Your First IQCP Inspection

Jane L. Smith MS MT(ASCP)SI, DLM
Date April 7, 2016

The following information in this presentation is intended as an aid in the development of your facility's IQCPs. Specific requirements for IQCPs can be found from CMS and your accreditation organization.
Your Speaker

Jane L. Smith MS MT(ASCP)SI, DLM
Technical Manager, Scientific Affairs

- Volunteered on CLSI POCT04-A3 (Point of Care IVD Testing) and QMS03 (Training and Competence Assessment) documents
- Currently directing a cross functional IQCP team to provide IQCP support materials for Alere products
- Volunteer Inspector for CAP
Agenda

1. Updates on IQCP from CAP, CMS, COLA, and TJC
2. Observations from Completed IQCP Inspections
3. IQCP Inspection Helpful Hints
4. IQCP Inspection Question and Answer Session
Updates on IQCP from CAP, CMS, COLA, and TJC
CAP IQCP Resources

IQCP Resources FAQ (56 questions)
- Check webpage for updates.

POC Checklist 2015

All Common Checklist 2015
- Read every line and have all the documentation listed under notes and comments.

Instructions for Inspecting IQCP

2015 IQCP Requirements

IQCP Inspector Tip Sheet

IQCP Dos and Don’ts
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 11/23/2015)

- 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 follow the entire testing process, from sample introduction through the analytic pathway. It must also be a different type of material or from a different lot number than used to calibrate the instrument. 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.

Highlights of CAP IQCP Resources FAQs

What are the QC requirements if I have multiple identical instruments/devices/cartridges in use but do not wish to develop an IQCP? (UPDATED 11/23/2015)

• 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 (e.g., 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.

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 (e.g., 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.

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.
- The laboratory needs to perform its own evaluation of all five elements of risk.
- Laboratories cannot use manufacturer risk assessment alone

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.
Will the checklist requirements for more frequent QC for some types of testing still apply (eg, 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.
What are the QC requirements if I have multiple identical instruments/devices/cartridges in use but do not wish to develop an IQCP?

• Without an IQCP, the existing CLIA and 2015 CAP checklist requirements will apply; generally, at least two levels of external QC for each device and cartridge, each day of testing (or more frequently as specified in a discipline or subdiscipline).

What is required for ongoing assessment of an IQCP?

• Ongoing assessment must include evaluation of errors relating to the different phases of the testing process, QC failures and corrective action, and complaints from clinicians and other providers on the quality of results. It must also include a determination of the need to reassess 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.
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.

Data sourced from CAP IQCP FAQs Dec. 18, 2015 Permission granted by College of American Pathologists.
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:
  - Risk Assessment, including evaluation of all of the following:
    - All five required elements (Reagents, Environment, Specimen, Test System, Testing Personnel)
    - All phases of testing: pre-analytic, analytic, and post-analytic
    - Data from the laboratory’s own environment, instrument/equipment performance, and testing personnel
    - All variations in test performance (eg, multiple test sites, devices, types of testing personnel, etc)
How will IQCP be inspected (continued)?

- 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.
- Approval of the written IQCP by the laboratory director prior to implementation (signed and dated)
- Ongoing assessment of errors, QC failures, and complaints, including the need to reassess the risk assessment and quality control plan
- Annual review of each IQCP
- 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 with 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.
The QC study performed to assess the performance and stability of the tests must support the QC frequency and elements defined in the laboratory's quality control plan. The study must include data representing, at a minimum the maximum interval between runs of external quality control. The laboratory may use historical data during the risk assessment for tests already in place.
Hello Jane,

The Lab Director should be involved in the design function of the IQCP study. They must review and sign the study before implementation. CAP is not restrictive of the tool used to perform the IQCP, however, it must include all five required elements (reagents, environment, specimen, test system, and testing personnel). All phases of testing must be addressed (pre-analytic, analytic, and post-analytic). Data from the lab's own environment, instrument/equipment performance, and testing personnel must be used. All variations in test performance, for example multiple test sites, devices, types of testing and personnel must be studied. Concerning your question about whether CAP has a recommended study for QC, there are so many variables involved with the labs that are CAP accredited, each site must develop their own protocol to assess the risk at their facility.

Thank you for your question.

