

COLA'S

inSights

INTO
IQCP



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FROM THE CHAIR



As the NEW Chair of COLA's Board of Directors, I would like to welcome you to this edition of COLA Insights. Our goal, through this publication, is to offer our accredited laboratories the opportunity to be updated on relevant issues that impact the laboratory and provide for the most up to date information on technology and regulatory changes.

Education is at the forefront of our services for Clinical Laboratories. Through our new educational subsidiary, COLA Resources Inc. (CRI®), whose **mission is to "Provide educational and consultative services aimed at improving laboratory medicine and patient care."** Laboratorians have the opportunity to access a broad spectrum of educational tools. From our Continuous Quality Program (CQP), which is a combination of education and consultation, to our Online Courses and Live Webinars, Software Programs and Symposia, our goal is to assist laboratory healthcare professionals drive efficiencies within their laboratories. The new CRI® Individualized Quality Control Program (IQCP) Program is the newest product offering and was developed to assist laboratories adhere to the new CMS guidelines that will be implemented on January 1, 2014. With the CRI® IQCP program, customers have available a series of in-depth products and interactive tools to aid the Laboratory Director in making the best choices in Risk Management for their site.

The CRI® IQCP Workshops and Clinical Laboratory Symposiums are excellent events, where Continuing Education Credits can be earned in an interactive and engaging environment. The CRI® IQCP Workshop provides a hands-on event that includes presentations from Education, Regulatory and Industry leaders. This event is an opportunity for healthcare professionals to learn the regulatory guidelines, and obtain industry insights and Accreditation Organization perspective.

The CRI® Symposium for Clinical Laboratories – Education for Laboratory Excellence provides high quality educational sessions, and affords attendees the opportunity to network, and compare the latest innovations in laboratory diagnostics. We hope you will have the opportunity to attend the next CRI® Symposium for Clinical Laboratories scheduled for October 2014!

Thank you for your continued support of COLA and we look forward to assisting you in providing quality patient care.

Richard A. Wherry, M.D.
Chair, COLA Board of Directors

COLA INSIGHTS

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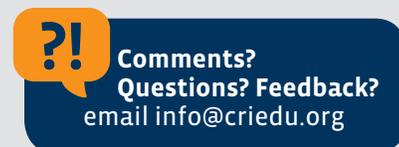
COLA INSIGHTS is published periodically by CRI®, 9881 Broken Land Parkway, Suite 215, Columbia, MD 21046-1195.

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EQC Begins Transition to IQCP January 1, 2014

What changes and what remains the same.

Starting January 1, 2014 CMS is implementing a new alternative Quality Control (QC) option. CLIA laboratories can voluntarily begin to transition away from Equivalent Quality Control (EQC) and begin using the default CLIA Quality Control (QC) requirement or Individualized Quality Control Plan (IQCP). The cornerstone of IQCP is identifying, evaluating, and controlling potential sources of error relevant to the individual laboratory. Performing a Risk Assessment will result in the development of an IQCP, achieved by implementing targeted quality control measures. According to CMS, “There will be an IQCP Education and Transition Period to allow laboratories an opportunity to learn about IQCP and implement their chosen QC policies and procedures. The IQCP Education and Transition Period will begin on 01/01/2014, and conclude on 01/01/2016.”¹

Laboratories will have three acceptable QC options during the IQCP Education and Transition Period:

1. Follow the CLIA QC regulatory requirements as written
2. Continue to follow the Equivalent Quality Control (EQC) procedures as described in the current Interpretive Guidelines²
3. Implement IQCP

At the end of the Education and Transition Period (1/1/2016), EQC will no longer be an acceptable option to meet CLIA QC requirements and will be removed from the regulatory guidelines. Therefore, it is important that laboratories understand that on January 1, 2016, only two options will remain to meet CLIA QC compliance.

1. Follow the CLIA QC regulatory requirements as written (Two levels of QC for each day of testing), or
2. Implement IQCP, as applicable

The Centers for Medicare and Medicaid Services (CMS) define IQCP as the “Right QC” for the test as it is performed in your laboratory given your lab’s unique circumstances.

*IQCP is Quality Control based on Risk Management.*³ Risk is a measure of the severity of the impact of a potential error, multiplied by the probability of how likely it is that the error will occur, and your ability to detect the error if it should occur. Identifying, evaluating, and controlling these potential errors through quality control measures is the cornerstone of IQCP.

IQCP is inclusive. While only specific tests qualified for EQC (Equivalent Quality Control – the alternative QC program replaced by IQCP), all specialties (except Pathology, and its associated subspecialties of Histopathology, Oral Pathology, and Cytology) are eligible for IQCP.

