

COLA'S

inSights

INTO

Quality Laboratory Medicine

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FROM THE CHAIR



As the New Year arrives and laboratories face many new guidelines and regulations, our purpose is to keep COLA Accredited labs informed and ready for what lies ahead. In this issue of InSights we look at many components of what comprises Quality Laboratory Medicine. As with all of our InSights publications, we encourage you to share this issue with your staff and colleagues to provide clear and thought provoking information. COLA Resources Inc. (CRI), COLA's Education subsidiary and leader in laboratory education, has created multiple educational products, tools and scheduled events to provide your laboratory with the resources needed to deliver superior laboratory services.

Included in this issue are: *Overview of IQCP*, discussing *Why this new guideline is so important?*, and *IQCP Preparation and Planning*, informing you on how CRI is ready to help your lab during the Education and Transition Period. As laboratories transition from Equivalent Quality Control (EQC) to the Individualized Quality Control Plan (IQCP), CRI has many IQCP initiatives planned for 2014, offering excellent tools to assist during this transition. The first IQCP LIVE webinar was held on Wednesday January 29th with guest speaker, Judy Yost, CMS' Director of the Division of Laboratory Services. The event provided an in-depth look at IQCP, was a great success and will be available on LabUniversity as a Webinar CEExpress course.

CRI® is excited to announce our upcoming series of IQCP Workshops, where participants will have the opportunity to speak with CMS representatives, participate in hands on development of an IQCP, and obtain invaluable feedback from the experts! We hope that you will take advantage of these opportunities as you prepare to implement the new CMS Interpretive Guidelines for quality control. Join us at one of our four events: Winston – Salem, NC on February 26, 2014, Dallas, TX on May 8, 2014, Columbus, OH on July 15, 2014, and Orlando, FL along with our Symposium for Clinical Laboratories from October 15-18, 2014.

Reducing Citations and Quality Laboratory Management, one of our featured articles, examines some of the top 5 citations observed in our COLA Labs and provides information on how COLA, through the services provided by their education subsidiary, CRI, can help laboratories achieve good laboratory practices. Finally, COLA is extremely excited announce that we are the first private laboratory accrediting organization to have earned deeming authority in California, proving our standards of promoting excellence in laboratory medicine and patient care are equal to or more stringent than the State's unique regulations for licensure and registration.

COLA has been a leader in Laboratory Excellence for over 25 years. We at COLA appreciate being your Accrediting Organization and welcome the start of a new year and new experiences!!

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

COLA INSIGHTS

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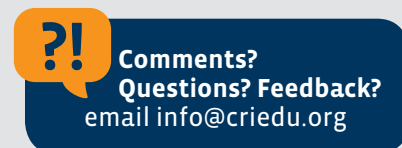
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Overview of IQCP

Why is this new guideline so important?

The Centers for Medicare and Medicaid Services (CMS) has released their Interpretive Guidelines for the Individualized Quality Control Plan (IQCP) for non-waived laboratories. Beginning January 1, 2014 CLIA laboratories **must begin to transition away from Equivalent Quality Control (EQC). EQC must be phased out** by January 1, 2016. As of that date, labs **must either follow the default CLIA Quality Control (QC) requirement or develop and implement an Individualized Quality Control Plan (IQCP).** Many laboratories are seeking guidance on how to best understand IQCP. The first step is to define the concept of IQCP.

The goal of IQCP is identifying, evaluating, and controlling potential sources of error relevant to the individual laboratory. This should be done by performing a Risk Assessment of each applicable test system in your laboratory. Performing a Risk Assessment will result in the development of an IQCP, and your laboratory's compliance is achieved by implementing the targeted quality control measures. The new program encompasses all three phases of clinical testing — pre-analytical, analytical, and post-analytical.

CRI®'s Continuous Quality Advisor Irwin Rothenberg provides additional insight as to why IQCP is important. "As we know by now, IQCP is the most effective QC. It customizes QC plans to fit unique laboratory circumstances while optimizing the use of integrated controls, allowing your lab to be flexible in how it complies with QC requirements. Individualized Quality Control Plans are adaptable; they incorporate variable sources of information, and utilize and formalize information already maintained by your laboratory." Mr. Rothenberg goes on to explain that "All of this is done with the goal of providing alternative quality control while still meeting CLIA rules and regulations."

By assessing the potential errors (risks) involved in laboratory particular test in your laboratory, and expanding the scope of "quality control," IQCP compels the laboratory to not only effectively communicate with the clinical staff but also gives you a clear message to share.

