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RESOURCES

GENERAL:

WHAT IS IQCP AND WHY DO WE NEED IT?

1. What is IQCP?

IQCP stands for Individualized Quality Control Plan, and is the formal policy name for the alternative CLIA quality control (QC) option that will provide for equivalent quality testing for 42 CFR 493.1250. IQCP has been incorporated in Appendix C of the State Operations Manual.

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 Appendix C of the State Operations Manual under 42 CFR 493.1250. All three parts are required for IQCP.

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

IQCP's QC protocol will not necessarily reduce QC, but will instead 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, and test systems, etc.

ACCREDITATION ORGANIZATION/EXEMPT STATES

4. Are accrediting organizations (AO) and exempt states (ES) required to accept the use of the IQCP option?

It is optional for AOs and ESs to incorporate IQCP into their standards. However, any standards they use will need to either be equivalent to the current CLIA regulations, or be an acceptable equivalent to the IQCP option as described under 42 CFR 493.1250 of Appendix C of the State Operations Manual and approved by CMS. Accredited laboratories and laboratories in exempt States must follow the QC requirements of their accreditation organization or exempt State.

5. What are the IQCP requirements for CAP and Joint Commission?

Laboratories that are accredited by any of the CMS-approved accreditation organizations must follow that organization's IQCP requirements. We recommend that you contact the accreditation organization directly for details.

6. Are SA or RO staff expected to review IQCP material from accredited labs?

No, SA and RO staff should not review IQCP material from accredited laboratories. SA and RO staff should refer the laboratory, with their IQCP questions, back to their respective AO.

ELIGIBILITY- FOR IQCP

7. Are all specialties and subspecialties eligible for IQCP?

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

8. Where do I go to find out if a particular test is or is not affected by these changes? Is there a list of some kind?

The new CLIA IQCP quality control option was developed for nonwaived tests. For test categorization and current lists of waived tests, please visit the FDA website at <http://www.fda.gov/medicaldevices/deviceregulationandguidance> - or - from CMS website at www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Categorization_of_Tests.html

9. Is blood bank eligible for IQCP, or is it excluded?

Immunohematology is one of the specialties that is eligible for IQCP. Laboratories may choose to follow the applicable regulations at §493.1256(d)(3)-(5) and §493.1256(e)(1)-(4), or implement IQCP. However, the regulations at §493.1271 are not eligible for IQCP and must be followed whether or not the laboratory chooses to implement IQCP.

EQC REMOVAL

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

CMS will not be grandfathering test systems under the EQC policies and procedures. However, historical data accumulated during the time that the EQC evaluation protocol was in use could (and likely should) be used in the development of the laboratory’s IQCP.

11. What happened to Equivalent Quality Control (EQC)? And Why?

IQCP replaced EQC. IQCP is a total quality assurance process that represents an innovative QC approach, considers the entire testing process, and provides flexibility. Although EQC is no longer an acceptable QC option, the EQC data may be used by laboratories as part of the historical data to support their QCP.

12. Can you use EQC as your IQCP (if you validate)?

EQC is no longer an acceptable QC option. Laboratories using EQC will need to either implement IQCP or follow the CLIA requirements for quality control procedures. No test systems using EQC will be grandfathered for IQCP. Laboratories may use the EQC validation study data as part of the IQCP data, but would still need to show other data such as proficiency test results, QC records, QA records, test verification/validation performance specification results, etc. to show that the test is stable for the established QC frequency.

- 13. It is stated that IQCP is optional and voluntary, but must labs currently using EQC change to something else? i.e. mfg. requirements?**

The laboratory must be either following the CLIA QC regulations or implementing IQCP. If the lab chooses to implement an IQCP, the associated QCP may not be less stringent than the manufacturer's QC requirements. And laboratories implementing IQCP for new tests are encouraged to perform control procedures at more frequent intervals during initial implementation, allowing the laboratory to identify performance issues that could indicate a need to adjust the QCP.