Keep these important points in mind:

- IQCP includes, for each test, a risk assessment performed within your laboratory based on your unique circumstances
- IQCP recognizes that all phases of testing impact quality; therefore, the scope of risk assessments must encompass the entire testing process: pre-analytic, analytic, and post-analytic phases
- IQCP focuses on the “right” QC for each test, which is not necessarily less frequent QC
- IQCP is formalized as a documented Quality Control Plan. It may be electronic or hard copy; it may be documented as part of the testing procedure or as a separate manual

IQCP is voluntary. Like the other CLIA QC requirements, IQCP is intended for non-waived testing; however, you may perform a risk assessment and develop an individualized plan for ANY test, including waived testing. You may use IQCP for all, some, or none of the test systems in your laboratory. Laboratories can continue to run the CLIA “default” QC – two levels of external control each day of patient testing – instead of implementing Individualized QC Plans.

The manufacturer’s QC recommendation will remain the minimum acceptable QC protocol, but it may be necessary to develop an IQCP if you chose to follow this protocol. If the manufacturer’s QC recommendations for the test are less than the default CLIA requirement of two levels per day (for instance, the manufacturer’s instructions say to run controls with each lot number change), your lab may:

- Perform the default requirement of two levels per day AND run controls with each lot number change (to satisfy the manufacturer’s requirement); OR
- Develop an IQCP for the test to show that all relevant errors will be detected if the manufacturer’s protocol is followed

>> CONTINUED ON PAGE 4

EQC BEGINS TRANSITION TO IQCP JANUARY 1, 2014

In other words, you may not simply follow the manufacturer’s less stringent QC requirements without first performing a risk assessment to determine if this amount of QC is the “right” QC.

An IQCP is not necessary if the manufacturer’s stated number, type, and frequency of control procedures meet or exceed the CLIA requirement of two levels of external controls each day. If the manufacturer’s instructions specify more than two levels per day, you may not use an IQCP to reduce the number of daily controls to less than the manufacturer’s recommendation. In other words, since the manufacturer’s QC recommendations will remain the minimum acceptable QC requirement, if the manufacturer recommends two or more levels per day, your lab may not develop an IQCP with less than the number specified by the manufacturer.

COLA Resources Inc. (CRI®) anticipated the need and has created a comprehensive program to address the critical changes in laboratory QC. The CRI® IQCP Program is designed to assist you in developing and implementing IQCP, customized to the diversity and unique testing conditions in your laboratory. Our goal is to provide education and technical guidance through the entire process, relieving the burden of Lab Directors who often have limited time and capacity to create QC programs from scratch.

Although the debate surrounding QC may continue, healthcare providers at all levels of patient care (physicians, nurses, laboratory personnel, etc.) will agree that IQCP will enable laboratories to meet their unique quality control requirements while achieving regulatory compliance, thus paving the way to continuous quality patient care.

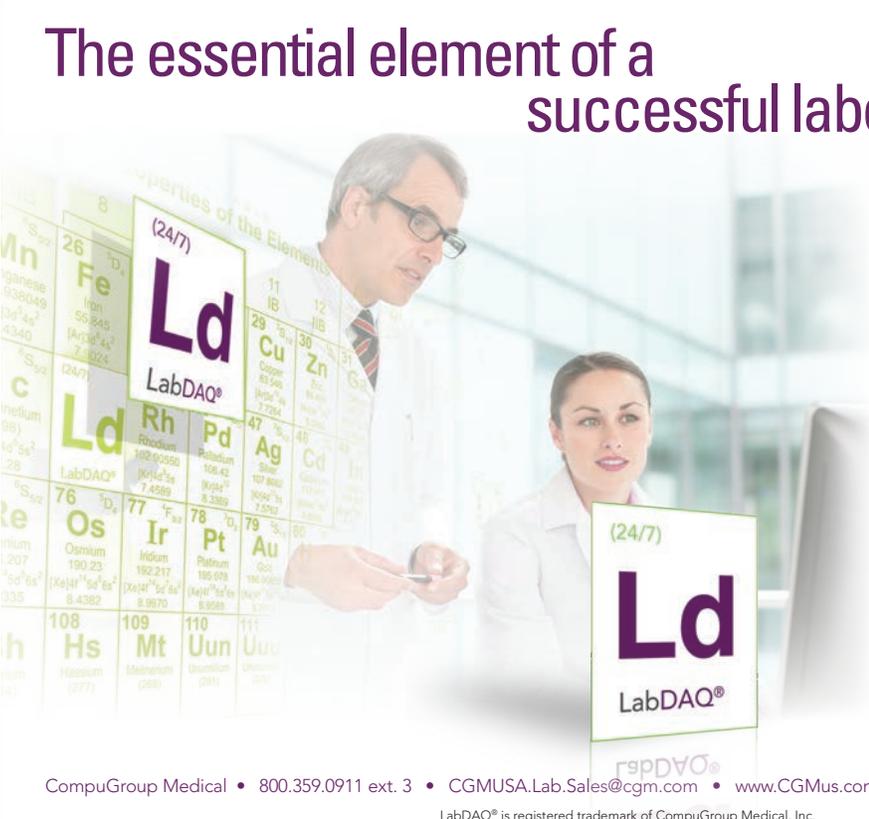
RESOURCES:

¹ *IQCP announcement letter for CLIA CoC and PPM laboratories* [PDF, 100KB] <http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/IQCP-announcement-letter-for-CLIA-CoC-and-PPM-labs.pdf>

² *Interpretive Guidelines for Laboratories - Appendix C. Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services.* www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Interpretive_Guidelines_for_Laboratories.html

³ COLA Resources Inc. *IQCP Implementation Guide*. 2013.

