

COLA'S

inSights

INTO *COLA Updates*



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FROM THE CHAIR

“Everything on this earth is in a continuous state of evolving, refining, improving, adapting, enhancing ... changing.”

— Steve Maraboli, PhD, author of *Life, the Truth, and Being Free*

This exemplifies COLA’s philosophy. We continually strive to revise and improve our processes to ensure that our service is the best that it can possibly be. Many changes occur behind the scenes before we can announce a new development. Recent enhancements (such as our newly launched educational platform, and the sleek new look of our websites) involved months of unseen work before the current versions would be visible.

We didn’t even change to our new tagline, *Accreditation, Education, Innovation*, without several committee discussions and reviews.

Accreditation: In this edition of *Insights*, we announce several improvements to our accreditation criteria. Most of the articles in this issue concentrate on these revisions.

Education: Education has been the focus of several recent improvements. As mentioned, we launched a new platform to host our online education courses and products; this year also marked the beginning of a new approach to offering webinars; and we continually strive to enhance your experience while attending our *Symposium for Clinical Laboratories*. In another article in this issue, we solicit your help to continue to improve our educational offerings.

Innovation: From ongoing additions to *COLAcentral* to the launch of the *Myconsultantcentral* “yellow pages,” COLA endeavors to offer innovative methods to help you provide quality patient care. The process is continuing even now as we explore several new innovative strategies to enrich our services. Details on the latest strategy, the concept of continuous quality, will be released soon.

We know that in some circumstances, change can be unnerving. However, none of our changes can happen without you. We depend on your feedback, comments, and suggestions to know what areas to target and where to make improvements. Still, throughout it all, one thing remains unchanged: our commitment to provide you with the highest service possible to help you provide the best possible care to your patients.

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



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.

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Criteria Updates

As part of our commitment to provide the best possible service, COLA has been reviewing and revising our accreditation criteria. The process, which began several months ago, can be likened to how seeds grow and develop to become fruit-bearing trees. Many things have happened without you being aware of them.

This article details updates to COLA criteria that take effect **June 18, 2012**. Many of these are very minor: punctuation and grammar modifications, and updating to the use of current terminology. Some criteria were changed so the wording more accurately reflects their intent. For some criteria, the annotation (the clarifying information) was updated while the wording of the criteria itself remained the same. Finally, some criteria were updated to reflect the current interpretation of the CLIA** regulations.

Since some updates require more explanation, subsequent articles in this edition of *Insights* provide more details on these criteria. This issue also includes a Technical Bulletin that can be printed and kept for reference.

MINOR UPDATES

The following table lists the criteria that were updated to correct grammar, punctuation, and/or current terminology changes.

For a complete listing of all modified criteria, see page 14.

Type of change	Criteria
Change in punctuation and/or sentence structure	FAC 9 & 16 QC 1 & 21 PST 20 QA 3, 5 & 6
Change in terminology "Reference range" replaces "Normal range"	PRE 7 APM 15 VER 4 & 8 PST 16 QA 12
"Critical values" replaces "Alert (panic) values"	APM 15 & 18 PST 20
"Parameters" replaces "Indices"	QC 16
Website correction	QC 10

* CMS is the abbreviation for the Centers for Medicare and Medicaid Services.

** CLIA is an abbreviation for the Clinical Laboratory Improvement Amendments of 1988.



>> CONTINUED ON PAGE 4

CRITERIA UPDATES

SPECIFIC UPDATES

The changes to these criteria were more detailed, but most were edited so the wording reflects current interpretation and practice. For some, the criterion itself was modified. For others, only the annotation was modified. Still others reflect changes in both the criterion and the annotation. In each case, the changes are underlined.

Evaluation Grouping: Personnel (PER)

Since citations in the Personnel grouping continue to be among our Top Ten citations, modifications to these criteria help clarify ways to comply with them. Additional information on PER 3 and Competency Assessment can be found in subsequent articles.

PER 2 Reason for update: Emphasizes the need to fill all required positions.

PER 2 Are all required positions for your laboratory filled and are all the individuals filling those positions qualified by education and experience?

If your state has more stringent personnel standards or licensure requirements than CLIA and COLA, the laboratory director must ensure that all personnel meet these requirements.

There must be a qualified individual designated for each of the positions specified in CLIA based on the complexity of your laboratory. NOTE: If qualified, the lab director (and others) may fill multiple positions.

PER 3 Reason for update: Reflects the current credentialing practices and provides clarification about what is required.

Please note that COLA follows the guidelines set forth by CMS as to what is acceptable as proof of education and experience. Certification (MT, RN, MLT, MLS, CMA, etc.) alone is not acceptable. A copy of the diploma and/or degree reflecting the highest qualifying level of education is required and must be maintained as part of the personnel file. (For more information, see the article beginning on page 8.)

PER 3 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 the date of graduation. These should be kept in the personnel file for review by the COLA surveyor.

Resumes are sufficient for documenting years of experience.

Foreign credentials must be evaluated by an acceptable credentialing agency for US equivalency. Language translation of documents is not sufficient to meet this requirement.

PER 5 Reason for update: More clearly denotes the CLIA-defined elements of competency assessments. (For more information, see the article beginning on page 10.)

PER 5 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.

>> CONTINUED ON PAGE 5

CRITERIA UPDATES

Methods of competency assessment may include (but are not limited to):

- Direct observation of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing;
- Monitoring the recording and reporting of test results;
- Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records;
- Direct observation of performance of instrument maintenance and function checks;
- Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and
- Assessment of problem-solving skills.

