The Individualized Quality Control Plan (IQCP) as a CLIA QC Option

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Overview of Presentation

- How did the Individualized Quality Control Plan (IQCP) approach evolve as a voluntary option under CLIA?
- What laboratories or tests are eligible for IQCP?
- What is required as part of an IQCP?
- Is IQCP approved for use in accredited laboratories or exempt states?
- What resources can help laboratories develop and implement an IQCP?

CLIA Quality Control Milestones…

1992: Final CLIA Regulations published:
Follow manufacturer requirements

Concerns from industry, laboratories, experts, etc.

CMS: Updated all QC requirements

IQCP

EQC (Equivalent QC)
[DEFAULT: 2 levels of QC/day of testing]

Eligibility for IQCP

- Nonwaived tests in all CLIA specialties/subspecialties are eligible for IQCP except those in…..
  - Pathology
  - Histopathology
  - Oral Pathology
  - Cytology
- Certain specialty/subspecialty QC requirements are not eligible for IQCP in…..
  - Routine Chemistry
  - Immunohematology
  - Clinical Cytogenetics
  - Histocompatibility Testing

IQCP Considerations

- IQCP is a voluntary option that covers all phases of the testing process and became effective on January 1, 2016
- CLIA regulations have not changed
- IQCP may or may not reduce the amount or frequency of QC required; it is intended to ensure effective QC for each laboratory and its tests
- An IQCP can be developed for individual test systems using information from many existing quality practices
- Laboratories may choose to implement IQCP or must meet CLIA regulatory QC requirements

Elements Required in the IQCP Process

Development of an IQCP for each test system includes three required elements:

1. Risk Assessment – identifies and evaluates potential failures and sources of error in the entire testing process (preanalytic, analytic, postanalytic phases of testing)
2. QC Plan (QCP) – documentation of the laboratory's processes and procedures performed to reduce the chance of possible failures and errors in the testing process. The QCP must ensure that the accuracy and reliability of the results, for that test system, are appropriate for patient care
3. Quality Assessment (QA) - the continuous process of monitoring the effectiveness of your QCP

Risk Assessment

- Risks are potential failures and sources of error that can impact the accuracy and precision of test results
- Five required components of the risk assessment:
  1. Specimen
  2. Test system
  3. Reagent
  4. Environment
  5. Testing personnel

- Risk assessment for a given test system may differ among laboratories
- A laboratory's own data, whether new or historical, is used to determine potential risks
- The laboratory must provide documented evidence that the risk assessment was conducted - can documented using different methods

QC Plan (QCP)

- Use the completed risk assessment to develop the individualized QCP based on the laboratory's specific circumstances (e.g. frequency, volume, type, and complexity of testing), clinical and patient information, and the testing environment
- The QCP must be signed and dated by the laboratory director and must –
  - Monitor over time the accuracy and precision of test performance
  - Include the number, type, and frequency of required QC and defined criteria for acceptability
- The QCP may also include –
  - Electronic, procedural, or internal controls
  - Required personnel training and competency assessment
  - Equipment calibration
  - Other specified quality control activities

Quality Assessment (QA)

- **QA is an ongoing review process to**
  - Monitor and assess the effectiveness of the QCP
  - Identify errors or failures, their cause and impact on patient care
  - Take appropriate corrective action to resolve problems
  - Re-evaluate the risk assessment and make any needed changes to the QCP
- **The QA component of the IQCP process can be part of the laboratory's ongoing QA activities**

Laboratory Director (LD) Responsibilities for IQCP

- **The LD is responsible for:**
  - Providing accurate and reliable test results that are appropriate for patient care
  - Ensuring that IQCP meets the requirements as set forth in the CMS CLIA Interpretive Guidelines
  - Signing and dating the QCP when implemented
  - Re-signing updated QCP if changes are made
- **The LD may assign in writing:**
  - The responsibility for establishing IQCP as part of the laboratory's overall QC program to the Technical Consultant or Technical Supervisor
  - Portions of IQCP tasks (i.e. data collection and information gathering) to other qualified laboratory employees

Clinical and Laboratory Standards Institute Microbiology QC References

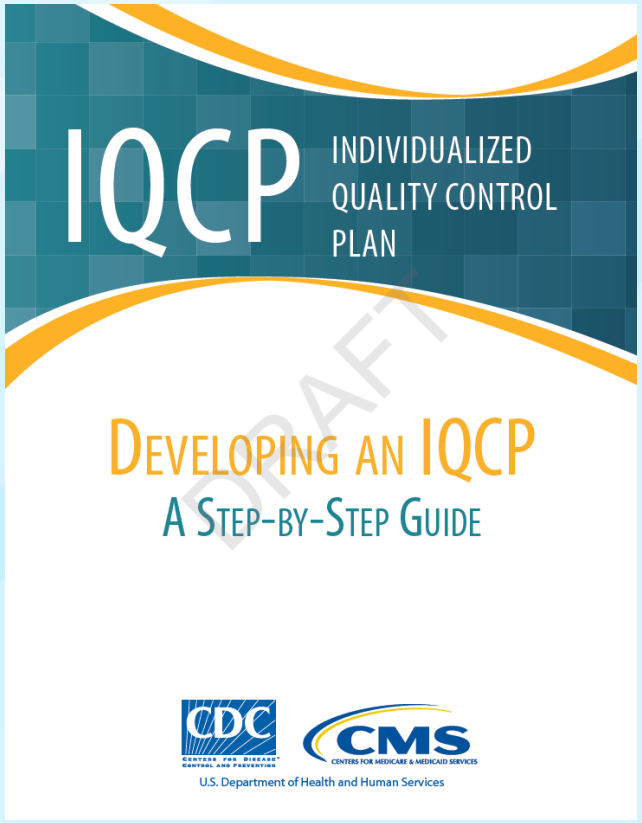
- CLIA Interpretive Guidelines (version 05/21/04) had references to CLSI microbiology QC documents at D5477 and D5507, with additional references in CLIA S&C-09-06
- All CLSI references have been removed in the revised CLIA Interpretive Guidelines published on 1/9/15
- Microbiology laboratories now have two options for CLIA QC:
  - Follow all applicable CLIA QC regulations; or
  - Implement IQCP

IQCP and Accredited Laboratories or Laboratories in Exempt States

- As of May 2016, IQCP is approved as an option for:
  - American Osteopathic Association (AOA)
  - College of American Pathologists (CAP)
  - COLA
  - The Joint Commission (JC)
  - NY State
  - WA State
- Accredited laboratories should continue to meet their accrediting organization's current QC standards until they receive notice from their accrediting organization about any QC changes

CMS/CDC IQCP Educational Resources

- **CMS CLIA Brochures**
  - #11: CLIA Individualized Quality Control Plan (IQCP) Introduction
  - #12: Considerations when Deciding to Develop an IQCP
  - #13: What is an IQCP?
- **Workbook developed by CDC and CMS**
  - Uses an example scenario and follows a step-by-step process
  - Includes fillable forms
- **Workbook and brochures posted at:**
  www.cms.hhs.gov/clia/
  wwwn.cdc.gov/CLIA/Resources/IQCP/
- **Mail inquiries to: IQCP@cms.hhs.gov**



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