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

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No Disclosures

- *I have nothing to disclose with respect to financial interests related to this presentation.*

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?
- When does IQCP become effective?
- What resources can help laboratories develop or 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

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

IQCP

EQC	IQCP
Transitional	Updated Solution
Standardized	Customizable
Rigid	Flexible
Narrow scope Limited regulations Limited specialties	Broader scope More regulations All but Path
Analytic	Pre to Post Analytic
Requires Internal QC Decreases External QC	Does Not Require Internal QC May or may not decrease QC

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Individualized Quality Control Plan (IQCP)

CLIA

- ☑ **Customizes** QC Plan for each test in its unique environment
- ☑ **Optimizes** use of electronic/integrated controls
- ☑ **Offers** laboratories **flexibility** in achieving QC compliance
- ☑ **Adaptable** for future advancements in technology
- ☑ **Incorporates** other sources of Quality Information
- ☑ **Strengthens** Manufacturer/Laboratory partnerships
- ☑ **Formalizes** risk management data already maintained within the laboratory
- ☑ **Provides** equivalent quality testing to meet the CLIA QC regulations

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Eligibility for IQCP

- **Nonwaived tests in all CLIA specialties/subspecialties are eligible for IQCP except those in…..**
  - Pathology
  - Histopathology
  - Oral Pathology
  - Cytology
- **Although general QC requirements are eligible, certain specific 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
- No CLIA regulations will change
- 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
- As of 1/1/16, laboratories may choose to implement IQCP or must meet general CLIA QC requirements at §493.1256(d) – Test two external controls each day of patient testing

IQCP Requirements: Following Manufacturer's Instructions

- **Laboratories that perform nonwaived tests must follow all manufacturer's instructions for commercial tests**
- **When manufacturer's instructions for QC are absent or less stringent than the CLIA QC requirements, the laboratory must meet CLIA QC requirements or may choose to develop an IQCP**
- **Although CLIA does not set minimum QC requirements under an IQCP -**
  - the amount or frequency of QC specified in the IQCP cannot be less than in the manufacturer's instructions
  - the laboratory must have a risk assessment and documentation to support the quality activities described in the QC Plan

IQCP Requirements: Steps in the 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

IQCP Education and Transition Period January 1, 2014 – December 31, 2015

- **During this time laboratories should learn about IQCP and make transition plans**
- **Three options to meet CLIA requirements during this time period**
  - Follow CLIA QC requirements as written in regulations
  - Continue to follow EQC procedures currently allowed
  - Implement IQCP
- **No control procedure regulatory citations will be issued for laboratories using IQCP or EQC unless serious quality problems identified during inspection**
- **Deficiencies will be cited if Immediate Jeopardy is identified during this period**

Effective Date for IQCP
January 1, 2016

- **At the end of the Education/Transition period, laboratories may choose to implement IQCP or must meet general CLIA QC requirements at §493.1256(d) – Test two external controls each day of patient testing**
- **All new and existing test systems will need to be in compliance**
- **The CMS CLIA Interpretive Guidelines will be revised:**
  - EQC will be removed
  - IQCP will be inserted

IQCP and Accredited Laboratories or Laboratories in Exempt States

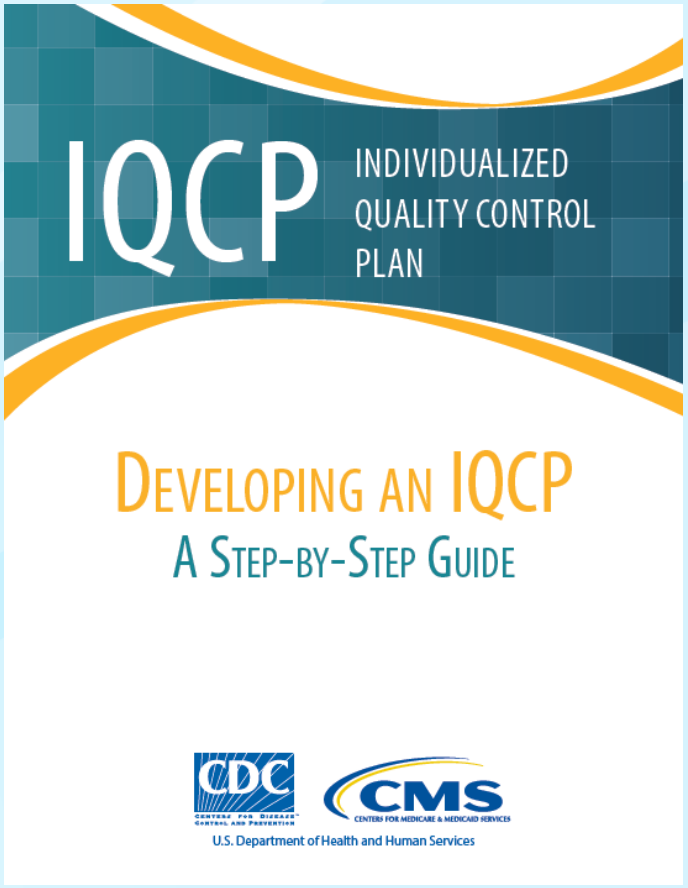
- **CMS solicited accrediting organizations and exempt states to determine their interest in IQCP as a voluntary option**
- **As of May 2015, IQCP is approved as an option for:**
  - CAP
  - COLA
  - NY State
  - WA State
- **Accredited laboratories should continue to meet their accrediting organization's current QC standards until they receive notice from their accrediting organization about any QC changes**

