individuals (52 pathologists and 59 cytotechnologists) from participating in-state laboratories were administered the two proficiency tests. The routine annual test of the MCPTP was administered to individuals following normal practice. CytoView™ II was designed to emulate the MCPTP glass slide examination in which the individual selects the order of slide viewing and may change answers up until the test is submitted. Like the glass slide test, when a pathologist chose to examine a marked test, CytoView™ II allowed the pathologist to review areas marked by the cytotechnologist and to see the diagnostic category chosen by the cytotechnologist. The slides used by the MCPTP were validated during 11 years of testing. The virtual slides were captured from the MCPTP's glass slides but were not field validated as images. The study recognized the need for field validation of all slides (glass and virtual) and concluded that, if both glass and virtual slides are referenced and field validated, the result of testing would be equivalent. This study was published in Acta Cytologica [Gagnon M., Inhorn S., and Hancock J., *et al., Comparison of Cytology Proficiency Testing-Glass Slides* vs. *Virtual Slides*, 48 Acta Cytologica 788–794 (2004).] If digital images are permitted as cytology PT challenges, this system could be available for cytology PT.

9. Approval of Programs

Two State-operated programs applied for CMS approval in 1993. The MCPTP met the regulatory cytology PT requirements and was subsequently granted CMS approval in May 1994 for testing to begin calendar year 1995. The MCPTP developed its cytology program to provide PT for all individuals (in-state and out-of-state) who evaluate gynecologic cytology preparations from residents of Maryland. The MCPTP did not possess sufficient materials to offer cytology PT nationally. After applying for approval in 1993, the Wisconsin

Cytology Proficiency Testing Program subsequently withdrew its application for approval in October 1994, when Wisconsin was unable to obtain a sufficient number of referenced glass slides necessary to provide a statewide program.

In 1997, the CAP submitted an application to become an approved cytology PT program. The CAP requested the use of in-house proctors, selected from the laboratory's staff, to administer the PT. The CDC and CMS agreed with the proposal to use proctors to administer the PT and notified CAP of its determination. However, the initial application as well as subsequent submissions (1997 through 2004) that CAP provided to the agencies were not in conformance with the CLIA regulatory requirements and could not be approved. In November 2004, the submissions were ultimately withdrawn by CAP and replaced with a significantly revised and more comprehensive application in March 2005.

In March 2004, The Midwest Institute for Medical Education (MIME) submitted an application for approval of a gynecologic cytology PT program under CLIA. After careful review, the program was approved and national testing of all individuals was required beginning on January 1, 2005.

In December 2004, CMS mailed a memorandum to the Directors of State Survey agencies informing them of the enforcement responsibilities effective for calendar year 2005. The memorandum stated that the PT implementation was to first emphasize an educational approach and that no sanctions would be imposed against laboratories unless they failed to comply with the following dates: (1) Ensure that all individuals are enrolled in a CMS approved cytology PT program by June 30, 2005; (2) ensure all individuals have been tested at least once by April 2, 2006; and (3) ensure that affected individuals achieve a passing score by December 31, 2006.

In December 2004, CMS also held conferences with the CMS regional offices and State Agencies to provide information on the enforcement dates that laboratories must meet. In January 2005, CMS mailed individual letters to all laboratories certified in cytology notifying them of the required enrollment and participation in a CMS-approved cytology PT program for all individuals examining gynecologic preparations. In February 2005, CMS held a Partners in Laboratory Oversight Meeting with the accreditation organizations and States with CLIA-approved licensure programs to provide information on the approved program and enforcement responsibilities. CDC and CMS participated in numerous audio conferences with the cytology professional organizations to inform laboratories and individuals of the need to participate in the MIME program. CMS held national Open Door Forum teleconferences in January 2005 and March 2006 inviting all laboratories and the public to participate in discussions and ask questions about the requirements, and providing additional venues for CMS to further explain the mechanics of the PT process. CMS developed and continues to maintain a Web site, *http://www.cms.hhs.gov/clia*, containing information on PT, as well as a document for download titled ''Informational Supplement'' that is specific to cytology PT.

In February 2005, the ASCP submitted an application for approval in 2006. In March 2005, the CAP submitted its application for approval to provide PT for the 2006 testing cycle. The CAP program was approved September 1, 2005 for testing to begin in January 2006. The ASCP acquired the MIME program on February 26, 2006 and met the requirements for testing in 2006. Currently there are 3 CMS-approved gynecologic cytology PT programs; the MCPTP, ASCP, and CAP.

10. Opposition to Cytology PT

In November 2004, CAP sent a letter to HHS requesting a 1 year moratorium on requiring individual enrollment in the MIME program. Following this letter, CDC and CMS met separately with CAP and the ASCP regarding the requested moratorium and their pending applications. At these meetings, the organizations also asked for expedited reviews of their PT program submissions to receive approval by January 1, 2005. Expedited reviews were granted; however, neither program met the requirements for approval under CLIA. The CAP application was subsequently revised, resubmitted, and approved by CMS to begin cytology PT in calendar year 2006.

A coalition of State and national pathology societies submitted a letter in June 2005 asking the Secretary of HHS to re-evaluate the ''relevance, validity, and ultimate effectiveness'' of cytology PT. The letter also suggested that if cytology PT were to be continued, it should be conducted on an educational basis. The letter called upon Congress to intervene and for HHS to thoroughly review the existing regulation.

E. Recent Congressional Actions

On September 20, 2005, 103 Members of the United States House of Representatives sent a letter to the Secretary of HHS expressing concern about CMS' implementation of the 1992 requirements. The letter specifically addressed the absence of provisions addressing technology advancements made after the rule was written and suggested that the testing of individuals, as opposed to performance by the laboratory overall, was not based in statute but was devised by CMS in the 1992 regulations. It also suggested that the imposition of Federal penalties on individuals supplanted the licensing authority of State governments. The letter requested that CMS suspend cytology PT until the regulations were revised.

We carefully reviewed all the concerns raised about cytology PT in the letter from these Members of Congress and concluded that they did not warrant interruption of the ongoing testing of individuals required by statute. CMS (in its former status as the Health Care Financing Administration) and CDC had previously considered these issues and declined to make changes that we believed to be contrary to statutory requirements. However, we had modified the cytology PT requirements where possible, for example, reducing testing to once-per-year rather than multiple times per year. (*See* § 493.855(a) of the CLIA final rule with comment published February 28, 1992).

The contention that laboratories should be tested rather than individuals is contrary to the plain language of the statute, and therefore was not considered in the development of the cytology PT program and was subsequently ruled out by CLIAC in considering possible refinements to the program. In addition, findings from individual testing in the State of Maryland indicated that certain individuals and certain subgroups (for example, pathologists working without cytotechnologists) had higher rates of test failure that would probably not be identified if cytology laboratories were scored as a whole rather than scoring each individual as required by the statute and current regulations.

We stated our intention to review the entire program after a full year's worth of national data were available and committed to working with the stakeholders and the CLIAC. We have fulfilled these commitments, giving rise to this proposed rule, as discussed in section II of the preamble.

On November 9, 2005, in the 109th Congress, the Proficiency Testing Improvement Act of 2005 (H.R. 4268) was introduced in the House of Representatives. The legislation would have prohibited the Secretary of HHS

from conducting laboratory PT of individuals involved in screening or interpreting cytological preparations for 1 year and required the Secretary to revise the PT requirements before resuming the program in order to (1) reflect the collaborative clinical decision-making of laboratory personnel; (2) revise grading or scoring criteria to reflect current practice guidelines; (3) provide for testing to be conducted no more often than every 2 years; and (4) make other revisions as necessary to reflect changes in laboratory operations and practices since the original PT regulations were promulgated. This bill was referred to the House Committee on Energy and Commerce on November 9, 2005 and to the Subcommittee on Health on November 22, 2005.

On December 16, 2005, a second Proficiency Testing Improvement Act of 2005 (H.R. 4568) (identical to H.R. 4268) was introduced in the House of Representatives. This bill passed the House on December 17, 2005 and was referred to the Senate Committee on Health, Education, Labor, and Pensions on January 27, 2006. The Senate took no action on this bill.

On September 21, 2006, the Cytology Proficiency Improvement Act of 2006 (H.R. 6133) was introduced in the House of Representatives. This bill required the Secretary of HHS to revise national quality assurance standards to include requirements for each clinical laboratory to (1) ensure that all individuals involved in screening and interpreting cytological preparations participate annually in an approved continuing medical education program in gynecologic cytology that provides each participant with gynecologic cytologic preparations designed to improve locator, recognition, and interpretive skills; and (2) maintain a record of such program results. The Secretary was also required to terminate the existing individual cytology PT program. This bill was referred to the House Committee on Energy and Commerce on September 21, 2006 and to the Subcommittee on Health on October 2, 2006.

On November 15, 2006, an identical bill to H.R. 6133 was introduced in the Senate (S. 4056), and was referred to the Senate Committee on Health, Education, Labor, and Pensions.

In December 2006 the 109th Congressional session came to an end with no action taken on H.R. 6133 or S. 4056.

In the 110th Congress, the Cytology Proficiency Improvement Act of 2007 (H.R. 1237) was introduced in the House of Representatives on February 28, 2007, and was referred to the House Committee on Energy and Commerce on that date, and to the Subcommittee on Health on March 1, 2007. This bill was identical to H.R. 6133 from the 109th Congress.

A Senate version of the Cytology Proficiency Improvement Act of 2007 (S. 2510) was introduced on December 18, 2007. While very similar to H.R. 1237, this bill included some additional requirements for how the results of an individual's participation in continuing medical education would be used. S. 2510 was referred to the Senate Committee on Health, Education, Labor, and Pensions.

H.R. 1237 was subsequently amended to be identical to S. 2510 and was passed by the House of Representatives on April 8, 2008.

In December 2008 the 110th Congress ended with the Senate having taken no action on S. 2510.

II. Rationale for Proposed Rule

CLIA regulations for cytology PT were published in 1992 and implemented in Maryland in January 1995 following approval of the Maryland Cytology Proficiency Testing Program (MCPTP). The first program approved for nationwide cytology PT was the MIME program in 2005.

To address the numerous concerns voiced about cytology PT implementation, the CMS presented a status report on cytology PT implementation during the CLIAC meeting in February 2005 and described the Cytology Personnel Records System (CYPERS). CYPERS was developed and implemented by us to maintain the confidentiality of an individual's enrollment, participation, and PT scores, and to allow us to monitor individual performance in cytology PT. The notice for the new Privacy Act System of Records, CYPERS, was published in the **Federal Register** on January 14, 2005 (70 FR 2637). Also at the February 2005 CLIAC meeting, public comments opposing the implementation of cytology PT through the MIME program were presented by the ASC and ASCP, highlighting their concerns which included, (1) perceived problems with the scoring scheme and validation of slides; and (2) the regulations' failure to consider the semi-automated technology used in current practice. CLIAC recommended consideration be given to revising the cytology PT regulations ''based on current practice, evidence-based guidelines and anticipated changes in technology'' as reflected in updated comments from the professional organizations and the public. (These recommendations and proposed revisions are documented on the CLIAC Web site at *http://www.cdc.gov/cliac/cliac0205.aspx*, summarizing the February 2005 CLIAC meeting).

In September 2005, CLIAC recommended formation of a cytology PT workgroup to consider potential changes to the regulations. In addition, comments and data were solicited from professional organizations on the potential impact of any proposed regulatory revisions on laboratories, cytology PT programs, and the cytology workforce.

In November 2005, CDC and CMS staff met with the Cytology Education and Technology Consortium (CETC) to solicit suggestions from the professional organizations represented in the consortium (ASCP, CAP, International Academy of Cytology (IAC), ASC, ASCT and the Papanicolaou Society of Cytopathology (PSCO)) and their members for recommendations for specific changes to the regulations. Following this meeting, the CETC and the ASCT provided comments identifying potential issues to be considered for regulatory revisions. The comments provided by the CETC were endorsed by all member organizations with the exception of CAP. The issues identified included: Testing the individual compared to testing the laboratory; impact of new technology; frequency of testing; number of challenges per testing event; categories of challenges; grading scheme point values; validation of challenges; remediation for failure; testing site; and confidentiality.

At the February 2006 CLIAC meeting, CMS provided preliminary data on the status of 2005 cytology PT results. CDC provided information on the process for revising the regulations and announced the formation of a cytology PT workgroup. The purpose of the workgroup, which was comprised of practicing pathologists and cytotechnologists, was to develop suggestions for proposed revisions to the cytology PT regulations and to present their findings to CLIAC for consideration in making recommendations to HHS for revisions to the regulations.

In March 2006, the cytology PT workgroup met for 2 days to develop suggestions for proposed revisions to the cytology PT regulations. These suggestions included: Using the term ''challenges'' instead of ''slides'' to accommodate other testing media; defining challenges as case equivalent (glass slides, virtual slides, or other approved media); reducing the frequency of testing; increasing the

number of challenges per testing event; requiring field validation of challenges with disclosure of the validation process to participants by the PT program; and changing the scoring scheme for pathologists and cytotechnologists to eliminate the automatic failure for misdiagnosis of a HSIL or cancer (Category D).

At a June 2006 CLIAC meeting, CLIAC reviewed the suggestions for regulatory revisions proposed by the workgroup. The CLIAC made the following recommendations: (1) Use the preamble to encourage laboratories to participate in educational laboratory programs in addition to individual proficiency testing; (2) require oversight organizations/agencies and surveyors to determine if laboratories participate in educational programs and provide laboratories with identification of available resources; (3) change the term ''slides'' to ''challenges'' to allow for the use of virtual slides; (4) define a challenge as a case equivalent-glass slide, virtual slide, or other approved media; (5) add a requirement for a transition phase for all new technology (for example, virtual slides), and to allow the individual to request retesting with glass slides; (6) reduce the frequency of testing to a 3-year test cycle using 20 challenges for every test (initial and retest); (7) retain four diagnostic categories and continue to require at least one challenge from each of the four categories; (8) change language to state ''individuals who score <90 percent'' (as opposed to ''who fail''); and (9) change the grading scheme to a unified model for both cytotechnologists and pathologists and eliminate automatic failures for misdiagnosis of one HSIL or cancer (Category D). The following grading scheme was recommended by the CLIAC:

MODEL X–20 SLIDE TEST—UNIFIED

Correct response	Examinee response			
	A—UNSAT	B—NEGATIVE	C—LSIL	D—HSIL
A—UNSAT	5	0	0	0
B—NEGATIVE	2.5	5	0	0
C—LSIL	0	0	5	5
D—HSIL	0	−5	5	5

CLIAC also made recommendations for PT programs, including the following: (1) Require biopsy confirmation of HSIL or cancer (Category D) challenges, but not LSIL (Category C) challenges; (2) require field validation, monitor challenges continuously, and remove challenges that fail field validation; (3) require validation procedures to be disclosed by the PT program; (4) allow the PT programs to determine alternate options for test sites for missed tests (that is, excused absences and retesting) (they noted that the preamble could be used to encourage more options for test sites); (5) allow the PT programs to determine the proctor requirements; (6) provide more specific educational feedback on result discrepancies; and (7) require PT programs to disclose the appeal process in writing. A summary of this meeting is found at *http://www.cdc.gov/cliac/*.

CDC and CMS met with the 3 approved cytology PT programs on August 28, 2006 to solicit input on operational issues. Issues discussed included: Quality assurance of the testing process; proctor requirements; testing sites; validation of testing materials; biopsy confirmation of HSIL or cancer (Category D) and LSIL (Category C); comparable test sets; and administrative issues. In addition, programs were asked to provide data for the impact analysis.

