AMERICAN SOCIETY FOR
CYTOTECHNOLOGY

March 15, 2009

Department of Health & Human Services
Centers for Medicare & Medicaid Services
7500 Security Boulevard,
Baltimore, MD 21244–1850

On behalf of the American Society for Cytotechnology, I am pleased to submit our organizational response to the "Proposals to Improve Cytology Proficiency Testing Required by the Clinical Laboratory Improvement Amendments of 1988."

The ASCT has a strong history of representing our members' position on legislative and regulatory issues, and now is no exception. The attached document is a summary of the ASCT membership response to this NPRM. This response was gathered using a web-based survey sponsored by the ASCT. The survey results and corresponding comments are organized by the categories listed in the NPRM.

The ASCT appreciates the opportunity to comment on this NPRM. We thank the CMS and the CDC for the careful consideration of this document during deliberations on the final rule. We believe that these comments will provide a strong foundation for that process. Please do not hesitate to contact me should you wish to discuss this response with us as we await the final rule.

Respectfully,

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American Society for Cytotechnology
Membership Survey based on
NPRM January 16, 2009

Submitted March 16, 2009

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On behalf of the American Society for Cytotechnology (ASCT), representing cytotechnologists, we respectfully request that the Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC) consider our comments and suggestions for improvements in the existing Cytology Proficiency Testing (PT) program.

Following the publication of the Notice of Proposed Rule Making, January 16, 2009, ASCT developed an on-line survey directly addressing the key issues for which Center for Medicare Services (CMS) requested input. The survey closed Feb 13, with 315 participants. 66% of the participants are ASCT members and 34% are non members. The *membership* (66%) responders are represented in this statement. Although there are no significant differences, a separate document will be submitted with the results of all 315 participants.

Proficiency Testing is but one component of a strong regulatory environment to ensure high quality testing and patient safety in gynecologic cytology. Other components are established and are fully operational and well documented in most cytology laboratories.

<u>As a Cytotechnologist organization, we agree that some of the current PT regulations could be retained:</u>

- That it is the responsibility of the laboratory to ensure that each individual examining cytology preparations is enrolled in an approved program. Emphasis here is twofold- that it remain the laboratory's responsibility AND that testing be for each individual cytotechnologist AND pathologist evaluating cytologic preparations.
- That it is the responsibility of the laboratory to ensure that individuals successfully participate or that individuals who fail a test are retested within the required timeframes.
- That it is the responsibility of the laboratory to take appropriate remedial actions for individuals failing a test event.
- That the testing of non-screening technical supervisors be on test sets that have been prescreened.
- That the program content be on glass slide test sets. Options should be made available however, to those trained in newer technologies or those requesting on-line testing events should they become available.
- That the language within the regulation refer specifically to gynecologic testing, thus excluding non-gynecologic specimens from proficiency testing.

<u>Seventy-five percent or more of our members felt very strongly about the following issues in the current Proposed Rule:</u>

Cytology Challenges and New Technology:

- CMS should include criteria for pilot testing before any new cytology testing media is approved by CMS.
- Pilot testing will most likely increase the cost of cytology PT.
- Enrollment and participation in an educational program should be required for all cytology laboratories.

Frequency of Testing:

- A longer testing interval of 3-5 years was requested by many.

Number of Challenges:

- Ten cytology challenges per test are appropriate to test individual performance.
- There will definitely be logistical concerns and additional costs associated with administering a proficiency test event with more than 20 cytology challenges. The most significant impact on laboratory operations will be a delay in patient testing if the proficiency test requires 20 challenges and 4-hour timeframe for administration. It will also create more stress for laboratory personnel and will require extending the number of testing days in order to accommodate laboratory operations.
- Laboratories would prefer a 2-hour rather than a 4-hour testing period.
- There should be at least one cytology challenge from each of the four response categories, as is currently required.
- Increasing the number of challenges will most likely increase the PT program's cost to administer the program.
- CMS should use analysis of the answer distance from the target answer to determine the statistical power of cytology PT with 20 challenges and a multinomial, weighted scoring system.

