Individualized Quality Control Plan (IQCP)

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When?

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The education phase ends Dec 31.
Do you want to reduce QC frequency below CLIA minimums?

- No  
  IQCP is not required

- Yes  
  Is the test waived?
    - No  
      Is the test eligible for IQCP per CMS
        - No  
          Ineligible tests include those under Anatomical Pathology and Cytopathology specialties  
          An IQCP is not allowed.
        - Yes  
          Do Manufacturer Instructions list a QC frequency less than CLIA minimum or don’t list a QC frequency at all?
            - No  
              QC Frequency may never be reduced below manufacturer’s recommendations
            - Yes  
              An IQCP is required to support reducing QC frequency
      IQCP is not required
    - Yes  
      IQCP is not required
It's a waivered test, not a wave test!!
Mandatory Elements of IQCP
Resources

• CMS IQCP Website
  Information, workbook, links

• CLSI EP23-A
  Laboratory QC based on Risk Management

• Your Test Sales Rep or Customer Service

• Bio-Rad IQCP Website
  Archived webinars and links to many resources
  www.QCNet.com/IQCP
Additional Resources
Resources
Resources

IQCP
INDIVIDUALIZED
QUALITY CONTROL
PLAN

DEVELOPING AN IQCP
A STEP-BY-STEP GUIDE

CDC
CMS
U.S. Department of Health and Human Services
Resources

The Individualized Quality Control Plan (IQCP) as a CLIA QC Option

Nancy Anderson, MMSc, MT(ASCP)
Chief, Laboratory Practice Standards Branch

American Society for Microbiology Meeting
June 1, 2015

Resources

Materials Developed Collaboratively by ASM, CAP, and CLSI

AST IQCP Introduction (5/31/2015)

AST IQCP Q&A (5/31/2015)

AST IQCP Template (5/31/2015)
- PPT
- PDF

AST IQCP Example (5/31/2015)

PowerPoint Presentations (6/8/2015)

Overview of CMS’ Vision for IQCP in Clinical Microbiology - Nancy Anderson, MMSc, MT(ASCP)

IQCP - Guidelines and Template for Getting Started - Linda C. Bruno, M.A., MT(ASCP)

Pulling It All Together - Real Life IQCP Examples - Susan E. Sharp, Ph.D., (D)ABMM, F(AAM)

List of Microbiology tests not requiring IQCP - Linda C. Bruno, M.A., MT(ASCP)
Resources

CMS Standards – Microbiology Tests that do NOT need IQCP

Linda C. Bruno, M.A., MT(ASCP)
Director, Microbiology and Molecular Labs
ACL Laboratories, Rosemont, IL
June, 2015

Resources

Individualized Quality Control Plan
IQCP Examples

Susan E. Sharp, Ph.D., ABMM, FAAM
Director, Airport Way Regional Laboratory
Director, Regional Microbiology and Molecular Infectious Diseases Laboratories

Kaiser Permanente
Department of Pathology

Associate Professor, Oregon Health and Sciences University, Department of Pathology

Portland, OR

The Joint Commission and IQCP
Before Getting Started

- CMS approval of our standards in June 2015
- QSA.02.04.01 EPs 1 – 8
  - Prepublication Standards
  - July Perspectives article
  - January 1, 2016 edition of CAMLAB
- Appendix C: IQCP – Eligible Requirements
- All specialties/subspecialties except Pathology
- All locations, test systems, and tests except Pathology
- Mirror the Interpretive Guidelines
- IQCP information entered into your e-App (currently under development)
- Surveyors may review all required documentation
QSA.02.04.01

The laboratory develops an individualized quality control plan (IQCP) in an eligible specialty or subspecialty.
QSA.02.04.01

**EP 1** A complete IQCP that consists of the following three parts:
- Risk assessment, Quality control plan, Quality assessment

**EP 2** A risk assessment that is established by the laboratory in its own environment by its own testing personnel.

*Note: The risk assessment may include test, method or instrument verification data; performance specifications; or historical quality control data. Published or manufacturer data may also be included, but cannot be the only data source for the risk assessment.*

**EP 3** A risk assessment that contains the following five components:
- Specimen, Environment, Reagent, Test system, Testing personnel
QSA.02.04.01

EP 4  ⚫ A risk assessment that encompasses the following three phases of the entire testing process:
  • Preanalytic, Analytic, Postanalytic

Note: The risk assessment identifies the sources of potential failures and errors for a testing process, and evaluates the frequency and impact of those failures and sources of errors.

EP 5  ⚫ Laboratories that develop an individualized quality control plan (IQCP) include the following: a risk assessment that includes the manufacturer’s instructions or other information needed to assess risk in all three phases of the testing process.

Note: The risk assessment includes function and maintenance checks as required by, and not less than, manufacturers’ instructions.
EP 6  Laboratories that develop an individualized quality control plan (IQCP) include the following: A quality control plan for devices at each location throughout a facility.

EP 7  Laboratories that develop an individualized quality control plan (IQCP) include the following: A quality control plan (or changes in the plan) that the laboratory director signs and dates before implementation.

EP 8  Laboratories that develop an individualized quality control plan (IQCP) include the following: A quality assessment that includes documentation of corrective action and preventive action to monitor ongoing effectiveness.
Resources

- **Joint Commission Connect™**
  - *Perspectives Articles*
    - March 2014: IQCP Model
    - July 2015: New Requirements
  - IQCP PowerPoint & Risk Assessment Template
  - Leading Practice Library: IQCP C. difficile Testing
    - Brochure #11 - 13
    - FAQs IQCP
    - IQCP benefits
    - IQCP workbook: Developing an IQCP, A Step-by-Step Guide

- **Lab Focus** publication (Aug/Sept 2015)

- Submit a question to Standards Interpretation
  [https://web.jointcommission.org/sigsubmission/sigsubmissionform.aspx](https://web.jointcommission.org/sigsubmission/sigsubmissionform.aspx)
Eligibility Determination for IQCP – CAP website tool

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

   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

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*?
Eligibility Determination for IQCP – 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)?
    - **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**
Required Elements of IQCP

• High Level – evidence of the following:
  1.) Risk Assessment
  2.) Quality Control Plan (QCP)
  3.) Quality assurance
Required Elements of IQCP

- Risk Assessment must include:
  1.) Specimen
  2.) Reagents
  3.) Environment
  4.) Personnel
  5.) Test System

(Pre-analytic, Analytic, Post-analytic)
Required Elements of IQCP

• Quality Control Plan must be documented:
  1.) If SOP is in place, it must be followed
  2.) Manufacturer’s requirements are the minimum
  3.) Must at least include the number, type, frequency of QC and criteria for acceptability
  4.) Laboratory Director must approve
Required Elements of IQCP

• Quality Assurance must monitor:
  1.) Testing process failures
  2.) Investigation of complaints or adverse patient outcomes
  3.) Evaluation of Corrective Actions
  4.) Annual review of effectiveness