



Meaningful Competency Assessment

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Objectives

- Differentiate between Competency Assessment and the traditional performance evaluation
- Outline the six CLIA-required components of Competency Assessment
- Apply methods described to conduct and document meaningful competency assessments
- Comply with COLA criteria that address Competency Assessments

The problem with competency assessment...

“It’s hard to see a problem clearly if you’ve already decided what to do about it.”

Levitt and Dubner








We can easily define competency, but evaluating competency in a meaningful way can be challenging.




Why the Emphasis on Competency?

- “Studies indicate that more education & training produce higher quality results.” Judy Yost, “CLIA Compliance, PT, and Quality Control: What’s New for 2012?” G2 Webinar 2012
- Competency confirms the effectiveness of training
- CLIA-defined Lab Director qualifications are stringent due to the overall responsibilities, but testing personnel qualifications are minimal, based upon complexity. Therefore, competence is critical.
- Errors may have impact on patients.

Assessing Competency vs. Performance Evaluations

	Team - work	Attendance and Punctuality	Productivity	Customer Service skills	Technical Competency
Personnel Evaluation					

Some items that might be included on a personnel evaluation

<u>Direct Observation</u> – routine patient testing	
<u>Direct Observation</u> – instrument maintenance	
<u>Review of Records</u> - intermediate test records	
<u>Monitor Result Reporting</u>	
<u>Blind Sample Testing</u> - PT can satisfy this component	
<u>Evaluation of Problem Solving Skills</u>	

Required for competency assessment for testing personnel

Assessing Competency

- WHO is required to undergo competency assessment?
 - Technical Consultant, Technical Supervisor
 - Clinical Consultant
 - General Supervisor
 - Testing Personnel

Assessing Competency

The Laboratory Director is not required to have competency assessment – BUT is responsible for all CLIA defined responsibilities.

Competency Evaluations

- **WHO should evaluate competency?**
- First it is important to have competent individuals assess the competency of the personnel under review. The reviewer should not be the Office Manager, the Nursing Supervisor, or others who do not perform lab testing.
- CLIA gives this responsibility to the TC (moderate complexity) or TS (high complexity).
- Competency must be evaluated by qualified individuals (TC/TS/GS).

CLIA Requirements for Personnel Competency Assessment

Six required elements of competency assessment

Competency Evaluations

- Two of the six required assessment activities involve Direct Observation:

1. Direct observation of routine patient test performance;

- 2. Direct observation of performance of instrument maintenance and function checks;

This can be documented with a detailed process oriented check list, per test or instrument.

Competency Evaluations

- Two of the six required assessment activities involve Review of Records:
- 3. Monitoring the recording and reporting of test results;
- 4. Review of intermediate test results, QC records, proficiency testing results, and preventive maintenance records;

Include with the competency documentation – records that were reviewed.

Competency Evaluations

5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples;

Rotate the performance of PT samples among testing personnel!

- 6. Assessment of problem-solving skills .
 - Use problem logs, QC corrective action, complaint investigations, specimen rejection incidents...

Competency Assessment

- *Don't waste paper*
- *Don't waste time*
- *Make it meaningful!*

***What does documentation
of competency assessment
look like?***

Six Month or Annually Evaluation and Competency Assessment

Employee name:

~~XXXXXXXXXX~~ ~~XXXXXXXXXX~~

Procedure observed/evaluated:

1. Direct Observation of patient or QC testing
2. Result review of patient, QC or PT testing ✓
3. Direct Observation or record review of instrument maintenance

Reviewed by:

~~XXXXXXXXXX~~ ~~XXXXXXXXXX~~

5/23/13

Lab Name				Employee Name			
Address				Employee Number			
City, State, Zip				Trainer			
I understand that by signing each section below I agree that I have been trained and am proficient in the item described. Furthermore, I agree to maintain my proficiency, request additional training if I feel that it should be become necessary, and assume responsibility for keeping abreast of any updates or changes.							
Employee Signature				Date			
Item	Date of proficiency	Employee initials	Trainer initials	Item	Date of proficiency	Employee initials	Trainer initials
Lab policies				Hcg test			
QA Plan				Microalbumin			
Safety				Ictotest			
Procedure manual				ESR			
QC procedures				PT INR			
Hematol				Rapid strep			
UA				Flu A/B			
Glucose				Mono			
Instrument maintenance				LIS reporting procedures			
DCA Vantage				CBC			
Send-out procedures				H Pylori			
Phlebotomy							

