CLIA &
Individualized Quality Control Plan (IQCP)

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CLIA

Objectives

- Provide Background & History of CLIA Quality Control
- Describe the Development of IQCP
- Present an Overview of Policies and Interpretive Guidelines related to IQCP
- Describe the Implementation Plan for Individualized Quality Control Plan(IQCP)
  - Education & Transition Period

In the Beginning……

Quality Control Milestones……

How does IQCP affect labs?

- Applies to CMS-certified non-waived labs
- Labs are already doing many of these activities, it's just not formalized
- EQC will no longer be acceptable and will be removed from the IGs
- IQCP does not have the same requirements as EQC

EQC vs. 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→Post Analytic
Requires Internal QC Decreases External QC	Does Not Require Internal QC May/may not decrease QC

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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The road to IQCP

Creating IQCP

IQCP Planning Team

- CMS convened a planning team in 2011 to oversee the implementation of IQCP
- Team mbrs include CO, RO & former deputy div dir. w/ expertise in CLIA & lab medicine
- Planning team instituted WG's to simultaneously accomplish multiple tasks

RO & SA Training

Interpretive Guidelines

Communications

AO/ES re-approvals

Education Outreach

Individualized Quality Control Plan

Policies & Regulations

The Foundations of IQCP

- Includes key concepts from CLSI EP-23, "*Laboratory Quality Control Based on Risk Management*"
- IQCP is not EP-23
- Labs are not required to incorporate EP-23

Where do we get our authority?

493.1250 Condition: Analytic Systems

- HHS is permitted to approve a procedure which provides equivalent quality testing to meet the Analytic Systems requirements in 493.1251 – 493.1283

How is IQCP enforceable?

- IQCP is not a regulation, however…
- IQCP will be an enforceable procedure for equivalent quality testing once published in Appendix C of the State Operations Manual
- EQC will no longer be acceptable and will be removed from the IGs

Mandatory vs. Voluntary

- IQCP is voluntary for laboratories
- Current CLIA control “default” regulations continue to be in effect
- EQC will be discontinued and will no longer be an acceptable QC option under CLIA

Will IQCP reduce QC?

IQCP is not intended to necessarily reduce QC requirements, but it is intended to ensure effective QC for each laboratory and the tests it performs.

IQCP Facts

- Existing CLIA QC & quality system concepts won't change
- No regulations will change!
- State and local regulations still apply
- Lab director will continue to have overall responsibility for QCP

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Laboratory Director Responsibilities

The LD is responsible for:

- Accurate and reliable test results that are appropriate for patient care
- Ensuring that IQCP meets the requirements as set forth in IQCP Interpretive Guidelines
- Signing and dating the QCP when implemented and updated.

Delegation of Duties by the LD

The LD may assign in writing:

- The responsibility for establishing IQCP as part of the laboratory's overall QC program to the TC/TS
- Specific portions of IQCP tasks to other qualified laboratory employees

Grandfathering of Current Systems

- No grandfathering for current systems using EQC
- However, historical data may be used in the development of an IQCP
- At the end of the Education & Transition Period, all existing and new test systems must comply with IQCP or “default” CLIA regulations

Manufacturer's Instructions

- Laboratories performing non-waived tests must follow all manufacturers instructions
- When the manufacturer's instructions for QC are absent or less stringent than the "default" CLIA control procedures…
  - the laboratory must choose to develop an IQCP or follow CLIA QC regulations

Minimum QC Frequency

- CLIA will not set a minimum QC frequency for labs performing IQCP
- However…
  - Performing no QC is unacceptable
  - QC frequency can not be less than the manufacturer's instructions
  - The RA & lab's data must support the QC frequency

Specialties/Subspecialties

All CLIA specialties/subspecialties will be included in IQCP, **except**...

- Pathology
- Histopathology
- Oral Pathology
- Cytology

How do the regulations relate to IQCP?

- All CLIA regulations remain in force and must be followed
- Only the eligible regulations identified in the following table(s) may be considered with IQCP
- Any IQCP eligible regulation that the lab chooses to replace with IQCP must be supported in the RA

Let's take a closer look….

Table 1: Eligibility for IQCP

CLIA Specialty/ Subspecialty	Eligible for IQCP?	General Regulations Eligible for IQCP	Specialty/Subspecialty Regulations Eligible for IQCP	Specialty/ Subspecialty Regulations NOT Eligible for IQCP
Bacteriology	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	§493.1261	N/A
Mycobacteriology	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	§493.1262	N/A
Mycology	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	§493.1263	N/A
Parasitology	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	§493.1264	N/A
Virology	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	§493.1265	N/A
Syphilis Serology	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	N/A	N/A
General Immunology	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	N/A	N/A

