Commentary provided by:
E Susan Cease MT(ASCP)
Laboratory Manager
Three Rivers Medical Center
Grants Pass, OR

EDUCATIONAL COMMENTARY – KEY COMPONENTS OF AN INDIVIDUALIZED QUALITY CONTROL PLAN

Educational commentary is provided through our affiliation with the American Society for Clinical Pathology (ASCP). To obtain FREE CME/CMLE credits, click on Earn CE Credits under Continuing Education on the left side of the screen

Learning Objectives

On completion of this exercise, the participant should be able to

- identify the mandatory elements of an individualized quality control plan (IQCP);
- understand how to identify situations in which a risk assessment must be completed; and
- determine which tests qualify for an IQCP.

IQCP: Introduction

The end of 2015 brought a flurry of activity as laboratories evaluated how the Individualized Quality Control Plan (IQCP) option from the Centers for Medicare & Medicaid Services (CMS) would affect their operations. Resources available from CMS, and then from accrediting agencies and vendors, provided guidelines and forms to assist labs in determining which test systems qualified for IQCP and how to develop a viable plan. Fast forward two years, and many labs have moved into the next phase of IQCP – the continual Risk Assessment (RA) and evaluation of the Quality Assurance cycle. The focus on defining how frequently external controls will be performed is just one component of an IQCP. This article will provide an overview of the components and a few of the tools that can be used in RA and evaluation of the IQCP.

IQCP = *I*ndividualized *Q*uality *C*ontrol *P*lan

Permits laboratories to develop site-specific quality plans for non-waived tests

IQCP: A Historical Review

The Centers for Medicare & Medicaid Services revised the Clinical Laboratory Improvement Amendments of 1988 (CLIA) interpretive guidelines (§493.1250) to implement IQCP and eliminate Equivalent Quality Control (EQC), effective January 1, 2016. Labs now have the option to implement IQCP or maintain the CMS-defined default frequency for external QC for qualifying non-waived tests.

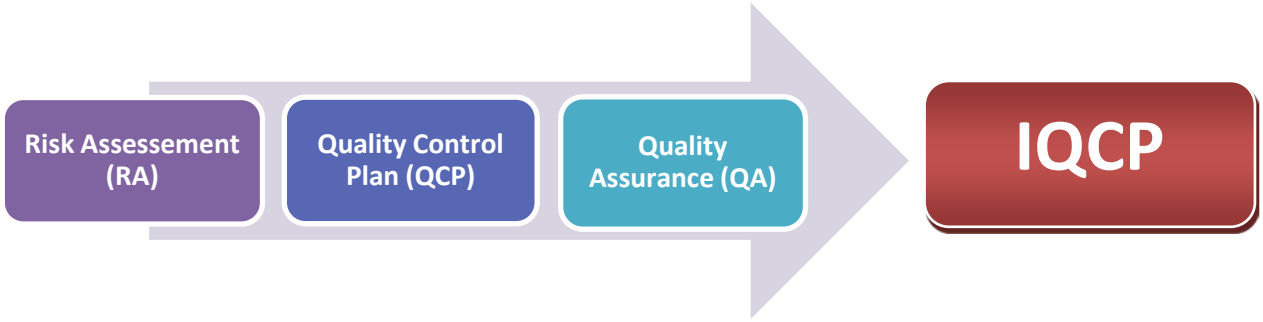
EQC is no longer an option for test systems with internal controls. EQC allowed external controls to be run with each new lot number, each new shipment, or once every 30 days, whichever was most frequent. For most tests, default QC frequency for external controls is two levels once per day of patient testing. Using RA, the lab may determine that less frequent QC provides acceptable QA, and it can develop and use an IQCP to manage that test. A laboratory cannot reduce the default frequency of external control

*If the manufacturer's QC protocol is less stringent than the regulatory requirement, **then** you will need to do an IQCP to follow the manufacturer's QC protocol.*

testing without using an IQCP, and under no circumstances can the lab reduce frequency below the manufacturer's recommendation.