NEW TEST SYSTEMS

- 14. How long do we have to follow CLIA QC regulations as written before we can implement IQCP for new test systems in our laboratory?**

For a new test, the laboratory could choose to collect data and develop a QCP prior to reporting test results. Alternatively, a laboratory that wishes to start reporting results right away, and has done everything needed for implementation (performance specs, SOP, training, etc.) would need to follow the CLIA QC regulations as written until the QCP is developed and approved by the LD.

- 15. What data is needed to support the new test system?**

Laboratories implementing IQCP for new tests are encouraged to perform control procedures at more frequent intervals during initial implementation, allowing the laboratory to identify performance issues that could indicate a need to adjust the QCP. It is up to the LD to determine the data requirements for the risk assessment, but it would be reasonable to assume that the data collected while running the CLIA QC regulations as written would be included.

LABORATORY DIRECTOR

- 16. When you say Laboratory Director, do you mean the medical director (pathologist)? Or the lab director who can be a medical technologist? Which one must sign the IQCP?**

The Laboratory Director (LD) is responsible for the overall operation and administration of the laboratory and must meet the CLIA regulatory qualification requirements appropriate for the complexity (moderate or high) of testing the laboratory is performing. The LD for CLIA purposes is the person identified on the CLIA certificate and in the CMS database as the LD. The LD must sign, date and approve the Quality Control Plan (QCP). The signature, date, and approval of the QCP cannot be delegated.

- 17. What personnel requirements apply to Individualized Quality Control Plan (IQCP) activities?**

In laboratories that choose to implement IQCP, the responsibility for ensuring that IQCP meets the requirements to assure the quality of laboratory services provided, identify failures in quality as they occur, and provide equivalent quality testing, resides with the laboratory director. The technical consultant/supervisor is responsible for establishing IQCP as part of

the laboratory's overall quality control program. The LD may assign, in writing, specific portions of IQCP tasks to other laboratory individuals. However, the LD remains responsible for the IQCP, and all CLIA personnel requirements must continue to be met.

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

The LD is responsible for deciding whether the laboratory will utilize IQCP for some or all of its tests and for ensuring that the QCP effectively meets the IQCP requirements. It is also incumbent upon the LD to consider the laboratory's clinical and legal responsibilities for providing accurate and reliable testing when approving and signing off on the QCP.

REFERRAL LABS

19. Is a physician office laboratory responsible for the IQCP records if they use an outside lab to perform all of their nonwaived testing?

Laboratories using a referral lab service for their patient's lab tests should verify that the provider of lab services has a valid and current CLIA certificate. Each lab holding a CLIA certificate is required to follow all CLIA regulations applicable to their certificate type and tests performed and maintain support documentation.

SURVEY PROCESS:

LABS WITH MULTIPLE TESTING SCENARIOS and/or LOCATIONS

20. In cases where multiple analytes are run on a *single* test system, (for example, a multi-channel chemistry analyzer), is it acceptable to perform one risk assessment that includes all of the analytes?

When performing a risk assessment for a *single* test system that tests for multiple analytes, the laboratory should consider the potential sources of error that apply to the test platform overall, plus any potential sources of error that are specific to each of the individual analytes, as applicable. These identified types of risks can be incorporated in a single risk assessment for the test system.

21. In the case where there are two *separate* test systems (i.e. *different* make and model) using similar methodologies, is it acceptable to perform one IQCP?

While the methodologies are similar, the test systems are not identical. It is likely that while some potential sources of error will be similar, others will be unique to each test system. Therefore, the laboratory must perform a separate IQCP for each individual test system.

22. In the case of multiple sites, with multiple numbers of the same device, is it acceptable to perform one RA to encompass all sites? How many QCP(s) are required? Does each individual compliance laboratory need to develop a separate, complete IQCP?

The IQCP applies to the one specific laboratory, hence "Individualized Quality Control Plan". Therefore, each CLIA laboratory, i.e. each CLIA certificate/number, must have its own IQCP.