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Continuing Education for IQCP

What are new frontiers in Continuing Education relating to IQCP?



Laboratories that are looking to make the shift from Equivalent Quality Control (EQC) to Individualized Quality Control Plan (IQCP) have not only the actual implementation of IQCP to plan for, but also the Continuing Education of personnel that must accompany it. According to Centers for Medicare & Medicaid Services (CMS) there will be a two year Education and Transition period from January 1, 2014 to January 1, 2016. Laboratories have a finite window to educate and train their staff on IQCP. This learning process should not only cover the rules and regulations of IQCP, but also the key concepts behind its enforcement.

IQCP is Quality Control based on Risk Management. Continuing education on IQCP can come in many forms. Workshops, webinars, and online courses are some of the most popular. Reviewing materials and texts for information are also good sources to stay informed on this advanced level of QC. In considering what to focus on as a topic of choice, two key concepts must be explored - Quality Control and Risk Management. You may think “I already know about Quality Control,” but have you considered learning the “why” instead of the “what?”

Quality Control (QC) is not simply drops of reagents used in a testing device or a colorimetric line you see. The ISO 9000 definition of Quality Control is “part of quality management focused on fulfilling quality requirements.”¹ CMS states that “QC consists of the procedures used to detect errors that occur due to test system failure, adverse environmental conditions and variance in operator performance, as well as the monitoring of the accuracy and precision of the test performance over time.”² The concept of QC in Continuing Education, as it relates to IQCP

looks at overall QC initiatives as well as technical aspects. Topics may include Standard Deviation, Sigma concepts, Coefficient of Variation, Mean, Accuracy, and Precision. This is also to be reflected in the examination of the three phases of testing pre-analytic, analytic and post-analytic. When you start to think that all of this may be “too technical,” consider the fact that it is the technicality of QC that makes it essential.

Risk Management is defined in ISO 14971 and referenced by CMS as the “systematic application of management policies, procedures, and practices to the tasks of analyzing, evaluating, controlling and monitoring risk.”³ Most people think of Risk Management in terms of insurance and business. In laboratory science, Risk Management seeks out errors with the potential to cause human harm. Risk Management consists of identifying, evaluating, and controlling the risk of these potential errors through a variety of quality control measures that become your IQCP.⁴ Continuing Education must be focused on these activities as they relate to the medical laboratory industry specifically.

The three components of Risk Management are Risk Identification, Risk Assessment, and Risk Mitigation. Laboratory personnel have to review each component and understand the actions that must accompany them. Excellent references are CMS and your Accrediting Organization, as they create and implement the guidelines. By referencing the regulations and guidelines, your laboratory staff will get the “who” behind the “what” as well. Over the next two years, the Education and Transition period is an excellent time to get your personnel acquainted with the concept of IQCP and to take advantage of the resources available. By ensuring that your staff has a primary understanding of these concepts and terms, your laboratory is taking steps to understand IQCP.

RESOURCES:

- ¹ International Standards Organization. *Quality management systems – Fundamentals and vocabulary*. ISO 9000. Geneva, Switzerland: International Organization for Standardization; 2005.
- ² Clinical Laboratory Improvement Amendments (CLIA) Equivalent Quality Control Procedures Brochure #4 (2013) <http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/downloads/6066bk.pdf> last accessed October 2013
- ³ International Standards Organization. *Medical devices – Application of risk management to medical devices*. ISO 14971. Geneva, Switzerland: International Organization for Standardization; 2007
- ⁴ CRI *IQCP Implementation Guide* (2013) Columbia, Maryland.



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CRI® IQCP Program

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CMS Individual Quality Control Plans (IQCP) Interpretive guidelines will begin implementation January 1, 2014. Laboratories will have a two year education and transitional period (January 1, 2014 – January 1, 2016) to assess and create new Individual Quality Control Plans for tests that formerly utilized Equivalent Quality Control (EQC) and for additional tests, if desired. This voluntary process includes not only educating your staff on IQCP, but creating documented Quality Control plans for each test performed in your laboratory. CRI®'s (COLA Resources Inc.) goal is to help your laboratory establish continuous quality standards through CRI®'s Individualized Quality Control Plan (IQCP) Program. The CRI® IQCP Program is designed to assist you in developing and implementing IQCP, customized to the diversity and unique testing conditions in your laboratory.

A key contributor to the development of an effective Individualized Quality Control Plan (IQCP) is education. At the core of IQCP is Risk Management. For some healthcare professionals this is a well-known and commonly used process; however for others this may be an area where knowledge is limited. CRI® IQCP Program is designed to educate and strengthen IQCP core competency by offering an array of tools to help develop an effective IQCP.

