**Individualized Quality Control Plan (IQCP) Frequently Asked Questions**

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**GENERAL QUESTIONS**

1. **Why has the CAP implemented the IQCP option for nonwaived testing and eliminated the Equivalent Quality Control (EQC) or internal control process-related checklist requirements?**

   The Centers for Medicare and Medicaid Services (CMS) has implemented IQCP as an acceptable QC option. **As of January 1, 2016,** the CMS no longer recognizes EQC as an acceptable option to meet Clinical Laboratory Improvement Amendments (CLIA) requirements for QC of nonwaived testing. Because of the CAP’s deemed status as an accrediting organization, the CAP revised its checklists for the 2015 edition to address these changes. The 2015 edition introduced IQCP and removed language from requirements that allowed for the use of EQC as an acceptable daily QC option. The new requirements for IQCP provide laboratories with the framework to implement IQCP, when appropriate, and offer flexibility to design a QC plan that meets the needs of the laboratory. These changes will ensure that CAP-accredited laboratories remain in compliance with the CLIA and CMS regulations.

2. **Do the new checklist requirements for IQCP apply to laboratories that are not subject to US regulations?**

   Yes, the changes to the checklist relating to quality control and IQCP apply to all participants in the Laboratory Accreditation Program, whether or not they are subject to US regulations.

3. **When did the checklist changes relating to IQCP occur?  (UPDATED 1/21/2016)**

   New requirements for IQCP were published on July 28, 2015 in the 2015 edition of the All Common Checklist. Existing requirements in the discipline-specific checklists (e.g., Chemistry, Point-of-Care Testing) were also revised at that time to remove provisions for EQC. **As of January 1, 2016,** all laboratories performing nonwaived testing must follow the minimum CAP requirements and default CLIA quality control regulations or implement an IQCP, if eligible, as defined in the 2015 CAP checklist for the QC of nonwaived testing.
4. **Where can I find the CAP checklist requirements for IQCP?**

   Five new requirements for IQCP are included in the 2015 All Common Checklist, along with introductory material and notes in the customary format. Revisions to additional requirements in the discipline-specific checklists (e.g., Chemistry, Point-of-Care Testing) were also made to remove provisions for EQC and introduce the option for IQCP.

5. **What does the CAP require for IQCP?**

   The 2015 edition of the All Common Checklist contains the requirements for IQCP, including Risk Assessment, Quality Control Plan, and Quality Assessment Monitoring. The checklist also requires the use of specific CAP forms to maintain a list of IQCPs and a summary of each IQCP.

   Master and custom versions of the 2015 edition checklists are available for download and review from the CAP website through e-Lab Solutions Suite.

6. **Is there a specific model and forms that I need to use to create my own IQCP?**

   A laboratory may develop its own model and forms when creating an IQCP or may adapt models and forms from available resources, such as those listed in FAQ #62. No specific forms are required when creating an IQCP.

   The CAP does require the use of special forms to facilitate an inspection to identify and summarize the IQCP's in use. Refer to the IQCP Resources page on the CAP website for the IQCP List and IQCP Summary forms.

7. **Can my laboratory submit an IQCP developed by my laboratory to the CAP Central Office or to one of the CAP's scientific resource committees for review and approval prior to implementation?**

   The College of American Pathologists (CAP) is an accrediting organization and does not offer this type of consulting service. It is the laboratory director's responsibility to review the IQCP risk assessment and approve the quality control plan prior to implementation. In addition to ensuring that the quality control plan ensures the quality and reliability of patient test results, the laboratory director must also ensure it meets the CAP's accreditation requirements, as well as federal and state regulations. For CAP-accredited laboratories, records for IQCPs implemented will be reviewed for compliance during the laboratory's next onsite inspection.

   The CAP provides a number of resources to aid in the development and implementation of an IQCP, including the checklist requirements in the 2015 edition (refer to FAQ #62 for a list of CAP and other resources).

8. **Can I use a commercial product for development of my IQCP?**

   The CAP does not require a specific format for the IQCP. Laboratories may develop their own model for designing an IQCP or use other resources, such as the CDC/CMS guide (Developing an IQCP: A Step-by-Step Guide), CLSI Guideline EP23-A (Laboratory Quality Control Based on Risk Management), CMS guidance and brochures, a manufacturer protocol, or other commercially available products.

   The CAP requires the use of specific CAP forms to maintain a list of the IQCPs in use and a summary of each. These forms are not intended for the development of an IQCP.
ELIGIBILITY TO USE IQCP

9. Does IQCP apply to all types of testing? What are the CAP’s IQCP eligibility requirements?

IQCP does not apply to waived testing. Laboratories must continue to follow manufacturer’s instructions for QC for both waived and nonwaived test systems, at a minimum.

