2015 Focus on Compliance

What You Really Need to Know About the Individualized Quality Control Plan (IQCP) and Ensuring Your Laboratory’s Compliance

Deborah A. Perry, MD, FCAP
Lyn Wielgos., MT (ASCP)
Disclosure

The following authors/planners/reviewers have financial interests/relationships to disclose:

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CALIFORNIA AND FLORIDA STATEMENT
This activity is approved for continuing education credit in the states of California and Florida.
Today’s Presenters

Deborah A. Perry, MD, FCAP

- Chair, CAP POCTC
- Medical Director, Children’s Pathology
  - Children’s Hospital & Medical Center in Omaha, Nebraska
- Section Director, Hematology
  - Methodist Pathology
- Pathology Board Certified
  - AP/CP
  - Hematology
  - Pediatric Pathology
Today’s Presenters

Lyn Wielgos, MT(ASCP)

- CAP Checklist Editor
- CAP’s accreditation programs for over 17 years
- Undergraduate degree in Medical Technology from Eastern Illinois University
- Laboratory experience in the core laboratory and transfusion service settings
Objectives

• Describe the different components of an IQCP
• Review new CAP checklist requirements for IQCP
• Use examples of IQCP to facilitate IQCP development
• Identify additional resources for developing an IQCP
• Prepare laboratory records for inspection of an IQCP

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Outline

• Quality Control History
• Definition of Individualized Quality Control Plan (IQCP)
• CAP checklist additions for IQCP
• Case examples using the CAP IQCP forms
• Resources
• Questions?
Historical Quality Control Options

• CLIA 1988 - final regulations published in 1992
  – Two levels of QC per day (default QC)
  – One-size fits all

• Equivalent Quality Control (EQC) option published in CMS Interpretive Guideline in 2004
  – First attempt at alternative QC
  – Two levels of QC per day or EQC
  – Disadvantages
    • Limited scope
    • Prescriptive
    • Analytical focus only
  – CMS will discontinue EQC on 1/1/2016
New QC Option - CMS Individualized Quality Control Plan (IQCP)

• CMS published new Interpretive Guideline with IQCP option in January 2014
• An all inclusive approach which evaluates the entire testing process
  • Pre-analytical, analytical, and post-analytical
• Voluntary quality control option based on risk management (concepts from CLSI’s EP23-A Guideline)
New QC Option - CMS Individualized Quality Control Plan (IQCP) cont.

- IQCP will not necessarily reduce the QC testing practices
- IQCP will allow you to develop a customized quality control plan for your laboratory specific to specimens, your test system, reagents, environment and testing personnel
- IQCP regulations contain some restrictions for eligibility of use
CMS Transition Period for IQCP

• IQCP is optional, but there will be **no** grandfathering of test systems already using EQC

As of January 1, 2014
1. Default CLIA QC or
2. EQC or
3. Implement an IQCP

On or After January 1, 2016
1. Default CLIA QC or
2. Implement an IQCP
CAP Implementation of IQCP

- CAP IQCP workgroup
  - Members
    - Checklist & POCT committee members & CAP staff
    - Scientific resource committees consulted
  - Goals
    - Develop CAP IQCP plan to provide to CMS
    - Develop CAP educational materials for laboratory staff & pathologists
    - Update CAP checklists to incorporate IQCP
    - Assist laboratories in preparing for CAP inspections
- CAP IQCP proposal received approval from CMS, April 2015
CAP Implementation of IQCP

• Updated IQCP checklist requirements published in July 2015 checklist edition
  – All Common Checklist
    • New IQCP section with five new IQCP requirements
  – Other Checklists (eg, Chemistry, Microbiology, & POCT)
    • Revisions to existing QC requirements throughout checklists to allow for use of traditional QC or IQCP
    • Provisions for EQC removed
• CAP option for IQCP is more restrictive than the CMS option in some areas
• Laboratories may develop their own model for designing an IQCP