Response Categories:

- CMS should include defined criteria in the regulations for "unsatisfactory" challenges.
- CMS should include defined criteria for "unsatisfactory" challenges for all preparation types.
- CMS should NOT add a fifth response category but should keep the current four response categories.

Cytology Challenge Referencing:

- CMS should require the three physicians certified in anatomic pathology to <u>independently</u> determine the response category for each cytology challenge.
- CMS should require all PT programs to include cytotechnologists in the review process for referencing cytology challenges.
- CMS should require that there be biopsy confirmation of LSIL (Category C) cytology challenges for PT, as is currently required.

Validation of Cytology Challenges:

- The regulations should absolutely require field validation for each cytology challenge before it is included in the test set.
- The regulations should also include specific criteria for initial field validation.
- CMS should require continuous monitoring of each cytology challenge and this requirement should be specified in the regulations. The criteria should be slide performance, slide quality and the number of appeals for that slide.
- It is most likely that these validation requirements will result in additional costs.

Scoring Scheme:

- The scoring scheme should be more stringent for pathologists than cytotechnologists based on their level of responsibility, similar to the current scoring scheme. Pathologists should be scored more stringently for "missing" LSIL & HSIL since they make the final interpretation. Having the same scoring scheme for cytotechnologists and pathologists would not meet the requirement of evaluating workplace performance, since the responsibilities in the workplace are quite different for CT and MD. The CT must locate and refer abnormalities and the pathologists must make the final interpretation. With or

without change, however, the existing PT does not reflect actual workplace performance. Some of our members suggested that CT's have three categories – Unsatisfactory, NILM, and Refer to Pathologist. These categories with the answer sheet and dotted slides go to the pathologist for final interpretation. This would be more representative of the level of responsibility in the workplace.

Retesting and Remediation:

- CMS should require that all testing be conducted in the laboratory.
- There should be two or three retesting events.

Appeals Process:

- The criteria for appeals should include, field validation results, quality of preparation, representation of the lesion, a time period for appeal, and an adjudication panel including MD's and Cytotechnologists.

Proctors:

- There was no strong consensus within the ASCT membership regarding proctors. Please see attached survey results.

General Comments:

- Many did not feel the Proposed Rule offered any improvements to the current regulatory structure.

Following are specific questions with member response data. Comments pertinent to *regulatory* change are also included.

Cytology Challenges and New Technology
Is this proposed definition for "cytology challenge" appropriate to address future technological advances? **64% Yes**
Should criteria be included in the regulations for pilot testing before CMS approval of any new *cytology testing media?* **84% Yes**
If specific criteria for pilot testing are required, what burden would be incurred by PT programs and laboratories participating in a pilot test? (Multiple responses were possible) **Financial burden was cited most frequently 73%,** Risk of failure 48% and legal risk 46%.
Would requiring pilot testing cause an increase in the cost of cytology PT? **84% Yes**
Should enrollment and participation in an educational program be required for all cytology laboratories? **80% Yes**
Should enrollment be required, how would this enrollment be monitored by CMS? (Multiple responses were possible) **Direct individual submission to CMS 35%, Accreditation Agency 35%,** responsibility of Technical Supervisor 23%, the ASCP CMP 14%, Direct individual submission to PT Provider 12%
If enrollment and participation in educational programs were to be required, what criteria would be appropriate for CMS to adopt through rulemaking to evaluate these programs? The criteria should NOT be stipulated in the regulations. It should be provided to CMS by the providers of the educational program and reported to CMS through the provider (perhaps attached to the PT identifier) Continuing Education must be relevant to Cytology, offered by a laboratory professional organization or approved by such organization. The ASCP CMP was mentioned repeatedly as a good model program. Proof of enrollment and submission of credits at intervals. 30 hours in 3 years would be reasonable.

