COLA'S Summer Edition 2021

inSIGHTS

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LETTER FROM THE CHAIR

SUMMER EDITION 2021

As we are laser focused on the impact that laboratory results can have on patient care, **Quality** is a term that is commonly included in the language of all laboratory professionals. We know that errors in laboratory testing can lead to delay in treatment, inappropriate treatment or misdiagnosis. Consequently, in the laboratory we do many things to monitor and improve quality, such as quality control, quality assessment, incident management, proficiency testing, and customer satisfaction surveys, to name a few.

This edition of inSights examines the basics of quality control, which is a critical component of any laboratory's commitment to achieving, improving and maintaining quality. And although the definition of quality may vary depending on the context, laboratory professionals are guided by a mission to produce "quality" laboratory testing that is ***accurate, appropriate, and timely.*** We hope that the information in this edition will help you implement a quality control plan that moves you closer to this goal.

William E. Kobler, MD, FAAFP
Chair, COLA Board of Directors

A BASIC OVERVIEW OF QUALITY IN THE CLINICAL LABORATORY

By Julie Boone MS, MT (ASCP)

Julie has worked 40 years as a clinical laboratory generalist with nine as a Surveyor with COLA. She has diverse workplace experiences ranging from bench tech at a small rural hospital to Hematology Supervisor within a large metropolitan multi-site system and development and management of physician office laboratories.

In our everyday lives, the **"quality"** of an experience, product or service is highly subjective and the evaluation of the "quality of something" may even change depending upon the difficulties or ease of the day. However, the ways in which we measure quality in a laboratory are highly analytical, allowing for an objective measurement, which can be reproduced again and again, to give us the confidence we want and expect in laboratory results.

The scientific principles, processes and tools underlying the achievement of quality in a laboratory have considerable depth. It requires the commitment and discipline of professionals applying these principles, processes and tools in a highly systematic way to ensure that individual patient results being reported are accurate. Naturally, fundamental to these efforts, regardless of the complexity of testing, is the routine performance of quality control (QC), a valuable tool in understanding the current performance of an analyzer, test kit or testing personnel. As testing becomes more complex, different systems are involved, such as instrument maintenance, environmental monitoring, personnel training, and competency. The multiple levels of quality are coordinated within the laboratory's quality assessment (QA) system.

INTERNAL QUALITY CONTROL

Anyone, even persons performing tests at home, must adhere to the essential elements of quality control. At-home assays for personal use, such as pregnancy tests and test kits for COVID-19, include manufacturer instructions for performing the test, reading the results and understanding the built-in controls to confirm that the test process is working. For example, if the expected line does not appear where indicated, the results are not valid. These types of controls are known as internal controls. Some tests in CLIA-designated waived laboratories use kits similar to those at-home assays with the same requirements to check internal QC. In addition, the manufacturer may require that external quality control products are used. Laboratories must follow the manufacturer's instructions precisely, and it is imperative that testing staff in every laboratory read the package inserts. Some laboratories will post package inserts near where the tests are being performed for quick reference, but these should be seen as supplemental to the established laboratory procedures approved by the Laboratory Director and compiled in accessible manuals or available online. Staff must be trained accordingly for the instruments in use at the laboratory.

EXTERNAL QUALITY CONTROL

External quality control is most often a product that will be run in the same manner as a patient sample but has expected values to check the accuracy of the test. It may come with the test kit, such as prepared vials of positive and negative Influenza or Streptococcus A, or it may need to be purchased separately, such as controls for urine dipstick test strips. Staff must adhere to the specific instructions in the package inserts for both the test kits and the control products. Test kit directions prescribe what to use for external controls, how many levels to run, and how often or under what circumstances to perform QC. Package inserts from control materials will list the expected values for each assay, which may differ for various test kits.

TRAINING

Testing personnel must be sure that QC materials in use are indicated for the test system they are using. Training for testing personnel must cover this, and it is important to review the written procedures to ensure it is being done correctly. For example, some urine strips will require that external QC be run every 30 days, or some may only require the external control when a new vial or lot number is opened. It is important to keep records of quality control performance to demonstrate that a test system was shown to be working at the time of reporting patients results. Data will be reviewed to confirm that the QC values recorded are within the acceptable limits as stated by the manufacturers, so laboratories must save package inserts or copies of them with expected values. Documentation must also indicate that the internal controls were checked and acceptable for every patient run. Evidence of compliance could be a checkmark on a form with a column for Internal Controls Acceptable or a comment appended to patient results in computerized results entry.