Not all non-waived tests are eligible for IQCP. Specifically excluded are any tests performed and billed under Anatomic Pathology, Oral Pathology, Histology, or Cytology. Test media and reagents used in Microbiology for identification and susceptibility testing are eligible for IQCP. In many laboratories, the Microbiology section uses IQCP to a greater extent than any other department.

Developing an IQCP: A Story in Three Parts



IQCP[1] is an all-inclusive approach to assuring quality. It includes many practices that a laboratory already uses to ensure quality testing, beyond requiring that a certain number of QC materials be tested at a designated frequency. IQCP uses a Risk Assessment (RA) to develop a Quality Control Plan (QCP) and monitors the effectiveness with Quality Assurance (QA).

RA is a detailed review of all three phases of testing (preanalytic, analytic, and postanalytic) using at least five components (specimen, environment, testing personnel, reagents, and test system).

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

QA is the review system for the ongoing monitoring of the effectiveness of QCP. The monitoring should include at least the following: specimen, environment, testing personnel, reagents, and test system.

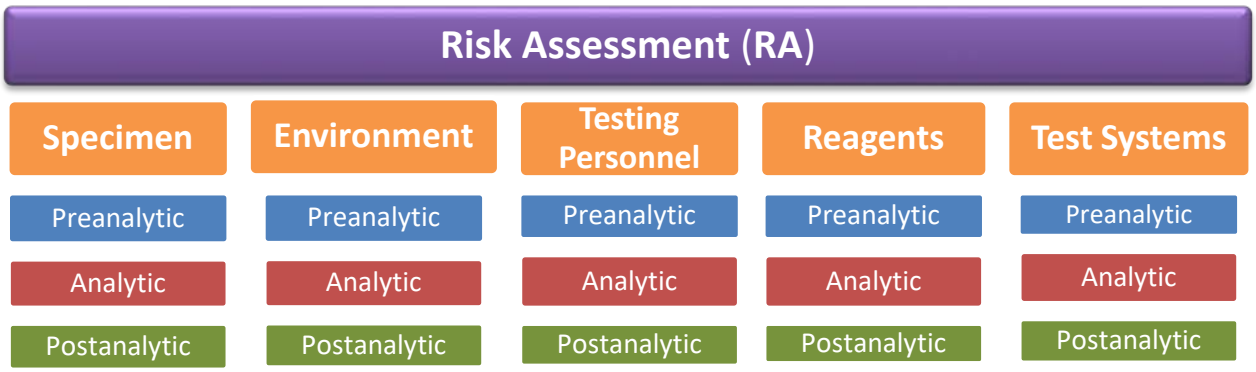
Risk Assessment

The RA will identify and evaluate any possible risks that may occur in your testing process. Risks are potential failures and sources of error that can affect the accuracy and precision of test results.

EDUCATIONAL COMMENTARY – KEY COMPONENTS OF AN INDIVIDUALIZED QUALITY CONTROL PLAN (cont.)

The RA requires review of the entire testing process (preanalytic, analytic, and postanalytic) across a minimum of five components: Specimen, Environment, Testing Personnel, Reagents, and Test System.

RA = 5 Components + 3 Phases



Step 1. Conducting the RA begins with compiling and reviewing data. Determine what you are already doing, collect data, and make sure you have a detailed process map. These data can be new or historical, but they must include the laboratory's own data; see **Table 1** for common data sources. It is important to have a multidisciplinary team working on the IQCP to ensure that all phases and components are evaluated during the assessment.

See the list of resources at the end for links to governmental and accreditation organizations that offer tool kits, forms, and instructions for all elements of the IQCP.

Table 1. Common data sources.

Sources for Data	
Laboratory procedures/standard operating procedures (SOPs)	Calibration data
Historical QC data, including data from a previously conducted EQC study	Instrument correlation data
Manufacturer's instructions/package inserts	Proficiency test results and data
Instrument and troubleshooting manuals	Records of complaints and corrected reports
Manufacturer's alerts and bulletins, FDA Alerts	Regulatory and accreditation requirements
Data obtained through verification or establishment of performance specifications	Scientific publications
Testing personnel training and competency records	Test process flowcharts or maps
Specimen-rejection logs	Turnaround time reports

EDUCATIONAL COMMENTARY – KEY COMPONENTS OF AN INDIVIDUALIZED QUALITY CONTROL PLAN (cont.)

