



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.

IQCP Interpretive Guidelines

Attached to this document are the IQCP Interpretive Guidelines (IGs) (Attachment 1). They provide the procedures for laboratories that wish to use IQCP to meet CLIA QC requirements for equivalent quality testing. IQCP builds on the key concept of Quality Systems, which was introduced in 2003 with the release of Subpart K, Quality System for Nonwaived Testing, by including all phases of testing in the risk analysis for each test system.

The CLIA regulation at 42 CFR 493.1250 provides the Department of Health and Human Services (HHS) with the authority to approve another QC procedure option for the Analytic Systems section of the CLIA regulations. With that in mind, CMS evaluated the regulations and determined that the scope of IQCP would include nonwaived testing in all CLIA specialties and subspecialties EXCEPT Pathology, Histopathology, Oral pathology, and Cytology.

IQCP Education and Transition Period

Beginning and ending dates: The IQCP Education and Transition Period will begin on 01/01/2014, and conclude on 01/01/2016.

Beginning of the IQCP Education and Transition Period: On the beginning date, laboratories may begin to implement IQCP as a QC option.

During the IQCP Education and Transition Period: Laboratories will have three acceptable QC options during the IQCP Education and Transition Period:

1. Follow the CLIA regulatory requirements as written.
2. Continue to follow the Equivalent Quality Control (EQC) procedures as described in the current Interpretive Guidelines in Appendix C.
3. Implement IQCP as described in Attachment 1, Individualized Quality Control Plan.

During this time, laboratories should learn about IQCP. We expect to amend Appendix C to insert IQCP effective 1/1/2016. When we do this, the current version of EQC in Appendix C will no longer be an acceptable option after 01/01/2016; therefore, laboratories using EQC should consider which QC option (regulatory requirements or IQCP) they would want to use when we ultimately do change over to IQCP. If a laboratory is considering the IQCP option, we recommend using the transition period to become familiar with IQCP and to test laboratory operations under that option. We will modify the IGs in Appendix C of the State Operations Manual (CMS Pub. 7) prior to the conclusion of the IQCP Education and Transition Period, to remove the EQC option and insert the IQCP option.

Conclusion of the IQCP Education and Transition Period: The IQCP Education and Transition Period will end on 01/01/2016. After that date, EQC will no longer be an acceptable option for CLIA QC compliance. There will be two acceptable options:

1. Follow the CLIA regulatory requirements as written.
2. Implement IQCP as described in Attachment 1, Individualized Quality Control Plan.

After the IQCP Education and Transition Period ends, laboratories will receive deficiency citations if they are not in compliance with one of these options.

Guidance for surveyors during the IQCP Education and Transition Period

During the IQCP Education and Transition Period, CMS will generally follow a policy of educational surveys for quality control requirements. Surveyors will continue to use the Outcome Oriented Survey Process (OOSP).

- When a surveyor identifies *quality testing problems* related to quality control methods, the surveyor will cite the applicable QC regulations(s) in 42 CFR 493.1256(d)(3)-(5), (e)(1)-(4), or the appropriate specialty or subspecialty requirements specified in Attachment 1, Individualized Quality Control Plan.
- The laboratory will only be cited as out of compliance with the CLIA quality requirements if it does no QC, or there are serious concerns about test quality, or there is immediate jeopardy (i.e., real or potential harm to patients).
- When a surveyor encounters a situation in which a laboratory is performing QC less frequently than current CLIA requirements, the surveyor would document the non-compliance by sending the letter contained in Attachment 2: General Letter for CoC Laboratories Which Have Been Doing QC That Does Not Meet CLIA. This letter explains that the laboratory must come into compliance by following the CLIA regulations as written or by implementing IQCP.
- When a surveyor encounters a situation in which a laboratory has already implemented IQCP that does not fully conform to the IQCP procedure in Attachment 1, Individualized Quality Control Plan, the surveyor would document this by sending the letter contained in Attachment 3: Letter for CoC Laboratories Which Have Already Attempted to Implement IQCP. This letter lists the specific IQCP items from Attachment 1, Individualized Quality Control Plan, that are not addressed in the laboratory's documentation.

Training and educational materials

Training for RO and SA surveyors is under development. RO training is scheduled to occur the week of September 16, 2013. SA training is scheduled to occur the week of November 18, 2013. More details and registration information will be sent at a later date.

Educational materials for laboratories are also under development. Materials will be released periodically before and during the IQCP Education and Transition Period. Laboratories are advised to check the CLIA web site for updated information: http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Individualized_Quality_Control_Plan_IQCP.html. State agencies should expect to receive questions and inquiries from laboratories during and after the IQCP Education and Transition Period.

Accredited laboratories and laboratories in exempt States

CMS-approved accreditation organizations (AOs) and exempt States (ESs) have been informed about IQCP. Each AO and ES will determine whether or not to incorporate IQCP into their standards for laboratories. Any related changes in standards must be reviewed and approved by CMS prior to implementation.

Laboratories that receive CLIA certification by virtue of accreditation by a CMS-approved AO, or are subject to regulation by an ES, should continue to follow the requirements of their AO or ES.

Further Information

An IQCP Timeline (Attachment 4) and a list of Frequently Asked Questions (Attachment 5) are included with this Memorandum. Please direct any questions to the IQCP mailbox, IQCP@cms.hhs.gov.

Effective Date: 01/01/2014 (beginning of IQCP Education and Transition Period). This policy should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators within 30 days of this memorandum.