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CORRECTIVE ACTION

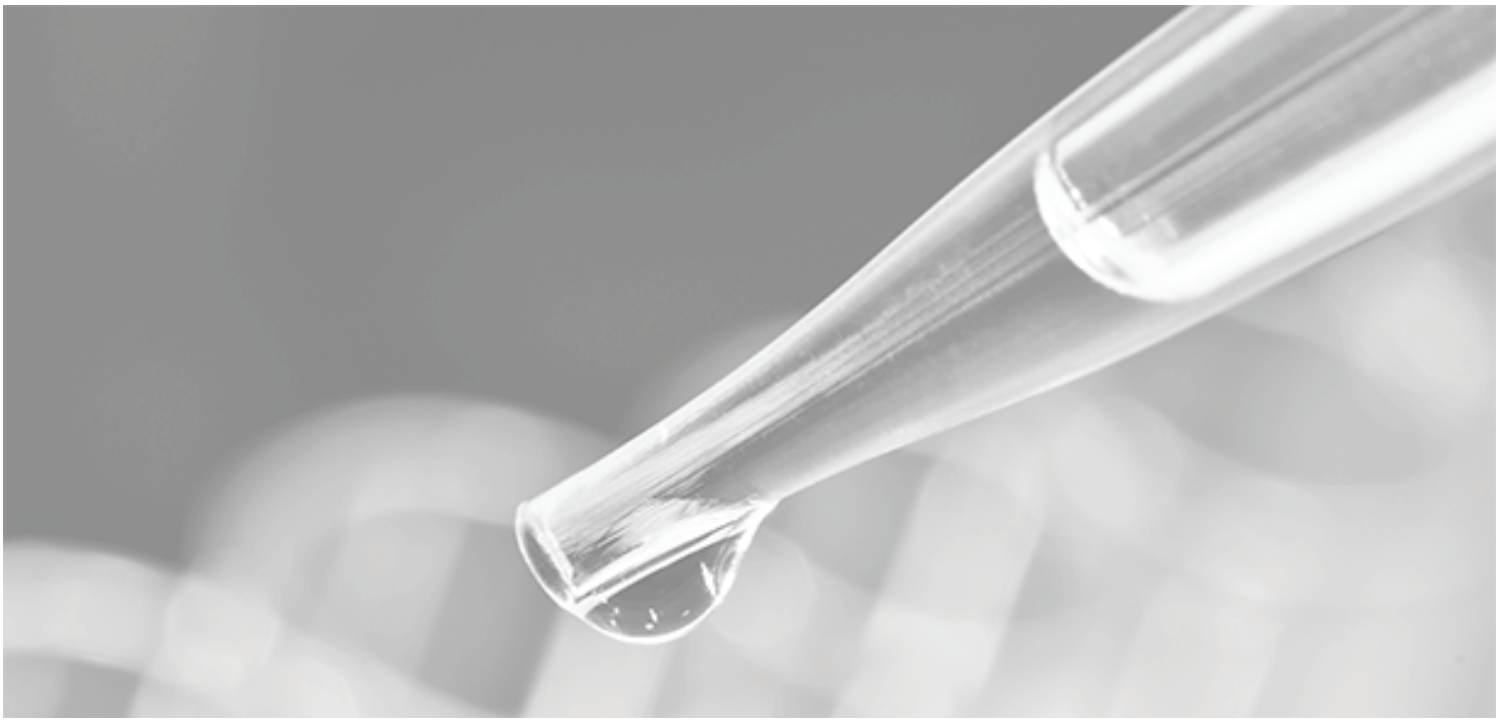
QC procedures must also include steps to take if the control does not give the expected result. These corrective actions must be done, documented and resolved before patient results are reported. Most commonly, staff will be directed to repeat the quality control run. However, it is unacceptable to repeat the control(s) multiple times until the results are what is expected. If the first repeat does not give correct values, testing personnel should follow additional steps to evaluate the problem. Testing personnel can begin the investigation by posing such questions as:

1. **Are the test kits and the controls past their expiration date?**
2. **Have they been stored correctly, adequately capped, brought to the correct temperature before using, and properly mixed?**
3. **Is a different lot of QC products being used that may have different acceptable values?**
4. **Was the timing correct when running the test, the first time, and was it performed strictly according to the manufacturer's directions?**