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CMS Eligibility to use IQCP

• CMS IQCP option eligibility:
  – Non-waived test systems
  – CMS subspecialties or subspecialties other than Pathology and Cytology
    • Exception for those that can come under multiple subspecialties (eg, FISH can be assigned to either histopathology or cytogenetics)
  – Eligible CLIA regulations
  – Follow manufacturer’s instructions at minimum
  – Must follow state laws and regulations
CAP Eligibility to use IQCP

- CMS IQCP eligibility criteria apply
- CAP defines additional criteria:
  - Testing must employ an internal quality control system (electronic, procedural, or built-in control)
  - Exception: Microbiology media and reagents used for microbial identification and susceptibility testing

**NOTE:** IQCPs in use that do not reduce the QC frequency below the minimum default QC requirement are not inspected with the IQCP checklist requirements
Eligibility Determination for Individualized Quality Control Plan (IQCP) Option

1. 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

   3. 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?*

   YES

   2. What is the complexity of the test?

      NONWAIVED

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

      WAIVED
Eligibility Determination – CAP Website Tool

3. 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?*

- **YES**
  - Ineligible for IQCP: Follow default CAP QC requirements

- **NO**
  - 4. Does the instrument or device have an internal control process (electronic, procedural, or built-in)?
Eligibility Determination – CAP Website Tool

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

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

      YES
      Eligible for IQCP: Follow Checklist requirements for IQCP

      NO
      Ineligible for IQCP: Follow default CAP QC requirements

   NO
   6. Does the test involve the use of microbiology media or reagents used for microbial identification or susceptibility testing?

      YES
      Ineligible for IQCP: Follow default CAP QC requirements

      NO
      Eligible for IQCP: Follow Checklist requirements for IQCP
CAP & CLIA Eligibility to use IQCP

• An IQCP is NOT needed if at least two levels of external QC for a non-waived test is performed each day of patient testing (or more frequent as defined by manufacturer)

• An IQCP is voluntary. However, without an IQCP, laboratories must follow the minimum daily QC requirements and default CLIA regulations for daily QC of non-waived testing
IQCP Option

Risk Assessment (RA)

+ 

Quality Control Plan (QCP)

+ 

Quality Assessment (QA)

= 

IQCP
IQCP

• Risk Assessment
  – Identifies and evaluates potential failures & sources of errors in the testing process
  – It must include evaluation of:
    • Specimen, test system, reagent, environment, testing personnel

• Quality Control Plan
  – A written document describing the practices and procedures performed by your laboratory to reduce the chance of possible failures and errors in your test processes
  – Ensures accurate, reliable test results
  – Proficiency testing, maintenance, training are components

• Quality Assessment
  – The continuous process of monitoring the effectiveness of the QCP
  – QC reviews, PT performance, complaints
IQCP or Can I get an incredible view of the Grand Canyon?
IQCP or Can I get an incredible view of the Grand Canyon?

- Risk Assessment (RA)
- Quality Control Plan (QCP)
- Quality Assessment (QA)
Risk Assessment - What could possibly go wrong?
Beginning the Risk Assessment

• Gather information to assess risks
  – Regulatory & accreditation requirements
    • Mandated QC procedures
    • Device failure notifications
  – Measuring System Information
    • Intended use
    • Instructions for calibration, maintenance, use, reagent storage
  – Laboratory information
    • Environmental conditions
    • Operator training & competency
Beginning the Risk Assessment cont.

- Gather information to assess risks
  - Publications & laboratory peers
    - Published performance evaluations
    - Published clinical studies
  - Clinical information
    - Clinical applications for use of test result
    - Foreseeable medical errors that could result from incorrect, delayed or no result
CLSI Guideline - Risk Assessment Using a Fishbone Diagram

Potential Error

Incorrect Test Result

Reagents

Environment

Specimen

Test System

Testing Personnel
Risk Assessment Components – Reagents

Shipping Conditions

Storage

Preparation Instructions

Expiration Date

Reagents
## CDC/CMS Handbook: Developing an IQCP – A Step-by-Step Guide

### Risk Assessment Worksheet

<table>
<thead>
<tr>
<th>Laboratory Name</th>
<th>Test System Name</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Risk Assessment Components</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>What are our possible sources of error?</td>
<td>What can go wrong?</td>
<td>Can our identified sources of error be reduced?</td>
<td>How can we reduce the identified sources of error?</td>
<td></td>
</tr>
<tr>
<td>Gather information, from the manufacturer's instructions and other resources, on how we should be performing the testing process.</td>
<td>Yes/No Not Applicable (N/A)</td>
<td>Indicate how to reduce possible error sources.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SPECIMEN</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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## Risk Assessment Components – Reagents

