MAY/JUNE — 2013

COLA'S

inSights

INTO *Quality Control*

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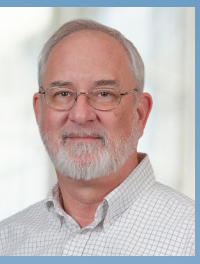

FROM THE CHAIR

Most of you have at least heard about the imminent changes in Quality Control that CMS is initiating. Many of you probably have questions about how these changes will affect you and your laboratory. Our hope is that this issue of *Insights* will answer some of those questions.

We begin by presenting a brief history of laboratory Quality Control. We follow this with articles that define IQCP and list some of its benefits. Since Risk Management is a core concept of IQCP, we provide a few key risk management aspects to help make it more understandable.

This newsletter is certainly not the only product we offer with information about quality in the medical laboratory. In fact, we are changing our business plans so we can offer more services. Our online courses and products and our Symposium for Clinical Laboratories will now be managed by our new subsidiary COLA Resources, Inc. (CRI). The final articles in this issue present details about our CRI and our online course offerings.

The next Symposium is scheduled for October 23 – 26, 2013 at the Hyatt Regency in St. Louis, MO. We will provide more information as it becomes available. Please periodically check our website (www.COLA.org) for updates.

W. James Stackhouse, MD, MACP
Chair, COLA Board of Directors

COLA

COLA INSIGHTS

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Evolution of Quality Control

Performing quality control (QC) reassures the healthcare team and patients that test results obtained on patient specimens are accurate. In an attempt to mimic patient specimens during all phases of the path of workflow, QC samples are handled, processed, and measured in the same manner as patient samples throughout the entire testing process.

Prior to the advent of automated laboratory instruments, manual laboratory tests were run in batches that included QC samples as well as patient specimens. In batch testing, all procedural steps were performed on all specimens simultaneously. If the test batch produced acceptable QC results, it followed that the patient results were also acceptable. Conversely, if the QC results were unacceptable, the patient results in that batch were also unacceptable. There was a direct relationship between QC results and patient test results. Since they were being tested concurrently, our assumption was that whatever caused the adverse effect on the QC samples caused the same adverse effect on the patient samples.

Quality Control changed as laboratory instrumentation evolved through technological advances and became more prevalent; the link between QC result and patient result blurred. Since instruments performed tests sequentially on single specimens, traditional test batches no longer existed. Laboratory professionals began testing control materials at specific times throughout the day, so Quality Control provided a snapshot of how instruments were operating at a given time, rather than how they were operating during a specific test batch. If QC results were acceptable, the instrument was presumed to be operating correctly; therefore, subsequent patient results were presumed to be acceptable. If QC results were not acceptable, it meant that an adverse event occurred at some point after the last time control materials were tested and accepted. Since that event affected instrument operations, causing it to produce unacceptable control results, it follows that any patient specimens run after the adverse event would also be unacceptable. When utilizing this QC method, it cannot be determined exactly when the adverse event occurred or how many patient results may have been affected.

Traditional QC methods detect systematic errors quite well, but do not fare as well with random errors. Systematic errors tend to be instrument related; thus, they are consistent and predictable. If reagents are deteriorating, all specimens tested with those reagents will be affected in a similar manner. The same is true if the instrument's calibration is drifting; both are examples of systematic errors. Random errors may be due to statistical probability, or related to an individual specimen or a single incorrect procedural action; which makes them more difficult to detect.

As testing technologies advanced, manufacturers made changes to improve the detection of both systematic and random errors. Built-in / internal, procedural, and electronic control devices were developed to better assess instrument operation and monitor additional sources of error. Although some thought this would make external control samples obsolete, controls that mimic patient specimens are still needed.

QC EVALUATION

Control acceptability limits must be determined prior to using the controls during a test run. When the test is qualitative, the controls are either acceptable or not acceptable; i.e., positive or negative, reactive or not reactive, etc.