External quality control for some systems includes the use of specific devices to confirm performance. These can be instead of or in addition to running QC materials with known values, as stated by the instructions in the package inserts. Variation in requirements among all test systems emphasizes the necessity of understanding manufacturers' instructions. For example, some test systems may consist of an external cartridge that performs a functional test on the reader with results displayed as either Pass or Fail. Other external devices may be in the form of a simulator or a cassette, which provides a means to confirm functionality. Additional quality checks may run without staff intervention. Analyzers with internal quality control may perform a self-test every time the analyzer is turned on or at pre-programmed intervals. The manufacturer may program a test system to check a code included on the reagent cartridge or cassette, providing the automated test reader with information such as the lot number and expiration date. Any combination of internal, external, manual, and automated steps will be specified by the manufacturer's instructions and must be precisely followed.
Evaluating quality control runs for quantitative tests is not as simple as for qualitative tests. Expected values for QC materials for quantitative assays are listed on package inserts as ranges, and any result within the range is acceptable.

Again, it is imperative to read the specific manufacturer's directions for both the control materials and the instrument they will use. The printed ranges may be vast and meant to start until the laboratory establishes its own, tighter limits. For example, controls for one chemistry analyzer list assay values as a range of means and are intended as a starting point before the laboratory verifies its limits.

Control materials may be assayed or unassayed. Assayed quality control provides ranges established or compiled by the manufacturer using instruments of the same types as their customer uses; again, it is vital to check that your laboratory's instrument is listed with corresponding control ranges. Unassayed controls do not have verified assigned values for assays per manufacturer, but they should provide stable performance through the expiration date for the tests they monitor. Laboratories must establish acceptable ranges for unassayed controls by repeatedly running them on multiple days, preferably by several testing personnel, until a minimum of 20 values are obtained, and the mean and standard deviation are calculated. Assayed controls must also be run multiple times to verify that the laboratory will achieve results within the same ranges as stated, but fewer runs are needed over several days.



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AN OVERVIEW OF QUALITY ASSURANCE (QA)

With quality control as a basic concept for ensuring accurate patient test results, good laboratory practice requires that additional evaluations are planned and monitored. These are all aspects of Quality Assessment (QA), which must be included in a QA plan for the laboratory. The plan must define methods to audit all aspects of the laboratory workflow and at that frequency these evaluations will be performed and documented. Although there are general requirements, the laboratory's written plan must consider and address specific circumstances of the individual laboratory. For example, if results are generated through a computer system, the instrument interface must be accurate. If results are entered manually, a plan to check the accuracy of the manual entry must be included in the QA plan. Calculations being performed by an analyzer versus a computer system versus manual calculation by testing personnel all need to be audited and verified for accuracy.

Monitors need to be defined that evaluate the three phases of the testing process, including pre-analytical, analytical, and post-analytical. For example, monitoring how a test is ordered, how samples are collected and stored, and if patients are adequately prepared, such as fasting, are excellent approaches for monitoring the pre-analytical phase of testing. For the analytical phase, check that the QC runs were acceptable, that instruments are properly maintained, and correct reagents are used, and that personnel are following the procedures. For the post-analytical phase, evaluate if reports are formatted and made available to the ordering physician within a reasonable time and ensure communication of critical results per the laboratory policy. Within these testing phases, monitors must also assess regulatory compliance, personnel training and competency, instrument validation and maintenance, environmental monitoring, and communications. All QA audits must be documented and available for future review.

An effective Quality Assessment plan will identify and correct problems. Any corrections implemented as a result of an assessment are then reviewed at pre-determined intervals to check that the problem is not recurring. One good way to structure QA is to include a calendar that states when each audit will be done. In addition, it is helpful if laboratory staff at all levels are involved in the QA process and that it is not just something being overseen by management.

In summary, you can see that “quality” in a laboratory is the continuous application of key principles, processes and tools by professionals who care about the outcome, namely ensuring that the laboratory is reporting accurate results which support diagnosis and treatment decisions in the care of patients. It is vital work and we can all be thankful for the incredible “work towards quality” performed in laboratories every day.

POLICIES AND PROCEDURES: FRAMEWORK OF QUALITY

By Kathryn Connolly, MT (ASCP), CQA (ASQ)

Kathryn Connolly, MT (ASCP), CQA (ASQ) is the Director of Quality Systems for COLA Inc. She is responsible for the development, implementation and continual improvement of COLA's internal quality management system in accordance with ISO 9001 requirements. Ms. Connolly is certified as a Quality Auditor and Lean Facilitator. She is an active member of the American Society for Quality, and serves as COLA's Delegate to Clinical Laboratory Standards Institute (CLSI).