The CRI® IQCP Program is intended to meet the following key objectives:

- Customize your QC Plan according to test method, utilization, environmental, and personnel competency to achieve clinical and economic benefits
- Optimize your current QC/QA processes
- Adhere to federal, state and accrediting organization requirements
- Ensure continuous quality patient care, with optimal clinical outcomes
- Identify new initiatives and ongoing measures to improve the quality of patient care

CRI®'s IQCP Program provides tools necessary in developing a QC plan unique to **your** laboratory, but also allows your laboratory the flexibility to access a format that will best suit **your** needs. CRI® IQCP Program is QCmadeEZ™.

The **CRI® IQCP Program Portfolio** includes:

- CRI® IQCP E-Optimizer
- CRI® IQCP Implementation Guide
- CRI® IQCP Educational Video
- CRI® IQCP Workshop
- CRI® IQCP LIVE Webinar Series

CRI® IQCP E-OPTIMIZER

This software tool provides all laboratories, from small POLs to hospitals and independent labs, with a guide or roadmap on how to perform a risk assessment and develop an IQCP. It is designed to assist laboratories to evaluate their current QC methods and receive customized recommendations on how to align their QC programs with IQCP guidelines.

You will be guided through a chronological set of questions, offering common examples of potential sources of error that could occur throughout all phases of testing, pre analytic, analytic, and post analytic. Based on your responses to these questions, an IQCP Summary Report will be generated which includes your overall risk score and the IQCP components that you have identified throughout your risk assessment. It will include a classification of risk, according to the score derived from your answers.

CRI® IQCP IMPLEMENTATION GUIDE

The CRI® Implementation Guide is an all-inclusive guide that can be used in the implementation of IQCP specific to your laboratory. It provides an overview of QC, including the evolution and basic concepts of QC, and continues with the introduction of the IQCP, its definition, how it is used and when it should be used. The IQCP Implementation Guide will provide a roadmap to performing true Risk Management unique to your laboratory. It will guide you through the performance of a Risk Assessment, by utilizing such tools as Process Mapping, Fishbone, and a Risk Identification Table. Includes completed examples and customizable templates to aid users in creating necessary documentation.

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CRI® IQCP PROGRAM

CRI® IQCP EDUCATIONAL VIDEO

This educational video, presented by the CRI®'s Quality Advisors, provides a high-level overview of IQCP, a CMS approved alternative Quality Control pathway replacing EQC. The video identifies the key elements, and necessary steps in implementing the IQCP guidelines in the clinical laboratory. It defines IQCP, reviews the evolution of this concept, beginning with basic quality control, and provides brief discussions of its components, implementation, and benefits.

Included in the video are two guest speakers: Dr. John Daly, COLA Inc.'s Chief Medical Officer (CMO), providing added insights into how the implementation of IQCP enhances the quality of patient care and the physician/patient relationship, and Kathy Nucifora, MPH, MT (ASCP), COLA's Accreditation Division Manager, reviewing the steps laboratories need to take in order to develop and implement IQCP.



CRI® IQCP WORKSHOP

This full day workshop includes informative presentations by several experts in the field of Risk Assessment, often including CMS representatives. Previous sessions have included *CLIA and the CMS IQCP Interpretive Guidelines*, *What does IQCP mean for your Laboratory and Industry Insight on IQCP*. This workshop also includes an exclusive opportunity to create an IQCP for your laboratory in Breakout sessions and the opportunity to review your plan with the experts! Each Workshop also provides the opportunity to earn P.A.C.E.® Continuing Education credit hours that can be directly applied to your laboratory Quality Assurance and professional licensure/certification requirements. Workshops are currently being planned for each region of the country. Contact CRI® today to register for the next workshop in your area.

Workshop Objectives:

- Review Concepts of Risk Management
- Identify Potential Sources of Error
- Process mapping and fishbone development
- Determine the level of risk
- Steps needed to mitigate and reduce residual risk
- Implementation of an IQCP

CRI® WEBINAR CEEXPRESS 21: COLA UPDATE — INDIVIDUALIZED QUALITY CONTROL PLANS

This recorded webinar will help you prepare for this transition and provide you with the information you will need to develop your QC plans. Many laboratories have successfully utilized Equivalent Quality Control (EQC), as an alternate QC option for technologies that have internal quality control mechanisms, as allowed for in 42CFR493.1250.

Participants will be able to:

- Follow the evolution of IQCP from conception to implementation
- Apply Risk Assessment tools in determining the most “effective QC” for your laboratory
- Walk through a sample Risk Assessment

The course links you to an archived version of the webinar slide and audio program, and to available pdf file resources. Your computer must have audio capabilities to hear the audio portion of the presentation. You must successfully complete the quiz and submit the course evaluation to receive credit. COLA is approved as a provider of continuing education programs in the clinical laboratory sciences by the ASCLS P.A.C.E.® Program. This course has been approved for 1 P.A.C.E.® contact hour.