CMS does recognize that it is becoming more common for large multi-site systems to standardize processes where feasible to achieve efficient operations. It would be acceptable if laboratories in a multi-site system collaborated on the common elements that could be used throughout their systems, for example, the process and format for developing IQCPs. For devices used throughout the system, the laboratories may also collaborate on those portions that are common to all, for example, the manufacturer's QC instructions. However, the end product must include an evaluation of the risks associated with each individual location, and each QCP must be approved by the LD for that laboratory. Also, each CLIA laboratory must produce its own supporting data for its QCP. Each device must be monitored in some way, as well as each location. Each CLIA laboratory must have its own IQCP documentation.

OUTCOME ORIENTED SURVEY PROCESS

23. What happens if your Laboratory Director signs off on your IQCP plan for a specific assay and the CLIA inspector does not think that the plan is adequate?

In general, it is not anticipated that a LD's risk mitigation approach would be cited directly as a deficiency. However, if the LD has made poor risk mitigation decisions, the outcome of those decisions would be expected to result in problems showing up with the test system in downstream areas such as QC, QA, PT, etc. which the surveyor will find during the outcome oriented survey process. When problems are found with the lab's QC, QA, PT, etc., then the surveyor would write citations in those areas pointing out those deficiencies in the lab's processes.

24. CLIA surveyors may be asked to review laboratories' IQCP materials in advance of a survey. How should the surveyor handle these requests?

In general, CLIA surveyors should not be reviewing individual laboratories' IQCP plans outside the context of a survey. Without the context of a survey, it is impossible to determine the adequacy of a laboratory's IQCP program. An inadequate IQCP would be expected to result in problems showing up with the test system in downstream areas such as QC, QA, PT, and this would not be evident to the surveyor outside the context of a survey.

25. If a laboratory is performing less QC than the "CLIA QC regulations as written" and indicates that they have not implemented IQCP, can the laboratory be cited for failing to implement IQCP?

Since IQCP is voluntary, the surveyor should write the deficiency against the CLIA QC regulation that the laboratory failed to follow. (The laboratory can include in their response that they are correcting the deficiency by either following the CLIA QC regulation as written or implementing IQCP.)

26. 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.

27. **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.

POINT of CARE TESTS

28. **For point of care analyzers that have single use cartridges containing more than one test, does a risk assessment need to be performed for each test or per cartridge type?**

When performing a risk assessment for a single test system that tests for multiple analytes, the laboratory should consider the potential sources of error that apply to the test platform overall, plus any potential sources of error that are specific to each of the individual analytes, as applicable. These types of risks can be incorporated in a single risk assessment for the test system.

29. **Does a risk assessment need to be performed for each test on a point-of-care "multi-analyte" style instrument located in different areas of the facility?**

For identical test systems that are located in multiple locations, one Risk Assessment (RA) for the one test system would be acceptable since the test system's potential failures would be the same. However, the one RA must consider any potential risks at those multiple locations and environments. The facility should have a QCP and QA for the test system at each location.

PPM CERTIFIED LABS

30. **How does IQCP affect a laboratory that holds a Certificate for Provider Performed Microscopy (PPM) or Certificate of Waiver (CW)?**

For laboratories performing Provider-Performed Microscopy (PPM) procedures, they must continue to follow the CLIA regulatory requirements for PPM and moderate complexity testing, § 493.19 and § 493.20. While IQCP may not be practical for PPM laboratories due to the nature of PPM testing, IQCP is available for those laboratories that would choose to implement it. For CW laboratories using tests categorized/approved by the FDA as waived tests, they must continue to follow manufacturer's instructions for these tests, and this requirement will not change. The new CLIA IQCP quality control option was developed for nonwaived testing.

RISK ASSESSMENT

31. **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.