ABC Clinical Laboratory

 Competency Assessment for *Mary Trench*

✓ Testing Personnel

Supervisor

Phlebotomist

	<i>Required Competencies</i>	<i>Specific test(s) / records reviewed</i>	<i>Competencies Met? Y/N</i>	<i>Date</i>	<i>Reviewer's Initials</i>
Direct observation of test performance	<ul style="list-style-type: none"> · Pre-analytic sample handling · Regent handling · Step by step procedure · Result interpretation 	Urinalysis dip stick ✓ CBC ✓ PT / INR ✓ All required competencies are OK	Yes	4/9/13	AR
Monitor test result recording & reporting	<ul style="list-style-type: none"> · Transcription ✓ · Timeliness ✓ · Follows Critical Value procedure ✓ 	Accession # M1234 Accession # M6789 Accession # M3456	Yes	4/9/13	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 ✓ 	PT worksheet dated 3/4/12 QC log dated 3/4/12 CBC/Emerald maintenance log dated 3/4/12	Yes	4/6/13	AR
Direct observation of instrument maintenance	<ul style="list-style-type: none"> · Performs, as required ✓ · Documents, as required ✓ · Identifies corrective action, if needed (N/A) 	CBC daily maintenance Urinalysis weekly maintenance	Yes	4/9/13	AR
Assessment of test performance (PT / blind samples)	<ul style="list-style-type: none"> · Achieves accuracy ✓ 	2012 - 1 PT event: 100%	Yes	4/6/13	AR
Assessment of problem-solving skills	<ul style="list-style-type: none"> · Identifies problems ✓ · Reports / documents problems & problem resolution ✓ 	Reviewed problem log for January 2012 - appropriate action taken, See 1/18/2012	Yes	4/6/13	AR
Competency has been satisfactorily demonstrated		✓ Yes	No		
Reviewer's Comments	<i>None</i>				
Corrective Actions	<i>N/A</i>				
Reviewer's Name	<i>Addie Roman, MLS</i>	Reviewer's Signature	<i>Addie Roman, MLS</i>		Date <i>4/12/13</i>
TC Review	<i>N/A</i>	Date			
LD Review	<i>Toni Marie Saxon, MD</i>	Date	<i>04/19/2013</i>		

- Patient testing
- Maintenance

Direct observation

- Intermediate records
- Reporting

Record review

- Blind sample testing
- Problem solving

Assess competency

Competency assessment – Serum Osmolarity

Direct observation – with DETAILS listing each critical step

Instrument maintenance



Test performance



Review of Records

Intermediate records – attach copy of Osmo worksheet with controls recorded

Result reporting – attach copy of final result with any result comments, critical values, etc

Blind Sample analysis

Attach copy of report and expected results

Problem Solving

“What if” scenarios

Attach problem logs with resolution

Competency assessment – Serum Osmolarity

Your documentation should include:

- Notation of direct observations
 - Includes each critical step in the test performance
- Copies of records reviewed
- Blind sample testing with results and acceptability
- Problem logs, quizzes, or “what would you do if” scenarios
- Conclusion – is the testing personnel competent to perform this test?
- Need for further training, if necessary
- Signature of testing personnel and person evaluating competency

FAQ

- Do personnel performing PPM require competency assessment?
- Who can evaluate competency?
- Do all elements of competency assessment need to be done at once?
- Does PT satisfy competency assessment requirements?
- Profiles – can you do one competency assessment for a panel of tests run on a single platform?

Waived Testing

- ***COLA WAV criteria section includes competency requirement for waived testing.***
- Why?
 - Many tests categorized as waived can have significant patient impact if not performed correctly.

