address the comments received during the public comment period. After the public comment period, a deletion will occur after EPA publishes a Notice of Deletion in the Federal Register. The NPL will reflect any deletions in the next final update. Public notices and copies of the Responsiveness Summary will be made available to local residents by EPA Region VIII.

IV. Basis for Intended Site Deletion

The following summary provides EPA's rationale for recommending deletion of the Whitewood Creek Superfund Site.

The Whitewood Creek Superfund Site is located in Butte, Meade and Lawrence Counties in western South Dakota. The Site includes the floodplain of an 18 mile stretch of Whitewood Creek between the Crook City Bridge and the confluence with the Belle Fourche River. The Site also includes areas surrounding the floodplain which fall within the 100 milligrams per kilogram (mg/kg) arsenic concentration isopleths as defined during remedial design (RD).

Disposal of mill tailings from area gold mines into Whitewood Creek for more than 100 years caused contamination at the Site. This practice ended in 1977. Homestake Mining Company (Homestake) of Lead, South Dakota was the largest contributor of this mine waste material. As Whitewood Creek flowed northeast out of the Black Hills, mine tailings were deposited on the banks of the creek and throughout the floodplain. An estimated 30 million tons of mill tailings were deposited within the Site. These tailings were found to contain elevated levels of arsenic and other heavy metals.

In 1981, at the request of the governor of South Dakota, the Site was placed on the ''Interim NPL''. Subsequently the Site was placed on the NPL on September 8, 1983 (48 Fed. Reg. 40658). The hazardous substance release pathways of concern at the Site were ground water and surface water. These pathways were used to develop the Site's hazard ranking system score. The hazardous substances of concern were arsenic, copper, zinc, selenium, and mercury.

Following placement of the Site on the Interim NPL, EPA, the State of South Dakota, and Homestake entered into a three-party agreement to perform studies to determine the nature and extent of contamination at the Site. In 1989, EPA determined that this study, combined with several others conducted between 1982 and 1986, constitutes the functional equivalent of a remedial investigation for the Site. The remedial investigation reports, as well as any other reports referred to in this notice, can be found in the public docket for this Site.

Under an administrative agreement with EPA, Homestake conducted a feasibility study in 1989 to evaluate cleanup alternatives. The feasibility study and the remedial investigation reports concluded that the primary concern for human health and the environment at the Site was exposure to arsenic-contaminated tailings, soils, and groundwater.

EPA issued a Record of Decision (ROD) for the Whitewood Creek Site on March 30, 1990. The remedy selected for the Site was two-fold; (1) remove and/or cover tailings-contaminated soils in existing residential areas; and (2) implement institutional controls (ICs) to control access to the tailings and groundwater. To achieve a detailed understanding of the ROD, refer to the ROD dated March 30, 1990.

In August of 1990, EPA and Homestake signed a consent decree (CD) for Homestake to conduct remedial design and remedial action (RD/RA) at the Site. Under EPA oversight, Homestake, in coordination with Site residents, developed plans and specifications for removal and/or cover of arsenic-contaminated materials at sixteen residential yards.

Homestake conducted cleanup of the residential yards in 1991 and 1992. A total of 4,500 cubic yards of contaminated material was removed from the individual sites and placed in an on-site disposal facility.

Community relations activities throughout the Superfund process at the Site included:

a. a public meeting followed by a comment period to present the preferred cleanup plan before issuing the ROD;

b. a responsiveness summary to address comments received from the public regarding EPA's proposed clean up plan;

c. regular site updates in the form of fact sheets mailed to the community;

d. meetings with site residents to develop acceptable cleanup plans for residential yards; and

e. community meetings.

