

COLA'S

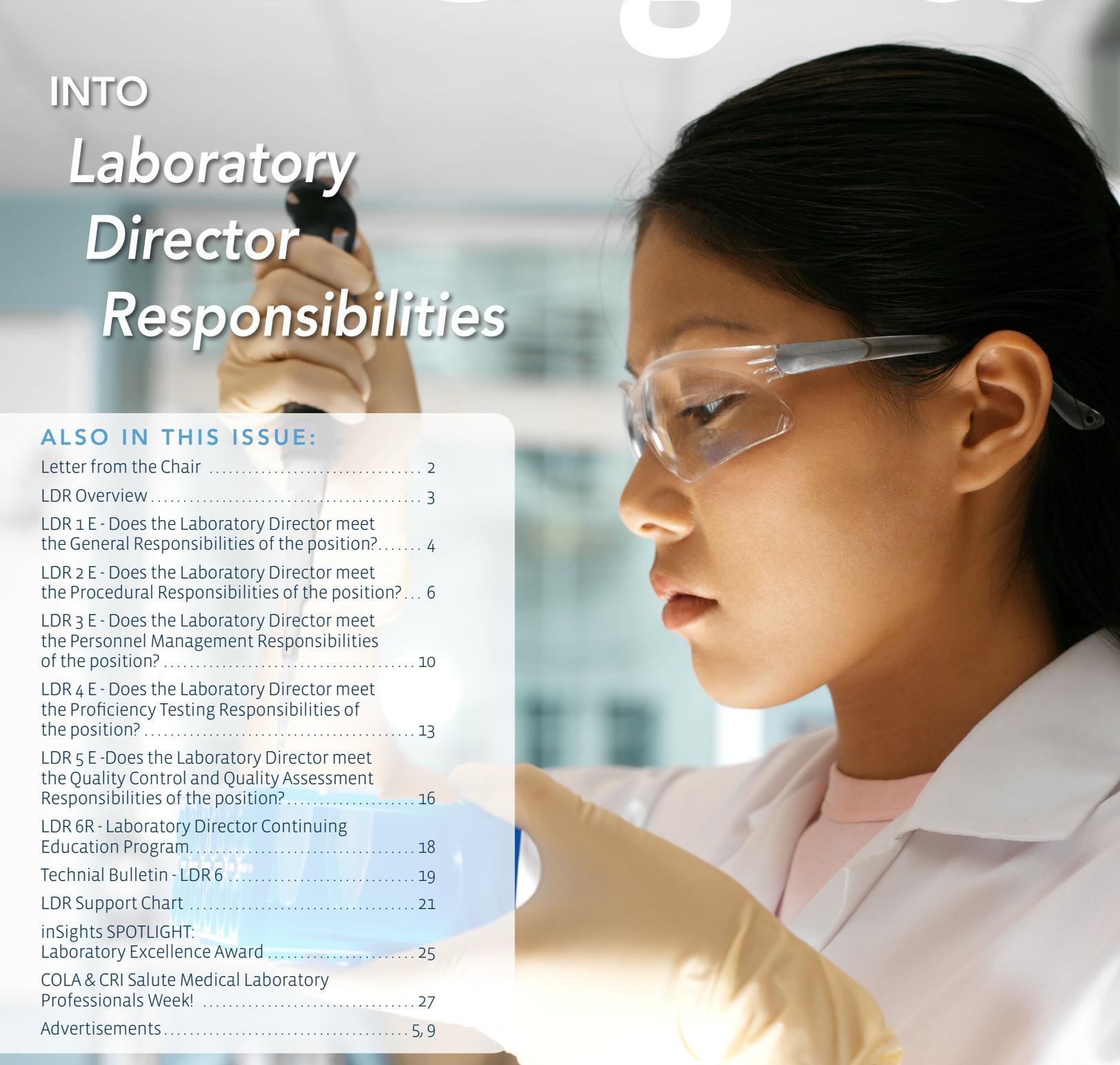
inSights

INTO

Laboratory Director Responsibilities

ALSO IN THIS ISSUE:

Letter from the Chair	2
LDR Overview	3
LDR 1 E - Does the Laboratory Director meet the General Responsibilities of the position?.....	4
LDR 2 E - Does the Laboratory Director meet the Procedural Responsibilities of the position? ...	6
LDR 3 E - Does the Laboratory Director meet the Personnel Management Responsibilities of the position?	10
LDR 4 E - Does the Laboratory Director meet the Proficiency Testing Responsibilities of the position?	13
LDR 5 E - Does the Laboratory Director meet the Quality Control and Quality Assessment Responsibilities of the position?.....	16
LDR 6R - Laboratory Director Continuing Education Program.....	18
Technical Bulletin - LDR 6	19
LDR Support Chart	21
inSights SPOTLIGHT: Laboratory Excellence Award	25
COLA & CRI Salute Medical Laboratory Professionals Week!	27
Advertisements	5, 9



FROM THE CHAIR



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

Welcome to COLA's March/April issue of Insights!

In this issue of COLA inSights we take an objective look at the Laboratory Director Responsibilities as they relate to COLA Accreditation. The Laboratory Director Responsibilities (LDR) Criteria are intended to give LD's the clear cut instruction needed to be an effective leader of the laboratory.

The COLA Accreditation Manual it states that *"The Laboratory Director is responsible for the overall operation and administration of the laboratory, and for assuring compliance with all applicable regulations. The Laboratory Director must meet education and experience requirements to hold the position, and must meet all of the responsibilities associated with the position, including ensuring that there are sufficient personnel with adequate experience and training to conduct the work of the laboratory. He or she must also ensure that every position in the laboratory is filled by an individual qualified to hold the position and able to perform the tasks required of the position."*

This issue of inSights will look at each of the Laboratory Director Responsibility criteria.

LDR 1 E - Does the Laboratory Director meet the General Responsibilities of the position?

LDR 2 E - Does the Laboratory Director meet the Procedural Responsibilities of the position? **LDR 3 E** - Does the Laboratory Director meet the Personnel Management Responsibilities of the position?

LDR 4 E - Does the Laboratory Director meet the Proficiency Testing Responsibilities of the position? **LDR 5 E** - Does the Laboratory Director meet the Quality Control and Quality Assessment Responsibilities of the position?

And the newest criteria **LDR 6R** - Has the Laboratory Director completed, within the last two years, four continuing education credits (CME or PACE) from the COLA Laboratory Director Continuing Education Program (LDCEP), or other equivalent laboratory director education program?

"COLA standards were developed by physicians, clinical laboratory scientists, and other clinical laboratory professionals. They are based on proven clinical laboratory standards and accepted good laboratory practices. These standards reflect requirements for procedures that are performed in the laboratory environment and are necessary for any laboratory to produce consistently accurate results. COLA standards have been deemed to be equivalent to the federal CLIA regulations."- 2013 COLA Accreditation Manual

In addition, we are excited to announce a new feature in COLA inSights: **inSights SPOTLIGHT: LABORATORY EXCELLENCE AWARD**. Beginning with this issue and in all future issues we will highlight a COLA Accredited laboratory that has been awarded the Laboratory Excellence (LEA) Award, or has demonstrated exemplary performance in laboratory medicine. We hope this acknowledgement inspires all of our laboratories to pursue Excellence in Laboratory Medicine!

As the Laboratory Director there is much required in terms of not only technical expertise but communication, education and leadership. Laboratory Directorship is sometimes challenged with employee turnover, limited budgets, and antiquated equipment. Some laboratories are state of the art, fully staffed and have unlimited budgets for everything from education to consumables. But as the Lab Director in either scenario you find a way for your staff to provide quality test results that directly affect patient care. We invite you to share this issue of inSights with your staff and colleagues to learn and share the requirements of a Laboratory Director and collaborate to ensure success in the laboratory.

COLA INSIGHTS

COLA is sponsored by the American Academy of Family Physicians (AAFP), the American Medical Association (AMA), the American Osteopathic Association (AOA), and the American College of Physicians (ACP); and is endorsed by 29 national and state medical organizations. Letters to the editor are welcome.

ADVERTISING POLICY

COLA accepts advertising requests for inclusion in its publications. All advertisements are subject to review and approval by COLA.

COLA reserves the right to reject or cancel any advertisement that is not in keeping with COLA's standards as a national accreditation organization and its publication standards.

COLA and its publications do not and will not endorse, directly or indirectly, any advertiser's products or services.

If you would like to discuss advertising opportunities, please contact COLA at 410.381.6581, ext. 3736.

© COLA 2012

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

COLA INFORMATION RESOURCE CENTER: 800.981.9883

This publication may be obtained through enrollment in a COLA accreditation program.

ALL RIGHTS RESERVED
Reproduction in whole or in part without written permission is prohibited.

www.colas.org
www.LabUniversity.org
www.COLAcentral.com
www.criedu.org

?! Comments? Questions? Feedback?
email info@criedu.org

LDR Overview

One of the main questions people ask when thinking of laboratories and their accreditation/certification is “Who is in charge?” This question raises many key concerns about how the laboratory is being managed, who delegates the roles and responsibilities of the personnel, and most importantly, who is ultimately responsible for each test result produced from the laboratory. Many laboratorians see the role of the Laboratory Director (LD) as glamorous because they oversee the entire laboratory, but in actuality it is a great responsibility that must be entered into cautiously.

The amount of time, energy and resources must be carefully considered when taking a Laboratory Directorship. These tasks become less daunting when there is a sincere plan of action for time management and effective communication. This issue of inSights on Laboratory Director Responsibilities will provide much needed discussion about the duties of the LD and how to ensure compliance with COLA Accreditation. Failure to fulfill the LDR criteria is a major cause of unsuccessful surveys.