- 32. Other IQCP webinars and symposiums I have attended indicate that the Risk Assessment includes the Frequency of Occurrence and Severity of harm matrix for each possible error. Does CMS require the laboratory demonstrate probability of harm against severity of harm? Is a Risk Acceptability Matrix required in the IQCP?**

CMS IQCP does not require a "risk acceptability matrix". It is the responsibility of the laboratory to demonstrate how it evaluated the frequency and impact of sources of error.

- 33. How do I need to account for “risks” outside the control of the lab; reagents transported to my facility by vendors or for non-lab personnel, who provide specimen collection services?**

The IQCP workbook, "Developing an IQCP A Step-by-Step Guide" published by the CDC and CMS(iqcpworkbook@cdc.gov), provides a helpful list of Risk assessment questions that may guide the reader in regards to evaluation risks surrounding specimen collection, the test system, reagents, and environment and testing personnel.

- 34. Do environmental risk factors include fire and/or emergency risk factors? For example, scales, oxygen tanks kept in hallways?**

The definition for Environmental Conditions is, "Conditions that may affect test system performance. These include, but are not limited to, temperature, airflow, light intensity, humidity, and altitude".

WAIVED VS NON-WAIVED TESTING

- 35. If we already run two levels of controls on a daily basis for a particular waived procedure do we need to have an IQCP plan for that procedure?**

No, you do not need an IQCP for a waived test. If your test is categorized and approved by the FDA as waived, you must continue to follow manufacturer's instructions for this test and you are encouraged to follow good laboratory practices. The new CLIA IQCP quality control option was developed for nonwaived testing.

- 36. If an instrument does both nonwaived and waived testing and our lab uses only waived tests, what are we responsible to do under IQCP regulations?**

IQCP was developed for nonwaived testing so laboratories performing only waived testing do not need to develop an IQCP. Laboratories using tests categorized/approved by the FDA as waived tests must continue to follow the manufacturer's instructions and are encouraged to use good lab practices. If your lab ultimately wishes to use the nonwaived part of the test system your lab must have the proper CLIA certification and follow all applicable CLIA nonwaived testing regulations.

- 37. We are using a HCG combo kit for serum (nonwaived) and urine (waived). How do we do an IQCP on this kit? Just the Serum part? or urine too?**

The new CLIA IQCP quality control option was developed for nonwaived testing. In this case,

the non-waived test (serum HCG) would be eligible for IQCP.

LABORATORY SPECIFIC TOPICS:

ARTERIAL BLOOD GAS TESTING

38. What are the CLIA requirements for QC on ABG analyzers - i.e. required liquid controls?

The CLIA regulations for blood gas analysis are found at 493 CFR 493.1267.

39. If a blood gas analyzer utilizes on-board liquid controls, may these controls be used in place of testing external quality controls?

With the advances in technology, certain instruments have introduced the use of on-board controls, that is, ampules or cartridges containing the same QC material that would traditionally be considered as external QC. For example, on-board control materials that have a similar matrix to that of patient specimens, are treated in the same manner as patient specimens, and go through all elements of the analytic process as applicable, will be considered acceptable to meet the regulatory requirement for control materials. The LD is responsible for the determination of what control materials to use in his/her laboratory.

BLOOD BANK PROCEDURES

40. What QC is required for antibody identification panels?

There are generally no daily quality control requirements for reagent red cell panels used in antibody identification. We encourage laboratories to follow the manufacturer's recommendations for QC. Laboratories may also choose to perform IQCP for antibody identification.

CLIA QC REGULATION vs. IQCP

41. How is performing IQCP different from following the CLIA QC regulation as written and what are its advantages?

Performing an IQCP customizes a QC Plan for each nonwaived test in its unique environment, and offers laboratories flexibility in achieving QC compliance. This QC compliance optimizes use of electronic/integrated controls, adapts to future advancements in technology, and incorporates other sources of Quality Information for a total quality review. It can also strengthen Manufacturer/Laboratory partnerships, formalize risk management decisions already maintained within the laboratory and provide equivalent quality testing to meet the CLIA QC regulations.