If enrollment and participation in educational programs were to be required, how might CMS monitor or evaluate an individual's participation in such a program? **Accreditation agency 36%,** Technical supervisor responsibility 31%, 22% PT provider and 19% monitored by individuals directly submitting credits to CMS
If educational programs were required, what enforcement actions might be appropriate for laboratories if laboratories/individuals did not participate in the required programs? **50% noted that an approved plan of correction be required**, 46% lab accreditation agency sanctions (these were not specified), 21% financial penalty to lab, 16% withhold PT results, and 8% loss of job.
Frequency of Testing
How many cytology challenges per test event are appropriate to assess individual performance? **76% preferred 10** followed by 21% at 20 slides.
Should annual testing continue to be required with 10 slides per test? **66% No**
Is 2 years an appropriate testing interval using 20 slides per test? **62% No**
Why would a testing frequency longer than every 2 years be appropriate? Many requested a 3 year interval citing less financial burden to laboratory and less cytotechnologists' stress. In addition, evidence is lacking that skills degrade over time.
What type of data should be collected to determine if a longer interval between testing is appropriate? How long should the data be collected? The current testing interval is largely arbitrary and there is no "evidence/data' to support this interval. CMS has given specific proficiency testing ID's, individuals have now tested for 2, 3, 4, years. Perhaps a pilot group could be constructed from those already tested and monitored going forward. Some of the group could have longer testing intervals, monitor pass rates.
Who should collect the data? **32% CMS,** 30% Laboratory, 26% PT providers.
What types of data are needed to validate testing less frequent than annually? There is no proven way to validate this. Comparison of testing data year to year would be the best method. Since annual testing is not validated and there is no method that less than annual would be any more amenable to validation. Is there evidence to show that annual testing has improved patient safety?
Number of Challenges
Are there logistical concerns and costs associated with administering testing events with more than 20 cytology challenges? **93% Yes**
If 20 cytology challenges are used, thereby requiring a 4 hour timeframe to administer the test, what would be the impact on the laboratory operation? (Multiple responses were possible) **91% delayed patient testing**, 82% employee stress, 81% extending testing days to meet daily operations, 67% cited increased staffing costs.
Would laboratories prefer a 4 hour testing timeframe biennially, rather than the current 2 hour testing timeframe annually? **75% No**
Should there be a requirement for each test set to contain at least one cytology challenge from each of the four response categories? **86% Yes**
Should there be a requirement for each test set to contain more than one cytology challenge from each response category? **68% No**
Are there a sufficient number of referenced cytology challenges available to assemble 20 cytology challenge test sets to test all cytology personnel nationally? Assumption is that the test would be administered to half the workforce one year and half the following year. **60% No**
Would increasing the number of cytology challenges increase the PT program's cost to administer the program? **75% Yes**
Would program costs to participants increase from a 10 slide annual test to a 20 cytology

