

ELABORATIONS

News and Issues for Washington's Clinical Laboratories

Volume XIX Issue 4

July/August 2014

Individualized Quality Control Plan (IQCP): A New Quality Control (QC) Option

The Centers for Medicare and Medicaid Services (CMS) is implementing a new quality control option based on risk management called Individualized Quality Control Plan (IQCP). IQCP will provide laboratories with flexibility in customizing Quality Control (QC) policies and procedures based on the test systems in use and the unique aspects of each laboratory.

IQCP is voluntary, but otherwise, laboratories must achieve compliance by following Clinical Laboratory Improvement (CLIA) QC regulations of performing two external levels of QC each day of testing. The laboratory director retains overall responsibility for ensuring that QC programs are established and maintained to assure the quality of the laboratory services provided, and to identify failures in quality as they occur.

The IQCP education and transition period began January 1, 2014 and ends December 31, 2015. During this period, the laboratory has three options:

- 1). Follow the CLIA regulatory requirements as written.
- 2). Continue to follow the Equivalent Quality Control (EQC) procedures as described in the regulations.
- 3). Implement IQCP as described below.

Effective January 1, 2016, EQC is no longer an acceptable option for QC. Therefore, laboratories using EQC should consider which QC option (two levels of control daily or IQCP) they would want to use. Educational materials will be released periodically during the IQCP Education and

Transition Period: Laboratories are advised to check the CLIA website for [updated information](#). CMS-approved accreditation organizations (AOs) and exempt States (ESs) will determine if they will incorporate IQCP into their standards for laboratories. Washington State Department of Health Laboratory Quality Assurance has already incorporated IQCP into its regulations.

All specialties except Pathology, Histopathology, Oral Pathology, and Cytology are eligible for IQCP. If the manufacturer's instructions are less stringent than the CLIA regulatory requirements for QC procedures, the laboratory must develop an IQCP.

An IQCP must include:

- 1). Risk Assessment (RA),
- 2). Quality Control Plan (QCP), and
- 3). Quality Assessment (QA).

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Practice Guidelines

The following practice guidelines have been developed by the Clinical Laboratory Advisory Council. They can be accessed at the [LQA website](#).

Acute Diarrhea	Lipid Screening
Anemia	PAP Smear Referral
ANA	Point-of-Care Testing
Bioterrorism Event Mgmt	PSA
Bleeding Disorders	Rash Illness
Chlamydia	Red Cell Transfusion
Diabetes	Renal Disease
Group A Strep Pharyngitis	STD
Group B Streptococcus	Thyroid
Hepatitis	Tuberculosis
HIV	Urinalysis
Infectious Diarrhea	Wellness
Intestinal Parasites	

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Risk Assessment: Risk assessment (RA) is the identification and evaluation of potential failures and sources of errors in a testing system. RA must include, at a minimum, an evaluation of the following five components in your laboratory:

- Specimen
- Environment
- Reagent
- Test System
- Testing Personnel

The scope of risk assessments must encompass the entire testing process including pre-analytic, analytic, and post-analytic. The laboratory director has the responsibility for ensuring that the risk assessment considers both CLIA requirements for accurate and reliable test results and that test result quality is appropriate for patient care.

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 effect of those failures and sources of error. In-house data, established by the laboratory in its own environment and by its own personnel, must be included to demonstrate that the stability of the test system supports the number and frequency of the QC documented in the IQCP.

ELABORATIONS is a free monthly publication of the Washington State Department of Health (DOH) Public Health Laboratories (PHL) and Office of Laboratory Quality Assurance (LQA).