- 42. If the lab is already following the CLIA and state regulatory requirements for QC, IQCP is an option and not a requirement, correct? Are risk assessments required even if the lab chooses to adhere to CLIA requirements rather than perform IQCP?**

If your QC policy is equal to or more stringent than the CLIA control requirements, you are in compliance and a risk assessment is not required.

DEFINE A TEST SYSTEM

- 43. Please define a “test system”.**

CLIA 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.

MANUFACTURERS’ INFORMATION

- 44. How should commercial in vitro diagnostic (IVD) manufacturers assist users with IQCP questions pertaining to product instructions for use (IFU), QC vouchers, and certificates of analyses?**

We are aware that manufacturers develop IQCP templates to aid in IQCP development. However, CMS is not planning to approve or endorse any IQCP templates. The IQCP procedure states, “*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.*” Each LD who chooses to use an IQCP template, either internally or externally developed, is responsible for ensuring that all the requirements of IQCP are met. Manufacturers should be prepared to answer questions from laboratories that may arise during the performance of the risk assessment and offer any additional information if possible.

- 45. I have always followed manufacturer’s instructions for Quality Control (QC) in my laboratory. Why do I need to do anything differently?**

During the 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. 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, the laboratory will examine the potential sources of error more thoroughly and determine the appropriate QC or quality practices to address them. After the laboratory completes this process, it is possible that the laboratory may determine that the amount of QC the laboratory has been doing all along is sufficient. However, the laboratory may discover potential sources of error that have not previously been considered, and may need to implement additional QC.

46. 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.

MICROBIOLOGY TESTS

47. What are the CLIA regulations that specifically address media QC requirements?

The CLIA regulations for media [42 CFR 493.1256 (e)(4)(i-iii)] state the laboratory must do the following before, or concurrent with the initial use;

- Check each batch of media for sterility if sterility is required for testing;
- Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and
- Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer.

48. How does the S&C letter #15-07-CLIA regarding the removal of the CLSI micro references from the CLIA Interpretative Guidelines (IG) affect me?

As mentioned in the S&C letter #15-07-CLIA, the laboratory will have the following two options: follow all applicable CLIA QC regulations, OR implement IQCP. Laboratories may use the data obtained while following the CLSI microbiology guidelines as part of the risk assessment.

49. Is there a plan by CMS to educate laboratories regarding the IQCP for microbiology?

The IQCP requirements for microbiology testing are the same as for other specialties and subspecialties. CMS currently has several guidance and educational resources available for IQCP on the CLIA website at http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Individualized_Quality_Control_Plan_IQCP.html. This includes the IQCP guidance in Attachment 1 of the S&C letter #13-54-CLIA, FAQs in the S&C letter #13-54-CLIA, IQCP educational brochures #11, #12, and #13, and the IQCP announcement letters. For other possible tools and resources outside CMS, CMS suggest you contact the manufacturer or professional organizations directly for their efforts.

50. Many bacterial culture media have been exempt from QC based on data collected by CLSI. Therefore, laboratories do not have in-house data on these media. Would laboratories have to do daily QC on all these media until they had in-house data to implement IQCP?

CLIA is not prescriptive about the data/evidence to be considered for the laboratory's IQCP. It is the LD's responsibility to determine acceptable data. However, the laboratory must document that its Quality Control Plan (QCP) is based on evidence of the test system's accuracy and stability, and supports the QC type, number and frequency in the QCP. In-house data, established by the laboratory in its own environment and by its own personnel, must demonstrate that the stability of the test system supports the number and frequency of the QC documented in

the QCP.

This in-house data may include historical QC data while using the CLSI guidance and the CLSI documents to assist with the Risk Assessment (RA) as part of the IQCP data. For example, laboratory documentation showing visual quality checks of media are acceptable in-house “data”. The laboratory may also include manufacturer’s quality certificates as part of the information considered in its risk assessment.