Competency assessment for specimen collection and processing personnel

- *Not required by CLIA, but certainly recommended*
- *Required by COLA*





What Do I Need to Do to Assess Personnel Competency?



IQCP

Evaluating potential errors related to your testing personnel is required as part of the risk assessment.

Complete and meaningful competency assessment of staff involved in ALL phases of testing should be part of ANY Individualized Quality Control Plan.

How to contact COLA

COLA central: **www.colacentral.com**

Email: **info@COLA.org**

Address: 9881 Broken Land Parkway, Suite 200 Columbia, MD 21046

Website: **www.cola.org**

Phone: 800-981-9883

Lab University

www.labuniversity.org

Competency Assessment course

<http://bit.ly/competencyassessment>

Email

kathyn@cola.org

Questions and Answers from Competency Assessment Webinar

Who should perform the competency assessment on the Technical Consultant?

A: Ideally, the Lab Director, but this can also be done for example, by another Technical Consultant within the same group.

Does competency have to be exactly every 12 months?

A: Competency can be done throughout the year; it does not have to be done all at once. I suggest that for your annual competencies, you do this each calendar year for your staff. COLA will not get real particular about it being exactly 12 months. That said; avoid doing competency assessment for example at the beginning of one year and at the end of the next year. You might miss an opportunity for improvement – which we should be celebrating!

How can we document the direct observation requirements for competency assessment?

A: For each test performed by the individual, document your observation of each step of the procedure. Use a list that denotes of each major step of the procedure, and check off each step as you observe. For example for CBC – did they check for adequate specimen, and properly labeled specimen? Did they make sure that the sample was well-mixed? If you make manual slides for differential, observe them making the slide to ensure that they achieve a feather edge. Do they recognize instrument flags and follow the procedure for resolving flags? Indicate in your documentation the date of the observation, and the session number of the patient testing observed. If you provide any feedback or if you identify a need for retraining, indicate this as well.

How can we perform and document competency assessment for phlebotomists?

A: My opinion on this is that there is no substitute for direct observation when performing competency assessment on phlebotomy staff. To supplement this, you can also do a quiz to cover things that may happen infrequently and are therefore not easy to observe. Such as what to do where should you obtain the specimen when a patient has had a mastectomy on one side. Competency for phlebotomy staff does not have to include the six required elements as for testing personnel.

How is competency assessment related to IQCP?

A: As part of the risk assessment for IQCP, labs must evaluate potential errors that are related to personnel issues, such as lack of training or lack of competency. IQCP gives us a great opportunity to make sure that our competency assessment programs are meaningful and effective. The risk assessment should include a review of any problems or failures a lab has had with the test(s) and should incorporate any corrective actions in to the competency assessment for that test. It's a great opportunity to connect the dots.

Who should do the competency assessment on the Clinical Consultant?

A: The Lab Director. If the LD/ CC are the same person, then competency is not required – BUT here's an idea – how about getting feedback from other physicians that use the lab's services? Ask if the reports include all information required and if they are easy to interpret? Ask the physicians if they know who to contact if they have questions about what test(s) should be ordered in a particular situation?

I work for a large group of labs in a health system – and the labs are geographically far apart. It is not easy to be on-site at each lab to do the direct observations. Any suggestions?

A: I understand that this can be a challenge. You can do the other portions of the competency assessment remotely, such as reviewing records and reporting. But you will need to visit each facility to do the direct observations. I suggest that you time this to coincide with routine visits to each site.

I work in a mass spec toxicology lab. I prep the specimens, inject the samples, and maintain the equipment, but I do not interpret the results. Am I required to undergo competency assessment?

A: Yes. The specimen prep, injection of samples, and maintenance of the mass spec are critical components of the testing process for mass spec. If you do not report results, than this component, for you, could be not applicable. But, all other components of the competency assessment would apply.

Do you have any suggestions for new and interesting things to help with competency assessment?