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Routine Chemistry	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	§493.1267(b),(c)	§493.1267(a), (d)
Urinalysis	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	N/A	N/A
Endocrinology	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	N/A	N/A
Toxicology	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	N/A	N/A
Hematology	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	§493.1269	N/A
Immunohematology	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	N/A	§493.1271
Clinical Cytogenetics	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	N/A	§493.1276

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Radiobioassay	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	N/A	N/A
Histocompatibility	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	§493.1278(b)(6), (c), (d)(6), (e)(3)	§493.1278(a), (b)(1-5),(d)(1-5), (d)(7), (e)(1-2), (f),(g)
Pathology	No	None (Not eligible for IQCP)	N/A	N/A
Histopathology	No	None (Not eligible for IQCP)	N/A	N/A
Oral Pathology	No	None (Not eligible for IQCP)	N/A	N/A
Cytology	No	None (Not eligible for IQCP)	N/A	N/A

Provider Performed Microscopy (PPM) procedures

- Definition of a PPM
- Is IQCP applicable to PPM procedures?
- Application of IQCP is test dependent
  - Reagents
  - Stains
- All CLIA regulations must continue to be followed

Interpretive Guidelines

Individualized Quality Control Plan

Individualized Quality Control Plan

Interpretive Guidelines

- IQCP
  - Introduction
  - Lab Director Responsibilities
  - Regulatory Considerations
  - RA
  - QCP
  - QA

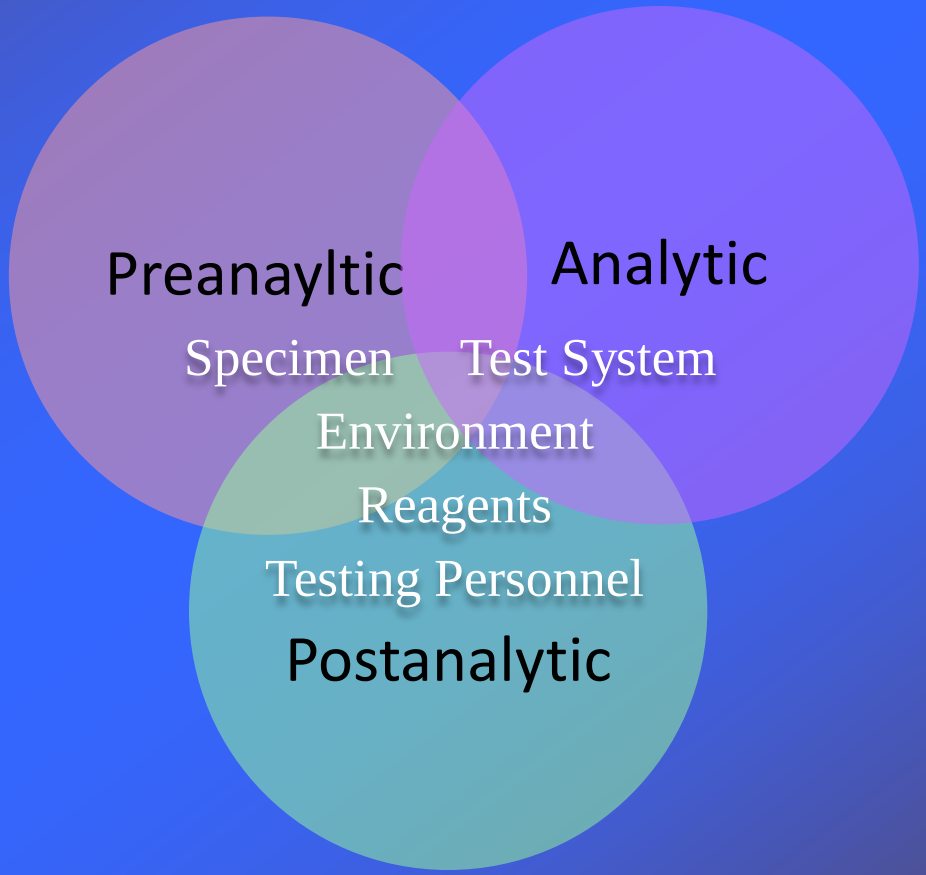
Risk Assessment - Definition

Risk assessment is the identification and evaluation of potential failures and sources of errors in a testing process.
(Interpretive Guidelines, Risk Assessment Section)

Risk Assessment

- Identify and evaluate risks
- Risks are potential failures and sources of error that can impact the accuracy and precision of test results
- Risk assessment is the first step in risk management

Risk Assessment in IQCP



Risk Assessment in IQCP: Components

5 Required Components:

- Specimen
- Environment
- Reagent
- Test system
- Testing personnel

Risk Assessment in IQCP: Entire Testing Process

Must consider the entire testing process:

- Pre-analytic
- Analytic
- Post-analytic

Risk Assessment: I did it my way!