<table>
<thead>
<tr>
<th>Possible Sources of Error</th>
<th>Can the sources of error be reduced?</th>
<th>How can we reduce the identified sources of error?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reagent stability compromised during shipping of new lots and shipments of reagent</td>
<td>Yes</td>
<td>Check each new lot and shipment of reagent with two levels of external control materials prior to use.</td>
</tr>
<tr>
<td>Manufacturer requires storage at 2-8 °C</td>
<td>Yes</td>
<td>Monitor refrigerator storage temperatures daily to confirm that temperatures are maintained within the required range.</td>
</tr>
<tr>
<td>Reagents must be brought to room temperature prior to use.</td>
<td>Yes</td>
<td>Include instructions in the laboratory procedure and train testing personnel on reagent preparation.</td>
</tr>
<tr>
<td>Reagents placed at room temperature (20-24 °C) are stable for 14 days and may not be refrigerated again.</td>
<td>Yes</td>
<td>Include instructions in the laboratory procedure and train testing personnel to record a 14-day expiration date on reagents placed at room temperature and check dates prior to use.</td>
</tr>
</tbody>
</table>
Risk Assessment Components - Environment

- Temperature
- Humidity
- Altitude
- Water
- Adequate space
- Lighting/intensity
- Noise & vibration
- Point-of-care testing sites
## Risk Assessment Components - Environment

<table>
<thead>
<tr>
<th>Possible Sources of Error</th>
<th>Can the sources of error be reduced?</th>
<th>How can we reduce the identified sources of error?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dropping of the instrument may cause the instrument to malfunction</td>
<td>Yes</td>
<td>Instrument will be stationed on a bench top in the in the ER</td>
</tr>
<tr>
<td>Instrument must be operated at temperatures of 20-30 °C</td>
<td>Yes</td>
<td>Room temperature will be monitored on a daily basis</td>
</tr>
<tr>
<td>Testing must be performed on a level, dry surface. It may not be moved during operation</td>
<td>Yes</td>
<td>Instrument will be stationed in a bench top area in the ER away from a sink. Personnel will be trained not to move the instrument during the testing process.</td>
</tr>
</tbody>
</table>
Risk Assessment Components - Specimen

- Specimen collection
- Specimen labeling
- Specimen storage, preservation, stability
- Specimen transport
- Specimen processing
- Specimen acceptability & rejection
## Risk Assessment Components - Specimen

<table>
<thead>
<tr>
<th>Possible Sources of Error</th>
<th>Can the sources of error be reduced?</th>
<th>How can we reduce the identified sources of error?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Only venous whole blood or EDTA plasma specimens may be used</td>
<td>Yes</td>
<td>Specimen collection instructions and criteria for acceptable specimens are defined in the procedure and are covered during training</td>
</tr>
<tr>
<td>Test must be performed within 4 hours of collection and be maintained at room temperature</td>
<td>Yes</td>
<td>Test is performed at the point-of-care using whole blood. Procedure requires testing immediately after specimen collection</td>
</tr>
<tr>
<td>Hemolysis during specimen collection must be avoided</td>
<td>Yes</td>
<td>Personnel are trained on the appropriate collection techniques.</td>
</tr>
</tbody>
</table>
Risk Assessment Components – Test System