Also as part of RD/RA, the following institutional controls have been implemented at the Site:

(a) Butte, Meade, and Lawrence Counties adopted ordinances that: prohibit construction of any new residential or commercial structures on the tailings deposits; restrict future development in tailings-impacted areas of the Site; and prohibit the removal and use of tailings from outside the tailings areas; however, mining would be allowed subject to South Dakota regulations. These ordinances were adopted in 1992 and 1993;

(b) since 1993, Homestake has been distributing a Site fact sheet at least once a year to educate the public on Site hazards and ways to minimize the risk posed by residual contamination;

(c) a State ban on shallow aquifer water supply wells in the floodplain of Whitewood Creek has been maintained.

Administration of the above institutional controls is on-going and will continue indefinitely. In addition, Homestake is responsible for several operations and maintenance (O&M) activities at the site including but not limited to:

(1) monitoring the surface water quality of Whitewood Creek at least four times yearly for significant releases of remaining hazardous substances at the Site;

(2) re-sampling the soil in residential yards at least once every five years to ensure that re-contamination has not occurred; in the event of unacceptable levels of recontamination, Homestake will remediate the yard; and

(3) submitting reports to EPA on O&M activities four times yearly.

Further details of Homestake's O&M responsibilities at the Site can be found in the *Whitewood Creek Superfund Site, Post Closure Operations, Maintenance, and reporting Plan,* dated July 27, 1994. Deletion of the Site from the NPL in no way affects Homestake's continued obligations to perform O&M at the Site.

Because hazardous substances remain at this Site EPA must review Site conditions no less often than every five years from the start of remedial action at the Site to ensure that the remedy continues to remain protective of human health and the environment. The first five year review will begin no later than September 1996.

Dated: November 8, 1995.

William P. Yellowtail,

Regional Administrator, U.S. E.P.A., Region VIII.

[FR Doc. 95–29037 Filed 11–29–95; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

Centers for Disease Control and Prevention

42 CFR Part 493

[HSQ–233–P]

CLIA Program; Cytology Proficiency Testing

AGENCY: Health Care Financing Administration (HCFA) and Centers for Disease Control and Prevention (CDC), HHS.

ACTION: Proposed rule.

SUMMARY: In this proposal, HHS is complying with a court order requiring publication of a proposed rule to require that cytology proficiency testing (PT) be conducted, to the extent practicable, under normal working conditions. In accordance with the court order, we are proposing to revise regulations that implement the Clinical Laboratory Improvement Amendments of 1988 (CLIA) to require that PT be conducted at a pace corresponding to the maximum workload rate for individuals examining cytology slides. As a separate matter, we use this opportunity to solicit comments on the use of computer facsimile representations of cytology specimens, as an alternative to glass slide PT.

DATES: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on January 29, 1996.

ADDRESSES: Mail written comments (1 original and 3 copies) to the following address: Centers for Disease Control and Prevention, Attention: HSQ–233–P, 4770 Buford Hwy, N.E., MS F11, Atlanta, Ga. 30341–3724.

If you prefer, you may deliver your written comments (1 original and 3 copies) to the following address: Room 309–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HSQ–233–P. Comments received timely will be available for public inspection as they are received in Room 309–G of the Department's offices at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690–7890).

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

FOR FURTHER INFORMATION CONTACT: Rhonda S. Whalen, (770) 488–7670.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 353 of the Public Health Service Act (42 U.S.C. 263a), which embodies provisions of the Clinical Laboratory Improvement Amendments of 1988 (CLIA), all laboratories that examine human specimens for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of, human beings must meet certain requirements to perform the examination. On February 28, 1992 (57 FR 7002), we published regulations to implement CLIA at 42 CFR part 493, with most sections of the regulations effective September 1, 1992. On January 14, 1993, plaintiffs, the Consumer Federation of America and Public Citizen, filed a lawsuit in the United States District Court for the District of Columbia, challenging the Department of Health and Human Services' implementation of CLIA (*Consumer Federation of America and Public Citizen* v. *HHS*, Civil Action No. 93–97 (D.D.C.)). As one aspect of their complaint, plaintiffs argued that the regulations violated the requirements of the law by failing to require cytology proficiency testing (PT) ''to the extent practicable, under normal working conditions.''

