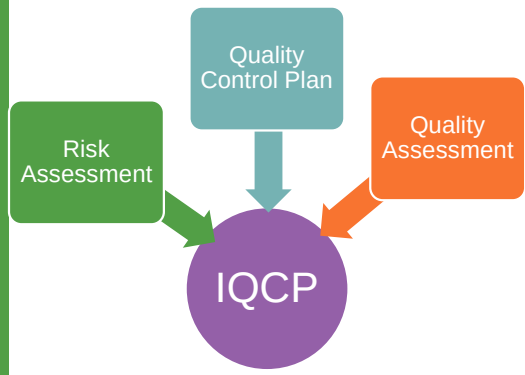
Alere™ Knowing now matters:

Your First IQCP Inspection



Jane L. Smith MS MT(ASCP)SI, DLM

October 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

Scientific Affairs

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 2016

All Common Checklist 2016

- 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

Highlights of CAP IQCP Resources FAQs

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.

Data sourced from CAP IQCP FAQs Dec. 18, 2015. Permission granted by College of American Pathologists.

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 (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.

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.

Data sourced from CAP IQCP FAQs Dec.15, 2015. Permission granted by College of American Pathologists.

Highlights of CAP IQCP Resources FAQs

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

Data sourced from CAP IQCP FAQs Dec. 18, 2015. Permission granted by College of American Pathologists.

Highlights of CAP IQCP Resources FAQs

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

Data sourced from CAP IQCP FAQs Dec. 18, 2015. Permission granted by College of American Pathologists.

Highlights of CAP IQCP Resources FAQs

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.

Data sourced from CAP IQCP FAQs Dec.18, 2015 Permission granted by College of American Pathologists.

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?

- 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.

Data sourced from CAP IQCP FAQs Dec. 18, 2015 Permission granted by College of American Pathologists.

Highlights of CAP IQCP Resources FAQs

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.

Highlights of CAP IQCP Resources FAQs

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)

Data sourced from CAP IQCP FAQs Dec. 18, 2015. Permission granted by College of American Pathologists.

Highlights of CAP IQCP Resources FAQs

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.

Data sourced from CAP IQCP FAQs Dec. 18, 2015. Permission granted by College of American Pathologists.

Read Every Line in the Requirement Text and Notes

Example: CAP Checklist COM.50300 Risk Assessment (RA)

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.

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

How To Get Help!

From: Laboratory Accreditation Program-General [mailto:accred@cap.org]

Sent: Friday, February 19, 2016 3:27 PM

To: Smith, Jane; Smith, Jane

Subject: SR 2460382 Re: Interpretation of the Requirement Text COM.50300 [REF:43770134012]

Hello Jane,

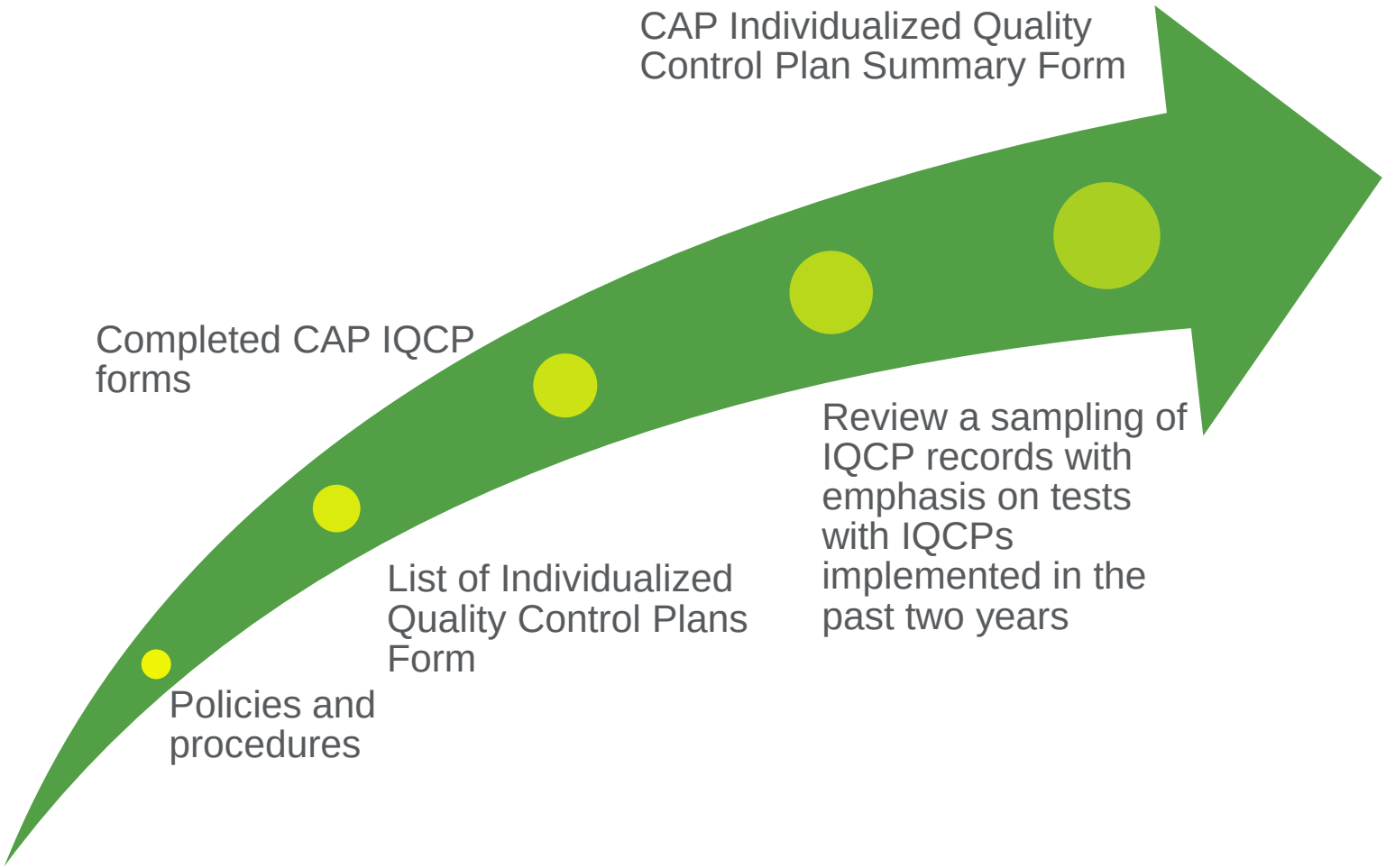
The Lab Director should be involved in the design function of the IQCP study. They must review and sign the study before implementation. CAP is not restrictive of the tool used to perform the IQCP, however, it must include all five required elements (reagents, environment, specimen, test system, and 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

