Individualized Quality Control Plan

IQCP

EQC	IQCP
Transitional	Updated Solution
Standardized	Customizable
Rigid	Flexible
Narrow Scope	Broader Scope
Limited regulations Limited Specialties	More Regulations (Excludes Pathology)
Analytic Phase Only	Pre Analytic/Analytic/Post Analytic Phases
Requires Internal QC	Does not Require Internal QC
Decreases External QC	May/May Not decrease QC

New CMS (CLIA) Approach to Quality

August 16, 2013

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

Effective Jan. 1, 2016

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 13-54-CLIA

DATE: **August 16, 2013**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

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

Memorandum Summary

- **IQCP:** The Centers for Medicare & Medicaid Services (CMS) is implementing a new quality control option for laboratories based on risk management.
- **Interpretive Guidelines:** The IQCP Interpretive Guidelines, included with this Memorandum, contain procedures for laboratories and guidance for Regional Office (RO) and State agency (SA) surveyors.
- **Education and Transition Period:** The IQCP Education and Transition Period will begin on 01/01/2014, and conclude on 01/01/2016.
- **Training and Education:** CMS will provide IQCP training for RO and SA surveyors, and IQCP educational materials for laboratories.

Introduction

As previously communicated in S&C 12-03 CLIA and S&C 12-20 CLIA, CMS is implementing a new quality control option based on risk management, 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. Laboratories will continue to have the option of achieving compliance by following all Clinical Laboratory Improvement Amendments (CLIA) QC regulations as written. The laboratory director retains overall responsibility for ensuring that QC programs are established and maintained to assure the quality of laboratory services provided, and to identify failures in quality as they occur.

There will be an IQCP Education and Transition Period to allow laboratories an opportunity to learn about IQCP and implement the laboratories' chosen QC policies and procedures. Before the IQCP Education and Transition Period begins, training will be provided to CLIA surveyors.

WHAT ARE THE 3 STEPS OF THE IQCP?

1. RISK ASSESSMENT

A Risk Assessment identifies and evaluates potential failures and sources of errors in your testing process. It must include, at a minimum, an evaluation of the following five components:

Specimen

Test system

Reagent

Environment

Testing personnel

2. QUALITY CONTROL PLAN (QCP)

A Quality Control Plan is a written document describing the practices and procedures performed by your laboratory to reduce the chance of possible failures and errors in your test processes. for patient care.

Electronic controls

Internal controls

Proficiency testing (PT)

Calibration

Maintenance

Training and competency assessment

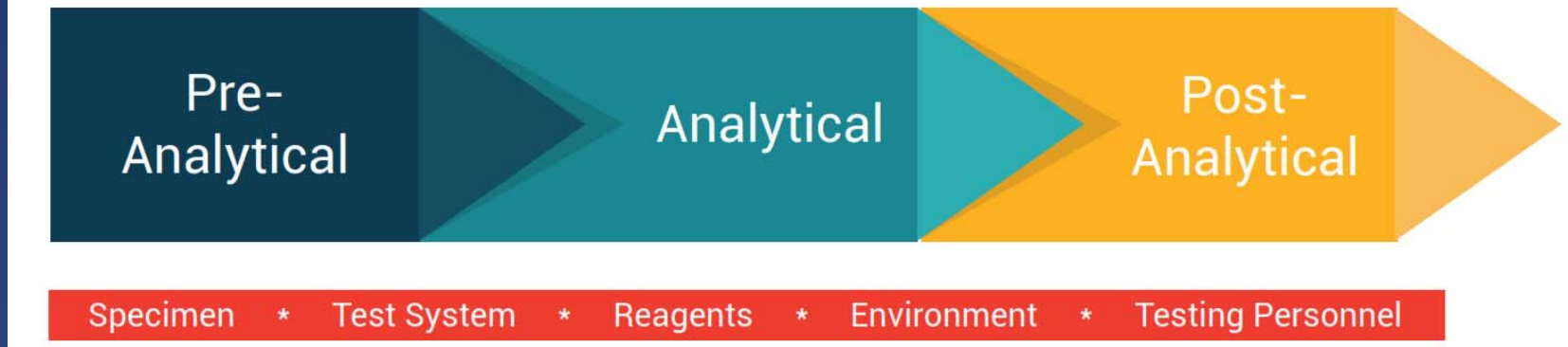
3. QUALITY ASSESSMENT (QA)

Quality Assessment is the continuous process of monitoring the effectiveness of the QCP.