Evaluation becomes more complicated with quantitative tests, which has gone through its own evolution.

In 1950, S. Levey and E.R. Jennings applied a monitoring process used in manufacturing to clinical laboratory testing.[1]

They suggested running control materials in duplicate and using an acceptable range of ±3SD (range with a lower limit of the statistical mean minus three standard deviations to the higher limit of the statistical mean plus three standard deviations). By graphing the QC results over time, laboratory professionals could visualize and monitor instrument performance.

By 1960, single QC samples, not duplicate, were being run and the ±3SD range was narrowed to ±2SD. As testing methodologies advanced and testing volume increased throughout the 1970s and 1980s, the 2SD limits became less than optimal.[2] There were too many false positives; QC appeared to be unacceptable even though the instrument was operating properly. In 1981, James Westgard and colleagues proposed using a multi-rule approach to evaluate QC results.[3] This approach became known as the "Westgard Rules" and is still widely used.

QUALITY CONTROL REGULATIONS

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) are the federal regulations that govern all US laboratory testing used for the "diagnosis, prevention, or treatment of any disease or

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EVOLUTION OF QUALITY CONTROL

impairment of the health of human beings."[4] When they became effective in 1992, the minimum requirement for QC was established as testing two levels of control materials each day of patient testing.

When the final CLIA rules were published in 2003 and became effective in early 2004, they included Appendix C, the Interpretive Guidelines for Laboratories.[5] These guidelines allow the Centers for Medicare and Medicaid Services (CMS) to modify the interpretation of the CLIA regulations without having to change the actual law. This allows new methodologies, new technologies, and new ideas to be considered as needed.

The Interpretive Guidelines addressed quality control from the onset, by allowing an alternative to daily external quality control as long as "equivalent quality testing" is assured. Since 2004, this alternative has been Equivalent Quality Control (EQC).

EQC allowed laboratories to decrease the frequency of running external controls for eligible tests, after they performed a successful standardized qualifying study. For a test to be eligible for EQC, one requirement was that it had internal controls. Even though many labs implemented EQC without difficulty, there were a number of potential errors that could lead to inaccurate results that were not detected by the test system's internal controls nor by the EQC qualifying studies. For example, incorrect specimen handling and processing would only be detected by the performance of external controls that require the same handling and processing as patient specimens. Thus, many criticized EQC from its inception.

Using ideas generated by laboratory professionals, accrediting organizations (including COLA), professional organizations, industry representatives, and government agencies, CMS implemented a new alternative quality control program titled "Individualized Quality Control Plan" (IQCP), which will replace EQC. It was created to help laboratory professionals develop customized QC plans based on managing risk and potential sources of error of the test systems they utilize. The laboratory's specific circumstances are addressed to establish the most effective QC plan for the testing performed. In other words, IQCP is customized quality control based on risk management.

CMS is currently drafting revisions to the Interpretive Guidelines to address IQCP. When the final guidelines are published, EQC will be phased-out and IQCP will be phased-in over a two year transitional period. During this time, COLA will work with CMS to provide education on how to implement IQCP. Both agencies will be available to answer questions about plan development. Laboratories may continue EQC protocols while they develop new individualized plans.

After the transitional period, EQC will no longer be an alternative QC option and laboratories will have to provide documentation of risk management actions and IQCP implementation if they want to perform alternative QC procedures.

For more information on the relationship of EQC and IQCP, see the ***Winter 2012-2013 issue of*** **Insights.** *Subsequent* Insights *issues and other educational products will offer additional information on implementing an Individualized QC Plan in your laboratory and on performing Risk Management procedures.*

RESOURCES:

[1] Levey S., Jennings ER., *The use of control charts in the clinical laboratory,* 1950, Arch Pathol Lab Med., 1992 Jul;116(7):791-8; discussion 799-803; http://www.ncbi.nlm.nih.gov/pubmed/1497455; *last accessed May 2013*

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What is IQCP?