For nonwaived testing, the CAP has defined eligibility requirements for IQCP. Eligibility is limited to tests meeting both of the following criteria:

1. The testing is performed in a discipline other than Anatomic Pathology (ANP) or Cytopathology (CYP). (Exception: tests in ANP or CYP that can be assigned to another discipline) and
2. The test system has an internal control process (electronic, procedural or built-in).
   (Exceptions exist in microbiology for media, ID systems and susceptibility testing, which qualify for IQCP even though there is no internal QC.)

For tests that do not meet the CAP’s IQCP eligibility requirements, the minimum daily QC requirements and default CLIA regulations, as defined in the 2015 CAP checklist, of at least two levels of external QC each day of patient testing (unless more stringent requirements exist), must be observed.

The CAP has developed an eligibility determination tool to assist in the determination of eligibility of a test system for a CAP IQCP. It is available on the CAP website (www.cap.org) or by clicking here.

10. Can an IQCP be used to reduce the frequency of calibration, AMR verification, or instrument comparison?

No. IQCP is applicable to QC only. The results and data from the above functions may be useful when conducting the Risk Assessment for an IQCP.

11. Is Microbiology testing eligible for IQCP?

Microbiology testing, including molecular infectious disease testing and direct antigen testing performed using nonwaived instruments or devices that have internal control processes are eligible for IQCP. In addition, microbiology testing performed using media, identification systems, and susceptibility test systems are eligible for IQCP. Laboratories must have an IQCP to define the use of reduced QC, even if following manufacturer’s instructions or Clinical and Laboratory Standards Institute (CLSI) guidelines. Previous data collected by the laboratory and manufacturer certificates of analysis may be used in the Risk Assessment. Without an IQCP, the minimum CAP checklist and default CLIA QC requirements are applicable.

Refer to the Microbiology Testing section (FAQs #42 - 50) for additional questions and answers on this topic.

12. How do I determine if an internal control process used by my instrument or device is sufficient to meet the CAP’s eligibility criteria to implement an IQCP?

The sufficiency of an internal control process must be evaluated by the laboratory as it performs a risk assessment. The laboratory must evaluate the manufacturer’s information to identify potential areas of risk, processes to mitigate risk (eg, internal control processes) and other sources of information, as available, and perform its own studies in its own environment to confirm that the defined control processes, frequency, and associated risk is acceptable. Retrospective data may be used in the risk assessment.
13. Which states do not allow IQCP?

State regulations may vary from state to state. Laboratories that are unsure of IQCP acceptability in their state should contact the state CLIA office to confirm acceptability of IQCP in the state or determine if there are any limitations. If state law does not allow for the use of the IQCP option, laboratories must follow the default QC requirements defined in the CAP 2015 checklist requirements, CLIA regulations, and applicable state requirements, whichever is the most stringent.

14. Are there any test systems or instruments that are exempt from IQCP?

The use of an IQCP is voluntary and there are specific eligibility criteria defined for use. If an IQCP is not implemented for eligible tests, laboratories must follow the minimum daily QC requirements and default CLIA regulations for daily QC of nonwaived testing, as defined in the 2015 CAP checklist. This will primarily impact laboratories that are using instruments or devices (eg, test kits) where an internal control process (electronic, procedural, or built-in) has been used for daily QC in lieu of an external quality control sample, especially those that use multiple identical instruments or devices.

The CAP has not categorized any specific instruments or test systems as exempt from IQCP.

15. Do I need to implement an IQCP if I am currently running at least two levels of external QC for a nonwaived test each day of patient testing (or following more stringent requirements as defined in the CAP checklist and CLIA regulations)?

No. There is nothing further you must do. If a test is eligible for an IQCP, the laboratory is NOT required to implement an IQCP, but has the option to implement an IQCP or follow the default QC requirements of at least two levels of external QC each day of testing (or more frequent as specified in a discipline or subdiscipline).

16. If my instrument has a control process that uses liquid control materials on-board the instrument or within a test cartridge, or uses a device, such as an optical filter or electronic control simulator, do I need to implement an IQCP to meet daily QC requirements? (UPDATED 05/13/2016)

The default CLIA regulations were written for the traditional daily testing of two levels of external control materials. To be considered an external control material, the control material must have a similar matrix to that of patient specimens, be treated in the same manner as patient specimens, and go through all elements of the analytic process as applicable. It must also be a different type of material or from a different lot number than used to calibrate the instrument (42CFR493.1256(d)(9)). Function checks, instrument/electronic checks, and procedural controls do not meet the definition of an external control material. Those types of checks only verify electronic components or detect function of the instrument and may only monitor a portion of the analytic process. Laboratories must carefully evaluate the control processes used to determine if they control the full analytic testing process.