On August 29, 1995, the court ruled that the regulations did not strictly conform to the statute. The court ruled that, within 90 days of this order, we publish proposed regulations in the Federal Register, in accordance with 42 U.S.C. 263a(f)(4)(B)(iv) regarding proficiency testing of cytologists, to ensure that cytologists are tested, to the extent practicable, under normal working conditions, and request public comment. The court further ruled that we are to issue a final rule regarding the same within a reasonable time thereafter. As provided in the court's August 29 ruling, the PT regulations promulgated by the Department on February 28, 1992, remain in effect pending the issuance of the final PT regulations required by the court. It should be noted that this particular notice only addresses matters in the court order pertaining to cytology PT, and it is not designed to respond to a separate part of the court order pertaining to test classification and personnel standards.

II. Proposed Rule

In this proposed rule, we are complying with that portion of the court order requiring the publication of proposed regulations and solicitation of public comment to ensure that PT of cytology personnel is conducted, to the extent practicable, under normal working conditions. We note, however, that the Department of HHS has filed a notice of appeal with respect to the order. If the order is reversed on appeal, we would still review the comments and carefully consider the appropriate course of action.

The current PT regulations are based on the principle that effective and appropriate PT should not be equated to the routine examination of patient specimens. Nevertheless, in accordance with the court's ruling, we are soliciting comments on a proposal to change the current regulations (which authorize the examination of PT slides at a rate of five slides per hour), to require the examination of PT slides at a new rate, which is set at the maximum workload rate of 12.5 slides per hour. To achieve this PT workload rate, in this rule, we are proposing to change the amount of time allowed for completion of the PT examination from 2 hours to 45 minutes, while retaining the same number of slides (10) per test. (For a 20-slide PT retest, the test time would change from 4 hours to 90 minutes.)

We recognize that there may be other options for complying with the court order requiring that PT be conducted under normal working conditions. One option for consideration to comply with the order would be to maintain the current 2-hour testing time period but increase the number of slides per PT examination (in other words, require the examination of 25 slides in a 2-hour period and, for a retest, require 50 slides to be examined in a 4-hour period). We are cautious about supporting this alternative because we have concerns about the practical feasibility of obtaining sufficient referenced slides for a nationally-administered 25-slide test set for PT; however, we are interested in receiving comments on this option. Another option would be to specify that PT be conducted at each individual's actual workload rate (which could be less than the maximum workload rate) for examining patient slides. We recognize that this alternative will present problems in administering PT but are interested in receiving comments on the appropriateness of such a proposal, together with

suggestions for specific regulatory language that could implement such a provision in a fair and consistent manner.

We also are interested in receiving comment on several alternatives.

- We are interested in receiving comment on the establishment of an average workload rate (perhaps within an interval) that would be based upon available empirical data on cytotechnologist productivity and would accurately reflect normal working conditions.
- We solicit comments on varying the ratio of abnormal PT slides so the failure rate would better reflect such a rate under ''normal working conditions.''
- We solicit comment on establishing differing definitions of ''normal working conditions,'' dependent on the ratio of abnormal PT slides.
- We solicit further comment on the feasibility of blind testing in cytology PT.
- We solicit comment on the feasibility and desirability of mandating unannounced PT, both on-site and off-premises.
- Finally, we solicit comment on the appropriateness of defining ''normal working conditions'' as maximum workloads for non-PT slides, as defined in § 493.1257(b).

A. Rationale for the PT Timeframe in Current Regulations

In the regulations published February 28, 1992, we established the time limits for cytology PT to provide for equitable testing on a national scale and to allow individuals sufficient time to complete the test at a normal pace without unduly restricting or extending the time for the examination. (57 FR 7041) This maximum time frame established for the administration of PT was not intended to hold individuals to a workload limit related to their examination of patient material because we believe that this would be an unreasonable standard, since there are salient differences between the routine examination of patient material and cytology PT.