- Let's all work together to reduce the risk and severity of harm to our patients
- Let's ensure that all staff involved in the testing process is not only properly trained but also competent in the testing procedure

- Let's ensure that the results provided are reported in a timely fashion and the information is not only received but accurately interpreted by the clinicians

IQCP allows for all of the components of the pre-analytical, analytical and post-analytical process to work together for quality test results.

IQCP is Quality Control (QC) based on risk management. QC is not limited to the controls or reagents used in performing an assay. QC is the entire process of ensuring that your laboratory is providing accurate results for each patient sample processed. By performing the Risk Assessment your laboratory will identify and document the sources of potential error, evaluate the cause, and control it through Risk Mitigation.

If laboratories who have always followed the manufacturer's QC are now wondering why they should do anything different, CMS's response is as follows:

"During test system development, manufacturers challenge their tests in many ways to identify possible failures and then build in features to reduce the risk of those failures. However, manufacturers' instructions for QC may not address all of the risks and variables that are specific for your laboratory's situation. CLIA QC regulations include a requirement to perform two levels of quality control each day of testing or alternatively, laboratories may choose an equivalent option in CMS' Interpretive Guidelines (IG). The intent of either option is to ensure accurate results."¹

It is important to prepare at the onset of the Education and Transition period (1/1/2014 -1/1/2016) COLA Resources Inc. (CRI®) encourages you to take advantage of the CRI® IQCP Program that is being offered to all medical laboratories. 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.

The CRI® IQCP program will assist you in meeting the following key objectives:

- Perform a meaningful Risk Assessment
- Customize your QC Plan according to test method, utilization, environmental factors, and personnel competency to produce a QC plan that is clinically and economically beneficial

>> CONTINUED ON PAGE 4

OVERVIEW OF IQCP

- Optimize your current QC/QA processes
- Adhere to federal, state and accrediting organization requirements
- Ensure continuous quality patient care, with optimal clinical outcomes
- Identifying new initiatives and ongoing measures to improve the quality of patient care

The CRI® IQCP Program provides tools necessary in developing a QC plan unique to your laboratory, by offering your laboratory flexibility to choose the format that will best suit your needs. From our January 29th Webinar with Judy Yost- Director of the Division of Laboratory Services for CMS, our CRI® IQCP Workshop Series that provides participants the opportunity to learn IQCP basics and create an IQCP with the experts, the CRI® IQCP E-Optimizer software and Implementation Guide to help you create your IQCP, to our online courses, CRI® will work with you to support your requirements as you embark upon the education and transition to IQCP.

RESOURCES:

Individualized Quality Control Plan (IQCP): A New Quality Control (QC) Option Memorandum <http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-54.pdf>



Get ahead of the game for the CMS Education and Transition Period with

CRI® IQCP IMPLEMENTATION TOOLS



\$249

This software tool provides all laboratories from small POLs, to hospitals and independent labs, with a roadmap on how to perform a risk assessment and develop an IQCP. Generates IQCP documentation including Risk ID Table and Fishbone Diagram based on your responses. A **must** for all labs.



\$199

This all-inclusive guide assists in the implementation of IQCP specific to your laboratory. It is the resource you need to perform true Risk Management unique to your laboratory. Develop a Risk Assessment Plan, by utilizing such tools as Process Mapping, Fishbone, and Risk Identification Table templates (includes completed examples).

CRI® IQCP IMPLEMENTATION PACKAGE **\$399**

The CRI® IQCP Implementation Package includes CRI® E-Optimizer Software Tool and the CRI® Implementation Guide as described above.

NOW AVAILABLE ONLINE AT WWW.CRIEDU.ORG/IQCP

Reducing Citations and Quality Laboratory Management

Top 5 Citations in COLA Labs and how COLA and the CQA Program can help

In the year 2013 many changes came to COLA Labs. The revised Accreditation Manual was released in June, the specific criteria for Lab Director Responsibilities (LDR) were implemented, and labs were provided with new resources from COLA in the form of COLA Resources Inc.® (CRI) the Education subsidiary. Surveys continued and citations were handed out for deficiencies noted by surveyors. As a laboratorian, you may fear the survey date as it comes and hold your breath until you get the report of how your site has fared. COLA Surveyors come to perform the surveys not as “lab cops” but as the intermediary for your lab and the COLA Accreditation Program. They are required to not only identify and document deficiencies in laboratory quality, but also to provide education and support to the laboratories they visit. A part of this education and support is provided in this issue of Insights in Quality Laboratory Management.