QC reviews
PT performance reviews
Chart reviews
Specimen rejection logs
Turnaround time reports
Complaint reports

STEP 1: RISK ASSESSMENT

A risk assessment is the process of identifying and evaluating the potential failures and errors that could occur during the preanalytical (before testing), analytical (testing), and postanalytical (after testing) phases of testing.


Pre-Analytical
Analytical
Post-Analytical
Specimen * Test System * Reagents * Environment * Testing Personnel

For example, an inadequate specimen volume (i.e. 0.5 ml of whole blood might be collected instead of 1.0 ml as specified by the manufacturers instructions) could fall under more than one risk assessment component:

1. Specimen- manufacturers instructions specify a minimum of 1.0 ml whole blood for the test system, or

2. Test System- wrong specimen volume would result in the reporting of wrong result or test system procedural error, or

3. Reagent- incorrect specimen volume would result in the test kit reagents performing improperly and producing incorrect test results.

RA: Sample Concerns

Based on method/analyte/device and current process

Integrity

- Air bubbles
- Clot
- Interferences

Amount

- Test pack underfilled
- Test pack overfilled

Incorrect Procedure/ Technique

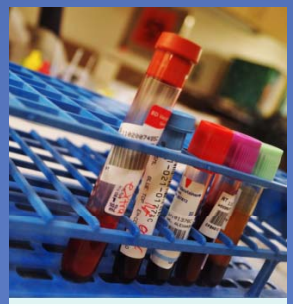
- Test pack handled improperly

Wrong Sample

- Sample collected on the wrong patient
- Wrong anticoagulant

General Specimen Questions to Consider in Your Laboratory

Think about your laboratory and your entire testing process as it relates to the specimen.



Do you see a potential risk of an error in test results if:	Answer
The manufacturer's instructions for specimen requirements including, but not limited to, specimen tube or container type, patient preparation, or specimen storage are not followed?	*Yes ___ No ___*
The current version of the manufacturer's instructions is not used?	*Yes ___ No ___*
The specimen is improperly labeled?	*Yes ___ No ___*
The specimen isn't accurately identified throughout the testing process?	*Yes ___ No ___*
Criteria for specimen rejection are not established and followed?	*Yes ___ No ___*

ASSESSING THE TEST SYSTEM RISKS

Review the manufacturer's instructions, technical bulletins, your policies and procedures, and any other documents associated with the test system. As your review these documents, stop and think about when and where in the testing process a potential error associated with the test system may occur.

RA: Testing System Concerns

Sample Analysis/ Analytical Process

- Adequate Precision
- Adequate Accuracy
- Correlation with Laboratory Method
- Interferences
- Intended Use
- Limitations
- Incorrect Analysis Mode
- Incorrect Program Parameters
- Instrument Error

- Loss/ Corruption of Data
- Electronic Components Failure
- Adequate Battery Charge
- Electronic QC Malfunction
- Adequate Battery Charge
- Software Failure
- Connectivity Software Failure

RA: Testing System Concerns

Measuring System

- Instrument Maintenance
- Dirty Optics
- Contamination
- Scratches

Printer System

- Instrument Failure/ Result Process

Do you see a potential risk of producing incorrect test results if:	Answer
Maintenance procedures are not consistent with the manufacturer's instructions?	*Yes ___ No ___*
The test is performed outside of its intended use as described in the manufacturer's instructions?	*Yes ___ No ___*
The limitations to the test system are ignored. For example, do lipemia or medications interfere with the test systems performance?	*Yes ___ No ___*
Built-in monitors do not exist for the test system, e.g. the ability to detect inadequate specimen volume?	*Yes ___ No ___*
The laboratory information system (LIS) isn't transmitting results or other information accurately?	*Yes ___ No ___*
The test system doesn't have a means to ensure positive patient identification, such as a functioning bar code reader?	*Yes ___ No ___*
There is no mechanism, such as an operator lockout, to ensure only trained personnel use the test system?	*Yes ___ No ___*