Evaluation Grouping: Facility (FAC)

FAC 13 Reason for update: **Emphasizes the need to protect all who may come in contact with sharps.**

FAC 13 Are all disposable sharps, needles, and syringes safely discarded in a separate, marked container for the protection of employees, patients and custodial staff?

It is important for the laboratory to utilize appropriate devices to prevent potential injury to employees and patients alike. Needles and other sharps must be disposed of in a “sharps container” which is clearly marked “biohazard.”

Ideally, needles should be self-sheathing and the sharps container is one which can be operated with one hand. Sharps containers must be closable, puncture resistant, and leak proof on the sides and bottom. They must be located as close as possible to the immediate area where sharps are used.

Needles should not be removed from syringes or blood tube holders and they should not be recapped, bent or sheared. Recapping needles is only permitted when required by a specific medical procedure, and in this case, a one-handed – scoop technique must be used.

If blood is collected in examining rooms, a sharps container should be in each room. If younger patients may be seen by the practice, this container should be mounted out of the reach of children. As an alternative, a portable phlebotomy tray including a sharps container may be used.



FAC 14 Reason for update: **Since this criterion’s focus is bloodborne pathogens, the references to hazardous chemicals and local fire codes were removed.**

FAC 14 Do you have a bloodborne pathogens exposure control plan?

This is an OSHA requirement and needs to be a written document. You should comply with OSHA requirements for handling bloodborne pathogens, state and/or local requirements for disposal of hazardous waste. You can obtain information from OSHA by calling (202)693-1999. This is OSHA’s general information number.

OSHA requires that all employees receive annual training in this plan.

FAC 15 Reason for update: **Clarifies the intent is to protect employees from exposures.**

FAC 15 Are protective clothing, gloves, masks, eye protection devices, and face shields available to personnel performing tasks that require the use of such articles?

OSHA requires protective clothing to be provided and laundered by the employer. These items of clothing are not to be worn outside of the work area, nor taken home for laundering. Gloves must be worn when performing phlebotomies and when handling containers of regulated body fluids. Masks, goggles, and/or face shields must be made available anytime there is a likelihood of an employee being splashed by blood or another contaminated substance (e.g., when emptying biohazardous waste, cleaning up a spill, etc.)

>> CONTINUED ON PAGE 6

CRITERIA UPDATES

Evaluation Grouping: Proficiency Testing (PT)

PT 8 Reason for update: Emphasizes that to be beneficial, PT reviews should be performed in a timely manner.

PT 8 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.

Evaluation Grouping: Pre-analytic (PRE)

PRE 11 Reason for update: Reflects change in CLIA interpretation: adds requirement to update clients when there are changes in specimen requirements.

PRE 11 Do you have written instructions for specimen collection, labeling, preservation, and conditions regarding specimen transport available for your clients and do you provide updates to your clients as they occur?

You should provide a specimen collection manual to each client who refers tests. This will substantially reduce the chance of invalid results caused by pre-analytic variability.

Evaluation Grouping: Maintenance (MA)

MA 23 Reason for update: Since many facilities have specific departments or qualified personnel who perform maintenance, the reference to “an outside firm” was removed.

MA 23 Are microscopes properly maintained?

Microscopes should be cleaned routinely in addition to any scheduled maintenance. It is particularly important to remove any accumulations of immersion oil from the condenser and objectives with a soft cloth and lens cleaner.

Evaluation Grouping: Calibration (CA)

CA 1 Reason for update: Verifies the need to perform calibration on Hematology analyzers at least every six months.

CA 1 For all non-waived tests and methods, as applicable, is calibration performed at the frequency recommended by the manufacturer or at the frequency determined by the laboratory if more stringent than the manufacturer?

Calibration is the process of method standardization according to manufacturer’s instructions or as determined by the laboratory during verification of performance specifications. This is performed by using calibrators (standards) of the number, type and concentration indicated by the manufacturer to actually set parameters in the instrument as the basis of determining all other test results. Automated cell counters must be calibrated at least every six months.

Evaluation Grouping: Quality Control (QC)

QC 10 Reason for update: Emphasizes that modifications to waived and non-waived tests can lead to the test being reclassified as high complexity.

QC 10 Are manufacturer’s instructions for the use of reagents, controls, and kits followed?

This criterion applies to waived and non-waived testing. Federally waived tests are those that appear on the FDA Internet site (<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfclia/testswaived.cfm>). Laboratories must follow manufacturer’s instructions for waived tests.

CLIA regulations require that waived and non-waived tests be reclassified as non-FDA approved high complexity tests when the laboratory alters or fails to follow the manufacturer’s instructions. When this occurs, the laboratory must comply with all high complexity Personnel requirements, and requirements for Performance Specifications for non-FDA approved tests (see VER 5-11). For non-waived tests, laboratories may elect to use reagents other than those of the test system manufacturer. This does not constitute a modification of the test system; however it does require verification of performance specifications (see VER 1-4).

>> CONTINUED ON PAGE 7

CRITERIA UPDATES

The table below identifies changes which constitute a modification of the FDA approved system. Examples of modifications include but are not limited to: (This table can be found on page 17.)

In addition, waived tests that are modified will be subject to all other requirements for non-waived testing, including, but not limited to Proficiency Testing, Quality Assessment, and Quality Control.