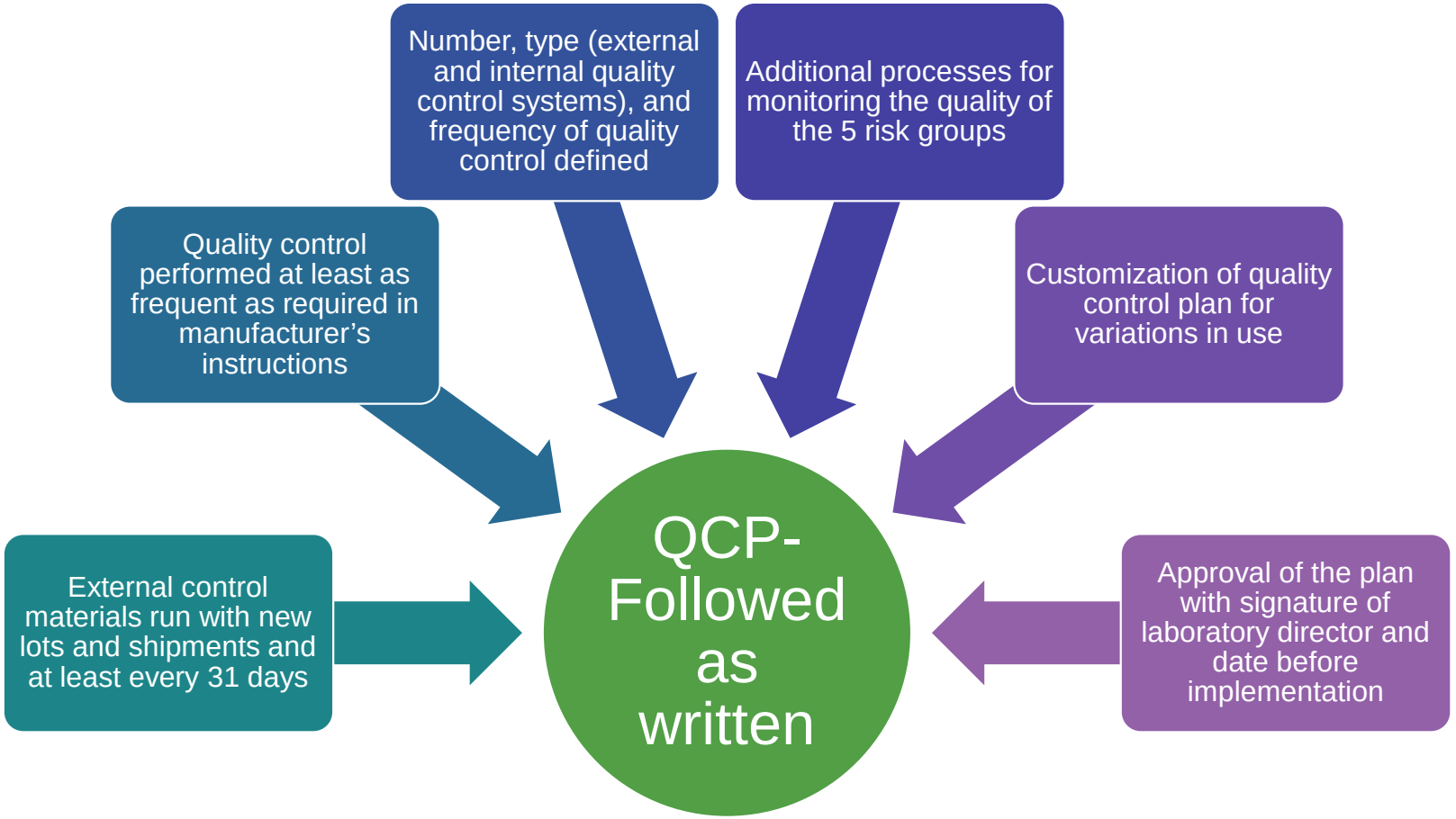


Data sourced from IQCP Inspector Tip Sheet Sept. 2015. Permission granted by College of American Pathologists.

IQCP Inspector Tip Sheet for Risk Assessment (RA)

Data sourced from IQCP Inspector Tip Sheet Sept. 2015. Permission granted by College of American Pathologists.

Inspector Tip Sheet for Quality Control Plan (QCP)



Data sourced from IQCP Inspector Tip Sheet 2015. Permission granted by College of American Pathologists

IQCP Inspector Tip Sheet for Quality Assessment (QA)

Data sourced from IQCP Inspector Tip Sheet Sept 2015. Permission granted by College of American Pathologists.