CRI® is constantly updating our webinar series', please visit our website www.criedu.org for our latest course offerings.

Developing an IQCP may seem difficult and time consuming. Our goal in the development of our IQCP Educational program is to provide for you an inclusive, flexible and easy to use program. CRI®'s IQCP Program provides tools necessary in developing a QC plan unique to your laboratory but also allows your laboratory the flexibility to access format that will best suit your needs. The CRI® IQCP Program provides building blocks necessary to develop a QC plan unique to your laboratory. CRI® IQCP Program is “QCmadeEZ”™. We welcome your comments/feedback on our product line and would like to thank you for your interest and support of CRI® educational products.



COLA Resources, Inc[®]
Leading Excellence in Laboratory Medicine

CRI[®] Individualized Quality Control Program (IQCP)

On January 1, 2014, the new Centers for Medicaid and Medicare (CMS) QC regulations will go into effect! **ARE YOU READY?**

To assist labs with this major change, CRI[®] has developed an Individualized Quality Control Program to help you implement the new CMS IQCP Guidelines. The CRI[®] IQCP Educational Program is designed to “put you in control of Quality Control.”

IQCP is quality control based on Risk Management. To successfully develop and implement IQCP, hospital laboratories and physician office labs must understand that IQCP is based on risk management concepts.

The CRI[®] IQCP Educational Program is the most comprehensive in the industry:

- Customized to the unique testing conditions in each laboratory: methods, utilization, environmental, and personnel competency that are clinically and economically beneficial
- Ability to optimize current QC/QA processes
- Adheres to federal, state and accrediting organization requirements
- Ensures continuous quality patient care with optimal clinical outcomes
- Identifies new initiatives and ongoing measures to improve the quality of patient care

The CRI[®] IQCP Program offers you a wide range of components to meet CMS' IQCP guidelines.

The CRI[®] IQCP Program provides the building blocks necessary to develop a QC plan unique to your laboratory and allows your laboratory the flexibility to access the format that will best suit your needs.

The Program Portfolio Includes:

- CRI[®] IQCP E-Optimizer
- CRI[®] IQCP Implementation Guide
- CRI[®] IQCP Instructional Video
- CRI[®] IQCP Workshop
- CRI[®] IQCP LIVE Webinar Series

For descriptions on each of the program portfolio components, please visit <http://criedu.org/iqcp/>

CRI® IQCP Workshop

Hands on practice and real world examples make this a unique experience



In October 2013, COLA Resources Inc. held its first IQCP Workshop in conjunction with the CRI Symposium for Clinical Laboratories in St. Louis, MO. Participants were treated to a series of informative talks, and a hands-on practicum. Speakers included Diana K. Fairbanks, MT(ASCP) Laboratory Consultant Department of Health & Human Services, Centers for Medicare/Medicaid Services, Region VII Division of Survey, Certification & Enforcement Kansas City, MO. Ms. Fairbanks spoke on the topic of “CLIA & Individualized Quality Control Plan (IQCP).” This presentation gave participants firsthand information directly from Centers for Medicare and Medicaid Services (CMS) on the upcoming regulations, implementation guidelines and timeframe for education and transition from EQC to IQCP.

Kathy Nucifora, MPH MT (ASCP) Accreditation Division Manager, COLA spoke on “*Individualized Quality Control Plans (IQCP): What Does it Mean for Your Laboratory?*” Ms. Nucifora’s objectives were that participants be able to: Understand the timelines for transition to IQCP, Anticipate COLA plans to implement IQCP, Identify tests performed in your laboratory that will be good candidates for IQCP, and Walk through a sample Risk Assessment.

To get the IQCP perspective from industry Andy Quintenz from Bio-Rad spoke on “*QC and Risk Management: A New Paradigm.*” His talk related Quality Control to the “warm fuzzy” feeling you get inside knowing that your testing results are accurate. The confidence that the laboratory has in reporting its results in part of the integrated system of manufacturers, regulating authorities, accrediting organizations and laboratories.

During the second half of the IQCP Workshop the participants used the tools provided (Fishbone Diagrams, Process Maps, Risk Identification Tables and Risk Manageability Matrix) to create an IQCP. Breaking into teams they selected product inserts from various waived and non-waived tests and used the information provided to perform a Risk Assessment. The product insert packets were varied to show that waived tests can benefit from having an IQCP performed for them as well, although they are not required to under the upcoming CMS regulations. It was exciting to see our participants take package inserts combined with the knowledge learned at the workshop, and delve into the IQCP process!