Evaluation Grouping: Post-analytic (PST)

PST 16 Reason for update: Clarifies the criterion by providing an example.

PST 16 Does the report contain: the reference range of the test and other pertinent information for interpretation?

For example, reports should indicate, where applicable for certain therapeutic drug levels, if a sample is a peak level or a trough level.

PST 24, 25, 26 Reason for update: States that either paper or electronic test reports are acceptable.

PST 24 Are all original or exact duplicate test reports, either paper or electronic (from in-house tests and reference laboratories) maintained, stored and preserved for at least two years?

PST 25 Are all immunohematology original or exact duplicate test reports and test records, either paper or electronic (from in-house or reference laboratories) maintained, stored and preserved for at least five years?

PST 26 Are all pathology, gynecologic cytology, and non-gynecologic cytology reports either paper or electronic maintained, stored and preserved for at least 10 years?

Evaluation Grouping: Quality Assessment (QA)

QA 2 Reason for update: Clarifies the intent of the criterion.

Note: QA 1 states that a QA Plan is needed; QA 2 states that the QA Plan must be implemented; QA 3 states that the plan must be monitored for effectiveness.

QA 2 Has the laboratory implemented its Quality Assessment Plan and performed ongoing reviews of all processes and procedures?

Quality Assessment reviews performed throughout the year should evaluate the general, pre-analytic, analytic, and post-analytic phases of laboratory processes. COLA suggests that laboratory personnel prioritize those activities which have significant impact on the quality of testing or the level of service provided if not performed properly. Ensure that these activities are monitored according to your Quality Assessment Plan.

Conduct Quality Assessment reviews of each process throughout the year according to your Quality Assessment Plan. Evaluate results of the reviews, design process improvements, take corrective action as needed, notify all staff of any changes, and monitor the effect of implementation of actions taken. ■





Current Credentialing Practices

The CLIA* regulations define specific job positions for laboratories performing non-waived testing. Labs performing moderate complexity testing must have a qualified:

- Laboratory Director
- Clinical Consultant
- Technical Consultant and
- Testing Personnel

The required positions are similar for laboratories performing high complexity testing, but they are not the same. These positions include:

- Laboratory Director
- Clinical Consultant
- Technical Supervisor
- General Supervisor and
- Testing Personnel

The titles used in your laboratory may be different than the titles listed in the regulations. However, each CLIA-defined position must be filled by qualified individuals who can meet the CLIA-defined responsibilities of the positions. The regulations also list specific eligibility pathways, based on education and experience, for individuals to qualify for these positions.

In addition to the education and experience requirements, CLIA states that laboratory personnel must be licensed in the State where the lab is located, if the State requires licensure. Thus, when applicable, a copy of the license must be maintained in the personnel file, and unlicensed personnel cannot fill the CLIA-defined positions.

Licensure is different than certification. While certification (MT, RN, MLT, MLS, CMA, etc.) has eligibility requirements, they are not necessarily based on education and experience. Therefore, certification **alone** is not acceptable as proof that individuals meet the CLIA eligibility requirements. A copy of the diploma and/or degree reflecting the highest qualifying level of education is required and must be maintained as part of the personnel file.

A resumé or CV is sufficient documentation of laboratory experience.

Most citations about educational qualification issues relate to diplomas, with some issues due to the schools themselves. The CLIA regulations state that the degrees must be obtained from accredited schools, so many “internet schools” and some home schools do not qualify. If it can be shown that an accredited educational program was followed, then the diploma is acceptable.

* CLIA is an abbreviation for the Clinical Laboratory Improvement Amendments of 1988.

PER 3: 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 the date of graduation. These should be kept in the personnel file for review by the COLA surveyor.

Resumés are sufficient for documenting years of experience.

Foreign credentials must be evaluated by an acceptable credentialing agency for US equivalency. Language translation of documents is not sufficient to meet this requirement.

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CURRENT CREDENTIALING PRACTICES

Another problem area occurs when personnel have foreign diplomas. These must be evaluated for educational equivalency. Merely translating the diploma from its original language to English does not satisfy this requirement. The evaluation must state whether the foreign education is equivalent to the education that would have been received in the United States.

Some organizations evaluate foreign diplomas and state whether the individuals are qualified to perform certain professional duties. For example, the agency report may state that someone is qualified to be a nurse. This does **not** satisfy the CLIA requirements. As stated earlier, the foreign education received must be evaluated and determined to be equivalent to education that would have been received in the United States.

The Centers for Medicare and Medicaid Services (CMS), who are charged with enforcing the CLIA regulations, have a list of agencies that can provide the proper educational evaluation.

These include:

- The International Education Research Foundation (www.ierf.org)
- The National Association of Credential Evaluation Service (www.naces.org) and
- The Association of International Credential Evaluators (www.aice-eval.org)

Note that two of these are “associations” whose websites list several different individual member organizations. Any of the organizations listed as members of these two associations would be able to provide an acceptable educational evaluation. Contact information for the member organizations can be found on the association websites. ■



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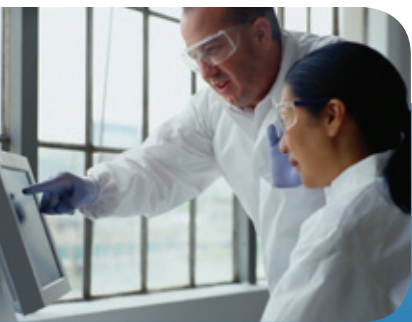
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PER 5: Does your director or Technical Supervisor / Technical Consultant follow written policies and procedures to periodically evaluate personnel

