CLIA Individualized Quality Control Plan (IQCP)

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CLIA QC Topics

- Background & History of CLIA QC
  - In the beginning…
  - 2003 Quality System Regulations
  - Inception of EQC--2004
- 2005 'QC for the Future' Meeting
  - Partnership w/ CLSI & development of EP-23
- CMS' High Level Implementation Plan for IQCP
  - Education & Transition Period

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Background & History of CLIA QC

- CLIA Law passed—1988
- Final CLIA Regulations published—1992
  - 5 basic QC requirements—mod. complexity
    - All QC actions acceptable—phase in
  - All requirements apply to high complexity
- Many expert meetings convened to no avail
- Quality System Regulations pub.—2003
  - Updated all QC requirements

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2003 Regulations--Inception of EQC

- New provision for alternative QC in CMS' Interpretive Guidelines (IG) in lieu of changing regulations w/ new technology, as long as "equivalent quality testing" is provided- See *42 CFR 493.1250*.
- Default: 2 levels external QC/day of testing

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Inception of EQC

- Equivalent QC or 'EQC' developed in IG as a voluntary alternative QC--2004
  - Option employed depends on the extent internal QC monitors total testing process
  - Minimizes amount of external QC required
  - Helps save costs/resources for labs
  - Acknowledge technological advances
  - Director responsible for choice of QC plan
  - Remaining quality systems must be acceptable

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EQC Follow Up

- Concerns expressed by industry, laboratories, experts, etc.
- Many laboratories adopted EQC successfully & have no quality issues
- CMS reached out to CLSI to facilitate development of an objective consensus QC guideline

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QC for the Future

- CLSI convened the well-attended ‘QC for the Future’ meeting in 2005
- Sponsored by accrediting orgs., industry, professional orgs. & gov’t. agencies
- Outcome:
  - Stakeholder concern that manufacturers don’t provide labs sufficient information
  - ‘One-size-fits-all’ QC doesn’t work w/ new technology

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Designing The "Right QC"

- CLSI meeting directed the development of Evaluation Protocol (EP)-23—Laboratory Quality Control Based on Risk Management
  - Chaired by James Nichols, PhD—Baystate Health
  - Assembled expert group
  - Published October, 2011

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The "Right QC" is IQCP

- CMS will incorporate key EP-23 concepts into CLIA Interpretive Guidelines (IG) as an alternative QC policy called IQCP
- Once effective, IQCP will supersede the current EQC policy
- Existing CLIA QC & quality system concepts won't change
- No regulations will change!
- CMS' survey process won't change

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The "Right QC" is IQCP

- Permits labs to develop an IQCP using many of their existing quality practices/information
- Is based on their patient population, environment, test system, clinical uses, etc.
- Applies to CMS-certified non-waived labs
- IQCP is a choice & default is 2 external QC/day
- Labs must follow mfr's. instructions if > CLIA
- Includes existing & new analytes/test systems

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Education & Transition Period for IQCP

- There'll be an education & transition period for labs before IQCP is fully effective
- Training, info & guidance for surveyors & labs will be provided prior to the effective date
- An electronic mailbox will be available for questions
- Labs should begin to learn about EP-23 & plan their transition before the IQCP policy eff. date

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Education & Transition Period for IQCP

- CMS will notify labs of important dates:
  - Effective date for the IQCP and
  - Date when EQC is no longer acceptable
- Following the effective date, labs must be in compliance w/ their QC choice
- Or deficiencies will be cited

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Education & Transition Period for IQCP

- CMS will solicit accrediting orgs (AO) to determine their interest in IQCP
- Accredited labs should continue to meet their accrediting org.'s QC standards until they receive notice from their AO

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Education & Transition Period for IQCP

- In the interim, CMS certified labs should continue to perform their existing QC procedures; learn about EP-23 & IQCP; begin planning & deciding next steps
- No regulatory citations will be issued until the effective date for the new IQCP
- Unless serious test quality problems are found
- Please stay tuned…..

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Where to Obtain Information

- **CMS/CLIA Web site:**

http://www.cms.gov/clia/

- **CMS CLIA Central office**:

410-786-3531

- **Judy Yost's email:**

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IQCP

THE END!!

Thank You!!!

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