The past year has brought numerous changes to all of our lives, especially to those working in laboratories. Given the new tests, necessary adaptations to our work environment and lessons learned from supply chain breakdowns, former policies and procedures may no longer reflect how our work is performed today. This article will review the basic principles associated with document control to ensure the laboratory continues to meet CLIA and COLA requirements.

The laboratory has a wide variety of documents related to its management system and technical operations. All of these documents are subject to some basic document control principles. Let's start by reviewing some terms commonly used to describe different types of documents that need to be controlled.

DOCUMENTS VERSUS RECORDS

Document is the term for any written or electronic material that provides information to the reader. Records are a specific subset of documents, which contain data or evidence that a specific activity was performed. For this article when we refer to documents, think rules, guidance, descriptions and even step-by-step directions regarding all aspects of the laboratory's operations. When we refer to records, think of data captured that provides evidence that an activity was performed.

INTERNAL & EXTERNAL DOCUMENTS

Laboratory operations rely on documents from different sources. These are commonly referred to as either internal or external. These documents can be in any format (paper or electronic.) Internal documents are written by or specifically for the laboratory. Internal documents include, but are not limited to, policies, procedures, job descriptions, even forms and templates such as test requisitions and reports.

External documents are written by entities outside of the laboratory for public access. Examples of external documents include, but are not limited to, manufacturer's instructions for equipment, package inserts for reagents or controls, and scientific texts or reference books.

REQUIRED DOCUMENTS

The CLIA regulations and COLA Accreditation Criteria require the laboratory to "document" a wide variety of activities. In some instances document is used as a noun, indicating the expectation for written material to provide guidance, rules, expectations, descriptions or instructions. In other instances, it is used as a verb indicating the need to collect and retain written evidence of an activity, outcome or result (a record). It is necessary to address each of these instances.

Although terms such as plans, procedures, policies, and programs are sometimes used interchangeably, each might not specifically require a written document. However, laboratories frequently choose to demonstrate how they meet the associated requirements in a written document.

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Procedures are by far the most common term for laboratories, as each test performed by the laboratory is required to have a written procedure that contains very specific elements. (See §493.1251 in the CLIA regulations as well as the Analytic Procedure Manual (APM) criteria in the COLA Laboratory Accreditation Manual.) Procedures describe exactly how a given task is performed and can communicate hand-offs or exchange of samples, data, or information between different personnel or departments.

When writing your own procedures, follow the four "C's": A good procedure will be:

- CLEAR - use terminology that staff can understand.
- CONCISE - stick to the basics, do not get too wordy.
- CONSISTENT - use a similar format or layout.
- COMPLETE - include all necessary information to prepare for an activity, conduct the activity, and conclude the activity, including specific information regarding preservation, retention, and/or disposal.

In the past year, it is safe to assume that most laboratories have had changes in their test menu or operations, which need to be reflected in new or revised procedures. Beyond simply fulfilling regulatory requirements, procedures are vital to the work of a laboratory. They serve several functions including helping to minimize errors or mistakes, ensuring that safety and quality requirements are followed, providing a basis for training, protecting against loss of operating knowledge, and standardizing how work is performed. Once written, procedures are often collected and stored in a binder or electronic file, also known as a procedure manual.

DOCUMENT CONTROL

The requirements for controlling documents include the following:

1. Identification
2. Approval
3. Maintaining currency
4. Version control / change management
5. Distribution
6. Accessibility
7. Retention & Disposal

These requirements apply to both internal and external documents. The methods utilized to implement these requirements will vary. Some laboratories will utilize specially designed software or applications to manage and control documents, while others will rely on manual processes. Either option is acceptable as long as each of the items below are addressed.

1. Documents need to have a unique identifier. This can be a single unique identifier or use a combination of items, such as the title or file name of the document, author, revision number or date.

2. Documents need to be reviewed and approved by the Laboratory Director, before being placed into use. The importance of approval is to ensure the document accurately communicates the pertinent information personnel need to know. There is no need to rewrite instructions from a manual for a given piece of equipment or product inserts, as long as these instructions represent exactly how the work is performed and have been approved for use.It is important to be able to identify the date a document was approved and who approved it. A signature or other indication of approval on the document itself will suffice.