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 processes and procedures 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 the 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 may include (but are not limited to):

- *Direct observation of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing;*
- *Monitoring the recording and reporting of test results;*
- *Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records;*
- *Direct observation of performance of instrument maintenance and function checks;*
- *Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and*
- *Assessment of problem-solving skills.*

Competency Assessment

The Centers for Medicare and Medicaid Services (CMS) have initiated increased emphasis on Competency Assessment because studies have shown that:

- More education and training of laboratory personnel produce higher quality laboratory results and
- Laboratory errors with potential patient impact are often caused by lack of competent personnel

Competency Assessment is the means to confirm that training is effective and that personnel are competent to perform laboratory testing that produces quality results. Competency must be assessed semi-annually for the first year and annually thereafter. Competency must also be demonstrated whenever new testing methods, kits and/or instruments are added.

Competency assessment is not limited to testing personnel. General Supervisors and Technical Consultants / Technical Supervisors must also have their competency assessed, based on their supervisory responsibilities. The competency of Lab Directors is not assessed directly since they are held to other standards to confirm that they are fulfilling their responsibilities.

CLIA does not specifically require assessment of the competency of personnel performing *only* pre-analytic and post-analytic activities, but does state that it is good practice to do so. COLA, on the other hand, requires competency assessment of all personnel involved in laboratory testing, including those involved in specimen collection and processing, and those responsible for supervision and compliance. This can be achieved through a good Quality Assessment program since it would address many of the competency requirements (see Table 1).

>> CONTINUED ON PAGE 11

Table 1:

Required Method	Possible Reviews / Documentation
Direct observation of test performance	Checklist documenting observation
Monitor test result recording & reporting	Observation; checklist documenting observation; review of records – patient charts, test reports, instrument reports, etc.
Review of worksheets, QC, PT & maintenance records	Review of records – QC, PT, maintenance records, etc.
Direct observation of instrument maintenance	Checklist documenting observation
Assessment of test performance	Review of records – PT scores, comparison of test results, etc.
Assessment of problem-solving skills	Quizzes, review of problem logs, review of non-conforming events and incidents, review of QC issues, review of specimen rejection issues, etc.

CLIA, and consequently COLA, require six methods to be included in Testing Personnel Competency Assessment. Other methods may be used in addition to these, when appropriate. Neither CLIA nor COLA defines how you should utilize these methods; therefore, it is acceptable to use them however they work best in your laboratory. Quizzes, checklists, document reviews, and other tools can be used, as long as all the methods are addressed. When applicable, make a note that a specific method does not apply to a particular individual. This will show that the method was addressed and not over-looked. Table 1 lists examples of actions that would be acceptable for each method.

Competency assessments must be documented and this documentation must be maintained in the personnel files. The documentation must state whether competency was demonstrated and what corrective actions were taken if it was not.

The form on the next page is an example of acceptable documentation for Competency Assessment. In addition, there is an electronic Competency Assessment Tracker available through COLAcentral, which also serves as a “tickler” file to remind you when assessments are due. For more information, click on Lab Operations on the Management/Compliance tab on COLAcentral. ■



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ABC Clinical Laboratory

Competency Assessment for *Mary Trench*

Testing Personnel

Supervisor

Phlebotomist

	Required Competencies	Specific Test(s) / Records Reviewed	Competencies Met? Y/N	Date	Reviewer's Initials
Direct observation of test performance	<ul style="list-style-type: none"> Pre-analytic sample handling Regent handling Step by step procedure Result interpretation 	<i>Urinalysis dip stick ✓ CBC ✓ PT / INR ✓ All required competencies are OK</i>	Yes	3/9/12	AR
Monitor test result recording & reporting	<ul style="list-style-type: none"> Transcription ✓ Timeliness ✓ Follows Critical Value procedure ✓ 	<i>Accession # M1234 Accession # M6789 Accession # M3456</i>	Yes	3/9/12	AR
Review of worksheets, QC, PT & maintenance records	<ul style="list-style-type: none"> Completes records as required ✓ At appropriate frequency intervals ✓ Dates & initials records ✓ If needed, takes corrective action & documents it appropriately ✓ Records are legible with appropriate corrections ✓ 	<i>PT worksheet dated 3/4/12 QC log dated 3/4/12 CBC/Emerald maintenance log dated 3/4/12</i>	Yes	3/6/12	AR
Direct observation of instrument maintenance	<ul style="list-style-type: none"> Performs, as required ✓ Documents, as required ✓ Identifies corrective action, if needed <p>N/A</p>	<i>CBC daily maintenance Urinalysis weekly maintenance</i>	Yes	3/9/12	AR
Assessment of test performance (PT / blind samples)	<ul style="list-style-type: none"> Achieves accuracy ✓ 	<i>2012 - 1 PT event: 100%</i>	Yes	3/6/12	AR
Assessment of problem-solving skills	<ul style="list-style-type: none"> Identifies problems ✓ Reports / documents problems & problem resolution ✓ 	<i>Reviewed problem log for January 2012 - appropriate action taken, See 1/18/2012</i>	Yes	3/6/12	AR
Competency has been satisfactorily demonstrated <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No					
Reviewer's Comments	None				
Corrective Actions	N/A				
Reviewer's Name	<i>Addie Roman, MLS</i>	Reviewer's Signature	<i>Addie Roman, MLS</i>	Date	<i>3/12/12</i>
TC Review	N/A	Date			
LD Review	Toni Marie Saxon, MD	Date	<i>03/19/2012</i>		

Educational Updates

To paraphrase the words of TV's Frasier Crane, "We're listening!" We have used your comments and suggestions to revise, improve and update our processes and we want to continue to do so. Please continue to talk to us: complete one of the Customer Service Evaluation Surveys; write to info@cola.org; or call 800-981-9883. "We're listening!"