We note several reasons why cytology PT is not identical to the routine evaluation of patient material, both in terms of the microscopic examination and the reporting of results. To assess the proficiency of personnel, slides used for cytology PT include a high percentage of abnormal preparations which could be up to 80 percent of the challenges for the testing event, whereas a laboratory's routine patient case load might vary, with abnormal cases representing 5 percent to 25 percent of the total volume. In our judgment, compared to normal cases, examination of abnormal cases may take significantly longer to analyze and determine conclusively whether the cells are benign or malignant and to specify the type of abnormality and recommendations for treatment or follow up. A complex scale for categorizing and grading such abnormal PT results is defined in the current regulation in abundant detail in the tables at 42 CFR 493.945. The 12.5 slides per hour maximum workload rate is based upon a normal, ''real world'' distribution of 5 percent abnormal slides per day. On the other hand, the PT rate of 5 slides per hour is based upon an intentionally constructed testing mixture of up to 80 percent abnormal slides in the PT test set.

The current PT regulation is based on the principle that, in the limited time available to conduct cytology PT, it is appropriate to test cytology personnel using a high rate of abnormal slides. The reason for this is that there are many types of diagnostic abnormalities and it is important to evaluate the examinee's ability to correctly identify the abnormal conditions. In our view, it is inefficient to test these individuals using the natural distribution rate of 5 percent abnormals because it would take many more PT examinations to develop any reliable information about an individual's proficiency over the spectrum of possible abnormal specimens. In addition, although all slides will be evaluated and assessed for appropriateness for inclusion in test sets, in some instances examinees may note that staining used for PT slides varies in intensity from that used in their laboratories for the evaluation of patient specimens. Since there is no uniform or standard format used by laboratories to report Pap smear results, for scoring purposes, PT report forms and nomenclature may be different from the examinee's usual workplace experience. Individuals, who are perfectly capable of examining patient slides, may need additional time to adjust to the testing model, which may include unavoidable differences from routine working conditions. Every effort should be made to ensure that individuals are fairly assessed in their ability to examine patient specimens and are not unfairly penalized for failure to perform satisfactorily in PT if they have no real problems examining patient material. We solicit comments as to whether or not these factors should be appropriately used to extend the amount of time allowed for a PT examination.

In the current CLIA regulations, we established the testing procedure using an above average ratio of abnormal slides, but a correspondingly longer period to review each slide, as an appropriate implementation of the obligation to test ''...to the extent practicable, under normal working conditions.'' In this context, it should be noted that we indicated in the February 28, 1992 regulations, at § 493.1257(b), the workload limit represents the maximum number, a total of 100 slides, that may be screened in a 24-hour period and ''*is not to be employed as a performance target for each individual,*'' [emphasis added].

Due to practical realities, we believe that cytology PT can not be conducted in a ''blind'' fashion. We believe that PT challenges cannot be inserted into the laboratory's routine workload because such slides would be immediately identifiable, and no oversight would be provided to ensure that consultation does not occur among individuals being tested. We invite comments on these limitations to blind PT and our view that individual PT needs to provide a reasonable time for these extraneous testing factors.

In summary, in the February 28, 1992 regulations, we determined that a 2-hour time period would be reasonable for the examination of a 10-slide test set, and the 2-hour time frame is supported by the State of Maryland's experience in administering cytology PT for over 6 years using this time frame. (In 1994, the Maryland program received approval under CLIA, and has a current enrollment of 80 laboratories.)

Consistent with the court's order discussed above, we hereby solicit comments on the proposal to change the rate for examination of PT slides to approximately 12.5 slides per hour, which equates to 45 minutes for a 10-slide test set and 90 minutes for a 20-slide test set. We also seek comments on the two options mentioned above. We also solicit comments on any other suggested procedures for complying with the court's order that PT be conducted under normal working conditions.

