Process for Revising Regulations for Cytology Proficiency Testing

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CLIAC Meeting
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Process Overview

- Focus is on developing regulation - not on changing the statute
- Must go through the rulemaking process
- Solicit comments
  - ✓ Cytology organizations
  - ✓ CLIA-approved PT programs
- Create a CLIAC workgroup
  - ✓ Consider the comments
  - ✓ Report findings to CLIAC
- CLIAC makes recommendations to HHS
- CDC/CMS develop proposed rule

Solicitation of Comments

Appropriate input from organizations/PT programs should result in a proposed rule that

- Addresses organizations'/programs' concerns
- Includes impact analysis with accurate cost/benefit projections
- Has expedited timeline for development

Statutory Requirement
Proficiency Testing-General

- Program must be offered by a private, nonprofit organization/State
- HHS must approve each program annually
- HHS must make test results available, include explanatory information for result interpretation
- Testing shall be conducted on a quarterly basis, except where HHS determines that a particular examination/procedure may be tested less frequently (but not less often than twice a year)

Statutory Requirements Cytology PT

Standards shall include

- Periodic confirmation and evaluation of the proficiency of individuals involved in screening or interpreting cytological preparations
- Announced and unannounced on-site proficiency testing
- Testing to take place, to the extent practicable, under normal working conditions

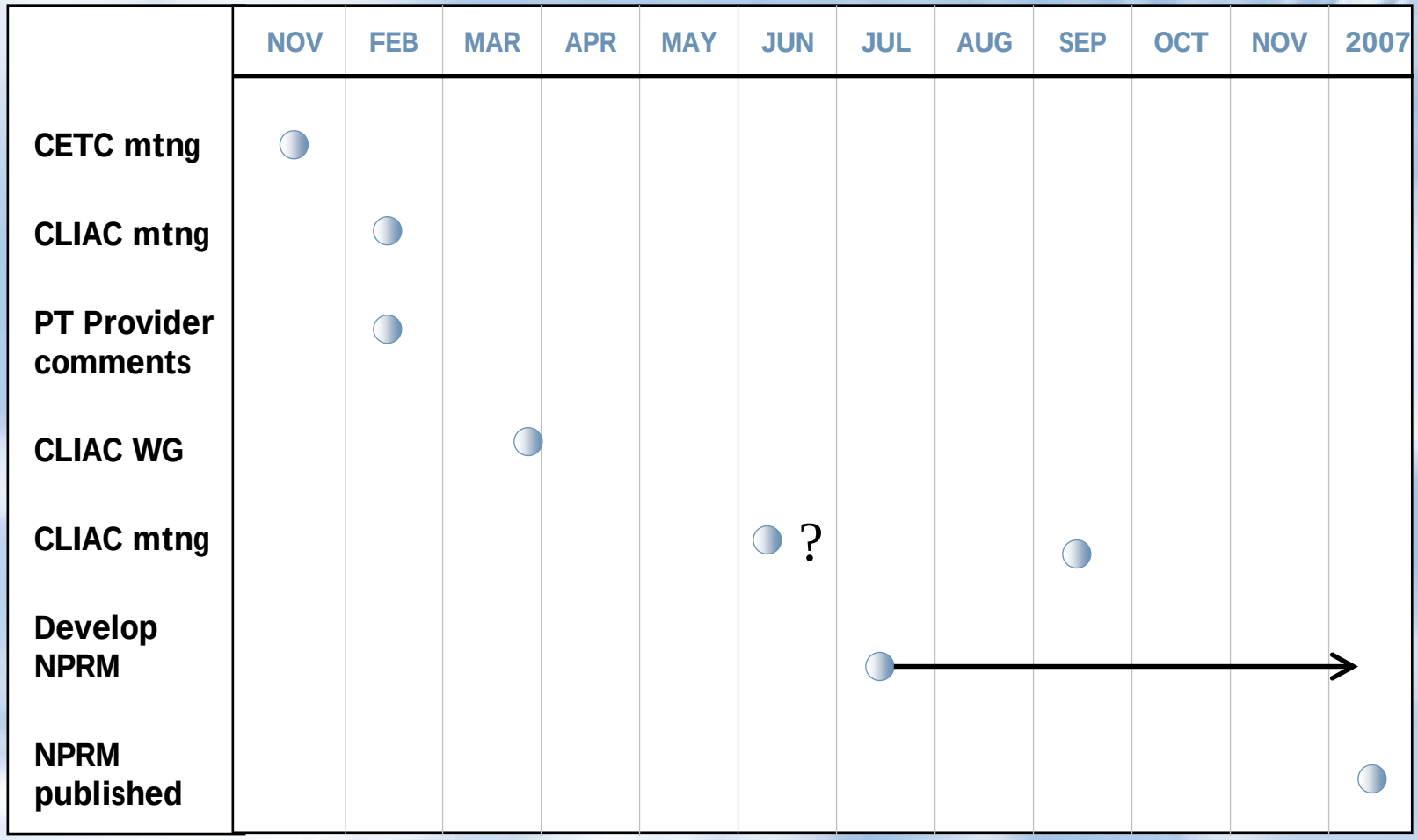
Statutory Requirements-Summary

- PT must be provided by a private, nonprofit organization
- Programs must be approved annually
- Test results must be available to the public
- Test individuals
- Announced and unannounced testing
- On-site testing
- To the extent practicable, test under normal working conditions
- Specifications for frequency of testing inconsistent

Proposed Rule

- Publication in the Federal Register
- Solicits public comment
- Includes comment period, generally 60 days
- Components of proposed rule
  - Preamble
  - Proposed requirements

Timeline for Revising Cytology PT Regulation



Following Publication of Proposed Rule

- Evaluate, respond to public comments
- Develop final rule
  - Preamble
    - Background, actions taken to develop final rule
    - Describe changes from proposed requirements
    - Complete impact analysis
  - Regulation
  - Effective date
- Usually takes 2-3 years

Meeting Dates

- CLIAC Workgroup – March 28-29, Atlanta
- CLIAC – potential dates:
  - May 31, June 1 (Wed, Thu)
  - June 13, 14, 15, 16 (Tue, Wed, Thu, Fri)
  - June 20, 21, 22, 23 (Tue, Wed, Thu, Fri)