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February 16, 2005

Statement of the

American Society for Clinical Pathology

before the

Clinical Laboratory Improvement Advisory Committee

on the

Future of Cytology Proficiency Testing Regulations

Chairman Sundwall, members of the Clinical Laboratory Improvement Advisory Committee (CLIAC), my name is Matthew Schulze and I am the Senior Manager for Federal and State Affairs for the American Society for Clinical Pathology. I appreciate the opportunity to provide the Society's statement to you today.

ASCP and the vast majority of members of the cytopathology laboratory community are concerned with the recent Centers for Medicare and Medicaid Services (CMS) decision to implement a nationwide cytology proficiency testing (PT) requirement through the approval of the Midwest Institute for Medical Education (MIME).

The CMS decision to approve MIME is in accordance with the role and responsibility of the agency. However, for more than a decade professional societies, including ASCP, have asked that these regulations be updated to reflect the current science and everyday operations of the nation's laboratories that provide cytology services. The decision to approve MIME was made late in the 2004 calendar year and caused a great deal of disruption among laboratories, with no apparent consideration for the significant budgetary implications of this action.

For many years the Society has had an ongoing dialogue with the federal government about ASCP's concerns with the science behind the CLIA Cytology PT requirements and how these programs were to be implemented. The years of communication with the federal government regarding the cytology PT regulations raise a broader concern. While ASCP and other scientific organizations have expressed concern about these regulations and have written letters and appeared before federal advisory bodies such as the Clinical Laboratory Improvement Advisory Committee, we do not believe that sufficient attention has been paid to address the integrity, validity and scientific questions surrounding CLIA's approach.

Attached to this statement are a number of communications between ASCP and the federal government related to our concerns. These letters document our long held belief that the CLIA Cytology PT requirements, as written, need to be modified in order to better protect women's health and reflect the scientific and everyday operations of our nation's laboratories.

Since the original release of the regulations governing cytology proficiency testing, there have been a number of important scientific, medical and technological advances that bear directly on the practice of cytopathology and the ability of cytology proficiency testing programs to protect patient health. Medical providers increasingly view the Pap smear as a screening tool, rather than a diagnostic tool. In addition the 2001 Consensus Guidelines for the Management of Women With Cervical Cytological Abnormalities has had an important impact on the practice of cytopathology.

Given our long held belief that these regulations need to be updated, ASCP requests that the federal government immediately reopen the regulations under CLIA governing cytology proficiency testing. In a letter to Dr. Robert Martin at CDC dated February 25, 1999, ASCP asked that our nation implement a multifaceted approach to cytopathology proficiency testing. Six years later we reiterate that request and ask that work on a modernized cytology proficiency testing regulation begin immediately.

To begin this process we recommend that CLIAC form a working group to provide CMS with advice regarding the scientific framework, proposed timeline and process for release of a new regulation.

While ASCP remains concerned about the integrity, validity and science of the CLIA approach to cytology proficiency testing, we are also a nonprofit dedicated to serving the nation's patients as well as the Society's members and customers. To that end, ASCP looks forward to working with CMS on approval of the **ASCP*STAR*** program for 2006. Given your very busy schedules, ASCP also wants to thank both CDC and CMS in advance for your willingness to work with us on an approval of our program.

Thank you for the opportunity to address the distinguished committee.

American Society for
Clinical Pathology®

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December 7, 2004

Thomas E. Hamilton
Director, Survey and Certification Group
Center for Medicaid and State Operations
Centers for Medicare and Medicaid Services (CMS)
Department of Health and Human Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, Maryland, 21244-1850

Dear Mr. Hamilton:

Thank you for agreeing to meet with the American Society for Clinical Pathology (ASCP) on December 10 from 1:00 pm to 3:00 pm regarding our desire to pursue an application for expedited approval of the **ASCP*STAR*** as an approved proficiency testing (PT) program. The Society wants to provide you with this communication in advance of our meeting so that you are aware of both our business- and science-related concerns.

The Centers for Medicare and Medicaid Services (CMS) decision to approve the Midwest Institute for Medical Education (MIME) as a national provider of cytology proficiency testing has caused a great deal of confusion among **ASCP*STAR*** customers. Many of our customers had already signed up for our program only to be confused as to whether or not participating would allow them to meet CLIA guidelines. Others have determined it is better not to participate and this is hurting our nonprofit endeavor.