You told us that you wanted Continuing Education Credit for live webinars.

We are now offering P.A.C.E.® credit for our webinar presentations and may occasionally offer CME credit for physicians, when the subject matter warrants it.

You told us that you wanted to hear about more cutting edge topics.

Subjects of recent webinars include the latest high level plans of CMS (including IQCP* and the patient access rule) and the role laboratories play in Accountable Care Organizations (ACO) and the Patient-Centered Medical Home (PCMH). Topics of future scheduled webinars include updates on proper coding and billing for the medical laboratory, and how to reduce and report bloodborne pathogen exposures.

You told us that you wanted more technical subjects.

Other recent webinars have offered details on Hematology testing and the PT/INR test. Future webinars will address microbiology serology updates and advances in transfusion medicine.

We are continuing to update our Symposium for Clinical Laboratories based on your feedback.

We strive to provide you with knowledgeable, respected speakers who have a flair for making the learning process enjoyable.

"I was very impressed with all presenters - very qualified and well respected within the COLA and laboratory communities."

"Speakers had a passion for quality patient care."

"The lectures were energetic and informative. I liked that it was interactive with the audience and I felt free to ask questions. A lot of good information came from the lecture, but I like that we were also provided with resources to go to for help."

* Individualized Quality Control Plans

We strive to provide you with relevant, practical topics that you can use to upgrade your laboratory practices and procedures.

"It finally clicked on how to bring together Quality Assessment."

"Always very PRACTICAL useful information and how to apply it in our facilities."

"First, I learned that we need to create a new QC strategy to minimize patient result risk factors. The second thing is not something that was learned but was experienced. I have never attended a COLA symposium and I experienced a feeling of "oneness" with my fellow laboratorians. This feeling has inspired me to want our laboratory to go above and beyond to achieve the best in patient testing and care."

We strive to provide you with useful resources and caring, helpful staff to guide you to success in providing the highest quality patient care.

"I loved the overall experience of feeling very important in my job field. I left the symposium wanting to definitely be the best lab employee I can be."

"This symposium was my first for COLA — I am rejuvenated and very excited to get back to my lab and implement everything I learned. And, I can't wait to get back and go to COLAcentral online to see what else I can learn. Also, I am impressed with the staff from COLA that are present — everyone is more than willing to help which proves the statement that COLA wants to help the laboratories be successful. Thank you."

Also, be sure to check out our new LabUniversity® site (www.labuniversity.org) including the step-by-step How-to Guide! ■



Updated Criteria

FAC 9 Are measuring devices, such as dilutors and volumetric, serological, and semi-automated pipettes of certified accuracy?

Disposable measuring devices should be of certified accuracy: this is printed on the pipette itself. Non-disposable pipettes, such as volumetric, should be of certified accuracy (CLASS "A"). Semi-automated pipettes frequently come with calibration collars and instructions for use. Diluters should also be checked as part of routine preventive maintenance. Semi-automated pipettes without a calibration mechanism should have their calibration verified at least once per year.

FAC 13 Are all disposable sharps, needles, and syringes safely discarded in a separate, marked container for the protection of employees, patients and custodial staff?

It is important for the laboratory to utilize appropriate devices to prevent potential injury to employees and patients alike. Needles and other sharps must be disposed of in a "sharps container" which is clearly marked "biohazard."

Ideally, needles should be self-sheathing and the sharps container is one which can be operated with one hand. Sharps containers must be closable, puncture resistant, and leak proof on the sides and bottom. They must be located as close as possible to the immediate area where sharps are used.

Needles should not be removed from syringes or blood tube holders and they should not be recapped, bent or sheared. Recapping needles is only permitted when required by a specific medical procedure, and in this case, a one-handed – scoop technique must be used.

If blood is collected in examining rooms, a sharps container should be in each room. If younger patients may be seen by the practice, this container should be mounted out of the reach of children. As an alternative, a portable phlebotomy tray including a sharps container may be used.

FAC 14 Do you have a bloodborne pathogens exposure control plan?

This is an OSHA requirement and needs to be a written document. You should comply with OSHA requirements for handling bloodborne pathogens, state and/or local requirements for disposal of hazardous waste. You can obtain information from OSHA by calling (202)693-1999. This is OSHA's general information number.

OSHA requires that all employees receive annual training in this plan.

FAC 15 Are protective clothing, gloves, masks, eye protection devices, and face shields available to personnel performing tasks that require the use of such articles?

OSHA requires protective clothing to be provided and laundered by the employer. These items of clothing are not to be worn outside of the work area, nor taken home for laundering. Gloves must be worn when performing phlebotomies and when handling containers of regulated body fluids. Masks, goggles, and/or face shields must be made available anytime there is a likelihood of an employee being splashed by blood or another contaminated substance (e.g., when emptying biohazardous waste, cleaning up a spill, etc.)

FAC 16 Are gloves worn when performing phlebotomies?

See commentary for FAC 15.