A: In the past, labs have done a scavenger hunt –or similar activities to make sure that staff know where to find answers and also this can be a good tool for evaluating problem solving skills. Another idea would be to have each testing personnel come up with a tool or a problem to solve – this gives them an opportunity to share their knowledge and to identify areas that may have presented them with challenges. Everyone has a stake in making sure that all staff are competent – so get them involved!

Do you recommend using competency assessment in the performance appraisal?

A: No, I don't. Competency assessment should be all about identifying needs for improvement and in my opinion should not be attached to the performance appraisal. Of course if there are repeated performance problems then this may need to be dealt with on a personnel level, but I believe that opportunities to improve and prevent future errors should be something that we all embrace, and should not be used as something that should be used punitively, unless it is a repeated pattern. Most problems are system problems rather than personnel problems.

Will attendees earn the 1.5 hours of PACE credit?

A: No, credit will not be earned for this webinar.

What kind of competency needs to be assessed for waived testing done by nurses and medical assistants if they are running step testings, flu etc.?

A: This is up to you. COLA does not require that all six components be included, as required for non-waived testing. So you could do direct observation, using a detailed list of the critical steps of the procedure. OR you could do written competency assessment. OR you could require that testing personnel perform blind sample testing.

Who evaluates competency of LD or Clinical Consultant?

A: Competency assessment is not required for the Lab Director. The Lab Director responsibilities will be evaluated in detail at the time of survey. If the Clinical Consultant and the Lab Director are the same person, competency assessment is not required. If they are two different people, then competency assessment is required for the Clinical Consultant. This should be done by the Lab Director, and is simply a review to determine if the CLIA responsibilities of the position are being met.

For nursing staff doing WBG testing do they need to have direct observation every year? We rotate PT testing so that everyone does it once a year and they had an initial direct observation done documented and retained--is this sufficient?

A: Yes. COLA requires that you have some sort of competency assessment defined and implemented for your waived testing personnel. If you are using PT for this and each person does it at least once per year, then this would satisfy the requirement for waived testing competency assessment.

Can the Lab Manager monitor test performance by personnel, if the Lab Manager's competency assessment is performed by the lab director?

A: "Lab Manager" is not a CLIA defined position. So to answer this question, the Lab Manager in your scenario has the minimum qualifications of a TC, TS or GS. The answer is yes. This should be spelled out in your competency assessment procedures.

Who should I contact to receive a copy of a competency assessment template?

A: We have several new competency assessment templates that will soon be posted to the next version of COLAcentral. In the meantime, I would be happy to send them to you. Email me at: kathyn@cola.org.

Do copies of patient reports for monitoring result reporting violate HIPPA?

A: Obviously for anything that you would send in to COLA, such as you would in response to a citation, needs to have Protected Health Information redacted. But for your lab's internal records, having copies of patient reports or log sheets with patient names included in the competency records would not violate HIPAA.

For the direct observation listing - can a copy of the procedure be attached with notation of the critical steps, rather than writing out a separate checklist?

A: Sure, this is a good idea!

Have you reviewed competency from toxicology labs and what are some suggestions for them due to the nature of the work and how they differ from a clinical laboratory?

A: I realize that toxicology labs, especially those performing mass spec, may be significantly different than other clinical labs. But the competency assessment requirements are the same. The same five components are required. There may be unique specimen requirements and certainly unique reporting requirements, as well as instrument maintenance requirements, so you would need to include those unique steps in your competency assessment.

Where can we find the template on competency assessment on COLA website?

A: These will be posted to the COLAcentral website in the near future. But for now, please email me at kathyn@cola.org and I will send them to you.

Should the lab director sign all competency evaluations?

A: No, not necessarily. The TC, TS, or GS can sign the competency evaluations.

If the TS/TC/GS also performs testing, who can/should perform the direct observation of patient testing and instrument maintenance at a small high complexity facility? The lab director does not perform any testing functions.

A: This is a common question. In a high complexity lab, both a TS and a GS are required positions. If these are different people, then the answer is easy; they can directly observe each other. If the TS and GS are the same person, and the Lab Director does not perform testing you could have other competent high complexity testing personnel do the direct observation component of the competency assessment. The final competency evaluation should be reviewed by the Lab Director in this case.

