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.