51. Is it acceptable to develop a master IQCP plan for culture media in the microbiology lab, with all the necessary elements covered, or does the lab need to develop an IQCP plan for each specific culture media type?

There is no specified way in which the laboratory must organize the risk assessment information for IQCP. For media, some laboratories have chosen to create a single IQCP that addresses all media used, while others might develop individual ones for each media type.

52. How is the QC for microbiology identification systems to be handled?

Microbiology identification systems (systems using two or more substrates or two or more reagents, or a combination), are subject to §493.1256(e)(1). The requirement at §493.1256(e)(1) states that the laboratory must check each batch/lot/shipment to verify positive and negative reactivity of each substrate. Laboratories that perform less QC than the regulations must develop an IQCP that supports their QC frequency.

53. Do we need to do an IQCP for antimicrobial susceptibility tests (AST)?

IQCP is strictly voluntary. Laboratories may choose to develop an IQCP or follow the CLIA regulations. Since the CLSI exceptions for AST were removed from IGs, laboratories have two choices: follow all applicable CLIA QC regulations; or implement IQCP.

54. What are the CLIA regulations that specifically address AST QC requirements?

AST is subject to the CLIA requirements at §493.1261(b)(1-2). These requirements state the laboratory must check;

- Each batch of media and each lot/shipment of antimicrobial agent(s) before, or concurrent with, initial use, using approved control organisms;
- Each day tests are performed, use appropriate control organism(s) to check the procedure;
- Zone sizes or MICs must be within established limits before reporting patient results.

- 55. The manufacturer for our blood culture instrument does not require QC. Per manufacturer's instructions, we monitor the temperature and perform preventative maintenance. What are the CLIA regulatory quality control requirements? Do we need to implement an IQCP? If so, what data is acceptable for performing the risk assessment?**

All laboratories have decisions to make on the analytic control procedures they will employ for any test system and/or instrument. CLIA regulations for the analytic phase of testing can be found in § 493.1250. Additional information for Bacteriology can also be found in §§ 493.1261 - 493.1278. The choice to use manufacturer's instructions (if they meet or exceed CLIA's regulations), CLIA QC regulations as written or to develop an IQCP is the decision of the LD.

- 56. CMS IQCP guidance states that the IQCP QCP cannot be less stringent than the manufacturer's instructions. Does this policy apply when the manufacturer recommends following the CLSI microbiology QC guidelines (which was removed from CLIA Interpretive Guidelines recently) for its QC?**

The State Operations Manual, Appendix C. interpretative guidelines states; "The laboratory must meet any and all regulatory requirements and comply with the manufacturer's requirements to the extent that the manufacturer's requirements do not conflict with any regulatory requirements. We encourage laboratories to also comply with the manufacturer's recommendations for testing to the extent that the manufacturer's recommendations do not conflict with any regulatory requirements."

- 57. Does the laboratory need to perform the CLIA regulatory daily QC and micro specialty QC requirements (i.e. end-user QC) for a period of time to collect supporting data for its IQCP?**

In general, CMS is not requiring that laboratories use the CLIA regulatory requirements as written to perform the IQCP RA. The LD is responsible for determining the most appropriate Quality Control Plan (QCP) for the test based on all of the data from the various sources available to him/her. Surveyors will continue to use the outcome oriented survey process to determine whether the laboratory is actually providing accurate and reliable test results and other related services, and is operating within the applicable CLIA regulations. It is the LD's responsibility to determine acceptable data. However, the laboratory must document that its Quality Control Plan (QCP) is based on evidence of the test system's accuracy and stability, and supports the QC type, number and frequency in the QCP.

- 58. Does CLIA require the IQCP RA to address the specimen source/type (e.g. urine, sputum, and stool) for micro tests?**

It is the LD's responsibility to determine what should be included in each of the five IQCP RA components. The specimen is one of the elements that must be included in a risk assessment. The risk assessment should consider both general risks and specific risks that apply to the sources and types of specimen that are received in the laboratory. There is no specified way in which the laboratory must organize the risk assessment information.