The laboratory must be under the direction of a qualified individual, and that individual must fulfill all the responsibilities of the Laboratory Director as outlined by CLIA and COLA. CLIA prohibits a Laboratory Director from directing more than five non-waived laboratories. Some states have further restrictions regarding the number of labs that an LD can direct. The Laboratory Director is responsible for the overall operation and administration of the laboratory, and for assuring compliance with all applicable regulations. The Laboratory Director must meet education and experience requirements (see PER evaluation grouping) to hold the position, and must meet all of the responsibilities associated with the position, including ensuring that there are sufficient personnel with adequate experience and training to conduct the work of the laboratory. He or she must

also ensure that every position in the laboratory is filled by an individual qualified to hold the position and able to perform the tasks required of the position.

The requirement for the laboratory to be under the direction of a qualified individual is not automatically met simply because the director meets the education and experience requirements described in the PER evaluation grouping. The individual must also demonstrate that he or she is providing effective direction over the operation of the laboratory. When determining whether the director responsibilities are being met, the surveyor will consider deficiencies found in other areas, such as facility administration; proficiency testing; and general, pre-analytic, analytic, and post-analytic systems.

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. Be it a Technical Supervisor, Technical Consultant or General Supervisor, the LD must ensure that whatever tasks are delegated to these individuals are performed properly and in compliance with all necessary regulations. If qualified, the Laboratory Director may hold other required positions in the laboratory. If so, he or she must also meet those responsibilities. Take the time to review this issue of inSights for true clarification and helpful tips to help Laboratory Directors ensure Excellence in Laboratory Medicine!

LAB DIRECTOR RESPONSIBILITIES

LDR 1 E Does the Laboratory Director meet the General Responsibilities of the position?

The day-to-day activities of the Laboratory Director (LD) are generally straight forward and should be clearly identified in your Job Description record. Although the responsibilities can usually be delegated to your technical staff, the responsibility of the accuracy of each test that is run through your laboratory is ultimately **“your”** responsibility.

- *The Laboratory Director must be accessible to the laboratory to provide onsite, telephone or electronic consultation as needed.*

As the LD duties are most likely included in a long list of other duties for this individual, there must be a clear commitment to stay constantly available to the laboratory and its staff. When not onsite, LD contact info should be readily available to staff and multiple contact options should be made available and listed in priority order.

- *May direct no more than five non-waived labs.*

CLIA prohibits a Laboratory Director from directing more than five non-waived laboratories.¹ CMS §493.1407 (d) CMS §493.1445 (d) standards “Note that for a Certificate of PPM, Certificate of Compliance or Certificate of Accreditation, an individual can only serve as the director for no more than five non-waived laboratories.”² Two states have more stringent restrictions: In PA a Lab Director may direct no more than two non-waived labs; and in GA a Lab Director may direct no more than three non-waived labs.

This requirement is not meant to stifle LD’s, confine them to a particular specialty or limit their income. This requirement is meant to ensure that adequate time and attention is spent on each laboratory they oversee. This is specific to non-waived testing as there are many defined requirements, including specific Quality Assessment/Quality Control measures. Compliance with these requirements must not only be closely monitored, but also documentation reviewed and signed off on by the LD.

- *Ensure that the physical plant and environmental conditions are appropriate for the testing performed and provide an environment safe from physical, chemical, and biological hazards.*

As the LD it is their responsibility to assess your facility for safety. This does not limit itself to the test bench but also wherever patient specimens are collected/discarded, reagents are handled, and testing performed. The safety plan should be coordinated with your facility maintenance manager. Non-healthcare personnel should never be allowed in the testing area other than to perform building maintenance, which includes basic cleaning of the laboratory but not any areas where there are biological hazards. For example, building

maintenance can mop the floors but should not be wiping off benchtops, instruments or records/filing systems. Imagine the worst case scenario that there is a biological contaminant that will not be contained to your laboratory as building maintenance workers travel throughout the facility, often using the same cleaning supplies/materials. Proper training should be provided to testing personnel on cleaning and maintenance of the physical plant.

Overall safety should be considered in your assessment. Remove trip/fall hazards like cords or boxes. All reagents, supplies and instruments should be properly stored and records kept on ordering, calibration and maintenance. Personal protective equipment should be made available to testing personnel and stored properly.

- *Ensure compliance with all applicable regulations.*

The best way to ensure that all applicable regulations are being met is to educate yourself and your staff on the regulations. From OSHA to FDA; Local, State and Federal regulations should be available to your staff and training should occur to ensure that all staff are adequately knowledgeable on the topic. Also there should be a mechanism in place to review the regulations and ensure that the most current information is communicated. Similar to when a new lot of kits or reagents is introduced to your laboratory, and you review the package insert to make sure the instructions for use have not changed.

Key Tips: How can the General Responsibilities be met?

- Make sure there is enough counter and storage space for testing. Ensure that electrical power, including shock and power surge protection, is adequate.
- Assure that your laboratory is complying with the Hazard Communications standard – see US Code of Federal Regulations 29CFR 1910.1200, at: http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=standards&p_id=10099 and the Bloodborne Pathogens standard – see US Code of Federal Regulations 29CFR 1910.1030, at: http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=standards&p_id=10051.
- Take appropriate safety measures, including the use of warning labels, and the provision of personal protective equipment.
- Assure that environmental conditions (temperature, humidity, etc.) that can affect testing are being monitored and acted upon in your laboratory.

- Review, become familiar with, and assure compliance with the CLIA regulations and the COLA criteria.
- Review, become familiar with, and assure compliance with any state or local laboratory regulations that apply to your laboratory.
- Get involved in the survey process (work with your laboratory staff to complete the Self-Assessment before the survey) and take advantage of the education that a surveyor can provide.
- Participate in the exit conference at the conclusion of your laboratory inspection.

RESOURCES:

1. COLA Accreditation Manual p.48 (revised June 2013)
2. Clinical Laboratory Improvement Amendments (CLIA) Application for Certification. <http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms116.pdf>



The right choice for proficiency testing

- Report online quickly.
- Perform only 3 testing events each year.
- Earn CME.

Maintain laboratory excellence with this trusted program from the AAFP. Flexible and simple, AAFP-PT has been the proficiency testing solution for more than 25 years.

Approved by CMS and COLA
 Enroll today.
 (800) 274.7911 or pt@aafp.org



LAB DIRECTOR RESPONSIBILITIES

LDR 2 E Does the Laboratory Director meet the Procedural Responsibilities of the position?

The purpose of this criterion is to ensure that the Laboratory Director is the active, hands-on leader of the laboratory.

- Ensure testing systems provide quality laboratory services for pre-analytic, analytic, and post-analytic phases of testing.

The Laboratory Director should be actively involved in each stage of the testing process. From specimen collection, processing and testing to results reporting and interpretation, the LD must be engaged. The LD should communicate with all personnel involved in each stage of testing. This includes the Phlebotomist, Medical Assistant, Nurse, or Medical Technologist that may be collecting samples in the pre-analytic stage. It includes the Medical Technologist, Medical Laboratory Technologist or other testing personnel performing the test protocol in the analytical stage. Finally it includes the laboratory staff who report the results either through an LIS or EHR system, and Clinicians who will interpret the results to deliver patient care.

The LD must be active in ensuring that all participants in each stage of testing are not only trained but competent in performing the various test systems in the laboratory. Documentation of training and the Competency Assessment will assist in ensuring that the laboratory has taken every stage of testing into consideration.

- Ensure test methods selected have the capability of providing quality results.

It does not need to be explained to the experienced laboratorian that not all test methods provide the same quality and accuracy. There are some test methods that are appropriate for screening versus others that are used for confirmatory diagnosis, and still others that function to provide a measurement of a specific analyte for various uses in patient care. As the Laboratory Director they must take the lead in researching test methodologies, how they are applicable to your patient population, medical system, etc. There cannot be a dependence on the “tried and true” methods simply because that’s “what we’ve always done.”

There should be regular reviews performed on various test methods available in comparison to your laboratory’s test system performance. This doesn’t mean that every time there is a new product or service out your lab is the first one in line to get it, but keep your laboratory informed of new technologies. There may be training and education, software upgrades, add-on packages, etc. that may enhance your current test system at a fraction of the cost. Conversely no LD wants to be burdened with an obsolete test system regardless of their testing volume. A good place to start would be to

work with suppliers and manufacturers to select test methods with proven accuracy that meet your needs.

- Ensure verification procedures used are adequate to determine accuracy, precision, and other pertinent performance characteristics of the method.

As part of your Laboratory Director responsibilities you must verify that the manufacturer’s stated performance characteristics are achieved in your lab (required for all new nonwaived methods added after April 24, 2003). Continue to monitor the test method’s performance over time. All of this should be properly documented as well.

- Ensure that reports of test results include pertinent information required for interpretation.

When reporting patient results, there are many things to take into consideration. The type of test ordered, when the results are needed back, and the demographics of the patient just to name a few. The test results that you are reporting to clinicians, either via an EHR, adding the results in the patient chart or sending the results via courier or inter-office mail, should always include information that is pertinent to interpretation for patient care. For example: two unique identifiers (patient name, DOB, age, etc.); source of specimen (plasma, serum, urine, etc.); if monitoring medication (treatment plan, interactions, or efficacy) provide the date/time of last dose; any restrictions given to patient (i.e.- fasting).