In a letter sent to you on November 10, 2004, the ASCP and the College of American Pathologists (CAP) requested a one-year moratorium on the mandatory requirement that laboratories enroll with MIME. We reiterate the request for a one-year moratorium. ASCP understands that CMS is currently developing a policy on how the approval of MIME affects the 3800 impacted laboratories and the CAP and ASCP Interlaboratory Comparison programs. We are hopeful that your policy will take into consideration the enormous impact immediate compliance would have on both providers and laboratories.

ASCP is also concerned with the lack of communication from the federal government to all professional organizations that previously expressed a desire to provide CMS approved PT. Specifically, we are troubled by the absence of timely information regarding changes to the cytology PT provider approval process that resulted from CMS discussions with MIME. Had this development been communicated, ASCP and other PT providers could have sought CMS approval without the need for expedited processing.

Earlier this year, CMS did communicate with ASCP to provide abbreviated instructions for submitting an initial application for CMS approval of the **ASCP*STAR*** program but it

did not address the modified requirements for PT. This communication arrived in the context of many years of dialogue with the federal government about our concerns related to the science of the CLIA Cytology PT requirements and how these programs were to be implemented.

The many years of communication with the federal government over your proposed regulations raise a broader concern. While ASCP and other scientific organizations have expressed concern about these regulations and have appeared before federal advisory bodies such as the Clinical Laboratory Improvement Advisory Committee, we are unaware of any actions taken by the federal government to address the integrity, validity and scientific questions surrounding the CLIA approach.

Attached for your information is a number of communications between ASCP and the federal government related to our concerns. These communications document our long held belief that the CLIA Cytology PT requirements, as written, need to be modified in order to protect women's health and reflect the scientific and everyday operations of our nation's laboratories.

While ASCP remains concerned about the integrity, validity and science of the CLIA approach to cytology proficiency testing, we are also a nonprofit dedicated to serving our members and customers. To that end, ASCP looks forward to working with CMS on an expedited approval of the **ASCP*STAR*** program.

The Society realizes that modifications to our program will be necessary in order to address CMS requirements and, in this regard, we trust that the CMS will be willing to provide the technical assistance that may be required to accomplish this goal. We would hope to be able to work together and develop the same cooperative relationship that was possible with MIME.

Sincerely,

John R. Ball

John Ball, MD, J.D., MACP

Attachments sent via fax

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WASHINGTON OFFICE

January 26, 1996

Centers for Disease Control and Prevention
Attention: HSQ-233-P
4770 Buford Highway, NE
MS F11
Atlanta, Georgia 30341-3724

Dear Sir or Madam:

The American Society of Clinical Pathologists (ASCP) appreciates this opportunity to comment on the proposed rule regarding the requirement that cytology proficiency testing be conducted, to the extent possible, under normal working conditions. In addition, as requested, we are commenting on the use of computer facsimile representations of cytology specimens as an alternative to glass slide proficiency testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

ASCP is a nonprofit medical specialty society organized for educational and scientific purposes. Its 75,000 members include board certified pathologists, other physicians, clinical scientists, and certified technologists and technicians. These professionals recognize the Society as the principal source of continuing education in pathology and as the leading organization for the certification of laboratory personnel. ASCP's certifying board registers more than 150,000 laboratory professionals annually, including more than 6,000 cytotechnologists.

Normal Working Conditions
We understand, that in accordance with the court ruling of August 29, 1995, the Department of Health and Human Services must ensure that cytologists are tested, to the extent practicable, under normal working conditions. Unfortunately, the CLIA statute as currently written does not and cannot mirror the normal working conditions of cytologists. Ideally, a multi-faceted approach to proficiency testing would best achieve the goal of testing the quality of gynecologic cytopathology interpretations under normal working conditions and, ultimately, best serve the public.

As we understand the current legislative framework for assessing normal working conditions, it is important to recognize that the laboratory director or the technical supervisor establishes and oversees the acceptable number of slides screened by individuals in the laboratory. That acceptable number is determined by the individual's experience, competency and consistency. Many laboratories may be more stringent in their evaluation of cytotechnologists because they have established internal limits below that of state or federal regulations.

Ratio of Abnormal Slides
"Normal working conditions" would require that a proficiency test contain 5-10% abnormal challenges. In a 10 slide test, this would mean that there should be no more than one abnormal slide representing low- and high-grade squamous intraepithelial lesions, cancer, and unsatisfactory samples. This would be contrary to the current regulation that states that each 10 slide test contain at least one example from each of these four categories. This would mean that each 10 slide test contain at least 3 abnormal challenges.