If the control process does not meet the criteria described for external control materials, the laboratory must either perform additional QC testing using appropriate external control materials or implement an IQCP to meet daily QC requirements. For on-board instrument controls that meet the above definition of an external control material, but have a variation in the preanalytic portion, such as with sampling of the control, an IQCP is not required; however, the laboratory can periodically verify proper sampling through proficiency testing, competency assessment, the use of other types of external control materials, and following processes defined in the manufacturer’s instructions, as applicable.
17. If I perform tests where there are no control materials available, do I need to implement an IQCP?

For tests where there are no control materials available, the laboratory must establish its own procedures for detecting errors and monitoring test performance. An IQCP is not required. This provision is included in the CLIA regulation 42CFR493.1256(h) and in the Laboratory General Checklist requirement GEN.30070. Some examples include tests for cold agglutinins and platelet function testing. Laboratories must follow manufacturer's instructions for quality control at minimum.

18. If an IQCP is not used, what are the CAP’s minimum requirements and default CLIA regulations for daily external QC for nonwaived testing?

Generally, the CAP and CLIA require at least two levels of external QC each day of patient testing. Different CAP and CLIA requirements exist in some discipline and subdiscipline areas (eg, coagulation, blood gases, and microbiology). The QC requirements for nonwaived testing, as written in the 2015 CAP checklists and CLIA regulations, must be followed if an IQCP is not implemented by January 1, 2016.

19. What are the QC requirements if I have multiple identical instruments/devices/cartridges in use but do not wish to develop an IQCP?

Generally, the CAP and CLIA require at least two levels of external QC for each device and cartridge, each day of testing. Different CAP and CLIA requirements exist in some discipline and subdiscipline areas (eg, coagulation, blood gases, and microbiology). The QC requirements for nonwaived testing, as written in the 2015 checklist edition, must be followed if an IQCP is not implemented by January 1, 2016.

20. Is an IQCP needed in flow cytometry for leukemia/lymphoma panel testing?

An individualized quality control plan (IQCP) is not required for leukemia/lymphoma immunophenotyping performed using flow cytometry. The Flow Cytometry Checklist requirement FLO.23737 defines the quality control requirements and the types of controls that may be used. As long as a laboratory has written guidelines defining criteria for acceptable performance of these controls and records of periodic performance, the laboratory should be considered in compliance.

21. Is an IQCP needed for molecular-based testing performed by my laboratory?

The IQCP option is limited to test systems that employ an internal (electronic/procedural/built-in) quality control system. These are methods that would have previously qualified for the equivalent quality control (EQC) option. A limited number of molecular-based methods qualify for the IQCP option, namely those commonly used for molecular infectious disease testing and a limited number of genetics tests that employ disposable single-use cartridges. These would include the use of test systems that have the internal control processes that are used for daily QC in lieu of external controls.

The IQCP option is not available for some types of molecular-based testing, such as fluorescence in situ hybridization (FISH), microarray, and next generation sequencing under the CAP’s accreditation programs. These include methods that do not have an internal (electronic/procedural/built-in) control system, but have specialized control processes and metrics to monitor the performance of the test. The quality control requirements for these methods are defined in the method specific sections of the applicable checklists. The control measures used must ensure accuracy and reliability of patient results and must follow manufacturer’s instructions (as applicable), as well as the CAP Checklist requirements.

IQCPF 7.0
22. Why did the CAP limit the eligibility to use an IQCP to tests with internal control processes?

While many of the elements of IQCP are not new for laboratories, the overall concept is a significant change. The CAP will limit the use of an IQCP to instruments or devices with an internal control for the 2015 checklist edition (with the exception of microbiology susceptibility, media, and identification systems; see FAQ #11 above) and will reevaluate this decision as we gain more experience with IQCP. This meets or exceeds the CLIA/CMS requirements and was approved by the CMS.

The use of internal control systems has been accepted by the CAP previously. Laboratories may continue to use internal control processes, but must implement an IQCP to do so. For the microbiology tests mentioned above, the CAP has accepted alternative quality control practices that followed microbiology guidelines from the CLSI. These practices may continue to be used if an IQCP is implemented.