/s/

Thomas E. Hamilton

Attachment (s)

Attachment 1: Individualized Quality Control Plan Interpretive Guidelines (IGs)

Attachment 2: General Letter for CoC Laboratories Which Have Been Doing QC That Does Not Meet CLIA

Attachment 3: Letter for CoC Laboratories Which Have Already Attempted to Implement IQCP

Attachment 4: IQCP Timeline

Attachment 5: Frequently Asked Questions

cc: Survey and Certification Regional Office Management

Attachment #1

INDIVIDUALIZED QUALITY CONTROL PLAN

D5445

§493.1256 Standard: Control Procedures

(d) Unless CMS Approves a Procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--

(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at §§493.1261 through 493.1278.

(d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section.

Interpretive Guidelines §493.1256(d)

INDIVIDUALIZED QUALITY CONTROL PLAN (IQCP)

INTRODUCTION

§493.1250 allows HHS to approve a procedure that provides equivalent quality testing to meet the Analytic Systems requirements in §493.1251 - §493.1283. CMS has approved a procedure which permits laboratories to develop and customize quality control procedures in their healthcare settings. This procedure is termed Individualized Quality Control Plan (IQCP). An IQCP is comprised of three parts, a risk assessment (RA), a Quality Control Plan (QCP), and a Quality Assessment (QA) plan. The RA is the identification and evaluation of potential failures and errors in a testing process. A QCP is a laboratory's standard operating procedure that describes the practices, resources, and procedures to control the quality of a particular test process. The QA is the laboratory's policy for the ongoing monitoring of the effectiveness of their IQCP.

When the manufacturer's instructions for quality control are absent or less stringent than the Analytic Systems control procedures listed in Table 1, Eligibility for IQCP, the laboratory must develop an IQCP if they wish to perform control procedures that are less stringent than the regulatory requirements. Laboratories have the flexibility to follow all regulatory requirements as written or customize their control procedures using the IQCP procedure. Whichever option is selected, laboratories are not permitted to establish quality control procedures that are less stringent than those specified by the manufacturer of the test system.

LABORATORY DIRECTOR RESPONSIBILITIES

Under subpart M, the laboratory director is responsible for ensuring that quality control (use D6020 or D6093 as appropriate) and quality assessment (use D6021 or D6094 as appropriate) programs are established and maintained to assure the quality of laboratory services, including the identification of failures in quality as they occur (use D6022 or D6094).

The laboratory director is responsible for deciding whether a laboratory will seek to meet its CLIA quality control obligations through IQCP, and if they decide to do so, they are also responsible for ensuring that the QCP they develop meets the IQCP requirements.

The laboratory director must consider the laboratory's clinical and legal responsibility for providing accurate and reliable patient test results (§493.1407 or §493.1445) prior to implementing a QCP that is less stringent than the specified Analytic Systems control regulations listed in Table 1, Eligibility for IQCP.

REGULATORY CONSIDERATIONS

All CLIA regulations, other than those specifically designated as eligible for IQCP in Table 1, Eligibility for IQCP, continue to be in force and must be followed.

Table 1, Eligibility for IQCP, lists those specialties/subspecialties and general regulations for which the laboratory has the flexibility to develop control procedures using the IQCP procedure. Table 1 also lists those specialties/subspecialties and specialty/subspecialty regulations which are not eligible for IQCP.

- The first column lists the CLIA specialties/subspecialties: Bacteriology, Mycobacteriology, Mycology, Parasitology, Virology, Syphilis Serology, General Immunology, Routine Chemistry, Urinalysis, Endocrinology, Toxicology, Hematology, Immunohematology, Clinical Cytogenetics, Radiobioassay, Histocompatibility, Pathology, Histopathology, Oral Pathology, and Cytology.*
- The second column indicates whether or not each specialty/subspecialty is eligible for IQCP. The specialties/subspecialties eligible for IQCP are: Bacteriology, Mycobacteriology, Mycology, Parasitology, Virology, Syphilis Serology, General Immunology, Routine Chemistry, Urinalysis, Endocrinology, Toxicology, Hematology, Immunohematology, Clinical Cytogenetics, Radiobioassay, and Histocompatibility. The specialties/subspecialties not eligible for IQCP are: Pathology, Histopathology, Oral Pathology, and Cytology.*
- The third column lists the regulations that are eligible for IQCP and may be applied to the eligible specialty/subspecialties listed in column one: §493.1256(d)(3)-(5) and §493.1256(e)(1)-(4).*
- The fourth column lists the specialty/subspecialty regulations that are eligible for IQCP: §493.1261, §493.1262, §493.1263, §493.1264, §493.1265, §493.1267(b),(c), §493.1269,*

and §493.1278(b)(6),(c),(d)(6),(e)(3).

- The fifth column lists the specialty/subspecialty regulations that are not eligible for IQCP: §493.1267(a),(d), §493.1271, §493.1276, and §493.1278(a),(b)(1-5), (d)(1-5),(d)(7),(e)(1-2),(f),(g).