Abnormal slides require more time to evaluate and interpret. For proficiency testing, a larger than normal percentage of abnormal slides must be present in order to examine an individual's skill. To test adequately the proficiency of personnel, additional abnormal challenges may be required so that individuals may be considered appropriately skilled under any conditions.

The ratio of abnormal slides present ultimately depends upon how literally "normal working conditions" is defined. Overall, we agree that <u>no more than</u> 100 slides in an eight hour period should be screened by individual cytotechnologists. This means a <u>maximum</u> limit of 12.5 slides screened per hour. Common experience reflects that 50-60 slides a day are screened by individual cytotechnologists, and test screening times must reflect this number. Normal working conditions, again depending upon an individual's experience and competence, would require that proficiency testing be conducted at a rate less than the maximum. Experience has shown that 6-10 minutes are required to review a normal slide and 10-15 minutes are required to review an abnormal slide.

If the ratio of abnormal slides is 5-10%, then ASCP recommends that proficiency testing be conducted at 10 challenges in 90 minutes. If the percentage of abnormal slides is increased, then ASCP recommends that the allotted time be increased accordingly.

Blind testing
We agree that proficiency testing using conventional Pap smears cannot be conducted in a blind fashion. Under normal working conditions, specimens are sent to the laboratory unprocessed and unstained. Proficiency testing challenges are processed and stained before they are sent to laboratories. Laboratory personnel would have no difficulty distinguishing between an actual specimen and the proficiency test sample. Also, laboratory personnel regularly consult on certain specimens. Consultation is a normal, acceptable part of the screening process. This consultation may interfere with the proficiency test result if the laboratory personnel were not informed that the specimen was part of an examination. For similar reasons, proficiency testing should always be announced. Since this is a test, it should be proctored and monitored appropriately. Unduly disrupting laboratory activity by producing unannounced tests may inconvenience patients as well as create unnecessary anxiety and morale problems with the laboratory personnel.

Computer-based Proficiency Testing
The use of computer technology in cytopathology is the subject of active research and development. Computer images will play an important role in the future of the field from a teaching and proficiency evaluation perspective. This technology is being studied in an attempt to simulate the screening technique used by cytopathology professionals, who currently view glass slides in standard practice. ASCP has been exploring this technology, and appreciates the interest and support of the Centers for Disease Control and Prevention (CDC). Yet, validity and reproducibility studies crucial to proper testing using standardized images still need to be performed.

ASCP Experience
ASCP received funding through a cooperative agreement with the CDC to develop an alternative method to assess the proficiency or competency of individual cytotechnologists and pathologists engaged in the screening, interpretation, and diagnosis of gynecologic cytology. Through our studies, we have found no assurance that marginal practitioners are reliably identified by a ten glass slide proficiency test. A ten glass slide test, while appearing to be a valid testing method, actually offers low reliability and precision. Any proficiency test for gynecologic cytology must adhere to strict validity and reliability criteria, this includes glass slides as well as computer-based proficiency testing.

Our experience indicates that it is possible to accumulate and assemble a sufficient number of challenges to test adequately cytopathology

professionals' ability using computer technology. We have demonstrated in our study that the use of computerized images supports the intent of the proficiency testing process to identify marginal cytopathology practitioners. The computerized system reflects the spirit of CLIA, assuming that we are working within the parameters of a test environment, not normal working conditions.

Measurement of Interpretive and Locator Skills
Computerized images can be used to test both interpretive and locator skills. As our research on cytology proficiency testing progresses, opportunities to simulate actual microscopic functions and practice should be available in the near future.

Phase-in Period
ASCP recommends a phase-in period for using computer-based cytology proficiency testing. Our study did not provide enough data to show a clear pattern between performance on the computerized images and glass slides. A phase-in period would allow a more extensive study to be conducted to verify performance comparability. It is also important to familiarize cytopathology professionals with this new test medium before they are required take a computerized proficiency test in gynecologic cytology.

ASCP suggests the use of computer images to assess interpretive or identification skills in the interim while computer technology is developed to aid in the assessment of locator skills. This use would allow marginal cytopathology practitioners to be identified, and would afford individuals the opportunity to become accustomed to this new test medium.

Modification of the Scoring System
The scoring system for proficiency testing should be modified. The current partial credit system seems logical for laboratory practice, but it does not work as anticipated in the testing situation.