Listed below is a chronology of events related to the implementation of cytology PT:

CHRONOLOGY OF EVENTS—IMPLEMENTING CYTOLOGY PT

October 1988	The Clinical Laboratory Improvement Amendments (CLIA) were enacted, amending the Public Health Service Act.
May 1990	CMS published a CLIA proposed rule.
February 1992	CDC and CMS published a CLIA final rule with comment period.
January 1993	Consumer Federation of America and Public Citizen filed a lawsuit challenging the timeframe for cytology PT.
January 1993	State of Maryland Cytology PT Program submitted an application for approval.
March 1993	CDC published a request for proposal to obtain referenced Pap smear glass slides for a national cytology PT program.
November 1993	CDC, CMS, and cytology organizations co-hosted ''Cytology PT Symposium'' to discuss alternatives to glass slide testing.
November 1993	State of Wisconsin submitted an application for cytology PT program approval.
December 1993	The CLIAC made recommendations concerning cytology PT.
May 1994	CMS approved the Maryland and Wisconsin State PT programs for testing in 1995. The Maryland State PT program has been reapproved annually since 1995.
September 1994	CDC awarded three cooperative agreements for development of prototype computer-based cytology PT programs.
October 1994	State of Wisconsin terminated its program prior to implementation.
December 1994	CDC and CMS published a rule extending the cytology PT enrollment date.
January 1995	CDC awarded a contract to compare glass slide PT and computer-based PT to workplace performance.
April 1995	CDC and the cooperative agreement awardees pilot tested the three cytology CBPT prototypes at national cytology meetings.
November 1995	CDC and CMS published a proposed rule to change the timeframe allowed for cytology PT testing based on a court order from the *Consumer Federation of America and Public Citizen* v. *HHS*, lawsuit (906 F.Supp., 657 (D. D.C. 1995).
October 1996	CDC developed a computer-based prototype called CytoView™ to test locator and interpretive skills.
March 1997	CAP submitted an application for cytology PT program approval.
June 1999	CDC developed CytoView™ II.

CHRONOLOGY OF EVENTS—IMPLEMENTING CYTOLOGY PT—Continued

March 2000	CDC and CMS withdrew the 1995 proposed rule and reinstated the 1992 PT timeframes pursuant to ruling by the appellate court.
July 2002	CDC and the State of Maryland completed a study comparing individual performance on glass slide PT and CytoView™ II.
March 2004	Midwest Institute for Medical Education (MIME) submitted an application for cytology PT program approval.
September 2004	CMS approved the MIME program to initiate testing in 2005.
November 2004	CAP requested a one year moratorium on the requirement to participate in cytology PT.
November 2004	CAP withdrew its application for program approval.
January 2005	CMS held an Open Door Forum to inform laboratories of the first approved national cytology PT program and respond to questions.
January 2005	CMS published a notice announcing a new System of Records, CYPERS.
February 2005	CMS held a Partners In Laboratory Oversight Meeting with accreditation organizations and States with CLIA-approved licensure programs to inform them of the requirement for all laboratories performing gynecologic cytology to participate in cytology PT.
February 2005	CMS presented details of the PT requirements for cytology laboratories to the CLIAC. The CLIAC recommended revisions be made to the regulations.
February 2005	ASCP submitted an application for cytology PT program approval.
February 2005	MIME initiated testing of cytology laboratories.
March 2005	CAP submitted a new application for cytology PT program approval.
June 2005	CAP sent a letter signed by State and national organizations to HHS expressing concern about cytology PT implementation. Response sent August 2005.
June 2005	ASCP submitted a new application for cytology PT program approval.
August 2005	State of Maryland and MIME cytology PT programs were reapproved for testing in 2006.
September 2005	CAP program was approved to initiate cytology PT in 2006.
September 2005	CLIAC recommended convening a cytology PT workgroup to consider potential changes to the cytology PT requirements.
September 2005	Some Members of the House of Representatives sent a letter to HHS expressing concern about implementation of the cytology PT regulation.
November 2005	At the CETC meeting, preliminary 2005 cytology PT results were presented and organizations were invited to submit suggestions for changes to revise the cytology PT regulation.
November 2005	H.R.* 4268 introduced—would have suspended cytology PT for one year.
December 2005	House of Representatives passed H.R. 4568 (identical to H.R. 4268) and sent it to the Senate.
January 2006	H.R. 4568 referred to Senate Health, Education, Labor and Pensions (HELP) Committee for consideration.
February 2006	ASCP acquired the MIME program.
February 2006	CDC announced the CLIAC Cytology PT workgroup would meet in March 2006.
March 2006	CLIAC Cytology PT workgroup met.
March 2006	CMS held a second Open Door Forum to respond to questions about implementation of cytology PT.
June 2006	Workgroup recommendations were reported to the CLIAC, which considered the recommendations and made its own recommendations to HHS for revisions to cytology PT requirements.
August 2006	CDC and CMS met with PT program representatives to solicit comments on the administration and operation of cytology PT.
September 2006	H.R. 6133 introduced—required the Secretary to terminate PT and replace with continuing medical education requirement.
November 2006	S.** 4056 introduced (identical to H.R. 6133).
December 2006	109th Congressional session ended without enactment of any cytology PT bill.
December 2006	State of Maryland, ASCP, and CAP cytology PT programs were reapproved for testing in 2007.
February 2007	H.R. 1237 introduced (identical to H.R. 6133). This bill was referred to the House Committee on Energy and Commerce, Subcommittee on Health.
December 2007	S. 2510 introduced (similar to H.R. 1237). This bill was referred to the Senate Committee on Health, Education, Labor, and Pensions (HELP).
April 2008	H.R. 1237 amended (so identical to S. 2510) and passed by the House of Representatives—would terminate cytology PT and replace it with continuing medical education requirement.
December 2008	110th Congressional session ended without enactment of any cytology PT bill.

Note to Reader:
* H.R. #### means a bill introduced in the United States House of Representatives.
** S. #### means a bill introduced in the United States Senate.

III. Provisions of the Proposed Regulations

This section provides an overview of the proposed revisions to the CLIA requirements for gynecologic cytology PT specified in Subpart A— General Provisions, § 493.2 Definitions; Subpart H— Participation in Proficiency Testing for Laboratories Performing Nonwaived Testing, § 493.803 Condition: Successful participation; Subpart I— Proficiency Testing Programs for Nonwaived Testing, § 493.905 Nonapproved proficiency testing programs, and § 493.945 Cytology; gynecologic examinations, established by the February 28, 1992 final rule with comment.

In addition, since the specialty of pathology includes, for purposes of proficiency testing, only gynecologic examinations within the subspecialty of cytology, we are proposing to replace the Condition: Pathology at § 493.853 with the new Condition: Cytology: gynecologic specimen examinations at § 493.853. We are proposing to remove and reserve § 493.855 Standard; Cytology: gynecologic examinations. The requirements currently at § 493.855 will be moved to a new condition section (that is, § 493.853 Condition: Cytology: gynecologic specimen examinations). We are proposing this change because no proficiency testing is required for histopathology (the other subspecialty in pathology). This change is needed to change cytology proficiency testing from a standard to a condition or we would be unable to limit the certificate in such a way as to

address cytology alone as opposed to all of pathology. We believe that if we do not propose this change, it could lead to the unintended consequence of taking an enforcement action in other subspecialties of pathology where problems do not necessarily exist.

We are soliciting specific comments on these proposed changes. The proposed revisions are based on our experience with the current cytology PT requirements, CLIAC recommendations made in June 2006, input from cytology PT programs, and comments solicited from the cytology organizations.

A. Cytology Challenges and New Technology

The requirements currently at § 493.855(b) specify that individuals be tested using glass slides, which was the standard of practice when the February 28, 1992 final rule with comment was published. Following the 1992 publication, semi-automated screening (computer-assisted and location-guided instruments) was developed for the evaluation of cytology preparations on glass slides. In March 2006, the CETC indicated that an increasing number of laboratories are routinely using newer technology to replace the traditional manual screening of conventional Pap smears, and stated that testing these laboratories in the manner described in the February 28, 1992 final rule with comment is inconsistent with the statutory language requiring testing of individuals ''under normal working conditions.'' The CETC further stated that the proposed PT requirements should accommodate technology currently in use in laboratories, and should be flexible enough to accommodate any technologies that might be used in the future, such as digital imaging. The ASCT suggested that PT options should be available for those individuals using semi-automated technology if requested, as well as glass slide challenges for manual examination.

The CLIAC recommended changing the regulatory language of ''slides'' to ''challenges.'' Several CLIAC members commented that the use of the term ''challenges'' would allow flexibility to PT programs transitioning from manual testing to newer technology and to individuals in selecting the testing media with which they are most familiar for examining patient specimens. The CLIAC subcommittee in their June 2006 meeting also recommended a phase-in period, including pilot testing, be required for programs that initiate testing using new technology.

Based on this input and to allow more flexibility, we are proposing to change the terminology ''glass slides'' to ''cytology challenges'' to allow for the approval of programs that use glass slides as well as semi-automated screening protocols, digital images, or other testing media in the future. In this rule, we are proposing at § 493.2 to revise the definition for ''challenge'' and add the definition ''cytology challenge'' which we propose will mean ''a sample consisting of gynecologic cytology material that is used to evaluate the individual's locator and identification skills. Cytology challenge material may include glass slides, digital images, or other CMS approved testing media.'' Presently, CMS is considering requiring programs to pilot test any new testing media and submit their data in their next application for approval. We are soliciting comments on the contents of this proposed rule, specifically:

- Is the proposed definition for ''cytology challenge'' appropriate to address future technological advances?
- Should criteria be included in the regulations for pilot testing before CMS approval of any new cytology testing media? If so, please specify the appropriate criteria.
- Should pilot testing include a comparison to current technology? What is an acceptable comparison?
- If specific criteria for pilot testing are required, what burden would be incurred by PT programs and laboratories participating in a pilot test?
- Would requiring pilot testing cause an increase in the cost of cytology PT?

B. Testing Individuals

The requirements in the February 28, 1992 final rule with comment reflected the provision in the CLIA statute at section 353(f)(4)(B)(iv) of the Public Health Service Act requiring ''periodic confirmation and evaluation of the proficiency of individuals involved in screening or interpreting cytological preparations, including announced and unannounced on-site testing of individuals, with testing to take place, to the extent practicable, under normal working conditions''. The CETC commented that the provision requiring testing of individual cytotechnologists and pathologists was the most troubling aspect of the statute. The CETC suggested that testing the laboratory as a whole, as is the case with non-cytology PT, would be a better approach for assuring the quality of laboratory results. The CETC suggested enrolling each laboratory on an annual basis with no formal enrollment of individuals, noting that individuals would be periodically tested through participation in laboratory PT.

Several CLIAC members suggested an approach to PT that would be consistent with the presentation made by the CAP during the meeting's public comment period. CAP suggested during the public comment period that cytology PT be modified to make it more consistent with the regulatory approach of the Mammography Quality Standards Act (MQSA). The CAP also suggested that the impetus for the MQSA was similar to CLIA because of similar quality-of-care concerns for diagnostic screening services and the same regulatory objective to reduce false negative rates. The Food and Drug Administration (FDA) does not agree with the CAP's additional assertion that, in implementing the mammography standards under MQSA, the FDA rejected PT as an assessment tool due to the lack of consensus on testing standards and measurements. FDA does agree that it instead focused on assessing the competency of the facility by evaluating outcomes produced by the facility. CAP requested that HHS consider an approach similar to the MQSA that would incorporate laboratory outcomes assessments and use other outcome measures, for example evaluation of laboratory QC and review of previously evaluated cases. While this approach for evaluating laboratory performance may have merit, it would require Congress to change CLIA to eliminate the requirement for the evaluation of an individual's proficiency. As such this cannot be addressed through rulemaking, and only changes to individual testing are included in this proposed rule. Through inspections that evaluate laboratory quality control (QC) and the rescreening of a sample of slides previously examined by the laboratory's cytotechnologists and pathologists, CMS has continued to identify serious problems, including significant misdiagnoses. These findings appear to demonstrate the need for continued PT of individuals.

The CLIAC noted that CAP, as an accreditation organization for many cytology laboratories, currently requires its accredited laboratories to participate in an educational peer comparison program in gynecologic cytology in addition to the required individual participation in cytology PT. CLIAC recommended that laboratories be strongly encouraged to participate in educational programs. While not required under CLIA, CMS has always encouraged laboratory participation in educational programs in gynecologic cytology as well as participation in

individual PT. The CLIAC recommended that oversight organizations and agencies, as part of their inspection process, determine whether laboratories participate in educational programs and for those not participating, assist in identifying available educational programs. CMS anticipates adding this recommendation to Appendix C of the State Operations Manual (CMS Pub. 7).

We are soliciting comments on the following:

- Should enrollment and participation in an educational program be required for all cytology laboratories? If so, how would this enrollment be monitored by CMS?
- If enrollment and participation in educational programs were to be required, what criteria would be appropriate for CMS to adopt through rulemaking to evaluate these programs?
- If enrollment and participation in educational programs were to be required, how might CMS monitor or evaluate an individual's participation in such a program?
- If educational programs were required, what enforcement actions might be appropriate for laboratories if laboratories/individuals did not participate in the required programs?

C. Frequency of Testing

The requirements currently at § 493.855(a), specify that laboratories must ensure that each individual engaged in the examination of gynecologic preparations participates in cytology PT at least once a year. Comments received from the CETC and ASCT stated that annual testing is excessive since there is no evidence that cytology screening and interpretive skills deteriorate after 1 year. The CETC further explained that cytology PT of individuals is not analogous to clinical laboratory PT which is dependent on instrument calibration and reagents that can vary by lot number. The CETC suggested the interval between testing events be lengthened to 5 years for well-trained cytology professionals, who assess cervical cytology preparations on a regular basis. The ASCT indicated that other safeguards are in place in cytology, for example, the biennial inspection of laboratories, and the requirements for 10 percent random rescreening of all negative specimens, correlation between cytology and histopathology reports, if available, and retrospective review of all negative specimens from the previous 5 years when a current HSIL or cancer (Category D) is identified. The ASCT suggested the testing interval for individuals be every 3 years.

At the June 2006 CLIAC meeting, The New York State Department of Health Cytology PT Program presented performance data, which revealed that individual failure rates plateaued over time and did not tend to increase after switching from annual to biennial testing. Frequencies other than every 2 to 3 years were also discussed. However, a concern was expressed that less frequent testing may allow poor performers to go undetected, thus jeopardizing the quality of Pap smear testing. After deliberations, the CLIAC recommended testing of individuals every 3 years.

In an effort to balance the quality concerns with the desire to reduce the testing burden, we are proposing at § 493.945(a) and (b) to reduce the frequency for gynecologic cytology testing from annual to every 2 years and increase the number of cytology challenges from 10 to 20 per testing event.

Comments are being solicited on the following questions which must be considered with the proposed grading changes that follow:

- How many cytology challenges per test event are appropriate to assess individual performance?
- Should annual testing continue to be required with 10 slides per test?
- Is 2 years an appropriate testing interval using 20 slides per test?
- Why would a testing frequency longer than every 2 years be appropriate?
- If an individual is allowed to pass a 20 cytology challenge test when an HSIL or cancer (Category D) cytology challenge is reported as Normal or Benign Changes (Category B), how long should the timeframe be between testing events?
- What type of data should be collected to determine if a longer interval between testing is appropriate? Who should collect the data? How long should the data be collected?
- What types of data are needed to validate testing less frequent than annually?