Sincerely,

Senior Inspection Specialist
IQCP Inspector Tip Sheet

IQCP Inspector Tip Sheet for Risk Assessment (RA)

- RA Identifies potential risks and processes to mitigate risk
- Preanalytic, analytic, and post analytic
- Review of the manufacturer’s instructions
- Data from the laboratory’s own environment
- Specimen, Test System, Reagent, Environment, Testing Personnel

Inspector Tip Sheet for Quality Control Plan (QCP)

- External control materials run with new lots and shipments and at least every 31 days
- Customization of quality control plan for variations in use
- Approval of the plan with signature of laboratory director and date before implementation
- Number, type (external and internal quality control systems), and frequency of quality control defined
- Quality control performed at least as frequent as required in manufacturer’s instructions

Additional processes for monitoring the quality of the 5 risk groups

QCP - Followed as written

Data sourced from IQCP Inspector Tip Sheet 2015. Permission granted by College of American Pathologists.
Inspector Tip Sheet for Quality Control Plan (QCP)

- External control materials run with new lots and shipments and at least every 31 days
- Quality control performed at least as frequent as required in manufacturer’s instructions
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QCP-Followed as written

Data sourced from IQCP Inspector Tip Sheet 2015. Permission granted by College of American Pathologists
IQCP Inspector Tip Sheet for Quality Assessment (QA)

- Monthly review of quality control and instrument/equipment maintenance and function check data
- Evaluation of errors relating to all phases of the testing process
- Annual reapproval of the quality control plan
- Separate monitoring for variations in testing
- Reevaluation of the risk assessment when failures are identified
- Evaluation of corrective actions taken if problems are identified
- Evaluation of complaints on the quality of testing

# Inspector IQCP Do’s and Don’ts

<table>
<thead>
<tr>
<th>IQCP REQUIREMENT</th>
<th>DO CITE IF:</th>
<th>DON’T CITE BECAUSE:</th>
</tr>
</thead>
<tbody>
<tr>
<td>COM.50300</td>
<td>1.) Risk Assessment (RA) is missing one or more of the five required components (specimen, reagent, environment, testing personnel, test system)</td>
<td>1.) The format of RA is not “user-friendly” - RECOMMEND</td>
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<td></td>
<td>2.) RA doesn’t cover all three phases of testing: pre-analytic, analytic, and post-analytic</td>
<td>2.) The RA doesn’t look like the ones in YOUR lab - DISCUSS</td>
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<td>3.) RA did not include in-house data (previous QC records, environmental monitoring, etc.) or did not involve laboratory personnel</td>
<td>3.) You disagree with the acceptability of a specific risk - DISCUSS</td>
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</tbody>
</table>
## Inspector IQCP Do’s and Don’ts

<table>
<thead>
<tr>
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<th>DON’T CITE BECAUSE:</th>
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</thead>
<tbody>
<tr>
<td>COM.50400, COM.50500</td>
<td>4.) Quality Control Plan (QCP) was not signed by the laboratory director prior to implementation</td>
<td>4.) You disagree with the frequency of the QC being run - RECOMMEND</td>
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<td>5.) QC is performed less frequently than specified in manufacturer’s instructions</td>
<td>5.) You think the QCP does not address potential risks - RECOMMEND</td>
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<td>6.) QCP is not followed as written</td>
<td>6.) You disagree with the acceptability of QC to mitigate a specific risk - DISCUSS</td>
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## Inspector IQCP Do’s and Don’ts

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<th>IQCP Requirement</th>
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<th>DON’T CITE BECAUSE:</th>
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<tr>
<td>COM.50600</td>
<td>7.) Quality Assurance process does not monitor devices used in all locations</td>
<td>7.) You don’t think that the lab has adequately addressed potential patient outcomes - RECOMMEND</td>
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<td>8.) Serious quality concerns or adverse patient outcomes have not been addressed – MAY ALSO NEED TO CITE TLC.10460</td>
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Individualized Quality Control Plan Summary

Complete a separate form for each IQCP in use and present to the inspector during the on-site inspection.

<table>
<thead>
<tr>
<th>Laboratory Name:</th>
<th>Laboratory Section/Department:</th>
<th>CAP Number:</th>
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1) **Instrument/Device**
   - Include name, manufacturer, and model

2) **Tests**
   - List all tests included under the IQCP

3) **Number of Devices In Use**
   - If used in more than one area

4) **List of Test Sites**
   - Use asterisk (*) if used in more than one area

   - Date of Director Approval
   - Date Implemented
   - Date Retired

   Click here to enter a date.
   Click here to enter a date.
   Click here to enter a date.