Step 2. After compiling the information, analyze all five components in each of the three phases of testing. A process map is commonly used to ensure that all steps of the testing process are covered; see **Figure 1**. Use tools like the Fishbone and the "5 Whys" to evaluate each step involved in the process map. **Figure 2** provides an example Fishbone diagram. Many accreditation agencies and vendors, as well as CMS, supply forms that you can adapt to your lab.

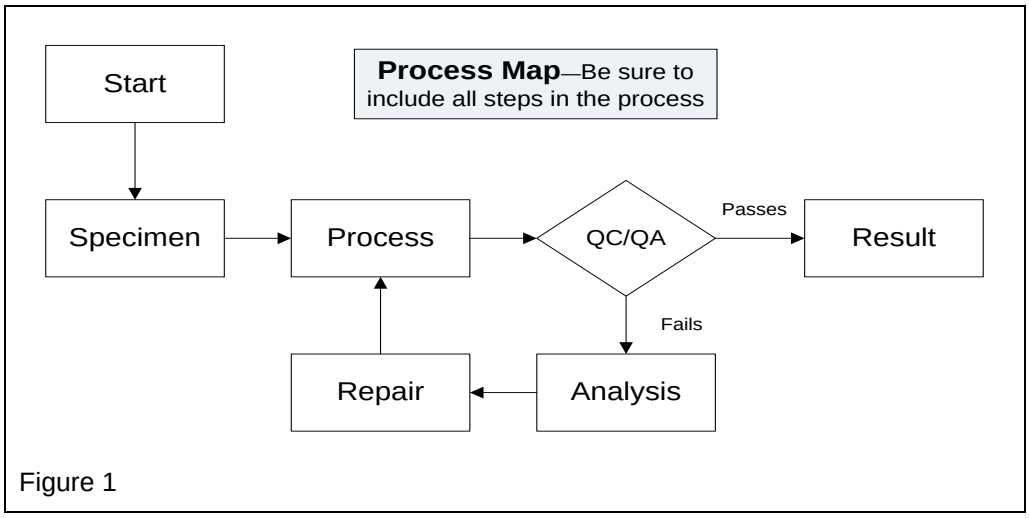


Figure 1

Questions You Should Ask as You Evaluate the Data:

What are the chances of an error happening at this point? Is there a step in the process that helps reduce the chance of an error? If not, how do I minimize or reduce the likelihood that this error could occur anywhere in the testing process? What is the impact to the patient?
Try using the 5 Whys. Why was the test delayed? Why did the sample have to be redrawn? Why was the first specimen rejected? Why did the phlebotomist draw the incorrect tube? Why is the training guide incorrect? Why was the SOP not updated when the kit was changed? Continue until you find the root cause. **Table 2** offers suggestions for steps/points to evaluate.

In laboratories with multiple identical devices (same make and model), an RA will need to be completed for each individual location and/or device, as well as when different groups of personnel perform the testing. All RA documentation must be maintained for at least two years after the corresponding QCP has been discontinued.