D. Number of Cytology Challenges

As currently specified at § 493.855(b), each individual is required to be tested with 10 glass-slide challenges. If a score of at least 90 percent is not achieved, an individual has not successfully completed the test and must be retested with an additional 10 glass slide test set. If the individual does not achieve at least 90 percent on the retest, each subsequent retest must include 20 glass slide challenges. The ASCT questioned whether a 10 slide test has the ability to accurately assess proficiency. However, the ASCT acknowledged that the increased time and cost required to administer a 20 challenge test might not be justified. The ASCT also noted that the requirement to include at least one challenge from each of the four response categories in a 10 challenge test set might be more a measure of mathematical and statistical skill used to ''game'' the system rather than a demonstration of diagnostic skill.

The New York State Department of Health Cytology PT Program provided data at the June 2006 CLIAC meeting supporting the premise that a 10 challenge test lacked the discriminatory power to differentiate between competent and incompetent examinees. The New York representative stated that a competent examinee failing a testing event is a lesser problem than an incompetent individual passing the event because of the high probability that the competent individual would pass the second test. An incompetent individual passing the testing event is a more serious problem as the individual could continue to examine patient specimens until the next testing cycle. New York used statistical examples to demonstrate how a larger sample size would increase the reliability and precision for identifying poor performers while not failing good performers. New York proposed that a more accurate assessment of proficiency would be an initial test consisting of 40 to 60 challenges followed by PT at 5 to 10 year intervals.

During discussion at the June 2006 CLIAC meeting, it was noted that a 10 slide test containing one challenge from each response category would allow an individual to make an educated guess through the process of elimination by selecting response categories that would result in the fewest lost points. Increasing the number of challenges to 20 would make it harder to ''game'' the test even with the requirement to include at least one challenge from each of the four response categories. In order to increase the discriminatory power of the testing event and decrease the opportunities for ''gaming,'' the CLIAC recommended 20 challenges for all testing events.

After considering these comments, we are proposing at § 493.945(b) that a minimum of 20 cytology challenges would be required for each testing event. In general, increasing the number of challenges in any test increases the statistical power to discriminate between truly incompetent and competent performers. We considered increasing the number of challenges to more than 20; however this would add additional costs and burden with no

established benefit. The calculation of statistical power is not straightforward for a test of this type, which is impacted by variables inherent in the population of examinees, the composition of the slide sets and the non-dichotomous scoring scheme. For these reasons, as well as the lack of actual performance data, it was not possible to calculate actual statistical power to compare the current and proposed number of challenges. However, according to Nagy and Collins (35 Acta Cytologica, 3–7, 1991), increasing the number of challenges from 10 to 20 will reduce the statistical probability that an individual who is not proficient will pass and will not substantially change the probability that a competent individual will fail. This conclusion was based on probability theory, a simple statistical binomial error model and the assumption that a competent cytologist routinely performs at 90 percent proficiency. A competent individual not passing the first test is a lesser problem, because of the high probability the individual would pass on the second test. Increasing the number of challenges can also minimize the probability of misclassifying a proficient performer as not proficient. No test is 100 percent sensitive and specific; therefore, for statistical reasons, some competent cytologists will not pass an individual test and, conversely, some who are not proficient will pass. As noted by Gifford, Green and Coleman (8 Cytopathology, 96–102, 1997) even competent performers will occasionally obtain a score of less than 90 percent and be subject to a retest.

In addition, statistical calculations can not take into account other factors such as test familiarity. Examinees become familiar with test formats and the testing process, and thus experienced examinees will have a better chance at passing than those taking the test for the first time (Nagy and Collins, 35 Acta Cytologica, 3–7, 1991). This has been demonstrated in the State programs in which pass rates have increased over time (Newton L.E., Cytopathology Proficiency Testing in New York State: the First 25 Years. 25(4) Laboratory Medicine: 230–231(1994) and Keller, B., information presented to CLIAC, June 20–21, 2006, *http://wwwn.cdc.gov/cliac/default.aspx*, Addendum H).

We are proposing to retain the requirement to include at least one cytology challenge from each of the four response categories. We are proposing to add the requirement that each testing event include two cytology challenges from the response Category ''D'' that includes HSIL or cancer. By requiring at least 2 high grade lesion or cancer challenges per test of 20 challenges, the test difficulty will be similar to that of the current test in which 1 high grade lesion or cancer challenge is required per 10 slide test. This will (1) ensure an evaluation of the ability to differentiate more severe lesions from less severe lesions; (2) evaluate major false negative calls (inability to distinguish a high grade lesion or cancer challenge from a normal challenge) on the basis of more than one challenge; and (3) promote equivalence among test sets and among PT programs (if only 1 high grade lesion or cancer challenge was required, some programs may only include 1 such challenge to make their test easier than a program that included 1 or more high grade lesion or cancer challenges). We are also maintaining the 4 hour time period for a 20 cytology challenge test, 45 day timeframe for retests, remedial action requirements for scoring less than 90 percent, mandatory rescreening, and cessation of the examination of patient specimens after a third score of less than 90 percent on the second retest (third test).

We are soliciting comments on the effects of these proposals on laboratories and individuals as follows:

- Are there logistical concerns and costs associated with administering testing events with more than 20 cytology challenges?
- If 20 cytology challenges are used, thereby requiring a 4 hour timeframe to administer the test, what would be the impact on the laboratory operation?
- Would laboratories prefer a 4 hour testing timeframe biennially, rather than the current 2 hour testing timeframe annually?
- Should there be a requirement for each test set to contain at least one cytology challenge from each of the four response categories or more than one cytology challenge from each response category?

We are also soliciting comments on the effects of these proposals on PT programs as follows:

- Are there a sufficient number of referenced cytology challenges available to assemble 20 cytology challenge test sets to test all cytology personnel nationally?
- Would increasing the number of cytology challenges increase the PT program's cost to administer the program?
- Would program costs to participants increase from a 10 slide annual test to a 20 cytology challenge biennial test?
- What statistical methods and testing research could CMS use to better determine the statistical power of a cytology proficiency test with 20 challenges and a multinomial, weighted scoring scheme?

E. Response Categories

The response categories described at § 493.945(b)(1) include: Unsatisfactory (Category A); normal or benign changes (Category B); low grade squamous intraepithelial lesions (LSIL)(Category C); and high grade squamous intraepithelial lesions (HSIL) or cancer (Category D). These response categories minimize the number of choices an individual can make during a testing event while retaining the general diagnostic categories used by most laboratories.

The CETC stated that while Bethesda 2001 terminology requires distinct interpretation of LSIL (Category C) and HSIL or cancer (Category D), the separation of these squamous abnormalities is not always an exact science and under the patient management guidelines of the American Society for Colposcopy and Cervical Pathology (ASCCP) both are referred for colposcopy. The CETC suggested only a small number of points be lost for failing to make this distinction. The ASCT suggested combining HSIL or cancer (Category D) and LSIL (Category C) to reflect the cytotechnologist practice of categorizing Pap smear diagnoses using three distinctions: Unsatisfactory, negative or normal, and ''refer to the pathologists.''

The CETC noted there were several concerns with the unsatisfactory category because studies have shown, even with obvious cases, it is difficult to achieve a consensus diagnosis with this response category. The ASCT suggested omitting the unsatisfactory category and eliminating the mandate to require at least one unsatisfactory slide in each test set. The ASCT stated that the 1992 description of unsatisfactory challenges is outdated and subjective, specifically the description of unsatisfactory challenges as those with scant cellularity, air drying, or obscuring material would not apply to liquid-based preparations; instead they suggested that the description for unsatisfactory included in the regulations should follow the less descriptive Bethesda 2001 terminology. Use of the Bethesda 2001 terminology would serve a dual purpose of not limiting programs that use different technology, for example semi-automated screening programs, and not restricting the specific criteria for unsatisfactory to the current preparation types.

To maintain the diagnostic categories used by most laboratories in reporting patient results, CLIAC recommended

retaining the four response categories. We agree with the CLIAC recommendation and are proposing to maintain the current four response categories: Unsatisfactory (Category A); Normal or Benign changes (Category B); LSIL (Category C); and HSIL or cancer (Category D).

While no change is proposed for the number of response categories, we are proposing at § 493.945, to change the description of the unsatisfactory category to reflect Bethesda 2001 terminology which states the specimen is processed and evaluated but unsatisfactory for evaluation of epithelial abnormality. All CMS approved cytology PT programs would be required to define the specific criteria used to describe the unsatisfactory response category.

We are soliciting comments on the following:

- Should criteria be defined in the regulation for ''unsatisfactory'' cytology challenges?
- If criteria for ''unsatisfactory'' are described, should the regulations include descriptions or criteria specific to each preparation type?
- Should a fifth response category be required, separating HSIL or cancer (Category D) to more closely follow Bethesda terminology? We note that Bethesda 2001 separates LSIL (Category C) from HSIL (Category D), and separates HSIL from cancer, also (Category D).
- If a fifth category of cancer is required, should an individual who has an incorrect response in this category be allowed to pass PT?

F. Cytology Challenge Referencing

The requirements currently at § 493.945(b)(1), specifies referencing each glass-slide challenge with 100 percent consensus by a minimum of three physicians certified in anatomic pathology. ASCT suggested referencing of the challenges include blind review by three cytopathologists on undotted slides; however, the organization also stressed the importance of including cytotechnologists in the review process, as this reflects the current practice of using a cytotechnologist as the initial screener and evaluator. A PT program recommended requiring each physician certified in anatomic pathology to independently review each challenge. CLIAC discussed these options but did not make a recommendation on changing the process for referencing the challenges.

CMS would encourage PT programs to use blind review or other mechanisms to ensure each cytology challenge is referenced in the correct category. In this proposed rule, we are proposing at § 493.945(c)(1)(i), to retain the requirement for 100 percent consensus by a minimum of three physicians certified in anatomic pathology. However, based on our experience, we are also proposing that each physician who references cytology challenges must examine gynecologic preparations on a routine basis.

We are soliciting comments on the following:

- Should the review of cytology challenges by three physicians certified in anatomic pathology be on undotted slides?
- Should the three physicians certified in anatomic pathology independently determine the response category for each cytology challenge?
- Should PT programs be required to include cytotechnologists in the review process for referencing cytology challenges? If so, describe a process for including cytotechnologists.

G. Biopsy Confirmation

The requirements currently at § 493.945(b)(1), specify biopsy confirmation of premalignant and malignant challenges. Consequently, PT programs need to obtain sufficient numbers of slides that meet the diagnostic criteria for these categories and have confirmatory histology. This requirement has resulted in the removal of potential PT challenges when sampling techniques fail to obtain diagnostic tissue or tissue samples are not consistent with the cytology diagnosis. It was stated at the June 2006 CLIAC meeting that while LSIL (Category C) is reproducible, there are instances of cytologic LSIL (Category C) that do not confirm by colposcopy. LSIL (Category C) lesions are often transient and may regress in the interval between the time the Pap smear is taken and the time of colposcopic biopsy. The CLIAC recommended removal of the requirement for biopsy confirmation of LSIL (Category C) challenges while retaining it for HSIL or cancer (Category D).

Based on the CLIAC recommendations and PT program comments, we are proposing to eliminate the requirement for biopsy confirmation of LSIL (Category C) cytology challenges used in PT testing. However, we are proposing at § 493(c)(1)(iii), to retain biopsy confirmation of HSIL or cancer (Category D) cytology challenges.

We are soliciting comment on the following:

- Should the requirement for biopsy confirmation of LSIL (Category C) cytology challenges for PT be retained?
- How many pathologists' diagnoses should be required for biopsy confirmation of these PT samples?

H. Validation of Cytology Challenges

As previously stated, the requirements currently at § 493.945(b)(1), include the referencing of challenges by three physicians certified in anatomic pathology and biopsy confirmation. The CETC stated that this initial validation process is inadequate and without additional validation processes, could lead to indiscriminate failure of qualified, competent personnel. The CETC recommended that a requirement for field validation of the challenges before inclusion in PT events be added, stating that slides used for PT must demonstrate they can be interpreted in a consistent manner by a significant number of practicing cytologists. The organization further stated that field validation must consist of statistical assessment of the performance of each challenge under actual testing conditions. An example would be validation of at least 20 responses for each challenge with a correct response from participants at least 90 percent of the time.

In addition, the CETC indicated that the validation must be ongoing with continuous monitoring because slides may become broken, faded, or the coverslip may become unattached during use and cease to meet validation criteria. The CETC recommended that individuals who fail a testing event based on a slide that falls below validation criteria for that testing cycle not be penalized and there should be no additional cost to the affected individual or his or her institution if retesting is necessary.

The need for field validation of challenges is supported by a CDC study ''*Comparison of Cytology PT—Glass Slides* vs. *Virtual Slides*.'' *See,* 48 *Acta Cytologica* (2004) 788–794. The performance of the participants on glass-slide and computer-based PT were compared in this study. The glass-slide PT challenges were field validated by inclusion in several testing cycles, but the computer-based challenges were only referenced by three physicians certified in anatomic pathology. Four computer-based challenges failed to obtain a 90 percent consensus during field testing. When the four challenges were excluded from the scoring, the results were similar for both types of PT. The authors concluded that each challenge must be field validated by cytotechnologists and pathologists.

The CLIAC acknowledged that all slides, particularly liquid-based

preparations, fade at a faster rate than conventional slides and may fail to meet field validation criteria over time. The CLIAC recommended adding a requirement for PT programs to field validate all challenges with continuous monitoring and removal of any challenge that fails to meet field validation criteria. The CLIAC also recommended that the validation process be disclosed to participants by the PT program. At a subsequent meeting, the PT programs suggested not including specific criteria for field validation in regulatory language, stating the criteria for validation may change as more knowledge is acquired about the process of validation and as technology changes.

To ensure consistent testing and minimize the concerns about inappropriate cytology challenges, validation criteria would be assessed by CMS during the PT program approval and reapproval processes. Although we are not proposing in this rule to include specific criteria for validation, we are proposing at § 493.945(c)(1)(ii), that programs are required to field validate and disclose the validation process to their participants.

We are soliciting comments on the following:

- Should the regulations include a requirement for field validation of each cytology challenge before inclusion in a test set?
- Should criteria for this initial field validation be stated in the regulations? If so, how should the criteria be defined?
- Should continuous monitoring of each cytology challenge be required?
- Should continuous monitoring criteria be specified in the regulations? If so what criteria should be required?
- Will the requirement for continuous field validation add any additional costs?

I. Scoring Scheme

The regulations currently at § 493.945(b)(3)(ii)(c) through (g), specify separate scoring schemes for cytotechnologists and technical supervisors (pathologists) for 10 slide and 20 slide tests. Cytotechnologists are not penalized for their inability to differentiate between LSIL (Category C) and HSIL or cancer (Category D), but technical supervisors (pathologists) lose points for incorrectly differentiating between the LSIL (Category C) and HSIL or cancer (Category D) categories.

The 1992 scoring scheme awards partial credit to cytotechnologists for reporting unsatisfactory or negative challenges as LSIL (Category C) or HSIL or cancer (Category D). A passing score is at least 90 percent as specified currently at § 493.855(b)(2) and (b)(3). The CETC attributed the difference in pass rates of the cytotechnologists and pathologists to the 1992 scoring scheme which awards partial credit to cytotechnologists, but penalizes pathologists. The CETC recommended separate schemes be retained and include only a small penalty for a pathologist not distinguishing between LSIL (Category C) and HSIL or cancer (Category D); no penalty for responding that a normal or benign challenge is unsatisfactory; a penalty for reporting an unsatisfactory as normal or benign change; and a zero score for reporting an HSIL or cancer (Category D) as normal or benign change (false negative) and a normal or benign change as HSIL or cancer (Category D)(false positive). The ASCT suggested a unified scoring scheme, stating that while pathologists are responsible and accountable for reporting results, cytotechnologists are accountable for the initial location, interpretation and marking of representative cells. The ASCT also suggested that the highly punitive point deductions for a single discrepancy (calling an HSIL or cancer (Category D) a normal or benign change (Category B)) be eliminated.

