CLI A
Quality Control Requirements
Present and Future

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Background
The Secretary shall issue standards to assure consistent performance by laboratories... Such standards shall require each laboratory... to maintain a quality assurance and quality control program adequate and appropriate for the validity and reliability of the laboratory examinations and other procedures of the laboratory ...
1992 CLIA Regulations

- Based standards on test complexity
- Regardless of test complexity, specified laboratory director responsibility for quality testing, QC procedures
- Through phase-in QC provisions, allowed previously unregulated laboratories time to become familiar with requirements
- Defined minimum QC requirements
- QC requirements divided into
  - General
  - Specialty/subspecialty
2003 CLIA Regulations

- Responded to public comments, CLIAC recommendations
- Ended phase-in QC requirements
- Created one set of non-waived requirements
- Re-formatted requirements to parallel specimen flow through laboratory
- Incorporated quality system concept throughout testing process (new subpart-Quality System)
- Maintained director responsibility for QC, with clarification that environment (including patient population), test system and personnel must be considered
2003 CLIA Regulations

• Control procedures must
  ❖ Detect immediate errors due to
    o Test system failure
    o Adverse environmental conditions
    o Operator performance
  ❖ Monitor over time accuracy/precision of test performance influenced by changes in
    o Test system performance
    o Environmental conditions
    o Operator variance
Appendix C
Interpretive Guidelines

• Procedures specified in guidelines to:
  - Address new technology
  - Provide flexibility
  - Accommodate stable test systems, test systems with built in QC through alternative QC mechanisms (Equivalent Quality control (EQC))
Dilemma

ALL TEST SYSTEMS, LABORATORIES (TESTING CONDITIONS) ARE NOT THE SAME
QC Requirements - General

• Applicable to diverse test systems/evolving technologies, but
  ❖ Cannot specifically address individual test systems/methodologies
  ❖ Do not provide framework for diversity
• May not always be practical/appropriate
• Sometimes difficult to implement
• QC materials may not be available
• Inconsistency in application to similar test systems in different specialties
Specialty/subspecialty QC

- Laboratory specialties/subspecialties no longer distinct/clear-cut
- A single instrument may include tests for
  - Coagulation/Chemistry
  - Blood gases/Chemistry/Microbiology
  - Molecular testing/Chemistry/Microbiology
  - Cytology/Chemistry
Problematic Test Systems

- Unitized test systems
- Test systems that incorporate multiple components or reactions
  - Immunohematology antibody screening panels
  - Allergen-specific IgE tests
  - Genetic testing micro-arrays
  - Microbiology identification systems
Need For Uniform Process

- QC exceptions currently addressed by methodology/reagents with data collection/evaluation strategies
- Data collection may not be feasible for rapidly expanding new technologies
- Uniform approach/process needed to
  - Determine applicability of QC requirements
  - Assist laboratories in reasonably/appropriately complying with CLIA requirements
Challenge

DEVELOP A PROCESS FOR DETERMINING APPROPRIATE QC AMONG ALL LABORATORIES/TESTING CONDITIONS
Built-in/ Internal QC

• Overall QC scheme would need to consider if
  - Test system has built-in or inherent QC checks (electronic QC, procedural QC)
  - Test system has other checks/balances in the testing process or is part of testing algorithm, etc.
Manufacturers’ Instructions

- Manufacturers’ instructions should identify components monitored/checked by built-in QC but instructions for some test systems
  - Provide insufficient information
  - Are ambiguous
- Currently, QC information is
  - Not explicit or conflicting
  - Located throughout product literature
Risk Analysis

Would focusing only on vulnerable areas of testing (using risk analysis) be sufficient in determining appropriate QC?
Evidence-based Data

• Would studies need to be conducted to collect performance data?
  - Manufacturer’s responsibility - help provide initial data
  - Laboratory’s responsibility – long term data collection

• Could a data template be developed?
  - Would need to describe all testing variables
    - Test system sources of error
    - Operator’s skills and training
    - Environmental conditions
    - Patient population
Responsibility for Data Evaluation

- Who would complete the template?
- Who would review and evaluate the template data?
- Could these responsibilities be shared by
  - Industry
  - Laboratory/professional organizations
  - Government
  - Partnership (industry/laboratory community/government)?
COULD A NETWORK OF LABORATORIES USING SPECIFIC TEST SYSTEMS COLLECT DATA NEEDED FOR THE EVALUATION OF QC ALTERNATIVES?
Regulatory Devices

• Traditional QC and alternative QC schemes would need to coexist
  ❖ CLIA applies to all laboratory testing sites
  ❖ CLIA needs to accommodate existing and diverse technologies, as well as evolving methodologies
  ❖ New rulemaking unlikely
QC Materials/ Mechanisms

- What type of controls would need to be used?
  - Electronic/built-in checks/procedural
  - Liquid
  - Other
QC Frequency

• At what frequency should these controls be tested?
• If other processes are employed, would traditional controls need to be tested at any interval? At what frequency?
Data Evaluation

If network QC data are collected

• What would be the mechanism used?
• Who would have responsibility for collecting and evaluating the data?