I realize that there may be small high complexity labs with only a Lab Director and a Lab Scientist who is serving as TS/GS AND is the only testing personnel. In this case, I suggest that the Lab Director and the TS/GS/TP get together and define a plan that assesses competency that makes the most sense in your situation. Is there a lab in the same health system that performs the same tests and that could provide a TS to evaluate competency? This is an opportunity to be creative – but there is also a need for “reasonableness” in this situation.

What do you do in a physician’s office setting where the testing personnel is only one person who also serves as the general supervisor, and the lab director/tech supervisor is offsite and doesn’t actually do any of the testing?

A: This is a similar question to the previous question. Surely the LD/TS visits on occasion? The TP/GS could plan to do a self-evaluation in the presence of the LD/TS – and gather and review the documentation together. Again, as far as what the Surveyor would expect, there is a need for “reasonableness” in this situation.

When doing Competency assessment we should include a list of the 6 elements evaluating?

A: It is not necessary to list the 6 elements in a “list” but the competency assessment should include evaluation of all 6 elements. As long as all 6 are present, the requirements will be met.

Are there COLA templates available for the technical supervisor competency assessment?

A: Yes, we have just developed a new template for TC/TS – based upon the CLIA defined responsibilities of these positions. We will be posting these to COLAcentral with the next version of the website. In the meantime I would be happy to email it to you. Please send me a request at kathyn@cola.org.

Is there a copy of the example you used on webinar for competency check off sheet on COLA website?

A: No, but I can send you a template that is similar. Please send an email request to me – at kathyn@cola.org.

I use nursing personnel for our lab. Part of their competency is to have their diploma evaluated by your COLA defined evaluators for the foreign schools. If they had their diploma evaluated by the nursing board, why must we get "your approved" evaluators to re-evaluate their credentials again.

A: CLIA requires that foreign education documents be evaluated for U.S. equivalency. Often the nursing board evaluates the educational documents for purposes of licensure, rather than equivalency to US education. The CLIA regulations focus on education requirements and so that is why we need the diplomas or degrees evaluated by a credentialing agency to establish US equivalency.

If the physician is doing PPM can PT serve as his competency?

A: If this physician is the Lab Director, then this is acceptable. If the physician is not the Lab Director, but rather is just one of the testing personnel for PPM, then the PT can be part of the competency assessment – but does not alone satisfy the requirement for competency assessment.

If lab director is also the Tech consultant in a small lab and performs some testing, who evaluates the Director?

A: It is not required for the Lab Director to undergo competency assessment for the positions that he/she holds, including testing personnel. That said, if there are other testing personnel, I would never discourage some sort of arrangement to have the other testing personnel provide feedback to the Lab Director in some fashion.

We are a physician office lab and have difficulties getting continuing education in at times. If additional training is needed for employees can that also count as continuing education?

A: Remedial training would not be the same as continuing education. Can you have the Lab Director give a presentation now and again about a current relevant lab topic? There are also free professional publications that include many interesting and relevant articles for lab staff. This can satisfy the requirement for continuing education – assign articles for staff to read and have them sign off that they read the article. You could also discuss current topics at regular staff meetings. So there are ways to provide continuing education. In general I think that training is different than continuing education.

As a working Lab Manager (MLT) do I qualify as the TC?

A: “Lab Manager” is not a CLIA defined position. But the requirements to be a Technical Consultant, which is a required position for a moderate complexity lab, is a minimum of a bachelor’s degree in a chemical, biological, physical, or medical technology plus a minimum of two years training or experience in non-waived testing. An MLT can qualify, but must have the bachelor’s degree. I would be happy to evaluate your credentials if you would want to send me your degree and resume – kathyn@cola.org.

Do only the lab personnel that perform maintenance for a specific test /analyzer need to have direct observation of maintenance or do all testing personnel need this?

A: I recognize that in some labs, the routine maintenance may be assigned to only certain personnel. But surely all testing personnel need to be familiar with operation of the instrument and for example what flags mean – or what to do if the instrument is not functioning as required. All testing personnel need to have direct observation of maintenance or function checks on some level. Maybe all they do routinely is clean the instrument – but they surely need to know what to do if something goes wrong, and what steps to take to troubleshoot.