The CLIAC recommended the removal of the automatic failure for reporting one HSIL or cancer (Category D) as a Normal or Benign Change (Category B). The CLIAC discussed the need to score the test so that more points are lost for misinterpretation of HSIL or cancer (Category D) as a Normal or Benign Change (Category B), but not so many points that missing a single challenge results in a failing score (less than 90 percent). It was noted that for a 20 slide test, a (−5), penalty for misinterpreting one HSIL or cancer (Category D) as a Normal or Benign Change (Category B) would result in a total loss of ten points which is a significant penalty commensurate with the seriousness of the error but does not result in an automatic failure. CLIAC also noted that if the point loss for a single challenge resulted in failure, the programs may be discouraged from including more than one of these types of challenges.

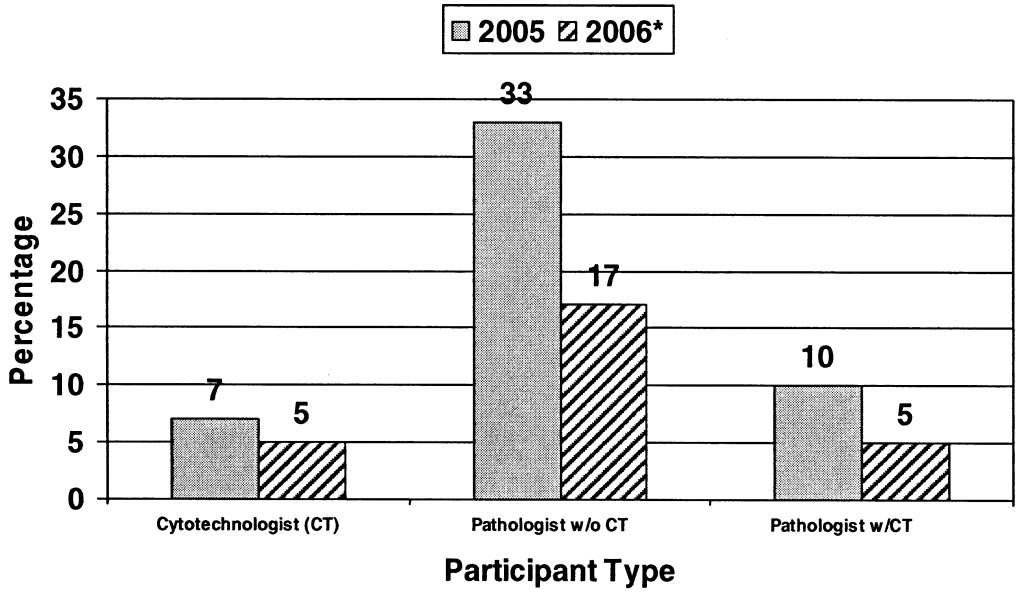
CLIAC recommended balancing the removal of the automatic failure with removing the partial credit obtained by cytotechnologists for reporting an Unsatisfactory or Normal or Benign Change as LSIL (Category C) or HSIL or cancer (Category D). Partial credit is awarded under the 1992 scoring scheme to cytotechnologists because this reporting would result in the slide being referred to the pathologist for further review. However, if the overcall diagnosis is signed out by the pathologist, this results in over treatment of the patient which may have serious consequences (costs, stress on the patient, and can lead to unnecessary procedures that could result in patient infertility). It was also noted that a flattening of the point values, less partial credit awards and fewer points deducted for calling an HSIL or cancer (Category D) a negative would decrease the ''gaming'' aspects, especially if the number of cytology challenges are also increased to 20 as discussed previously under ''Number of Cytology Challenges.''

CLIAC referenced another area where partial credit was not warranted was reporting an LSIL (Category C) challenge as Unsatisfactory (Category A). CLIAC noted this was one of the most reproducible diagnoses and that it would be reasonable to require both cytotechnologists and pathologists to make this distinction.

In consideration of the many comments and recommendations, in this proposed rule, the scoring scheme awards fewer partial credits to discourage over reporting and reduce the gaming aspects. It also eliminates the automatic failure for misdiagnosis of a single HSIL or cancer (Category D), which would balance the loss of partial credit for over reporting a single cytology challenge.

Although the ASCT suggested that a passing score should be changed from at least 90 percent to at least 80 percent, CMS experience with testing for the 2005 and 2006 testing cycles (see tables for data on the first and second failure rates for 2005 and 2006 testing cycles) demonstrates a low rate of failure on the initial test and an even lower failure rate on subsequent retests. Therefore, we propose at § 493.853(b)(3) to retain the 90 percent or higher as the passing score.

National Cytology Proficiency Testing Results
Failure Rates First Proficiency Test



•Preliminary 2006 data (January 1- December 5, 2006)

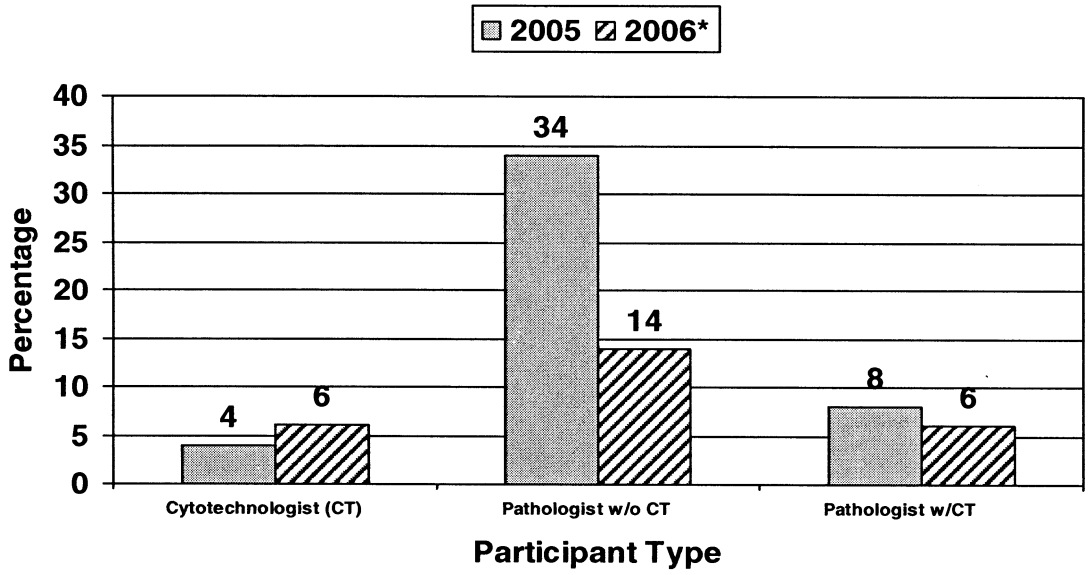
Failure rate initial tests	2005	2006*
Total Number Tested	12,831	12,217
Total Number of Failures	1,177	653
Cytotechnologists	447	282
Pathologists Without Cytotechnologists** ...	156	74
Pathologists With Cytotechnologists** ...	570	297

*Preliminary 2006 Data (January 1, 2006 through January 14, 2007).

Note: 2005 Data included a category of individuals (cytotechnologists and pathologists) who were not employed permanently at one laboratory during the year. Four of these individuals failed the first test but were not included in the bar graph.

**From a personnel perspective, cytology laboratories may be structured differently from one another. Currently the majority of laboratories have a pathologist who is assisted by a cytotechnologist during their daily routine. In such situations the cytotechnologist is generally responsible for locating and identifying cells that are abnormal. The pathologist would then be responsible for issuance of the final diagnosis on the slide in question. These scenarios are what is meant by "Pathologists with Cytotechnologists" in the charts located in this section. "Pathologists with Cytotechnologists" are tested in a manner similar to their daily routine. Pathologists who are assisted by cytotechnologists are given a choice to be tested with a test set that has been previously examined by a cytotechnologist who located and identified the abnormal cells or the pathologist may choose to be tested with a test set that has not been previously examined. The remainder of the pathologists work in laboratories where they are required to locate and identify abnormal cells and issue a final diagnosis without the assistance of a cytotechnologist. These scenarios are what is meant by "Pathologists without Cytotechnologists" in the charts. Pathologists who work without a cytotechnologist must be tested in the same manner as they perform their daily routine. They are therefore to be tested on a test set that has not been previously examined by a cytotechnologist.

National Cytology Proficiency Testing Results
Failure Rates Second Proficiency Test



* Preliminary 2006 data (January 1, 2006- January 14, 2007)

Failure rate second test (1st retest)	2005	2006 *
Total Number Tested	1,128	509
Total Number of Failures	110	33
Cytotechnologists	17	13
Pathologists Without Cytotechnologists	45	7

Failure rate second test (1st retest)	2005	2006 *
Pathologists With Cytotechnologists	45	13

* Preliminary 2006 Data (January 1, 2006 through January 14, 2007).

Note: 2005 Data included a category of individuals (cytotechnologists and pathologists) who were not employed permanently at one laboratory during the year. Three of these individuals failed the second test but were not included in the bar graph.

We propose to change the point values for a 20 cytology challenge test for a technical supervisor qualified under § 493.1449(b) or (k) to the following:

Correct response	Technical supervisor examinee response			
	A—UNSAT	B—NEGATIVE	C—LSIL	D—HSIL
A—UNSAT	5	0	0	0
B—NEGATIVE	2.5	5	0	0
C—LSIL	0	0	5	2.5
D—HSIL	0	−5	2.5	5

We propose to change the point values for a 20 cytology challenge test for a cytotechnologist qualified under § 493.1469 or § 493.1483 to the following:

Correct response	Cytotechnologist examinee response			
	A—UNSAT	B—NEGATIVE	C—LSIL	D—HSIL
A—UNSAT	5	0	0	0
B—NEGATIVE	2.5	5	0	0
C—LSIL	0	0	5	5
D—HSIL	0	−5	5	5

Comments are solicited on the following:

- Should the automatic failure for misdiagnosing an HSIL or cancer (Category D) as a Normal or Benign Change (Category B) be retained for pathologists and cytotechnologists?
- Should pathologists and cytotechnologists be evaluated using the same scoring scheme? If not, how should the scoring grid be composed?
- Should the cytotechnologist scoring scheme be more stringent than the current regulations?
- How would the same scoring scheme meet the statutory requirement for evaluating workplace performance of both cytotechnologists and pathologists with respect to their responsibilities in reviewing cytology preparations?

CMS has requested additional information from cytology PT providers to analyze trends in PT failures over time. This information should include, at a minimum, the impact of automatic failures due to missed High-Grade Lesions (HSIL), and the impact of false positives and false negatives on scores over time. Examples of information to be collected include:

- The number of automatic failures;
- The number of automatic failures with additional false positives;
- The number of automatic failures with additional false negatives;
- The number of automatic failures with both additional false positives and false negatives;
- The number and types of false positives that led to PT failure; and
- The number and types of false negatives that led to PT failure over time.

J. Retesting and Remediation

The requirements currently at § 493.855(b) allow a series of retests and remediation when an individual fails a testing event (that is, scores less than 90 percent). The CLIAC recommended changing the regulatory language to eliminate the word ''fail'' when an individual scores less than 90 percent to convey that an individual has not failed PT until all retesting is complete.

Under the current regulations, it is at the discretion of the PT program to select the type of information concerning incorrect responses to be provided to assist laboratories and individuals in determining the area(s) for remediation. For education and remediation, the CLIAC recommended that PT programs share additional, more specific information to examinees on each challenge that was missed.

The requirements currently at § 493.855(b)(1), requires retesting of any individual who does not obtain a score of at least 90 percent on a testing event. The ASCT commented that the regulation is confusing as to the total number of testing events permitted for an individual and recommended that only two retesting events (three total attempts) be allowed. The ASCT also suggested that all retesting events be performed at the individual's laboratory, rather than at the PT program's facility.

We are proposing to replace the term ''failure'' currently at § 493.855(c) with ''scores less than 90 percent'' in proposed § 493.853(c). The requirements currently at § 493.855(b)(2) and (b)(3), that laboratories provide remedial training and education in the area of failure, are retained in this proposed rule at § 493.853(c)(2)(i) and § 493.853(c)(3)(i), respectively. We are proposing to maintain the requirements at § 493.945 applicable to each approved PT program and to the approval and reapproval processes, and CMS would continue to review the information provided by PT programs to accompany the test score. The requirements currently at § 493.855(b)(2) and (b)(3), that laboratories provide remedial training and education in the area of failure, are retained in this proposed rule at § 493.853(c)(2)(i) and § 493.853(c)(3)(i), respectively. CMS is retaining the current requirement for an initial retest to take place not more than 45 days after receipt of notification of failure. In the event remediation is required as under proposed §§ 493.853(c)(2) and 493.853(c)(3), CMS is proposing to impose a 45 day period for retests, which will commence at the completion of remedial training at § 493.853(c)(2)(iii) and § 493.(c)(3)(iii). Currently, the PT programs determine the site of retesting events with CMS approval. We are proposing to retain this requirement in this rule, but solicit comments on this subject as follows:

- Should the PT programs provide more specific information concerning incorrect responses to the laboratory and individual to improve the testing process? Please clarify what information should be provided.
- Should all testing be conducted in the laboratory or should some testing be conducted at the location of the PT program?
- How many times should an individual be permitted to take a retest? Please provide rationale to support your recommendation.

K. Appeals Process

At this time, the PT program requirements for approval do not include an appeals process. However, CMS asks PT programs to describe their appeals process when applying for CMS approval and reapproval. It was noted at the June 2006 CLIAC meeting that some individuals were not aware they could appeal their score during the 2005 testing cycle because a written description of the appeals process was not provided by the PT program to participants unless requested. The CLIAC recommended that the PT programs describe their appeals process to all participants before enrollment in the program.

We are proposing at § 493.945(b)(4), that the PT program provide a written description of the appeals process and make it available to all enrolled individuals.

We are soliciting comments on the following:

- What criteria should be included in an appeals process?
- Should PT programs be required to provide participants with a description of their appeals process?
- When should a description of the appeals process be shared with the participants?

L. Testing Site for the First Event

The provisions currently at § 493.855(a) require announced or unannounced on-site testing for the first testing event. We are retaining this statutory requirement for on-site testing. However, a few individuals have requested more choices for testing locations including but not limited to professional meetings, seminars, and trade shows. We are soliciting the public's comments on this proposal.

M. Proctors

In the February 28, 1992 final rule with comment, we were silent on the use of a proctor to administer the testing event on-site. During the ongoing discussion with CAP regarding approval of their cytology PT program, CAP asked CMS whether in-house proctors could be used to administer the test. CAP stated that it would be less costly for programs and ultimately for laboratories if PT programs were able to use in-house laboratory personnel as test proctors. MIME also requested using laboratory proctors in their initial application.

During the review process, CMS evaluated the procedures the programs would use to ensure the integrity of the testing event. Both programs were approved allowing the use of in-house laboratory personnel as test proctors. At the August 2006 meeting, the PT programs were asked if the proctor responsibilities should be the laboratory's responsibility. Recommendations were made to hold

the laboratory responsible for proper administration of the testing event.