B. Current Status of Cytology PT Implementation

Prior to 1992, we anticipated that private, not-for-profit organizations and States would develop and administer cytology programs, as is the case for all other PT. However, following publication of the February 28, 1992 regulations, we received no applications for approval of a cytology PT program, but we did receive a number of comments expressing concerns about the feasibility of conducting a national cytology PT program to test individuals.

In June 1992, the Centers for Disease Control and Prevention hosted a meeting of the cytology professional organizations and States having cytology PT programs to solicit support in the development and implementation of a national cytology PT program. Participants at this meeting had reservations about the feasibility of conducting a national glass slide PT program that included on-site testing of individuals.

In March 1993, the Centers for Disease Control and Prevention issued a Request for Proposal for a contractor to undertake procurement of the glass slides for use in administering a national cytology PT program. No responses were received to the Request for Proposal. However, we did receive additional comments from cytology societies and individuals that echoed the comments previously received in response to the February 28, 1992 regulations. The commenters stated that conducting a national glass slide PT program with on-site testing of individuals was logistically and financially unworkable, due to the high cost of collecting the requisite number of glass slides representing appropriate diagnostic categories, and the time that would be needed to assemble and reference such a collection of slides. Several commenters also noted that, although a national program may be impossible to implement, implementing a cytology PT program by region or State might be feasible.

In November 1993, the Centers for Disease Control and Prevention cosponsored a cytology symposium to consider possible alternatives to a national cytology PT program using glass slides, and a number of potential approaches were discussed. The participants believed that the most promising strategy would be to develop a variety of cytology PT programs to accomplish the statutory mandate of testing the proficiency of cytology personnel. Alternative approaches suggested included State-administered glass slide programs, mailed glass slide programs, or national programs that use photographic facsimile representations (in other words, color transparencies, color plates, digitized computer images) of cytology preparations in lieu of glass slides.

In December 1993, the subcommittee on cytology of the Clinical Laboratory Improvement Advisory Committee met to review the proceedings from the symposium, and to make recommendations concerning cytology PT. Following the subcommittee meeting, the full Clinical Laboratory Improvement Advisory Committee met and endorsed the recommendations made by the subcommittee. The Clinical Laboratory Improvement Advisory Committee recommended that research studies be conducted to define outcomes and evaluate the effectiveness of both glass slide and alternative cytology PT programs and that regulatory changes be pursued to permit approval of alternative programs. The committee also encouraged professional organizations and States to develop programs to meet the current regulations and become operational.

Currently, cytology PT is not being conducted nationally. To date, two State-operated cytology PT programs have applied for approval under CLIA. The State of Wisconsin subsequently withdrew its application when it was unable to obtain a sufficient number of referenced glass slides. The other applicant, the State of Maryland Cytology Proficiency Testing Program, met the CLIA cytology PT requirements and was granted approval for calendar year 1995. To date, we have received no other applications.

C. Alternatives to Glass Slide Testing

The major impediment in making cytology PT available on a national basis has been and continues to be the difficulty in obtaining a sufficient number of properly referenced glass slides. We believe that programs using facsimiles of glass slides (in other words, computer images) may provide the most reasonable alternative to evaluating cytology performance using traditional glass slide programs.

Computer-based programs offer the advantage of providing for the accumulation and assembly of sufficient numbers of well-documented, referenced cytology preparations that can be used for testing individuals in a consistent and uniform manner. We believe that revising the requirements to allow the use of testing media other than glass slides is the most promising approach to making cytology PT available nationwide and would reflect the intent of the Congress in enacting the CLIA legislation. In the Report of the House Energy and Commerce Committee that accompanies the Clinical Laboratory Improvement Amendments of 1988, Public Law 100–578, H.R. Rept. No. 100–899, 100th Congress, 2nd Sess., pp. 29–31, HHS was 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 on-site proficiency testing.'' In addition, the Committee Report stated that the Committee expected HHS ''. . . to foster innovative approaches, including video technology, for developing proficiency testing for analytes for which such testing is not currently available.''