IQCP is the "Right QC." The Centers for Medicare and Medicaid Services (CMS) is implementing a new alternative Quality Control (QC) program titled Individualized Quality Control Plan (IQCP). They 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. 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.

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.

Individualized Quality Control Plan (IQCP)

CLIA

- ☑ **Customizes** QC Plan for each test in its unique environment
- ☑ **Optimizes** use of electronic/integrated controls
- ☑ **Offers** laboratories **flexibility** in achieving QC compliance
- ☑ **Adaptable** for future advancements in technology
- ☑ **Incorporates** other sources of quality information
- ☑ **Strengthens** Manufacturer/Laboratory partnerships
- ☑ **Formalizes** risk management data already maintained within the laboratory
- ☑ **Provides** equivalent quality testing to meet the CLIA QC regulations

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

IQCP – Risk Management

Risk Management can be defined as identifying, evaluating, and controlling risk; or more formally, as a combination of Risk Identification, Risk Assessment, and Risk Mitigation, a process we perform daily, whether or not we realize we are doing it. James Nichols, PhD, Professor of Pathology at Tufts University School of Medicine and Medical Director, Clinical Chemistry for Baystate Health in Springfield, MA states, "Risk management is essentially the process of sitting down and saying, 'What can go wrong when I perform a test?' and 'What do I do to prevent that error from happening?' We as laboratorians are actually trained to think in that manner, and we do that every day." [1]

The Centers for Medicare and Medicaid Services (CMS) has created a new alternative quality control program that incorporates the concept of quality control through risk management, named "Individualized Quality Control Plans" (IQCPs). Risk Management steps, however, are only one part of the IQCP program. It also includes a written QC Plan, and an assessment mechanism to evaluate the plan's effectiveness.

RISK MANAGEMENT

The first risk management step is to gather information about the testing process. You need to understand how the test results will be used medically. Certain test results are part of a myriad of information that will contribute to clinical decisions about patient care. Other test results are used immediately as the sole decision making criterion. Clearly in the latter situation, an inaccurate result has a much greater potential to cause harm, which explains why this information is important as we determine the type, number and frequency of quality control we need to perform.

Continue to gather information about the testing process by examining the measuring system or testing device. While much of this information is supplied by the manufacturer, you also have your own historical data to consider. Maintenance logs, QA and QC records, verification of performance specifications, and calibration and calibration verification reports are a few examples of documentation that can be reviewed.

Patient specimens and test reagents, calibrators, and controls are also part of the testing process. Errors (i.e., potential for harm) can occur with any of several different specimen or reagent handling and processing procedures. Gather information to assess these potential risks.

You also need information about the environment where the test system is located. Is testing performed in a hospital or reference laboratory, an office laboratory, a blood gas lab? Check the stability of room temperature and humidity. Does altitude affect the testing? Also consider lighting, electric, and other utilities.

You need to know information about who will be performing the test. Do testing personnel have laboratory medicine education and experience, or is their background in a different health care area? Have they been adequately trained to perform the test? Has their test performance competency been assessed and confirmed? Are they performing only laboratory testing, or are they performing patient care duties as well?

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IQCP – RISK MANAGEMENT

RISK IDENTIFICATION & ASSESSMENT

The next step is to review the gathered information to identify sources of potential errors. The goal is to identify areas that may lead to reporting inaccurate patient results, or that could potentially cause patient harm.

Once the potential errors are identified, they have to be evaluated to determine:

- How often they may occur;
- The severity of their consequences if they do occur; and
- How likely it is that they will be detected;

Determining what could cause errors will help you develop steps to take to detect, correct, and control them.

A final consideration before you implement your plan is to ensure you are compliant with all regulatory requirements. Even though the federal CLIA regulations define the ***minimal*** requirements, you have to be compliant with the ***most stringent*** applicable requirements; whether they are state or local laws, accrediting organization criteria, or facility or organization protocols. Additionally, the manufacturer's instructions must be followed.