The following skills are examined through cytology proficiency testing: 1) the ability to distinguish high-grade squamous intraepithelial lesions (HSIL) challenges (including cancer) from normal/infectious/reparative challenges; 2) the ability to distinguish normal/infectious/reparative challenges from abnormal challenges (e.g., squamous intraepithelial lesions, low-grade squamous intraepithelial lesions (LSIL), HSIL, and unsatisfactory); and 3) the ability to distinguish unsatisfactory challenges from normal/infectious/reparative challenges, LSIL challenges and HSIL

challenges. To better score these skills, a scoring system that gives a value of 1 for a correct response, and 0 for an incorrect response should be considered.

For example, full credit is given when challenges that are abnormal are properly identified as abnormal. This correct identification should be given a score of (1), and all other responses should be considered incorrect or (0). Challenges that are normal/infectious/reparative should receive a (0) score when they are classified as anything else (e.g. HSIL, LSIL, unsatisfactory). If the challenge is correctly identified, then full credit or a (1) is given. Similarly, unsatisfactory specimens should be given a score of (1) when correctly classified as unsatisfactory. No credit or (0) should be assessed when an unsatisfactory specimen is classified differently.

ASCP believes this clarification of the scoring system will simplify the process and provide a clearer picture of the proficiency of examinees. Our study data shows that participant responses followed this suggested scoring pattern. When the study participant could correctly identify and classify the challenge, full credit was received. When the participant could not identify and classify the challenge, the challenge was missed completely. We found there was only one challenge in which partial credit served as a middle ground between fully correct and fully incorrect.

Automatic Failure
While incorrectly identifying cancer cells is a grievous error in the laboratory, how it is scored for testing purposes must be carefully considered. The more difficult the challenge, the more likely the examinee, even an otherwise competent individual, is to answer incorrectly. If a higher percentage of HSILs are included on the test, and a single miscall results in an automatic failure, then the examinee has more opportunities to fail based on a single response.

Under the current scoring system, the number of opportunities to fail the test is influenced by the test specifications. If the test specifications are constructed to represent the normal workload, then the test should contain fewer abnormal challenges. ASCP suggests deleting the automatic failure rule and instead institute an absolute criterion standard to pass, which may be as high as 90%.

Number of Challenges Under Computerized Proficiency Testing
Under computerized proficiency testing, ASCP recommends increasing the volume of challenges to between 25 and 50. This higher volume of

challenges is not possible with glass slides, but is very possible with digitized images that can be stored in an item bank. The digitized images can be presented to the participant using an acceptable computer algorithm. Retesting, if necessary, should come from the same pool of materials.

Increasing the number of challenges reduces the error of measurement and increases the reliability of the pass/fail decisions. Also, if the volume is increased to 25-50 challenges, then 30% or 8-15 challenges could be HSIL. This will provide the proper number of challenges to identify reliably those participants who cannot correctly classify HSIL.

Bank of Challenges
ASCP also recommends constructing a field-tested bank of challenges. Between 250 and 500 challenges could be stored in the bank, depending upon the ultimate length of the proficiency test. The categories of these images should represent the test specifications. These challenges may be in any form, although a scannable format will probably be more acceptable to the cytology community. While most any software may be used to digitize the challenges, they should ultimately be presented using test administration software that allows the systematic recording and scoring of responses.

We suggest that an adequate field test should include 100 cytotechnologists and 100 cytopathologists. After the field testing is completed, challenges should be reviewed based on their statistical performance. The challenges that meet performance standards and survive the referencing process should then be placed in an image bank from which a benchmark scale will be constructed and a criterion standard (we recommend 90%) may be established on that scale.

Again, thank you for the opportunity to comment on this proposed rule. If you have questions or need additional information, please give me a call or contact Robin Stombler, Director of the ASCP Washington Office, at (202) 347-4450. For more specific information on the ASCP study on computer-based proficiency testing, please contact Theresa Somrak, Director of Cytopathology Education Consortium Activities, at (312) 738-4851.

Sincerely,

M. Desmond Burke, MD

M. Desmond Burke, MD
President

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30341-3724

March 19, 1996

RECEIVED
MAR 22 1996
Per

Ms. Theresa Somrak, JD, CT(ASCP)
Director, Cytopathology Education
Consortium Activities
2100 West Harrison Street
Chicago, Illinois 60612-3798

Dear Ms. Somrak:

I am responding to the recent letter from the Consortium expressing concerns about the publication of a proposed rule to revise the Clinical Laboratory Improvement Amendments of 1988 requirements concerning cytology proficiency testing (PT).