MOLECULAR TEST SYSTEMS & LDTs

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

Yes, IQCP may be used for LDTs and molecular tests in eligible specialties/subspecialties.

60. What if there is a molecular assay performed under the specialty of Pathology?

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 test system may be classified as either histopathology or cytogenetic. 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 cytogenetic, this laboratory would be allowed to use IQCP for the test.

QUALITY CONTROL

61. Where can we find the CLIA QC requirements?

The CLIA QC requirements can be found at 42 CFR §493, subpart K- Quality System for Nonwaived Testing. Note: Laboratories that obtain CLIA certification by virtue of accreditation by a CMS approved accreditation organization must follow all the requirements of the accreditation organization, which may be more stringent than the CLIA regulations.

62. 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 of the pre analytical, analytical and post analytical systems requirements in the CLIA regulations will remain in effect. CMS notes, however, that the CLIA Quality Systems requirements could be used to help a laboratory identify failures in a testing process and could be useful when performing a RA.

63. If a laboratory participates in a CMS approved proficiency testing program for an analyte, can the laboratory’s QCP state the proficiency testing (PT) will also count as quality control?

CMS does not consider PT the same as QC, and therefore, PT cannot be exclusively used as QC. However, both PT data and QC data should be evaluated as part of a laboratory’s risk assessment and ongoing quality assessment.

QC FREQUENCY - DOCUMENTATION – DATA

- 64. Can you please give an example of how QC frequency is determined based on the risk assessment performed (RA) and quality control plan (QCP) and how often does the IQCP needed to be reevaluated?**

The LD is responsible for making the decision on QC frequency after reviewing the results of the risk assessment. The data and information from the risk assessment must support the QC frequency decisions. Please refer to the IQCP Workbook for examples. Periodic review of the IQCP through the quality assessment program is required, but the frequency of the reviews is left up to the LD.

- 65. How many days and number of QC samples do I need to run for IQCP?**

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. The IQCP option is not prescriptive about the amount of data/evidence required to determine the laboratory's IQCP. It is the LD's responsibility to determine the acceptable amount of data.

- 66. 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. Their use is optional.

- 67. What documentation is required if a laboratory chooses to implement IQCP?**

CMS does not require any specific format. The LD choosing to implement IQCP is responsible to ensure that all IQCP requirements are followed and documented. Laboratories can use the forms in the IQCP workbook, materials obtained from other sources, or an in-house developed format. CLIA surveyors will use the outcome-oriented survey process to ensure that the IQCP has been implemented according to the requirements, regardless of the format of the documentation. The laboratory should be able to produce any documents (e.g., risk assessment, qualify assessment, data, etc.) that the surveyor requests to make a compliance determination.

RESOURCES

- 68. Where can laboratories and surveyors direct any questions about IQCP?**

Laboratories and surveyors can direct any questions about IQCP to the IQCP mailbox at this address: 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.

69. What type of information and tools for IQCP are available for laboratories?

CMS currently has several guidance and educational resources available for IQCP on the CLIA website ([http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Individualized Quality Control Plan IQCP.html](http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Individualized_Quality_Control_Plan_IQCP.html)). This includes the IQCP educational brochures #11, #12, and #13, and the IQCP announcement letters. For other possible tools and resources outside CMS, CMS suggests you contact the manufacturer or professional organizations directly for their efforts.

70. Where can I find other information and tools to navigate CLIA regulations?

Access CMS CLIA website at www.cms.gov/cli for the most current information. www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Categorization_of_Tests.html

DISCLAIMER:

The August 2016 edition of IQCP Frequently-Asked-Question is not a legal document. The official CLIA program provisions are contained in the relevant law, regulations, and rulings. For more information, you may access the regulations on the internet at <http://www.cdc.gov/cli/>. Use of trade names and commercial sources is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services.