



CLIA Final QC Regulation

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CMS



CLIA Final QC regulation

◆ Background

- Published Final rule with Comment 2/28/92.
 - Effective 9/30/92.
- Includes minimum standards for lab quality.
 - Based on test complexity, not location.
- Contained phase-ins that expired 12/31/02 for-
 - Moderate complexity QC.
 - Ph.D. Lab director board certification.
 - FDA role in CLIA QC.



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◆ Background cont'd.

- 1992 regulations needed to be updated to:
 - Reflect new technologies.
 - Respond to applicable comments.
 - Follow lab workflow/prevent errors.
 - Incorporate Quality Systems concepts.
 - Become more user friendly.
 - Include CLIAC recommendations.
 - Utilize data garnered from 10 yrs. of CLIA.



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Good News!!

- ◆ Final QC reg has 90 day effective date (4/24/03) & one survey cycle (2 yrs.) to--
 - Permit labs to comply.
 - Develop revised surveyor/lab guidelines.
 - Do public education & POL “how to” info.
 - Conduct surveyor training.
 - Review applicable AO standards for equivalency.
- ◆ Contains minimal changes; affects only moderate & high complexity labs.



CLIA Final QC Regulation

Bad News!!

- ◆ No comments solicited.
- ◆ Regulation is final.
- ◆ Not complete; other subparts to follow.



CLIA FINAL QC REGULATION

What's New??

- ◆ Contains mostly existing requirements.
- ◆ Adjusts requirement format to reflect:
 - Pre-Analytical phase;
 - Analytical phase and
 - Post analytical phase.
- ◆ Ends moderate complexity phase-in & eliminates default to high complexity QC for all tests.
- ◆ Legally bridges timeframe from 12/31/02 expiration to new effective date (4/24/03).



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What's New?? cont'd.

- ◆ Combines mod. & high complexity QC into nonwaived test QC.
- ◆ Eliminates FDA role in QC.
- ◆ Closes phase-in for high complexity Ph. D. lab directors; requires board cert. as of 2/24/03.
- ◆ Grandfathers existing high complexity Ph.D. directors.
- ◆ Reduces from 90% to 80% level of consensus for PT providers to grade.
- ◆ Includes changes from comments & CLIAC rec.



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What's new?? Cont'd.

- ◆ Encompasses only QC, QA & PTM.
- ◆ Integrates basic Quality Systems concepts & terminology; e.g., path of workflow.
 - Facilitates error identification & prevention.
 - Intersperses Quality Assessment throughout.
- ◆ Reduces most specialty/subspecialty QC.
 - Primarily Hematology & Microbiology
- ◆ Incorporates coordination with local, state & other federal laws. (NOTE: CLIA won't assess.)

CLIA final qc regulation



SO what does all this mean
for labs??



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Not much for most accredited labs!!



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- ◆ **Moderate & high complexity QC merged.**
 - Validation for new moderate complexity tests.
 - Mfgr. can assist, but lab must consider pt. population & unique environment.
 - Includes accuracy, precision, reportable range & reference intervals.
 - CLIAC recommendation.
 - Flexibility in QC no., type & frequency based on lab's systems; lab director responsible.
 - CMS will provide alternative mechanisms in Surveyor/Lab Guidelines w/ experts' input.



Clia final qc regulation

- ◆ ***New high complexity Ph. D. lab directors must have Board Certification.***
 - Approved boards listed on CMS website are expanded; incorporated into guidelines.
 - Effective **30** days after publication (Feb. 24).
 - Existing doctoral degreed directors are grandfathered permanently.
 - Requirement based on comments to 12/2001 NPRM & CLIAC recommendation.



Clia final qc regulation

- ◆ **Reduced frequency for most specialty QC.**
 - Based on data submitted by professional organization (ASM) &
 - Demonstrates improved technology (Hematology).
 - Decreases QC costs & workload for labs.
 - CLIAC recommendation.



Clia final qc regulation

- ◆ **Review of test systems for certain CLIA QC requirements by FDA.**
 - Favored by manufacturers, but labs had no expectation.
 - Review by FDA redundant since CMS &/or AOs assess QC.
 - Each lab has unique operational aspects.
 - FDA review would be incomplete & entailed >15,000 products.
 - FDA is process oriented; CLIA/CMS is outcome (test results) oriented.



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- ◆ **Re-formatted requirements parallel specimen flow thru the lab.**
 - Provides a more logical approach for labs.
 - Utilizes existing standards for PTM, QC, QA.
 - Creates 2 new subparts:
 - Facility Administration (J)
 - Quality Systems (K).
 - Facilitates error ID, prevention & reduction.
 - Inserts QA into all lab's systems/test phases.



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- ◆ **Facility Administration** includes:
 - Mostly requirements with general applications.
 - Federal, State & local law compliance.
 - Transfusion/FDA–related information.
 - Safety provisions.
 - Record keeping stuff.



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- ◆ **Quality Systems** includes:
 - Overview of Quality Systems & Assessment.
 - Calibration requirements.
 - Test verification standards.
 - Removal of FDA.
 - PT & test accuracy.
 - Test ordering, recording & reporting requirements.
 - Reagent storage & other QC information.
 - Specialty/subspecialty QC, etc.



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Flexibility to use alternative QC mechanisms is the highlight of the new regulation.

- ◆ CLIAC discussed & debated.
- ◆ CMS & CDC convened experts.
- ◆ Technology improved greatly since 1992.
- ◆ CMS learned one-size doesn't fit all.
- ◆ QC is only part of lab's Quality System.
- ◆ To determine a lab's QC mechanisms, the dir. may consider personnel training & competency, environment, pt. pop. & other unique aspects.



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- ◆ CMS will publish QC alternatives in Guidelines on web site with experts' input.
- ◆ Lab director must verify alternative mechanism with data & documentation prior to instituting.
- ◆ CMS won't be approving individual manufacturer's QC, but **each lab's approach**.
- ◆ Labs not using alternatives; reg contains a default.
- ◆ “Internal” QC must monitor entire test process or lab must add monitors to QC program.
 - Testing personnel, analysis & environment.
- ◆ AO's may have individual approaches.



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- ◆ Initially, *only* QC alternatives published in guidelines will be acceptable.
 - Will expand with experience & data.
- ◆ Separate documents to provide non-technical guidance about test verification & QC for smaller labs will also be available.
- ◆ General Final Regulation roll-out information now on CLIA website.



Clia final qc regulation

- ◆ Where to find information:
 - CMS Web site: www.cms.hhs.gov/clia
 - CMS Central Office: 410-786-3531
 - Judy Yost: jyost@cms.hhs.gov



The end!!—or is it
just the
beginning??

Thank you!!

Questions????