

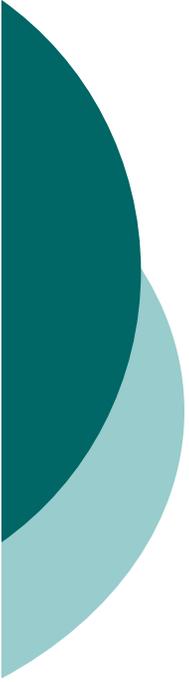


CLIAC Discussion of Work Group Report Cytology Proficiency Testing



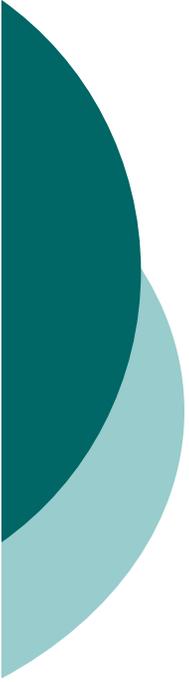
Individual vs. Laboratory Regulatory Options

- No change unless Congress changes the Law
 - *Use the preamble to encourage laboratories to participate in educational laboratory programs in addition to individual proficiency testing*
 - *Use guidelines to state that lack of participation in a laboratory program should be a flag to inspectors*



Individual vs. Laboratory Issues to Consider

- Is it necessary to participate in an annual laboratory educational program in addition to PT?
 - Added cost
 - Added benefits –
 - Program can validate challenges through educational programs
 - Participants lose familiarity of testing process



New Technology Regulatory Options

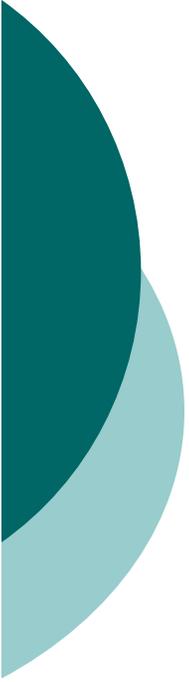
- Change current language of “slides” to “challenges” to allow for the use of virtual slides
- Define a challenge as a case equivalent – glass slide, virtual slide, or other approved media
- Add requirement for a transition phase for all new technology, when the individual can request retesting with glass



New Technology

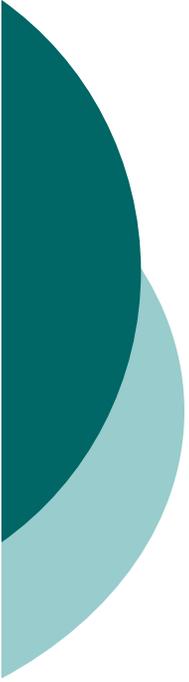
Regulatory Options, continued

- *Use flexible language that allows programs to adapt new technology to reflect actual practice*
- *Encourage developing tests that include new technology to simulate testing with a ThinPrep Imaging System or Location Guided Screening*



New Technology Issues to Consider

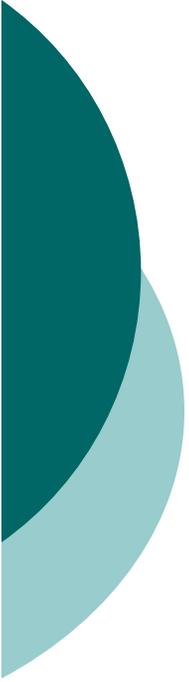
- How do we encourage inclusion of new technology by PT programs?
- How can the regulations be drafted to accommodate technology not yet available? (i.e., be flexible enough so that regulatory revisions are not needed as the technology evolves).



Frequency of Testing Regulatory Options

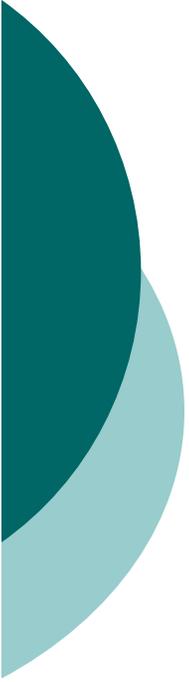
- Reduce the frequency of testing
 - Options:
 - 2-year test cycle
 - 3-year test cycle
 - >3-year test cycle

Decision is needed



Frequency of Testing Issues to Consider

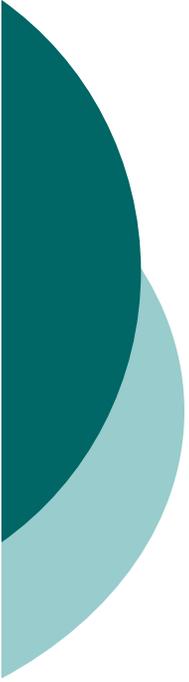
- Is it in the interest of Public Health to increase the interval between tests?
- If the time interval is too long, will participants have “first test experience” each time (i.e., lose familiarity)?
- How would you measure that increased intervals between testing cycles do not affect “quality of testing”?