Inspector IQCP Do's and Don'ts

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

Inspector IQCP Do's and Don'ts

IQCP REQUIREMENT	DO CITE IF:	DON'T CITE BECAUSE:
COM.50400, COM.50500	4.) Quality Control Plan (QCP) was not signed by the laboratory director prior to implementation	4.) You disagree with the frequency of the QC being run - RECOMMEND
	5.) QC is performed less frequently than specified in manufacturer's instructions	5.) You think the QCP does not address potential risks - RECOMMEND
	6.) QCP is not followed as written	6.) You disagree with the acceptability of QC to mitigate a specific risk - DISCUSS

Inspector IQCP Do's and Don'ts

IQCP REQUIREMENT	DO CITE IF:	DON'T CITE BECAUSE:
COM.50600	7.) Quality Assurance process does not monitor devices used in all locations	7.) You don't think that the lab has adequately addressed potential patient outcomes - RECOMMEND
	8.) Serious quality concerns or adverse patient outcomes have not been addressed – MAY ALSO NEED TO CITE TLC.10460	

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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.

Laboratory Name:		**Laboratory Section/Department:**		**CAP Number:**	

1) Instrument/Device Include name, manufacturer, and model	**2) Tests** List all tests included under the IQCP	**3) Number of Devices In Use**	**4) List of Test Sites*** 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

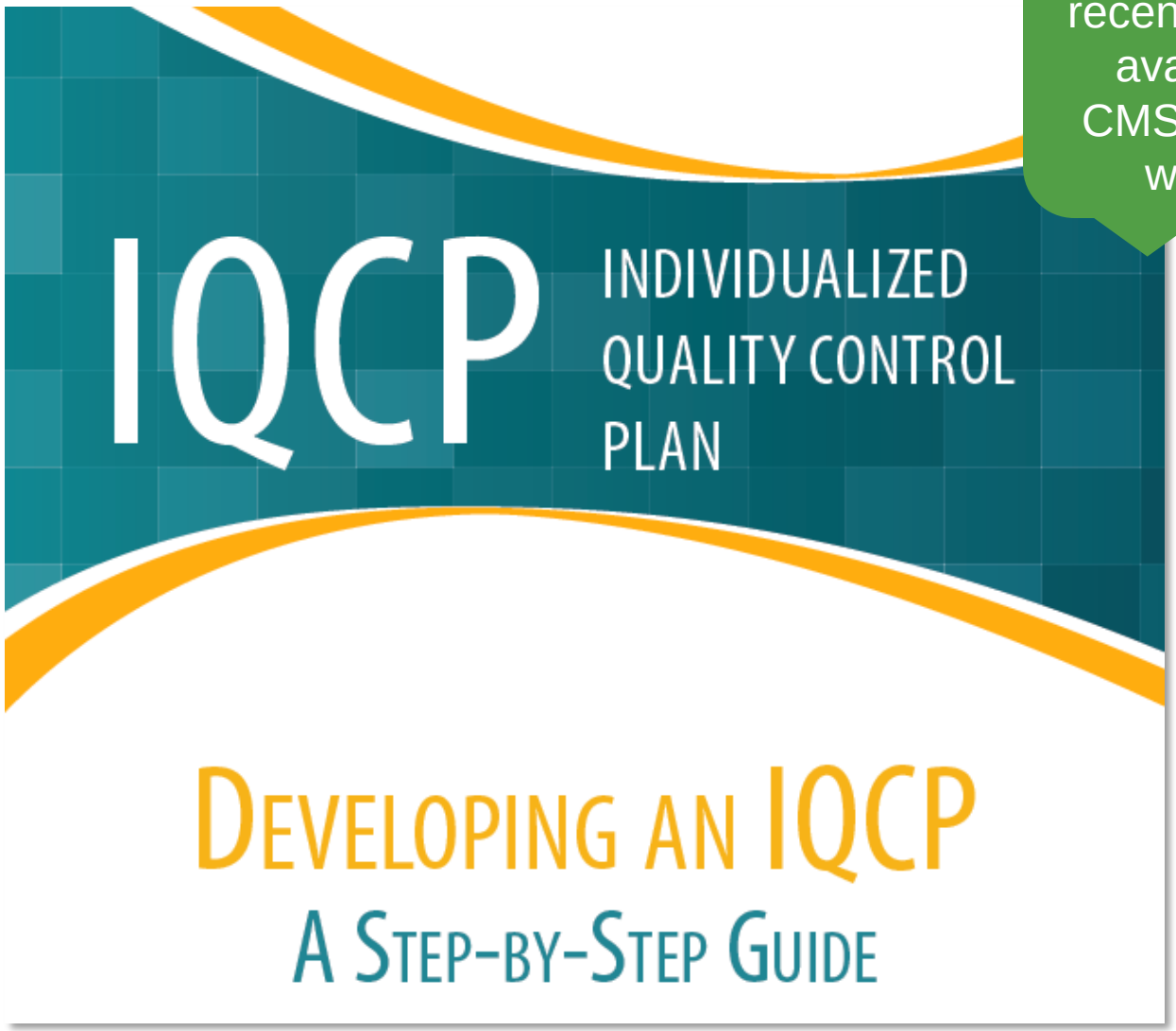
Reagents	Environment	Specimen	Test System	Testing Personnel	Other