3. Documents require biennial review to ensure they remain current, suitable and effective. This can be performed at one time or staggered to allow plenty of time for a thorough review. A signed cover page for an entire manual or signatures on each individual document provides evidence that the review was performed. Best practices suggest engaging front line staff to participate in the review. This helps to close the gap between work as imagined and work as actually performed. The goal is for the document to accurately reflect how a particular activity is performed in your laboratory. For external documents, this involves monitoring the release of new or updated versions. If a new version of a reference document is found, it needs to be reviewed to identify the changes and their effect on the laboratory's activities. Use of the new version should be approved and any references to the external document, within other documents needs to be updated.

4. When documents are revised, as often happens following a scheduled review, they need to be reapproved by the Laboratory Director before the change is implemented. Think of your documents as training material for your personnel. When a change is needed in a particular activity, the corresponding document needs to be updated, reviewed and approved just as described in 2 above. Once approved, the updated document can be used to train staff on the new way to complete the given activity. One note of caution: if the implementation date for a given change will be different from the date a changed is approved; best practice advises recording both dates.

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5. Changes need to be traceable from one version of the document to the next. This is accomplished in different ways. The simplest is use of a table that summarizes what changed and when. This is particularly important for laboratory surveys and comparing performance over time. During the laboratory survey, it might appear that a particular procedure is not being followed. You want to make survey the surveyor has an easy reliable way to identify which version of a procedure was in force when the work was conducted. Similarly, if an improvement or a decline in performance is identified and started at a specific time, you will want to see if there were any changes implemented at that point in time, which might explain the change in performance.

6. Manage the use of or access to obsolete documents to prevent unintended use. Obsolete documents must be retained for a minimum of two years and must be clearly labeled with the date discontinued. Automated systems typically have an archival feature that limits access to obsolete documents using permission levels assigned in the system. For manual systems, obsolete documents can be collected, labeled, and placed in a storage area separate from current documents for the required retention period. These materials are valuable when evaluating past performance and the impact of process changes. There may be times when it makes sense to revert to a prior version, and it is convenient to be able to retrieve the prior document rather than trying to recreate it.

7. Distribution includes knowing who needs access to which documents and all the places where a given document is stored. This is a necessity to ensure that all prior versions are replaced/updated when a new version is approved. Document control systems have built in features to help manage this. However, a spreadsheet, table or database can be used to support manual systems. The system should capture the unique identification of the document, how many copies exist, where each copy is stored, in addition to all the individuals that need access to the document to perform their assigned duties and responsibilities. When managing the distribution and access to external documents, be sure that you are adhering to all copyright protections.

8. The most current version of a document needs to be readily accessible to personnel in their work area. Whether hard copy or electronic, personnel should be able to access the procedure as they perform their work. This is especially important for new staff and new or changed procedures. If procedures are not easily accessible in the work area, personnel may rely on their memory or make a best guess rather than stopping work to go consult a procedure located elsewhere. This leads to procedures being performed in different ways by different staff members, resulting in potentially inconsistent outcomes. If the laboratory relies on an electronic or online system, there should be a backup plan in the event the electronic system is down.

9. Retention periods need to be established for each type of document. Under CLIA, most documents require retention for a minimum of two years, but certain types of documents related to Immunohematology or Anatomic Pathology have longer retention requirements. Refer to §493.1105 or criterion PST 27 in the COLA Laboratory Accreditation Manual for minimum requirements. The laboratory can choose to retain certain documents for a longer period, and state requirements can also be more stringent. Once documents have reached the end of their retention period, they should be disposed. The content of the documents needs to be carefully considered to determine the appropriate manner of disposal. For example, some documents include protected health information and cannot be placed in the normal trash. Different steps will be necessary to address hardcopy documents and electronic documents.

CONCLUSION

When our environment changes as drastically and quickly as it has in the past year, we often are caught up in just keeping operations running. Now that things are getting back to normal, it is time to complete a thorough review of our policies and procedures to ensure that they are updated to reflect any changes in the way work is performed today. This may seem like a daunting task initially, however taking it a step at a time, while keeping in mind the requirements associated with control of documents provides a solid footing for

REFERENCE

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SITUATIONAL OCCURRENCES IN QUALITY CONTROL

By : Annette Schulte, MT(ASCP)SBB

Annette Schulte, COLA Surveyor, has more than 30 years' experience in the clinical laboratory as a Medical Technologist including certification as an SBB. Her experience includes all areas of the laboratory including specialty areas of Molecular Diagnostics, Flow Cytometry, Transfusion Services, LIS, Quality Assurance and Leadership.