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[Public Health Laboratories](#)

The following list contains possible sources of information for conducting a risk assessment:

- Regulatory requirements
- Manufacturer's package insert (including intended use, limitations, environmental requirements, QC frequency, specimen requirements, reagent storage, maintenance, calibration, interfering substances, etc.)
- Manufacturer's operator manual
- Troubleshooting guide
- Manufacturer's alerts and bulletins
- Verification of establishment of performance specifications
- Testing personnel qualifications, training, and competency records
- QC data
- Proficiency testing data
- QA information, including corrective action
- Scientific publications
- Other information as appropriate

If a laboratory wishes to use IQCP, the laboratory must address each applicable regulatory QC requirement in its risk assessment that it wishes to replace with IQCP. In laboratories with multiple numbers of identical devices (same make and model), a single risk assessment may be performed for the test system. However, differences in testing personnel and environments where the test systems will be used must be taken into consideration when performing the risk assessment; therefore, there may be a need to customize a QCP for each individual location and/or device. Multiple devices may be included in a single QCP; however, performance specifications must be established or verified for each individual device and analyte.

Quality Control Plan: A QCP is a document that describes the practices, resources, and procedures to control the quality of a particular test process. The QCP must ensure the accuracy and reliability of test results, and that test result quality is appropriate for patient care.

The QCP must provide for immediate detection of errors that occur because of test system failure, adverse environmental conditions, and operator performance. It must also monitor, over time, the accuracy and precision of test performance that may be influenced by changes in the test system, environmental conditions, or variance in operator performance.

The QCP must at least include the number, type, frequency

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of testing and criteria for acceptable result(s) of quality control(s). 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

The task of development and implementation of QCP may be delegated (in writing) to a qualified individual. However, the laboratory director has the ultimate responsibility for the proper development and implementation of a QCP. There must be documented evidence that the laboratory director has approved, signed and dated the QCP.

Quality Assessment: All IQCP Quality Assessment monitoring must be part of the laboratory's overall Quality Assessment Plan. The laboratory must establish a review system for the ongoing monitoring of the effectiveness of its IQCP. The monitoring should include, but not be limited to, the following components: testing personnel, environment, specimens, reagents, and the test system. Re-evaluation of the IQCP should be considered when changes occur in any of the above components. Documents to consider for QA review may include, but are not limited to:

- QC review
- Proficiency testing records (scores, testing failures, trends)
- Patient result review
- Specimen rejection logs
- Turnaround time reports
- Records of preventive measures, corrective actions, and follow-up
- Personnel competency records

When the laboratory discovers a testing process failure, the laboratory must conduct an investigation to identify the cause of the failure, its effect on patient care, and make the appropriate modifications to its QCP, as applicable. The investigation must include documentation of all corrections. Corresponding corrective action for all patients affected by the testing process failure, and evaluation of the effectiveness of the corrective action necessary to resolve the failed QC, must be documented. If necessary, the laboratory must update the risk assessment with the new information and modify the QCP as needed.

This article was adapted from the Centers for Medicare and Medicaid Services (CMS) Memo Dated August 16, 2013.

Individualized Quality Control Plans (IQCP)

Key points:

- IQCP replaces EQC
- Education and Transition Phase: January 1, 2014 – December 31, 2015
- Becomes effective January 1, 2016
- Laboratories may establish an IQCP, perform CLIA QC default (two levels of external QC each day of patient testing), or follow the manufacturer’s requirements, if more stringent than CLIA default.

Laboratories can find IQCP educational materials at the **CLIA website**.

Look for more IQCP information in future issues of **Elaborations!**

Calendar of Events

Training Classes:

[2014 Northwest Medical Laboratory Symposium](#)

October 1-4 Portland, OR

[21st Annual Clinical Laboratory Conference](#)

November 10 Tukwila

[2015 ASCLS-WA Spring Meeting](#)

April 23-25, 2015 Olympia

Contact information for the events listed above can be found on page 2. The Calendar of Events is a list of upcoming conferences, deadlines, and other dates of interest to the clinical laboratory community. If you have events that you would like to have included, please mail them to ELABORATIONS at the address on page 2. Information must be received at least one month before the scheduled event. The editor reserves the right to make final decisions on inclusion.

For persons with disabilities, this document is available upon request in other formats. To submit a request, please call 1-800-525-0127 (TTY/TDD) 1-800-833-6388).

