CLIA & Individualized Quality Control Plan (IQCP)

Keith Scott, MLS(ASCP) CM
Laboratory Surveyor/Consultant
Centers for Medicare & Medicaid Services
Region 10
Western Division
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

- CLIA '67
- CLIA '88
- Quality Systems Regulations 2003
- Equivalent Quality Control "EQC" 2004
- "QC for the Future" 2005
- CLSI EP-23 2011
- Individualized Quality Control Plan "IQCP" 2013
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

<table>
<thead>
<tr>
<th>EQC</th>
<th>IQCP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transitional</td>
<td>Updated Solution</td>
</tr>
<tr>
<td>Standardized</td>
<td>Customizable</td>
</tr>
<tr>
<td>Rigid</td>
<td>Flexible</td>
</tr>
<tr>
<td>Narrow scope/Limited regulations</td>
<td>Broader scope/More regulations</td>
</tr>
<tr>
<td>Limited specialties</td>
<td>All but Path</td>
</tr>
<tr>
<td>Analytic</td>
<td>Pre→Post Analytic</td>
</tr>
<tr>
<td>Requires Internal QC</td>
<td>Does Not Require Internal QC</td>
</tr>
<tr>
<td>Decreases External QC</td>
<td>May/may not decrease QC</td>
</tr>
</tbody>
</table>
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
The road to IQCP
Creating IQCP

IQCP Planning Team

- IQCP IG Workgroup
- RO/SA Training Workgroup
- Communication Workgroup
- AO/ES re-approvals Workgroup
- Educational Outreach Workgroup
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
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
<table>
<thead>
<tr>
<th>CLIA Specialty/Subspecialty</th>
<th>Eligible for IQCP?</th>
<th>General Regulations Eligible for IQCP</th>
<th>Specialty/Subspecialty Regulations Eligible for IQCP</th>
<th>Specialty/Subspecialty Regulations NOT Eligible for IQCP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacteriology</td>
<td>Yes</td>
<td>493.1256(d)(3)-(5)</td>
<td>493.1261</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td></td>
<td>493.1256(e)(1)-(4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mycobacteriology</td>
<td>Yes</td>
<td>493.1256(d)(3)-(5)</td>
<td>493.1262</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td></td>
<td>493.1256(e)(1)-(4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mycology</td>
<td>Yes</td>
<td>493.1256(d)(3)-(5)</td>
<td>493.1263</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td></td>
<td>493.1256(e)(1)-(4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Parasitology</td>
<td>Yes</td>
<td>493.1256(d)(3)-(5)</td>
<td>493.1264</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td></td>
<td>493.1256(e)(1)-(4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Virology</td>
<td>Yes</td>
<td>493.1256(d)(3)-(5)</td>
<td>493.1265</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td></td>
<td>493.1256(e)(1)-(4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Syphilis Serology</td>
<td>Yes</td>
<td>493.1256(d)(3)-(5)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td></td>
<td>493.1256(e)(1)-(4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>General Immunology</td>
<td>Yes</td>
<td>493.1256(d)(3)-(5)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td></td>
<td>493.1256(e)(1)-(4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CLIA Specialty/Subspecialty</td>
<td>Eligible for IQCP?</td>
<td>General Regulations Eligible for IQCP</td>
<td>Specialty/Subspecialty Regulations Eligible for IQCP</td>
<td>Specialty/Subspecialty Regulations NOT Eligible for IQCP</td>
</tr>
<tr>
<td>----------------------------</td>
<td>--------------------</td>
<td>--------------------------------------</td>
<td>-----------------------------------------------------</td>
<td>------------------------------------------------------</td>
</tr>
<tr>
<td>Routine Chemistry</td>
<td>Yes</td>
<td>493.1256(d)(3)-(5) 493.1256(e)(1)-(4)</td>
<td>493.1267(b),(c)</td>
<td>493.1267(a),(d)</td>
</tr>
<tr>
<td>Urinalysis</td>
<td>Yes</td>
<td>493.1256(d)(3)-(5) 493.1256(e)(1)-(4)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Endocrinology</td>
<td>Yes</td>
<td>493.1256(d)(3)-(5) 493.1256(e)(1)-(4)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Toxicology</td>
<td>Yes</td>
<td>493.1256(d)(3)-(5) 493.1256(e)(1)-(4)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Hematology</td>
<td>Yes</td>
<td>493.1256(d)(3)-(5) 493.1256(e)(1)-(4)</td>
<td>493.1269</td>
<td>N/A</td>
</tr>
<tr>
<td>Immunohematology</td>
<td>Yes</td>
<td>493.1256(d)(3)-(5) 493.1256(e)(1)-(4)</td>
<td>N/A</td>
<td>493.1271</td>
</tr>
<tr>
<td>Clinical Cytogenetics</td>
<td>Yes</td>
<td>493.1256(d)(3)-(5) 493.1256(e)(1)-(4)</td>
<td>N/A</td>
<td>493.1276</td>
</tr>
<tr>
<td>CLIA Specialty/Subspecialty</td>
<td>Eligible for IQCP?</td>
<td>General Regulations Eligible for IQCP</td>
<td>Specialty/Subspecialty Regulations Eligible for IQCP</td>
<td>Specialty/Subspecialty Regulations NOT Eligible for IQCP</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>--------------------</td>
<td>---------------------------------------</td>
<td>-----------------------------------------------</td>
<td>-----------------------------------------------------</td>
</tr>
<tr>
<td>Radiobioassay</td>
<td>Yes</td>
<td>493.1256(d)(3)-(5) 493.1256(e)(1)-(4)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Histocompatibility</td>
<td>Yes</td>
<td>493.1256(d)(3)-(5) 493.1256(e)(1)-(4)</td>
<td>493.1278(b)(6), (c), (d)(6), (e)(3)</td>
<td>493.1278(a), (b)(1-5), (d)(1-5), (d)(7), (e)(1-2), (f)(g)</td>
</tr>
<tr>
<td>Pathology</td>
<td>No</td>
<td>None (Not eligible for IQCP)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Histopathology</td>
<td>No</td>
<td>None (Not eligible for IQCP)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Oral Pathology</td>
<td>No</td>
<td>None (Not eligible for IQCP)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Cytology</td>
<td>No</td>
<td>None (Not eligible for IQCP)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Table 1: Eligibility for IQCP
Microbiology Options