CLIA Specialty/ Subspecialty	Eligible for IQCP?	General Regulations Eligible for IQCP	Specialty/ Subspecialty Regulations Eligible for IQCP	Specialty/ Subspecialty Regulations <u>NOT</u> Eligible for IQCP
Bacteriology	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	§493.1261	N/A
Mycobacteriology	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	§493.1262	N/A
Mycology	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	§493.1263	N/A
Parasitology	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	§493.1264	N/A
Virology	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	§493.1265	N/A
Syphilis Serology	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	N/A	N/A
General Immunology	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	N/A	N/A
Routine Chemistry	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	§493.1267(b),(c)	§493.1267(a), (d)
Urinalysis	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	N/A	N/A
Endocrinology	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	N/A	N/A
Toxicology	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	N/A	N/A
Hematology	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	§493.1269	N/A
Immunohematology	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	N/A	§493.1271
Clinical Cytogenetics	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	N/A	§493.1276
Radiobioassay	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	N/A	N/A

<i>CLIA Specialty/ Subspecialty</i>	<i>Eligible for IQCP?</i>	<i>General Regulations Eligible for IQCP</i>	<i>Specialty/Subspeci alty Regulations Eligible for IQCP</i>	<i>Specialty/ Subspecialty Regulations NOT Eligible for IQCP</i>
<i>Histocompatibility</i>	<i>Yes</i>	<i>§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)</i>	<i>§493.1278(b)(6), (c), (d)(6), (e)(3)</i>	<i>§493.1278(a), (b)(1-5), (d)(1-5), (d)(7), (e)(1-2), (f), (g)</i>
<i>Pathology</i>	<i>No</i>	<i>None (Not eligible for IQCP)</i>	<i>N/A</i>	<i>N/A</i>
<i>Histopathology</i>	<i>No</i>	<i>None (Not eligible for IQCP)</i>	<i>N/A</i>	<i>N/A</i>
<i>Oral Pathology</i>	<i>No</i>	<i>None (Not eligible for IQCP)</i>	<i>N/A</i>	<i>N/A</i>
<i>Cytology</i>	<i>No</i>	<i>None (Not eligible for IQCP)</i>	<i>N/A</i>	<i>N/A</i>

Table 1: Eligibility for IQCP

Probe(s) §493.1256(d)

For each test system, does the laboratory perform quality control testing procedures as specified in the manufacturer's instructions? Use D5411.

If the manufacturer's instructions are less stringent than the CLIA regulatory requirements for control procedures, did the laboratory perform an IQCP or are they following the CLIA regulatory requirements for control procedures?

An IQCP must include:

- Risk Assessment (RA)
- Quality Control Plan (QCP)
- Quality Assessment (QA)

Risk Assessment

Risk assessment is the identification and evaluation of potential failures and sources of errors in a testing process.

Risk assessments for IQCP must include, at a minimum, an evaluation of the following five components:

- Specimen
- Environment
- Reagent
- Test system
- Testing personnel

The scope of risk assessments must encompass the entire testing process: preanalytic, analytic, and postanalytic phases and include, at a minimum, the evaluation of the five risk assessment components listed above. Use D5445.

The laboratory director has the responsibility for ensuring that the risk assessment considers both the CLIA requirements for accurate and reliable test results and that test result quality is appropriate for patient care.

Conducting the Risk Assessment

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.

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 QCP. Use D5425. Data from verification or establishment of performance specifications and historical (existing) QC data can be included. Published data or data from manufacturers (e.g., package inserts) may be taken into consideration, but may not be used as the sole criteria for decision-making. All RA documentation must be maintained for at least two years after the corresponding QCP has been discontinued. Use D3029.

Note: Manufacturer-provided tools and templates, if available, may be helpful for laboratories implementing IQCP; however, laboratories will need to supplement these materials with laboratory-specific information as part of the Risk Assessment. The manufacturer information is not sufficient in and of itself.

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
- Manufacturers' alerts and bulletins
- Verification or 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 they wish to replace with IQCP. See Table 1, Eligibility for IQCP, in Regulatory Considerations section for applicable QC regulatory requirements.

Laboratories must assess information provided by manufacturers, including the manufacturer's instructions, in order to perform the risk assessment specific to their laboratory. If a laboratory needs additional information that does not appear in the manufacturer's instructions in order to conduct the risk assessment, the manufacturer should be contacted to request the needed information.

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.

Note: Multiple devices may be included in a single QCP; however performance specifications must be established or verified for each individual device and analyte.

Probes §493.1256(d)

Does the laboratory's RA support its frequency of testing quality control samples? Use D5445.

Has the laboratory included all 5 components and all phases of testing in their risk assessment, and have they reasonably identified and evaluated the potential failures and sources of error? Use D5445.

Has the laboratory conducted a risk assessment for each location where testing is performed on multiple numbers of identical devices (same make, model)?

For example:

- Multiple lab/testing locations within a single CLIA number
- Point-of care devices throughout health care/laboratory systems
- Multiple identical devices or kits in a single location

Has the laboratory identified the sources of potential failures and sources of error contained in the most current manufacturer's instructions?

Has the laboratory documented all activities completed for the risk assessment? Does the laboratory have documentation, including data, to support their risk assessment? Use D5481.

SPECIMEN

Probe §493.1256(d)

Has the laboratory identified and evaluated the potential failures and sources of error in the preanalytic phase, as applicable, for

- *Patient preparation*
- *Specimen collection*
- *Specimen labeling*
- *Specimen storage, preservation, and stability*
- *Specimen transportation*
- *Specimen processing*
- *Specimen acceptability and rejection*
- *Specimen referral*

ENVIRONMENT

Probes §493.1256(d)

Has the laboratory evaluated environmental conditions which may affect test system performance including, but not limited to:

- *Temperature*
- *Airflow/ventilation*
- *Light intensity*
- *Noise and vibration*
- *Humidity*
- *Altitude*
- *Dust*
- *Water*
- *Utilities (Electrical failure/power supply variance or surge)*
- *Adequate space*

How does a mobile laboratory ensure the accuracy of test results when instruments and reagents are transported from one test site to another?