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



http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/IQCP-Workbook.pdf

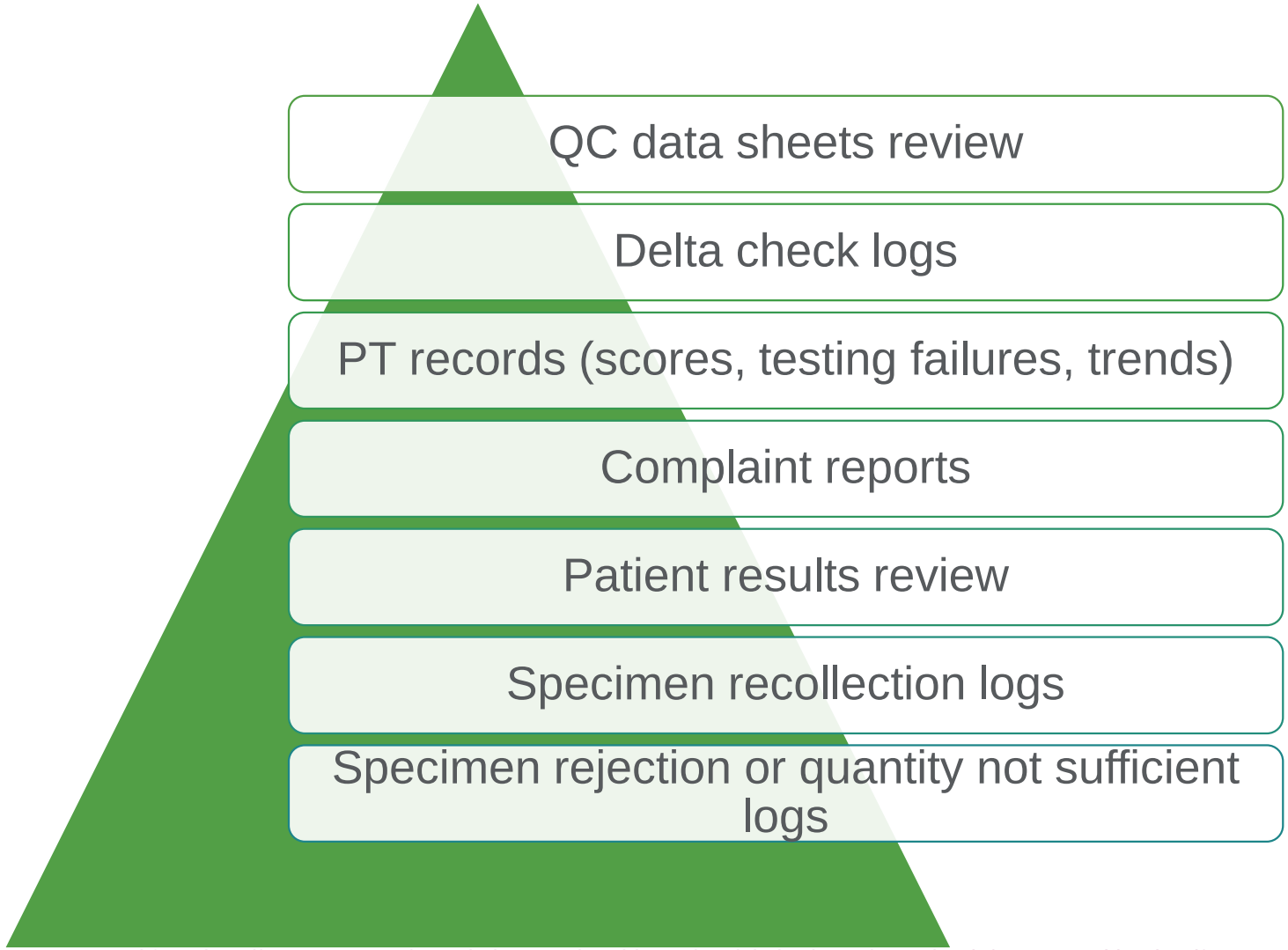
Quality Control Plan Tips to Remember

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.**

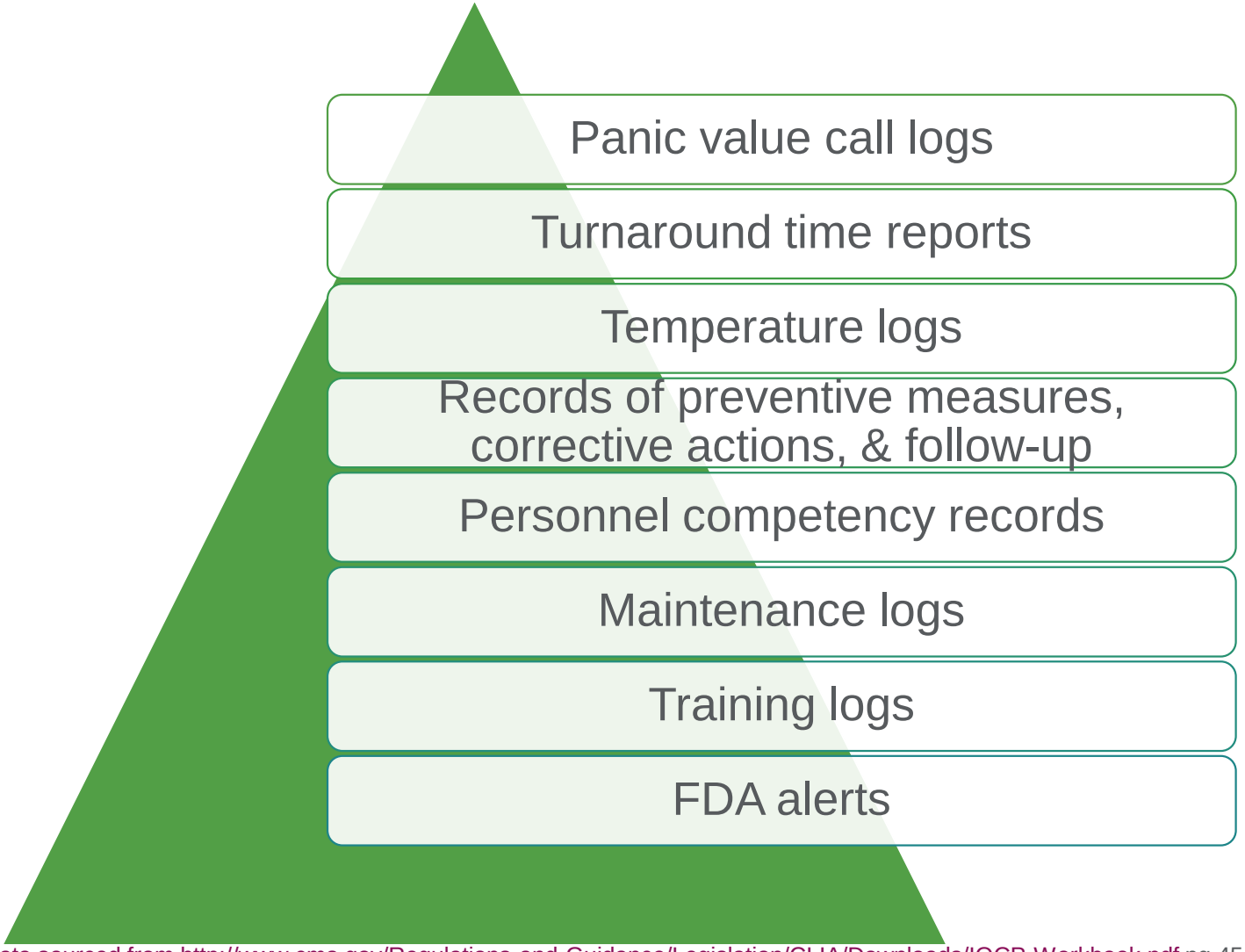
Data sourced from: http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/IQCP-Workbook.pdf pg 42