• CLIA regulations
• CLSI Microbiology documents
  – Media QC
  – Sensitivity QC (MICs and KB)
  – Multiple reagent ID Systems
• IQCP
Interpretive Guidelines

Individualized Quality Control Plan

IQCP = RA + QCP + QA
Individualized Quality Control Plan

- Quality Control Plan
- Risk Assessment

Individualized Quality Control Plan

CLIA
Interpretive Guidelines

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

Entire Testing Process
- Preanalytic
- Analytic
- Postanalytic

Test System

Testing Personnel

Environment

Specimen

Reagents
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
The laboratory director must ensure that the risk assessment considers both the CLIA requirements for accurate test results and 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)*
“I” Means Individualized

An individualized QCP is based on the lab’s specific circumstances (type of testing, test volume, availability of clinical info, test complexity, patient population & environment).
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)*
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.
If necessary, the laboratory must update the risk assessment with the new information and modify the QCP.
Education and Transition Period

Look closer...
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.
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 Manufacturer’s 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, all other regulations must be met
  – 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 - 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 & Quality System concepts won’t change
• No regulations will change!
• Minimally, labs must follow mfr’s. instructions
• Lab director has overall responsibility for QCP
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

IQCP@cms.hhs.gov
Individualized Quality Control Plan (IQCP)

The "Individualized Quality Control Plan" (IQCP) is the Clinical Laboratory Improvement Amendments (CLIA) Quality Control (QC) policy currently under development as an alternate QC option allowed by 42CFR493.1250. The guidance and concepts for IQCP are a formal representation and compilation of many things laboratories already do to ensure quality test results. IQCP permits the laboratory to customize its QC plan according to test method and use, environment, and personnel competency while providing for equivalent quality testing.

Refer to the downloads and the related links section below for the following information:

- CLIA Individualized Quality Control Plan (IQCP) benefits
- Implementing the Individualized Quality Control Plan (IQCP) for Clinical Laboratory Improvement Amendments (CLIA), file: CMS1253857; and

Any questions about IQCP should be forwarded to IQCP@cms.hhs.gov.

Downloads
Where to Obtain Information

CMS/CLIA Web site:
www.cms.hhs.gov/clia/

S&C: 13-54-CLIA


CMS CLIA Central Office:
410-786-3531

IQCP Link:
IQCP@cms.hhs.gov
THE END!!

Thank You!!!