It is also important to provide a critical result indicator with results reporting. This could be an asterisk next to the test result value or a different color/font for the critical result so that it stands out among the results being reported. Best practices also include the inclusion of the normal test value range on the results reporting documentation. Keep in mind that just because you have highlighted the critical value, there is no guarantee that the clinician fully understands the relevance of the critical value in respect to treatment options for patient care. Although there is some training on laboratory services in the curriculum of the various schools of medicine, there may be variation in the level of knowledge of what lab results mean for various tests and also how test results interpretation varies from patient to patient based on a number of variables. It is the duty of the Laboratory Director to ensure that all personnel involved in the post-analytic stage of testing are well versed in the meaning behind the values being reported from the laboratory. If you are unable to provide this information research the various partners such as the

manufacturer and the reference laboratory for educational information to share.

These COLA criteria are directly related to this lab director responsibility:

PST 9-16

Guidelines on what the test report should contain.¹

- Ensure that consultation is available to the laboratory's clients on matters relating to the quality of the test results reported and their interpretation concerning specific patient conditions.

Even before the 2014 FDA ruling requiring that laboratories provide laboratory testing information to patients, COLA accredited laboratories are required to be prepared to communicate effectively with the laboratory's clients. This includes patients and ordering physicians. There must be a protocol in place to share pertinent information for patient care with each group.

- Ensure that an approved procedure manual is available to all personnel.

The LD must ensure that there is a reviewed and approved procedure manual for all tests performed in the laboratory. This manual must be available at all times and accessible by all testing personnel. For example, the only copy should not be in the LD's office which is locked during times when they are not onsite. There should be documentation of the personnel receiving full training on the contents of the procedure manual as well.

If any additional information is needed to ensure that your laboratory's procedure manual is compliant please reference COLA LabGuide 1 – "Contents of a Procedure Manual."

These COLA criteria are directly related to this lab director responsibility:

ORG 13 R

Is the procedure manual easily accessible to your personnel?

It is important for laboratory personnel to have easy access to the procedure manual. Staff should not rely on memory as this may lead to erroneous results if the procedure isn't remembered correctly.²

ORG 16 R

Does the LD sign and date each new procedure prior to use?

- Ensure that laboratory personnel are performing the test methods as required for accurate and reliable results.

The Laboratory Director is directly responsible for all test results that are reported from the laboratory. This responsibility is not to be taken lightly and the guidelines are specific to ensure that testing personnel have all of the resources necessary available to ensure accurate results. For each criteria for COLA accreditation there is a clear mandate to LD's to ensure that accurate and reliable results are the required for each sample that is processed through the laboratory.

For example, your laboratory protocols state to only process pregnancy tests for females, and if the patient information states that a sample to be tested is from a male, then there needs to be a review of the requisition process and discussion with the testing personnel involved in the pre-analytic stage.

These COLA criteria are directly related to this lab director responsibility:

ORG 14 R

Do personnel follow all procedures as written in the procedure manual?

If you have someone from outside your practice prepare your procedure manual, make sure the procedures reflect the way your personnel actually perform the tests in your laboratory.

NOTE: A copy of the manufacturer's package insert or operator's manual, or a copy of a textbook description of the test procedure may be used in the manual if it provides the information required under Section APM. Any components of the test procedure that are not addressed by the manufacturer, such as the steps to be taken when a test system is malfunctioning, must be written into the individual procedure. You can also maintain a general policy statement in the laboratory for these procedures.³

PST 1 R

Does your laboratory have a written procedure to correct laboratory errors when they are detected?

The laboratory policy should define who to notify when an error occurs, how to correct the error, the importance of maintaining the original and corrected report in case medical decisions or procedures were initiated based on the erroneous result. It should also require that each of these items be documented for review as part of the quality assessment process.

It is important that the laboratory track errors and evaluates the circumstances associated with them, according to their established Incident Management Program, for consideration of potential harm to patients. See Criteria QA 20.⁴

PST 6 R

Does the laboratory policy prohibit reporting test results when they exceed the reportable range established by the laboratory and is corrective action taken and documented in accordance with any deviation in this policy?

Patient results should not be reported in numbers when the results exceed the reportable range. The results may be reported as "greater than" the maximum verified reportable range. An alternative to this would be to follow the manufacturer's directions for diluting a patient specimen when it exceeds the reportable range. When

>> CONTINUED ON PAGE 8

doing this, however, don't forget to multiply the result you get by the dilution factor.⁵

Key Tips: How can the Procedural responsibilities be met?

- Work with your laboratory staff to select test systems carefully and monitor their performance in the pre-analytic, analytic, and post-analytic phases of testing.
- Work with suppliers and manufacturers to select test methods with proven accuracy that meet your needs.
- Verify that the manufacturer's stated performance characteristics are achieved in your lab.
- Assure that Quality Control is performed, that it is regularly reviewed by appropriate technical staff to monitor the test method's performance over time, and that when problems are identified, they are corrected prior to reporting patient test results.
- Ensure that personnel follow the manufacturer's directions and use good laboratory practices.
- Make sure that test reports include all necessary information that could be significant for interpreting the results. For example:
 - Patient sex and age,
 - Time of last dose, for medication levels,
 - The source of the specimen,
 - If the patient was fasting.
- Be available to discuss laboratory results with laboratory clients (ordering physicians or patients).
- The procedure manual must include a procedure for every test performed and be available to laboratory personnel.

• Review, approve, date and sign all procedures before they are put into use. Review, approve, date and sign all new procedures and all changes to procedures.

- A new Lab Director must review, approve, date and sign all procedures as soon as they become the Lab Director.
- Annual review of procedures can be delegated to a qualified individual, as long as there are no changes to the procedures.

RESOURCES:

- 2,3,1. COLA Accreditation Manual (revised June 2013) p. 129
- 8,9. COLA Accreditation Manual (revised June 2013) p. 43
4. COLA Accreditation Manual (revised June 2013) p. 128
5. COLA Accreditation Manual (revised June 2013) p. 129



RX series

RELAX, WE'VE GOT YOU COVERED

The RX daytona and RX imola fully automated benchtop chemistry analyzers have been developed by Randox to meet the growing needs of clinical laboratory testing. Robust hardware combined with intuitive software, an extensive dedicated test menu and exceptionally low downtime ensures unrivalled precision and accuracy for results you can trust.

The RX daytona offers a high performance solution to mid-volume clinical chemistry testing and a throughput of 450 tests per hour including ISE.

The RX imola has a throughput of 560 tests per hour including ISE and is capable of handling the workload of a medium to high throughput laboratory.



RANDOX

Randox Laboratories-US, Ltd. 515 Industrial Boulevard, Kearneysville, West Virginia, 25430
T: (+1) 866 4 RANDOX F: (+1) 866 RANDOX | W: www.randox.com E: marketing@randox.com

LAB DIRECTOR RESPONSIBILITIES

LDR 3 E Does the Laboratory Director meet the Personnel Management Responsibilities of the position?

The Laboratory Director should ensure that the staffing of the laboratory is not only adequate - but appropriate for the type of testing performed.

- **Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise, accurately perform tests, and report test results.**

As the Laboratory Director it is tempting to take on too many, or conversely, too few tasks. Some LD's are the sole proprietor and wear many hats in the laboratory. Being the General Supervisor, Technical Supervisor (for high complexity laboratories) and Laboratory Director simultaneously is not impossible, but it may become overwhelming. Many tasks can be delegated to other qualified testing personnel. There should be a clear workflow for each test system that identifies each person involved in the testing process and how their actions interact with the previous and next stage of testing.

Proper staffing is the core of laboratory excellence. If you have too many or too few testing personnel the outcome may be equally as debilitating. If you have too few people during a shift quality can be compromised, priority testing may not get done and a litany of other short staffing challenges can occur. If there are too many people during a shift, duties may go unperformed due to staff thinking that "someone else has done it." The LD must find the perfect balance of personnel to keep the laboratory a safe, effective and efficient place to work.

This COLA criterion is directly related to this lab director responsibility:

PER 2 E

Are all required positions for your laboratory filled and are the individuals filling those positions qualified by education and experience?

For detailed information on education and experience requirements and eligibility pathways for all CLIA defined positions, refer to the COLA Accreditation Manual, Section III, and "Personnel Requirements" chart or to COLA LabGuide 4 "Personnel for Nonwaived Testing." If your state has more stringent personnel standards or licensure requirements than CLIA and COLA, the laboratory director must ensure that all personnel meet the more stringent requirements.¹

- **Ensure that prior to testing patient specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of services offered, and have**

demonstrated that they can perform all testing operations reliably to provide and report accurate results.

Simultaneously as you hire staff for the laboratory you are also ensuring that their education, training and experience are compliant for the level of testing they will be performing. These requirements are not interchangeable and I would say "the complexity needs to be determined for the test system used." As part of your laboratory's plan, assure that personnel are provided with adequate training for the duties and testing that they will be performing. This could be completed by having staff attend a manufacturers training session or scheduled observation of the test being performed. Personnel can view training videos, webcasts, etc. to gain insight on test systems. The LD must verify that all personnel have documentation of the necessary education and experience. Best practices would suggest that multiple copies of the documentation be kept for placement in multiple places such as the employee's file, the QA manual and the LD records.

This COLA criterion is directly related to this lab director responsibility:

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. 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

- **Ensure that policies and procedures are established for monitoring individuals who conduct pre-analytic, analytic, and post-analytic phases of testing to verify that they maintain competency**
 - To process specimens,
 - Perform test procedures, and
 - Report test results promptly and proficiently.