REAGENT

Factors to consider in the risk assessment for reagents, quality control materials, calibrators, and similar materials may include, but are not limited to:

- *Shipping/Receiving*
- *Storage condition requirements*
- *Expiration Date (may differ based on storage requirements)*

- Preparation

Probes §493.1256(d)

Has the laboratory assessed test system failures which may result from reagent, quality control material, and calibrator contamination or deterioration and reagent lot variation?

Has the laboratory addressed the risk of inadvertently mixing reagents from different kits or lot numbers, if applicable?

TEST SYSTEM

The risk assessment must include function checks and maintenance checks as required by, and not less than, manufacturer instructions. In addition, the risk assessment should take into consideration the laboratory's test volume, and intended use of the test results (i.e., screening or diagnostic).

Additional factors to consider in the risk assessment for analyte and test systems may include, but are not limited to:

- 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

TESTING PERSONNEL

Laboratories must involve a representative sample of testing personnel in the process of conducting the risk assessment. It is not necessary for all personnel to be involved.

Probe §493.1256(d)

Has the laboratory assessed the risks associated with testing personnel by evaluating the following:

- Training
- Competency
- Appropriate education and experience qualifications
- Adequate staffing

After the laboratory 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 risk assessment is then used to develop the Quality Control Plan (QCP).

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 the immediate detection of errors that occur due to 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. Use D5441.

The QCP must at least include the number, type, frequency of testing and criteria for acceptable result(s) of the quality control(s). Use D5441 or D5469, as appropriate.

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 QCPs may be delegated (in writing) to a qualified individual. (§493.1407(e)(14) or §493.1445(e)(15)). However, the laboratory director has the ultimate responsibility for the proper development and implementation of a QCP. (§493.1407(b) or §493.1445(b)). There must be documented evidence that the laboratory director has approved, signed and dated the QCP (§493.1251(d)). Use D5407.

Probes §493.1256(d)

Does the laboratory have a written QCP for each test system, as applicable? Use D5441 or D5445, as appropriate.

Does the QCP specify the number, type, and frequency of testing of the quality control material(s)? Does it provide for immediate detection of errors? Use D5441. Does it contain criteria to determine acceptable quality control results? Use D5469.

Does the QCP require that the laboratory will perform QC as specified by the manufacturer's instructions? If performing QC less frequently than required by the manufacturer, use D5411 or D5445, as appropriate.

Is there documented evidence of laboratory director approval of the QCP before it was put into use? Use D5407.

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 their IQCP. The monitoring should include, but is not limited to, the following components: testing personnel, environment, specimens, reagents, and test system. Reevaluation of the QCP 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 results review*
- *Specimen rejection logs*
- *Turnaround time reports*
- *Records of preventive measures, corrective actions, & 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 impact on patient care, and make appropriate modifications to their QCP, as applicable. The investigation must include documentation of all corrections, corresponding corrective actions for all patients affected by the testing process failure, and evaluation of the effectiveness of the corrective action(s). The laboratory must implement the correction(s) and corresponding corrective action(s) necessary to resolve the failure and reduce the risk of recurrence of the failure in the future. If necessary, the laboratory must update the risk assessment with the new information and modify the QCP, as needed.

Probes §493.1256(d)

Has the laboratory established a review system for the ongoing monitoring of the QCP (use D5391, D5791 or D5891 as appropriate) and evaluation of its effectiveness? (Use D5393, D5793 or D5893 as appropriate)

In the event of a testing process failure, has the laboratory evaluated all patient test results since the last acceptable quality control? Use D5783.

Acknowledgement

Section 493.1250 allows HHS to approve a procedure that provides equivalent quality testing to the analytic systems requirements in §493.1251 - §493.1283. In light of advancements in technology, CMS has adopted a risk based approach termed Individualized Quality Control Plan (IQCP). The Clinical and Laboratory Standards Institute (CLSI) document EP23-A—“Laboratory Quality Control Based on Risk Management; Approved Guideline” provides helpful guidance to laboratories on the development of quality control plans for test systems. Portions of the EP23-A document capture the principles of our intended policies. So, as EP23-A is a copyrighted work of CLSI, we obtained CLSI’s permission to utilize those portions of the CLSI EP23-A Guideline that captured our intended policies for IQCP under the equivalent quality testing provisions of the CLIA program.

GENERAL LETTER FOR CoC LABORATORIES WHICH HAVE BEEN DOING QC THAT DOES NOT MEET CLIA

Dear Laboratory Director,

A representative of the [State Survey Agency] surveyed your laboratory on [date] for the Centers for Medicare & Medicaid Services (CMS) for Clinical Laboratory Improvement Amendments (CLIA) certification purposes. Thank you for your cooperation and the courtesies extended to the surveyor. At the time of your survey, the surveyor observed certain QC practices that did not fully meet the 2003 CLIA regulations.