Quality Assessments - Documents to Consider



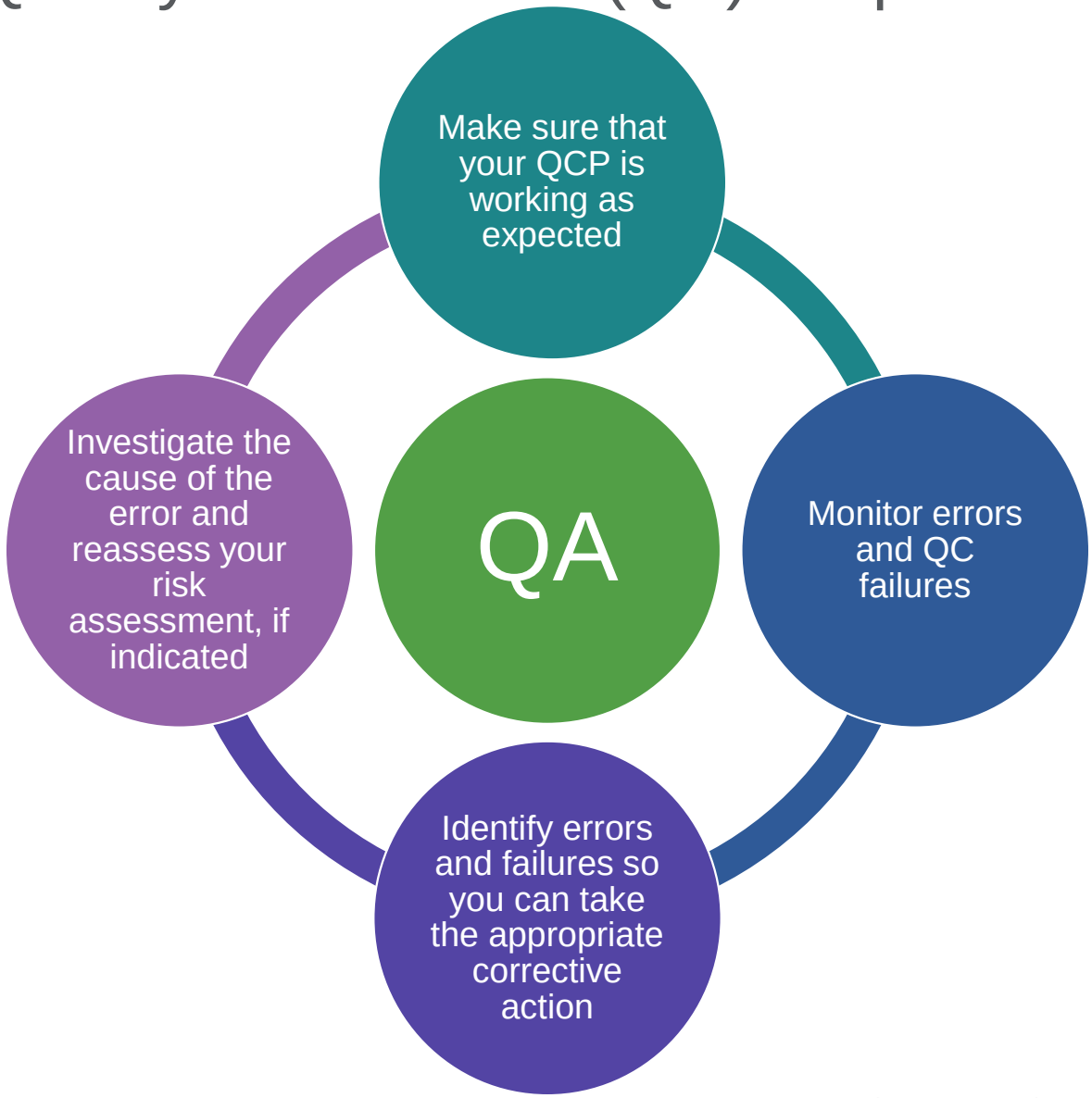
Data sourced from http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/IQCP-Workbook.pdf pg 45

Quality Assessments - Documents to Consider



Data sourced from http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/IQCP-Workbook.pdf pg 45

Quality Assessment (QA) Helps You…..