5) **Control Processes Used to Monitor Risk**
   - Include a brief statement about each control process – list the monitor and frequency evaluated

<table>
<thead>
<tr>
<th>Reagents</th>
<th>Environment</th>
<th>Specimen</th>
<th>Test System</th>
<th>Testing Personnel</th>
<th>Other</th>
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- This is not to be used for risk assessment data.
- Only quality control measures.

The form is intended to be used for developing an IQCP or the performance for a risk assessment. The form is to be completed by laboratories preparing for a CAP inspection. Inspectors will use this form and IQCP List as tools for audit the IQCPs in use during a CAP onsite inspection.

Permission granted to use this form by College of American Pathologists.
Many Great Pages Worth Reading…

This is the most recent document available on CMS.gov IQCP webpage

Quality Control Plan Tips to Remember

A complete QCP must:

- **Provide** for immediate detection of errors for each phase of the testing process (i.e. before, during, and after testing) for the test.

- **Specify** the number, type, and frequency of testing QC material(s).

- **Contain** criteria to determine acceptable QC results.

- **Require** the laboratory perform QC as specified by the manufacturer’s instructions, but not less than the manufacturer’s instructions.

- **Indicate** that your Laboratory Director reviewed, signed, and dated the QCP document.

- If your QCP does not address all five items listed above, you do not have a QCP.

- Go back and investigate what is missing.

Quality Assessments - Documents to Consider

- QC data sheets review
- Delta check logs
- PT records (scores, testing failures, trends)
- Complaint reports
- Patient results review
- Specimen recollection logs
- Specimen rejection or quantity not sufficient logs

Quality Assessments - Documents to Consider

- Panic value call logs
- Turnaround time reports
- Temperature logs
- Records of preventive measures, corrective actions, & follow-up
- Personnel competency records
- Maintenance logs
- Training logs
- FDA alerts

Quality Assessment (QA) Helps You…..

Make sure that your QCP is working as expected

Monitor errors and QC failures

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

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

Individualized Quality Control Plan (IQCP)

Implementation Guide

Permission to Use Copyrighted Material granted by:
COLA Resources, Inc., (CRI) a laboratory medicine educational and consulting organization, located at 9881 Broken Land Parkway, Suite 215 Columbia Maryland 21046
The Joint Commission (TJC) Update  IQCP is Not Required

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<td>(2-3 levels external QC/day)</td>
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<tr>
<td>EQC</td>
<td>✗</td>
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<tr>
<td>(Equivalent QC)</td>
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<tr>
<td>IQCP</td>
<td>✔️</td>
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</table>
Observations from Completed IQCP Inspections
CLIA Inspector Comments

Inspection Observations:

• I’ve only seen a few IQCPs implemented, but they were good. I had a couple of proactive labs and they were prepared.
Know What Tests Qualify for IQCP

Inspection Observations:

• Labs are unfamiliar with the eligibility determination requirement.
• The lab had incorporated or listed waived tests on their form which are ineligible tests
Eligibility Determination for Individualized Quality Control Plan (IQCP) Option

Does your state/jurisdiction allow for use of an IQCP to reduce the frequency of daily external quality control?

NO

Ineligible for IQCP: Follow IQC requirements in state regulations and default CAP QC requirements

WAIVED

Ineligible for IQCP: Follow manufacturer’s QC instructions and CAP Checklist requirements for waived testing

NONWAIVED

What is the complexity of the test?

Ineligible for IQCP: Follow default CAP QC requirements

Is the test under the CMS specialty of Anatomic Pathology (ANP) or Cytopathology (CYT), not including tests that can be assigned to other CMS specialties?

YES

Ineligible for IQCP: Follow default CAP QC requirements

NO

Does the instrument or device have an internal control process (electronic, procedural, or built-in)?

Does the test involve the use of microbiology media or panels used for microbial identification (with 2 or more substrates) or susceptibility testing?

NO

Ineligible for IQCP: Follow default CAP QC requirements

YES

Do the manufacturer’s instructions allow for external quality control materials to be run less frequently than the default*** CLIA and CAP QC frequency?

Ineligible for IQCP: Follow default CAP QC requirements

NO

Eligible for IQCP: Follow Checklist requirements for IQCP

*** The default CAP QC frequency for external quality control materials is as follows:

1) Quantitative tests—six controls at different concentrations each day of patient testing, except for coagulation tests (two levels every eight hours, and Blood Gas testing (one level every eight hours).

2) Qualitative tests—positive and negative controls each day of patient testing.