*******List the specific D-tags from 493.1256 not met by the laboratory here. Include a description of each regulatory citation in clear language to accompany the citation and clarify it.*******

We are issuing this non-compliance notice as a letter, rather than a formal enforcement action (Form CMS-2567), as part of an educational effort. The following information is provided to help you ensure your laboratory's CLIA compliance by its next routine biannual recertification survey. You should start planning now to allow sufficient time to implement the necessary changes by the time of your next survey.

All other applicable unmet CLIA requirements are cited on the CMS-2567, deficiency report, and must be corrected timely.

CLIA Quality Control (QC) Policies and Oversight

For the past several years, CLIA has been in an educational survey mode for certain QC regulations. During this time, laboratories that may not have fully met the 2003 CLIA QC regulations in their entirety were not sanctioned as long as such deficient practices did not result in "Immediate Jeopardy" or serious quality testing problems.

CMS recently completed development of a new alternative QC option, called Individualized Quality Control Plan (IQCP). IQCP can be described as QC based on risk management. The IQCP policies and procedures require the identification and evaluation of potential failures in a testing process, and the development of control procedures to reduce the risk of an incorrect patient test result. IQCP allows flexibility for laboratories to design QC policies and procedures based on the characteristics of each non-waived test system in use and the unique aspects of each laboratory's operation. The policies and procedures for IQCP are contained in the optional IQCP Interpretive Guidelines (IGs), which are available on the CLIA web site at www.xxxx.gov. Additional educational IQCP materials can be found at www.yyyy.gov.

IQCP Education and Transition Period

Beginning on 01/01/2014, CMS entered an Educational and Transition Period aimed at the eventual implementation of IQCP. During this time, laboratories now have an opportunity to refresh their knowledge of the CLIA QC regulations and to learn about IQCP. By the end of the IQCP Education and Transition Period, each laboratory's QC policies and procedures will need to be transitioned to one of two QC options: 1) Follow the CLIA regulations for control procedures as written or 2) Implement IQCP as described in the IQCP IG. (Note: Laboratories should be aware that QC procedures contained in

manufacturer's instructions may not meet CLIA regulations; for those test systems, laboratories must choose to implement IQCP or follow the CLIA QC regulations.)

During the IQCP Education and Transition Period, CLIA surveys will continue in the educational mode, that is, laboratories must perform some level of QC. However, in those situations where serious testing problems result from deficient QC practices, where no QC is performed at all, or immediate jeopardy is found, deficiencies will be cited.

IQCP Implementation

We expect that the IQCP Education and Transition Period will come to a close, the current EQC in Appendix C of the SOM will be retired, IQCP will be adopted in its place and CMS CLIA surveys will no longer be conducted in the educational mode effective 01/01/2016. When these things transpire, there will be two options for CLIA compliance:

- 1) Follow the CLIA QC regulations as written, or
- 2) Implement IQCP as described in the IQCP IGs.

QC procedures that do not meet one of these two options noted above will be considered out of compliance and the laboratory will be cited accordingly (Form CMS-2567). Therefore, by the time your laboratory receives its next routine biannual CLIA survey, the IQCP Education and Transition period will be over and your the laboratory will be expected to be in compliance with one of these two options.

At the time of your most recent survey, your laboratory was provided with educational materials on IQCP. We encourage you to review them carefully, study the IQCP Interpretive Guidelines at www.xxxx.gov, start evaluating your QC procedures, and begin to make your transition plans accordingly. If you have any questions or concerns, please contact [insert SA contact information].

Sincerely,

LETTER FOR CoC LABORATORIES WHICH HAVE ALREADY IMPLEMENTED IQCP

Dear Laboratory Director,

A representative of the [State Survey Agency] surveyed your laboratory on [date] for the Centers for Medicare & Medicaid Services (CMS) for Clinical Laboratory Improvement Amendments (CLIA) certification purposes. Thank you for your cooperation and the courtesies extended to the surveyor.

At the time of your survey, the CLIA surveyor noted that your laboratory has already implemented an Individualized Quality Control Plan (IQCP) for some or all of your testing. You are commended for taking a proactive approach to implementing IQCP.

The optional IQCP procedure is fully described in Attachment I, Individualized Quality Control Plan, found at www.xxxx.gov. While on-site, the surveyor noted that, as reflected in your laboratory's documentation, some aspects of your IQCP implementation did not appear to fully meet Attachment I, Individualized Quality Control Plan. Specifically, we recommend that you review your IQCP documentation for the presence of the following items [select as appropriate].

- The Risk Assessment (RA) must address all 5 required components: specimen, environment, reagent, test system, and testing personnel
- The RA must cover the 3 phases of testing: preanalytic, analytic, and postanalytic
- The RA must include in-house data, established by the laboratory and by its own personnel
- The quality control plan (QCP) must be approved, signed, and dated by the laboratory director
- The quality assessment (QA) program must include a review system for the ongoing monitoring of IQCP effectiveness

CLIA Quality Control (QC) Policies and Oversight

For the past several years, CLIA has been in an educational survey mode for certain QC regulations. During this time, laboratories that may not have fully meet the 2003 CLIA QC regulations in their entirety were not sanctioned as long as such deficient practices did not result in "Immediate Jeopardy" or serious quality testing problems, or no QC was performed.

As you know, CMS recently completed development of a new equivalent QC option, called IQCP. IQCP can be described as QC based on risk management. The IQCP policies and procedures require the identification and evaluation of potential failures in a testing process, and the development of control procedures to reduce the risk of an incorrect patient test result. IQCP allows flexibility for laboratories to design QC policies and procedures based on the characteristics of each non-waived test system in use and the unique aspects of each laboratory's operation. The policies and procedure for IQCP are contained in the optional Attachment I, Individualized Quality Control Plan, which is available on the CLIA web site at www.xxxx.gov. Additional educational IQCP materials can be found at www.yyyy.gov.