ASSESSING REAGENT RISKS

Review the manufacturer's instructions, technical bulletins, your policies and procedures, and any other documents associated with the reagent. As you review these documents, stop and think about when and where in the testing process a potential error associated with the reagent may occur

RA: Reagent Concerns

Test Pack Reagent Degradation

- Temperature
- Humidity
- Dust and debris

Quality Control Material Degradation

- Shipping
- Storage
- Used past expiration date

Quality Control Material Use

- Appropriate Preparation
- Appropriate Use
- Adequate Mixing
- Storage

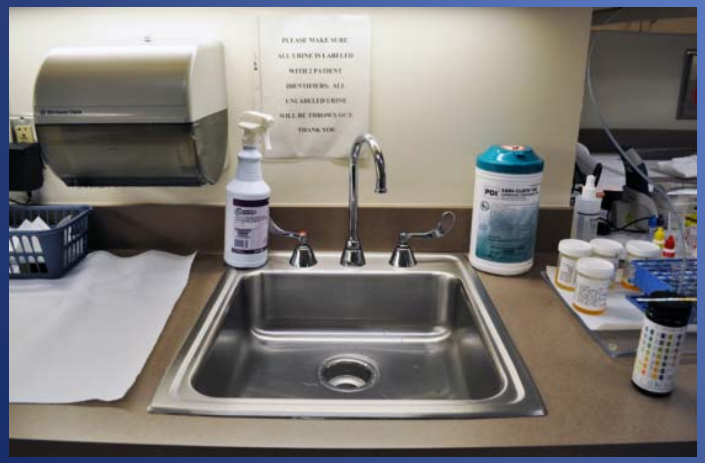
Calibration Verification Material Degradation and Use

- Shipping
- Storage
- Used past expiration date
- Inadequate mixing
- Appropriate preparation
- Appropriate use

Do you see a potential risk of producing incorrect test results if:	Answer
Storage requirements for reagents are not followed?	*Yes ___ No ___*
Integrity of reagents are not checked when received? (e.g. some manufacturers ship reagents on dry ice or icepacks to maintain required temperatures.)	*Yes ___ No ___*
There is a delay in storing reagents upon receipt?	*Yes ___ No ___*
Reagents are shipped to the laboratory at a time when staff are not available to ensure proper storage (e.g. a weekend or holiday)?	*Yes ___ No ___*
Reagents with different lot numbers are mixed? (Consider if the test system has a mechanism to identify reagent lot numbers or if the laboratory will need to track them manually.)	*Yes ___ No ___*
Manufacturer's instructions for reagent preparation are not followed? (e.g. reconstitution of reagents or bringing to room temperature)	*Yes ___ No ___*
The specified type of water required by the test system is not used?	*Yes ___ No ___*

ASSESSING ENVIRONMENT RISKS

Review the manufacturer's instructions, technical bulletins, your policies and procedures, and any other documents associated with the environment. As you review these documents, stop and think about when and where in the testing process a potential error associated with the environment may occur.



RA: Testing Environment Concerns

Atmospheric Environment

- Temperature
- Humidity
- Dust and debris

General Environment

- Airflow/ventilation

Utility Environment

- Electrical Availability
- Interferences
  - Radio Frequency
  - Electromagnetic
- Light Intensity

Do you see a potential risk of producing incorrect test results if:	Answer
The manufacturer's instructions for space and the testing environment are not followed?	*Yes ___ No ___*
The manufacturer's ventilation and airflow requirements are not adhered to?	*Yes ___ No ___*
There is insufficient lighting and space for workflow and the test system?	*Yes ___ No ___*
The manufacturer's instructions for maintaining the appropriate temperature and humidity for the test system are not followed?	*Yes ___ No ___*
Workspace is not free of clutter, dust, or debris?	*Yes ___ No ___*

ASSESSING TESTING PERSONNEL RISKS

Review the manufacturer's instructions, technical bulletins, your policies and procedures, and any other documents associated with testing personnel. As you review these documents, stop and think about when and where in the testing process a potential error associated with testing personnel may occur.

