Individualized Quality Control Plan (IQCP)

How to complete a risk assessment

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IQCP is the topic on the minds of all clinical laboratorians, and there are many questions surrounding this new QC option. A few commonly asked questions and their answers are included below, created with input based during a Q&A session with Dr. Susan Sharp.

What is IQCP?

IQCP stands for "Individualized Quality Control Plan" and is an alternative option provided by CLIA for a QC testing plan for non-waived tests systems. It is replacing the Equivalent QC option that many labs currently use.

What are the components of the IQCP?

The IQCP has 3 key elements:

1. **Risk Assessment** (RA) includes the identification, evaluation, and mitigation of "significant" potential failures (hazards/errors) that can impact test result quality in all three phases (pre-analytical, analytical, and post-analytical) of the testing process. The CMS mandates, at a minimum, that RA includes the evaluation of the specimen, environment, reagent, test system, and testing personnel. The IQCP policy highlights many resources to assist with the RA process
2. **Quality Control Plan** (QCP) describes the practices, resources, and procedures to control the quality of a particular test process, ensure the accuracy and reliability of test results, and ensure that result quality is appropriate for patient care
3. **Quality Assessment** (QA) monitors the ongoing effectiveness of the IQCP

When does it need to be implemented?

January 1, 2016

Are there other options?

Yes. The other option will be to follow the default CLIA regulations, which is to perform QC every day of testing for all test systems.

How do you define a "test system," and how do you address QC (risk) of each individual component of the test system?

Answer provided by Dr. Susan Sharp.

CMS defines a "Test System" as: the instructions and all of the instrumentation, equipment, reagents, and supplies needed to perform an assay or examination and generate test results. (Note: The reference CLSI EP-23A uses the terminology "measuring system" for test system).
Reference for answer: CLIA 493.2, See Definitions and look under EXAMPLE - https://www.law.cornell.edu/cfr/text/42/493.2; and CLSI document EP-23A, http://clsi.org/blog/2011/10/01/clsi-publishes-new-guideline-laboratory-quality-control-based-on-risk-management-ep23-a/).

CMS recommends some areas to evaluate for potential sources of error for the entire test system to include in your risk assessment on page 3 of the following CMS guidance document (http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIAbrochure13.pdf).

How do you perform a risk assessment?

To start your IQCP risk assessment for Systems, do the following three tasks:

1. Identify the risks for potential error associated with your test system (includes preanalytical, analytical and post analytical area of testing).

NOTE: Some possible risks are listed below - some, but not all, may apply to your test system (Note: this is not meant to be an exhaustive listing):

- Inadequate sampling
- Clot detection capabilities
- Capabilities for detection of interfering substances (e.g., hemolysis, lipemia, icterus, turbidity)
- Calibration associated issues
- Mechanical/electronic failure of test system

- Optics
- Pipettes or pipettors
- Barcode readers
- Failure of system controls and function checks
- Built-in procedural and electronic controls (internal controls)
- External or internal liquid quality control (assayed vs. unassayed)
- Temperature monitors and controllers
- Software/Hardware
- Transmission of data to LIS
- Result reporting

2. Determine the frequency of occurrence and severity of harm for each identified risk. CMS states the following: *"To conduct a risk assessment, the laboratory must identify the sources of potential failures and errors for a testing process and evaluate the frequency and impact of those failures and sources of error"(*CMS reference: Survey and Certification: 13-54-CLIA, August 16, 2013).

The following tables may be used to determine the frequency and impact of failures. These are only examples; other words and definitions may be used:

Frequency of Occurrence
Unlikely (once every 2-3 yrs)
Occasional (1/yr)
Probable (1/mo)
Frequent (1/wk)

Severity of Harm
Negligible (temporary discomfort)
Minor (temporary injury; not requiring medical intervention)
Serious (impairment requiring medical intervention)
Critical (permanent impairment requiring medical intervention)

3. Define measures that are in place to control, reduce or mitigate these risks.

As an example**,** you might develop a table that includes all of these items. This is only one example of how this may be developed; many other ways will also be acceptable.

RISK	Frequency of Occurrence	Severity of Harm	Measure(s) to Control Risk	Relevant Documentation
Mechanical/ electronic failure of test system	Unlikely	Negligible	All mechanical and electronic maintenance are performed properly and at regularly scheduled intervals as defined by the manufacturer.	SOP.1111 Manufacturer's Instruction Guide
Failure of system controls and function checks	Unlikely	Negligible	All system controls and function checks are performed properly and at regularly scheduled intervals as defined by the manufacturer.	SOP.2222 Manufacturer's Instruction Guide
Built-in procedural and electronic controls (internal controls)	Occasional	Minor	All built-in procedural and electronic controls (internal controls) are performed properly and at regularly scheduled intervals as defined by the manufacturer. All testing personnel have had appropriate training (TR). Regular competency assessment (CA) done on staff.	SOP.3333 Manufacturer's Instruction Guide TR.aaaa CA.xxxx

Where can you find more information?

The Centers for Medicare & Medicaid Services (CMS) has published several useful documents including brochures, frequently asked questions, and a step-by-step guide to help develop your own IQCP. These documents and details on the IQCP can be found at their website found at the following link: http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Individualized_Quality_Control_Plan_IQCP.html

ASM has also published additional helpful documents to help you get started on your individual plans as well. These are available at http://clinmicro.asm.org/index.php/lab-management/laboratory-management/445-iqcp-iqcp.