The CLIAC recommended that the PT programs determine the proctor requirements. However, to maintain consistency among programs, all PT programs must meet the same requirements. We are proposing at § 493.945(b)(5) and (b)(6), to add the following requirements: (1) PT programs must provide training for the laboratory proctor, which includes written instructions for the laboratory to determine the number of proctors needed to administer the PT event and a contingency for a backup proctor; (2) written instruction for the laboratory director and proctor to ensure program procedures are fulfilled; (3) a proctor examination that evaluates the proctor's understanding of proper testing protocol; and (4) the laboratory director must sign a written agreement stating the laboratory is responsible for and accepts responsibility for administering the PT as defined by the program and CMS. In the event of an improperly administered test, each individual tested in the laboratory would be assigned a score of ''zero''. We are also proposing a prohibition on the use of resources capable of assisting individuals with the interpretation of testing materials during the testing event, and on duplication of testing material by any means including photography.

We invite comments on the following:

- What specific criteria should there be for selection of the proctor?
- How often should proctor training and testing be required?
- What penalties should be applied to laboratories and individuals when testing is not conducted according to requirements?

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, 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, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Collection of Information Requirements

Under the Paperwork Reduction Act (PRA) of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Therefore, we are soliciting public comments on each of these issues for the information collection requirements discussed below.

Note: All of the data that follows are based on actual 2005 cytology proficiency testing data. The 2006 data are significantly lower. The Paperwork Reduction Act (PRA) at 1320.3(h)(7) (5 CFR Part 1320) states that examinations designed to test the aptitude, abilities, or knowledge of persons tested and the collection of information for identification or classification in connection with such examinations are not considered ''information'' under the PRA and is exempt from burden estimates unless the Office of Management and Budget determines otherwise. Therefore, this section below applies to laboratories and laboratory employees, but does not apply to the proficiency testing programs described in this rule.

Condition: Cytology: gynecologic specimen examinations § 493.853.

Section 493.853(a)(2) states that the laboratory must provide the Proficiency Testing (PT) program with information necessary to identify all laboratory employees at its facility who are to be tested.

The burden associated with this requirement is the time and effort put forth by the laboratory to provide the necessary information. The estimated total number of laboratory employees taking the PT once every 2 years is approximately 12,831. It will take an estimated 5 minutes per person to provide the information necessary to enroll for testing. The approximate biennial total per laboratory employee is 5 minutes. Therefore the total annual burden is 533.4. (12,831 laboratory employees × 0.08 hours = 1026.48 biennial hours or 513.24 hours annually)

Section 493.853(b)(2) requires a laboratory to notify each laboratory employee of the date, time and location of testing.

The burden associated with this requirement is the time and effort put forth by the laboratory to notify its employees. We estimate the total number of laboratories is 2,142 in which a total of approximately 12,831 laboratory employees are employed, who need to be notified once every 2 years. It will take less than one minute for the laboratory to notify its employees of the date, time and location of testing. The total burden is one minute per laboratory and the national biennial total burden is 2,142 minutes or 35.7 hours. The annual burden is 17.8 hours.

Section 493.853(b)(3)(ii) states that for an individual with an excused absence, the laboratory must contact the PT program to determine the date, time, and location of the make-up examination.

The burden associated with this requirement is the time and effort put forth by the laboratory to obtain the information. There will be approximately 260 excused absences in a 2 year testing period. It will take approximately 10 minutes to contact the PT program to gather this information. The estimated biennially total is 10 minutes per laboratory employee and the national total burden is 44.2 hours biennially. (260 excused absences × .17 hours = 44.2 hours OR 22.1 hours annually)

Section 493.853(c)(2)(i) states that when a laboratory employee fails the cytology PT test the second time, he or she must obtain documented remedial training and education in the area of failure.

The burden associated with this requirement is the time and effort put forth by the employee to complete training and obtain documentation of that training. There will be approximately 110 laboratory employees who fail the second test (performed on-site at the laboratory). It will take approximately 4 hours per laboratory employee to complete the remedial training and obtain the necessary documentation. The national total is 440 hours biennially. (110 laboratory employees × 4 hours = 440 hours biennially OR 220 hours annually)

Section 493.853(c)(2)(ii) states that if a laboratory chooses to direct a laboratory employee who failed the first and second tests to continue examining patient Pap smears, all patient Pap smears must be re-examined by a laboratory employee who has passed the PT test and the re-examination must be documented.

The burden associated with this requirement is the time and effort put for by the laboratory to document that the patient Pap smears were re-examined. There will be approximately 110 laboratory employees who,

biennially, fail the second tests. It will take an estimated 10 seconds per slide to document that patient Pap smears were re-examined. Considering an average of 75 Pap smears that would be examined per day by a laboratory employee who would re-examine patient smears, the estimated total burden biennially for each laboratory employee who is re-screening smears is, 12.5 minutes per day or .21 hours. There would be approximately 20 working days until each laboratory employee may be retested. Each laboratory employee's burden is 4.17 hours; therefore, the total national burden is 34,650 hours, biennially. (*Rescreening Time:* 75 slides per day × 20 days = 1,500 slides to be rescreened per failed laboratory employee. 1,500 slides per failed laboratory employee × 110 failed employees = 165,000 slides to be rescreened. 165,000 slides to be rescreened × .21 hours per slides = 34,650 hours OR 17,325 hours annually. *Documentation Time:* 165,000 slides to be rescreened × .003 hours = 495 hours biennially OR 247.5 hours annually.)

Section 493.853(c)(3) states that when a laboratory employee has failed the first, second, and third cytology PT test, he or she must obtain 35 hours of documented, continuing education and discontinue examining patient Pap smears until he or she passes a PT test.

The burden associated with this requirement is the time and effort put forth by the employee to obtain and document the continuing education. There will be approximately 10 laboratory employees, biennially, who fail three tests. It will take an estimated 35 hours to obtain the required continuing education per laboratory employee. The total national burden, biennially, will be approximately 350 hours. (10 laboratory employees × 35 hours = 350 hours biennially OR 175 hours annually)

Cytology: gynecologic examinations § 493.945.

While the requirements below are subject to the PRA, we believe the burden associated with these requirements is exempt from the requirements of the PRA as defined in 5 CFR 1320.3(h)(7).

Cytology: gynecologic examinations § 493.945.

Section 493.945(a) requires PT programs to notify the laboratory at least 30 days before the testing event of the location, date, and time of testing. For those individuals who score less than 90 percent on the initial testing event, a second test must be scheduled by the laboratory and the individual must take the test within 45 days after the laboratory is notified to ensure the laboratory's compliance with § 493.853(c).

Section 493.945(b)(1)(i) states that if slides are still subject to retention by the laboratory, they may be loaned to a proficiency testing program if the program provides the laboratory with documentation of the loan of the slides and ensures that slides loaned to it are retrievable upon request.

Sections 493.945(b)(4), (5), and (6) require the program to:

- Provide a written description of the appeals process that is available to all individuals enrolled in the program.
- Provide training for laboratory designated proctors that includes—

(1) Written instructions for the laboratory to determine the number of proctors needed to administer the proficiency testing event, including contingency for a backup proctor if needed;

(2) Written instructions for the laboratory director and proctor to ensure program procedures are fulfilled; and

(3) A proctor examination that evaluates the proctor's understanding of proper testing protocol.

Provide a written agreement, to be signed by the laboratory director and returned to the program before testing, stating the laboratory is responsible for and accepts responsibility for administering the proficiency testing as defined by the program and CMS.

Section 493.945(c)(1)(ii) requires the program to disclose their method of continuous field validation to participants before enrollment in the program.

We have submitted a copy of this proposed rule to OMB for its review of the information collection requirements described above. These requirements are not effective until they have been approved by OMB.

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule; or

2. Mail copies to the address specified in the **ADDRESSES** section of this proposed rule and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, *Attn:* CMS Desk Officer, *OIRA_submission@omb.eop.gov* or fax (202) 395–6974.

VI. Regulatory Impact Statement

A. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), Executive Order 13132 on Federalism, and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Order 12866 (as amended by Executive Order 13258, which merely reassigned responsibility of duties) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We do not believe this proposed rule would constitute an economically significant rule because it has no budget implications that would impact Medicare and Medicaid benefit payments by over $100 million in any one year. However, if finalized, the proposed rule would revise the requirements for cytology proficiency testing (PT) and would affect laboratories and individuals now subject to participation in PT, and could have some budget implications. In addition, this proposed rule, if finalized, would revise the requirements for cytology PT programs, which would cause the three existing PT programs to incur some costs as they modify their CMS-approved programs to meet the requirements specified in this rule. It may also have an effect on some States regarding State PT requirements. Therefore, we have prepared a RIA although the specified threshold to require a full analysis has not been met.

The RFA requires agencies to analyze options for regulatory relief of small businesses, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, almost all cytology laboratories are considered to be small entities. The cytology PT programs are also considered small entities due to their nonprofit status. Individuals and States are not included in the definition of a small entity. Based on our initial analysis, we expect that this proposed rule would not have a significant impact on a substantial number of small

businesses or other small entities because only two of the proposed changes to the current PT requirements are anticipated to have non-negligible impacts, and these two changes are largely offsetting (that is, the increase in number of cytology challenges per test from 10 to 20, and decreased frequency of testing from annually to every other year). For the two year test cycle, there would be no increase in the amount of time an individual would spend taking the test. And although the number of challenges per test would increase, because the frequency of testing would decrease, programs would not need to increase the inventory of challenges to provide testing. Therefore, the Secretary has determined that this proposed rule would not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us 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 100 beds. This proposed rule would not affect small rural hospitals because only two of the proposed changes to the current PT requirements are anticipated to have non-negligible impacts, and those two changes are largely offsetting (that is, the increase in number of cytology challenges per test from 10 to 20, and decreased frequency of testing from annually to every other year). Therefore, for purposes of our obligations under section 1102(b) of the SSA, we are not providing an analysis.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately $130 million. Based on our assessment, this rule would have no consequential effect on State, local, or tribal governments, or on the private sector. We anticipate that States will not incur substantial costs if this proposed rule is finalized because it does not contain changes that would result in significant cost differences from the regulations that are currently in place. We have determined that this proposed rule generally does not significantly affect States' rights, roles, and responsibilities. This proposed rule would impact one State cytology PT program (Maryland), which currently meets the Clinical Laboratory Improvement Amendments of 1988 (CLIA) requirements for CMS approval, and would require the State to update their program requirements to meet the new final requirements.

The objective of this regulatory impact analysis is to summarize the cost and benefits of implementing the regulations we are proposing. The conclusions and assumptions contained in this RIA are based on cytology PT data from 2005, the first year national testing took place.

Public health benefits are not anticipated from the proposed changes to the cytology PT requirements compared to those in the existing regulation in terms of reducing the number of incorrect diagnoses or other public health measures (for example, reduction in false negative or false positive cervical cancer diagnoses, reduction in cervical cancer morbidity or mortality) based on analysis of relevant available data. As no data are available to suggest otherwise, we believe that the proposed changes may produce virtually the same results as the existing regulation in terms of PT outcomes (for example, examinee proficiency, number of examinees passing each test). We believe that the proposed regulations will result in a reduced burden on the population being tested and their employers. Some of this reduced burden is quantifiable in monetary terms as cost savings associated with less frequent testing; however, other effects can not be quantified.

No distributional effects from the proposed changes are anticipated as they do not result in significant changes in treatments or outcomes for different groups. Further, the proposed changes are unlikely to increase market prices for Pap smears or other health care costs as they are not anticipated to result in any significant change in PT outcomes, or to increase the costs associated with gynecologic cytology PT.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This proposed rule will not have a substantial direct effect on State or local governments, preempt States, or otherwise have a Federalism implication.

B. Anticipated Effects

This proposed rule includes changes that, if finalized, would impact 2,142 cytology laboratories and 12,831 individuals (reference: *http://www.cms.hhs.gov/CLIA/downloads/2005FinalTestingResults080906MDMIME.pdf*) who screen or interpret the 65 million gynecologic cytology preparations in the U.S. each year (references: Solomon D., Breen N., and McNeal T. *Cervical cancer screening rates in the United States and the potential impact of implementation of screening guidelines:* 57(2)CA A Cancer Journal for Clinicians, 105–111(2007) and Eltoum I. A., and Roberson J.: *Impact of HPV testing, HPV vaccine development, and changing screening frequency on national Pap test* volume, 111(1) Cancer Cytopathology 34–40(2007)). These laboratories and individuals are required to participate in PT under the regulations implemented by the February 28, 1992 final rule with comment implementing the CLIA statute. This proposed rule also includes changes that would impact the three existing CMS-approved cytology PT programs.

Although we have insufficient data to calculate the actual costs and benefits that would result from these proposed changes, we are providing an analysis of the potential impact based on available information and certain assumptions. We expect these proposed requirements to result in a negligible increase in burden or cost to the PT programs and a decreased burden for laboratories and individuals, with little or no change in the cost for laboratory or individual participation in cytology PT. We do not anticipate there would be any effect on the Medicare and Medicaid programs.

This proposed rule includes requirements for laboratories, individuals who conduct cytology testing, and cytology PT programs that would revise those specified in the February 28, 1992 final rule with comment. Implementation of these proposed requirements in a final rule would result in changes that are anticipated to have quantifiable and non-quantifiable impacts.

The following proposed regulatory changes, if finalized, will result in quantifiable impact:

- Decrease the testing frequency from once per calendar year to once every two calendar years.
- Increase the number of cytology challenges per testing event for the first two testing events from 10 to 20 and require no more than 4 hours rather than the current 2 hours for completion of the test.

The following changes are anticipated to have minor impact on regulated parties, but data are insufficient to quantitatively evaluate their effects:

- Expand test medium options to allow other potential media such as computer-based virtual slides or alternative testing formats, in addition to glass slide cytology challenges.
- Revise the scoring scheme for technical supervisors (pathologists) and cytotechnologists to eliminate the partial credit for reporting response Category C (LSIL) as response Category A (Unsatisfactory) and reduce the penalty score for reporting response Category D (HSIL or cancer) as response Category B (Normal or Benign Changes). In addition, for cytotechnologists, remove the partial credit for over reporting response Category A (Unsatisfactory) and response Category B (Normal or Benign Changes) cytology challenges as either response Category C (LSIL) or response Category D (HSIL or cancer).
- Eliminate the requirement for tissue biopsy confirmation of response Category C (LSIL) cytology challenges.
- Make the laboratory director responsible for ensuring proper test administration (meeting CMS requirements) when PT is held on-site in the laboratory and reporting identifying information for all individuals to CMS and PT programs.
- Allow appropriately trained proctors to administer the testing event on-site in the laboratory.
- Revise the description of the response Category A (Unsatisfactory) to reflect the current Bethesda 2001 Terminology criteria for ''unsatisfactory for diagnosis'' as approved by CMS.
- Increase the required number of response Category D (HSIL or cancer) cytology challenges to at least two in a 20 cytology challenge test, which is equivalent to the current requirements for one per 10 challenge test.
- Require continuous field validation of cytology challenges throughout their use in testing.
- Require the PT program to inform participants of the appeals process in writing.

The potential impact of each of these proposed changes is discussed below.

1. Quantifiable Impact

Decrease the testing frequency from once per calendar year to once every two calendar years and increase the number of cytology challenges per testing event for the first two tests from 10 to 20, requiring no more than 4 hours rather than the current 2 hours for completion of the test.

a. Rationale

The 10 slide test required once per calendar year in the current rule was implemented to limit the number of slides that would have to be accumulated and referenced to provide national testing to all individuals who examine gynecologic cytology preparations. The increase in the number of cytology challenges from 10 to 20 is proposed in conjunction with the increase in time between testing events from 1 to 2 year cycles. These changes are linked and are considered here together.