For the final session of the Workshop each group had a spokesperson who explained their group’s IQCP and the methodology they used to create it. Each participant left the session with the confidence that they could create an IQCP for their laboratory’s test systems. The workshop allowed attendees the opportunity to have their IQCP’s reviewed by CRI IQCP experts and their colleagues. By sharing their example IQCP’s the participants were able to compare techniques and experiences with each other and share lessons learned from their respective laboratories. This is the core of IQCP, reflecting the most effective QC in your laboratory. The success of this seminal workshop has already resonated well in the scientific community and the series will continue into 2014 with workshops to be held in Charlotte, NC, Dallas, TX, Columbus, OH, and Orlando, FL. Registration for these events and additional information regarding our IQCP Program can be found by visiting our website: www.criedu.org or by contacting the CRI team directly at 1-800-981-9883.



CRI® IQCP Workshop Attendee Follow Up

Greetings IQCP Workshop Participant,

On behalf of CRI® I would like to again thank you for participating in our first CRI® IQCP Workshop in St. Louis! Our expectation is that the IQCP Workshop provided much needed information, insight and confidence for you to create and implement an IQCP for your laboratory.

As a Thank You, CRI® is extending an **EXCLUSVE** offer to the IQCP Workshop participants. Please visit our website www.criedu.org Enter Coupon Code: **CRIIQCP50** at checkout and receive an instant \$50 discount on the CRI® IQCP E-Optimizer and IQCP Implementation Guide. This exclusive coupon code will only be active from November 1 – December 2, 2013!

Remember to visit our websites www.criedu.org or www.labuniversity.org to access our complete portfolio of IQCP products:

- CRI® Educational Video: Implementing an IQCP (Individualized Quality Control Plan)
- Webinar CEexpress 21: COLA Update – Individualized Quality Control Plans*
- Webinar CEexpress 16: CMS CLIA Update – Current and Future Events*
- Risk Management in the Clinical Laboratory*
- LabGuide 53: Individualized Quality Control Plans

* P.A.C.E.® credit and/or CME credit earned as indicated upon registration.

In addition, CRI® is excited to announce our upcoming series of IQCP Webinars and Workshops, presented by leading experts in the field of IQCP, including Judy Yost, CMS' Director of the Division of Laboratory Services. Program schedule and details will be available on our website: www.criedu.org and www.labuniversity.org

Our mission at CRI® is to ***“Provide educational and consultative services aimed at improving laboratory medicine and patient care.”*** We would like to thank you for your support of our mission and look forward to our continued partnership as we work to meet this mission.

Respectfully,



Rose Mary Casados
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Competency Assessment

IQCP is looking at you kid

“You are what the French call *Les Incompétent*,” became one of the famous lines from the 1990 movie *Home Alone*.¹ It was a conversation between siblings, where one was making a generalization of the other about his ability (or lack thereof) to pack his own suitcase and basic life skills as an eight year old. But as the movie unfolds the movie’s main character Kevin proves not only is he competent at taking care of himself, but a quite ingenious and resourceful young man. Competency is an ability or skill — defined by Miriam Webster Learner’s Dictionary.² It is defined by CMS as “Competency is the ability of personnel to apply their skill, knowledge, and experience to perform their laboratory duties correctly.”³

Competency is very often confused with the term training. Training, again defined by Miriam Webster Learner’s Dictionary is “a process by which someone is taught the skills that are needed for an art, profession, or job.” To be clear, once you have been trained on a skill you can then be assessed for competency on said skill. Simply because you have been taught something does not necessarily mean that you can perform the task correctly. We have always heard the adage ‘Practice makes perfect’, so let’s take it further and say that “Perfect practice makes perfect performance.’ If you learn how to do something incorrectly, you will perform the task incorrectly. It is the equivalent of learning how to do something correctly and then performing the task incorrectly.

Competency assessment is used to ensure that the laboratory personnel are fulfilling their duties as required by federal regulation.⁴ Even among larger laboratories with more formal structure, there has historically been little uniformity as to what constituted a valid assessment of competency. In recent years, there has been a regulatory emphasis on competency assessment, as an important quality tool to reduce laboratory errors.

WHO SHOULD PARTICIPATE IN A COMPETENCY ASSESSMENT?

Personnel should not be offended or insulted when asked to participate in a Competency Assessment. COLA Accreditation Criteria includes Competency Assessment as part of your laboratory’s Accreditation requirements. The new CMS IQCP Guidelines include Competency Assessments as part of your laboratory’s Individual Quality Control Plan.^{5,6} In determining who

should participate in a Competency Assessment the decision is based on a few factors. COLA criteria mandates that “All staff are to be included in this process from personnel involved in specimen collection and processing to those responsible for supervision and compliance.”⁷ Under CLIA regulations, all testing personnel must have their training documented and their competency verified.

Ask the question “Does your Laboratory Director or Technical Supervisor / Technical Consultant follow written policies and procedures to periodically evaluate personnel performance and competency of all staff involved in pre-analytic, analytic, and post-analytic phases of testing, as well as those responsible for supervision and consultation?” That is the concept of who needs to participate in a Competency Assessment.