For the year 2013 the top 5 citations in COLA Laboratories were as follows:

1. PER 4A

Does each laboratory employee adequately fulfill the responsibilities for the position(s) they hold? (Cited specifically for the Laboratory Director)

2. PER 5 R

Does your 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?

3. QC 10 R

Are manufacturer's instructions for the use of reagents, controls, and kits followed?

4. CA 2 R

Is calibration verification performed, according to the manufacturer's instructions including:

- *The number, type and concentration of materials to be used,*
- *Use of materials at low, medium and high values within the reportable range, as determined by the laboratory,*
- *Acceptable limits for calibration verification, once every six months or more often if required by laboratory procedures?*

5. PER 3 R

Does the personnel file contain documentation of the person's education and experience that qualifies them for the position they hold in the laboratory?

The main challenges that COLA Laboratories were cited for were related to documentation. (Insert groan here.) As laboratorians we know the saying “If you didn’t document it, you didn’t do it.” And for compliance sake that is true. Each QA plan should include a series of checks and double checks for all types of documentation: verifying specimen Identifiers, verifying data entry either automated or manual, are thermometers checked for accuracy at regular intervals? Labs must document every step of the process, and at times it can seem like “busy work”, but it is essential in providing quality patient care. Treat each specimen as if it were your own; wouldn’t you expect excellent documentation of the testing process?

COLA has made the documentation process even easier in terms of providing an online portal option for COLA Laboratories. By utilizing COLACentral Labs can upload QA/QC documentation, update test menus (verified with COLA of course) and personnel records with a push of a button. There are multiple free education and resource items available including video tutorials on how to get the most out of COLA Central, and the Insights Newsletter. In reviewing the top 5 citations lets look at ways to prevent them in 2014.

1. PER 4A

Does each laboratory employee adequately fulfill the responsibilities for the position(s) they hold? (Cited for the Laboratory Director)

In 2013 Lab Director Responsibilities was actually the most frequent citation. As LDs you set the standard for the laboratory. The new LDR criteria specifically address the Lab Director responsibilities, as defined in CLIA. Many LDs are extremely busy with other tasks, but must understand that by taking on this responsibility they are responsible for the accuracy of EACH test result that leaves their laboratory. If certain responsibilities are too great they may be delegated to a General Supervisor, Technical Supervisor or a Technical Consultant. “Some responsibilities of the Lab Director may be delegated to a qualified individual. However, it remains the responsibility of the Lab Director to ensure that all delegated duties are properly performed.”¹

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2. PER 5 R

Does your 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?

The guidelines for the leadership roles in COLA Laboratories are clearly outlined in the Accreditation Manual. Under “EVALUATION GROUPING: Personnel” the requirements for each level of testing and personnel position are outlined. Page 63 begins the discussion on Competency Assessments and the documentation necessary to evaluate competency.²

3. QC 10 R

Are manufacturer’s instructions for the use of reagents, controls, and kits followed?

According to the Accreditation Manual, “Laboratories must follow manufacturer’s instructions for waived tests. CLIA regulations require that waived and non-waived tests be reclassified as non-FDA approved high complexity tests when the laboratory alters or fails to follow the manufacturer’s instructions. When this occurs, the laboratory must comply with all high complexity Personnel requirements, and requirements for Performance Specifications for non-FDA approved tests (see VER 5-11).”

Examples of what laboratories do in modifying the test system are provided as well. These include but are not limited to:

- Change in specimen handling instructions
- Change or elimination of a procedural step
- Using a different sample matrix (plasma versus urine)
- Using or promoting the test for another purpose (screening versus diagnostic)

These modifications of the manufacturer’s procedure may be all valid to your laboratory but must be verified for accuracy to ensure compliance. Imagine making a cake and substituting apple sauce for vegetable oil, it seems like a reasonable alternative but if your cake mix manufacturer states in the directions “use only vegetable oil” you have just ruined the cake. The majority of Test systems have been vetted by the FDA and if they are laboratory produced, they require documentation to the FDA of their efficacy as well. Don’t just change or omit a little thing here or there without documenting and verifying the process used.

4. CA 2 R

Is calibration verification performed, according to the manufacturer’s instructions including:

- the number, type and concentration of materials to be used,
- use of materials at low, medium and high values within the reportable range, as determined by the laboratory,
- acceptable limits for calibration verification, once every six months or more often if required by laboratory procedures?

Calibration Verification time is always an exciting time in the laboratory! It can be, if you make it part of your overall Quality Laboratory Management plan and not a bi-annual (or as directed) chore. Many test system manufacturers provide extensive information on Cal-Ver. Calibration Verification is an essential part of quality in laboratory medicine as it verifies the accuracy of your test system over the entire reportable range.

