ASCP Framework
for a
Revised Cytology Proficiency Testing Regulation

Executive Summary

The American Society for Clinical Pathology's (ASCP) Board of Directors issues the following statement outlining a framework for a revised cytology proficiency testing (PT) regulation. This framework provides additional detail for the regulatory changes that ASCP has supported in a variety of forums.

The public, the United States Department of Health and Human Services (HHS) and key members of the United States Congress continue to seek assurance that the cytotechnologists and pathologists who screen or interpret cytological preparations are competent and adequately protect women's health. In order to provide this "public assurance of competence" ASCP will advocate that a revised regulation contain the following elements:

- *Compliance with Individual Cytology PT* -- The responsibility for monitoring the performance of individual cytology PT should be moved to the laboratory director. A high complexity laboratory director, as defined by CLIA, should have the responsibility to ensure that each of the cytotechnologists and pathologists who screen or interpret cytological preparations pass individual cytology PT testing. This transfer of authority to the laboratory director is consistent with the current regulations for the Clinical Laboratory Improvement Amendments (CLIA).
- *Less Frequent Testing Intervals* -- Adoption of a revised regulation with less frequent testing interval requirements (3-5 years). After passage of an initial PT requirement, practitioners should be required to participate in annual educational proficiency assessments in the off years.
- *A Revised Grading System* -- Adoption of a uniform grading scale would assure fairness for all participants.

ASCP is a 501(c)(3) not-for-profit public foundation committed to working with the cytopathology community, lawmakers and regulators to implement a modernized regulation that is fair to the public and to the cytotechnologists and pathologists who screen or interpret cytological preparations.

Framework for a Revised PT Regulation

This document represents the sum of previously issued ASCP statements including: presentations at the Clinical Laboratory Improvement Advisory Committee (CLIAC); collaboration with the Cytology Education and Technology Consortium (CETC); an April 2007 presentation to the leaders of the American Society for Cytotechnology; and a March

2007 statement regarding pending legislation that has been introduced in the United States Congress.

Compliance with Individual Cytology PT

ASCP supports a revised cytology proficiency testing regulation that moves the responsibility for monitoring the performance of individual cytology PT to the laboratory director, as designated under the regulations governing the Clinical Laboratory Improvement Amendments (CLIA) Subpart M, Section 493.1443. This change should be reflected in the final rule as adopted through the regulatory steps currently being pursued by the Centers for Medicare and Medicaid Services (CMS) and Centers for Disease Control and Prevention (CDC).

A high complexity laboratory director, as defined by CLIA, should have the responsibility to ensure that each of the cytotechnologists and pathologists who screen or interpret cytological preparations pass individual cytology PT testing. This structure would be in the line with the laboratory director responsibilities outlined in CLIA Subpart M, Section 493.1445 which states:

> "The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations."

Failures would require appropriate remedial education and repeat testing to ensure the effectiveness of the remediation. This would be enforced by the accrediting agencies who would review laboratory PT and quality assurance records during their accreditation visits. The PT test methodology should track closely the guidelines recommended by the Cytology Education and Technology Consortium (CETC) in the document entitled, *Scientific Issues Related to the Cytology Proficiency Testing Regulations*, with an emphasis on education for deficiency. This framework, originally proposed by the CETC, would maintain the concept of individual responsibility.

These recommended changes would reflect existing CLIA regulations (Subpart M, Section 493.1445) and remove monitoring and enforcement of the cytology PT program from the federal government level and transfer these responsibilities to the laboratory director and accrediting agencies.

The CETC document can be accessed at the following URL:
http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=1481513

Less Frequent Testing Intervals

Less frequent assessment than the current annual requirement is appropriate for the well-trained cytology professional assessing cervical cytology slides on a regular basis. The

CETC recommended 5 year intervals as long as there are stipulations that individuals new to practice be assessed. ASCP supports the adoption of a revised regulation with less frequent interval requirements (3-5 years). After passage of an initial PT requirement, practitioners should be required to participate in annual educational proficiency assessments in the off years.