According to CLIA regulations and COLA Accreditation Criteria “Documented competency assessment is required for individuals fulfilling the following personnel responsibilities outlined in Subpart M of the CLIA regulations: clinical consultant (CC), technical consultant (TC), technical supervisor (TS), general supervisor (GS) and testing personnel (TP). Clinical consultants, technical consultants, technical supervisors, and general supervisors who perform testing on patient specimens are required to have the six required methods in their Competency Assessment in addition to a competency assessment based on their Federal regulatory responsibilities.”⁸

Unlike COLA, CLIA currently does not require Testing Personnel who perform waived testing to participate in Competency Assessments, but they do note in their recommendations that “Even though CLIA has no specific requirements for personnel performing waived testing, you need to ensure that patient testing results are correct to assist in making an accurate patient diagnosis. You will need to ensure that testing personnel are following all manufacturers’ instructions. Testing personnel who are properly trained and performing the test correctly will aid the physician/provider in making an accurate patient diagnosis.”⁹ As a COLA Accredited laboratory, you are ahead of the game in ensuring that all personnel involved are properly trained and competent in performing patient testing. New COLA criteria for waived testing, including competency requirements, were implemented in June 2013.

WHEN SHOULD A COMPETENCY ASSESSMENT BE PERFORMED?

“Evaluations should occur semi-annually for the first year and annually thereafter for all testing personnel, supervisors and technical consultants.”¹⁰ More importantly COLA mandates that “Personnel must not report test results for patient specimens until, training is complete and competency is verified for each test procedure they perform.”¹¹ **In other words, no Competency Assessment, no testing for you!**

WHAT IS GOING TO BE ASSESSED?

Methods of competency assessment must include, but are not limited to:

- Direct observation of routine patient test performance
- Monitoring the recording and reporting of test results
- Review of intermediate test results or worksheets
- Direct observation of instrument maintenance
- Blind sample testing (such as Proficiency Testing)
- Assessment of problem solving skills

Competency Assessment, which includes the six methods, must be performed for testing personnel for **each test that the individual is approved by the laboratory director to perform**. It is also good to know that Proficiency Testing (PT) performance may be used as part of your competency assessment; however use of PT performance alone **is not sufficient to meet all six required methods**.

To ensure that your personnel can successfully complete a Competency Assessment, training them properly from the start is fundamental. For quality test performance in your laboratory, training must ensure that all testing personnel are familiar with the following for each test procedure¹²:

- The test name and purpose of the test
- The equipment necessary to perform the test
- Specimen collection and handling
- Preparation, labeling, use, and storage of reagents, standards, and controls
- Special requirements, safety procedures, etc.
- Instrument maintenance, function checks, and calibration, when applicable
- Step-by-step performance of the test procedure
- Quality control procedures including what constitutes acceptable results and when to report patients
- How to recognize and interpret inconsistent results and test system problems and perform troubleshooting
- Recommended corrective action when controls are unacceptable

- Necessary calculations and derivation of results, when applicable
- Reference ranges and critical values
- Result reporting
- Quality assessment procedures

Training and personnel evaluation are not the same as competency assessment. While training is important to ensure competency, training is a process to provide and develop the knowledge, skills, and behaviors to meet established requirements. Documentation of training does not satisfy the requirement for documented competency assessment. Personnel evaluation evaluate other behaviors and attributes as they relate to the position or job (such as internal or external customer service). Competency is the application of the knowledge, skills and behaviors for performance. The difference between training and competency is that training happens before someone begins testing and competency assessment confirms that they are doing the testing correctly.¹³

WHO SHOULD EVALUATE COMPETENCY?

First it is important to have competent individuals assess the competency of the personnel under review. The reviewer should not be the Office Manager, the Nursing Supervisor, or others who do not perform lab testing. CLIA gives this responsibility to the TC (moderate complexity) or TS (high complexity). Competency must be evaluated by qualified individuals (TC/TS/GS). Other competent staff members may assist with portions of the competency assessment – but the TC/TS/GS/LD MUST evaluate the overall results of the competency assessment and sign off on the final document.

HOW IS THE COMPETENCY ASSESSMENT PERFORMED?

Two of the six required assessment activities involve Direct Observation:

- Direct observation of routine patient test performance
- Direct observation of performance of instrument maintenance and function checks

This can be documented with a detailed process oriented check list, per test or instrument.

Two of the six required assessment activities involve Review of Records:

- Monitoring the recording and reporting of test results
- Review of intermediate test results, QC records, proficiency testing results, and preventive maintenance records

>> CONTINUED ON PAGE 14

Two of the six required assessment activities include with the competency documentation – records that were reviewed:

- Assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples; PT records should be included
- Assessment of problem-solving skills. Include problem logs, QC corrective action, complaint investigations, specimen rejection incidents...

The Competency Assessment documentation must include the results of the Assessment, who performed the Competency Assessment, who evaluated the testing personnel, and Conclusions. Conclusions should indicate 'Is the person deemed competent?' Are there any necessary remedial action(s) to be taken, re-assessment of personnel if necessary, and has the Competency Assessment been reviewed and bears the signature of TC/TS/GS/LD?