To promote the development of alternative PT programs in cytology, the Centers for Disease Control and Prevention awarded three 1-year cooperative agreements in 1994. These agreements included provisions for the development of computer-based PT programs to measure cytology performance, and provisions for the evaluation of such programs through pilot studies. Early in 1995, the Centers for Disease Control and Prevention awarded a 2-year contract to compare the actual work performance of cytology personnel with their performance in both a glass slide PT program and a computer-based PT program, which simulates the screening process and includes the evaluation of locator and interpretive skills.

D. Request for Comments on Computer-Based Cytology PT Programs

We are soliciting comments on expanding the CLIA regulations to permit the use of computer facsimile representations of cytology specimens as an alternative to glass slide PT examinations. We are particularly interested in receiving comments from individuals and organizations with experience in computer systems for microscopic examination of cytology preparations (glass slides) and the ability of this technology to closely simulate normal working conditions.

We are specifically soliciting comments which respond to the following questions:

1. Should computer-based cytology PT programs measure both interpretive and locator skills? Interpretive skills are those required to look at a particular cell or set of cells and determine a diagnostic condition; locator skills are those required to scan a slide and select a cell or group of cells for interpretation. As technology is now available to measure interpretive skills but development is needed to expand capabilities to include locator skills, should we consider a phase-in period during which PT programs would be required only to evaluate interpretive skills?

2. How can computer-based PT programs meet the provisions in the law requiring unannounced testing and that testing take place, to the extent practicable, under normal working conditions? At the current level of technology, computer testing events to evaluate interpretive and locator skills would probably need to be announced

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.

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

forms) may add to the anxiety level associated with PT participation and adversely affect PT performance. Decreasing the time frame in which individuals must complete the PT examination may increase the overall costs of cytology PT due to an increase in the failure rate of individuals who would be forced to examine PT slides at a rate greater than their normal workload rate (for individuals who examine slides at a workload rate that is less than the maximum). In the case of pathologists, who do not routinely screen slides and therefore are not subject to a workload limit, a higher failure rate might also be expected.

Costs associated with taking the second test and rescreening slides for the 20 work days between tests would increase in proportion to the increased failure rate. In addition, if a greater number of individuals must take the third retest off-site, we assume one day of work per examinee would be lost.

The costs of this proposed rule would be confined to the difference in lost wages because of an expected increase in rates of failure for both cytotechnologists and cytopathologists and an increase in costs needed because of rescreening more slides and retraining an increased number of examinees.

Estimated Costs

The data we are using in this proposed rule are the data we used to determine the impact of the February 1992 rule. The regulatory impact analysis in that rule projected national costs from data pertaining to 1990 that we received from the Maryland State Cytology Testing Program. We have no more recent data from which to project national figures at this time, and there is no other HCFA-approved testing program to validate or invalidate the Maryland State experience.

The base population that we are using for this impact analysis consists of 7,950 cytotechnologists and 8,690 pathologists. We are assuming a range of wages for cytotechnologists of $14 to $20 per hour and for pathologists a range of $75 to $110 per hour. We are assuming that conducting an on-site test that lasts 45 minutes will consume 2 hours per examinee, instead of the 5 hours we currently allot for each examinee to take a 2-hour test.

Based on these assumptions, we project the following: The first round of tests will cost from $2.0 to $2.9 million. This represents savings of $3.0 to $4.3 million from our estimate of what it would cost to test under current requirements.

In order to measure the possible costs of retesting, we estimated that under the new time constraints 25 percent of the examinees would fail the first test. We project that costs associated with taking the second test, assumed to be conducted off-site, will be $3.1 to $4.5 million.

We estimate that 25 percent of the persons taking the second test will fail that examination and that it would cost $1.7 to $2.4 million for the rescreening required and from $0.4 to $0.7 million in time lost to conduct the third test. Again, we assume one day of work per examinee will be lost due to off-site testing. If an on-site testing option is offered and selected, costs may be significantly lower.