23. Do I need to implement an IQCP for my blood bank antibody identification panels?

No, IQCP is not applicable to antibody panels used in the transfusion service laboratory. An antibody panel is considered a critical material and is subject to TRM.31241 for inspection and testing, as applicable, of new lots before use. This involves visual inspection of new lots and shipments for appropriate physical characteristics (e.g. no hemolysis) and quality control following manufacturer's instructions described in the product insert. If the manufacturer does not provide specific instructions for QC, the laboratory must define its own mechanisms to detect errors and monitor test performance. Because antibody panels are not used alone for identification of an antibody, laboratories typically have a variety of other control processes that are being used as part of the work-up, such as having specific rules for ruling in or ruling out antibodies based on panel reactions, correlating the results of the antibody screen to the antibody panel, and performing antigen typing on the patient to confirm the absence of the corresponding antigen. The control criteria used must be defined in the procedure.

24. Can I use an IQCP for some analytes on a test platform and not others?

Yes. The Risk Assessment may indicate that an IQCP is a viable option for some analytes, but may not be suitable for others due to identified risks.

25. If an instrument or device is used to perform multiple tests, is a separate IQCP required for each test?

Many of the same risks will apply to all tests performed on an instrument or device; however, risks may vary for specific tests. The Risk Assessment performed must address all potential areas of risk for each test, as well as the instrument or device. Based on the outcome of the Risk Assessment, a single IQCP may or may not be appropriate for the instrument or device.

26. Can I add an additional test performed on the same instrument or an additional test site onto an existing IQCP? (NEW 05/13/2016)

A laboratory may modify an existing IQCP to include additional tests performed on the same instrument or additional test sites; however, there may be different risks that were not already addressed by the existing risk assessment and quality control plan. The following actions should be taken:

- Review and modify the existing risk assessment to ensure that risks specific to the new test or test site have been properly evaluated for each of the five components of IQCP (reagents, environment, specimen, test system, testing personnel) and the three phases of testing.
- Evaluate laboratory-specific data (historical or new) relating to the modifications and...
include a summary of the evaluation with the risk assessment.

- Obtain laboratory director approval of the modifications to the quality control plan.
- Retain records of the risk assessment and changes to the quality control plan.
- Ensure that appropriate ongoing quality assessment processes are in place for the added test or testing site.
- Update CAP forms (IQCP List and IQCP Summary) for inspection readiness.

# RISK ASSESSMENT

## 27. What are the components of a Risk Assessment?

The required components of a Risk Assessment include evaluation of:

1. Five required elements: reagents, environment, specimen, test system, and testing personnel
2. All phases of testing: pre-analytic, analytic, and post-analytic
3. Data from the laboratory’s own environment, instrument/equipment performance, and testing personnel
4. All variations in test performance (eg, multiple test sites, devices, types of testing personnel)

## 28. Can a single Risk Assessment be used for multiple laboratories with multiple CAP numbers?

No. Each laboratory with a separate CAP number must conduct its own risk assessment. Affiliated laboratories (or systems) may use the same or similar format and some of the same resources (eg, manufacturer’s information) when evaluating the risks, but the data collected and risk assessment must be specific to the laboratory for each separate CAP number. This is required to ensure that variations in use and practice are evaluated.

## 29. Is a separate Risk Assessment required for each site if the same instrument/device/test is used in multiple areas within a CAP number?

No. The laboratory has an option. Individual assessments may be performed or a single risk assessment (RA) may be used when there are multiple sites performing testing under a single CAP number. If a single RA is performed, all variations in the required components must be taken into account when conducting the RA (eg, differences in sites, environments, or personnel). A laboratory can then develop one IQCP that accounts for all of the differences in the RA or can develop individual IQCPs to address differences by site. Each device used must be monitored in some way, as well as each location.

## 30. Do I have to perform all new studies to gather data/information for my Risk Assessment?

No. Historical data accumulated during the laboratory’s routine operations may be used.

If the laboratory is implementing a new test, instrument, or device, it will need to gather information on the laboratory-specific risks associated with the test, including evaluation of laboratory-specific data. This may be done during the test method verification process prior to use for patient testing. Alternatively, the laboratory may choose to begin using the test after the test method is verified and perform quality control using external quality control materials following the default CLIA and CAP checklist requirements, until sufficient data can be collected to perform the risk assessment and implement a quality control plan.

## 31. How much in-house data is needed to show that the internal control process used by my instrument or device is sufficient? The 2014 checklist edition allowed my laboratory...
32. My instrument (or kit) manufacturer provides risk assessment information for implementing an IQCP. Is this acceptable to use?