RA: Operator Concerns

Capacity (Ability)

- Training
- Competency
- Untrained operator

Staffing

- Inadequate Staffing

Do you see a potential risk of an error in test results if:	Answer
Laboratory personnel do not have a formal certification or license if required by the state?	*Yes ___ No ___*
The laboratory does not have adequate personnel to perform patient testing in a safe and timely manner?	*Yes ___ No ___*
There is no documentation of CLIA-required competency assessment for all laboratory personnel?	*Yes ___ No ___*
Laboratory personnel are not trained on specimen requirements (collection and type) required for the test system?	*Yes ___ No ___*
Laboratory personnel are not trained to follow the manufacturer's instructions in their entirety?	*Yes ___ No ___*
Laboratory personnel make transcription errors when reporting results, either written or when using an LIS?	*Yes ___ No ___*

1	2	3	4
Risk Assessment Components	What are our possible sources of error? What can go wrong?	Can our identified sources of error be reduced?	How can we reduce the identified sources of error?
	Gather information, from the manufacturer's instructions and other resources, on how we should be performing the testing process.	Yes/No Not Applicable (N/A)	Indicate how to reduce possible error sources. • Internal controls • Actions taken by laboratory • Safeguards in the test system or laboratory practices
SPECIMEN	Documentation of specimen re-collection. Manufacturer's instructions: • Use lithium heparin tubes for whole blood or plasma specimens • Use no additive or serum separator tubes for serum specimens	Yes	Retrain testing personnel on re-collection policy. Train testing personnel to verify use of proper specimen collection tubes.
	Testing time frame/stability of specimen. Manufacturer's instructions: • Whole blood - run within 60 minutes of collection • Store serum or plasma in capped tubes at 2°C to 8°C for 48 hours or at -10°C for up to 5 weeks	Yes	Train testing personnel to verify and document: • Collection time and time of receipt in laboratory • Proper storage and processing of specimen

1	2	3	4
Risk Assessment Components	What are our possible sources of error? What can go wrong?	Can our identified sources of error be reduced?	How can we reduce the identified sources of error?
	Gather information, from the manufacturer's instructions and other resources, on how we should be performing the testing process.	Yes/No Not Applicable (N/A)	Indicate how to reduce possible error sources. • Internal controls • Actions taken by laboratory • Safeguards in the test system or laboratory practices
TEST SYSTEM	QC Results: Manufacturer's instructions - test system does not prevent patient results from being reported when QC is unacceptable.	Yes	Assure testing personnel review each QC result upon completion of the test run. Document QC results in QC log. Report patient results only when QC is acceptable.
	Specimen volume.	N/A	The test system will not perform the test if the specimen volume does not meet the minimum volume requirement.

1	2	3	4
Risk Assessment Components	What are our possible sources of error? What can go wrong?	Can our identified sources of error be reduced?	How can we reduce the identified sources of error?
	Gather information, from the manufacturer's instructions and other resources, on how we should be performing the testing process.	Yes/No Not Applicable (N/A)	Indicate how to reduce possible error sources. • Internal controls • Actions taken by laboratory • Safeguards in the test system or laboratory practices
REAGENT	Reagent expiration date - the test system's QC does not detect the use of expired reagents prior to testing. Manufacturer's instructions - do not use discs after expiration date.	Yes	Train testing personnel to check reagent expiration dates prior to using them for testing.
	Testing the external normal and abnormal controls. Manufacturer's instructions: • Test and document external normal and abnormal controls: ◦ Every 30 days ◦ At change of reagent disc lot number ◦ Whenever laboratory conditions have changed significantly ◦ When training or retraining of personnel is indicated ◦ Whenever test results do not match patient symptoms or clinical findings	Yes	Train testing personnel to perform external QC procedures, as described in the manufacturer's instructions.

