



CLIA

Quality Control Requirements Present and Future

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Background



CLIA Law

“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

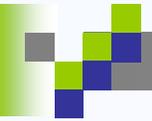


Challenge

**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

A decorative graphic on the left side of the slide, consisting of a grid of small squares in shades of green, blue, and grey, arranged in a pattern that tapers to the right.

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
 - o Test system sources of error
 - o Operator's skills and training
 - o Environmental conditions
 - o 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)?

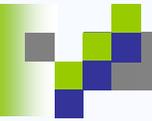


Consideration

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?