Yes. It is acceptable to use information provided by an instrument or kit manufacturer as a supplement in the risk assessment. However, it does not replace the need for a laboratory to perform its own evaluation of all five elements of risk and cannot be used alone.

33. Do I need to use a probability chart like the one described in the CLSI's EP-23A guideline when performing my risk assessment?

The CAP does not require the use of a probability chart when evaluating the risks identified. As stated in COM.50300 (Risk Assessment), the intended medical uses of the test and impact if inaccurate results are reported (clinical risk) need to be evaluated for the potential sources of error; however, the checklist requirement is not prescriptive on how this must be done. The CLSI's EP23-A guideline describes the use of the probability chart and many laboratories find this a useful tool in determining if the level of risk is acceptable. Other processes may be acceptable. It is the role of the laboratory director to confirm that the level of risk is acceptable prior to approving the quality control plan for an IQCP.

QUALITY CONTROL PLAN DEVELOPMENT

34. What is required in the written Quality Control Plan for a test with an IQCP?

The written Quality Control Plan must include, at a minimum, the number, type (internal, electronic, external, etc) and frequency of testing for QC, and the criteria for acceptable performance. The data from the Risk Assessment must support the rationale for the plan. The plan may allow for less than the CLIA requirements, but cannot be less than the manufacturer's requirements for QC.

Additionally, the CAP will require external QC to be performed at least every 31 days and for each new lot and shipment for tests that have daily QC requirements (see FAQ #50 for microbiology exceptions). The laboratory will determine if the external QC must be run on each device or instrument or on a subset of devices, based on the manufacturer's instructions and the findings of the risk assessment and define the requirements in the written quality control plan.

The written plan must be signed and dated by the Laboratory Director prior to implementation. This approval cannot be delegated.

35. Why is the CAP requiring external controls to be run at least every 31 days if an IQCP is in place?

IQCPF 7.0
While many of the elements of IQCP are not new for laboratories, the overall concept is a significant change. The CAP decided to define a minimum frequency for performing external quality control to include new lots and shipments of reagents and at least every 31 days. Laboratories must also follow manufacturer’s instructions at minimum. The CAP will reevaluate this decision as we gain more experience with IQCP.

36. For the external QC at least every 31 days, how many levels of controls need to be run? If multiple devices are in use, can we run the external QC using a subset of devices?

The laboratory must define the control procedures to be followed based on the risk assessment performed. The decision on the number of controls needed and the use of subsets of devices using the same reagent lot if multiple devices are used may be defined by the laboratory in the quality control plan, if appropriate, and be approved by the laboratory director based on the risk assessment evaluation and the supporting data used in the risk assessment. The laboratory director is ultimately responsible for the control procedures defined. The effectiveness of the control measures defined in the quality control plan must be evaluated on an ongoing basis as part of the quality assessment monitoring process.

37. Can I use my IQCP to reduce the type and/or frequency of QC to be less stringent than the manufacturer’s instructions?

No. At a minimum, laboratories must follow all manufacturer instructions for internal and external quality control.

The laboratories are not required to follow manufacturer’s recommendations. The All Common Checklist requirement COM.50500 currently contains a statement indicating that the IQCP needs to be in compliance with manufacturer’s instructions and recommendations. The reference to recommendations in this requirement will be removed in the 2016 edition. The CAP has posted a correction to the 2015 checklist edition on the CAP website with this updated interpretation that is effective for inspections performed with the 2015 checklist edition. The Checklist Errata document for the 2015 edition can be found by logging into e-LAB Solutions Suite on the CAP website (www.cap.org) and going to CAP Accreditation Resources, Accreditation Standards and Manuals.

38. Will the checklist requirements for more frequent QC for some types of testing still apply (e.g., coagulation, blood gases) if a laboratory implements an IQCP?

During the Risk Assessment process for a test that is eligible for IQCP, the laboratory must evaluate the potential sources of errors, manufacturer’s instructions, and historical test performance to identify the appropriate control processes. The laboratory’s Quality Control Plan may define a frequency less than the minimum frequency defined in the CAP checklist if it is determined to be acceptable based on the risk assessment.

If an IQCP is not implemented, the minimum QC frequency defined in the CAP checklists and default CLIA requirements must be followed.

In all cases, manufacturer’s requirements for QC must be followed, at a minimum.
and revise the IQCP.

Quality control and instrument/equipment maintenance and function check data must continue to be reviewed at least monthly.

Additionally, each IQCP must be assessed **annually** for effectiveness and revised, as necessary.