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

According to CLIA regulations and COLA Accreditation Criteria “Documented competency assessment is required for individuals fulfilling the following personnel responsibilities outlined in Subpart M of the CLIA regulations: clinical consultant (CC), technical consultant (TC), technical supervisor (TS), general supervisor (GS) and testing personnel (TP). Clinical consultants, technical consultants, technical supervisors, and general supervisors who perform testing on patient specimens are required to have the six required methods for testing personnel in their Competency Assessment in addition to a competency assessment based on their Federal regulatory responsibilities.”²

CRI Continuous Quality Advisor Irwin Rothenberg thinks of Competency Assessment in these terms “Think about the effect on laboratory quality to have competency assured for all those whose activities directly affect the laboratory operation. One possibility is to consider incorporation of competency assessments of laboratory-related activity into staff evaluations. It is also important to remember that this is often the staff that interacts directly with patients providing pre-test preparation information.”³

This COLA criterion is directly related to this lab director responsibility:

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?

This is not simply a review of the individual’s initiative, interpersonal relationships, and work ethic although these are important attributes. The focus of this process is the individual’s ability to perform assigned tasks according to defined process and procedure to assure accurate and reliable laboratory results. The review must address the competency of each individual to fulfill the duties and responsibilities of their position including assessment of actual test performance and interpretation of results.

All staff are to be included in this process from personnel involved in specimen collection and processing to those responsible for supervision and compliance. Evaluations should occur semi-annually

for the first year and annually thereafter for all testing personnel, supervisors and technical consultants.

Methods of competency assessment must include, where applicable:

- (i) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing;
 - (ii) Monitoring the recording and reporting of test results;
 - (iii) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records;
 - (iv) Direct observation of performance of instrument maintenance and function checks;
 - (v) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and
 - (vi) Assessment of problem solving skills.⁴
- **Whenever necessary, identify the need for remedial training or continuing education to improve skills.**

As a LD you have the additional responsibility of identifying the need for your staff to improve their skills. This can be accomplished by a variety of methods. From having them participate in training on a new piece of equipment, reviewing operation manuals or educational brochures, to taking online courses and attending conferences and workshops, there is always a way to keep your staff learning. All training and continuing education must be documented and verified by the LD.

This COLA criterion is directly related to this lab director responsibility:

EVALUATION GROUPING - PERSONNEL: TRAINING

*The director must document personnel training in the personnel files of laboratory staff, including his or her own file. Continuing education is also important for staff, and can be provided by one-on-one instruction, in-service programs, training on instruments or kits by the manufacturer, or formal continuing education activities such as LabUniversity®. Some states have specific continuing education requirements for laboratory personnel in order to meet licensure requirements.*⁵

- **Maintain a written list of responsibilities of each individual in the laboratory that specifies the level of activity each is authorized to perform; whether supervision is required for specimen processing, test performance or results reporting; and whether consultant or director review is required prior to reporting patient test results.**

Each position in the laboratory must come with a proper job description. Even as new responsibilities and duties are added they

>> CONTINUED ON PAGE 12

LAB DIRECTOR RESPONSIBILITIES | LDR 3 E

must be documented for not only accountability but to ensure proper utilization of your staff. If you are using your most senior medical technologist ordering office supplies versus reviewing Quality Control documentation, this may be a misuse of your personnel's time and talents. There are many instances where laboratory staff are overworked yet still underutilized. By clearly identifying what the day to day expectations of the testing personnel are, you can then delegate responsibilities appropriately and effectively. According to CRI Continuous Quality Advisor Nancy Alers "An adequate job description outlines the main duties or responsibilities associated with the position. From management's point of view, having a detailed job description allows for a more targeted approach when hiring because it makes clear what kind of skills/knowledge a person must possess in order to fit the bill." ⁶

If you have waived testing that can be performed by Medical Assistants, but then expect them to also perform certain non-waived tests while "supervised", there is a clear misconception of the roles and responsibilities in your laboratory. Although this example may seem extreme it could happen if the LD does not understand that specific activities require education, certification and experience. Regardless of the person's seniority, how many years they have been in the lab, there must be a clear definition of what they can and cannot do.

This COLA criterion is directly related to this lab director responsibility:

PER 1 R

Is there a written job description for each employee that describes individual duties and responsibilities?

A written job description aids employees in understanding what is expected of them and defines their authority to act and/or make decisions in various circumstances. It should include a list of tasks and responsibilities for all phases of laboratory testing (pre-analytic, analytic, and post analytic). This is a good place to identify the level and type of testing each employee is qualified to perform.⁷

- In a high complexity laboratory, ensure that a general supervisor provides onsite supervision of high complexity test performance by minimally qualified testing personnel.

The LD in a high complexity laboratory is responsible for complying with the CMS/CLIA/COLA guidelines for high complexity laboratories.

Individuals who require supervision qualified for high complexity testing via Sec. 493.1489(b)(5).⁸

HIGH COMPLEXITY LABORATORIES (the full list of personnel qualification categories is listed in the COLA Accreditation manual)⁹

KEY TIPS: How can the Personnel Management responsibilities be met?

- Be involved in the hiring of personnel and make sure they have the necessary education and experience.
- Evaluate the volume of testing performed, the number of testing personnel, and turn-around-times to ensure adequate personnel are available.
- Develop job descriptions for all laboratory personnel and keep them updated.
- Assure that personnel are provided with adequate training for the duties and testing that they will be performing.
- Verify that all personnel have documentation of the necessary education and experience.
- Assign, in writing, the duties/responsibilities to each person involved in all phases of the testing process and keep the list of assigned duties current.
- Establish standards for personnel performance and assure that personnel competency reviews are completed every six months for first year & annually thereafter. This should include observation of personnel as they perform procedural steps in the pre-analytic, analytic and post-analytic phases of testing.
- Require and provide remedial training when needed.
- Provide opportunities for continuing education.
- High complexity directors must employ a general supervisor and that person must be onsite when high complexity testing is performed by individuals that require supervision as described in §493.1489(b)(5) of the CLIA regulations.

RESOURCES:

1. COLA Accreditation Manual (revised June 2013) p. 64
2. COLA Accreditation Manual (July 2013) PERSONNEL REQUIREMENTS:PER 5 p.65
3. *Lab Competency Assessment for Medical Office Staff* Irwin Rothenberg MBA, MS, MT(ASCP). <http://www.criedu.org/lab-competency-assessment-medical-office-staff/>. October 29, 2013.
4. COLA Accreditation Manual (revised June 2013) p.64
5. COLA Accreditation Manual (revised June 2013) p. 63
6. Have you read your job description? Nancy Alers MS, MT(ASCP)CM. COLA Resources Inc. Quality Advisor Blog. <http://www.criedu.org/read-job-description/>. January 24, 2014
7. COLA Accreditation Manual (revised June 2013) p. 64
8. Centers for Medicare & Medicaid Services, HHS § 493.1489 Standard; Testing personnel qualifications. <http://www.gpo.gov/fdsys/pkg/CFR-2011-title42-vol5/pdf/CFR-2011-title42-vol5-sec493-1489.pdf> (last accessed March 2014)
9. COLA Accreditation Manual (revised June 2013) p. 164

LAB DIRECTOR RESPONSIBILITIES

LDR 4 E Does the Laboratory Director meet the Proficiency Testing Responsibilities of the position?

Proficiency Testing is a critical point of ensuring quality in laboratory testing. The Laboratory Director must take a vital role in PT performance.

- Ensure that the laboratory is enrolled in an approved Proficiency Testing (PT) program.

The laboratory must enroll in an approved proficiency testing (PT) program as a requirement of COLA accreditation. For practices with multiple locations, each of which has its own CLIA number, each laboratory location must enroll separately in proficiency testing and independently perform its own proficiency testing.

Proficiency Testing (PT), like the COLA Accreditation program, is an independent, external assessment providing feedback on your laboratory performance. PT is one way of comparing your laboratory's results with other laboratories using the same instrument or kit. All COLA-accredited laboratories must enroll and participate in an approved PT program. Proficiency testing measures the laboratory's ability to analyze specimens of unknown value and obtain accurate results within an established range. If the laboratory has adequate instrument maintenance, personnel training, and quality control procedures, proficiency testing should be successful. Unsuccessful proficiency testing is an indication of possible problems in these areas, and a warning that patient testing may not be accurate.

Proficiency Testing must be performed on all regulated analytes. The approved PT providers offer the majority of the regulated analytes tested in laboratories. If certain regulated analytes are not available from your primary PT provider, you should enroll with an additional PT program.

COLA strongly recommends that laboratories perform PT on unregulated analytes as an added measure of external quality assessment. If the lab is not enrolled in PT for unregulated analytes, then some form of external comparison, such as split specimen analysis, must be performed twice yearly. And because COLA believes that Waived Testing is also important to patient care, COLA now has an educational enforcement criteria requiring PT on waived testing. See the Waived Testing Evaluation Grouping, WAV 10.¹

This COLA criterion is directly related to this lab director responsibility:

PT 1 E

Have you been continuously enrolled, and have you successfully participated in one or more CMS-approved Proficiency Testing (PT) program(s) for all regulated analytes?

Enrollment is required for all regulated analytes on your test menu. See the list of approved PT programs. You should authorize your PT

program to send your PT data to COLA by submitting the PT Data Release Form to your PT provider(s). This form serves as confirmation that COLA may receive your PT data. Please complete this form and forward to your PT provider and also send a copy to COLA if you have not done so.

- Ensure that PT samples are tested in the same manner as patient samples.

Proficiency Testing specimens must be tested in the same fashion as patient specimens. Retain written documentation of every step of testing to verify that PT specimens have been handled properly.

Specifically:

- Test PT samples with the regular patient workload using routine methods
- Test PT samples the same number of times as routine patient specimens

This COLA criterion is directly related to this lab director responsibility:

PT 5 R

Do you follow the same procedures for testing PT samples as you do for patient samples?

PT specimens should be treated just like patient specimens—e.g., if a patient specimen is routinely run once, the PT specimen must be run once. In addition, the person who performs PT testing should vary if more than one person normally performs the test on patients. (For instance, the supervisor should not be the only person who performs testing on PT specimens; all persons who perform testing on patients should take a turn at performing PT testing.)

