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Individualized Quality Control Plans (IQCP) Changes to the CMS Quality Requirements

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CLIA Quality Control Evolution of the Process

- In 2003, the Quality System Regulations were written
- In 2004, Equivalent QC was implemented
- 2005 “QC for the Future” Meeting was held
  - Was held to address concerns expressed by industry, accrediting agencies, laboratories, professional organizations, and governmental agencies

"QC for the Future" Meeting Outcome

- Stakeholder concern that manufacturers don't provide laboratories sufficient information
- One-size-fits all QC doesn't work with new technologies

Equivalent Quality Control

- **CLIA stated that "For each test system the laboratory must test, at a minimum, two levels of external QC materials each day". EQC allowed labs to reduce this frequency by using processes like:**
  - **internal monitoring systems built into instruments (written guidance from the manufacturer)**
  - **External QC**

Designing an New QC Model

- Clinical Laboratory Standards Institute (CLSI) meeting developed Evaluation Protocol (EP)-23 "Laboratory Qualify Control Based on Risk Management"
- Protocol published in October 2011
- Note that CLIA regulations have not been changed

Development of IQCP

- CMS incorporated key EP-23 concepts into the CLIA Interpretative Guidelines as an acceptable QC policy called IQCP
- Applies to CMS certified non-waived laboratories
- Covers all phases of the testing process
- Note: IQCP is not EP-23

Why has CMS dropped References to CLSI EP-23 Document in Survey Manuals and Interpretive Guidelines?

- CMS lawyers picked up references to CLSI in guidance documents
- Advised CMS against government regulations recommending a specific use of any private entities' standards/publications

Quality Control Changes from CMS

- CMS is implementing a new quality control option based on Risk Management; Individual Quality Control Option (IQCP)
- IQCP provides laboratories with flexibility in customizing QC policies and procedures based on the test systems in use

Individualized Quality Control Plan(IQCP)

- IQCP applies to CMS certified non-waived laboratories
- IQCP is a voluntary program
- IQCP replaces Equivalent Quality Control (EQC)
- OQCP applies all phases of the testing process

Benefits of IQCP

- Formalizes risk management decisions
- Can be customized based on patient population, environment, test system, personnel, test uses
- Offers flexibility to achieve QC compliance for each test
- Adaptable to future technology advances

Laboratory Options for QC

- Laboratories have two options to comply with Quality Control:
  - Follow rules defined in CLIA 493.1256(d)(3)
  - Develop an Individualized Quality Assurance Plan
  - Joint Commission has adopted IQCP. CAP process being developed

Implementation of the IQCP Process

- Individualized Quality Control Planning is in an Education and Transition period
- This transition period began on 01/01/2014 and concludes on 01/01/2016

EQC versus IQCP

EQC

- Standardized process
- Rigid
- Narrow scope
- Applies to analytic processes
- Requires internal QC
- Decreases External QC

IQCP

- Customizable
- Flexible
- Broader scope
- Pre→ Post Analytic
- Does not require internal QC
- May/may not decrease QC

IQCP can apply to the following Laboratory Subspecialties

- Bacteriology
- Mycobacteriology
- Mycology
- Parasitology
- Virology
- Syphilis Serology
- General Immunology
- Routine Chemistry
- Urinalysis
- Endocrinology
- Toxicology
- Hematology
- Immunohematology
- Clinical Genetics
- Radiobioassay
- Histocompatibility

Subspecialities that IQCP does not Apply

Pathology

Histopathology

Oral Pathology

Cytology

Laboratory Director Quality Related Responsibilities

- Responsible for ensuring that quality control and quality assessment programs are established and maintained, including identification of failures in quality as they occur
- Deciding whether the lab will seek to meet CLIA using IQCP, and if they decide to do so, ensuring that a Quality Control Plan is developed

Delegation of Duties by the Laboratory Director

- **Must be assigned in writing**
  - **Establishing IQCP as part of the lab's overall plan to TC/TS**
  - **Specific portions of IQCP tasks to other qualified laboratory employees**

Components of an IQCP

Risk Assessment

Quality Control Plan

Quality Assessment

Risk Assessment

Identification of potential failures

Determination of the source of error (risk)