PER 2 Are all required positions for your laboratory filled, and are the individuals filling those positions qualified by education and experience?

If your state has more stringent personnel standards or licensure requirements than CLIA and COLA, the laboratory director must ensure that all personnel meet these requirements. There must be a qualified individual designated for each of the positions specified in CLIA based on the complexity of your laboratory. Refer to chart.

NOTE: If qualified, the laboratory director (and others) may fill multiple positions.

** See COLA Accreditation Manual ©2011, p. 3-14; pdf p. 48/167*

>> CONTINUED ON PAGE 15

UPDATED CRITERIA**PER 3 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 the date of graduation. These should be kept in the personnel file for review by the COLA surveyor.

Resumes, etc. are sufficient for documenting years of experience.

Foreign credentials must be evaluated by an acceptable credentialing agency for US equivalency. Language translation of documents is not sufficient to meet this requirement.

PER 5 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 may include (but are not limited to):

- *Direct observation of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing;*
- *Monitoring the recording and reporting of test results;*
- *Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records;*
- *Direct observation of performance of instrument maintenance and function checks;*
- *Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and*
- *Assessment of problem-solving skills.*

PT 8 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.

PRE 7 Does the requisition that accompanies the patient specimen contain the following: clinical information, including gender, age, specimen source (when appropriate), and other relevant and necessary information?

Gender and age are important for interpretation of results to correctly identify the patient reference range. Other relevant and necessary information to include will be dependent upon the test requested.

For example:

- *For glucose or lipids, indicate whether the patient is fasting*
- *For drug levels, indicate the dosage of medication the patient is on and the time the last dose was taken*
- *For cultures, indicate the source of the specimen and whether the patient is already on antibiotics or may have just completed a course of antibiotics*

>> CONTINUED ON PAGE 16

UPDATED CRITERIA

PRE 11 Do you have written instructions for specimen collection, labeling, preservation, and conditions regarding specimen transport available for your clients and do you provide updates to your clients as they occur?

You should provide a specimen collection manual to each client who refers tests. This will substantially reduce the chance of invalid results caused by pre-analytic variability.

APM 15 Does the procedure manual include for each test, where applicable: reference ranges, reportable ranges, and critical values, and when to immediately notify the physician of critical values?

APM 18 How the laboratory reports results (including critical values)?

Describe how the laboratory provides test results to the ordering practitioner. This may vary depending on whether the patient is waiting for results, or if a critical value is obtained. Include descriptions of how reports are created, distributed, and maintained for future reference.

MA 23 Are microscopes properly maintained?

Microscopes should be cleaned routinely in addition to any scheduled maintenance. It is particularly important to remove any accumulations of immersion oil from the condenser and objectives with a soft cloth and lens cleaner.

VER 4 Prior to patient testing, have each of the following performance specifications been verified and documented for each non-waived test or method:

Reference range?

The range of values expected for a given population.

VER 8 Prior to patient testing, have each of the following performance specifications been verified and documented for each non-waived test or method: **Reference range?**

The range of values expected for a given population.

CA 1 For all non-waived tests and methods, as applicable, is calibration performed at the frequency recommended by the manufacturer or at the frequency determined by the laboratory if more stringent than the manufacturer?

Calibration is the process of method standardization according to manufacturer's instructions or as determined by the laboratory during verification of performance specifications. This is performed by using calibrators (standards) of the number, type and concentration indicated by the manufacturer to actually set parameters in the instrument as the basis of determining all other test results. Automated cell counters must be calibrated at least every six months.

EXCEPTIONS:

- Microscopic tests, and manual tests (e.g. manual differentials or microbiology susceptibility tests) not performed on an instrument do not require calibration.
- For most prothrombin time devices, calibration is not practical.
- Many point of care or unit use devices are factory calibrated and do not permit user calibration. Such devices are required to have calibration verification performed. Refer to CA 2.*

* See COLA Accreditation Manual ©2011, p. 3-49; pdf p. 83 /167

QC 1 Do you have a quality control program that monitors the complete analytic process for each test performed?

A quality control program must be capable of detecting errors throughout the complete analytic process. This includes errors related to test system components and environmental conditions, as well as operator variance. The quality control program must detect both immediate errors and those that occur over time. Generally, a quality control program includes running control materials prior to or concurrent with patient specimens. The program defines the number, type, and frequency of controls performed; the established or expected ranges for control values; a process for identification and review of system problems; description of corrective actions to be taken when unacceptable results are obtained; and documentation of all activities.

>> CONTINUED ON PAGE 17

UPDATED CRITERIA

QC 10 Are manufacturer’s instructions for the use of reagents, controls, and kits followed?

This criterion applies to waived and non-waived testing.

Federally waived tests are those that appear on the FDA internet site (<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfclia/testswaived.cfm>). Laboratories must follow manufacturer’s instructions for waived tests.

CLIA regulations require that waived and non-waived tests be reclassified as non-FDA approved high complexity tests when the laboratory modifies the manufacturer’s instructions. When this occurs, the laboratory must comply with all high complexity Personnel requirements, and requirements for Performance Specifications for non-FDA approved tests (see VER 5-11). In addition, waived tests that are modified will be subject to all other requirements for non-waived testing, including, but not limited to Proficiency Testing, Quality Assessment, and Quality Control.*

*For non-waived tests, laboratories may elect to use reagents other than those of the test system manufacturer. This does not constitute a modification of the test system; however it does require verification of performance specifications (see VER 1-4).***

The table on the right identifies changes which constitute a modification of the FDA approved system.