Notify your PT program prior to the cut-off date for result submission of any problems with PT specimens or lab accidents with your PT specimens. The PT program is obligated to provide replacement samples for specimens not received on time or for “problems” such as samples received in a condition that renders them unacceptable for testing. Notify your PT program and COLA, in writing, of any incorrect grading in final reports.

- Ensure that PT results are returned on time to the PT program.

Every PT program has a specific timeframe that the PT results must be reported by. Please refer to your laboratory's PT provider for further details.

>> CONTINUED ON PAGE 14

LAB DIRECTOR RESPONSIBILITIES | LDR 4 E

- Ensure that PT results are reviewed by the appropriate staff and the corrective action plan is followed when PT results are found to be unsatisfactory.

If your laboratory fails a single testing event, it receives a performance score of “unsatisfactory” for that analyte. Your laboratory must take appropriate action to identify the problem, correct it, and document the corrective action in the laboratory records. These records will be reviewed by the COLA surveyor during document review at your laboratory’s on-site survey.²

This COLA criterion is directly related to this lab director responsibility:

PT 8 R

Are all PT results reviewed and evaluated by the laboratory director or other qualified designee in a timely manner?

Be sure to document this review by dating and initialing. In order to be effective and to provide the laboratory time to take any required corrective action, the review should be completed within 30 days.

- Ensure that PT samples are tested according to COLA and CLIA regulations prohibiting referral of specimens and communication of results.

There may be no inter-laboratory communication of results until **after** the date the laboratory must report PT results to the program for the testing event. **The laboratory must not send PT samples or portions of samples to another laboratory for analysis which it is certified to perform in its own laboratory.** Any laboratory that CMS determines has intentionally referred its PT samples to another laboratory for analysis will have its CLIA certification revoked for at least one year. COLA will deny accreditation to a lab if it intentionally refers a PT specimen to another laboratory for analysis. COLA will not accept reapplication for one year.

Any laboratory receiving PT specimens from another lab for testing must notify CMS of the receipt of those samples. Failure to notify CMS may result in revocation of the receiving laboratory’s CLIA certificate. COLA will deny accreditation to a lab if it intentionally accepts a PT specimen from another laboratory for analysis. COLA will not accept reapplication for one year.

The individual testing the PT specimen and the laboratory director must sign an attestation statement that PT specimens are tested in the same fashion as patient specimens. Retain all PT records for two years.

These COLA criteria are directly related to this lab director responsibility:

PT 6 E

Does your laboratory policy prohibit communication with another laboratory to discuss PT results, for both regulated and unregulated

analytes, prior to the cut-off date for submission of test results for that event?

No communication is allowed prior to the cut-off date for submission of test results for that event.

PT 7 E

Does your laboratory policy prohibit sending any PT samples to another laboratory for analysis?

This includes PT for regulated, unregulated, waived, and non-waived tests. Sending PT samples to another laboratory to be tested is a direct violation of the CLIA regulations and will result in loss of your CLIA certificate.

KEY TIPS: How can this responsibility be met?

- Select an approved PT provider that meets your needs.
- Maintain continuous enrollment in a PT program.
- Make sure testing personnel understand all the rules and requirements for testing PT samples, and the importance of submitting results on time.
- Review, initial, and date all PT reports and evaluate your lab’s performance.
- Require staff to investigate any unacceptable results and any results that do not reflect the lab’s performance (see COLA criterion PT 10) and to take corrective action when needed. Review, approve, initial, and date all PT failure investigations conducted by your staff.
- Retain documentation of all PT activities for 2 years.

RESOURCES:

1. COLA Accreditation Manual (revised June 2013) p. 66
2. COLA Accreditation Manual (revised June 2013) p. 68

Important Information For You and Your Laboratory Director

EDUCATION STARTS NOW... PREPARE AS IQCP REPLACES EQC

Register today for this one-day interactive educational workshop on Individualized Quality Control Plan (IQCP).

CRI®'s IQCP Workshop Series comes to the Sheraton Columbus at Capitol Square

Prepare to implement the new Centers for Medicare & Medicaid Services (CMS) IQCP Interpretive Quality Control Guidelines.

Date: Tuesday, July 15, 2014

Time: 8:30am – 4:00pm

Location: Sheraton Columbus at Capitol Square

75 East State Street

Columbus, OH 43215



Presenters include Keynote speakers from leading Accrediting Organizations (CMS and COLA)!

This full day workshop offers six (6) P.A.C.E.® credits.

Topics include:

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

Registration: Non-COLA Members— \$249 • COLA Members — \$199

Continental breakfast & lunch will be provided.

To register, visit www.criedu.org or www.labuniversity.org or call CRI® at 1-800-981-9883.



COLA Resources, Inc.
Leading Excellence in Laboratory Medicine

9881 Broken Land Parkway, Suite 215
Columbia, MD 21046-1195
Phone 1.800.981.9883 | Fax 410.381.8611
www.CRledu.org

LAB DIRECTOR RESPONSIBILITIES

LDR 5 E Does the Laboratory Director meet the Quality Control and Quality Assessment Responsibilities of the position?

QC and QA Responsibilities fall first on the Laboratory Director as the leader of the laboratory. It is the QC/QA activities that provide the quantitative and qualitative analysis of the performance of your laboratory on a day to day basis.

- Ensure that Quality Control and Quality Assessment programs are established and maintained to identify failures in quality as they occur.

As the Laboratory Director it is their responsibility to develop comprehensive policies and procedures for the performance and acceptability of quality control. This will come from diligent research of testing protocols, communicating with the staff and with your Accrediting Organization. According to CMS “The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. The laboratory must document all general laboratory systems quality assessment activities.”¹

For each non-waived test on the lab menu, decide whether to follow the CLIA default QC requirement or to develop and implement the Individualized Quality Control Plan (IQCP). See: http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Individualized_Quality_Control_Plan_IQCP.html

- Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system.

This criterion is one that is reflective of the specific testing in your laboratory. Many things can influence test systems: volume and frequency of testing, and environmental conditions to name a few. You have to identify what is acceptable performance in your laboratory. This process of seeing what works best for your lab must always take into consideration the manufacturer’s instructions for the test system. Your QC must remain compliant as part of this process.

Review QC regularly to confirm that policies and procedures are being followed by all staff. Develop and implement a quality assessment plan that monitors the overall quality of the total testing process and ensures continuous improvement of the laboratory’s performance and services. Included in a good QA process is identification of process deviation, corrective action to ensure deviation will not repeat, COMMUNICATION to staff on the issue and

corrective action. It would be aligned with best practices to also include a copy of the communication.

- Ensure that remedial actions are taken and documented whenever significant deviations from the laboratory’s established performance characteristics are identified, and that patient test results are reported only when the system is functioning properly.

The LD is responsible for establishing written policies and procedures for evaluating performance specifications. Specify the remedial actions to take when they are not met.

Make sure laboratory policy states that patient results are not to be reported when the test system is not functioning properly (i.e., QC is out of range). Also include guidance to repeat any patient specimen testing performed when QC was out of range. Document and verify that all staff follows this policy.

Review and initial quality control results, graphs, and problem logs regularly and verify that appropriate remedial actions are performed and documented.

KEY TIPS: How can the Quality Control and Quality Assessment responsibilities be met?

- Develop comprehensive policies and procedures for the performance and acceptability of Quality Control.
- Assure that appropriate technical staff review QC regularly to confirm that policies and procedures are being followed by all staff.
- Assure that appropriate technical staff review and initial Quality Control results, graphs, and problem logs regularly, and verify that appropriate remedial actions are performed and documented.
- Develop and implement a Quality Assessment plan that monitors the overall quality of the total testing process and ensures continuous improvement of the laboratory’s performance and services.
- Assure that QA reviews are effective at identifying and preventing errors, and that corrective actions are followed up for effectiveness.
- Establish written policies and procedures for evaluating performance specifications. Specify the remedial actions to take when they are not met.
- Make sure laboratory policy states that patient results are not to be reported when the test system is not functioning properly (i.e., QC is out of range, etc.). Ensure that all staff follow this policy.

RESOURCES:

1. CMS § 493.1239 Standard: General laboratory systems quality assessment.
<http://www.gpo.gov/fdsys/pkg/CFR-2003-title42-vol3/xml/CFR-2003-title42-vol3-part493.xml#seqnum493.1239>



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

CRI[®] Mission: "Provide educational and consultative services aimed at improving laboratory medicine and patient care."

CRI[®] Individualized Quality Control Program (IQCP)

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

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

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

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

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

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

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

The Program Portfolio Includes:

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

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

LAB DIRECTOR RESPONSIBILITIES

LDR 6 R Laboratory Director Continuing Education Program

The COLA Accreditation criteria will soon be changed to include the requirement for Laboratory Directors to complete a minimum of four (4) continuing education credits (CME or P.A.C.E.) every two years. As a COLA Accredited laboratory you may have recently received a Technical Bulletin “2014-3: New Survey Criteria - LDR 6 R” outlining the process.