We estimate that 25 percent of those failing the second test would fail the third test (260 persons) and that it would cost from $0.6 to $0.8 million in lost time to retrain cytotechnologists and from $3.3 to $6.5 million to retrain pathologists. The costs of retraining include the cost of 40 days of time lost; this includes 5 days for training and 35 days waiting for the next examination to be given, assuming the examinations are not offered more than once a month. We have no data or information on which to base an estimate of the cost of the training itself.

The total costs attributable to the proposed PT requirements would range from $10.9 to $17.8 million in the first year of testing in a nationwide cytology PT program. This represents an increase of $0.5 to $1.6 million over our original projected costs of $10.4 to $16.1 million (excluding the cytology slide test costs which would remain unchanged in this proposed rule) for our current PT requirements. This difference reflects the impact of the assumed increase in the test failure rate on the associated costs of retesting and retraining an increased number of examinees and rescreening more slides. It is possible that costs would go down somewhat in subsequent years: the Maryland State Cytology Testing Program showed a decrease in the percentage of examinees failing the testing after the first year.

PROJECTED ANNUAL COSTS OF CYTOLOGY PROFICIENCY TESTING

	Low	High
Conduct of first testing	$2,025,000	$2,895,000
Conduct of second testing	3,058,000	4,467,000
Cost to rescreen for 20 workdays	1,667,000	2,383,000
Conduct of third testing	384,000	733,000
Loss of 40 days Cytotechnologist	561,000	802,000
Loss of 40 days Cytopathologist	3,246,000	6,493,000
Costs through hired testing	10,941,000	17,773,000

The effect of the proposed change on the only HCFA-approved cytology PT program, Maryland State Cytology Testing Program, is difficult to predict, until we are notified whether the program intends to make revisions to its requirements for examination of PT slides complying with these proposed revisions (if finalized). However, if Maryland maintains an approved program, we predict that it would have comparable increases in costs after the first test because of the greater number of persons failing.

If Maryland chooses not to make the revisions, the program would fail to meet the criteria for CLIA-approval as a cytology PT program. HCFA would notify the program of the nonapproval, and the program would then have to notify all laboratories enrolled in the program of the nonapproval and the reasons for nonapproval within 30 days of the HCFA notification. If this occurs, until other State programs are approved or a nationwide cytology PT program is available, none of the cytotechnologists and pathologists in this country who examine gynecologic cytology preparations would be participating in an approved cytology PT program.

We are not preparing an analysis for either the RFA or section 1102(b) of the Act because we have determined, and the Secretary certifies, that this proposed rule would not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals.

Also, we considered the economic aspects of whether or not the proposed change would reduce or increase health care costs by leading to the correct earlier diagnosis of pap smears that would otherwise be misread as false positive or false negative under the existing regulations. Because the potential economic effects of this proposal are so speculative pertaining to any impact on health care costs, we are unable to factor such costs into this analysis. Similarly, we considered the economic impact on individuals due to

loss of employment, but again, we are unable to factor such costs into this analysis because the economic effects are so speculative.

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

List of Subjects in 42 CFR Part 493

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

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

PART 493—LABORATORY REQUIREMENTS

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

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

2. Section 493.855, paragraph (b) introductory text is revised to read as follows:

§ 493.855 Standard; Cytology: gynecologic examinations.

* * * * *

(b) The laboratory must ensure that each individual participates in an annual testing event that involves the examination of a 10-slide test set as described in § 493.945. Individuals who fail this testing event are retested with another 10-slide test set as described in paragraphs (b)(1) and (b)(2) of this section. Individuals who fail this second test are subsequently retested with a 20-slide test set as described in paragraphs (b)(2) and (b)(3) of this section. Individuals are given not more than 45 minutes to complete a 10-slide test and not more than 90 minutes to complete a 20-slide test. Unexcused failure to appear by an individual for a retest will result in test failure with resulting remediation and limitations on slide examination as specified in (b)(1), (b)(2), and (b)(3) of this section.