challenge biennial test? **73% Yes**
What statistical methods and testing research could CMS use to better determine the statistical power of a cytology proficiency test with 20 challenges and a multinomial, weighted scoring scheme? (Multiple responses were possible) **79% selected analysis of the answer distance from the target answer**, 65% experience levels of participants, 59% location of targets within test set
Response Categories
Should criteria be defined in the regulation for "unsatisfactory" cytology challenges? **90% Yes**
If criteria for "unsatisfactory" are described, would the regulations include descriptions or criteria specific to each preparation type? **93% Yes**
Should a fifth response category be required, separating HSIL or cancer (Category D) to more closely follow Bethesda terminology? We note that Bethesda 2001 separates LSIL (Category C) from HSIL (Category D), and separates HSIL from cancer, also (Category D). **79% No**
If a fifth category of cancer is required, should an individual who has an incorrect response in this category be allowed to pass PT? **71% Yes**
Cytology Challenge Referencing
Should the review of cytology challenges by three physicians certified in anatomic pathology be on undotted slides? **68% Yes**
Should the three physicians certified in anatomic pathology independently determine the response category for each cytology challenge? **89% Yes**
Should PT programs be required to include cytotechnologists in the review process for referencing cytology challenges? **96% Yes.** Of those responding yes, the process for including CT was; **80% include pathologists and Cytotechnologists**, 77% supervisory Cytotechnologists and pathologists, 43% Cytotechnology educators and 31% any Cytotechnologists could be included.
Should the requirement for biopsy confirmation of LSIL (Category C) cytology challenges for PT be retained? **86%Yes**
How many pathologists' diagnoses should be required for biopsy confirmation of these PT samples? **48%-3,** 33%-2,14%-5, 4%-1
Validation of Cytology Challenges
Should the regulations include a requirement for field validation of each cytology challenge before inclusion in a test set? **96% Yes**
Should criteria for this initial field validation be stated in the regulations? ***95% Yes*** *Of those responding yes the definition of criteria were;* **PT Targeted categories (A (Unsat), B (NILM), C (LSIL), D (HSIL/CA) 71%** and Bethesda criteria 26%.
Should continuous monitoring of each cytology challenge be required? **92% Yes**
Should continuous monitoring criteria be specified in the regulations? **91% Yes**. Of those responding Yes, the required criteria should be (from multiple possible responses); **Slide performance 93%,** Slide quality 92%, Number of appeals for that slide 86%.
Will the requirement for continuous field validation add any additional costs? **84% Yes**
Scoring Scheme
Should the automatic failure for misdiagnosing an HSIL or cancer (Category D) as a Normal or Benign Change (Category B) be retained for pathologists and Cytotechnologists? **69% Yes**
Should pathologists and cytotechnologists be evaluated using the same scoring scheme? **66% No**
If you answered no to the above question, how should the scoring grid be composed? **96% more stringent for Path**

Should the cytotechnologist's scoring scheme be more stringent than the current regulations? **96% No**
How would the same scoring scheme meet the statutory requirement for evaluating workplace performance of both cytotechnologists and pathologists with respect to their responsibilities in reviewing cytology preparations? The same scoring scheme would not meet the requirement of evaluating workplace performance, since the responsibilities in the workplace are quite different for CT and MD. The CT must locate and refer abnormalities and the Pathologists must make the final interpretation. With or without change, however, the existing PT does not reflect actual workplace performance. Several suggested that CT's have three categories- Unsat, NILM, Refer to Pathologist. These categories with the answer sheet and dotted slides go to the pathologist for final interpretation.
Retesting and Remediation
Should the PT programs provide more specific information concerning incorrect responses to the laboratory and individual to improve the testing process? **70% Yes**
Should all testing be conducted in the laboratory? **90% Yes**
Should some testing be conducted at the location of the PT program? **72% No**
How many times should an individual be permitted to take a retest? **Two and three retesting events were cited with equal frequency.**
Appeals Process
What criteria should be included in an appeals process? The following criteria were selected; **field validation results 89%,** time frame for appeal (77%), quality of preparation 86%, **representation of the lesion 87%,** and 75% adjudication panel including MDs and cytotechnologists.
Should PT programs be required to provide participants with a description of their appeals process? **98% Yes**
When should a description of the appeals process be shared with the participants? **Most 64% preferred before the provider was selected**, 19% after a failure, 15% at the time of testing event.
Proctors
What specific criteria should there be for selection of the proctor? (Multiple responses possible.) **53% selected CT and MD only**, 36% selected other lab professionals and 42% lab administrators. In the 17-20% range residents and prep staff were also mentioned.
How often should proctor training and testing be required? **Prior to test was most frequent response 36%,** 28% said only if procedures change.
What penalties should be applied to laboratories and individuals when testing is not conducted according to requirements? **32% laboratory should sanction individuals who do not follow requirements**, 20% require pay for outside proctor, 19% all in lab must retest as a second event, 19% CMS sanctions.

The ASCT appreciates the opportunity to represent its membership in regards to the proposed rule in Proficiency Testing and respectfully submits these comments to CMS. In addition to the membership survey from which this response was compiled, members were provided a tool for individual responses, which were encouraged.