The rationale for increasing the number of test challenges from 10 to 20 is to improve the test sensitivity. Generally, increasing the challenges from 10 to 20 for the initial test and first retest in this proposed rule was based on the desire to increase statistical validity, while also attempting to minimize the overall costs expended to provide and take a test with a larger number of challenges.

With regards to the temporal spacing of tests, the skills required in locating and identifying cytologic abnormalities are not quickly lost. These skills are based on knowledge and memory, or ''semantic'' knowledge accumulated by training and experience and this knowledge is durable (Nagy G.K. and Newton L.E., *Cytopathology proficiency testing: Where do we go from here*? 34(4)Diagnostic Cytopathology 257–264 (2006)). Therefore, it is not expected that cytotechnologists and pathologists, who routinely examine gynecologic cytology specimens, would lose these skills and knowledge over a period of 1 year or 2 years.

b. Potential Impact

Increasing the number of cytology challenges to 20 for each test is proposed in conjunction with decreasing the testing frequency from annual testing to ''at least once every 2 calendar years.'' These changes would have the following effects on laboratories:

- Decrease the burden by decreasing the frequency for which laboratories would have to prepare for testing (for example, the time needed to schedule testing, provide for proctor training, proctor preparation for the testing event, and arranging for make-up testing for individuals who miss the testing event or retesting for individuals scoring less than 90 percent).
- Increase the length of time for taking the first two tests from 2 hours to 4 hours corresponding to the increase in number of cytology challenges from 10 to 20.

c. Estimated Costs

The baseline for measuring costs and benefits of the proposed change is found in the existing regulation that is equivalent to no change. The primary cost impacts of the proposed change compared to the baseline are attributable to time-related changes: (1) A reduction in the frequency of testing from annually to every other year; and (2) an increase in the time needed to take each of the first two tests by increasing the number of cytology challenges from 10 to 20. To reflect the impact of these time-related changes and permit meaningful comparison, annual testing costs are estimated for a common base population of examinees. The costs of the proposed changes (testing every other year with 20 cytology challenge tests for all tests) are estimated using one-half of the base population, and the costs of the existing regulation (annual testing with 10 challenge tests for the first and second tests; 20 cytology challenge tests for the third and fourth tests) are estimated using the entire base population. Annual testing costs are expressed in constant 2005 dollars.

A lack of detailed information about testing costs and related resource use precludes the use of scientifically defensible probability distributions for cost estimates. The assumptions used and described constitute plausible alternatives, which provide a reasonable basis for calculation of costs. These assumptions are stated explicitly, and most include a range of estimates represented by a high and low value, such that all values with lower cost implications are reflected in the total low estimates and those with higher cost implications are reflected in the total high estimates. The assumptions stated below are used to estimate the annual testing costs under the existing regulation and for the proposed changes in testing frequency and number of cytology challenges.

The primary costs associated with cytology PT under the existing regulation and the proposed changes are the value of lost examinee and proctor work time associated with testing requirements. The assumptions used to estimate the time requirements are detailed below. Other costs associated with operating cytology PT programs are not quantified due to the limited information concerning these costs, and that the most substantial ones can be characterized as sunk (fixed) costs required for initial start-up of a program. Initial and ongoing slide acquisition costs are assumed to be negligible as they are currently donated. Ongoing

costs for sustaining program operations are primarily fixed costs including overhead, administration, challenge referencing, challenge validation, maintenance and storage costs. The requirement for continuous field validation as proposed in this rule would be new; however, the existing CMS-approved PT programs have already implemented validation processes. We assume that these costs would continue at more or less the same level as long as there is a regulation requiring cytology PT using the current technology, so the anticipated cost impact for the proposed changes is assumed to be negligible over time. If a program incorporates new technology, we would anticipate an initial increase for start-up costs which may be offset by decreased operating costs over time for the program, but actual costs for such a program are unknown at this time. We are soliciting input from the public on this subject.

d. Examinee Population

The base population used for this impact analysis consists of a total of 12,831 individuals taking the first test with the following breakdown; 6,530 (50.9 percent) cytotechnologists, 5,833 (45.5 percent) pathologists with cytotechnologists, and 468 (3.6 percent) pathologists without cytotechnologists based on CMS' Final 2005 National Cytology Proficiency Testing Results. (Table 1, Source: *http://www.–cms.–hhs.–gov/–CLIA/–downloads/–2005–Final–Testing Results–080906MDMIME.pdf*, accessed 4/13/2007). The same base population is assumed to take the first test annually under the existing regulation. For the proposed change to testing every other year, it is assumed that one-half of this base population of examinees will test each year. This assumption is consistent with information received from the current PT program regarding how they would implement the proposed change. For annual testing under the existing regulation, the number of examinees for the second, third, and fourth tests corresponds to the 2005 base population used for the first test, and is based on this population's test results from the same source as follows in the table below. Similarly, for the proposed change to testing every other year, it is assumed that one-half of these examinees will test each year.

TABLE 1—BASE POPULATION NUMBER OF EXAMINEES BY TEST

	First	Second	Third	Fourth
Cytotechnologists	6,530	435	13	0
Pathologists with Cytotechnologists	5,833	561	31	3
Pathologists only	468	132	16	1
Total	12,831	1,128	60	4

Source: CMS' Final 2005 National Cytology Proficiency Testing Results.

e. Hourly Salary and Total Compensation

Cytotechnologist hourly compensation is assumed to range from $36.64 to $42.76 in 2005 dollars. This range of estimates is based on the 2005 hourly median wage rates of $26.17 reported for cytotechnologist staff for the low estimate and of $30.54 for cytotechnologist supervisor for the high estimate by the ASCP 2005 Wage and Vacancy Survey, which were then multiplied by 1.4 to estimate total hourly compensation including benefits. These wage rates are similar to those reported by the U.S. Department of Labor, Bureau of Labor Statistics, Occupational Employment Statistics, May 2005 national wage estimates for Medical and Clinical Laboratory Technologists (29–2011) at the 75th and 90th percentiles, $26.94 and $31.98, respectively. (Steward, CA and NM Thompson, ASCP 2005 Wage and Vacancy Survey. Lab Medicine 37(8): 465–469, 2006)

Pathologist hourly compensation is assumed to range from $58.98 to $117.77 in 2005 dollars. This range of estimates is based on the 2005 mean hourly wage rates of $42.13 reported for Health Diagnosing and Treating Practitioners, All Other (29–1199) for the low estimate, and of $84.12 reported for Physicians and Surgeons, All Other (29–1069), Medical and diagnostic laboratories for the high estimate by the U.S. Department of Labor, Bureau of Labor Statistics, Occupational Employment Statistics, May 2005, which were then multiplied by 1.4 to estimate total hourly compensation including benefits.

TABLE 2—HOURLY SALARY AND TOTAL COMPENSATION COST ASSUMPTIONS

[2005 dollars]

	Salary		Total compensation	
	Low	High	Low	High
Cytotechnologist	$26.17	$30.54	$36.64	$42.76
Pathologist	42.13	84.12	58.98	117.77

f. Examinee Time and Travel

1. First and second tests.

Under both the existing regulation and the proposed changes, it is assumed for simplicity sake that 100 percent of testing is on-site, requiring only examinee time for taking the test.

10 challenge test: Examinee time for taking the test under the current regulation requiring annual testing with a 10 challenge test for the first and second tests for cytotechnologists and pathologists without cytotechnologists is assumed to range between a low of 1 hour and a high of 2 hours, the maximum allowed time. For pathologists with cytotechnologists, the time for taking the 10 challenge test for the first and second tests ranges from 30 minutes to 2 hours, the maximum allowed time. (Gagnon M.B., Inhorn S., and Hancock J. *et al. Comparison of Cytology Proficiency Testing—Glass Slides* vs. *Virtual Slides* 48(6)Acta Cytologica: 788–794(2004))

20 challenge tests: For cytotechnologists and pathologists without cytotechnologists, examinee time is assumed to range between a low of 2 hours and a high of 4 hours, the maximum allowed time. For pathologists with cytotechnologists it is assumed to range between a low of 1 hour and a high of 4 hours, the maximum allowed time.

2. Third and fourth test.

Travel and test time: Under both the existing regulation and the proposed changes, it is assumed for simplicity sake that 100 percent of testing is off-site, requiring examinees to travel. (The third test may be on-site; however, a cytology PT program proctor is required, so in either case, at least one person must travel and incur travel-related costs.) Examinee travel time under the existing regulation and the proposed changes is assumed to require 2 lost work days of 8 hours each. This would be the total combined amount of examinee time lost due to taking the test and traveling. (Under both the existing regulation and the proposed changes, third and fourth tests are 20 cytology challenge tests.)

Individuals taking the third and fourth tests are assumed to incur travel expenses for off-site testing. Travel-related expenses per examinee for each test are assumed as follows: $350 for transportation-related costs (airfare and ground transportation) plus 2 days at the maximum federal per diem expense for unspecified locations (includes one day of lodging) of $150, totaling $500 in 2005 dollars.

The estimated total annual examinee time and travel costs provided in Table 3 are for a national base population using the number of examinees in 2005 (12,831) as broken down in Table 1 for the existing regulation, and one-half the number of examinees for the proposed change. For the first and second tests, the applicable number of examinees is multiplied by test time as detailed in this section for the 10- and 20-challenge tests, respectively, and the corresponding hourly compensation assumptions for cytotechnologists and pathologists in Table 2. For the third and fourth tests, the applicable number of examinees is multiplied by travel expenses ($500) and 16 hours (2 days) for test and travel time as described in this section, with the latter also multiplied by the corresponding hourly compensation assumptions in Table 2. It is assumed that these total national estimates apply to all laboratories, and that only laboratories directly bear the examinee time and travel costs by compensating examinees (their employees) for their test and travel time, and paying either their employee's or the program-supplied proctor's travel expenses. We note that neither examinees nor the PT programs are assumed to bear these costs.

TABLE 3—ESTIMATED TOTAL ANNUAL EXAMINEE TIME AND TRAVEL COSTS OF CYTOLOGY PROFICIENCY TESTING

[2005 dollars]

Estimated total annual examinee time and travel costs of cytology proficiency testing (2005 dollars)				
	Existing regulation annual testing/10 challenge first and second tests; 20 challenge third and fourth tests		Proposed change testing every other year/all 20 cytology challenge tests	
	Low	High	Low	High
First Test	$438,877	$2,042,583	$438,907	$2,042,819
Second Test	40,268	200,430	40,334	200,751
Third Test	81,974	127,457	40,808	63,128
Fourth Test	5,775	9,537	2,887	4,769
Total	566,893	2,380,008	522,936	2,311,467

Note: The differences are due to rounding the numbers of examinees and dollar amounts to whole numbers.

g. Lost Work Days

Under both the existing regulation and the proposed changes, individuals who do not pass the second test are required to have all their slides rescreened until they pass the subsequent test, and those who do not pass the third test are to cease examining gynecologic cytology specimens. It is assumed that 20 work days are lost by individuals taking the third test between the second and third tests, and that an additional 20 work days are lost by individuals taking the fourth test between the third and fourth tests due to these requirements. For those taking the fourth test, an additional 5 work days are lost due to training requirements in the existing regulation for examinees scoring less than 90 percent on the third test. Insufficient information is available to estimate training costs. However, under the current regulations, individuals failing the third or fourth test or both are experiencing these lost work days.

The estimated total annual cost of lost work days as described in this section is provided in Table 4. These are national total estimates for all third and fourth test examinees for the existing regulation (see Table 1 for breakdown of the 2005 examinees used as the base population), and one-half the number of examinees for the proposed change. As described in this section, estimated lost work days associated with rescreening are 20 8-hour days (160 hours) for each third and fourth test examinee. The hours per examinee are multiplied by the applicable number of national examinees and the corresponding hourly compensation assumptions for cytotechnologists and pathologists in Table 2. It is assumed that these total national estimates apply to all laboratories, and that only laboratories directly bear the cost of lost work days by compensating examinees (their employees) for these days. We note that neither examinees nor the PT programs are assumed to bear these costs.

TABLE 4—ESTIMATED TOTAL ANNUAL COSTS OF LOST WORK DAYS FOR CYTOLOGY PROFICIENCY TESTING

[2005 dollars]

Estimated total annual costs of lost work days for cytology proficiency testing (2005 dollars)				
	Existing regulation annual testing/10 challenge first and second tests; 20 challenge third and fourth tests		Proposed change testing every other year/all 20 cytology challenge tests	
	Low	High	Low	High
Third Test	$519,741	$974,571	$258,083	$481,285
Fourth Test	37,747	75,373	18,874	37,686
Total	557,488	1,049,944	276,957	518,971

h. Proctor Time

Proctors are used for each testing event, with the amount of proctor time required including pre-test, test, and post-test time. Proctors are assumed to be cytotechnologists. Since cytotechnologists serving as proctors are not available for other work, this lost time is a cost. The following assumptions are used to estimate proctor time per examinee. Combined pre-test and post-test proctor time per test-taker is assumed to range from a low of 30 minutes to a high of 1 hour under both the existing regulation and the proposed rule. Proctor test time per examinee is directly related to the number of examinees per proctor. The range for this ratio is assumed to vary from one to five examinees per proctor. (ASCP GYN PT 2007 Enrollment Booklet (accessed May 2007) *http://ascp.–org/proficiencyTesting/pdf/2007enrollment_PT.pdf* and 2007 CAP PAP PT Program General Information Booklet (accessed January 2008) *http://www.cap.org/apps/docs/proficiency_testing/pap_pt/2008_pap_pt_program_information.pdf).*

i. 10 Challenge Test

Applying the one to five range of examinees to a single proctor to the examinee time assumptions for the 10 challenge test of 1 to 2 hours for cytotechnologists and pathologists without cytotechnologists, the proctor test time per examinee ranges from 12 minutes to 2 hours, and for pathologists with cytotechnologists (examinee time of 30 minutes to 2 hours), the proctor test time per examinee ranges from 6 minutes to 2 hours. Adding the proctor time per examinee combined pre-test and post-test assumptions (30 minutes to 1 hour) to the proctor time per examinee test time estimates results in a total proctor time per examinee range of 42 minutes to 3 hours for cytotechnologists and pathologists, and a range of 36 minutes to 3 hours for pathologists with cytotechnologists.

j. 20 Challenge Test

Applying the one to five range of examinees to a single proctor to the examinee time assumptions for the 20 challenge test of 2 to 4 hours for cytotechnologists and pathologists without cytotechnologists, the proctor test time per examinee ranges from 24 minutes to 4 hours, and for pathologists with cytotechnologists (examinee time range 1 hour to 4 hours), the proctor test time per examinee ranges from 12 minutes to 4 hours. Adding the proctor time per examinee combined pre-test and post-test assumptions (30 minutes to 1 hour) to the proctor time per examinee test time estimates results in a total proctor time per examinee range of 54 minutes to 5 hours for cytotechnologists and pathologists, and a range of 42 minutes to 5 hours for pathologists with cytotechnologists.