* * * * *

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: November 21, 1995.

Helen Smits,

Deputy Administrator, Health Care Financing Administration.

Dated: November 21, 1995.

Frances Lee de Peyster,

Director, Centers for Disease Control and Prevention, Washington Office.

Dated: November 21, 1995.

Donna E. Shalala,

Secretary.

[FR Doc. 95–29190 Filed 11–27–95; 11:59 am]

BILLING CODE 4120–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Parts 611, 672, and 676

[Docket No. 95111 3267–5267–01; I.D. 110295B]

Groundfish of the Gulf of Alaska; Limited Access; Foreign Fishing; Proposed 1996 Harvest Specifications

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed 1996 initial specifications for groundfish; apportionment of reserves; request for comments.

SUMMARY: NMFS proposes initial harvest specifications for groundfish and associated management measures in the Gulf of Alaska (GOA) for the 1996 fishing year. This action is necessary to carry out management objectives contained in the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP).

DATES: Comments must be received by Decemberr 29, 1995.

ADDRESSES: Comments must be sent to Ronald J. Berg, Chief, Fisheries Management Division, Alaska Region, National Marine Fisheries Service, P.O. Box 21668, Juneau, AK 99802–1668, Attn: Lori Gravel.

The preliminary Stock Assessment and Fishery Evaluation (SAFE) Report, dated September 1995, is available from the North Pacific Fishery Management Council, 605 W. 4th Ave Suite 306, Anchorage, AK 99501–2252.

FOR FURTHER INFORMATION CONTACT: Kaja Brix, 907–586–7228.

SUPPLEMENTARY INFORMATION:

Background

The domestic and foreign groundfish fisheries in the exclusive economic zone of the GOA are managed by NMFS according to the Fishery Management Plan for Groundfish of the Gulf of Alaska. The FMP was prepared by the North Pacific Fishery Management Council (Council) under the authority of the Magnuson Fishery Conservation and Management Act. The FMP is implemented by regulations for the foreign fishery at 50 CFR part 611 and for the U.S. fisheries at 50 CFR parts 672, 676, and 677. General regulations that also pertain to the U.S. fisheries appear at 50 CFR part 620.

This action proposes for the 1996 fishing year: (1) Specifications of total allowable catch (TAC) for each groundfish target species category in the GOA and apportionments thereof among domestic annual processing (DAP), joint venture processing (JVP), total allowable level of foreign fishing (TALFF), and reserves; (2) apportionments of reserves to DAP; (3) apportionments of the sablefish TAC to vessels using hook-and-line and trawl gear; (4) apportionments of pollock and Pacific cod TAC; (5) ''other species'' TAC; (6) halibut prohibited species catch (PSC) limits; and (7) fishery and seasonal allocations of the halibut PSC limits.

Comments on the proposed 1996 specifications and proposed apportionments of reserves are invited from the public through December 29, 1995. After again consulting with the Council, NMFS will publish final specifications for the 1996 fishing year in the Federal Register.

Regulations at § 672.20(c)(1)(ii)(A) require that one-fourth of the preliminary or proposed specifications (not including the reserves and the first quarterly allowance of pollock), one-fourth of the inshore and offshore allocations of Pacific cod in each regulatory area, and one-fourth of the halibut PSC amounts become effective at 0001 hours, Alaska local time, January 1, on an interim basis, and remain in effect until superseded by the final harvest specifications.

NMFS is publishing, in the Rules and Regulations section of this Federal Register issue, interim TAC specifications and apportionments thereof for the 1996 fishing year that will become available 0001 hours, A.l.t., January 1, 1996, and remain in effect until superseded by the final 1996 harvest specifications.

1. *Proposed Establishment of TAC Amounts and Apportionments Thereof Among DAP, JVP, TALFF, and Reserves*

Under § 672.20(c)(1)(ii), NMFS, after consultation with the Council, publishes in the Federal Register proposed specifications of annual TAC