- Mechanical/electronic failure
- Inadequate sampling
- Capability to detect interfering substances (e.g., lipemia, hemolysis)
- Calibration problems
- Failure of system controls and function checks
- Clot detection capability
<table>
<thead>
<tr>
<th>Possible Sources of Error</th>
<th>Can the sources of error be reduced?</th>
<th>How can we reduce the identified sources of error?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overfilling or underfilling of the test cartridge with patient specimen will cause an error with specimen sampling</td>
<td>Yes</td>
<td>Staff training on the filling of the test cartridge. Add a step in the procedure to confirm that specimen is at the fill line prior to testing.</td>
</tr>
<tr>
<td>Writing on the front of the test cartridge with brightly colored ink will interfere with the test</td>
<td>Yes</td>
<td>Staff training and procedure will include writing the patient name and medical record number in black ink on the back of the cartridge.</td>
</tr>
<tr>
<td>Test cartridge with specimen must be inserted in the instrument within 15 minutes</td>
<td>Yes</td>
<td>Testing is performed at the point-of-care to avoid delays. Timing to be included in staff training and in the procedure.</td>
</tr>
<tr>
<td>If built in internal control is not within acceptable limits, no patient result will be reported</td>
<td>Yes</td>
<td>Instrument has a lock out feature. Troubleshooting guide available to staff with contact information for immediate assistance.</td>
</tr>
</tbody>
</table>
Risk Assessment Components – Testing Personnel

• Appropriate education and experience
• Adequate numbers of staff
• Training
• Competency
• Non-laboratory testing personnel
## Risk Assessment Components – Testing Personnel

<table>
<thead>
<tr>
<th>Possible Sources of Error</th>
<th>Can the sources of error be reduced?</th>
<th>How can we reduce the identified sources of error?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Testing personnel incorrectly collecting and testing specimens</td>
<td>Yes</td>
<td>Initial training of all testing personnel and competency assessment program. Monthly review of instrument error logs.</td>
</tr>
<tr>
<td>Untrained personnel performing the test</td>
<td>Yes</td>
<td>Lock out of unauthorized users by instrument. User ID to be assigned after completion of training for each user. User ID to be removed if user fails competency assessment or if competency assessment is overdue.</td>
</tr>
</tbody>
</table>
Risk Assessment Components Completed

A. Reagents
B. Specimen
C. Environment
D. Test System
E. Testing Personnel
• Assess the likelihood or probability of harm for each failure and the severity of harm to a patient for each failure

• ISO 14971 Semi-quantitative approach can be used to estimate the probability of a failure rate – historical data can be used
  – Frequent = once per week
  – Probable = once per month
  – Occasional = once per year
  – Remote = once every few years
  – Improbable = once in the life of the measuring system
CLSI EP23-A Guideline - Risk Estimation

- What are the consequences of an incorrect result, delayed result, or no result?
- Severity of Harm semi-quantitative scale of severity levels (ISO 14971)
  - Negligible = inconvenience or temporary discomfort
  - Minor = temporary injury or impairment not requiring professional medical intervention
  - Serious = injury or impairment requiring professional medical intervention
  - Critical = permanent impairment or life-threatening injury
  - Catastrophic = patient death
- Use probability or likelihood of a failure leading to harm combined with severity of that harm to evaluate risk to the patient
# Risk Acceptability Matrix – Based on ISO 14971

<table>
<thead>
<tr>
<th>Probability of Harm</th>
<th>Negligible</th>
<th>Minor</th>
<th>Serious</th>
<th>Critical</th>
<th>Catastrophic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequent</td>
<td>unacceptable</td>
<td>unacceptable</td>
<td>unacceptable</td>
<td>unacceptable</td>
<td>unacceptable</td>
</tr>
<tr>
<td>Probable</td>
<td>acceptable</td>
<td>unacceptable</td>
<td>unacceptable</td>
<td>unacceptable</td>
<td>unacceptable</td>
</tr>
<tr>
<td>Occasional</td>
<td>acceptable</td>
<td>acceptable</td>
<td>acceptable</td>
<td>unacceptable</td>
<td>unacceptable</td>
</tr>
<tr>
<td>Remote</td>
<td>acceptable</td>
<td>acceptable</td>
<td>acceptable</td>
<td>acceptable</td>
<td>unacceptable</td>
</tr>
<tr>
<td>Improbable</td>
<td>acceptable</td>
<td>acceptable</td>
<td>acceptable</td>
<td>acceptable</td>
<td>acceptable</td>
</tr>
</tbody>
</table>

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Arizona Rainbow
Quality Control Plan (QCP)

A QCP is a document that describes the practices, resources, and procedures to control the quality of a particular test process.

