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