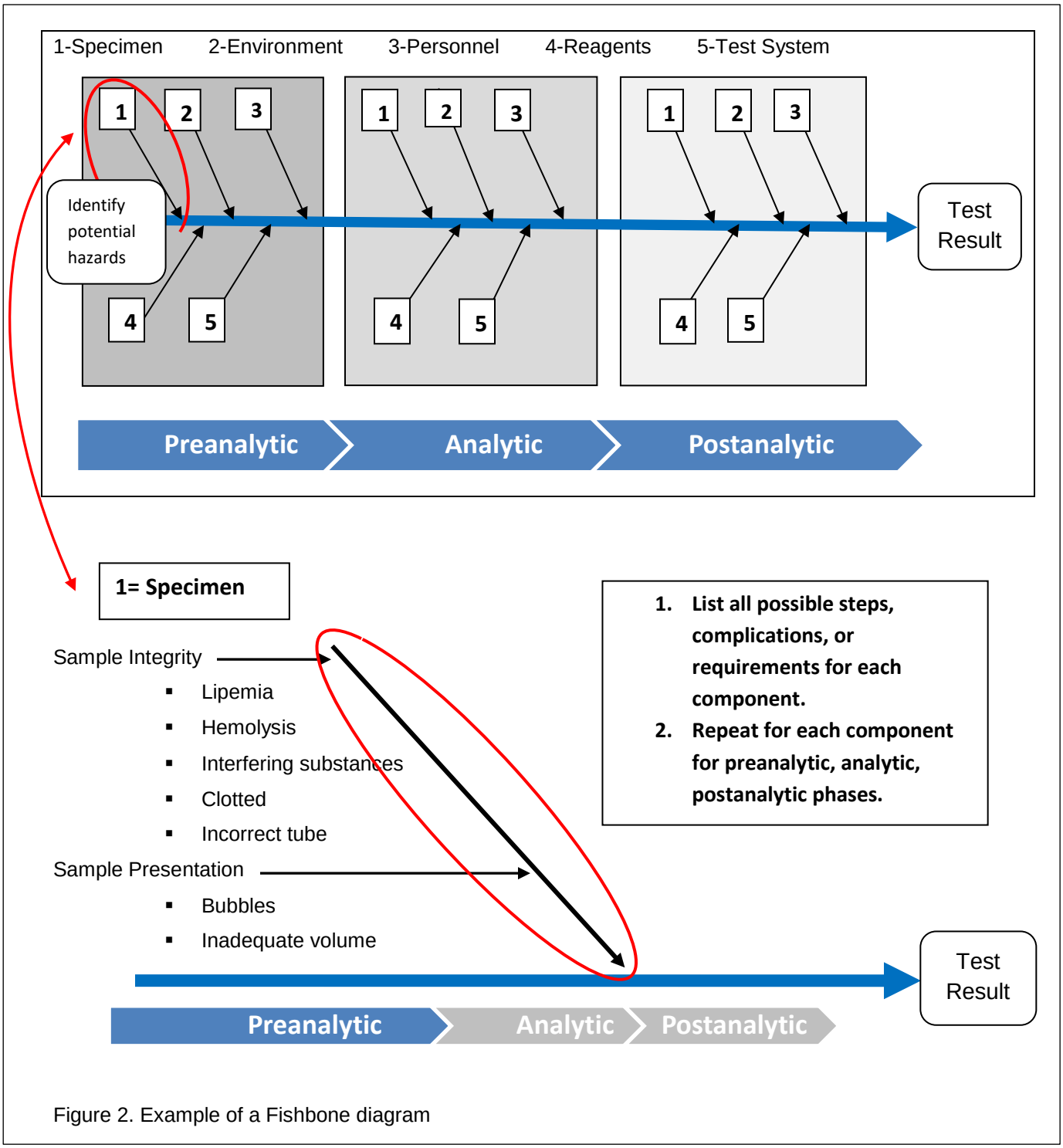


Figure 2. Example of a Fishbone diagram

Table 2. Components of a Fishbone diagram and points to consider for each.

Component	**Points to Consider** Must include preanalytic, analytic, postanalytic for each component
SPECIMEN	• Patient preparation • Specimen collection • Specimen labeling • Specimen storage, preservation, and stability • Specimen transportation • Specimen processing • Specimen acceptability and rejection • Specimen referral
ENVIRONMENT	•Temperature • Airflow/ventilation • Light intensity • Noise and vibration • Humidity • Altitude • Dust • Water • Space • Utilities (electrical failure/power supply variance or surge)
TESTING PERSONNEL	• Training • Competency • Education and experience • Staffing
REAGENT	• Shipping/receiving • Storage condition requirements • Expiration date (may differ based on storage requirements) • Preparation
TEST SYSTEM	• Inadequate sampling • Clot-detection capabilities • Capabilities for detection of interfering substances (e.g., hemolysis, lipemia, icterus, turbidity) • Calibration-associated issues • Mechanical/electronic failure of test system • Optics • Pipettes or pipettors • Bar code readers • Failure of system controls and function checks • Built-in procedural and electronic controls (internal controls) • External or internal liquid quality control (assayed vs unassayed) • Temperature monitors and controllers • Software/hardware • Transmission of data to LIS • Result reporting

Step 3. Rate the risks identified in the assessment by severity and likelihood of occurrence. One common approach is to use an RA tool. An example is the Risk Matrix.[2]

Establish the *frequency of occurrence* and *severity of harm* using the criteria listed.