At a minimum your QCP must include the number, type & frequency of testing control material, as well as criteria for acceptable quality control.
Quality Control Plan – Where to begin

• List control processes identified from the risk assessment, including:
  o External QC
  o Internal control processes (built-in/procedural/electronic)
  o Personnel training and competency assessment
  o Equipment and environment monitoring
  o Result reporting error checks
  o Other specified control activities

• Ensure that it provides for the immediate detection of errors during the different phases of the testing process

• Confirm that the QCP follows manufacturer’s instructions and regulatory requirements at minimum
# Example Quality Control Plan

<table>
<thead>
<tr>
<th>Laboratory Name: Northfield Laboratory</th>
<th>CAP#: 11111-11</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Type of Control</th>
<th>Frequency</th>
<th>Criteria for Acceptability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Internal QC every time a test is performed</td>
<td>Each time of use</td>
<td>Within manufacturer’s limits using automated lockout</td>
</tr>
<tr>
<td>Two levels of external quality controls from the manufacturer</td>
<td>Each new lot and shipment of reagents Every 31 days Monthly supervisory review</td>
<td>Within defined QC limits</td>
</tr>
<tr>
<td>Monitoring of reagent storage areas</td>
<td>Daily Monthly supervisory review</td>
<td>Within 2-8°C</td>
</tr>
<tr>
<td>Record and monitor open expiration dates</td>
<td>Each day of use</td>
<td>In date reagents used</td>
</tr>
<tr>
<td>Staff training and competency on specimen collecting and testing process</td>
<td>Initial training, 6-month competency for new personnel, ongoing annual competency</td>
<td>Complete training checklist and procedure review. Pass competency assessment with minimum score of 90%.</td>
</tr>
<tr>
<td>Monitoring of room temperature</td>
<td></td>
<td>Within 20-24°C</td>
</tr>
<tr>
<td>ETC…</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Laboratory Director: Joan Smith, MD Date: 6/5/2015
Quality Control Plan (QCP)

A complete QCP must:

- Provide for immediate detection of errors for each phase of the testing process
- 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
Quality Assessment
Quality Assessment (QA)

- Monitoring to include the following: reagents, specimen, environment, test system, and testing personnel
- Ongoing assessments may include, but are not limited to, the review of the following records:
  - Quality control
  - Proficiency testing
  - Patient results review
  - Specimen rejection logs
  - Turn around time reports
  - Error/corrective action logs
  - Personnel/competency
  - Instrument maintenance logs
Quality Assessment Process

• If errors are identified, adjust the quality control plan to prevent future failures. Patients potentially affected by the failure need to be identified and corrective actions taken.

  - Investigate identified failures
  - Continue to monitor the effectiveness of the QPC
  - Adjust the QCP as needed
IQCP Completed!

Risk Assessment (RA) + Quality Control Plan (QCP) + Quality Assessment (QA) = IQCP
Microbiology and Quality Control

- Since May 2004 Microbiology quality control obligations were met with CLSI references
- October 31, 2014 CMS memorandum:
  - CLSI document references will be removed from the upcoming revision of survey procedures and interpretive guidelines (IGs) for laboratories
- Why did this happen?
  - CMS removed mention of CLSI documents from its interpretive guidelines for QC because government agencies, cannot make private guidelines regulatory in effect unless those guidelines are available for free
- What now for laboratories? 2 options for CLIA QC compliance:
  - Follow all applicable CLIA QC regulations
    OR
  - Implement IQCP
Microbiology and IQCP

• ASM, CLSI and CAP are working together to provide guidance for microbiology laboratories

• Commercial MIC Antimicrobial Susceptibility Testing (AST) systems
  - IQCP introduction, Q&A, Template
  - Disk diffusion IQCP example