Permission granted to use this form by College of American Pathologists
Eligibility Determination for Individualized Quality Control Plan (IQCP) Option

Does your state/jurisdiction allow for use of an IQCP to reduce the frequency of daily external quality control?

NO

Ineligible for IQCP: Follow QC requirements in state regulations and default CAP QC requirements

WAIVED

YES

Ineligible for IQCP: Follow manufacturer’s QC instructions and CAP Checklist requirements for waived testing

NONWAIVED

What is the complexity of the test?

Is the test under the CMS specialty of Anatomic Pathology (ANP) or Cytopathology (CYP), not including tests that can be assigned to other CMS specialties?

NO

Ineligible for IQCP: Follow default CAP QC requirements

YES

Does the test, instrument or device have an internal control process (electronic, procedural, or built-in)?
* ANP or CYP tests are ineligible for IQCP unless the testing can be billed under another CMS specialty.

** The default CAP QC frequency for external quality control materials is as follows:

1) Quantitative tests - two controls at different concentrations each day of patient testing, except for Coagulation tests (two levels every eight hours) and Blood Gas testing (one level every eight hours)

2) Qualitative tests – positive and negative controls each day of patient testing.
Individualized Quality Control Plan Summary

List of Individualized Quality Control Plans

• Inspection Observations:

These documents should be available as stand alone documents for the inspection team.

In the summary plan, test systems were not listed.

Data sourced from CAP All Common Checklist July 28, 2015  Permission granted by College of American Pathologists.
Inspection Observations:

- Laboratories have received IQCP support documents from manufacturers. They have not added their own lab’s data and included this information in their plan.
- Laboratories have not evaluated potential sources of error in preanalytic, analytic and postanalytic testing process.
• Laboratory was too vague on addressing potential risks associated with the instrument being used in multiple environments. The RA with multiple identical devices must show an evaluation was performed if there are differences in testing personnel and or environments where testing is performed.
• POCC was only person involved in writing IQCP. The laboratory must involve a representative sample of testing personnel in the process of conducting the RA.
Laboratory’s risk score was high for a risk, and when asked what was done for mitigation they didn't have an answer. Laboratory must have documentation for what do you do to reduce mitigating factor.

Data sourced from CAP All Common Checklist July 28, 2015  Permission granted by College of American Pathologists.
• Frequency and type of QC has not been transferred from the test procedure and specified in their IQCP.
• IQCP does not include manufacturer’s instructions to ensure the frequency of QC is not less than required by manufacturer. Package inserts should be available as part of the laboratory’s documentation to ensure frequency of QC is appropriate.
Inspection Observations:

- Some labs have not specified how IQCP will be incorporated into their QA programs, and how it will be evaluated/corrective actions if needed. Review and documentation of QC and corrective actions is being done but documentation in QA monitoring has been incomplete.
Laboratory Comments Post Inspection

Laboratory Comments about IQCP Inspections

- The IQCP was good enough for our laboratory director to sign how was it lacking? Laboratory thought that was the purpose of the "individual" in the IQCP.
- The inspector was very knowledgeable and respectful. The inspector was very patient and even provided suggestions on how to improve my IQCP.
- We did not have to revert to doing 2 or 3 levels of QC daily or every 8 hours because we had a signed IQCP even though our inspector thought our IQCP was lacking in areas.
### Individual Quality Control Plans:

<table>
<thead>
<tr>
<th>Risk assessments, validation data, approved quality plans and ongoing quality assessments. These documents must be retained for two years following the discontinuing of testing or the Individual Quality Control Plan.</th>
<th>Document Retention Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 years</td>
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</table>
IQCP Inspection Helpful Hints
Top Tips

- Read all the CAP FAQs
- CAP FAQs are updated frequently
- Use Email Contacts
- Best Guide: Developing an IQCP A Step-by-Step Guide
- Read CAP Inspecting the New IQCP
- Training, Competency, and Educational Documentation
- Read Every Line of the CAP Checklist Including Requirement Text and Notes
- Extra External Quality Control Materials
- Read AACC POC List Serve
- Watch EALERTS from CAP
- E-Alerts from TJC
For More Information

<table>
<thead>
<tr>
<th>CMS</th>
<th><a href="mailto:IQCP@cms.hhs.org">IQCP@cms.hhs.org</a></th>
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<td></td>
<td>Go to the Leading Practice Library</td>
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IQCP Inspection Question and Answer Session
Thank you!

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