QC PLAN

Now you can use your Risk Assessment to begin Risk Mitigation. Since risk cannot be eliminated completely, as you evaluate each possibility, you are also devising ways to detect and control each potential error. Your Quality Control Plan is a summary of the risk management steps you just completed. It will document the mechanisms you listed to detect and control each potential risk. It can be written as part of the test procedure, or as a stand-alone quality manual; and it can be stored electronically, or as a hard copy.

When you implement the plan, you have to ensure that all staff involved have been thoroughly trained. All personnel have to know what to do prevent errors, and what to do if an error occurs.

Even though it may seem like an ending point, implementing the QC plan is not the last step. You have to continuously monitor the plan's effectiveness, and make necessary changes to improve it over time. By doing so, you can continue to provide high quality, accurate laboratory test results that lead to high quality patient care.

RESOURCES:

[1] Malone, B., Clinical Laboratory News: *A New Approach to Quality Control*, November 2011; http://www.aacc.org/publications/cln/2011/november/Pages/ANewApproachtoQualityControl.aspx#; *last accessed Apr 2013*

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EVOLUTION OF QUALITY CONTROL

[2] Webinar: *Goodbye EQC, Hello Individualized Quality Control: Will you be Ready for Inspection?* originally presented by Nils Person, PhD, FACB, Senior Clinical Consultant, Siemens Healthcare Diagnostics on March 28, 2013; http://www.whitehatcom.com/siemens; *last accessed May 2013*

[3] James o. Westgard, Patricia L. Barry, and Marian R. Hunt, *A Multi-Rule Shewhart Chart for Quality Control in Clinical Chemistry*, Clinical Chemistry March 1981 vol. 27 no. 3 493-501; http://www.clinchem.org/content/27/3/493.full.pdf+html?ijkey=5e65216e8b829297acbe1f584bf37fdaabe97ab3&keytype2=tf_ipsecsha; *last accessed May 2013*

[4] Clinical Laboratory Improvement Amendments, Subpart A, Section 493.1 Basis and scope; http://www.cdc.gov/clia/regs/subpart_a.aspx#493.1; *last accessed May 2013*

[5] Clinical Laboratory Improvement Amendments, Interpretive Guidelines for Laboratories; ; *last accessed May 2013*

COLA Resources, Inc.

COLA employees strive to promote laboratory excellence and quality, since these characteristics define our purpose, determine our goals, and drive our decisions. This is evidenced in the formation of our new subsidiary – COLA Resources, Inc. (CRI). Scheduled to launch in July 2013, CRI's mission is to "provide educational and consultative services aimed at improving laboratory medicine and patient care."

While COLA focuses on accreditation, CRI's strength is education – "Leading Laboratory Excellence through Education." CRI will be a leading provider of educational products through our www.LabUniversity.org and www.CRIedu.org websites. COLA's current interactive online courses; CEexpress, MLE CEexpress, and Webinar CEexpress courses; and downloadable guides and manuals will continue to offer valuable information in various formats.

Table 1 provides a partial list of courses available through www.LabUniversity.org.

Online Course Offerings to Answer Your Quality Questions
Online Courses
Calibration Verification
CLIA 88 Requirements for the Medical Laboratory
Introduction to Quality Management Systems in the Medical Laboratory
Quality Assessment Basics
Quality Control for the Laboratory
Verification of Performance Specifications
CEexpress courses
03: Quality Systems
05: Prevent Pre-anayltic Errors
Webinar CEexpress courses
06: Introduction to Quality Control
07: Evaluate QC & Take Corrective Actions
08: Verification of Performance Specifications
09: Calibration & Calibration Verification
10: Quality Assessment - Introduction and Overview
11: Quality Assessment - General & Pre-anayltic Systems
12: Quality Assessment - Analytic & Post-analytic Systems

The Following Courses are Offered Individually and as the Discounted Quality Management Systems Program
Introduction to Quality Mangement Systems
QMS: Process Flowcharting
QMS: Quality Manual
QSE: Assessments
QSE: Continual Improvement
QSE: Customer Focus
QSE: Documents and Records
QSE: Equipment
QSE: Facilities and Safety
QSE: Information Management
QSE: Nonconformance Management
QSE: Organization
QSE: Personnel
QSE: Process Management
QSE: Purchasing and Inventory

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EDUCATION FOR LABORATORY EXCELLENCE

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Education for Laboratory Excellence

COLA thanks the following companies for their financial support of the Symposium for Clinical Laboratories.