• PowerPoint presentations
  – Overview of CMS’ vision for IQCP in clinical microbiology
  – IQCP guidelines and template
  – Real life IQCP examples
  – List of microbiology test NOT requiring IQCP
CAP Checklist Updates
Risk Assessment – COM.50300

COM.50300  Risk Assessment  Phase II

The IQCP for a test/device/instrument includes a risk assessment to evaluate potential sources of error to include all of the following:

– Pre-analytic, analytic, and post-analytic phases of the testing process

– Intended medical uses of the test and impact if inaccurate results are reported (clinical risk)

– Components of the tests including Reagents, Environment, Specimen, Testing Personnel, and Test System
The IQCP for a test/device/instrument includes a risk assessment to evaluate potential sources of error to include all of the following:

- Variations in the components based on use of the tests (e.g., use in different environments, by different personnel, or multiple identical devices)
- Data from the laboratory's own environment, instrument/equipment performance, and testing personnel
- Manufacturer's instructions and recommendations
Risk Assessment – COM.50300

The checklist NOTE highlights the following:

• Representative sample of testing personnel must be used to conduct the risk assessment.

• Published data and information is not a substitute for a laboratory's own studies and evaluation (can be used to supplement only).

• Each laboratory must have its own IQCP approved by its laboratory director. Affiliated laboratories may use data from other sites to supplement risk assessments and to support their findings.

• Multiple identical devices may share the same risk assessment, but differences in use must be evaluated (eg, testing personnel, environment, patient population).

• QC study performed for risk assessment must support the QC frequency and elements defined in the laboratory’s quality control plan.
Quality Control Plan Elements – COM.50500

COM.50500  Quality Control Plan Elements  Phase II

The individualized quality control plan must define all aspects monitored based on the potential errors identified during the risk assessment, including the following parameters as applicable:

• The number, type (external and internal quality control systems), and frequency of quality control
• Criteria for acceptable performance
• Monitoring of the testing environment and reagents
• Specimen quality
• Instrument calibration, maintenance, and function checks
• Training and competency of testing personnel
• Provisions for multiple identical devices and variation for uses covered under one IQCP
Quality Control Plan Elements – COM.50500

The checklist NOTE highlights the following:

• **Follow manufacturer’s instructions and recommendations for QC at minimum**

• **Must meet regulatory and CAP accreditation requirements**

• **Include the use of external control materials at least every 31 days and with new lots and shipments of reagents**
Quality Control Plan Approval – COM.50400

COM.50400  Quality Control Plan Approval  Phase II

The IQCP includes a written quality control plan approved by the laboratory director prior to implementation.

NOTE: The quality control plan may be part of a test procedure or be a separate written plan. As an efficiency, a single plan may address multiple tests performed on one device. A separate, quality control plan approved by the laboratory director must be in place for each laboratory with a separate CAP and CLIA number.

• Laboratory director (on CAP & CLIA certificate) is ultimately responsible for the plan.
Quality Assessment Monitoring – COM.50600

COM.50600  Quality Assessment Monitoring  Phase II

Ongoing quality assessment monitoring is performed by the laboratory to ensure that the quality control plan is effective in mitigating the identified risks for the IQCP and includes the following:

– Review of quality control and instrument/equipment maintenance and function check data at least monthly
– Evaluation of errors relating to pre-analytic, analytic, and post-analytic phases of the testing process
– Review of complaints from clinicians and other healthcare providers regarding the quality of testing to confirm the clinical efficacy of testing
– Evaluation of corrective actions taken if problems are identified
– Re-approval of the quality control plan by the laboratory director or designee at least annually

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IQCP Test List – COM.50200

COM.50200 IQCP Test List  Phase II

The laboratory has identified all tests using an IQCP and completed the CAP's forms for laboratories using an individualized quality control plan.

• Required forms:
  – List of Individualized Quality Control Plans
  – Individualized Quality Control Plan Summary

• Forms may be downloaded from the CAP website (http://www.cap.org) through e-LAB Solutions Suite under CAP Accreditation Resources, Accreditation Forms and Instructions
Case Examples using CAP IQCP Forms

List of Individualized Quality Control Plans

Complete the fields below for each IQCP in use and present to the inspector during the on-site inspection. Fill out a separate Individualized Quality Control Plan Summary form for each IQCP listed.