The estimated total annual proctor time costs as described in this section are provided in Table 5. These are national total estimates for all examinees for the existing regulation (*see* Table 1 for base population) and one-half the number of examinees for the proposed change. Using the ranges stated in this section for the combined proctor pre- and post-test time, and the test time per examinee for the 10- and 20-challenge tests, respectively, these ranges are multiplied by the number of total examinees and the proctor (cytotechnologist) hourly total compensation assumptions (Table 2) to estimate the high and low total national annual proctor costs. It is assumed that these total national estimates for the first tests apply to all laboratories, and that only laboratories directly bear the proctor time costs by compensating proctors (their employees) for this time. It is assumed that the total national estimates for proctor time costs for the second, third, and fourth tests apply to all laboratories with examinees who are required to participate in repeat testing. For the second test, the laboratories would directly bear the proctor time costs as described above. For the third and fourth tests, the PT programs would directly bear these proctor time costs by compensating proctors (their employees). Hence, examinees are not assumed to bear these proctor time costs; PT programs do not bear proctor time costs of the first and second tests; and laboratories do not bear proctor time costs of the third and fourth tests.

TABLE 5—ESTIMATED TOTAL ANNUAL PROCTOR TIME COSTS FOR CYTOLOGY PROFICIENCY TESTING

[2005 dollars]

Estimated total annual proctor time costs for cytology proficiency testing (2005 dollars)				
	Existing regulation annual testing/10 challenge first and second tests; 20 challenge third and fourth tests		Proposed change testing every other year/all 20 cytology challenge tests	
	Low	High	Low	High
First Test	$307,717	$1,645,961	$190,198	$1,371,741
Second Test	26,875	144,700	16,572	120,797
Third Test	1,979	12,828	989	6,414
Fourth Test	132	855	66	428
Total	336,703	1,804,344	207,826	1,499,379

k. Packaging and Shipping Costs

For each test under both the existing regulation and the proposed changes, packaging and shipping costs for each slide set are assumed to range from a low of $5 to a high of $20 for the first test, and from a low of $15 to a high of $30 for the second test (PT program meeting, August 2006). No packaging and shipping costs are used for the third and fourth tests because of the assumption that off-site testing will occur at PT program locations.

The estimated total annual shipping and packaging costs as described in this section are provided in Table 6. These are national total estimates apply to all examinees for the existing regulation (see Table 1 for base population), and one-half the number of examinees for the proposed change. It is assumed that PT programs directly bear the costs for shipping and packaging. We note that neither laboratories nor examinees are assumed to bear these costs.

TABLE 6—ESTIMATED TOTAL ANNUAL SHIPPING AND PACKAGING COSTS OF CYTOLOGY PROFICIENCY TESTING

[2005 dollars]

Estimated total annual shipping and packaging costs of cytology proficiency testing (2005 dollars)				
	Existing regulation annual testing/10 challenge first and second tests		Proposed change testing every other year/ all 20 cytology challenge tests	
	Low	High	Low	High
First Test	$64,155	$256,620	$32,080	$128,320
Second Test	16,920	33,840	8,475	16,950
Total	81,075	290,460	40,555	145,270

Using the assumptions stated above, the estimated total annual testing costs in 2005 dollars are provided in Table 7 below.

TABLE 7—ESTIMATED TOTAL ANNUAL COSTS OF CYTOLOGY PROFICIENCY TESTING

[2005 dollars]

Estimated total annual costs of cytology proficiency testing (2005 dollars)				
	Existing regulation annual testing/10 challenge first and second tests; 20 challenge third and fourth tests		Proposed change testing every other year/all 20 cytology challenge tests	
	Low	High	Low	High
First Test	$810,749	$3,945,164	$661,185	$3,542,879
Second Test	84,063	378,970	65,381	338,498
Third Test	603,693	1,114,856	299,881	550,827
Fourth Test	43,654	85,765	21,827	42,883
Total	1,542,160	5,524,756	1,048,274	4,475,088

The national total annualized impact for all examinees in all laboratories of the monetized costs for the proposed changes compared to the existing regulation based on the estimates in Table 7 is a cost savings. The range of estimated savings is projected by taking the difference in the Table 7 total low and high estimates, respectively, between the existing regulation and the proposed changes. The estimated annual impact of the proposed changes ranges from a minimum savings of $493,886 (the difference in the low estimates) to a maximum savings of $1,049,668 (the difference in the high estimates) in 2005 dollars. Of the total estimated cost savings, the savings to PT programs ranges from a minimum of $41,575 to a maximum of $152,032, with the remainder of the estimated total savings to laboratories, and no estimated impact on examinees.

l. Non-Quantifiable Impacts

Expand test medium options to allow other potential media for example, computer-based virtual slides or alternative testing formats, in addition to glass slide challenges.

Rationale

Implementation of cytology PT on a national level was significantly delayed following the 1994 effective date required by the February 28, 1992 final rule with comment because no PT program requested CMS approval. The Maryland Cytology Proficiency Testing Program (MCPTP) was approved to initiate testing in 1995, but PT under that program is limited to those cytologists who examine cytology preparations from Maryland residents. In 2004, the Midwest Institute for Medical Education (MIME), the first national cytology PT program, was approved. Delay in implementation was largely due to the perception that providing a sufficient quantity of good quality glass slide preparations, as required at § 493.945(a), for use in testing would be burdensome to collect, reference, validate and maintain. The life cycle of glass slide preparations is somewhat limited due to stain fading, slide breakage, or loss. For some methods of liquid-based preparations, slides are typically usable for no more than 2 years, inclusive of time spent collecting, referencing, and validating. One way to expand the life cycle of a glass slide would be to capture a digital image of the slide preparations as a ''virtual slide,'' usable indefinitely, and thus requiring fewer slides for PT. Other computer-based test media may become available as technology advances. Therefore, in defining a cytology challenge, for PT purposes, we are proposing to permit the use of computer-based virtual slides or other CMS-approved media, in addition to traditional glass slides, expanding the options for PT programs. We anticipate that by providing flexibility for alternatives to glass slides this change could encourage the development and use of other media and testing formats.

Potential Impact

As technology for gynecologic cytology testing continues to evolve, we anticipate that the cost of PT programs that use virtual slides or other imaging technology would be less than glass slide programs, in spite of the initial implementation costs for equipment to produce virtual slides or other types of images or materials. Developmental costs for alternative formats may be offset by the decreased number of slides or other testing materials that would be needed, their validation and maintenance costs, and the costs associated with test delivery. However, data for estimating these costs are unavailable. A potential benefit of computer-based PT is that the test challenges are stable and uniform throughout testing events and to individuals being tested.

m. Eliminate the Requirement for Tissue Biopsy Confirmation of Response Category C (LSIL) Cytology Challenges

Rationale

Current requirements at § 493.945(b)(1) specify biopsy confirmation of premalignant and malignant challenges, which would include challenges in LSIL (Category C) response and Category D (HSIL or cancer). This requires PT programs to obtain sufficient numbers of slides if they meet the diagnostic criteria for these response categories and have confirmatory histologic specimen reports. Although patients with LSIL (Category C) and HSIL or cancer (Category D) are both referred for colposcopy, LSIL (Category C) lesions may be transient and regress in the interval between the time the Pap smear specimen is taken and the time of colposcopic biopsy. There are instances of LSIL (Category C) lesions that may not be confirmed by tissue biopsy. Continuing to require biopsy confirmation for LSIL (Category C) challenges would make it more difficult for PT programs to continue to find sufficient numbers of LSIL (Category C) challenges. In addition, it is proposed that all cytology challenges be field validated. This validation would confirm and strengthen the reproducible nature of LSIL (Category C) cytology challenges, and serve the same purpose as biopsy confirmation.

Potential Impact

Removal of this requirement should make it easier for PT programs to obtain cytology challenges in the response Category C (LSIL) and result in a cost savings. These savings are not quantifiable since challenges are currently donated and the cost for each laboratory to provide assurances that biopsy confirmation has been done has not been captured. These costs would vary by laboratory on the basis of the ease of use of its record-tracking system and the number of LSIL (Category C) cytology challenges it donates to a PT program.

n. Modifications to the Scoring Scheme

Rationale

The proposed scoring scheme maintains the same four response categories as in the current rule with changes to the scores for certain responses. These changes include two specific score changes in the technical supervisor (pathologist) scheme and six changes for cytotechnologist scoring that can be grouped in three categories, as described below. The only difference between the two proposed schemes is that technical supervisors receive partial credit (2.5 points) for misclassifying response Category C (LSIL) as response Category D (HSIL or cancer) and response Category D (HSIL or cancer) as response Category C (LSIL) while cytotechnologists receive full credit (5 points).

o. Scoring Changes for False Positives (Over Reporting)

Eliminating partial credit to the cytotechnologist when over reporting response Categories A (Unsatisfactory) and response Category B (Normal or Benign Changes) as response Category C (LSIL) or response Category D (HSIL or cancer) lessens the asymmetry in the scheme whereby false positives are currently given less punitive weight than false negatives. Although this change will effectively change the point values in the four boxes in the upper right hand quadrant of the scoring scheme table, it is addressed here as one change. It is expected that cytotechnologists would be able to differentiate these categories in their normal daily practice, and by awarding partial credit for making errors on the test, cytotechnologists might be prone to report results toward the positive side when they would not normally do so in practice. The current scheme, therefore, provides more opportunities for

cytotechnologists to manipulate the test system by over reporting to obtain a favorable score. The proposed scheme will more closely correspond to routine practice in which cytotechnologists report unsatisfactory and negative results.

p. Removal of Partial Credit for Miscalling LSIL as Unsatisfactory

A second proposed change for both scoring schemes (technical supervisors and cytotechnologists) is the removal of partial credit for reporting response Category A (Unsatisfactory) for a response Category C (LSIL) cytology challenge. The rationale for this change is that an LSIL (Category C) cytology challenge is easily differentiated from an unsatisfactory cytology challenge and individuals should, therefore, be able to make this determination. In addition, as described above for making false positive calls, allowing partial credit for reporting an LSIL (Category C) challenge as an unsatisfactory challenge provides an incentive for examinees to report unsatisfactory slides when in doubt. A slide miscalled as unsatisfactory in practice leads to unnecessary repeat testing.

q. Reduced Penalty for False Negatives (Under Reporting)

The proposed change to reduce the penalty score for reporting response Category B (Normal or Benign Changes) for a response Category D (HSIL or cancer) is made on the basis of a number of comments from professional organizations and recommendations from the CLIAC that suggest the current scheme is overly punitive. If finalized, this change will affect the sequence of events for retesting and remediation for individuals found to have questionable proficiency in this area. In the current rule, on a 10 slide test, one misclassification of a response Category D (HSIL or cancer) challenge as response Category B (Normal or Benign Changes) will result in a score of less than 90 percent and a 10 slide retest within 45 days. If the individual passes the retest there are no additional consequences.

If the same misdiagnosis is made on the second 10 slide retest, remediation, rescreening and a 20 slide retest will follow. In the proposed scheme, on a test with 20 cytology challenges that must include at least two cytology challenges in response Category D (HSIL or cancer), if an individual miscalls one of the HSIL or cancer (Category D) cytology challenges as normal or benign changes and makes no other errors, he or she will pass the test. With two misses of HSIL or cancer (Category D) on the proposed 20 cytology challenge test, the individual will score less than 90 percent and will be subject to a 20 cytology challenge retest. In summary, the current rule allows for two opportunities to miss an HSIL or cancer (Category D) on a total of 20 slides (given as 10 slide tests in two testing events) before rescreening is initiated. In the proposed rule, two misses of HSIL or cancer (Category D) on 20 slides (in one testing event) results in a retest. (Missing one HSIL or cancer (Category D) cytology challenge results in a passing score). Rescreening of patient specimens would be initiated in the proposed scheme if an individual missed four HSIL or cancer (Category D) cytology challenges on a total of 40 cytology challenges in two PT events, assuming no other errors were made. A comparison between the current and proposed rule for this one type of false negative error is depicted in Table 3 below.

TABLE 8—COMPARISON OF CURRENT AND PROPOSED RULE TESTING SEQUENCES

Current rule		Proposed rule	
1st test: 10 challenges	one miss* = 85 percent (one miss on 10 challenges).	1st test: 20 cytology challenges ...	one miss* = 90 percent—pass. two missed* = 80 percent (two misses on 20 cytology challenges).
45 days—retest			
2nd test: 10 challenges	one miss* = 85 percent (equivalent to 2 misses* on 20 challenges).	2nd test: 20 cytology challenges ..	one miss* = 90 percent. two missed* = 80 percent (4 misses* on 40 cytology challenges).
Remedial training on identification of HSIL OR Cancer All slides rescreened Retest			
3rd test: 20 challenges	one miss* = 80 percent	3rd test: 20 cytology challenges ...	two missed* = 80 percent.
Cease slide examination 35 hours of remedial training Pass 20 cytology challenge test			

Note to Reader: * miss = Reporting response Category B (normal or benign changes) for response Category D (HSIL or cancer).

Potential Impact:

Overall pass rates:

The proposed scoring scheme incorporating all of the changes described above, designed to be applied to a 20 cytology challenge test, cannot be directly compared to the current scheme with 10 challenges due to the differences in point values. The proposed scheme is more stringent in some areas (cytotechnologists scoring) and less stringent in others (pathologists scoring). We are uncertain whether these changes, coupled with the increase in the number of cytology challenges, would have any impact on the overall pass rates. The increase in cytology challenges should increase test sensitivity, while the scoring scheme changes may make the test more difficult to ''second guess'' but more easily passed for those pathologists unable to correctly identify HSIL or cancer (Category D). For the purposes of calculating costs attributed to retesting and remediation for the proposed rule, we have assumed the pass rates would not change.

r. Administrative Changes for Which Impact Would Be Negligible

In the process of approving and operating gynecologic cytology PT programs, certain administrative practices have been developed and are followed by PT programs, and laboratories as part of the program operations. CLIAC, PT programs, and professional organizations recommended incorporating these practices into the regulation to ensure that they are consistently met by all PT programs and laboratories. However, since these practices are generally part of the process at this time, we anticipate no measurable impact if they are adopted as requirements.

Written agreements: As specified at § 493.945(b)(6), the PT program must provide a written agreement to be signed by the laboratory director accepting responsibility for test administration should be of minimal impact to the PT programs and the laboratory director, since under § 493.853(b), the laboratory director must now ensure that individuals participate in on-site PT. In addition, requiring the laboratory to identify all individuals who perform gynecologic cytology examinations to CMS and PT programs, as proposed at § 493.853(a)(2), would have a minimal impact on laboratories, since this information is already provided when the laboratory enrolls in a PT program. It is not possible to calculate the minor impact of these changes to the requirements.

Proctor Training: As proposed at § 493.853(b)(4) and § 493.945(b)(5), the proctor training and examination requirements, as well as the proctor responsibility for test administration would have a negligible impact as PT programs may use laboratory-designated proctors to conduct testing, and the proctors must be trained, capable of test administration, and tested to assure competency. The resultant score of ''zero'' for all individuals in the laboratory if the proctor does not appropriately administer the testing event could impact laboratories, and lead to required remediation and limitation of slide examinations, if individuals are not retested or do not pass a subsequent examination. However, it is not possible to project whether this potential change would increase cost, but it is not expected to be significant since adequate proctor training and appropriate test administration are now part of PT program operations.

Bethesda 2001 Terminology: We propose changing the description of the response Category A (Unsatisfactory) to match the current Bethesda 2001 Terminology. We do not anticipate that it would have a measurable impact on the overall cost of the program.

Inclusion of at least two HSIL or cancer cytology challenges per test: As required at § 493.945(b)(1)(ii), including a minimum of two response Category D (HSIL or cancer) cytology challenges in a 20 cytology challenge test would be equivalent to requiring at least one response Category D (HSIL or cancer) cytology challenge in a 10 slide test set (currently at § 493.945 (a)(1)). This change should have little or no impact as long as the number of required cytology challenges per testing event is doubled.