In the clinical laboratory setting, whether part of a physician’s office laboratory or the hospital clinical laboratory, good laboratory practice and quality patient care are key objectives. The Laboratory Director is among the key personnel who play a major role in achieving these objectives. The Laboratory Director is responsible for the overall operation of the lab, and the competency of all laboratory personnel. Lab Director responsibilities fall into five major categories: (1) General Duties; (2) Procedural Duties; (3) Personnel Duties; (4) Proficiency Testing Duties; and (5) Quality Control Duties.¹

The new COLA criterion, LDR 6, will be effective when the revised Accreditation Manual is published in the spring of 2014, and reads as follows:

LDR 6 R *Has the Laboratory Director completed, within the last two years, four continuing education credits (CME or PACE) from the COLA Laboratory Director Continuing Education Program (LDCEP), or other equivalent laboratory director education program?*

Due to the significance of the CLIA-defined responsibilities of the Laboratory Director, COLA requires all Laboratory Directors, except those who have completed the qualifying requirements for this position within the last two years, to complete four education credits biennially. To ensure that COLA Laboratory Directors are able to meet this new requirement, the LDCEP continuing education modules are free of charge for COLA labs, and are available through LabUniversity via a link on COLACentral®.

To enroll in the COLA courses, go to www.colacentral.com, look under the “Education/Resources” tab > Select menu item “Lab Director Continuing Education for COLA Labs.” This takes you to the description page on LabUniversity. Only one bundle is required over a two year period, and new bundles will be added to the current offering. Each LD may **enroll in one** of the following Laboratory Director Continuing Education course programs: LDCEP1, LDCEP2, LDCEP3 or LDCEP4. Each of these modules is four (4) CME credits. To take the course you must create an account on www.LabUniversity.org. Once you have selected the course from the LabUniversity catalog on “Your Shopping Cart” page you must key in the Coupon

Code “LDCEP” to take the course for free.

As Laboratory Directors you have the choice to earn continuing education hours from a multitude of sources. Attending webinars, symposiums, lectures, or other means of education may be applicable for meeting the COLA LDR 6 criterion. Continuing education credits from other sources will be accepted as long as the subject matter is relevant to the CLIA-defined Laboratory Director responsibilities.

COLA believes in “Accreditation through Education.” Our goal is to provide COLA laboratories with the educational tools they need to succeed in not just accreditation, but also providing quality patient care.

RESOURCES:

1. COLA Technical Bulletin 2014-3: New Survey Criteria - LDR 6 R

COLA Technical Bulletin

2014-3: New Survey Criteria - LDR 6 R

COLA is adding a new criterion to the Laboratory Director criteria grouping, requiring four continuing education credits related to Laboratory Director responsibilities, every two years for Laboratory Directors.

In the clinical laboratory setting, whether part of a physician's office laboratory or the hospital clinical laboratory, good laboratory practice and quality patient care are key objectives. The Laboratory Director is among the key personnel who play a major role in achieving these objectives. The Laboratory Director is responsible for the overall operation of the lab, and the competency of all laboratory personnel. Lab Director responsibilities fall into five major categories: (1) General Duties; (2) Procedural Duties; (3) Personnel Duties; (4) Proficiency Testing Duties; and (5) Quality Control Duties.

The new COLA criterion, LDR 6, will be effective when the revised Accreditation Manual is published in the spring of 2014, and reads as follows:

LDR 6 R *Has the Laboratory Director completed, within the last two years, four continuing education credits (CME or PACE) from the COLA Laboratory Director Continuing Education Program (LDCEP), or other equivalent laboratory director education program?*

Due to the significance of the CLIA-defined responsibilities of the Laboratory Director, COLA requires all Laboratory Directors, except those who have completed the qualifying requirements for this position within the last two years, to complete four education credits biennially. To enroll in the COLA courses, go to www.colacentral.com and enroll in one of the following Laboratory Director Continuing Education course modules: LDCEP1, LDCEP2, or LDCEP3. Each of these modules is four credits. Continuing education credits from other sources will be accepted as long as the subject matter is relevant to the CLIA-defined Laboratory Director responsibilities.

The LDCEP continuing education modules are free of charge for COLA labs, and are available through COLAcentral®.

To access the continuing education modules:

1. Go to www.colacentral.com
2. Log onto the COLAcentral® website.
3. Go to "Education/Resources". Select "Lab Director Continuing Education for COLA Labs".
4. This takes you to the description page on LabUniversity.
5. Choose the program you wish by clicking the "Purchase" button.
6. This takes you to the LabUniversity Login page. Click "Start Browsing" to enter the catalog.
7. Again choose the program you want and add it to the cart.
8. Proceed to your Cart.
9. On this page, you must enter the Coupon Code "**LDCEP**" and click "Apply" for the discount to be applied.
10. The Purchase total will go to zero.
11. Proceed to Checkout. Either Sign In on the Information page if you are a current learner on LabUniversity or you may Create a New Account.

COLA CRITERIA UPDATE

LIVE Webinar with Kathy Nucifora, MPH, MT(ASCP),
Accreditation Division Manager, COLA

Wednesday, June 18, 2014 | 2:00-3:00PM EST



Kathy Nucifora, MPH,
*MT(ASCP), Accreditation
Division Manager, COLA*

The clinical laboratory environment is continually evolving. This webinar will help your lab keep up to date with COLA requirements for accreditation, as well as understand the drivers for change in laboratory medicine. This webinar will also address IQCP and Required responses and Cease Testing Enforcement for PT failures. Get the latest information on current and upcoming revisions right from COLA's Accreditation Division Manager. This webinar offers one (1) P.A.C.E.® credit. Registration is now open!

Registration

Non-COLA Members - \$99

COLA Members - \$85

[Register Now](#)



COLA Resources, Inc.
Leading Excellence in Laboratory Medicine

9881 Broken Land Parkway, Suite 215

Columbia, MD 21046-1195

Phone 1.800.981.9883 | Fax 410.381.8611

www.CRledu.org | www.labuniversity.org

Meeting Laboratory Director Responsibilities

A handy reference guide of methods Laboratory Directors can use to meet the COLA LDR Criteria

General Responsibilities	How can I meet this responsibility?
<p>Must be accessible to the laboratory to provide onsite, telephone or electronic consultation as needed.</p> <p>May direct no more than five nonwaived labs.</p> <p>Ensure that the physical and environmental conditions are appropriate for the testing performed and provide an environment safe from physical, chemical, and biological hazards.</p> <p>Ensure compliance with all applicable regulations.</p> <p>Verify that responsibilities that can be delegated are properly performed, if delegated.</p>	<ul style="list-style-type: none"> • Make sure there is enough counter and storage space for testing. Ensure adequate electrical power that includes shock and power surge protection. • Take appropriate safety measures, use warning labels, and provide personal protective equipment. • Monitor environmental conditions (temperature, humidity) that can affect testing. • Review and become familiar with the CLIA regulations or the requirements of your accrediting organization, if applicable. • Review and become familiar with any state or local laboratory regulations that apply to your laboratory. • Get involved in the survey (inspection) process and take advantage of the education that a surveyor can provide.
Procedural Responsibilities	How can I meet this responsibility?
<p>Ensure testing systems provide quality laboratory services for pre-analytic, analytic, and post-analytic phases of testing.</p> <p>Ensure test methods selected have the capability of providing quality results.</p> <p>Ensure verification procedures used are adequate to determine accuracy, precision, and other pertinent performance characteristics of the method.</p> <p>Ensure that reports of test results include pertinent information required for interpretation.</p> <p>Ensure that consultation is available to the laboratory's clients on matters relating to the quality of the test results reported and their interpretation concerning specific patient conditions.</p> <p>Ensure that an approved procedure manual is available to all personnel.</p>	<ul style="list-style-type: none"> • Select test systems carefully and monitor their performance in the pre-analytic, analytic, and post-analytic phases of testing. • Work with suppliers and manufacturers to select test methods with proven accuracy that meet your needs. • Verify that the manufacturer's stated performance characteristics are achieved in your lab (required for all new nonwaived methods added after April 24, 2003). • Review quality control for the test and monitor the test method's performance over time. • Ensure that personnel follow the manufacturer's directions and use good laboratory practices. • Make sure that test reports include all necessary information that could be significant for interpreting the results. For example: <ul style="list-style-type: none"> • Patient sex and age • Time of last dose for medication levels • The source of the specimen • If the patient was fasting • LMP for Pap Smears
<p>Ensure that laboratory personnel are performing the test methods as required for accurate and reliable results.</p>	<ul style="list-style-type: none"> • Be available to discuss laboratory results with patients. • The procedure manual must include a procedure for every test performed and be available to laboratory personnel. • Review and sign the procedure manual at least annually and sign, date, and approve new procedures before first use.

Personnel Responsibilities	How can I meet this responsibility?
<p>Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise, and accurately perform tests and report test results.</p>	<ul style="list-style-type: none"> • Get involved in the hiring of personnel and make sure they have the necessary education and experience. • Evaluate the volume of testing performed, the number of testing personnel, and turn-around times.
<p>Ensure that prior to testing patient specimens, all personnel have the appropriate education and experience, and receive the appropriate training for the type and complexity of services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.</p>	<ul style="list-style-type: none"> • Provide personnel with training for the duties and testing that will be performed. • Observe personnel as they perform pre-analytic, analytic and post-analytic phases of testing. • Verify that all personnel have documentation of the necessary education and experience.
<p>Have a written list of responsibilities of each individual in the laboratory that specifies the level of activity each is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.</p>	<ul style="list-style-type: none"> • Provide personnel with training for the duties and testing that will be performed and ensure that the training is adequate. • Develop job descriptions for all laboratory personnel and keep up to date. • Assign, in writing, the duties/responsibilities to each person involved in all phases of the testing process and keep the list of assigned duties current.
<p>Ensure that policies and procedures are established for monitoring individuals who conduct pre-analytic, analytic, and post-analytic phases of testing to verify that they maintain competency to process specimens, perform test procedures, and report test results promptly and proficiently.</p>	<ul style="list-style-type: none"> • Establish standards for personnel performance and conduct personnel competency assessments (every 6mo for 1st year & annually thereafter). • Require and provide remedial training when needed.
<p>Whenever necessary, identify needs for remedial training or continuing education to improve skills.</p>	<ul style="list-style-type: none"> • Provide opportunities for continuing education.
<p>Ensure that a general supervisor provides on-site supervision of high complexity test performance by certain testing personnel.</p>	<ul style="list-style-type: none"> • High complexity directors must employ a general supervisor and that person must be onsite when high complexity testing is performed by individuals that require supervision as described in the CLIA regulations [individuals who qualified for high complexity testing via Sec. 493.1489(b)(4).]