Complete a Risk Matrix and use the frequency and harm values to assess whether the risk is acceptable or unacceptable.

Frequency of Occurrence	Severity of Harm
•**Unlikely** (once every2-3 yrs) •**Occasional** (1/yr) •**Probable** (1/mo) •**Frequent** (1/wk)	•**Negligible** (temporary discomfort) •**Minor** (temporary injury; not requiring medical intervention) •**Serious** (impairment requiring medical intervention) •**Critical** (permanent impairment requiring medical intervention)

EDUCATIONAL COMMENTARY – KEY COMPONENTS OF AN INDIVIDUALIZED QUALITY CONTROL PLAN (cont.)

For example, an error that can cause serious harm, but is unlikely to occur, may be an acceptable risk. The RA for any given test system may look very different in different laboratories. For example, the same risk may be assigned different frequency or severity ratings by different sites, based on testing personnel, intended medical use, or specific environmental factors.

Frequency of Harm	Severity of Harm			
	Negligible	Minor	Serious	Critical
Frequent	**Not Acceptable**	**Not Acceptable**	**Not Acceptable**	**Not Acceptable**
Probable	**Acceptable**	**Not Acceptable**	**Not Acceptable**	**Not Acceptable**
Occasional	**Acceptable**	**Acceptable**	**Acceptable**	**Not Acceptable**
Unlikely	**Acceptable**	**Acceptable**	**Acceptable**	**Acceptable**

After the lab has identified the sources of potential failures and errors for a testing process, the findings are used to develop the QCP. *Any factors deemed Not Acceptable should be monitored*.

Quality Control Plan

The QCP is a written document that will define how you monitor the accuracy and precision of the performance over time. It must include the number, type, and frequency of QC testing with criteria for acceptable QC results

The QCP will describe the practices, resources, and procedures to control the quality of a particular test process. It should be able to provide for the immediate detection of errors that occur and identify changes that happen over time in the test system, environmental conditions, or variance in operator performance.

CLIA does not require the use of any specific tools or format in the development of an IQCP. The new IQCP option gives laboratories the flexibility to determine the appropriate control frequency and required monitors for their unique environment.

Although an annual review by the Medical Director or his/her designee is required, an additional monthly or quarterly review may also be required, depending on your accrediting body. See **Figure 3**.

In other words, include

- *What you monitor or audit*
- *How often you monitor/audit (frequency)*
- *How you know it is acceptable*

And have documentation available to support compliance with the plan.

EDUCATIONAL COMMENTARY – KEY COMPONENTS OF AN INDIVIDUALIZED QUALITY CONTROL PLAN (cont.)

Example: Quality Control Plan

Laboratory ABC Test/Instrument XYZ

Type of Control	Frequency	Criteria for Acceptability
Internal QC every time a test is run	Every use	Within manufacturer's limits using automated lockout
Two levels of EQC	Weekly	Within defined QC limits
Monitor temp of reagent storage area	Daily, monthly supervisor review	Within 2°-8°C
Training and Competence Assessment	At initial training, 6 months later, then annually	Successful test performance including external QC and PT testing
Etc.		
Monthly review of QMP data	Monthly by Supervisor	All elements meet criteria for acceptability.
Review by Medical Director	Annually	All elements meet criteria for acceptability.
Etc.		

Reviewed and Approved
Medical Director _____Date_____

MONTHLY QC REVIEW/IQCP ASSESSMENT FORM

TEST SYSTEM _____

LOCATION(S) _____

1. Determine if the IQCP Quality Control, Instrument/Equipment Maintenance, and Function checks were performed as defined in the IQCP.
2. Evaluate errors relating to preanalytic, analytic and postanalytic phases of testing
3. Review any complaints from clinicians and/or other healthcare providers regarding the quality of testing.
4. Describe and evaluate corrective actions taken if problems were identified.
5. Did the IQCP mitigate potential risk for the test system?
   If the IQCP did not mitigate potential risk, list additional investigation activities and suggestions for modification of the IQCP.