We appreciate your comments about reducing the incidence of cervical cancer, and we agree that education of the medical community and the public is key to increasing the number of women screened for cervical cancer and ensuring that women with abnormal Pap smears receive adequate follow-up and treatment. Several professional societies as well as the National Cancer Institute and the Centers for Disease Control and Prevention are actively engaged in such activities.

With respect to cytology PT, specifically you suggested an evaluation of individual competency by the laboratory director, using a variety of educational assessment programs, similar to those available from several professional organizations. You also proposed PT of the laboratory as a whole, using mailed regulatory challenges of various formats including glass slides, photomicrographs, and/or computer-based images. We have received numerous comments about the methodology for conducting cytology PT, and all comments will be carefully evaluated and considered.

We share your concerns about the validity of cytology PT, using any testing modality, and agree with you that computer images could play a role in the future of cytopathology. At this time, we believe that computer-based testing may be the most promising approach to developing a more equitable, cost-effective, nationwide program in cytology PT.

We appreciate receiving your views on these important issues, and we share your concerns about establishing regulations that ensure quality testing in cytology.

Sincerely yours,

Joe Bone for

Carlyn L. Collins, M.D., M.P.H.
Director
Division of Laboratory Systems
Public Health Practice Program Office

AMERICAN SOCIETY OF CLINICAL PATHOLOGISTS
2100 WEST HARRISON STREET • CHICAGO, ILLINOIS 60612-3798 • (312) 738-1336

JAMES LINDER, MD, President

Address Reply to:
2100 West Harrison Street
Chicago, Illinois 60612-3798

February 25, 1999

Robert Martin, Dr. PH
Director, Public Health Practice Program Office
Centers for Disease Control and Prevention
4770 Buford Highway-NE
Atlanta, Georgia 30341-3724

Dear Dr. Martin:

The American Society of Clinical Pathologists (ASCP) is a nonprofit medical specialty organized for educational and scientific purposes. Its 75,000 members include board certified pathologists, other physicians, clinical scientists and certified technologists and technicians. The ASCP appreciates and recognizes the challenges in the development and implementation of a national cytopathology proficiency test (PT) program that meets current CLIA regulations. The ASCP has discussed issues affecting PT in cytopathology with the Centers for Disease Control and Prevention (CDC) and the Health Care Financing Administration (HCFA). This letter confirms the ASCP's commitment to work with the CDC and HCFA to enhance the quality of gynecologic cytopathology interpretations among laboratories.

In August of 1998, the ASCP presented various education assessment programs that in our opinion address the spirit of cytology PT requirements of CLIA'88. The ASCP recommends a multifaceted approach to cytopathology PT, thereby achieving the goal of enhancing cytopathology interpretations. We support the use of a variety of programs including those using glass slides, photomicrographs, and when appropriate, computer-based assessment.

Educational assessment programs developed by the ASCP and other professional organizations have become widely used within laboratories as part of their overall quality improvement programs. ASCP education programs offer opportunities for cytopathology professionals to comply with mandated cytology PT.

Educational assessment programs using glass slides and photomicrographs are currently provided to cytopathology professionals with ASCP Self-Assessment (ASA) Workshops and ASCP*STAR*. ASCP CheckPath provides self assessment using color transparencies. The ASA Workshops formatted according to CLIA'88 are administered at national and regional meetings. ASCP*STAR* is a mailed-out glass slide program. CheckPath is a mailed-out photomicrograph program. ASA Workshops provide assessment of individuals whereas ASCP*STAR* and CheckPath assess individuals as well as the laboratory.

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Outlined below are issues and concerns expressed by the CDC and HCFA regarding cytology PT programs, and ASCP's responses and solutions to those concerns.

- **Off-site vs. On-site Testing/Security Issues**
  The Laboratory Director Programs such as STAR and CheckPath occur on-site, at the work place. The Laboratory Director is responsible for assuring that members of staff complete the program independently. The ASA Workshops, although done off-site, are monitored and address security issues. The ASA Workshops may be administered at schools of cytotechnology, universities, as well as national and regional meetings held by professional organizations.

