MLN Connects™

National Provider Call

Clinical Laboratory Improvement Amendment CLIA Individualized Quality Control Plan (IQCP) Information & Questions

Staff of
Division of Laboratory Services
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Agenda

IQCP Discussion Topics

- What is IQCP?
- What is the rationale for IQCP?
- Why should I use IQCP?
- When do I implement IQCP?
- What happens during the Education &Transition period? After?
- What other important information must I consider?
- What resources are available?
- Q & As

CLIA IQCP Information & Questions

What is IQCP?

- A voluntary, flexible alternative QC protocol with added value that, if followed, grants compliance with CLIA QC regulations & provides equivalent quality.

CLIA IQCP Information & Questions

What is IQCP?

- IQCP has three parts:
  - Risk Assessment (RA)-identify sources of potential failures/errors
    - Specimen
    - Environment
    - Reagent
    - Test system
    - Testing personnel
  - Quality Control Plan (QCP) –practices & procedures to control test quality
  - Quality Assessment (QA)—ongoing monitoring of effectiveness of IQCP

CLIA IQCP Information & Questions

What is IQCP?

- IQCP includes the entire testing process
  - Pre-analytical—sample collection through storage
  - Analytical—testing process & system
  - Post Analytical—result reporting

CLIA IQCP Information & Questions

What is the rationale for moving to IQCP?

- Changes in healthcare environment & delivery of services
- Advances in technology
- Regulatory 'one-size-fits –all' no longer suitable
- Equivalent Quality Control (EQC) as an alternative was a 1st step; proved too limited & rigid
- Need a flexible program & plan for the future that evaluates the entire testing process

CLIA IQCP Information & Questions

Why should I use IQCP?

- Provides a customizable framework for a unique QC plan for each test
  - Includes specimen, environment, test system, personnel, etc.
  - Uses data & information already available
  - Is broad in scope: considers all phases of test process & specialty requirements
  - RA review & documentation lead to a comprehensive QCP w/ appropriate controls & quality activities
  - Can be used for compliance w/ future technology

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When do I implement IQCP?

- The Education & Transition period for IQCP—
  - **Started: January 1, 2014**
  - **Ends: December 31, 2015**

- IQCP is Voluntary
- Available for all non-waived tests, except Pathology
- IQCP is not EP-23
- Accredited laboratories—talk to your AO

CLIA IQCP Information & Questions

What happens during the Education &Transition period? After?

During:

- Educational CMS surveys--no citations
- Continue existing quality practices and--
- Begin to plan transition for non-waived tests
- Continue development of educational materials

CLIA IQCP Information & Questions

What happens during the Education & Transition period? After?

After:

- Must be in compliance with either—
  - CLIA QC regulations or
  - IQCP

  Or:

  Deficiencies will be cited

CLIA IQCP Information & Questions

What other important information must I consider?

- Test method verification data
- PT performance
- Personnel training & competency
- QC corrective actions
- Instrument maintenance records
- Always follow manufacturer's instructions!

CLIA IQCP Information & Questions

What Resources Are Available?

- ✓ Send questions to IQCP Mail Box:

IQCP@cms.hhs.gov

- ✓ CLIA & IQCP Interpretive Guidelines, Letters & Brochures on CMS CLIA web site:

www.cms.hhs.gov/clia/

Question and Answer Session

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