**40. Why is the CAP requiring a reassessment of the IQCP at least annually?**

The IQCP option was new to the 2015 edition. The CAP decided to take a more stringent approach than the CMS in this area to encourage laboratories to more closely evaluate effectiveness of the quality control plan that was implemented. The CAP will reevaluate this decision as we gain more experience with IQCP.

**41. Does the quality assessment monitoring for IQCP need to be included in the quality management (QM) program?**

If used, IQCP must be incorporated into the quality management program. Ongoing quality assessment of an IQCP must include evaluation of errors relating to the different phases of the testing process, QC failures and corrective action, complaints from clinicians and other providers on the quality of results, and an annual assessment of the effectiveness of the IQCP. Some of these items are often included in the QM plan already. The laboratory may consider including ongoing assessment of these items as quality indicators.

**MICROBIOLOGY TESTING**

**42. Do I need an IQCP for my microbiology testing?**

The 2015 Microbiology Checklist includes a number of revisions based on changes in the CMS Interpretive Guideline. Along with the removal of the EQC option, the CMS also removed provisions from the CMS Interpretive Guideline that allowed laboratories to follow alternate frequencies for quality control of microbiology media, susceptibility testing, and identification systems that were based on published guidelines from the CLSI. If a laboratory wishes to continue to follow the alternate QC protocols for exempt media, weekly QC for susceptibility testing, or streamline QC for identification systems, a laboratory must perform a risk assessment and implement an IQCP. These changes are described in the checklist.

For other types of microbiology testing that employ an internal (electronic/procedural/built-in) control system in lieu of external QC, such as direct antigen test kits or instruments for molecular infectious disease testing, an IQCP must also be implemented if external QC is not run following the requirements as defined in the CAP checklist and default CLIA regulations.

An IQCP is not needed for reagents where the checklist and other regulations define specific quality control requirements, such as weekly QC for Gram stains (MIC.21540), the testing of new lots and shipments of certain tests described in MIC.21624 (eg, PYR, catalase, coagulase, latex coagulation tests, optochin, bacitracin, indole, and Streptococcal grouping reagents), or the monthly QC of typing antisera described in MIC.21628 (e.g. Salmonella, Shigella).

Non-exempt media that is routinely checked per batch/lot/shipment for sterility, ability to support growth, and biochemical reactivity (if appropriate) would not need an IQCP, as the CLIA default QC is already being performed.

A tool, **“Microbiology: When is the Individualized Quality Control Plan (IQCP) Option Applicable?”**, is available on the IQCP Resources page on the CAP website to help identify when an IQCP is needed for microbiology testing.
43. Can I still use the CLSI documents as a basis for my quality control criteria for antimicrobial susceptibility testing, identification systems (eg. streamlined QC), and media?

The CLSI documents (M2, M7, M22, M50, M100) may not be used as the sole criteria for establishing the control criteria. If the defined frequency of quality control is less stringent than the CAP checklist requirements and default CLIA quality control regulations, the laboratory must implement an IQCP. If the risk assessment performed justifies the quality control criteria as spelled out in the CLSI documents, it may be part of your quality control plan.

44. Are specific tools available for developing an IQCP for microbiology tests or reagents?

Members from the CAP, the American Society of Microbiology (ASM) and the CLSI have worked collaboratively to produce templates that may be used to develop an IQCP for antimicrobial susceptibility testing, microbiology identification systems, and microbiology media. Templates and examples can be downloaded from the IQCP Resources page on the CAP website. Other resources are described in FAQ #62.

45. Does my laboratory need to create a risk assessment for bacterial cultures?

There are no requirements for a risk assessment or IQCP to be implemented for microbiology cultures. Neither the CLIA regulations nor the CAP Checklists define a specific QC requirement for microbiology cultures. The IQCP requirements apply to identification systems and media involved in this process.

46. Do I need to perform a risk assessment on each type of media used or can I group them as agar media on plates and broth media?

The Microbiology Checklist requirement MIC.21240 contains the requirements for media QC and the use of an IQCP. Not all media have an equal risk for failure; therefore, if the laboratory decides to include more than one type of media in a single IQCP, the IQCP documents must clearly list all types of media included and the risk assessment must include an evaluation of the risks for all types of media included, including the use of a laboratory's own data (e.g. historical performance, problem logs) in this evaluation. In addition, please note that at a minimum, laboratories must follow manufacturer's guidelines for performing end user quality control. Some manufacturers require end user quality control for media while others do not.

If end user quality control is performed on media that meets the default CLIA regulations and CAP checklist requirements, an IQCP is not required.