How can we document a direct observation on a PRN employee? He/she might not be able to perform all the tests in 12-month period?

A: If a person has not performed a particular test in more than a year – then it is very important to document competency assessment, including direct observation. You should try to do as much of the competency assessment for as many tests as possible at times when this person is scheduled to work. If necessary, I think you could do direct observation of patient testing using previously tested samples.

When do we do semi-annually competency?

A: The first year after the employee began performing the test(s). Some labs do the first competency assessment at about 4 months after the person starts testing, and then again at 12 months. This is fine.

Slide 15 #5 - Do we need to assess test performance on all 3 types of samples mentioned or just 1 of the 3?

A: Any one of the three listed (PT, internal blind samples, or previously tested samples) can be used to meet this component. It is not necessary to do all three.

What about testing personnel that have been employed for many years? Do you need to evaluate each test each year?

A: Yes.

Please clarify every lab personnel must have done a blind sample annually?

A: A required component of competency assessment is to include testing of blind samples, to make sure that the person is able to get the results that are expected. Proficiency Testing can satisfy this

requirement. Or, you can use previously tested samples. There is no specific regulation related to competency that delineates the number of blind samples required annually. If you would like to discuss this further, I am happy to have a conversation – feel free to call COLA and ask for me.

If the Laboratory Director is to document the competency assessment for the Laboratory Supervisor, what suggestions do you have to validate and document this?

A: “Laboratory Supervisor” is not a CLIA defined position – so I am going to assume that you are talking about a Technical Supervisor, Technical Consultant, or General Supervisor. I suggest that the Lab Director and the Lab Supervisor sit down together to go over all of the responsibilities and the competency components. The Lab Director in this case would need to take some responsibility for being familiar with the test performance, documentation, problem solving, and reporting. They could read through the procedures together and make sure that all steps in the testing process are done as prescribed in the procedure. This should be documented as any other competency.

Can we document personnel performance improvement as a result from competency as part of our regular PI plan log? If so, we would not necessarily include staff name, so how would we tie the individual's report to the PI report on file?

A: Yes, you can use remedial training plans and follow up as a performance improvement activity. The need for performance improvement or additional training should be documented with the competency assessment for the individual. For the PI report, you would not need to include employee names, but could report, for example, that nine out of 10, or 90% of staff passed the competency assessment for X test(s). Remedial training was performed for the one personnel who did not pass initial competency. Remedial training consisted of..... Following the remedial training, the competency assessment (or whatever part of the competency that they failed) was administered again and the person passed. Then describe how/if you would change your process based upon the findings of the PI activity.

How should you do a competency for test that requires subjective interpretation? For example toxicology chromatography?

A: COLA requires that each procedure for mass spec include detailed identification criteria that spell out the requirements for identification of a particular target analyte. In addition to the direct observations and review of documents I suggest that select chromatograms be presented as blind samples for the person to identify any target analytes.

How should we perform a competency assessment for a laboratory with only one employee who performs testing (the laboratory supervisor)?

A: See above.

What is the best way to access competency at the Point-of-Care for over 1700 glucometer users?

A: You may find that it is not feasible to implement a direct observation competency or blind sample testing for that large of a group. But you can administer a required written competency – that can be done and submitted to the lab electronically. There are programs that you can use that will calculate a score so that you do not have to individually grade 1700 exams. I suggest that the exam be set up to notify the user of any missed answers, so to be sure that they have the correct information. For any user with an unacceptable score (whatever you determine to be the cutoff, i.e. <80%) you can assign someone to do remedial training.

If you think this is still unmanageable, you can write up a review of the procedure – like a PowerPoint presentation or video, and require all POC personnel to review and sign off that they understand. I

would focus on common problems that staff report with this particular test, to make sure they all are aware of the correct procedure to follow.

What kind of competency assessment is required for nursing personnel performing waived POCT such as POC Glucose?