IQCP Education and Transition Period

Beginning on 01/01/2014, CMS entered an Educational and Transition Period aimed at the eventual implementation of IQCP. During this time, laboratories now have an opportunity to refresh their knowledge of the CLIA QC regulations and to learn about IQCP. By the end of the IQCP Education and

Transition Period, each laboratory's QC policies and procedures will need to be transitioned to one of two QC options: 1) Follow the CLIA regulations for control procedures as written or 2) Implement IQCP as described in Attachment I, Individualized Quality Control Plan. (*Note:* Laboratories should be aware that QC procedures contained in manufacturer's instructions may not meet CLIA regulations; for those test systems, laboratories must also choose to follow the CLIA QC requirements or implement IQCP)

During the IQCP Education and Transition Period, CLIA surveys will continue in the educational mode, that is, laboratories must perform some level of QC. However, in those situations where serious testing problems result from deficient QC practices, where no QC is performed at all, or immediate jeopardy is found, deficiencies will be cited.

IQCP Implementation

The IQCP Education and Transition Period will come to a close, the current EQC will be retired, IQCP will be adopted in Appendix C of the SOM and CMS CLIA surveys will no longer be conducted in the educational mode on 01/01/2016. When these things transpire, there will be two options for CLIA compliance:

- 1) Follow the CLIA QC regulations as written, or
- 2) Implement IQCP as described in the IQCP IGs.

QC procedures that do not meet one of these two options noted above will be considered out of compliance and the laboratory will be cited accordingly (Form CMS -2567). Therefore, by the time your laboratory receives its next routine biannual CLIA survey, the IQCP Education and Transition period will be over and the laboratory is expected to be in compliance with one of these two options.

At the time of your most recent survey, your laboratory was provided with educational materials on IQCP. We encourage you to review them carefully, study the IQCP Interpretive Guidelines at www.xxxx.gov, evaluate your QC procedures, and continue to make your transition plans accordingly. If you have any questions or concerns, please contact

Sincerely,

Attachment 4: IQCP Timeline

Week of September 15, 2013	IQCP Training for RO CLIA surveyors
Week of November 18, 2013	IQCP Training for SA CLIA surveyors
January 1, 2014:	IQCP Education and Transition Period Begins
January 1, 2016:	IQCP Education and Transition Period Ends

FAQs for IQCP

GENERAL:

1. What is IQCP?

IQCP stands for Individualized Quality Control Plan, and will be the formal policy name for the alternative CLIA Quality Control (QC) option that will provide for equivalent quality testing for 42 CFR 493.1250 after it is incorporated in Appendix C of the State Operations Manual. Prior to placing IQCP in Appendix C, however, we will allow for an educational period in which the former “Equivalent Quality Control” (EQC) will remain in Appendix C, and IQCP will be available for voluntary use as described in Attachment 1- Individualized Quality Control Plan (IQCP). We will be retiring EQC and adopting IQCP in Appendix C as the official alternative quality control method for CLIA after the IQCP Educational and Transitional period.

2. What are the three parts of an IQCP? What is required in an IQCP?

The IQCP consists of three parts: Risk Assessment (RA), Quality Control Plan (QCP), and Quality Assessment (QA), all of which are outlined in the Attachment 1- IQCP.

3. Is IQCP intended to reduce the amount of quality control in laboratories?

This new QC protocol will not necessarily reduce QC, but instead, IQCP will permit the laboratory to develop an effective QC protocol that recognizes technology enhancements that are built into test systems and be customizable to reflect the laboratory’s own unique environment, patients, testing personnel, test systems, etc.

4. Are CLIA QC regulations changing to accommodate IQCP? What about other CLIA quality system requirements?

No, CLIA QC regulations will remain the same as published in 2003. All the preanalytical, analytical and postanalytical systems requirements in the CLIA regulations will remain in effect. We are exercising our enforcement discretion to allow laboratories to use the Attachment 1- IQCP in lieu of certain regulatory requirements in anticipation of placing IQCP in Appendix C of the State Operations Manual as an official “Equivalent Quality Control” method. We note, however, that the regulatory requirements which one would use IQCP in lieu of may present useful concepts to consider when laboratories using IQCP seek to identify where failures in a process may occur and should be considered during the IQCP RA.

5. Will accrediting organizations (AO) and exempt states (ES) be required to accept the use of the IQCP option?

It will be optional for AOs and ESs to incorporate IQCP into their standards; however, any standards they use will need to either be a regulatory equivalent to the current CLIA regulations, or an acceptable equivalent to the IQCP option as laid out in Attachment 1- IQCP. Additional guidance on this matter will be forthcoming. In general, accredited laboratories and laboratories in exempt States should follow the current AO/ES QC requirements during the transition period until IQCP is fully effective and then follow the AO/ES QC protocol subsequently approved by CMS.

6. Are all specialties and subspecialties eligible for IQCP?

All CLIA specialties, with the exception of pathology, will be eligible for IQCP. Pathology will be reconsidered at a later date.