  Individuals participating in an in-house or mailed in program could be required to sign a statement of independent workmanship affirming that the PT was, in fact, performed independently. The ASCP-BOR requires this of histotechnologists who complete their practical for certification. In addition, an audit procedure could be used where laboratories are randomly selected for an audit of PT procedures to assure compliance. States, such as California, employ this method to assure compliance of state licensure laws.

Psychometric Issues

The ASCP considers the psychometric issues related to cytology proficiency testing of prime importance. These psychometric issues apply whether the test uses computerized images or glass slides. The primary psychometric concern is reliability. The second most pressing psychometric concern is with field test procedures. The third psychometric concern is how the 90% standard was established and how it will be used to make pass/fail decisions.

- **Reliability/Number of challenges**
  The reliability of the test as stipulated in the regulations is of concern. Because the mandated cytology PT is extremely brief, only (10 challenges or test items) the error of measurement is very high and there is little confidence in the accuracy of the decisions made about the competency of cytotechnologists or cytopathologists. There is little reliability that the test passes those who are competent and fails those who are not.

  The ASCP recommends assessing proficiency using at least 20 slides or challenges. Ten slides or challenges is not statistically significant for assessment purposes. STAR provides 20 slides in a two year cycle, 10 slides per year, a preliminary score is given after one year and a composite score is given after completion of the two year cycle. ASA Workshops present 20 slides for review. CheckPath presents 20 challenges over the course of a year.

- **Validation/Field Testing**

  The second most pressing psychometric concern is validation of the challenges or test items using field testing. Field testing of test items is important for building an item bank and making pass/fail decisions. A large and systematic field testing project should be completed using a large sample of cytotechnologists and pathologists to establish a benchmark scale that is representative of the ability required for competence. The initial referencing by three pathologists, no matter how qualified they are, is not adequate statistically. An extensive field test should be undertaken regardless which method, glass slides or a computerized format, is used.

- **Standard-Pass/Fail**

  The third psychometric concern is how the 90% standard was established and how it will be used to make pass/fail decisions. It is important that more difficult challenges earn more weight than easier challenges, making the pass/fail decisions more accurate and equitable for all participants.

  Ninety percent correct "sounds" competent, but what does that mean in terms of ability. One must ask the question "90% of what?" If a participant is presented with challenges that are obvious, then 90% correct is probably a reasonable standard. However, if a participant is presented with more ambiguous test items, that are subject to different interpretations by competent professionals, 90% is an unreasonable standard. This is why the difficulty of the PT must be considered. Test equating provides methods for accounting for the difficulty of a test before the criterion standard is implemented. Thus the criterion standard is 90% correct. The "of what" is defined by all challenges included on the benchmark scale and accounted for through the equating process. Therefore, a participant that received less than a 90% correct score on a PT comprised of difficult challenges, is not penalized when compared to a participant that received a 90% correct score of a PT comprised of relatively easy or obvious challenges.

- **Grading/Scoring System**

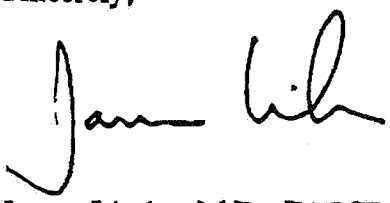
  The ASCP suggests eliminating the automatic failure score for interpreting a high grade squamous intraepithelial lesion (HSIL) as normal. Otherwise, the PT is essentially a one challenge test. (Currently, if participants categorize an HSIL image as normal, they fail the PT.) In the laboratory, if a cytotechnologist or pathologist is unsure about a HSIL interpretation, additional information can be requested, a new slide can be requested, or there is an opportunity to consult with colleagues. These resources are not present in the testing situation. The participant must make a decision based on the information available only. Even though the image has been referenced (3 pathologists), there is still room for disagreement among the experts, especially for more difficult or complex challenges.

  If the length of the test is increased to 20 or 30 challenges, then a greater percentage of challenges may be HSIL. A participant who misses several of these will probably fail to meet the criterion standard. Conversely, the probability of answering all HSIL challenges correctly is less than 100%, making automatic failure inappropriate.

A multi-option approach to PT in cytopathology is feasible to implement, complies with the spirit of CLIA'88 and is the most cost effective use of increasingly scarce health care resources. ASCP looks forward to working with you in promoting quality cytopathology practice through this multi-optioned approach.

If you have questions or need additional information, please give me a call or contact Theresa M. Somrak, Director, Cytopathology Education Consortium at (312)738-4851.

Sincerely,



James Linder, M.D., FASCP
ASCP President