A: See above. If you are a smaller facility then you could rotate the PT challenges among all of the POCT nursing personnel, or document a direct observation.

In a medical office with 3 MD, nurses with sm lab doing RTc, TC, UC and some waived tests- mono hcg rsv,flu, I work as a part time Technical consultant, which do not leave me enough time for direct observation. Can I delegate to lead tech?

A: As long as you are the one to do the final evaluation and determination of competency based upon the reviews and direct observation reports, and as long as the lead tech is deemed competent by you, then COLA does not object to you delegating portions of the competency assessment.

Where is the personnel competency manual located on the COLA or the Lab University website?

A: There is no competency manual – but COLA does have some new competency templates that will be available in a “Solutions Library” with the next version of COLAcentral. In the meantime, however, I would be happy to email them to you. Please send me an email request: kathyn@cola.org

If lab do not start actual sample then how soon do we need to start competency assessment?

A: The requirement is semiannual competency for the first year of testing. So do what makes sense to you. If you do training, for example, in January, but do not start patient testing until April 1, I would think that it might be important to do some retraining and consider April 1 as the start of testing. So you would then do competency assessment twice between April 1 and April 1 of the following year.

Any ideas about how to go paperless or at least reduce paper to document competency? Online applications? Use of Adobe acrobat?

A: Sure – you can use Word – and store your competencies electronically. I have seen many labs do this successfully. Be sure to back up your files regularly. Learning Management Systems can be used to administer reviews and exams if you choose to use those as part of competency assessment.

Can an MLT manager evaluate MT testing personnel if the Director has delegated it?

A: CLIA says that the person who evaluates and determines competency must have qualifications of a Technical Consultant in a moderate complexity lab – or the qualification of a Technical Supervisor or General Supervisor in a high complexity lab. So if an MLT meets these, there would be no problem with that person evaluating competency on others. But the MLT would have to meet the qualifications. Both Technical Consultant and Technical Supervisor qualifications include a minimum of a bachelor’s degree, as far as education. Please contact me directly if you want to review the MLT qualifications together. kathyn@cola.org

How are COLA surveyors being trained to consistently evaluate the competency assessments?

A: We have done training for COLA Surveyors specifically on competency assessment several times. We also administer annual competency exams for all Surveyors, as well as do a “mock” survey annually. Each of these cover competency assessment review.

Will an educational approach be used in the next year to help labs meet this measure or will the focus be punitive?

A: If you are talking about general competency assessment – I encourage Surveyors to use a helpful, educational approach, but if lacking competency assessment or any of the components of competency assessment, this must be cited as a deficiency.

If you are talking about the 2016 implementation of the new COLA requirement that the Clinical Consultant review lab reports initially and with any changes, - we will define an education period to make sure labs have a chance to get a process developed.

When did phlebotomy become a required competency? I have done quizzes in the past but was always told it was not absolutely necessary.

A: The COLA criterion PER 5 has always required competency assessment for “all staff involved in pre-analytic, analytic, and post-analytic phases of testing, as well as those responsible for supervision and consultation.” However, we have chosen to implement this on an educational basis if competency assessments are complete on everyone but just not the phlebotomists. Competency assessment on phlebotomists does not have specific required elements –so the laboratory can decide how to perform and document competency for phlebotomists and specimen processors.

Is it helpful to involve staff to the point of having them in charge of their own checklist? The tech would be responsible to come to the supervisor and ask to be 'watched' while performing a certain test or maintenance. Does this aid the process or falsely sway the results since the tech has prior knowledge of the observation?

A: I don't think that the testing personnel should be in charge of their own checklist. Rather, I suggested testing personnel should be invited to make suggestions for some of the elements of competency assessment, based upon their experience.

For direct observation, more than likely the testing person is going to be aware that they are being observed. Are the results of the direct observation falsely sways the results due to the fact that they know they are being observed? I do not know, but there is still an advantage to demonstrating a procedure step by step as part of the competency assessment. Direct observation is not the only required component of competency assessment – so if a person is doing something wrong on a routine basis, hopefully this will be evident somewhere in the process.