Number of Challenges Regulatory Options

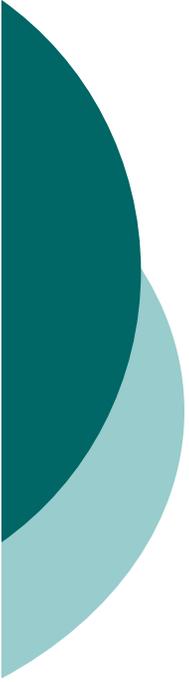
- Change the language to include 20 challenges for initial tests and retests with four hours allowed for each test
- Leave language of 10 challenges

Decision is needed



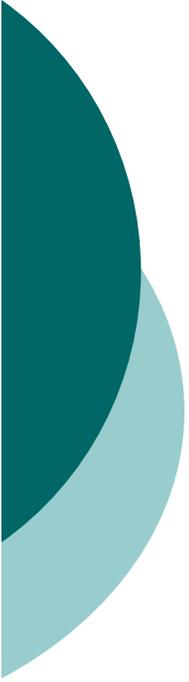
Number of Challenges Issues to Consider

- If the interval between testing cycles is increased, should the number of challenges per set be increased?
- Increasing the number of challenges is proportionate to the time required to take the test. Is there added benefit to increasing the number of challenges?



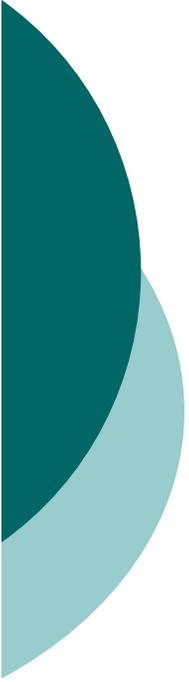
Categories of Challenges Regulatory Options

- No change in the four categories
 - Unsatisfactory
 - Negative
 - LSIL
 - HSIL (includes cancer)



Categories of Challenges Issues to Consider

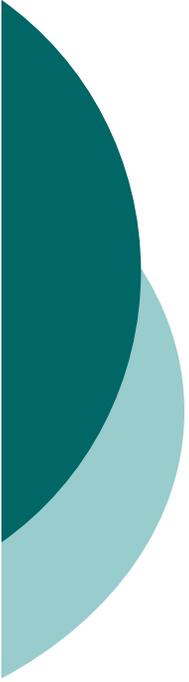
- Should the categories be consistent with clinical treatment options



Number of Challenges/Category Regulatory Options

- No change if 20 challenges per test
- Change language if 10 challenges are kept in place to include
 - At least 1 HSIL and 1 Negative in all test sets
 - At least 1 LSIL and 1 Unsatisfactory in 50% of the test sets

Decision is needed



Number of Challenges/Category Issues to Consider

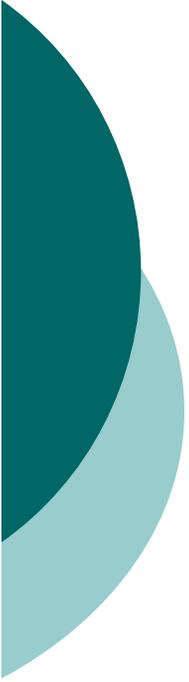
- What criteria (# slides/category) are needed to ensure slides sets are of comparable difficulty and composition?