1	2	3	4
ENVIRONMENT	Room temperature: Manufacturer's instructions - operate test system at temperatures between 20°C and 25°C.	Yes	Record room temperature daily in the morning and afternoon, and adjust as needed to maintain 20° - 25°C.
	Proper ventilation of instrument: Manufacturer's instructions - do not locate test system in front of room air in-take and out-take flow vents.	Yes	Move test system to a location away from air conditioning vents to meet manufacturer's requirements.
TESTING PERSONNEL	Improperly trained personnel.	Yes	Train testing personnel on specimen requirements, and proper performance of test according to manufacturer instructions.
	Competency assessment does not include all CLIA required elements.	Yes	Evaluate competency assessment policy and procedures, rewrite to include all CLIA required elements. Perform and document competency assessment for all testing personnel. Competency assessments required for new employees at least every six months, and annually thereafter, or when test methodology and test system changes.
	Verbal reporting of test results prior to LIS entry.	Yes	Update policy to require testing personnel do not verbally release results until they are entered into the LIS.

Quality Control Plan

At a minimum, your QCP must include the number, type, and frequency of testing control materials, as well as criteria for acceptable quality control. If indicated by the risk assessment, your QCP may also incorporate the use of:

- **Electronic controls**
- **Equipment maintenance**
- **Internal controls**
- **Personnel training and competency assessment**
- **Equipment calibration**
- **Other specified quality control activities**

1. **Document temperatures** for the refrigerator and freezer and room temperature each day. The acceptable criteria for temperature ranges must be included in the temperature logs.
2. **Verify specimen collection tubes** for acceptability upon receipt in the laboratory. Document improperly collected specimens following established Specimen Rejection Policy.
3. **Verify specimen collection and receipt times** on the test order forms prior to loading the sample.. Train testing personnel regarding specimen collection and storage.
4. **Test and document reagent stability** by running external normal and abnormal controls per manufacturer's instructions
5. **Verify and document Internal QC** as "acceptable" for each patient test performed before patient results are reported.
6. **Document the date and time** when reagent are removed from the refrigerator.
7. **Verify that training of testing personnel**, upon hire and when indicated, documents successful demonstration of competency as indicated by laboratory policy and regulations.

Do the QC activities identified in your Risk Assessment:	Answer
Provide for immediate detection of errors for each phase of the testing process (i.e. before, during, and after testing) for the test?	*Yes ___ No ___*
Specify the number, type, and frequency of testing QC material(s)?	*Yes ___ No ___*
Contain criteria to determine acceptable QC results?	*Yes ___ No ___*
Require the laboratory perform QC as specified by the manufacturer's instructions, but not less than the manufacturer's instructions?	*Yes ___ No ___*
Indicate that your Laboratory Director has reviewed, signed and dated the QCP document?	*Yes ___ No ___*


Quality Assessment
Risk Assessment
Quality Control Plan

Quality Assessment (QA) can be described as a multi-part activity.

Monitor and Assess

The laboratory must establish and follow written policies and procedures to monitor and assess, and when indicated, correct problems identified. The monitoring should include, but is not limited to, the following risk assessment components: specimen, test system, reagents, environment, and testing personnel.

Corrective Action

The QA must also include a review of the effectiveness of corrective actions taken to resolve problems identified. The laboratory must update the risk assessment and modify the QCP, as necessary based on the information obtained from the QA.

Example of a QC activity:

* Recording the room temperature on a log sheet
* Documenting controls on log sheets
* Documenting personnel training

Example of a QA activity:

* Reviewing the room temperature log sheet for problems and evidence of corrective actions
* Reviewing control documents for out of range values and corrective actions taken
* Reviewing personnel training records for completion of required trainings and competency assessments

DOCUMENTS TO CONSIDER FOR QUALITY ASSESSMENT MONITORING AND REVIEW MAY INCLUDE:

- QC data sheets review
- Delta check logs
- PT records (scores, testing failures, trends)
- Complaint reports
- Patient results review
- Specimen recollection logs
- Specimen rejection or quantity not sufficient logs
- Turnaround time reports
- Temperature logs
- Records of preventive measures, corrective actions, & follow-up
- Personnel competency records
- Maintenance logs
- Training logs

Quality Assessment helps you:

*** Make sure that your QCP is working as expected**

*** Monitor errors and QC failures**

*** Identify errors and failures so you can take the appropriate corrective action**

*** Investigate the cause of the error and reassess your risk assessment, if indicated**

*** Evaluate whether any changes need to be made in the QCP**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