Data sourced from http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/IQCP-Workbook.pdf pg 45

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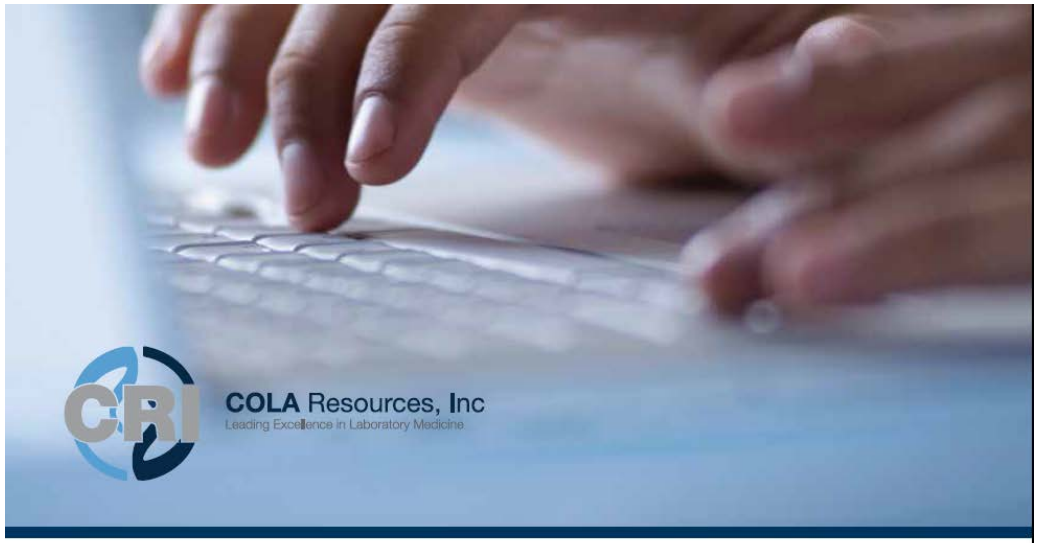

Individualized Quality Control Plan (IQCP)

IMPLEMENTATION GUIDE

QCmadeEZ™

The Joint Commission (TJC) Update IQCP is Not Required

	Jan. 1, 2016
Default (2-3 levels external QC/day)	☑
EQC (Equivalent QC)	☒
IQCP	☑

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

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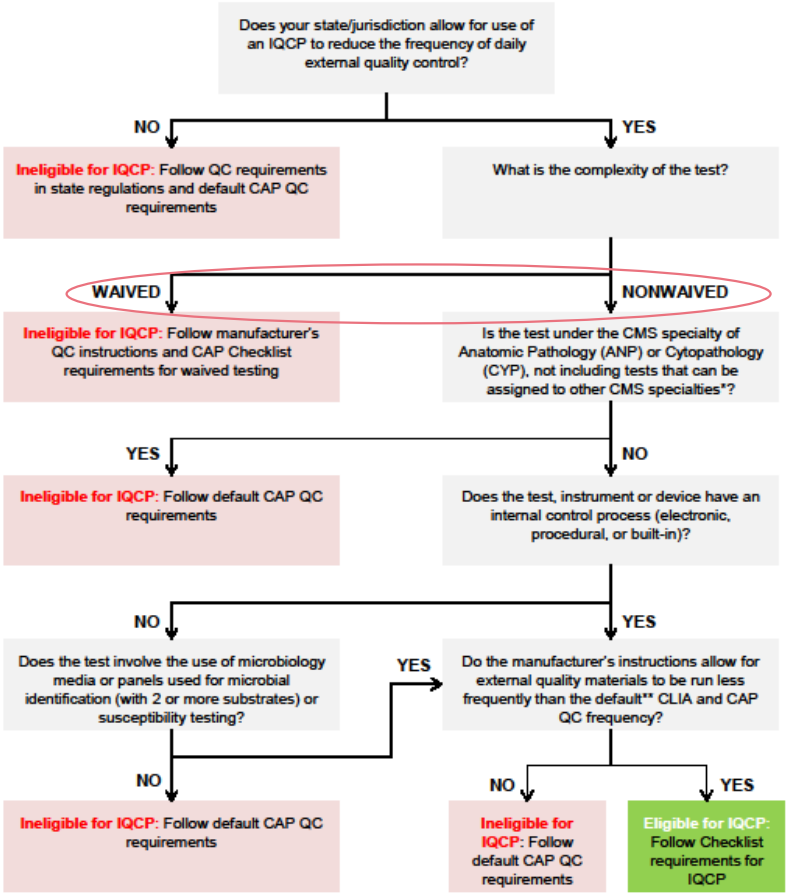
Eligibility Determination for Individualized Quality Control Plan (IQCP) Option



* 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.

