and occur at testing centers, rather than in the laboratory.

3. Should the number of slides or challenges in the current regulations be changed for computer technology? Since this technology is not limited by ability to collect referenced glass slides, it is possible to provide more challenges (images or portions of slides) to evaluate proficiency.

4. Should the scoring system be modified for computer-based programs?

Finally, we recognize that this technology is relatively new and, while it affords many advantages, we are most interested in obtaining comments about the acceptance of computer-based programs for evaluating cytology skills.

Following receipt and analysis of the comments, we plan to consider these suggestions and comments and, if warranted, develop a proposed rule to expand the regulations to allow approval of cytology PT programs that include computer-based testing media as an alternative to glass slides. In any such proposed rule on computer-based testing, we would provide specific revisions to the regulations. We would respond to comments on the proposed rule when we finalize any changes to our existing rules.

III. Proposed Revision to the Regulations

This proposed rule is in response to the court's decision that the 12.5 slide per hour rate contained in § 493.1257(b), must, in the court's opinion, also be the rate for cytology PT, which is delineated at § 493.855(b). Accordingly, the Department complies with the court decision and proposes and solicits comments on revisions to § 493.855(b) to change the time frame in which individuals must complete: a 10-slide test, from not more than 2 hours to 45 minutes; and a 20-slide test, from not more than 4 hours to 90 minutes.

IV. Response to Comments

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

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, agencies 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 Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

• Whether the information collection is necessary and useful to carry out the proper functions of the agency;

• The accuracy of the agency's estimate of the information collection burden;

• The quality, utility, and clarity of the information to be collected; and

• Recommendations to minimize the information collection burden of the affected public, including automated collection techniques.

Section 493.855 contains the requirement that laboratories ensure that each individual engaged in the cytological examination of gynecologic specimens participate in an annual testing event. We estimate that 15,000 individuals would be subject to testing. Once each year they must complete required reporting forms, estimated to take 10 minutes per response. The total burden associated with this requirement is estimated to be 2,500 hours.

Section 493.855 is currently approved under OMB approval number 0938– 0612, with an expiration date of February 28, 1998.

Comments should be sent to HCFA, OFHR, MPAS, C2–26–17, 7500 Security Boulevard, Baltimore, Maryland 21244– 1850 and to the OMB official whose name appears in the **ADDRESSES** section of this proposed rule.

VI. Regulatory Impact Statement

Consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612), we prepare a regulatory flexibility analysis unless we certify that a rule would not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, all clinical laboratories are considered to be small entities. Individuals and States are not included in the definition of a small entity.

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. Such an analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 50 beds.

This proposed rule would modify the CLIA regulations published February 28, 1992 by changing the current requirements authorizing the examination of PT slides at a rate of five slides per hour, to require the examination of PT slides at the maximum workload rate of 12.5 slides per hour (for examination of patient preparations). This proposed revision is in accordance with the court order requiring us to publish a notice of proposed rulemaking that would require PT to be conducted within the time frame corresponding to the maximum workload rate for individuals examining cytology slides. There are approximately 16,600 cytotechnologists and pathologists and one HCFA-approved cytology PT program that could be affected by this rule; however, the significance of the effect would vary depending on the number of individuals having to take a second or third retest and whether or not the one cytology PT program in Maryland approved by HHS under current regulations would seek approval, if the proposed revised criteria for cytology PT are finalized.

The final rule published February 28, 1992 (57 FR 7002) and subsequently revised December 6, 1994 (59 FR 62606) provided a phase-in period for enrollment in a HCFA-approved cytology PT program. Specifically, as of January 1, 1995, individuals must enroll in an approved program, if one is available in the State in which he or she is employed (currently only Maryland). Under the CLIA cytology PT requirements, each person examining cytologic preparations is tested on his or her ability to categorize each slide into one of four response categories. After an initial PT failure, the examinee must take a second 10-slide test within 45 days. In the event of a second failure, the laboratory must provide immediate remedial training to any individual who fails the second test or retest.

The second failure also triggers a mandatory rescreen of all subsequent slides by another cytologist until the individual is retested. Failure of the third test, consisting of 20 slides, results in immediate suspension of an individual's screening privileges. The individual must complete remedial training of at least 35 hours before he or she can be retested. Successful completion of a 20-slide test is required before screening of gynecological slides may resume.

Ås mentioned earlier in this preamble, other factors (for example, variations in staining intensity and nonroutine nomenclature on report