Exception: Under CLIA, certain tests may be assigned to one of several specialties/subspecialties. If the test is eligible for IQCP under one of those potential specialties/subspecialties, then the laboratory may elect to use IQCP for the test regardless of whether it assigned the test a “pathology” specialty/subspecialty in that particular laboratory. For example, a Fluorescence In Situ Hybridization (FISH) test system may be classified as either histopathology or cytogenetics. So, if a laboratory assigns the FISH test to histopathology, it would at first appear to be excluded from IQCP under the pathology exception. However, because the test may also be classified as cytogenetics, this laboratory would be allowed to use IQCP for the test.

7. What is the timeline for Implementing IQCP?

A timeline for SA training and IQCP implementation is included in this Survey & Certification (S&C) letter announcing the beginning and end of the Education and Transition period. Also in this S&C letter, we are instructing our survey teams to provide the laboratories with an ample Education and Transition period and have provided resources on the CLIA website, such as documents Attachment 1-IQCP and Attachment 5-FAQs, to learn about, understand, apply and implement IQCP, http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Individualized_Quality_Control_Plan_IQCP.html.

8. Will there be an Education and Transition period?

Yes, we are providing an Education and Transition period to allow interested laboratories, to learn about and implement IQCP. During this time, survey teams will be instructed to not cite QC deficiencies except in cases of immediate jeopardy, a laboratory has failed to implement any form of QC, or serious quality problems are identified. The laboratories may also continue to use existing EQC policies and procedures in Appendix C of the State Operations Manual (SOM) until the Education and Transition period expires, at which time IQCP will replace the current EQC option.

9. What happens to Equivalent Quality Control (EQC)? And Why?

The laboratory may continue to use the EQC policies and procedures in Appendix C of the SOM until that option is replaced with IQCP at the end of the Education and Transition period. To reiterate, IQCP will replace the current EQC when it is formally published in Appendix C of the State Operations Manual which we anticipate doing at the end of the Education and Transition period. IQCP is a total quality assurance process that represents an innovative QC approach, considers the entire testing process, and provides flexibility.

10. Will any test systems currently eligible for EQC be “grandfathered”?

We do not anticipate grandfathering test systems under the current EQC policies and procedures. However, historical data accumulated during the EQC evaluation protocol and its ongoing usage could (and likely should) be used in the development of the laboratory’s IQCP.

11. When can we expect more information?

Communication about IQCP implementation will be ongoing. IQCP updates will be provided on each Regional Office (RO) call, in the CLIA CNN newsletter, and new FAQs will be distributed as needed throughout the implementation process. Always check the CMS CLIA website at: www.cms.hhs.gov/clia for the most current information.

12. Where can laboratories and surveyors direct any questions about IQCP?

Laboratories and surveyors can be directed to the Survey & Certification (S & C) letters and pertinent IQCP information on the CLIA website at: www.cms.hhs.gov/clia/ and may forward their specific inquiries to the IQCP mailbox at this web link: IQCP@cms.hhs.gov.

Accredited laboratories should contact their AOs for guidance, and laboratories in exempt States should contact their States directly. ROs and State agencies (SAs) should keep CMS' Central Office (CO) CLIA staff informed of inquiries about IQCP received from external sources.

SURVEYORS:

13. How will the IQCP policy affect the current survey process?

The CMS Outcome Oriented Survey Process is not changing but some of the information reviewed may be different. The quality focus of the current CLIA survey process will work well in conjunction with the IQCP policy, but some slight adjustments may be necessary. Any necessary adjustments will be thoroughly communicated with the RO and SA during training and prior to the implementation of the IQCP.

14. In States with laboratory licensure, will State QC standards that are more stringent than CLIA still have to be met by laboratories subject to that State's requirements?

Yes, more stringent State requirements must still be met by laboratories, if applicable.

15. What type of information will be made available for the SA surveyors?

Additional tools, workshops, educational materials, CLIA brochures, etc., will be developed for both the surveyors and laboratories. ROs are heavily involved in the design and development of the Attachment 1-IQCP, SA training, and ongoing IQCP implementation. RO input and participation are critical to the success of the Education and Transition period and, potentially, the ultimate adoption of IQCP for the CLIA program.

16. What training will be provided to the SA surveyors?

CO individuals and outside experts have already provided the attendees at each 2012 Consortium meeting a presentation titled "Introduction to Risk Management Principles". SA training on the new QC policy and Attachment 1-IQCP will be conducted November 18-22, 2013. More details will follow as the training is developed.

17. How will the training for the surveyors ensure consistent application of this new QC policy?

Training for surveyors will be developed jointly, with CO and RO participation. RO input and expertise are essential to ensure adequate and effective training. The training will take a practical approach and involve all aspects of the survey process once key requirements and policies are outlined and understood. This will include: what the surveyors should expect to see and review in the laboratory, what deficiencies to cite if noncompliance is determined, using examples, scenarios and test cases. It is anticipated that follow-up training sessions will be necessary after the initial training.

18. What if the surveyor doesn't agree with the way the LD has addressed the risks in the QCP?

The surveyors will be trained to determine if a risk assessment was performed, if the identified risks were evaluated, if the QCP includes any risk(s) that the laboratory director has determined needs to be mitigated, and that quality assessment is occurring and ongoing.

LABORATORIES:

19. What type of information about IQCP will be made available for laboratories?

Specific guidance in Attachment 1-IQCP, CLIA brochures, educational materials, etc., will be made available, as well as links to the IQCP resources on the CLIA website, www.cms.gov/clia/, to assist with IQCP implementation.