- The risk assessment for any given test system may look very different in different laboratories
- For example, the same risk may be assigned to different components by different laboratories

Risk Assessment in IQCP: Data

Data requirements

- Laboratory's own data required
- Can be new data or historical

Laboratory: Risk Evaluation

- The laboratory evaluates the risks
- There are many methods to evaluate risks
- IQCP does not mandate any specific method of risk evaluation
- The laboratory must provide documented evidence of the risk assessment

Laboratory Risk Evaluation

The laboratory director must ensure that the risk assessment considers both the CLIA requirements for accurate test results and the responsibility for ensuring that test result quality is adequate for patient care.

Linking the RA to QCP

After the lab has identified the sources of potential failures and errors for a testing process and evaluated the frequency and impact of those failures and errors, the resulting RA is used to develop the Quality Control Plan (QCP). *(Interpretive Guidelines, Risk Assessment Section)*

Quality Control Plan - Definition

A QCP is a document that describes the practices, resources, and procedures to control the quality of a particular test process. *(Interpretive Guidelines, Quality Control Plan Section)*

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"I" Means Individualized

Customized/individualized QCP based on lab's specific circumstances (type of testing (subspecialty/specialty), test volume, availability of clinical info, test complexity, patient population & environment.

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The QCP Must…

- Monitor over time the accuracy and precision of test performance
- Include the number, type, and frequency of QC
- Define criteria for acceptability of QC

Other information to consider

If indicated by the evaluation of the risk assessment, the QCP may also include

- electronic controls,
- procedural controls,
- training and
- competency assessment,
- other specified quality control activities

Quality Assessment

- The laboratory must establish a review system for the on-going monitoring of the effectiveness of their QCP.
- The monitoring should include at least the following: testing personnel, environment, specimens, reagents, and test system. *(Interpretive Guidelines, Quality Control Plan Section)*

QA

When the laboratory discovers a testing process failure, the laboratory must conduct and document an investigation to identify the cause of the failure, its impact on patient care, and make appropriate modifications to their QCP

QA

If necessary, the laboratory must update the risk assessment with the new information and modify the QCP

Education and Transition Period

Look closer…

CLIA

Before Education & Transition Period for IQCP – CLIA Surveyors

- Principles of Risk Management at each division meeting
- National Surveyor Training on IQCP – November 18 – 22, 2013
- S&C 13-54-CLIA letter released August 16, 2013 provides information, timelines and policy decisions.

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Timeline

Begins: January 1, 2014

Ends: January 1, 2016

Preparing for Implementation of IQCP - Laboratories

- IQCP Education & Transition (E/T) Period
  - Two years long
  - Learn about IQCP & ask questions
  - Make transition plans
  - Begin to implement qc option if MI QC frequency is less than current CLIA QC regulations

Three Options for Compliance during E&T period….

- Follow the CLIA regulatory QC requirements as written
- Continue to follow the EQC procedures as described in the current IGs
- Implement IQCP as described in S&C-13-54-CLIA

Timeline for Surveyors

- **January 1, 2014**: Surveyors will survey according to instructions for Education and Transition Period (S&C Letter 13-54-CLIA)
- **January 1, 2016**: Surveyors will survey for compliance with CLIA QC regulations or IQCP

Timeline for Laboratories

- **January 1, 2014**: Laboratories may use CLIA QC regulations, EQC, or IQCP
- **January 1, 2016**: Laboratories must follow CLIA QC regulations or IQCP

During Educational and Transition (E/T) Period

- If a laboratory opts to use IQCP….
  - Surveys will be educational for labs implementing IQCP, all other regulations must be met
  - Surveyors are directed to use a “Dear Laboratory Director letter" to report any findings for IQCP related issues.

Education & Transition Period for IQCP

- No control procedure regulatory citations will be issued prior to the end of the education & transition period unless serious test quality problems are found

- If Immediate Jeopardy is identified, deficiencies will be cited.

End of the Education and Transition Period

- The CLIA Interpretive Guidelines will be revised
  - EQC will be REMOVED
  - IQCP will be INSERTED

After: E/T Period vs Implementation

- Implementation of IQCP
  - After January 1, 2016
  - The lab will have IQCP or default QC regulations
  - All new and existing test systems must be in compliance

Education & Transition Period for IQCP

All questions regarding IQCP may be directed to our electronic mailbox

IQCP@cms.hhs.gov

Education & Transition Period for IQCP

- CMS has solicited accrediting orgs (AO) to determine their interest in IQCP
- Adoption of IQCP "requirements" in AO/ES programs is voluntary
- Accredited labs must continue to meet their accrediting org.'s QC standards

To summarize…..

- Once effective, IQCP will supersede the current EQC policy
- Existing CLIA QC & QS concepts won't change
- No regulations will change!
- Minimally, labs must follow mfr's. instructions
- Lab director has overall responsibility for QCP

To summarize…..