>> CONTINUED ON PAGE 24

MEETING LABORATORY DIRECTOR RESPONSIBILITIES

PT Responsibilities	How can I meet this responsibility?
<p>Ensure that the laboratory is enrolled in an approved proficiency testing (PT) program.</p>	<ul style="list-style-type: none"> • Select an approved PT provider that meets your needs. • Maintain continuous enrollment in a PT program. • Make sure lab staff understands all the rules and requirements for testing PT samples, and the importance of submitting results on time. • Review, initial, and date all PT reports and evaluate your lab's performance. • Investigate any unacceptable results and any results that do not reflect the lab's performance and take corrective action when needed. • Retain documentation of all PT activities for 2 years.
<p>Ensure that PT samples are tested in the same manner as patient samples.</p>	
<p>Ensure that PT results are returned on time to the PT program.</p>	
<p>Ensure that PT results are reviewed by the appropriate staff and the corrective action plan is followed when PT results are found to be unsatisfactory.</p>	
QC and QA Responsibilities	How can I meet this responsibility?
<p>Ensure that quality control and quality assessment programs are established and maintained to identify failures in quality as they occur.</p>	<ul style="list-style-type: none"> • Develop comprehensive policies and procedures for the performance and acceptability of quality control. • For each nonwaived test on the lab menu, decide whether to follow the CLIA default QC requirement or to develop and implement IQCP. See: http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Individualized_Quality_Control_Plan_IQCP.html • Review QC regularly to confirm that policies and procedures are being followed by all staff. • Develop and implement a quality assessment plan that monitors the overall quality of the total testing process and ensures continuous improvement of the laboratory's performance and services. • Make sure that QA reviews are effective at identifying and preventing errors, and corrective actions are followed up on for effectiveness. • Establish written policies and procedures for evaluating performance specifications. Specify the remedial actions to take when they are not met. • Make sure laboratory policy states that patient results are not to be reported when the test system is not functioning properly (i.e., QC is out of range). Verify that all staff follows this policy. • Review and initial quality control results, graphs, and problem logs regularly and verify that appropriate remedial actions are performed and documented.
<p>Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system.</p>	
<p>Ensure that remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified, and patient test results are reported only when the system is functioning properly.</p>	



COLA chosen as first private laboratory organization to receive state deeming authority in CA.

COLA, an internationally-respected, non-profit clinical laboratory accreditation organization has been awarded deemed status from Laboratory Field Services (LFS) in California.

Clinical Laboratories in California can now choose COLA for their laboratory accreditation. Laboratories in CA that are accredited by COLA under its deeming status and who pass their surveys will meet state and federal requirements. **Thus CA laboratories can meet dual requirements with one accreditation.**

COLA's Accreditation Program in CA is centered on 5 key components:

- 1 A focus on ongoing education
- 2 Customer support line
- 3 Continuous Quality Advisors
- 4 COLAcentral, a real-time web portal to enable labs to track their accreditation status and manage lab operations more efficiently
- 5 Consultative approach

COLA knows California

COLA is the first private laboratory organization to receive deemed status by LFS due to its in-depth knowledge of California's unique clinical laboratory licensure laws and its experience accrediting 8,000 laboratories nationally and nearly 500 in California.

The laws and regulations in this state are complex and continually evolving. COLA keeps current on changes and can help guide you to ensure that you are in compliance with state mandates.



To learn more call 800-981-9883 or go to COLA's dedicated California web portal:
www.cola.org/CA

inSights SPOTLIGHT: LABORATORY EXCELLENCE AWARD



As a new feature in **COLA inSights** COLA will be featuring a laboratory that has shown excellence not only in their compliance with accreditation standards, but also overall high quality patient care. COLA Accredited laboratories that meet the Laboratory Excellence Award (LEA) criteria in their past survey have had no citations; no unsuccessful Proficiency Testing (PT) for any regulated analyte/subspecialty/specialty for the past 2 years, and had no substantiated complaints for the past 2 years.

About the Lab:

Night Lite Pediatrics Urgent Care is the leading practice for outpatient urgent medical care of children and adolescents needing emergency services in the evenings and weekends in Central Florida. Night Lite Pediatrics is managed by board certified, critical care doctors. There are nine Central Florida locations, open until midnight every day of the year.

This location has received the Laboratory Excellence Award for the third consecutive year. Night Lite Pediatrics Urgent Care is the fastest growing pediatric urgent care in Florida, seeing over 50,000 patients annually. This year is Night Lite Pediatrics' 10 Year Anniversary.

Night Lite Pediatrics provides rapid diagnosis and care, including on-site laboratory and radiology services, a patient observation area, procedure rooms for the treatment of

lacerations and fractures, IV access and spinal taps. The centers treat minor broken bones, lacerations, sprains, fevers, diarrhea, vomiting, dehydration and ear, nose and throat infections. Night Lite Pediatrics also treats children with asthma and respiratory illnesses, as well as chronic illnesses such as diabetes, cystic fibrosis, Crohn's disease and colitis.

**CONGRATUALIONS TO THE
STAFF AT NIGHT LITE
PEDIATRICS! KEEP UP THE
GREAT WORK!**

NIGHT LITE PEDIATRICS URGENT CARE

Oviedo, FL

Laboratory Director:
Ayodeji Otegbeye, MD

Laboratory Manager: Tejal V. Desai



CRI®'s LabUniversity™ is enhancing our Learning Management System (LMS) platform!

LabUniversity™ is introducing a new, innovative and responsive user interface that adapts to different hardware devices- from conventional desktops and laptops to mobile devices such as iPads, tablets, and smartphones!

The New LabUniversity™ will work across a wide variety of platforms:

- Windows
- Mac
- Linux
- iOS (iPads, iPhones)
- Android
- Blackberry
- Windows Phone

Now you can take many of our courses, purchase educational materials, and watch live and archived webinars from anywhere on just about any device. Begin a course on one device at work and finish it up later right where you left off on a different device at home.

Exciting Features:

- Our new platform will allow for our cutting edge curriculum to be added more quickly to an already expansive set of choices. So the latest and greatest in educational material will be right at your fingertips in the coming months
- An updated dashboard upon login that allows you to immediately pick up where you left off with just one click
- Updated course interface with easier recognition of what's been completed and where you are currently
- Instant connections to vital news and information from COLA Resources Inc.

Please note that this transition is occurring this month and LabUniversity™ will be inaccessible over the weekend **beginning Friday, January 24.**

Rest assured that any courses started before the transition will automatically be saved and can be resumed and available for access once the transition is **complete Monday, January 27!**

Once the transition is complete, feel free to browse our course catalogue, view content and continue learning with CRI®. We appreciate your patience during this transition and welcome you to the new LabUniversity™. *A Quality Solution for Busy Professionals...*



COLA Resources, Inc®
Leading Excellence in Laboratory Medicine

9881 Broken Land Parkway, Suite 215
Columbia, MD 21046
Phone: 1.800.981.9883 | Fax: 410.381.8611
www.CRIedu.org

COLA Salutes Medical Laboratory Professionals

A Salute to Laboratory Professionals, Yesterday and Today

Medical Laboratory Professionals Week (MLPW), held annually during the last full week of April, is a celebration of the medical laboratory professionals and pathologists who play a vital role in health care. MLPW is a time for medical laboratory personnel to celebrate their professionalism and be recognized for their efforts. It affords an opportunity to inform and educate medical colleagues and the public about the medical laboratory and the impact of these dedicated, skilled professionals have on the quality of overall patient care.

Because lab personnel often work behind the scenes, few people know much about the critical testing they perform every day. Fewer still have an understanding of the industry's long and proud tradition, dating back to the early 1900s. What follows is a short history of the profession's beginnings, including profiles of several laboratory industry "pioneers." We honor their contributions and those of thousands of other laboratorians as we observed MLPW!

HISTORY OF THE PROFESSION

The medical laboratory profession formally began in the 1920s, following the invention and widespread use of diagnostic tools such as the microscope; prior to that most lab testing was performed by physicians. In the late 1890s, some medical professionals even argued that hospital labs were scientific "luxuries," requiring too much space and expense to administer, and that clinical tests were too time consuming to conduct. In a 1900 article in the *Journal of the American Medical Association*, Dr. Charles Nicoll Bancker Camac, Director of the Laboratory of Clinical Pathology at Cornell University, defended the need for hospital labs, refuting such popular misconceptions as patients might accidentally drink poisonous

laboratory reagents, or staff members might appropriate laboratory apparatus for their personal use. Camac went on to suggest that "the maintenance of the laboratory can well be accomplished on \$50 a year!"¹

Early laboratory technicians received on-the-job training under the direct supervision and tutelage of hospital pathologists. In 1928, the American Society of Clinical Pathologists established a standing committee called the Board of Registry whose purpose was to establish requirements for lab technician certification. In 1933, this group published a list of 34 accredited "schools." Most students entering these hospital-based programs were high school graduates. The earliest programs included those at University of Wisconsin, University of Minnesota, and University of Texas Medical Branch.^{2,3,4}

Many of the pioneers of the profession in the America were actively involved in education, and helped to advance the profession by expanding academic programs dedicated to laboratory medicine. Following are some notable examples:

WALTER REED (1851 – 1902), was born in Harrisonburg, Virginia, the youngest child of



a family of five whose father was a Methodist minister. Reed studied medicine at the University of Virginia, obtaining his

M.D. at the age of 18 - the youngest medical graduate then known. A promotion to Captain in the U.S. Army brought him to Baltimore and gave

him the opportunity to undertake further study at Johns Hopkins University.