Grading Scheme Regulatory Options

- Change scoring grid to remove automatic failure (-5 points for calling a HSIL slide negative)
- Change scoring grid to “0” points for a correct response of LSIL called unsatisfactory
- If another grading scheme model is selected change language

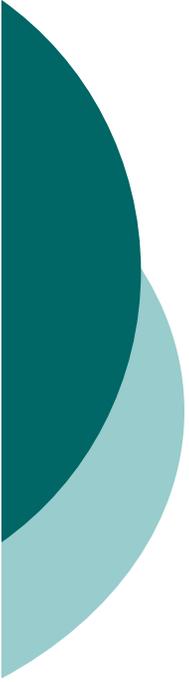
Decision needed



Grading Scheme

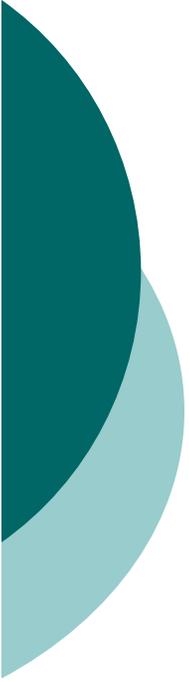
Issues to Consider

- Does the grading scheme reflect decision points in “normal laboratory working conditions”?
- Should pathologists be scored differently from cytotechnologists?
- Should a false negative carry deduct more points than a false a positive?



Validation Regulatory Options

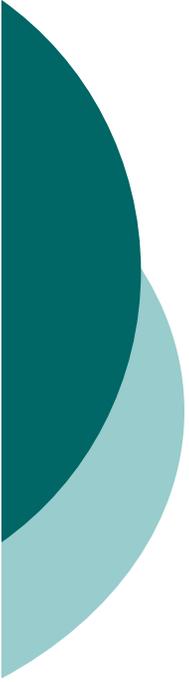
- Add requirement to include field validation of challenges in addition to referencing by 3 pathologist
- Add requirement for PT providers to disclose what validation process is used
- Delete language for biopsy confirmation of LSIL (leave HSIL biopsy confirmation)



Validation

Issues to Consider

- How can the subjective nature of cytologic interpretation be taken into account in validating test material?
- What number of pathologists/cytotechnologists must agree on a slide to yield statistical accuracy?

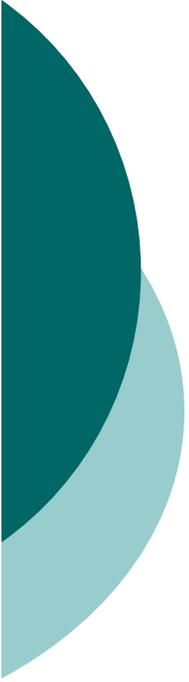


Testing Site Regulatory Options

[Allow off-site testing]

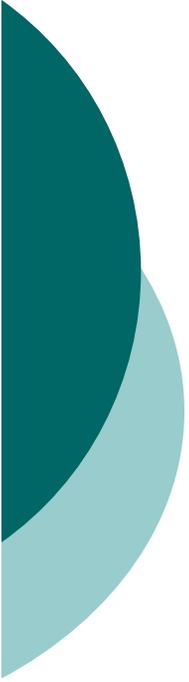
[Allow laboratories to designate a proctor]

- *Law states on-site testing, however, the PT provider can determine alternate test site for retesting– the preamble could be used to encourage more options for test sites*
- *The PT provider determines the proctor requirements*



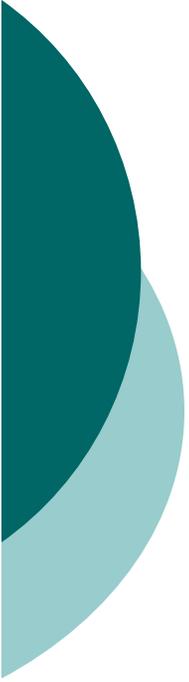
Testing Site Issues to Consider

- What are the advantages/disadvantages of other testing venues, i.e., mailed glass slide programs, computer-based testing? How much of the test needs to be administered on-site to meet the statute?
- With on-site testing, should the examination be proctored? How would you do this?
- What are the advantages/disadvantages of testing off-site?
- Does the test being administered on-site minimize disruption in laboratory operation?



Retesting/Remediation Regulatory Options

- Add requirement for PT providers to disclose the appeal process in writing
- Change language to state individuals who scores < 90% must... (as opposed to "who fail")
- *Individuals are currently required to pass one testing cycle before switching PT providers*



Retesting\Remediation Issues to Consider

- What are the advantages/disadvantages of other testing venues, i.e., mailed glass slide programs, computer-based testing? How much of the test needs to be administered on-site to meet the statute?
- With on-site testing, should the examination be proctored? How would you do this?
- What are the advantages/disadvantages of testing off-site?
- Does the test being administered on-site minimize disruption in laboratory operation?