OrchardSoftware Harvest the Power

CGM CompuGroup Medical

AUDIT MicroControls

MedicusMiddleware

AAFPPT The Physician's Proficiency Testing Program

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COLA RESOURCES, INC.

CRI augments the online educational offerings through Live Webinars and the Symposium for Clinical Laboratories (which provides classroom style learning) to assist laboratory professionals continuing to strive for laboratory excellence.

CRI will also employ a new innovative tool to help you establish quality improvement standards – our Continuous Quality Program (CQP). Since CRI believes quality is an everyday process, the Continuous Quality Program is designed to help laboratory professionals achieve and maintain quality standards *every day of testing*. The program employs experienced and knowledgeable Continuous Quality Advisors (CQAs) to assist you in achieving quality standards. In addition, through consultative services, and the launch of the Individualized Quality Control Program (IQCP), CRI will guide laboratory professionals in the development of a customized quality plan that supports the unique, individual needs of the laboratory.

Please visit www.labuniverity.org or www.CRIedu.org for additional information.

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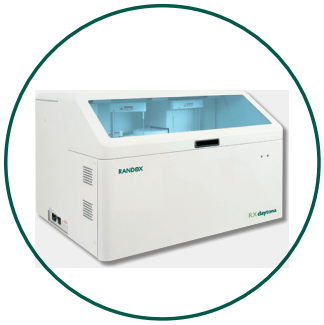

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COLA Compliance Tip

QC24

Focus: COLA criterion QC24

COLA recognizes that CLIA regulations provide an alternative that laboratories may elect for eligible test systems that have successfully completed a qualification procedure.
Laboratories that desire to use these procedures must:

1. **Verify the eligibility of their test system.**
2. **Select the appropriate Equivalent Quality Control Procedure.**
3. **Successfully complete the qualifying study.**
4. **Monitor test and test system performance to include:**
   a. **Taking corrective action, and**
   b. **Resuming daily external quality control until problems are resolved; and**
   c. **Repeating the EQC qualifying study.**

COLA recognizes that the CLIA regulations provide laboratories with an alternative to performing two levels of external quality control each day of patient testing. "Equivalent Quality Control" (EQC) was adopted and allowed if certain eligibility and qualification studies were met. EQC is being phased out by CMS and replaced by **Individualized Quality Control Plans (IQCP)**, a policy that allows laboratories to customize their QC plan for each test to ensure quality test results. COLA will also adopt IQCP as the new alternative quality control option; changes to this criterion are under development.

IQCP uses risk assessment to determine the best QC protocol for each test you perform, based on relevant factors that can impact test performance, including features unique to your laboratory. As the new guidelines are developing, you can learn more about IQCP from the CLIA web site:

www.cms.gov/RegulationsandGuidance/Legislation/CLIA/Individualized_Quality_Control_Plan_IQCP.html

If you are currently using EQC, you may continue to follow an approved EQC protocol until COLA notifies you that the official change has been made to this criterion. The transition from EQC to IQCP will take place over a two year educational period. When the transition is complete, EQC will no longer be an option for quality control, but your lab may implement IQCP if you so choose.

Labs will always have the option to continue to perform the default requirement of two levels of external controls each day of testing.

COLA labs can start preparing for IQCP by:

- **Learning about Risk Assessment and IQCP;**
- **Identifying the tests for which the lab has utilized EQC; and**
- **Deciding whether to implement IQCP or the default QC (2 levels QC each day) for each test.**

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