Reviewed by: _____ Date: _____

Figure 3. Example monthly or quarterly review documentation.

EDUCATIONAL COMMENTARY – KEY COMPONENTS OF AN INDIVIDUALIZED QUALITY CONTROL PLAN (cont.)

Based on CAP and COLA documents.

Annual Review: Instrument XYZ Lab ABC Location: North Side

☐	Quality Control performed appropriately and reviewed monthly	QC issues resolved?	
☐	Temperature log sheets completed and reviewed monthly	Out of range or missing temperatures resolved?	
☐	Maintenance logs completed and reviewed monthly	Incomplete data? Corrective actions recorded?	
☐	Instrument issues resolved and recorded	Instrument failures or downtime?	
☐	Proficiency testing performed and reviewed	Unsuccessful PT performance?	
☐	Sampling of personnel training/competency reviewed	Retraining needed?	
☐	Sampling of patient results reviewed	Reporting errors corrected?	
☐	Relevant quality indicators reviewed	Turnaround time, corrected reports, specimen rejection, etc.?	
☐	Laboratory occurrence reports	Corrective actions completed?	
☐	Complaint reports	Physician or caregiver concerns?	
☐	IQCP reapproval by laboratory director or designee	**Questions or concerns identified in the review/reapproval?**	

- Have test process failures been identified?
    a. Assess the use (e.g. timely, effective) of the monthly review process of Quality Control, temperature, and maintenance logs to identify problems
    b. Record any corrective action for patient results affected by the testing process failure.
    c. Evaluate the effectiveness of the corrective action taken.
- Have any changes been made to the five elements of the Risk Assessment (i.e. specimen, reagents, environment, testing personnel, test system) requiring reevaluation of the Quality Control Plan?
- Have any changes been made to the Quality Control Plan?
    a. Specify any updates/modifications
- Have revisions to the Quality Control Plan been signed by the laboratory director (including signature and date)?
- Is the IQCP sufficient to mitigate risk in this laboratory? If no, explain actions to be taken.