IQCPE 4.0
FEBRUARY 2016

Permission granted to use this form by College of American Pathologists

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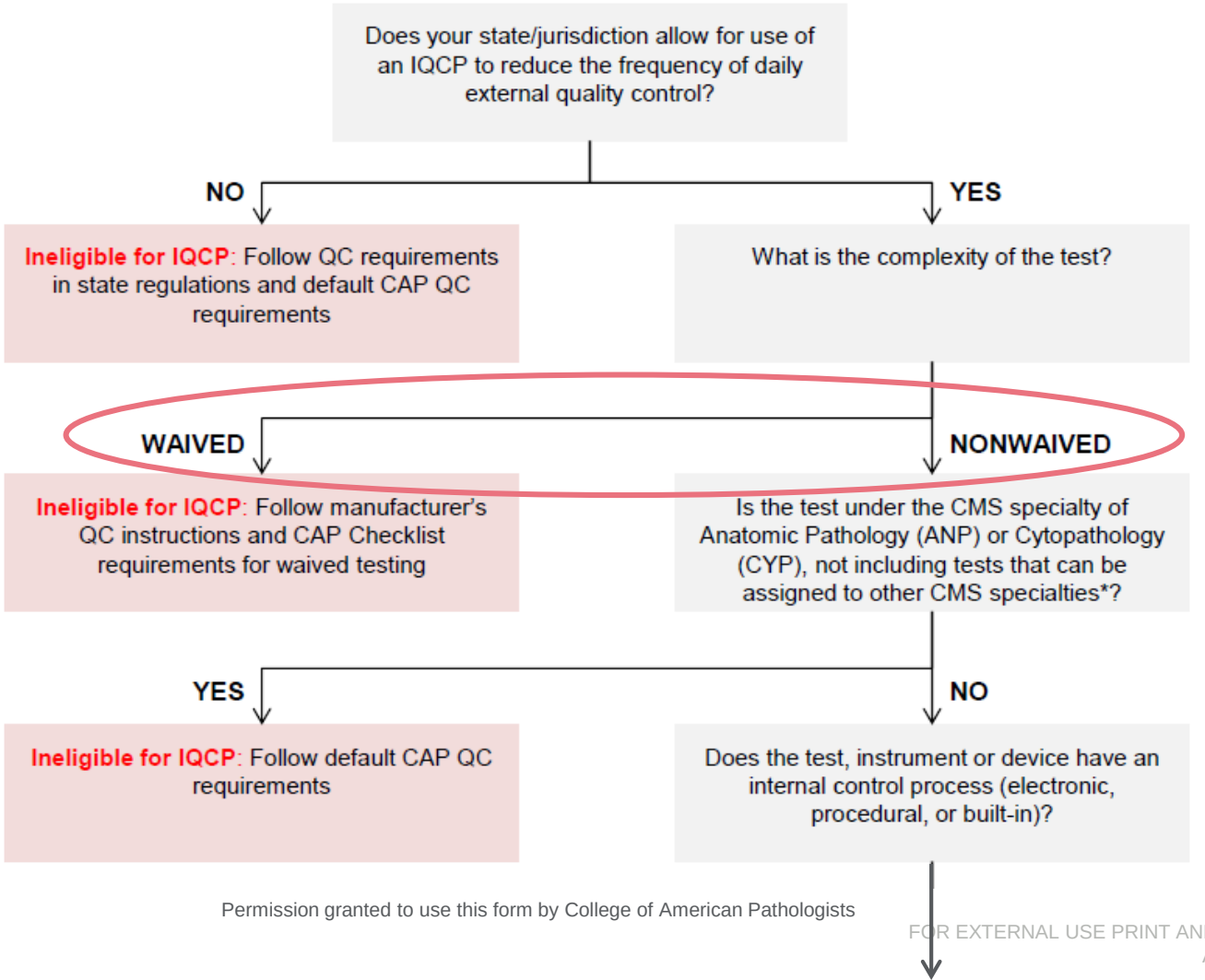
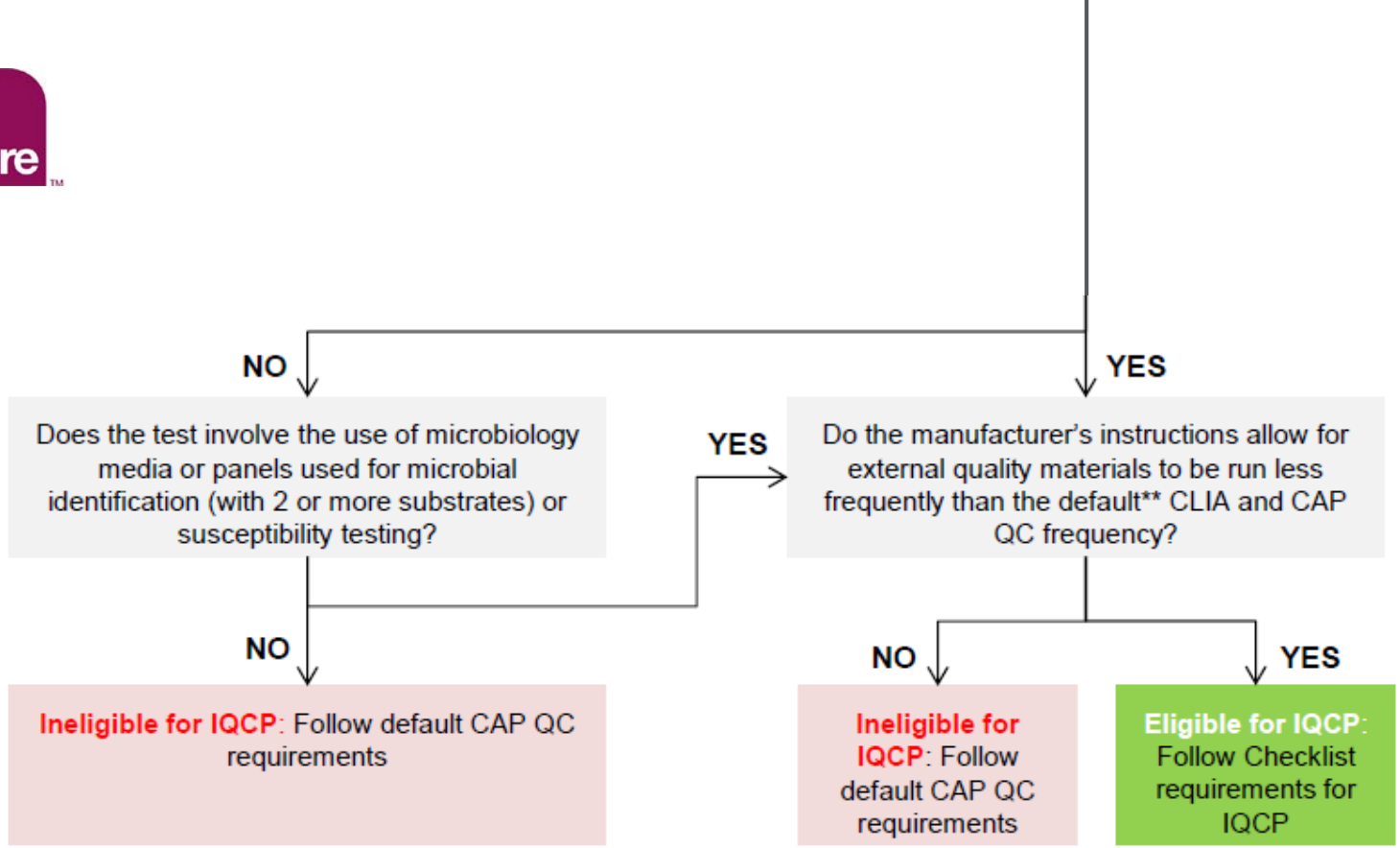
Eligibility Determination for Individualized Quality Control Plan (IQCP) Option