Continuous Validation of Cytology Challenges: Requiring PT programs to provide continuous validation of cytology challenges throughout their use in testing is currently a routine practice conducted by the three CMS-approved PT programs. This revision, proposed at § 493.945(c)(1)(ii), should not have an impact if required, and would ensure that cytology challenges maintain their acceptability for use in testing.

Appeals: The proposed rule specifies at § 493.945(b)(4) that PT programs would provide their appeals process in writing to all enrolled individuals. This change would have a minimal impact on program costs, since it could be done electronically or added to enrollment forms or other materials provided to each individual before their participation in a PT event.

C. Alternatives Considered

Because the proposed revisions to the gynecologic cytology PT requirements are interdependent, alternatives to each proposed change can not be considered separately without having an effect on the total process. Therefore, it is necessary to take these complexities into account when considering alternatives to the changes that are proposed.

For expansion of the test medium used, we considered maintaining the current requirement for glass slide challenges. However, the lack of adequate numbers of glass slides for a national PT program is the reason for the lengthy delay in national cytology PT implementation. Allowing other potential media would provide flexibility for future technology and accommodation of all individuals who need to be tested. In addition, to ensure continued testing of workplace performance, as more laboratories use computer-assisted screening, the regulations would need to be expanded to allow other types of challenges.

We considered testing frequencies less often than once every 2 years, but decided against incorporating a frequency of once every 3 years (recommended by CLIAC) or longer (recommended by some cytology professional organizations) due to concern that less frequent testing may allow poor performers to go undetected for a longer period of time. After agreeing to propose a testing frequency of at least once every 2 years, we also considered keeping the required number of ten challenges per event. However, this may also decrease the ability of the test to identify poor performers.

In determining the appropriate number of cytology challenges per testing event, we considered including more than 20, but we were unable to identify reliable data showing that the additional benefits for testing with a greater number of slides support the additional costs and resources that would be required. Also, as noted above, finding enough acceptable slides for testing was the primary cause for the delay in implementation of cytology PT and greatly increasing the number of challenges in each test could potentially produce a similar effect.

In looking at the total number of cytology challenges per event, we propose to increase the required number of response Category D (HSIL or cancer) cytology challenges from at least one in a 10 challenge test to at least two in a 20 cytology challenge test, and we considered whether requiring fewer or more of these challenges would be appropriate. However, we concluded that requiring at least two response Category D (HSIL or cancer) cytology challenges would be comparable with requiring at least one on a 10 challenge test, and data do not indicate this to be a problem.

Several alternatives were considered for revisions to the scoring scheme. The organizations provided variations on the scoring scheme and several other variations were suggested by the CLIAC workgroup to the CLIAC committee. CLIAC was presented with a data comparison of the various schemes. The schemes did not produce a wide variation in the number of individuals passing the testing event, so the CLIAC concluded that the scheme chosen should be reflective of normal work performance. Therefore, we believe the grading scheme proposed provides a greater balance between the identification of false positives and the identification of false negatives.

The only alternative to eliminating tissue biopsy confirmation of response Category C (LSIL) would be to continue to require this confirmation. The

feedback from the professional organizations and CLIAC was that this requirement eliminated potential challenges due to the current practice where patients with this diagnosis may not receive a biopsy for confirmation. Therefore, we are proposing to eliminate this requirement.

For the minor administrative changes that are being proposed, the only alternatives considered were to not make these changes. However, since the changes would standardize practices that are already in place among PT programs and laboratories, it seems reasonable to specify these practices in the appropriate sections of the regulation to ensure that they continue to be met by all as part of the PT process.

D. Conclusion

For these reasons, we are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined that this 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.

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

Administrative practice and procedure, Grant programs—health, Health facilities, Laboratories, Medicaid, Medicare, Penalties, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 493—LABORATORY REQUIREMENTS

1. The authority citation for part 493 continues to read as follows:

Authority: Secs. 353 of the Public Health Service Act, secs. 1102, 1861(e), the sentence following sections 1861(s)(11) through 1861 (5)(16) of the Social Security Act (42 U.S.C. 263a, 1302, 1395x(e),the sentence following 1395x(s)(11)through 1395x(s)(16).

Subpart A—General Provisions

2. Section 493.2 is amended by—

A. Revising the definition of ''Challenge.''

B. Adding the definition of ''Cytology challenge'' in alphabetical order.

C. Revising paragraph (4) of the definition ''Unsuccessful participation in proficiency testing.''

The revisions and additions read as follows:

§ 493.2 Definitions.

* * * * *

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

* * * * *

Cytology challenge means a sample consisting of gynecologic cytology material that is used to evaluate the individual's locator and identification skills. Cytology challenge material may include glass slides, digital images, or other CMS approved testing media.

* * * * *

Unsuccessful participation in proficiency testing * * *

* * * * *

(4) Failure of a laboratory performing gynecologic cytology to meet the standard at § 493.853.

* * * * *

Subpart H—Participation in Proficiency Testing for Laboratories Performing Nonwaived Testing

3. Section 493.803 is amended by—

A. Revising paragraph (b).

B. Redesignating paragraph (c) as paragraph (d).

C. Adding a new paragraph (c).

The revisions and addition read as follows:

§ 493.803 Condition: Successful participation.

* * * * *

(b) Except as specified in paragraph (d) of this section, CMS imposes sanctions as specified in subpart R of this part when a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte, or test as defined in this section.

(c) For gynecologic cytology, CMS imposes sanctions as specified in subpart R of this part when a laboratory fails to ensure that each individual performing gynecologic specimen examinations—

(1) Is enrolled in a CMS approved cytology proficiency testing program;

(2) Participates successfully in gynecologic cytology proficiency testing at least every 2 years; and

(3) Takes the applicable remedial action as described in § 493.853(c) when scoring less than 90 percent on gynecologic cytology proficiency testing.

* * * * *

4. Section 493.853 is revised to read as follows:

§ 493.853 Condition: Cytology: gynecologic specimen examinations.

To participate successfully in a cytology proficiency testing program for gynecologic specimen examinations (Pap smears), the laboratory must meet the requirements for an individual's enrollment, participation, and remediation as specified in paragraphs (a) through (c) of this section.

(a) *Enrollment.* The laboratory must—

(1) Ensure that each individual performing gynecologic specimen examinations is enrolled in a gynecologic cytology proficiency testing program approved by CMS; and

(2) Provide the proficiency testing program and CMS with the information specified by CMS that is necessary to identify all individuals performing gynecologic specimen examinations.

(b) *Participation.* The laboratory must ensure that—

(1) Each individual performing gynecologic specimen examinations is initially tested on-site in the laboratory on an announced or unannounced basis at least once every 2 calendar years;

(2) Each individual is notified of the date, time, and location of each announced testing;

(3) Each individual attains a score of at least 90 percent on each testing event and, if applicable, participates in remediation as specified in paragraph (c) of this section;

(i) An individual with an unexcused absence will receive a score of ''zero;''

(ii) For an individual with an excused absence, the laboratory must contact the proficiency testing program to determine the date, time, and location of the make-up examination;

(4) For on-site testing, if the laboratory chooses to designate a proctor, rather than have the proficiency testing program administer the test, the laboratory must ensure the testing event is properly administered as specified in this section. Any inappropriately administered testing event will result in a ''zero'' score for all participants. The laboratory is responsible for ensuring—

(i) All proctors successfully complete the proctor examination before administering the testing event;

(ii) The proctor follows the proficiency testing program's requirements for testing;

(iii) Each individual is tested independently, except as provided at § 493.945(c)(2);

(iv) Resources capable of assisting the individual in slide interpretation, including text books or electronic media, are not allowed in the testing area;

(v) All materials and results are kept confidential before, during, and after testing; and

(vi) Testing materials, including but not limited to glass slides, images, and test result sheets are not reproduced.

(c) *Remediation.* The laboratory must ensure that each individual who scores less than 90 percent on a testing event completes the required remediation and is retested within 45 days after completion of the remediation. If an individual scores less than 90 percent on:

(1) An initial test, the individual must be retested not more than 45 days after receipt of notification of his or her score.

(2) A second test (first retest), the individual must—

(i) Obtain documented remedial training and education in the area of deficiency;

(ii) Have all gynecologic preparations evaluated subsequent to the notification of the second test score reexamined by an individual who has successfully participated in a CMS approved proficiency testing event during the current 2 year cycle. Reexamination of gynecologic preparations must be documented.

(iii) Be retested within 45 days after completion of the remediation.

(3) A third test or any subsequent retest, the individual must—

(i) Obtain at least 35 hours of documented, continuing education in gynecologic cytology that focuses on the incorrect response categories; and

(ii) Discontinue examining gynecologic preparations immediately upon notification of a score of less than 90 percent and not resume examining gynecologic preparations until the individual obtains a score of at least 90 percent on a retest.

(iii) Be retested within 45 days after completion of the remediation.

§ 493.855 [Removed and Reserved]

5. Section 493.855 is removed and reserved.

Subpart I—Proficiency Testing Programs for Nonwaived Testing

6. Section 493.905 is revised to read as follows:

§ 493.905 Nonapproved proficiency testing programs.

If a proficiency testing program is disapproved or denied approval by CMS, CMS will notify the program and the program must notify all enrolled laboratories of the nonapproval and the reason for the nonapproval within 30 days of notification. The program will be disapproved or denied approval if the program—

(a) Fails to meet any criteria contained in § 493.901 through § 493.959 for approval of the proficiency testing program; or

(b) Is determined by CMS to have submitted falsified information to obtain approval of the program.

7. Section 493.945 is revised to read as follows:

§ 493.945 Cytology: Gynecologic examinations.

To be approved for proficiency testing in gynecologic cytology, the program must meet the requirements specified in paragraphs (a) through (c) of this section.

(a) *Frequency of testing events.* The program must provide:

(1) An initial, on-site test at least once every 2 years on an announced or unannounced basis. For announced testing events, the program must notify the laboratory at least 30 days before the testing event of the location, date, and time of testing. However CMS has the authority to authorize alternative sites for testing.

(2) A second test within 45 days after the laboratory is notified of an individual score of less than 90 percent on the initial testing event.

(3) A third test and any subsequent retests within 45 days after completion of remediation as specified in § 493.853(c)(2) and (c)(3). Any third test or subsequent retests must be administered by the proficiency testing program and may not be proctored by a laboratory designee.

(b) *Program description.* The program must—

(1) Provide test sets for each testing event composed of the following:

(i) A minimum of 20 cytology challenges. Proficiency testing programs may obtain glass slides from a laboratory provided the glass slides have been retained by the laboratory for the required period specified in § 493.1105(a)(7) and § 493.1274(f)(2). If slides are still subject to retention by the laboratory, they may be loaned to a proficiency testing program if the program provides the laboratory with documentation of the loan of the slides and ensures that slides loaned to it are retrievable upon request.

(ii) At least one cytology challenge representing response categories A, B, and C and at least two cytology challenges from response Category D for reporting proficiency testing results. The four response categories and their descriptions are as follows:

Response category	Description
A	Unsatisfactory: Specimen processed and evaluated but unsatisfactory for evaluation of epithelial abnormality. These factors include minimum squamous cellularity (conventional smears and liquid-based preparations), absence of endocervial/transformation zone component, or obscuring factors (>75 percent of squamous cells obscured assuming no abnormal cells identified).
B	Normal or Benign Changes includes: (1) Normal, negative or within normal limits. (2) Infection other than human papillomavirus (HPV) (for example, Trichomonas vaginalis, changes or morphology consistent with Candida spp., Actinomyces spp. or Herpes simplex virus). (3) Reactive and reparative changes (for example, inflammation, effects of chemotherapy or radiation).
C	Low Grade Squamous Intraepithelial Lesion includes: (1) Cellular changes associated with HPV. (2) Mild dysplasia/CIN–1.
D	High-Grade Lesion and Carcinoma includes: (1) High grade squamous intraepithelial lesions which include moderate dysplasia/CIN–2 and severe dysplasia/carcinoma in-situ/CIN–3. (2) Squamous cell carcinoma. (3) Adenocarcinoma and other malignant neoplasms.

(2) Ensure individuals complete a 20 cytology challenge testing event within 4 hours.

(3) Ensure that all 20 cytology challenge test sets provide for equitable testing among participants.

(4) Provide a written description of the appeals process that is available to all individuals enrolled in the program.

(5) Provide training for laboratory-designated proctors that includes—

(i) Written instructions for the laboratory to determine the number of proctors needed to administer the proficiency testing event, including contingency for a backup proctor if needed;

(ii) Written instructions for the laboratory director and proctor to ensure program procedures are fulfilled; and

(iii) A proctor examination that evaluates the proctor's understanding of proper testing protocol.

(6) Provide a written agreement, to be signed by the laboratory director and returned to the program before testing, stating the laboratory is responsible for and accepts responsibility for administering the proficiency testing as defined by the program and CMS.

(c) *Evaluation of an individual's performance*. The program must—

(1) Determine the accuracy of an individual's response on each cytology challenge by comparing the individual's response with the correct response specified by the four response categories listed in paragraph (b)(1)(ii) of this section. Determination of the correct response for each cytology challenge must include:

(i) A 100 percent consensus agreement among a minimum of three physicians who meet the requirements of cytology technical supervisor (as specified in subpart M of this part) and examine gynecologic preparations on a routine basis.

(ii) Continuous field validation of each cytology challenge by a method acceptable to CMS and that is disclosed to participants before enrollment in the program.

(iii) Confirmation by tissue biopsy of all cytology challenges that have a correct response of Category D (HSIL or cancer) either by comparison of the reported biopsy results or reevaluation of biopsy slide material by a physician certified in anatomic pathology.

(2) Test individuals qualified as cytology technical supervisors (as specified in subpart M of this part) under conditions comparable to their workplace performance in cytology. A cytology technical supervisor who routinely interprets gynecologic preparations that have—

(i) Been previously examined by a cytotechnologist may participate in the testing event using either a test set that has not been previously screened or a test set selected at random that has been previously screened by a cytotechnologist who works in the same laboratory.

(ii) Not been previously examined must be tested using a test set that has not been previously screened.

(3) Adhere to the grading scheme as follows:

(i) The individual's score for a testing event is determined by adding the point values achieved for each cytology challenge.

(ii) The point values for a 20 cytology challenge test for a technical supervisor qualified under § 493.1449(b) or (k) are:

Correct response	Technical supervisor examinee response			
	A—UNSAT	B—NEGATIVE	C—LSIL	D—HSIL
A—UNSAT	5	0	0	0
B—NEGATIVE	2.5	5	0	0
C—LSIL	0	0	5	2.5
D—HSIL	0	−5	2.5	5

(iii) The point values for a 20 cytology challenge test for a cytotechnologist qualified under § 493.1469 or § 493.1483 are:

Correct response	Cytotechnologist examinee response			
	A—UNSAT	B—NEGATIVE	C—LSIL	D—HSIL
A—UNSAT	5	0	0	0
B—NEGATIVE	2.5	5	0	0
C—LSIL	0	0	5	5
D—HSIL	0	−5	5	5

Subpart M—Personnel for Nonwaived Testing

§ 493.1451 [Amended]

8. In § 493.1451(c)(5) the reference ''493.855'' is revised to read ''493.853.''

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: November 13, 2007.

Julie Gerberding,

Director, Centers for Disease Control and Prevention.

Dated: November 15, 2007.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: October 9, 2008.

Michael O. Leavitt,

Secretary.

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