20. Does IQCP apply to Laboratory Developed Tests (LDTs) and molecular assays?

Yes, IQCP may be used for LDTs and molecular tests, except those in the specialty of pathology, if the laboratory chooses that option.

Exception: Under CLIA, certain tests may be assigned to one of several specialties/subspecialties. If the test is eligible for IQCP under one of those potential specialties/subspecialties, then the laboratory may elect to use IQCP for the test regardless whether it assigned the test a "pathology" specialty/subspecialty in that particular laboratory. For example, a Fluorescence In Situ Hybridization (FISH) test system may be classified as either histopathology or cytogenetics. So, if a laboratory assigns the FISH test to histopathology, it would at first appear to be excluded from IQCP under the pathology exception. However, because the test may also be classified as cytogenetics, this laboratory would be allowed to use IQCP for the test.

21. Must an IQCP be performed if the laboratory chooses the default regulation?

No, IQCP is not necessary if the laboratory chooses to meet the default regulation. However, after the IQCP Education and Transition Period, the current EQC in Appendix C of the SOM will no longer be acceptable, and any laboratory that chooses to do QC less frequently than the default regulatory requirements.

22. Will laboratories be required to use a process map, fishbone diagrams, formal risk assessment charts and protocols, etc. in their IQCP?

No, CLIA will not require the use of these tools in the development of an IQCP.

23. Must the laboratory have data to support its decisions for the RA and QCP, and must they be documented?

Yes, the laboratory must have sufficient data to support their decisions, and all IQCP activities must be documented per Attachment 1- IQCP.

24. Who is responsible for the laboratory's IQCP?

Per the existing CLIA regulations, the laboratory director is responsible for deciding whether the laboratory will utilize IQCP for some or all of its tests and for ensuring that the QCP he/she develops effectively meets the IQCP requirements. It is also incumbent upon the laboratory director to consider the laboratory's clinical and legal responsibilities for providing accurate and reliable testing when approving and signing off on the QCP. Lastly, the laboratory director may assign, in writing, specific duties for the IQCP to qualified individuals in the laboratory but is still responsible overall for the entire testing process.

25. Will laboratories be able to identify immediate or potential test problems with IQCP?

Yes, laboratories will better be able to expeditiously identify problems because their QCP will be focused on addressing those known issues and indicating more quickly when a problem occurs in any phase of testing. An effective IQCP should identify all clinically significant failure modes for all of the testing processes, and also include a plan to mitigate all identified risks for inaccurate patient results.

26. Will laboratories need to perform all new studies to gather data/information for the RA and QCP development for existing tests in the laboratory?

Much of the data/information needed by the laboratory to perform the RA for each test will be data that has already been accumulated in the process of routinely operating the laboratory, meeting CLIA regulations, and implementing quality systems. For example, verification of manufacturer's performance specifications, QC records, corrective actions, etc. There must be documented data that demonstrates the stability of the test system and supports the QC type and frequency in the QCP.

27. I have always followed manufacturer's instructions for Quality Control (QC) in my lab. Why do I need to do anything differently?

During test system development, manufacturers challenge their tests in many ways to identify possible failures and then build in features to reduce the risk of those failures. However, manufacturers' instructions for QC may not address all of the risks and variables that are specific for your laboratory's situation.

CLIA QC regulations include a requirement to perform two levels of quality control each day of testing or alternatively, laboratories may choose an equivalent option in CMS' Interpretive Guidelines (IG). The intent of either option is to ensure accurate results.

Recognizing through experience and discussions with experts that advancements in technology may provide other ways to obtain equivalent quality, CMS developed a more flexible option for laboratories to achieve compliance. CMS is pleased to announce that it is offering a new option in the IGs), Individualized Quality Control Plan (IQCP), which is customizable and offers laboratories that flexibility for compliance.

IQCP provides a framework for customizing a QC plan for your test systems and your laboratory's unique environment. By performing the steps in IQCP, you will examine the potential sources of error more thoroughly and determine the appropriate QC or quality practices to address them. After you complete this process, it is possible that you may determine that the amount of QC you have been doing all along is sufficient. However, you may discover potential sources of error that you had not previously considered, and may need to implement additional QC. In either case, you will have a comprehensive QC plan which reflects your laboratory's unique operation and the documentation to support your QC practices. And don't forget, IQCP is optional; you may always choose to achieve compliance simply by following the CLIA QC regulations.

28. Must the laboratory still follow the manufacturer's instructions if it chooses IQCP?

Yes, the manufacturer's instructions must, at a minimum, be followed. Whichever option is selected, laboratories are not permitted to establish quality control procedures that are less stringent than those specified by the manufacturer of the test system.

29. What happens when multiple identical devices are used by the laboratory (e.g., identical devices at different locations)?

The new QC policy (IQCP) will apply to all new and existing non-waived tests. If laboratories have multiple identical devices, the IQCP may be developed for the test system taking into consideration the unique environment, testing personnel, etc. However, if those devices are dispersed throughout a healthcare facility, the QCP must be developed for the devices at the different locations. Each device must be monitored in some way.

30. How will the laboratory know that its QCP is working?

An important part of IQCP is the Quality Assessment (QA). Once a QCP is created, the QA plan is developed. A QA plan includes monitors which help to identify problems in a process, through continuous monitoring, investigation, and problem solving, and thereby allows adjustments to be made to the QCP as the data warrants.