<table>
<thead>
<tr>
<th>Laboratory Name:</th>
<th>Northfield Laboratory</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) Laboratory Section/Department</td>
<td>2) Instrument/Device Include name, manufacturer, and model</td>
</tr>
<tr>
<td>Point-of-Care Testing - Surgery</td>
<td>Brand A Coagulation Analyzer</td>
</tr>
<tr>
<td>Point of Care Testing – ER, CCU, ICU</td>
<td>Brand B Critical Care Analyzer</td>
</tr>
<tr>
<td>Point of Care Testing Section - ER</td>
<td>Brand C Cardiac Analyzer</td>
</tr>
<tr>
<td>Microbiology</td>
<td>Brand D Rapid Strep Test Kit</td>
</tr>
<tr>
<td>Respiratory Therapy</td>
<td>Brand E Blood Gas Analyzer</td>
</tr>
</tbody>
</table>
# Case Examples using CAP IQCP Forms

## 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>Northfield Laboratory</th>
<th>Laboratory Section/Department:</th>
<th>Point-of-Care Testing - ER</th>
<th>CAP Number:</th>
<th>11111-11</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>1) Instrument/Device</th>
<th>2) Tests</th>
<th>3) Number of Devices In Use</th>
<th>4) List of Test Sites*</th>
<th>Date of Director Approval</th>
<th>Date Implemented</th>
<th>Date Retired</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brand C Cardiac Analyzer</td>
<td>Troponin, CK-MB, Myoglobin</td>
<td>1</td>
<td>n/a</td>
<td>8/1/2015</td>
<td>8/1/2015</td>
<td>n/a</td>
</tr>
</tbody>
</table>

## 5) Process Used to Monitor Risk

*List control processes put in place based on risk assessment – define 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>
</tr>
</thead>
<tbody>
<tr>
<td>Two levels of external QC with new lots and shipments</td>
<td>Daily room temperature monitoring in testing area</td>
<td>Written specimen collection procedures with defined acceptability criteria</td>
<td>Internal controls each time a test is performed</td>
<td>Staff training and competency on specimen collection and testing process</td>
<td></td>
</tr>
<tr>
<td>Record and monitor open expiration dates (14 days)</td>
<td>Instrument maintained on designated bench top away from the sink</td>
<td>Testing performed at the point-of-care with immediate testing after the specimen is collected</td>
<td>Two levels of external QC every 30 days</td>
<td>Assigned user ID codes with lock out for unauthorized users</td>
<td></td>
</tr>
</tbody>
</table>
Inspection Preparation

• All laboratories inspected on or after January 1, 2016 must do the following:
  – Discontinue EQC option AND
  – Perform external quality control following the frequency defined in the CAP inspection checklist (default CLIA QC) OR
  – Implement an IQCP, if eligible
Inspection Preparation

• Provide CAP IQCP forms to inspection team upon request
• Have risk assessment records, quality control plan, and quality assessment records readily available
• Retain IQCP records for the length of time that the IQCP is in use, plus two years
CAP Website Resources

- CAP.org
- Eligibility Determination for IQCP Option
- CAP/ASM/CLSI Microbiology IQCP template and examples
- CAP IQCP Q&A
- CAP forms and instructions needed for inspection
- Webinar presentation with Q & A (will be posted in approximately one month after the webinar)
Other Resources for Developing an IQCP

- Clinical and Laboratory Standards Institute Guideline EP23-A and companion documents
- http://clinmicro.ams.org/iqcp
- Manufacturer tools, if available
Summary

• IQCP is voluntary, but EQC is no longer an option as of 1/1/2016

• There are specific eligibility criteria

• IQCP must be developed for each test system/device/instrument for each location

• Risk assessment must evaluate all phases of testing and the required five components

• Quality control plan must follow manufacturer’s instructions at a minimum

• Errors identified through quality assessment process require careful evaluation for risk
GO BUILD YOUR IQCP!
Questions