In summary, by taking the necessary documented steps to properly train then assess the competency of testing personnel, your laboratory is ensuring regulatory and Accreditation compliance. Testing patient samples are critical for proper patient care. The

testing processes may not be as easy as packing a suitcase, or using household items to defend one's home against burglars, but they can be simplified, verified and validated. Each step is critical in its successful completion to provide quality patient care and creates a competent and capable laboratory staff.

RESOURCES:

- ¹ Hughes Entertainment. Home Alone (1990). <http://www.imdb.com/title/tt009785/>
- ² <http://www.learnersdictionary.com/definition/competency>
- ^{3,4,5,7,10,12} CLIA Brochure #10 - What Do I Need to Do to Assess Personnel Competency? http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIA_CompBrochure_508.pdf
- ⁶ Implementing the Individualized Quality Control Plan (IQCP) for Clinical Laboratory Improvement Amendment http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/SCLetter12_20-.pdf
- ^{8,9} COLA Accreditation Manual (July 2013) PERSONNEL REQUIREMENTS:PER 5 p.65
- ¹¹ COLA Accreditation Manual (July 2013) PERSONNEL REQUIREMENTS:WAV 6 R p.105
- ¹² COLA LabGuide 16 Personnel Training & Competency Assessment www.colacentral.com

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IQCP and Industry Quality Control Planning

How will IQCP affect the laboratory devices and equipment Industry?



The new implementation of Individualized Quality Control Plan (IQCP) by Centers for Medicare & Medicaid Services (CMS) will bring with it many changes in regards to laboratories meeting the minimal QC requirements for all eligible non-waived tests performed in laboratories. IQCP is replacing Equivalent Quality Control (EQC) as we are now looking towards incorporating Risk Management in Quality

Control. Many laboratories will begin performing IQCP evaluations for tests in the upcoming education and transition period (January 1, 2014 – January 1, 2016) and the first place to start when assembling your reference materials will be the manufacturer’s product insert and operator’s manual. IQCP was developed to include the known risk mitigation included in your manufacturers testing guidelines, but at the same time allow your laboratory the flexibility of ensuring that it is the “right QC” for your lab.¹

The *CLIA Individualized Quality Control Plan Introduction Brochure* states that laboratories will be required to “Review the manufacturer’s instructions for control procedures. If the manufacturer’s instructions are absent or less stringent than the CLIA QC requirements (perform two levels of quality control each day of patient testing) then you must decide whether to implement the CLIA QC requirements or develop an IQCP. Performing an IQCP may allow laboratories to continue QC practices for non-waived tests that meet manufacturer’s instructions but are less stringent than CLIA QC requirements. You may have already acquired useful information, knowledge and experience in the performance of your test that would assist in the development of your IQCP. Contact the manufacturer for additional data that may help you develop an IQCP. If the manufacturer’s instructions are equal to or more stringent than the CLIA QC requirements, then you will not need to do anything differently.”²

So will industry increase their QC to make it automatically CLIA compliant? Will they keep things as they are and let the labs sort out the proper QC to use? Will they do a combination and make suggested notations in their package inserts for “IQCP Compliant QC”?

Currently industry is waiting on CMS and Accrediting Organizations

like COLA to create the training guidance for their Surveyors. This is most likely due to the fact that the Surveyors are the ones who will be reviewing the IQCP plans and determining if they are compliant or not. During the two year education and transition period “The laboratory will only be cited as out of compliance with the CLIA quality requirements if it does no QC, or there are serious concerns about test quality, or there is immediate jeopardy (i.e., real or potential harm to patients).”³

So there will most certainly be an influx of calls, emails and letters to manufacturers to gain as much information as possible on the level of QC required by them and the existing risk management features in their products. Andy Quintenz from Bio-Rad commented that only a few companies are currently looking at IQCP other than Point of Care Testing manufacturers. “Some companies



Andy Quintenz, Bio-Rad

like Bio-Rad are putting up information on our websites, but a lot of it is going to come from what the Surveyors are going to do.” At this juncture industry has a wait-and-see methodology regarding IQCP, which is understandable due to the fluidity and exchange of ideas allowed during the education and transition period.

As for the Laboratory Director, in looking for answers from industry about IQCP, start with what you already have. Review your package inserts, Operators Manuals and any QC update materials that are available for your test. IQCP takes into consideration that there is existing Risk Mitigation research that the manufacturers have performed in the creation of the test. Look at the test from the Pre-analytic, Analytic and Post-analytic stages. What wording or terminology is used in the materials provided that will help you identify risks or potentials sources of error when performing your test? Have you searched their website and/or call the Technical Support line to ask questions? The overarching goal and theme of IQCP is the influence and policies that the Laboratory Directors will take in creating Quality Control Plans for their testing, and industry will certainly follow suit.

RESOURCES:

- ^{1,2,3} CLIA Brochure #11 *CLIA Individualized Quality Control Plan Introduction*
<http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIAbrochure11.pdf>

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