Laboratories must provide accurate and reliable laboratory results to the clinicians. To ensure this, the laboratory must have a robust quality control (QC) plan with effective reviews that identify the potential instrument, technique/personnel, reagent, or QC issues. In addition, the QC plan should delineate the number, type, and frequency of the controls to be run, expected range and established limits of acceptability, description of the corrective action to be performed for unacceptable QC values, the process of review, and a means for ensuring documentation and storage of all QC records. This section will review some common pitfalls identified in laboratories and when to document and perform corrective action in these instances.

We will be discussing pitfalls related explicitly to QC for quantitative assays. The easiest way to monitor quantitative QC results is by utilizing a Levey-Jennings (LJ) chart to plot the data points. The LJ chart assists the user in quickly identifying shifts or trends throughout the week, month, or over the use of the QC lot. It is essential to review these charts weekly so you can identify trends or shifts in data that could potentially lead to issues with your patient results before the monthly review. In addition to the LJ chart, many laboratories utilize Westgard Rules to assist them in determining the acceptance or rejection of QC data based on statistics.

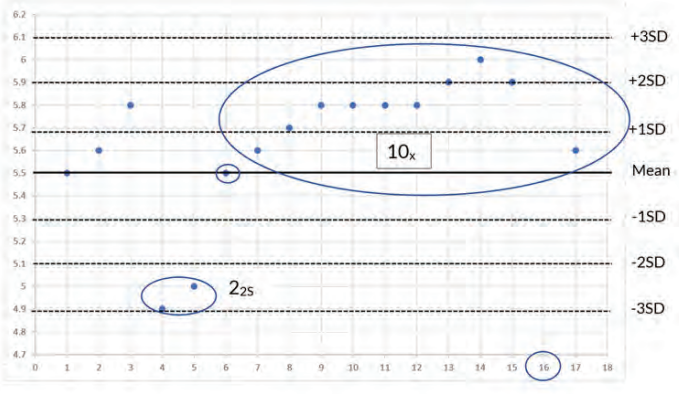
The LJ chart below demonstrates many pitfalls that the laboratory may come across during the month. Hopefully, your QC does not look like this chart!

(1) The value for the 4th data point notes that the QC is outside of 2 Standard Deviations (SD) but within 3SD. If the laboratory is running two or more levels of QC, they may choose to utilize this Westgard Rule (12S) as a warning. Some laboratories do not realize that if the control result is outside 2SD the following day (2_{2S}), they should reject that QC value, perform corrective action, and document this action.

(2) The value on the 6th data point noted below shows that the QC value obtained was on the mean after the 2_{2S} violation. This notes a shift in QC values probably due to calibration, new reagent, new QC vial, maintenance, or another action performed by the testing personnel. The testing personnel must document their corrective action so when the data is reviewed; it is easy to determine the cause of this shift.

(3) The following ten values note another Westgard rule violation (10x). This shows a definite trend upwards in the QC data. Noting the corrective action documented on the 5th data point could assist the reviewer in determining the cause of the trend. When data is consistently above or below the mean, it is essential that the laboratory act on this trend and document this corrective action.

The last item identified on this LJ chart is QC data missing for the 16th point. It appears that this assay is run daily, but there is no QC data for the date. Inadequate frequency of running QC is commonly seen for infrequently ordered assays. If a laboratory does not perform QC daily for infrequently ordered assays, the laboratory should institute a method to ensure that QC is not missed on the day a patient is tested. An example of a strategy to assist the lab would be a log, notating the assays and a checkmark that the QC was performed. If QC was missed on a day and patients were assayed and resulted from that day, it is essential that the laboratory review all patient data and QC values from before and after the omitted QC to ensure the quality of patient results. The laboratory should perform an incident investigation to identify the root cause, patient outcomes, and corrective action signed by the Laboratory Director.



Remember that a robust quality control plan with weekly and monthly reviews is essential to ensure accurate and precise reporting of your patient results.

INDIVIDUALIZED QUALITY CONTROL PLANS (IQCP) FIVE YEARS LATER

Has the laboratory community embraced risk assessment?

By Kathy Nucifora, MPH, MT (ASCP)

Kathy Nucifora, MPH, MT (ASCP), joined COLA Inc. as the Accreditation Division Manager in November 2009 and in 2019 became COLA Inc.'s Chief Operating Officer. Kathy has a wide range of experience managing clinical laboratories, including large and small POLs, and large and small hospital laboratories. She has lectured on many relevant laboratory topics, including IQCP.