CMS IQCP Resources

- **CMS CLIA Website for IQCP includes a variety of links to resources related to the implementation of IQCP**
  http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Individualized_Quality_Control_Plan_IQCP.html
- **Examples:**
  - Survey and Certification letter describing IQCP that includes the IQCP Interpretive Guidelines (S&C: 13-54-CLIA)
  - IQCP Frequently Asked Questions
  - CLIA Brochures
    - #11: CLIA Individualized Quality Control Plan Introduction
    - #12: Considerations when Deciding to Develop an IQCP
    - #13: What is an IQCP?
- **IQCP mailbox: IQCP@cms.hhs.gov**

CDC/CMS Educational Workbook

- **Incorporates an example scenario and forms that can be used to develop an IQCP**
- **Can be downloaded at:**
  - wwwn.cdc.gov/CLIA/Resources/IQCP/
  - http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Individualized_Quality_Control_Plan_IQCP.html
- **Free hardcopies to be available by request from CDC**



Example Risk Assessment Questions and Form Workbook Separates Each of Five Components

Do you see a potential risk of an error in test results if:	Answer
The manufacturer's instructions for specimen requirements including, but not limited to, specimen tube or container type, patient preparation, or specimen storage are not followed?	*Yes ___ No ___*
The current version of the manufacturer's instructions is not used?	*Yes ___ No ___*
The specimen is improperly labeled?	*Yes ___ No ___*

1	2	3	4
Risk Assessment Components	What are our possible sources of error? What can go wrong?	Can our identified sources of error be reduced?	How can we reduce the identified sources of error?
	Gather information, from the manufacturer's instructions and other resources, on how we should be performing the testing process.	Yes/No Not Applicable (N/A)	Indicate how to reduce possible error sources. • Internal controls • Actions taken by laboratory • Safeguards in the test system or laboratory practices
	Documentation of specimen re-collection. Manufacturer's instructions: • Use lithium heparin tubes for whole blood or plasma specimens • Use no additive or serum separator tubes for serum specimens	Yes	Retrain testing personnel on re-collection policy. Train testing personnel to verify use of proper specimen collection tubes.

QCP Worksheet with Example

QUALITY CONTROL PLAN WORKSHEET

Laboratory Name_____ Test System Name _____

1 Type of Quality Control	2 Frequency	3 Criteria for Acceptability (Range of Acceptable Values)

1 Type of Quality Control	2 Frequency	3 Criteria for Acceptability (Range of Acceptable Values)
Temperature Checks Room Refrigerator Freezer A	Record room temperature daily, in the morning and afternoon. Record refrigerator and freezer each day of patient testing.	20°C – 25°C (Room) 2°C – 8°C (Refrigerator) -10°C – -20°C (Freezer) Recorded on temperature log sheets
Verify specimen collection tubes for acceptability upon receipt in the laboratory.	With each specimen	Refer to Specimen Rejection Policy and record all improperly collected tubes on specimen rejection log sheet.
Verify specimen collection time and time received by the laboratory.	With each specimen	If the time lapse for specimen collection and receipt is greater than 60 minutes, aliquot and store according to manufacturer's instructions (2°C – 8°C for 48 hrs or freeze at -10° C up to 5 weeks).
Internal Quality Control	Performed with each reagent disc.	Must be documented as acceptable on quality control log sheet prior to reporting results.

Laboratory Director Signature_____ Date _____

QA Worksheet with Example

Laboratory Name_____ Test System Name _____

QA ACTIVITY (TO MONITOR)	FREQUENCY	ASSESSMENT OF QA ACTIVITY (Was there variation from established policy and procedures?)	CORRECTIVE ACTION (WHEN INDICATED)
Supervisor reviews and signs instrument print-outs and QC logs	Monthly	Yes	Remedial training of testing personnel Reassess testing personnel performance
Competency Assessment	Annually after first year of employment	No	Rewrite competency assessment training program to ensure it is up to date.
Laboratory Director reviews and signs QC logs	Quarterly	No	N/A

CAP Forms

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Instructions for Con
Quality Control Plan

Complete the CAP's List of Individualized C
to an inspector during an onsite inspection

- The laboratory is performing a nonv IQCP; AND
- The laboratory has implemented an materials to be at least as stringent defined in the CLIA regulations and

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List of Individualized Quality Control Plans

Complete the fields below for each IQCP in use and present to the inspector during the on-site inspection. Fill out a separate Individualized Quality Control Plan Summary form for each IQCP listed.

Laboratory Name: | **CAP Number:**

1) Laboratory Section/Department	2) Instrument/Device Include name, manufacturer, and model	3) Tests List all tests included under the IQCP

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Individualized Quality Control Plan Summary

Complete a separate form for each IQCP in use and present to the inspector during the on-site inspection.

Laboratory Name: | **Laboratory Section/Department:** | **CAP Number:**

1) Instrument/Device Include name, manufacturer, and model	2) Tests List all tests included under the IQCP	3) Number of Devices In Use	4) List of Test Sites* If used in more than one area	Date of Director Approval	Date Implemented	Date Retired
				Click here to enter a date.	Click here to enter a date.	Click here to enter a date.

5) Process Used to Monitor Risk

List control processes put in place based on risk assessment – define the monitor and frequency evaluated.

Reagents	Environment	Specimen	Test System	Testing Personnel	Other

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The findings and conclusions in this report are those of the author and do not necessarily represent the official position of the Centers for Disease Control and Prevention.