In the movie “Flight” the inebriated pilot of a plane that crash landed resulting in loss of life, could not have his blood toxicology screen admitted into evidence because “the test equipment used not having been calibrated within a reasonable amount of time, the name of the hospital staff who drew the samples not having been documented.”³ Never let your level of zeal or enthusiasm for policies and procedures effect the quality of the results produced in your laboratory.

5. PER 3 R

Does the personnel file contain documentation of the person’s education and experience that qualifies them for the position they hold in the laboratory?

“CLIA specifies the education and experience that an individual must have to fill the required positions. Documentation should verify the highest level of education that qualifies the individual for the position held in the laboratory. Appropriate documents include a copy of a diploma or degree, or a transcript indicating date of graduation. These should be kept in the personnel file for review by the COLA surveyor.”⁴ Education documentation is often one of easiest things to correct. Human Resources should have copies of documentation on file as well as your Laboratory Director. It is not enough to say that they are on file ‘somewhere’.

The COLA Accreditation manual states “Résumés, etc., are sufficient for documenting years of experience. Foreign credentials must be evaluated by an acceptable credentialing agency for US equivalency. Language translation of the documents is not sufficient to meet this requirement.” Even Continuing Education documentation needs to be available for

surveyors. Print off the certificates or make copies from a learning event that your staff has attended and place them in the Personnel file as well as the QA binder.

COLA understands all of the variables involved in providing excellence in laboratory medicine. In providing their laboratories a myriad of tools and resources, COLA and COLA Resources Inc. aims to support laboratory success at every turn. Aligned with its educational activities, CRI®'s Consultative Services are geared toward educating participants to adopt and maintain higher quality safeguards and standards to improve the accuracy of clinical test results, thereby improving patient care and laboratory medicine procedures. The Continuous Quality Program, through the Continuous Quality Advisors, will provide assistance to healthcare professionals; at ALL levels of laboratory testing, achieve continuous quality standards and quality patient care. CRI® will deliver tailored educational tools and uniquely-designed consultative services to participating healthcare professionals, physician offices, and laboratories, with the goal of specifically applying quality-based measures to the laboratory practices of those participants.

The Continuous Quality Program is designed to yield the following positive outcomes:

- Reduce laboratory deficiencies
- Reduce unnecessary, redundant testing
- Allow for increased efficiencies for health care providers and patients

Again, reducing the number of citations your laboratory may receive during a survey is possible. There are some COLA Labs that pass surveys with no citations and receive the "Laboratory Excellence Award". How do they do it? They invest the time and effort needed to stay compliant. COLA is ready to help you reduce and even prevent citations while continuing to provide excellence in laboratory medicine.

RESOURCES:

1. "Evaluation Grouping: Laboratory Director Responsibilities" COLA Accreditation Manual (Revised June 2013) p.49
2. P.63
3. "FLIGHT" <http://www.themoviespoiler.com/Spoilers/flight.html>
4. "Personnel Requirements" COLA Accreditation Manual (Revised June 2013) p. 64



COLA HIPAA ALERT

COLA has a model HIPAA Business Associate Agreement for its customers who do not have their own agreement. This model agreement has been revised to reflect recent changes due to HITECH amendments. If you relied on the former COLA agreement your lab will need to download this new revised agreement.

Please visit <http://www.cola.org/hipaa-information/> for more information and to download the new agreement. Completed forms can be sent to COLA for signature via fax to 410-381-8611 or mailed to: COLA, Attn. HIPAA Compliance, 9881 Broken Land Pkwy. Suite 200, Columbia MD 21046.



Accreditation Education Innovation

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Start planning now for the
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COLA Resources, Inc[®]
Leading Excellence in Laboratory Medicine

IQCP Preparation and Planning

Help you prepare your lab during the Education and Transition Period

Effective preparation in the implementation of IQCP is critical. On January 1, 2014 the Centers for Medicare and Medicaid Services (CMS) initiate the new alternative Quality Control (QC) option. CLIA laboratories must begin to transition away from Equivalent Quality Control (EQC) and begin using the either the default CLIA Quality Control (QC) requirement or Individualized Quality Control Plan (IQCP). 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

During this time, non-waived laboratories performing all types of testing (with the exception of Pathology, Histopathology, Oral Pathology and Cytopathology) should review the CLIA Specialty/ Subspecialty criteria to determine if their test systems are included under the IQCP Guidelines.² Once you have identified that your test system is eligible for IQCP, begin reviewing the Interpretive Guideline. There are a number of resources available to assist you in transitioning from the current EQC to IQCP. For example, CMS is providing an IQCP response email address for laboratories to address their questions to (IQCP@cms.hhs.gov), CRI® offers an extensive IQCP educational platform and a Quality Advisor staff available to address any question you may have. If your laboratory is accredited you should contact your Accrediting Organization to ensure that you have the most current information available and applicable to your laboratory.