A Revised Grading System

The grading scheme proposed under the rules published in 1992 is based on a clinical triage algorithm in use since the late 1960's. Therefore, to reflect the many scientific developments in the field, ASCP has proposed that a new grading scale that reflects the current clinical triage algorithm. Adoption of a uniform grading scale would assure fairness for all participants.

Public Assurance of Competency

Why is it important to maintain the concept of individual responsibility in a revised regulation or in legislation pending in Congress? The public, the US Department of Health and Human Services and key members of Congress will continue to seek assurance that cytotechnologists and pathologists who screen or interpret cytological preparations are competent and adequately protecting women's health. An assurance of individual responsibility can be accomplished through the adoption of a regulation that implements this framework to move the responsibility monitoring for individual cytology PT performance to the high complexity laboratory director, as defined by CLIA.

Role of Federal Legislation in Revising Cytology PT Regulations

In 2005, ASCP supported HR 4268 at the request of College of American Pathologists (CAP). This bill later became HR 4568, which passed the House of Representatives in the 109th Congress. Passage of this legislation, with ASCP's support, had the effect of motivating government regulators to take action to revise the currently flawed regulations; an ongoing process. ASCP has consistently urged that the federal government implement an expedited regulatory process to revise the cytology PT regulations, yet progress is slow.

In the 110th Congress, ASCP supports the underlying motivation of HR 1237, the Cytology Proficiency Improvement Act of 2007 which is to revise the cytology PT regulations. However, ASCP has concerns about elements of the legislation as well as the unintended consequences of CAP's proposal to use the legislation to model a replacement regulation after the Mammography Quality Standards Act (MQSA). If HR 1237 were to become law, HHS would still be tasked with drafting a new regulation. A new regulation, based on the current version of HR 1237, could be like the current regulation, three pages long, or substantially longer (the current MQSA regulation exceeds 75 pages). The MQSA regulations can be found at the following URL: http://www.fda.gov/cdrh/mammography/frmamcom2.html.

Given the uncertainty of the legislative process it is the considered opinion of ASCP that revision of the current regulation could still achieve the desired outcome for all involved, especially if the framework suggested above is implemented. However, should HR 1237, or a variation of the legislation, move forward in the 110th Congress, ASCP is dedicated to working with the cytopathology community, lawmakers and regulators to implement an approach that maintains the high standards that are demanded by the public and our profession.

ASCP's Role as a Non-Profit

It is important to emphasize that ASCP is a 501(c)(3) not-for-profit public foundation, organized for scientific, educational and charitable purposes. In order to qualify as a 501(c)(3), ASCP is required to operate under a number of organizational rules and operational principles, focusing on the public good. A 501(c)(3) is permitted under this designation to have a certain level of advocacy that meets Internal Revenue Service guidelines. Non-profits also must provide *nonpartisan* analysis that is available to the general public. Under this designation, ASCP is not allowed to form a Political Action Committee (PAC) or contribute to the political campaigns of politicians. ASCP is proud of its role as a 501(c)(3) dedicated to patient safety, public health and the practice of pathology.

Trade associations and professional organizations, such as CAP, are organized as a 501(c)(6), and are considered business leagues and operate under different rules. The primary purpose of these entities is to promote the common business interests of their members. These entities are also allowed to establish a PAC that makes campaign contributions to legislators and candidates.

Both types of organizations play important but different roles in advocating on behalf of a profession.

Next Steps

ASCP is committed to working with the cytopathology community, lawmakers and regulators to implement a revised cytology PT regulation, whether through regulatory or legislative channels. To accomplish this goal ASCP will take the following steps:

- Communicate with HHS about the urgent need to expedite the rule-making process to revise the current regulation.
- Communicate the ASCP position to the regulators at CMS and CDC and the CLIAC.
- Disseminate ASCP position to our membership via e-Policy, a post to the American Society for Cytopathology list serve and other mechanisms.

- Disseminate the ASCP framework to leaders of pathology and cytology organizations.

- Communicate the ASCP framework to key leaders on Capitol Hill.