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** 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.

CAP Checklist COM.50200 IQCP Test List/Summary

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.

CAP Checklist COM.50300 Risk Assessment (RA)

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.

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

CAP Checklist COM.50300 Risk Assessment (RA)

Inspection Observations:

- 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.

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

CAP Checklist COM.50300 Risk Assessment (RA)

Inspection Observations:

- 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.

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

CAP Checklist COM.50300 Risk Assessment (RA)

Inspection Observations:

- 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.

CAP Checklist COM.50500 Quality Control Elements

Inspection Observations:

- Frequency and type of QC has not been transferred from the test procedure and specified in their IQCP.

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

CAP Checklist COM.50500 Quality Control Elements

Inspection Observations:

- 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.

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

CAP Checklist COM.50600 Quality Assessment Monitoring

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.

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

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.

Documentation Ideas…….

Individual Quality Control Plans:	Document Retention Period
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.	2 years

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

CMS	**IQCP@cms.hhs.gov** iqcpworkbook@cdc.gov
CAP	accred@cap.org
Joint Commission	qualitylabs@jointcommission.org Go to the Leading Practice Library
COLA	info@cola.org
Alere	IQCP@alere.com www.alere.com/IQCP

IQCP Inspection Question and Answer Session

9975 Summers Ridge Road
San Diego, CA 92121
Tel: 877.441.7440
Fax: 877.441.7441
Web: www.alere.com

Thank you!

Anywhere Medical Center Laboratory
Acme Company Test Example QCP Worksheet

These examples are not meant to be all inclusive of all possible QC procedures that may apply to your laboratory

Laboratory: Anywhere Medical Center- Acme Company test- Location: NICU		
Type of Quality Control	**Frequency**	**Criteria for Acceptability (Range of Acceptable Values)**
Procedural Control	With each patient specimen	Must be documented as acceptable according to package insert on the quality control log sheet prior to reporting results.
Temperature Checks	Record room temperature daily, in the morning and afternoon. Record refrigerator and freezer each day	List all range as specified in the package insert for room, refrigerator and freezer. These ranges will be recorded on the temperature log sheets.
Verify specimen collection tubes for acceptability upon receipt in the laboratory	With each patient specimen	Refer to Specimen Rejection Policy and record all improperly collected tubes on specimen rejection log sheet.
External Quality Control Normal and Abnormal Values	Assay normal and abnormal quality control no less than stated on package insert. Also see package insert for additional conditions to be run.	Acceptable external control values are within laboratory determined ranges. Results must be recorded on quality control log sheet prior to reporting results.
Reagent Device Storage	With each reagent device	Document date and time on reagent device when removed from the refrigerator. Follow package insert instructions for handling reagents.
Training	With each new testing personnel and when indicated	Successful demonstration of test performance. Document training activities.
Competency Assessment	Six months and one year after initial training, annually thereafter.	All testing personnel must successfully meet all six CLIA elements for competency assessment.
Laboratory Director Approval and Signature_____ Date_____		
Laboratory Director or Designee Review and Signature_____ Date_____		

http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/IQCP-Workbook.pdf pg. 37-38

Anywhere Medical Center Laboratory
Acme Company Test Example QA Worksheet

Laboratory: Anywhere Medical Center- Acme Company test- Location: NICU			
QC Process to Monitor	Frequency	Assessment of QC Process (Was there variation from established policy and procedures?)	Corrective Action (When indicated)
Review all temperature logs	Monthly	Yes	Remedial training of testing personnel. Reassess testing personnel performance.
Review all specimen rejection logs	Monthly	Yes	Remedial training of processing personnel. Reassess processing personnel performance.
Review QC logs	Daily	No	
PT Records	Monthly	No	
FDA Alerts	As Needed	No	
Review training logs	As needed based on staffing	No	
Review personnel qualifications	As needed based on new hires.	No	
Review competency assessments	Annually	No	

Data sourced from: Developing a Successful IQCP: Let's Keep it Simple Slide 68 Elia Mears, MHA MT(ASCP)SM
Field Surveyor The Joint Commission Stacy Olea, MBA, MT(ASCP), FACHE Executive Director Laboratory Accreditation The Joint Commission AACC July 2015