* See COLA Accreditation Manual ©2011, pp. 3-46 & 3-47; pdf pp. 80 & 81/167

** See COLA Accreditation Manual ©2011, pp. 3-45 & 3-46; pdf pp. 79 & 80/167

Examples of modifications include but are not limited to:

Modification of Manufacturer Instructions
Change in specimen handling instructions
Change in incubation times or temperatures
Change in specimen or reagent dilution
Using a different calibration material (or changing the manufacturer’s set points)
Introducing a different antibody (source, monoclonal versus polyclonal)
Change or elimination of a procedural step
Change or addition of detector (conjugate) or substrate
Change in the solid phase
Change in the cutoff or method of calculating the cutoff for semi-quantitative assays
Change in the endpoint or calculation of the endpoint
Addition of adsorbent
Change in the strain of antigen in serologic assays
Changing the calibrator/reference material
Using a different sample matrix (plasma versus urine)
Using or promoting the test for another purpose (screening versus diagnostic)
Changing the type of analysis (qualitative results reported as quantitative)

QC 16 For each quantitative test performed, are quality control data prepared and plotted with each testing event, or are statistical parameters calculated to permit the laboratory to assess continued accuracy and precision of the method?

Control charts, graphs, or statistical parameters (i.e. mean, SD, and CV) should be maintained for all quantitative tests performed by the laboratory. Many instruments and Laboratory Information Systems have the capability to track this information electronically. This data should be reviewed weekly (or following every 5-7 data points if performed infrequently) to detect changes, such as shifts or trends, that may be indicators of test system problems that need to be addressed.

Such routine reviews may permit the laboratory to recognize a developing potential problem and take action to prevent unacceptable results, which could ultimately impact the quality of patient results or create disruptions in access to needed testing due to instrument, test system, or environmental failures.

>> CONTINUED ON PAGE 18

UPDATED CRITERIA

QC 21 Are stains (other than gram or acid-fast stains) checked for positive and negative reactivity (if applicable), and to ensure they provide the expected characteristics on each day of use?

PST 16 Does the report contain: the reference range of the test and other pertinent information for interpretation?

For example, reports should indicate, where applicable for certain therapeutic drug levels, if a sample is a peak level or a trough level.

PST 20 Is a record kept of who was notified of critical values as established by the laboratory?

A record, either paper or electronic, must be kept indicating when an appropriate individual is notified of a critical value. At a minimum the record should include who was notified, when and by whom. As previously noted, miscommunication can be a significant source of errors in the health care environment. For this reason laboratories should utilize a read back requirement whenever providing patient results verbally. It is advisable to define this in the procedure for notification as well as including a reminder of the requirement on logs or documents used for notification.

PST 24 Are all original or exact duplicate test reports, either paper or electronic (from in-house tests and reference laboratories) maintained, stored and preserved for at least two years?

The laboratory must have a system for retaining copies of all reports including original, preliminary, corrected and final reports.

PST 25 Are all immunohematology original or exact duplicate test reports and test records, either paper or electronic (from in-house or reference laboratories) maintained, stored and preserved for at least five years?

PST 26 Are all pathology, gynecologic cytology, and non-gynecologic cytology reports, either paper or electronic maintained, stored and preserved for at least 10 years?

This requirement only pertains to laboratories that process cytology and pathology requests and reports through the laboratory. Be aware that state regulations may mandate longer retention.

QA 2 Has the laboratory implemented its Quality Assessment Plan and performed ongoing reviews of all processes and procedures?

Quality Assessment reviews performed throughout the year should evaluate the general, pre-analytic, analytic, and post-analytic phases of laboratory processes. COLA suggests that laboratory personnel prioritize those activities which have significant impact on the quality of testing or the level of service provided if not performed properly. Ensure that these activities are monitored according to your Quality Assessment Plan.

Conduct Quality Assessment reviews of each process throughout the year according to your Quality Assessment Plan. Evaluate results of the reviews, design process improvements, take corrective action as needed, notify all staff of any changes, and monitor the effect of implementation of actions taken.

QA 3 Do your Quality Assessment reviews enable the laboratory to identify and correct problems?

The purpose of the Quality Assessment review is to monitor whether processes and procedures related to pre-analytic, analytic, and post-analytic phases of laboratory testing are being performed properly.

As the assessments reveal deviations between policy and performance this alerts the laboratory that a problem exists. The laboratory must then review the process and data obtained by the assessment to develop corrective actions aimed at preventing recurrence.



>> CONTINUED ON PAGE 19

UPDATED CRITERIA

QA 5 Is the information obtained during quality assessment reviews shared with the laboratory staff and other individuals as appropriate and is this recorded?

The director or consultant should discuss the quality assessment review with all appropriate staff so that everyone knows what problems were identified and what corrective actions are being implemented. By involving staff in the review and correction, one can better assure that the root cause of the problem will be identified and corrected.

Effective communication of Quality Assessment issues is essential in preventing recurrences. Documentation of these activities is essential to create a record that can be referred to in the future, should questions arise.

QA 6 Does the quality assessment review evaluate the laboratory's processes for patient preparation, and for specimen collection, handling, labeling, transport, and acceptability?

The review should look at these criteria and determine if they are correct and appropriate for your lab, and verify that lab personnel are following them.