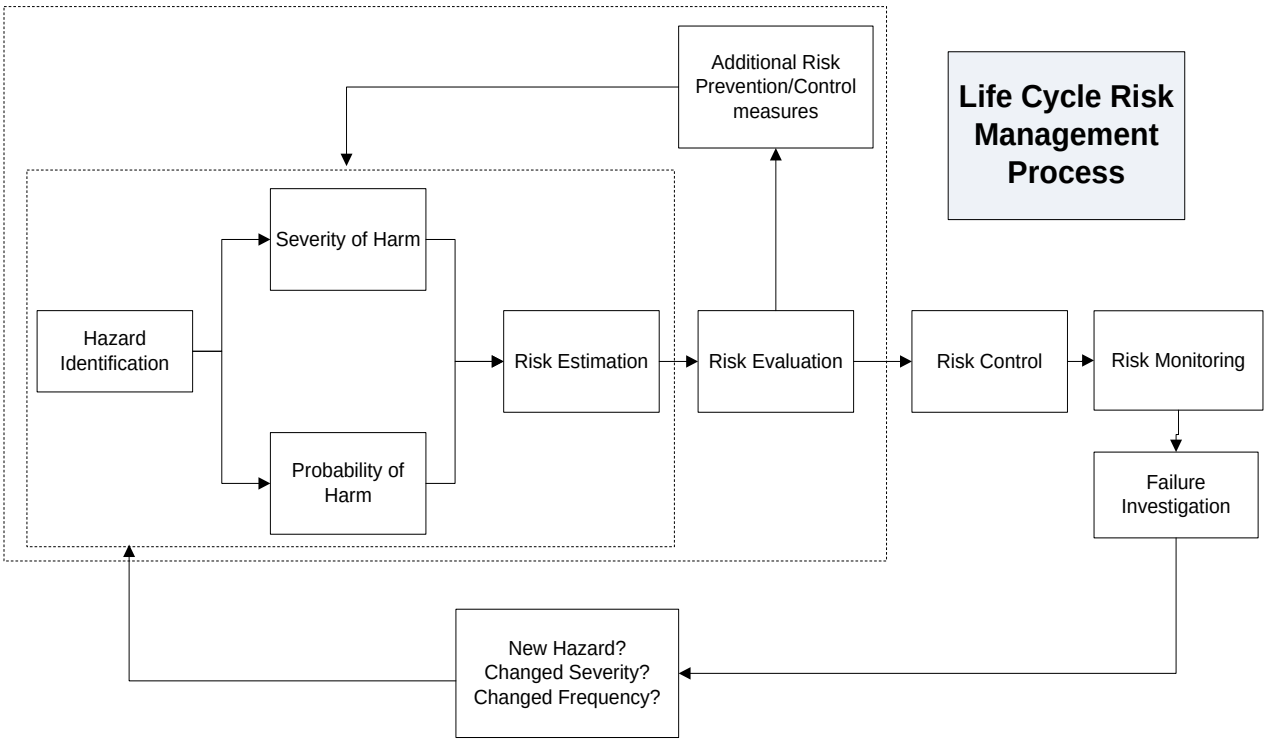
Reviewed by_____ Date_____

Quality Assurance

QA is the review system for the ongoing monitoring of the effectiveness of the QCP. The monitoring should include at least the following: specimens, reagents, environment, testing personnel, and test

system. This should be reflected in the documentation required to comply with the Quality Management Plan (QMP).

Whenever a step or process fails to meet the criteria set out, the cycle begins again. You also need to reassess whenever any component or step in the system changes. If the testing location is changed, the humidity changes as a result of a new cooling system, the manufacturer modifies the kit, or the job description of staff performing the testing changes, you will need to perform a new RA.



When the laboratory discovers a testing process failure, you will need to conduct an investigation to identify the cause of the failure, its impact on patient care, appropriate corrective action for affected patients, and appropriate modifications to the QCP to prevent recurrence. The investigation must include documentation of all corrections, corresponding corrective actions for all patients affected by the testing process failure, and evaluation of the effectiveness of the corrective action(s). The laboratory must implement the correction(s) necessary to resolve the failure and reduce the risk that the failure will recur in the future.[1]

EDUCATIONAL COMMENTARY – KEY COMPONENTS OF AN INDIVIDUALIZED QUALITY CONTROL PLAN (cont.)