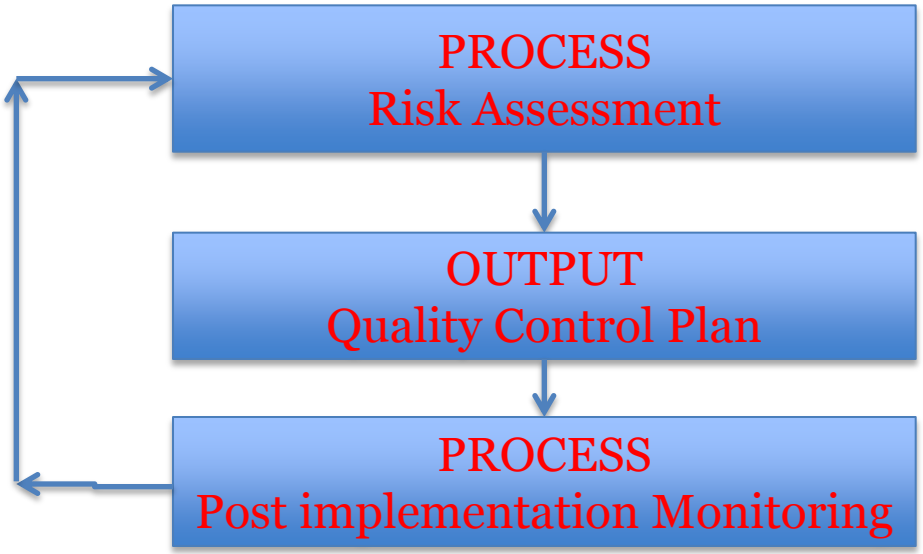
Evaluation of risk

Determination of likelihood of harm

Identification of mitigations

Determination of residual risk

Risk Assessment



RISK ASSESSMENT

The identification and evaluation of potential failures and sources of errors in a testing process

- **Identifies and evaluates risks**
- **The first step in risk management**

Measures system information

Identifies effective controls

Risk Evaluation

	Severity of Harm				
Probability of harm	**Negligible**	**Minor**	**Serious**	**Critical**	**Catastrophic**
Frequent	**Unacceptable**	**Unacceptable**	**Unacceptable**	**Unacceptable**	**Unacceptable**
Probable	**Acceptable**	**Unacceptable**	**Unacceptable**	**Unacceptable**	**Unacceptable**
Occasional	**Acceptable**	**acceptable**	**Acceptable**	**Unacceptable**	**Unacceptable**
Remote	**Acceptable**	**Acceptable**	**Acceptable**	**Acceptable**	**Unacceptable**
Improbable	**acceptable**	**acceptable**	**acceptable**	**acceptable**	**acceptable**

Analysis of QC Samples

Intralaboratory Quality Control

Interlaboratory Quality Control

Controls build into the measuring system

- **Function checks**
- **Electronic system checks**
- **Calibration checks**

Information Gathering for Risk Assessment

- **Regulatory and accreditation requirements**
  - **Mandated QC**
- **Measuring system information**
  - **Intended use**
- **Laboratory information**
  - **Operator competency**
- **Publications and reports from peer labs**
  - **Clinical studies**
- **Clinical information**
  - **Clinical decision levels**

Scope of Lab QC Based on Risk Management

- Based on performance required for the intended medical application of the test results
- Uses risk mitigation information obtained from the manufacturer and identified by the laboratory
- Uses all applicable regulatory and accreditation requirements

Quality Control Plan

Assures test results are relevant, accurate and reliable for patient care

Tracks a number of factors that affect quality

- Failures of measurement system
- Operator error
- Environmental conditions

Monitoring the testing process for the occurrence of errors

Introducing control procedures to mitigate the occurrence of errors

Quality Control Plan

Requires and understanding of the preexamination (preanalytical) processes

An examination of the analytical processes

An examination of the postanalytical processes

And the identification of the weaknesses (potential failures) in the processes

Measuring Systems

Measuring system information

- Medical requirements for test results
- Regulatory requirements
- Measuring system information
  - Provided by the manufacturer
  - Provided by the laboratory
- Information about the health care and testing site

Steps in Developing the Quality Control Plan

- Hazard identification
- Risk elimination
  - Probability of harm
  - Severity of harm
- Risk evaluation
- Risk control
- Writing the laboratory Quality Control Plan

Quality Control Plan

The plan is pro-active.

- Addresses potential risks before failures occur

Includes prevention strategies and monitoring strategies

Quality Assessment

- Method of surveying the Quality Control Plan effectiveness and performance
- A living process that is modified over time
- Requires ongoing monitoring and review of documentation of findings

Quality Assessment

Monitors may include:

- Review of QC data
- PT results
- Competency Assessments
- Patient test results review
- Rejection rates
- Turn-around-time
- Corrective actions on non-conforming events

Summary

IQCP transition period ends January 1, 2016

IQCP does not apply at this time to Cytology/pathology

IQCP is based on risk management

- Assessing and eliminating risk to patient

Summary

IQCP is based on CLSI document

EP-23-A "Laboratory Quality Control Based in Risk Management"

CLIA rules have not been changed

IQCP replaces EQP as a QC method

Readings

CLSI EP-23-A “Laboratory Quality Control Based on Risk Management; Approved Guidelines”

Individualized Quality Control Plan: Introduction; CLIA Document, July 2013 www,cms.hhs.gov/clia

Effect on Microbiology Laboratories Due to the Removal of References to the Clinical Laboratory Standards Institute (CLSI) and to CLSI Documents, October 31, 2014