Like the other CLIA QC requirements, IQCP is intended for non-waived testing; however, identifying potential errors is a good practice for any test, including waived testing. You may use IQCP for all, some, or none of the test systems in your laboratory (except Pathology). 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 focus of IQCP is to ensure that laboratories have taken the time to identify and document potential sources of error that may cause harm to the patient.

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.

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

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IQCP PREPARATION AND PLANNING

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.

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.

CRI® LIVE WEBINAR

On Wednesday January 29, 2014 join CRI® as we welcome Judy Yost, CMS' Director of the Division of Laboratory Services. Ms. Yost will discuss the newly implemented Individualized Quality Control Plan (IQCP) for non-waived laboratories. The Education and Transition Period for IQCP is January 1, 2014- January 1, 2016. Get ahead of the game and get the inside scoop on this landmark guideline.

At the end of the session, participants will:

- prepare for the timeline and effective dates for the major milestones of IQCP implementation
- distinguish and apply the key components and policies associated with IQCP
- assess the added value of IQCP versus traditional QC practices

For laboratories, the focus should be on getting ready for the guidelines to be fully implemented. **Do not wait**, begin performing your Risk Assessment now. As the new guideline looks at the Pre-analytic, Analytic and Post-analytic phases of testing consider the variables that are inside and outside of your laboratory and how they affect patient test results. Begin the dialog now with Hospital and Facility Administrators to emphasize the importance and diligence this new guideline will require for compliance. Begin allocating time and resources to participate in educational activities and to procure materials and data that you will need to complete the Risk Assessment and IQCP. Lab Directors especially must comprehend the overall concept and implementation support needed to be successful.

Start early, give your laboratory a head start on IQCP and allow time for your QC plan to be effective. 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. Individualized Quality Control Plan (IQCP):A New Quality Control(QC)Option Memorandum <http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-54.pdf>



COLA Accreditation, California & Your Laboratory



California Deeming!

COLA's dedication to quality patient care is recognized

In 2013, COLA became the first private laboratory accrediting organization to earn deeming authority in California, proving its standards of promoting excellence in laboratory medicine and patient care are equal to or more stringent than the State's unique regulations for licensure and registration. Deeming authority in California is comparable to COLA's deeming authority at the federal level with the Centers for Medicare and Medicaid Services (CMS). COLA already supports over 500 laboratories in California through a program of voluntary education, consultation, and accreditation. This puts COLA in a unique position to support the needs and goals of laboratories in the great Golden State.

With the approval by Laboratory Field Services (LFS), COLA-accredited laboratories will be recognized by the State's as meeting its laboratory laws and regulations in addition to the requirements of CLIA. Under the terms of formal agreement, COLA-accreditation will be accepted in lieu of the routine inspection and oversight provided by LFS.

Over the next several months, COLA and LFS will be working together to inform laboratories of this new agreement and to prepare for exchange of information between the two organizations. All COLA-accredited laboratories will be informed of COLA's deeming authority relationship with LFS. LFS will be changing the status of COLA labs in the State's licensing database to deemed status. During the next renewal cycle, COLA-accredited laboratories will receive a Certificate of Deemed Status which is equivalent to the previously held State Laboratory License.

CRI, as the education partner with COLA, is developing education and learning opportunities that will support laboratory professionals, laboratory directors and other healthcare providers in understanding the unique California laws and regulations.

Develop Your Laboratory's IQCP Now!

Announcing the first of CRI®'s IQCP Workshop Series

Date: Wednesday, February 26, 2014

Time: 8:30am – 4:00pm

Location: Wake Forest Biotech Place

575 N. Patterson Ave.

Winston-Salem, NC 27101



Prepare to implement the new Center for Medicaid & Medicare (CMS) IQCP Interpretive Quality Control Guidelines:

An event every Laboratory Professional should attend.

Presented by experts in the field of Risk Management, this Workshop will highlight:

- Review of Risk Management
- Process for Reducing and Mitigating Residual Risk
- Developing Process Mapping and Fishbone Tools
- Developing an Individualized Quality Control Plan

Full day workshop offers P.A.C.E.® credits.

Registration: Non-COLA Members - \$249

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