47. Do I need an IQCP for blood cultures?

There are no CLIA regulations or CAP checklist requirements for daily QC on blood culture instruments. Laboratories must follow manufacturer's instructions for function checks and maintenance. However, a laboratory may implement an IQCP for blood culture media listed as exempt in the CLSI/NCCLS Standard M22-A3 if it wishes to accept quality control performed by the media manufacturer in lieu of performing its own end user quality control. Media quality control is addressed in the Microbiology Checklist requirements MIC.21240 and MIC.21420.

48. If my laboratory (satellite lab) does microbiology culture set up and blood culture collection and sends the cultures to an affiliated laboratory for testing, do we need an IQCP for the media involved?

If the satellite laboratory is receiving the media from the laboratory that will be performing the testing, it is not responsible for the end user quality control of the media. The reference laboratory is responsible for quality control of the media, including the use of an IQCP, when appropriate. The satellite laboratory is responsible for a visual examination of the media as stated in MIC.21420 to confirm that the media was not adversely affected during transport. The
satellite laboratory may also have an IQCP for the extent of their handling of the media.

Any laboratory that orders and receives media directly from the manufacturer is subject to quality control requirements for the media, including IQCP, as listed in MIC.21240 and MIC.21420, regardless of whether it performs testing on cultures or refers it to another laboratory.

If any culture result, such as findings of “no growth”, are reported by the satellite laboratory, it is responsible for the quality control of the media involved, including the use of an IQCP when appropriate, regardless of whether it receives the media directly from the manufacturer or from another laboratory.

49. What can I use for historic data when developing an IQCP for media listed as exempt in the CLSI/NCCLS Standard M22-A3 when I have not been doing end user quality control at my laboratory?

While there must be assessment of laboratory-specific data included in the risk assessment, the IQCP option is not prescriptive on the amount of data or evidence required for the risk assessment. It is the laboratory director’s responsibility to determine the acceptable amount of data. The following are examples of historical sources of data that may be used as part of the risk assessment:

- Records from visual quality checks of media upon receipt
- Data regarding transport and storage conditions of media
- Problem logs
- Manufacturer’s quality certificates.

There is an example of an IQCP for microbiology media available on the CAP website that was developed in collaboration by members of the CAP, ASM, and CLSI that may provide additional guidance. This example along with other microbiology tools can be downloaded from the IQCP Resources page on the CAP website.

50. How does the requirement for external QC at least every 31 days in COM.50500 apply to microbiology testing using media, identification systems, and susceptibility systems?

The requirement for external QC to be performed at least every 31 days only applies to testing where the checklist requires daily quality control as the default QC frequency. It does not apply to quality control of microbiology media and identification systems because the minimum QC frequency is for new lots and shipments. For susceptibility testing, the requirement is met by the performance of external controls on a weekly basis.

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RECORD RETENTION

51. What records are required? What is the retention time for this information?

All information, records, or data used in conducting the Risk Assessment (eg, previous QC data, manufacturer’s package insert, information or instructions, instrument maintenance and function records, proficiency testing data, environmental data), and the Quality Control Plan must be maintained for the life of the IQCP plus two years (five years for Transfusion Medicine).

Records and data collected during the ongoing monitoring and assessment of the IQCP must be retained for two years (five years for Transfusion Medicine).

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CAP INSPECTIONS

IQC7.0
52. What if my laboratory is being inspected with the 2014 checklist edition after January 1, 2016?

All laboratories with CAP inspections occurring after January 1, 2016 will be evaluated for compliance with the QC requirements for nonwaived testing, as published in the 2015 checklist edition, regardless of the checklist edition being used for inspection.

For laboratories that will be inspected with the 2014 checklist edition and the inspection window allows for inspection after January 1, 2016, the CAP has provided a transition packet to alert them to this change and provide tools to prepare for inspection.

53. What happens if my laboratory was not able to complete all the necessary risk assessments and implement IQCP for all areas of the laboratory by January 1, 2016? (UPDATED 1/21/2016)

The CAP must abide by the rules stipulated by Centers for Medicare and Medicaid Services (CMS). CMS has stated that there will be no extension to the January 1, 2016 implementation date. If the laboratory does not have an IQCP in place for tests performed using instruments or devices where QC is performed less frequently than stated in the default CLIA regulations and CAP checklist requirements, the laboratory must perform daily external quality control at the required frequency until an IQCP can be implemented by the laboratory. If the laboratory is cited with a deficiency relating to the performance of EQC and the lack of an IQCP during on onsite inspection conducted after January 1, 2016, the laboratory will have 30 days to respond to the deficiency with its corrective actions.