In 1893 Reed was appointed curator of the Army Medical Museum and Professor of Bacteriology and Clinical Microscopy at the Military Academy in Washington. With the outbreak of the Spanish-American War in 1898 he applied for active service and was posted for duty in Cuba, first to study typhoid and subsequently as Director of Yellow Fever Commission. In 1901 he led the team that postulated and confirmed the theory that yellow fever is transmitted by a particular mosquito species, rather than by direct contact. This insight gave impetus to the new fields of epidemiology and biomedicine, and most immediately allowed the resumption and completion of work on the Panama Canal (1904–1914) by the United States.

Sadly, one year after his return trip from Cuba, Major Reed died from peritonitis following an appendectomy performed by his friend, Major William C. Borden, Commander of the Army General Hospital. Following Reed's death, Borden became dedicated to seeing the completion of a new hospital which would co-locate the Army hospital, the Army Medical School, the Army Medical Museum and the Surgeon General's Library. Borden was instrumental in naming the new hospital in the Nation's capital Washington, D.C. after his friend, Major Walter Reed.

EMMA PERRY CARR (1880–1972), was born in Holmesville, Ohio. Her father and grandfather, both country doctors, valued and encouraged education for their children. After Carr graduated from high school, she entered Mount Holyoke College, a women's college in Massachusetts. After earning her Ph.D. in 1910 she returned to Mount Holyoke

>> CONTINUED ON PAGE 30

SYMPOSIUM

FOR CLINICAL LABORATORIES

Education for Laboratory Excellence

October 15-18, 2014
Buena Vista Palace Hotel & Spa

ORLANDO



REGISTER TODAY FOR CRI®'S ANNUAL SYMPOSIUM FOR CLINICAL LABORATORIES!

October 15-18, 2014
Buena Vista Palace Hotel & Spa
1900 E Buena Vista Drive,
Lake Buena Vista, Florida 32830

At CRI®'s Symposium for Clinical Laboratories, attendees participate in EDUCATION FOR LABORATORY EXCELLENCE - making a positive impact for quality patient care. Participants can attend a wide selection of educational sessions, **earn up to 20 CME or P.A.C.E® credits**, network with other healthcare professionals and visit the exhibit hall featuring the latest laboratory technology, equipment and supplies.

Continuing Education for the Clinical Laboratory Professional

The CRI® Symposium for Clinical Laboratories provides the opportunity to meet personal, professional, and organizational goals at a reasonable cost. The Symposium is designed to provide physicians, laboratory directors, technical consultants, laboratory managers, testing personnel, and other healthcare professionals with continuing education that's critical to operating a successful and compliant medical diagnostic laboratory. The educational sessions will offer:

- Continuing education to enhance competency and maintain state licensure
- CME credits for physicians to qualify as laboratory director for a moderate complexity laboratory, as outlined by CLIA
- Tools assisting in:
 - Meeting the requirements of CLIA, COLA, and other accrediting organizations
 - Improving laboratory processes and procedures
 - Preventing laboratory errors
 - Improving efficiency and promoting quality in laboratory operations

PLAN NOW! ATTEND THIS EDUCATIONAL EVENT!
WWW.CRIEDU.ORG/SYMPOSIA



COLA Resources, Inc®
Leading Excellence in Laboratory Medicine

9881 Broken Land Parkway, Suite 215
Columbia, MD 21046-1195
Phone 1.800.981.9883 | Fax 410.381.8611
www.CRledu.org

COLA SALUTES MEDICAL LABORATORY PROFESSIONALS WEEK



to join the faculty. Mount Holyoke had a long tradition of training women chemists, and Carr set out to make the

program even stronger. She personally taught freshman general chemistry, a task that would normally have fallen to a junior instructor, so she could ensure the students' first exposure to chemistry was one that would impress and inspire. Even so, Carr felt that the influence of a good classroom teacher was not enough. Students, she believed, should be engaged in real, hands-on research in order to understand and appreciate how chemistry works. To this end, she initiated a research program at Mount Holyoke. Her work led to a better understanding of the nature of double bonds between carbon atoms in molecules.

ERNEST EVERETT JUST (1883 – 1941), born in Charleston, South Carolina, was an African-American biologist and educator who pioneered many areas on the physiology of development, including fertilization, experimental parthenogenesis, hydration, cell division, dehydration in living cells and ultraviolet carcinogenic radiation effects on cells.



It was during his university years at Dartmouth College that Just discovered an interest in biology after reading a paper on fertilization

and egg development. He graduated as the sole magna cum laude student in 1907, also receiving honors in botany, sociology and history. Just's first job out of college was as a teacher and researcher at the traditionally

all-black Howard University. Later, in 1909, he worked in research at Woods Hole Marine Biological Laboratory in Massachusetts. Just furthered his education by obtaining a Doctor of Philosophy degree from the University of Chicago, where he studied experimental embryology and graduated magna cum laude.

“We feel the beauty of nature because we are part of nature and because we know that however much in our separate domains we abstract from the unity of nature, this unity remains. Although we may deal with particulars, we return finally to the whole pattern woven out of these.”
– Ernest Everett Just

HOW FAR THE PROFESSION HAS COME

Today, more than 300,000 medical laboratory professionals around the country perform and interpret some ten billion laboratory tests in the U.S. every year. Medical laboratory scientists analyze a wide array of test results and relay them to physicians and other members of the health care team. They perform complex tests, including chemical, biological, hematological, immunologic, microscopic and bacteriological, requiring expert training, and exceptional analytical skills.

Indeed, laboratorians play an increasingly vital role in the diagnosis and prevention of disease and are considered “a key member of a health care team,” according to the American Society of Clinical Laboratory Science.” Lab testing has an estimated impact on over 70 percent of medical decisions, a percentage that will only grow as baby boomers retire and preventive coverage – including screening tests

performed by labs – increases as part of federal healthcare reform.

Accordingly, the job forecast for MLS graduates is very positive. According to the Bureau of Labor Statistics, “Employment of medical laboratory scientists is expected to grow by 14 percent between 2008 and 2018, faster than the average for all occupations. The volume of laboratory tests continues to increase with both population growth and the development of new types of tests.”⁶

CONCLUSION

MLPW is an event in which all laboratorians can participate. Many members plan displays, host open houses, talks at local schools, and various other activities in their institutions or local areas. Some labs obtain proclamations by mayors or governors, while others seek coverage of their many accomplishments on local TV and radio stations.

Whatever activities your lab plans each year, take MLPW and every week, to educate patients about the vital work of laboratories and the critical role they play on the healthcare team. All of us in this industry – including those who pioneered our way – chose this profession for the same reason: to provide accurate test results, thus ensuring quality patient care. Share what you love about laboratory medicine, encourage more people to join us and celebrate the great work done we do each day!

FUN FACTS ABOUT MEDICAL LABORATORY SCIENCE IN THE UNITED STATES

- The North Port forensic laboratory in North Port Florida is the oldest forensics laboratory in the U.S, established since 1789.⁷
- Founded in 1919, Shiel Medical Laboratory is one of the oldest continuously operating clinical laboratories in the United States, and the largest privately held laboratory in New York.⁸

- In 1925, the University of Wisconsin General Hospital established one of the earliest laboratory training programs in the nation. Medical Technology became an undergraduate major at the University of Wisconsin-Madison in 1936 and continued until the program's close in 2012.⁹
- The CLS program at the University of Minnesota is the oldest baccalaureate medical laboratory educational program in the United States, with the first students graduating in 1923.¹⁰
- The American Society for Clinical Pathology (ASCP) is the world's largest professional membership organization for pathologists and laboratory professionals. Their mission is to provide excellence in education, certification and advocacy on behalf of patients, pathologists and laboratory professionals across the globe. With more than 100,000 members, the society's influence has guided the application and evolution of the pathology and laboratory medicine specialty since 1922.¹¹
- The American Society for Clinical Laboratory Science (ASCLS) — previously the American Society for Medical Technology (ASMT) — reflects our professional association's many contributions to the profession and practitioners in clinical laboratory science, organized in 1933 and incorporated in 1936.¹²
- Medical Laboratory Professionals Week originated in 1975 as National Medical Laboratory Week, or NMLW, under the auspices of the American Society for Medical Technology, now called the American Society for Clinical Laboratory Science (ASCLS).¹³

RESOURCES:

1. F. William Sunderman, Sr. The History of Proficiency Testing/Quality Control Clinical Chemistry July 1992 vol. 38 no. 7 1205-1209. <http://www.clinchem.org/content/38/7/1205.long>
2. <http://www.pathology.wisc.edu/education/cls>
3. <http://cahp.umn.edu/CLS>
4. <http://shp.utmb.edu/cls/history.asp>
5. <http://ascls.org/about-us/celebrate/medical-lab-professionals-week>
6. <http://stats.bls.gov/opub/mlr/2009/11/art5full.pdf>
7. http://wiki.answers.com/Q/Which_city%27s_police_department_boasts_the_oldest_forensic_laboratory_in_the_US
8. http://www.shiel.com/about_shiel
9. <http://www.pathology.wisc.edu/education/cls>
10. <http://cahp.umn.edu/CLS>
11. <http://ascp.org/About-the-ASCP>
12. <http://ascls.org/about-us/ascls-history>
13. <http://ascls.org/about-us/celebrate/medical-lab-professionals-week>