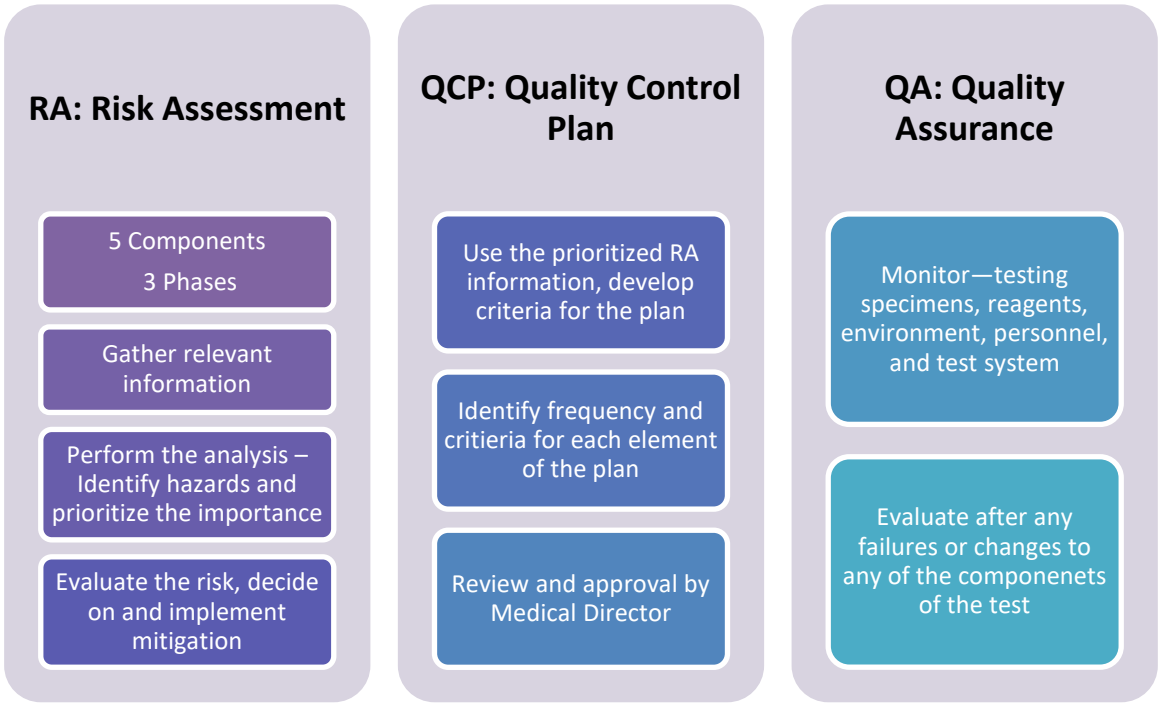
Summary

An Individualized Quality Control Plan is a cycle with three main components. There are required elements, but it also offers the flexibility to customize the plan to fit a specific laboratory and location. Multidisciplinary teams ensure that the IQCP plan is robust and conforms to frequency guidelines, and the medical director review and integration into the Quality Management Plan ensures that all departments are aware of the IQCP. An Individualized Quality Control Plan is about the patient and ensuring that we provide accurate, dependable results — every time.

Key Points

- One IQCP for each location/site of testing
- Cannot go below manufacturer's recommendation for QC frequency
- Cannot use manufacturer's data or template IQCP alone—must contain *your* data and match *your* process
- Must have data to support frequency of external controls
- IQCP must be incorporated into the overall lab Quality Management Plan (QMP)
- Medical Director must review, approve, and sign the initial IQCP
- The Medical Director, or designee, must review and sign the IQCP annual review
- There must be evidence of review and evaluation whenever there is a change in any of the components of the plan
- Multidisciplinary teams are necessary to build a robust plan
- Laboratories implementing IQCP for new tests are encouraged to perform control procedures more frequently during initial implementation, allowing the laboratory to identify performance issues that could indicate a need to adjust the QCP

EDUCATIONAL COMMENTARY – KEY COMPONENTS OF AN INDIVIDUALIZED QUALITY CONTROL PLAN (cont.)



References

1. Centers for Medicare & Medicaid Services. Developing an IQCP A Step-By-Step Guide https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/IQCP-Workbook.pdf. Accessed February 10, 2018.

2. Clinical and Laboratory Standards Institute. *EP23-A Laboratory Quality Control Based on Risk Management: Approved Guideline*. Wayne, PA: Clinical Laboratory Standards Institute; 2011. CLSI document EP23-A.

3. Centers for Disease Control and Prevention. Clinical Laboratory Improvement Amendments (CLIA): Individualized Quality Control Plan. https://wwwn.cdc.gov/clia/resources/iqcp/. Accessed February 10, 2018.

4. Joint Commission website. https://www.jointcommission.org/. Accessed February 10, 2018.

5. Centers for Medicare & Medicaid Services. Individualized Quality Control Plan. https://www.cms.gov/regulations-and-guidance/legislation/CLIA/Individualized_Quality_Control_Plan_IQCP.html. Accessed February 10, 2018.

6. College of American Pathologists website. http://www.cap.org/web/home. Accessed February 10, 2018.

7. IQCP from COLA. http://www.cola.org/programs-services/iqcp-program/. Accessed February 10, 2018.

8. CLIA Brochure 12. https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIAbrochure12.pdf. Accessed February 10, 2018.

9. CLIA Brochure 13. https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIAbrochure13.pdf. Accessed February 10, 2018.

10. Tague NT. *The Quality Toolbox*. 2nd ed. Milwaukee, WI: ASQ Quality Press; 2005.