54. What if I am assigned to do an inspection after January 1, 2016 with the 2014 checklist edition?

Teams that are inspecting laboratories with the 2014 checklist edition after January 1, 2016, are provided with instructions, training, and the revised 2015 checklist requirements.

55. How will IQCP be inspected?

Inspectors will look for compliance with the requirements defined in the 2015 checklist for IQCP.

For each CAP number, requirements for compliance will include:

1. Risk Assessment, including evaluation of all of the following:
   a. All five required elements (Reagents, Environment, Specimen, Test System, Testing Personnel)
   b. All phases of testing: pre-analytic, analytic, and post-analytic
   c. Data from the laboratory’s own environment, instrument/equipment performance, and testing personnel
   d. All variations in test performance (eg, multiple test sites, devices, types of testing personnel, etc)

2. Written Quality Control Plan defining types of control processes used, criteria for acceptable performance, and frequency evaluated. QC may not be performed less frequently than defined in the manufacturer’s instructions.

3. Approval of the written IQCP by the laboratory director prior to implementation (signed and dated)

4. Ongoing assessment of errors, QC failures, and complaints, including the need to reassess the risk assessment and quality control plan

5. Annual review of each IQCP

6. Use of CAP forms to maintain a list of Individualized Quality Control Plans and a summary of each IQCP

Inspectors may cite deficiencies when any of the above elements are not in compliance.
checklist requirements. The decision on whether the level of risk for any of the elements evaluated in the risk assessment is acceptable is left to the discretion of the laboratory director.

FORMS

56. Where can I find the IQCP forms mentioned in the All Common Checklist requirement COM.50200 (IQCP Test List/IQCP Summary)? (NEW 1/21/2016)

The forms and instructions can be downloaded from the IQCP Resources page on the CAP website.

57. Do I need to submit the IQCP Test List and the IQCP summary form to the CAP? (NEW 1/21/2016)

No, the forms are not submitted to the CAP unless specifically requested. The forms must be available to inspectors at the time of inspection; they may also be requested by the inspection team ahead of time. The Test List and Summary form should be updated between inspections to ensure readiness for inspection.

58. Why is the IQCP Summary Form required? (NEW 1/21/2016)

The IQCP option was new to the 2015 edition. The summary form is intended to facilitate the inspection process. Inspectors can use the IQCP summary form to gain a high-level view of the control processes that the laboratory has put in place based on their Risk Assessment. The CAP will reevaluate the utility of this form as we gain more experience with IQCP.

59. Do I need to make changes to the IQCP forms if my laboratory modifies an existing IQCP, such as adding tests or test sites? (NEW 05/13/2016)

Yes. The forms need to be updated to ensure inspection readiness and to provide inspectors with accurate information. Changes can be noted directly on the IQCP Summary Form indicating what was changed and the date changes were made. The most recent version of the IQCP Summary form posted on the CAP website has a revision history section at the end that may be used for this purpose.

60. Am I still required to use the CAP IQCP Summary Form if I have used a software program for the development of my IQCP? (NEW 1/21/2016)

Yes. If one or more IQCPs are in use, laboratories must complete the CAP IQCP List and IQCP Summary forms and provide a copy to the inspector during the laboratory’s next on-site inspection.

61. How do I fill in the summary form for Microbiology media? (NEW 1/21/2016)

The forms and instructions can be downloaded from the IQCP Resources page on the CAP website. A microbiology media example form is included on page 5 of the instructions.

OTHER RESOURCES

62. Where can I find other sources of information on IQCP?

The CAP website has a variety of resources on the IQCP Resources page that will provide further information on IQCP.
be updated as new resources become available.

Aside from the resources listed below, laboratories may also wish to contact the manufacturers of instruments or devices to determine if they provide any information or tools for conducting a risk assessment.

**CAP IQCP Resources:**

- [Eligibility Determination for Individualized Quality Control Plan (IQCP) Option](#)
- [Microbiology: When is the Individualized Quality Control Plan applicable?](#)
- CAP/ASM/CLSI Microbiology IQCP template and examples
- CAP forms and instructions for inspection
- [CAP IQCP webinar presentation August 2015 (Focus on Compliance webinar series)](#)

**Other Resources:**

- Clinical and Laboratory Standards Institute (CLSI) Guideline EP23-A, Laboratory Quality Control Based on Risk Management (www.clsi.org) and companion documents
- [The Centers for Medicare and Medicaid Services guidance and brochures](#)
- [CDC/CMS Handbook: Developing an IQCP – A Step-by-Step Guide](#)
- Manufacturer tools, if available