BACKGROUND

Initially, the Clinical Laboratory Improvement Amendments (CLIA) of 1988 did not allow flexibility in the quality control (QC) requirements for newer technologies that included either internal or electronic controls or both. However, when the regulations were updated in 2003, a door was opened for alternate QC plans at § 493.1250: "Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in §§493.1251 through 493.1283 ***unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing.*** In addition, the laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in §493.1289 for each specialty and subspecialty of testing performed."

We all remember the first iteration of alternate QC – Equivalent Quality Control (EQC). While this optional QC plan did allow for some flexibility for a limited number of laboratory tests, namely those with either internal or electronic controls or both, EQC only considered the analytic phase of testing and had no allowance for QC optimization based upon risk. And in fact, the EQC defined protocols intended to reduce external QC frequency were, in many cases, a "one and done" exercise that did not encompass a comprehensive evaluation of the quality of the test system. Most importantly, EQC did not factor in pre-analytic or post-analytic variables, which can be significant contributors to laboratory errors, and was not meant to be customized for each laboratory's unique environment.

The industry recognized the shortcomings of EQC, and in October of 2011, the Clinical Laboratory Standards Institute (CLSI) published a consensus document, "Laboratory Quality Control Based on Risk Management; Approved Guideline," EP 23-A, which provided a roadmap for using risk management in clinical laboratories to optimize QC plans. The concept of risk management was not entirely new to clinical laboratories, but a formal process of evaluating and mitigating specific risk factors was not typically used in developing specific QC plans for laboratory tests. The CLSI document paved the way for Individualized Quality Control Plans (IQCP), which was phased in as an alternate QC option over two years and implemented on January 1, 2016, replacing EQC as the only alternate QC option that can replace regulatory QC requirements.

IQCP is an alternate QC option that requires a risk assessment that considers sources of error in all three phases of testing and customizes the QC plan to each laboratory's circumstances. Importantly, it requires that the risk assessment and QC plan be reviewed routinely and updated if necessary, based upon a review of the laboratory data and performance of the test overall. Looking back over the past five years, we can now reflect on this quality control optimization journey and consider whether the laboratory community has genuinely embraced risk assessment as a means to implement QC that reduces errors.

ADOPTION OF IQCP

A poll of COLA Surveyors showed a wide range of adoption of IQCP in laboratories across the country, primarily dependent on the type of testing performed in the laboratory. Sixteen COLA Surveyors estimated that overall, an average of 43% of laboratories had implemented IQCP for at least one test. The estimated percentage is much higher, 90%, in laboratories that utilize kit tests and/or tests that use single-use cartridges. In addition, these test systems frequently have manufacturer QC requirements that are less stringent than the regulatory requirement, thus providing a financial incentive to implementing IQCP. Are laboratories using IQCP solely to reduce QC frequency?

Those who have approached IQCP with this narrow objective may have missed the entire point of risk assessment. But according to one Technical Consultant, there are positive signs that the definition of QC is slowly evolving toward a more meaningful way to achieve quality test results.

Geri R. Becker, MT(ASCP) is the owner and operator of Applied Becker Consulting, a laboratory consulting company based in Texas. With over three decades of immersion in the dynamic clinical lab industry, Geri leads the team at Applied Becker Consulting. In addition to setting the firm's direction and strategy, she brings extensive lab management, technical and protocol, lab testing, and instrumentation expertise to bear on each client's environment and specific goals. Prior to founding Applied Becker Consulting, she managed a highly specialized endocrinology laboratory and successfully maintained standards compliance. She has been working with laboratories as a Technical Consultant and has guided countless laboratories through the implementation of IQCP. When asked about her experience in the field, Ms. Becker shared her insights on IQCP over the last five years.

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A TECHNICAL CONSULTANT'S PERSPECTIVE ON IQCP

Q: From your experience working with laboratories, has the implementation of IQCP successfully got laboratory personnel to understand and embrace risk management as a tool in developing QC plans? Do you have the sense that those who have implemented IQCP only did so to reduce QC frequency?