- IQCP Interpretive Guidelines…
  - Introduction
  - Lab Director Responsibilities
  - Regulatory Considerations
  - RA
  - QCP
  - QA

To summarize……

- Education & transition period for labs before IQCP is fully effective

  Begins: January 1, 2014

  Ends: January 1, 2016

- Info & Guidance on IQCP can be found at..

www.cms.hhs.gov/clia/

Questions about IQCP?

All questions regarding IQCP may be directed to our electronic mailbox

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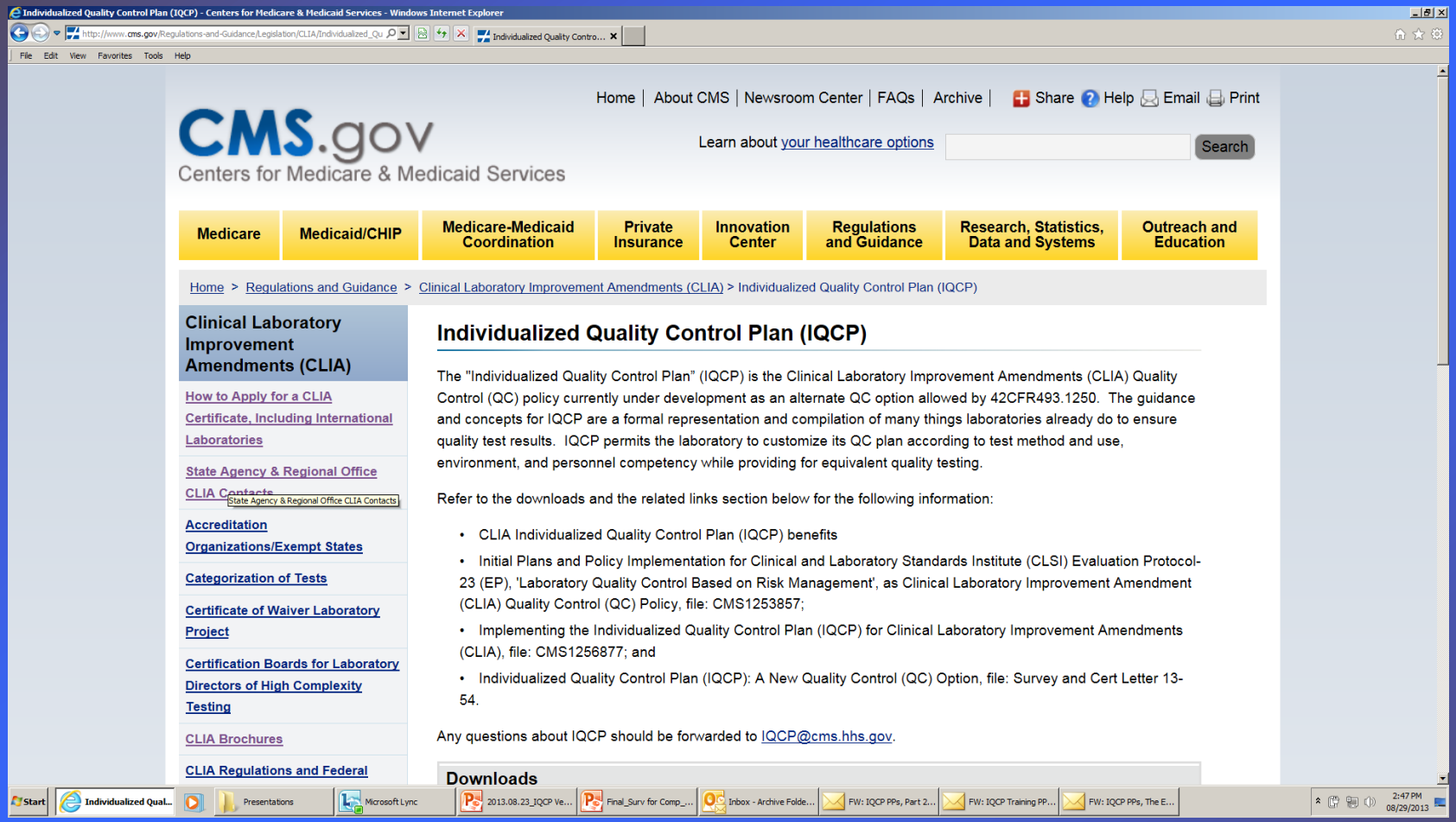
CLIA website - IQCP



http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Individualized_Quality_Control_Plan_IQCP.html

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Where to Obtain Information

CMS/CLIA Web site:

www.cms.hhs.gov/clia/

S&C: 13-54-CLIA

http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-54.pdf

CMS CLIA Central Office:

410-786-3531

Judy Yost's email:

Judith.yost@cms.hhs.gov

IQCP Link:

IQCP@cms.hhs.gov

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THE END!!

Thank You!!!