QA 12 If you perform the same test using different methods or instruments, do you evaluate the variance in the results produced by each method at least twice a year?

When multiple methods are used to perform the same test, it is important for the laboratory and the practitioners it supports to understand the relationship between results produced by each method. This is most critical when tracking results on a specific individual over time. If significant variances in results are present, they could potentially be interpreted as denoting changes in the patient's condition, when in fact they are merely the result of a bias among methods.

This is easily done by split specimen analysis. If any bias is noted, it is important to reflect the difference in the reference ranges that are used on the test report. This requirement also includes back-up instruments. ■

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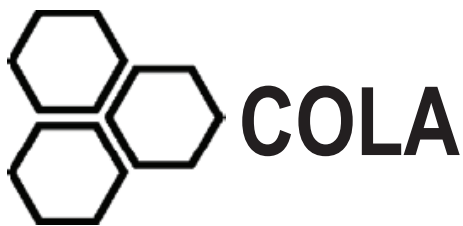
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COLA PATIENT SAFETY PROGRAM 2012:

FDA voluntary reporting of device-related adverse events

COLA began the COLA Patient Safety Program in 2008 with the intent of focusing on areas in laboratory medicine that are found to have high error rates and significant impact on patient safety. COLA is also focused on reducing the frequency of citations for criteria that impact, or have the potential to impact, patient safety. Through this program, COLA will identify an existing COLA criterion as the patient safety goal for each year, and provide education on good laboratory practices for implementation of that goal. The program has also been integrated into the COLA survey process.

The COLA Patient Safety Goal for 2012 addresses:

ORG 9: Does the laboratory have a procedure for the FDA voluntary reporting of device-related adverse events?

Previous Patient Safety Goals have included proper patient identification, and proper specimen identification and labeling that continues throughout the path of workflow – all of which are essential parts of a safe testing process. But what happens when a testing device malfunctions and either causes, or has the potential to cause, harm?

Every laboratory should have a procedure for voluntary reporting of device related adverse events to the FDA. Lack of a procedure is a common deficiency seen during lab surveys.

A medical device is any item that is used for the diagnosis, treatment, or prevention of a disease, injury, or other condition, that is not a drug or biologic. Consequently, the definition includes devices that may be used in medical laboratories such as instruments, reagents, blood collection devices, and other components of test kits.

Although voluntary, the laboratory has a responsibility to protect the safety of patients and

employees by reporting in-vitro diagnostic devices that do not perform correctly to the manufacturer.

- Inaccurate test results produced by an in-vitro device (IVD) and reported to the health care professional may lead to medical situations that fall under the definition of serious injury, and therefore are reportable events.
- Device malfunctions or problems that are reportable may relate to any aspect of a test, including hardware, calibration, reagents, or labeling; or to user error.
- Device related adverse events can cause serious employee or patient injuries that are life threatening; or result in permanent impairment of a body function or permanent damage to a body structure.

The laboratory should have written procedures for 1) the identification and evaluation of adverse events that effect employees or patients, 2) the timely submission of required medical device reports, and 3) compliance with record keeping requirements.

The COLA website has a resource regarding voluntary FDA reporting at:

www.cola.org/?page_id=417.

There are additional resources on COLAcentral.

More information can be found on the FDA website:

www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm and

www.fda.gov/Safety/MedWatch/ucm133050.htm

Laboratories that are part of a larger organization (e.g., hospital laboratories) should document participation in the overall institutional Medical Device Reporting (MDR) process.



COLA Technical Bulletin

2012-1: Updates to Survey Criteria

COLA periodically reviews the criteria for accreditation, and will make changes to the criteria and / or related annotation for several reasons.

- To clarify language, so that the intent of the criterion is clear.
- To incorporate new information, which may be in response to changes in technology or regulatory emphasis.

Updates from the most recent review will be effective as of 6/18/2012.

Based on the most recent review, the terminology used has been updated to reflect current usage. For example, the term “alert (panic values)” has been replaced with “critical values,” and the term “normal range” has been replaced with “reference range.”

For a few criteria, more specific guidance has been provided:

- CA 1** The following sentence has been added to the annotation: ***“Automated cell counters must be calibrated at least every six months.”***
- PT 8** The criterion has been edited. It now reads “Are all PT results reviewed and evaluated by the laboratory director or qualified designee ***in a timely manner.***”
The annotation has been modified, with the addition of ***“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.”***
- PER 2** The criterion has been edited. It now reads “Are all required positions for your laboratory filled ***and are the individuals filling those positions qualified by education and experience?***”
The annotation has been modified with the addition of ***“There must be a qualified individual designated for each of the positions specified in CLIA based on the complexity of your laboratory. NOTE: If qualified, the lab director (and others) may fill multiple positions.”***
- PER 3** The criterion has been edited. It now reads ***“Does the personnel file contain documentation of the person’s education and experience that qualified them for the position they hold in the laboratory?”***
The annotation has been expanded to clarify the requirement. It now reads ***“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. Resumes are sufficient for documenting years of experience. Foreign credentials must be evaluated by an acceptable credentialing agency for US equivalency. Language translation of documents is not sufficient to meet this requirement.”***
- PER 5** The annotation has been expanded to include the following text ***“Methods of competency assessment may include (but are not limited to): 1) Direct observation of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing; 2) Monitoring the recording and reporting of test results 3) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records; 4) Direct observation of performance of instrument maintenance and function checks; 5) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and 6) Assessment of problem-solving skills.***

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