A: Yes, in my experience, laboratory testing personnel do exhibit a more comprehensive understanding of the variables that make up risk management. But this has been a secondary outcome. Absolutely, most of my clients seek to perform QC less frequently. There are valid reasons for this:

- **Test systems that are suited for IQCP tend to be cartridge-based tests.**
  - Reactions take place within a closed system.
  - Closed systems are equipped with internal procedural controls that will alert the end-user of QC failures, e.g., sample flow problems, overfill, damaged cartridges.
  - The cartridges, shipped in a box are pre-calibrated, controlled, and optimized by the manufacturer to perform well in a controlled environment with trained operators.
  - Electronic, procedural controls are performed with these test system analyzers, which are essentially incubators, processors, and/or readers, to ensure the measurement systems are functioning properly.
  - The manufacturer calibrated these test systems, allowing the end-user no control over calibration or any other measurement adjustments
- **These end-users tend to be lower volume testing centers. They cannot afford to perform at least two levels of controls every day for all of their test systems.**
- **The technological advances with in vitro diagnostic test systems have made the actual patient testing process simple.**

Q: Do most laboratories you have worked with that have implemented IQCP feel that the investment of their time in the risk assessment has been valuable?

A: Yes. This is most likely because I am the one who works to help the laboratories to develop their IQCP and who works with them to ensure that we have gathered all the data; compiled, analyzed and approved the initial reports; and finally, ensured that we are reviewing our risk assessment protocol quarterly, culminating in an annual, semi-quantitative review report.

Q: Can you give any examples where the use of IQCP has improved the quality of laboratory testing by minimizing the risk of errors?

A: Yes. I think the positive impact is realized by implementing a laboratory's Quality Assessment (QA) program. The IQCP is a useful QA tool that provides the testing personnel with a better understanding and working knowledge of QA implementation. Many laboratories are staffed by healthcare professionals who have purposefully chosen not to study laboratory medicine. When these people are tasked with performing laboratory duties, they are faced with many challenges. I show my clients how all the parts of their IQCP work together, they can then embrace the quality concept and are equipped and empowered to work on their QA program.

Q: Did CLIA get it right with IQCP? We know EQC was not successful – because only the analytic phase was considered, and EQC did not invite laboratories to customize or optimize their QC plans. Did IQCP successfully address the issue of "one size does not fit all" for QC, considering new technologies?

A: Partially, I think there is still room for improvement. The regulations are lagging behind technology. As a Technical Consultant for various laboratory types, I have seen variability among the accrediting agencies with how much a laboratory is allowed to customize its IQCP. As newer technologies become available for testing, as the laboratory workforce and oversight management continue to change, I think it will be essential for IQCP regulations to keep pace with these changes.

Q: How do Laboratory Directors feel about IQCP?

A: The Laboratory Directors with whom I've worked like the IQCP. I cannot think of any who have wanted to revert to an "every day of testing, perform at least two levels of QC" protocol. QA approval for a test system can be simplified through the use of an IQCP.

- **The manufacturers have great technology and reliable reagents.**
- **Most laboratories maintain stable environmental conditions for testing and supplies storage.**
- **The most significant variables lie within our testing personnel and sample collections. With the implementation of a solid training and competency assessment program, the risk assessment approach works well.**

CONCLUSION

While there has been substantial adoption of IQCP, especially for kit test and cartridge-based tests, if the laboratory community had fully bought in to risk assessment as a tool for developing optimum QC plans, we would see more laboratories implementing IQCP for tests that are not kit or cartridge-based. We see some movement in this direction, but we are not there yet.

More data demonstrating that IQCP is worth the investment of time and analysis is needed to move the needle further and show that laboratorians are well-positioned to be the experts on risk management.

SAVE THE DATE

LABORATORY ENRICHMENT FORUM

MAY 5-6, 2022
CHARLOTTE, NC

COLA Training and Development
LABORATORY ENRICHMENT FORUM

COLA's Annual Laboratory Enrichment Forum will provide an engaging opportunity to share ideas with a diverse group of professionals committed to the highest quality in laboratory services.

Some of the brightest minds in the industry will share their perspective on the latest developments in laboratory science, along with the essentials of CLIA compliance and accreditation.

For more information, please visit:
www.cola.org/save-the-date

COLA

OUR COMMITMENT TO YOU

We are a physician-directed organization whose purpose is to promote health and safety through accreditation and educational programs.

ABOUT COLA:

For more than 30 years, COLA's accreditation program has provided an extra pair of eyes for laboratories striving to produce quality test results. COLA is also the only provider of a laboratory accreditation program with quality-engineered processes certified to ISO 9001. This means our customers benefit from unique services that are standardized and represent a commitment to customer satisfaction. Just as importantly, COLA provides materials to guide successful completion of inspections and adherence to regulations; and has a dedicated staff of subject matter experts steered by a coaching approach.