The Ins and Outs of Training, Competency and Educational Requirements

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Learning Objectives

1. Identify training needed for specimen collection for CAP, TJC, COLA, and CLIA
2. Name who can perform the competency assessments in POCT per CLIA
3. Describe the competency requirements for waived testing for CAP, TJC, COLA, and CLIA
4. Recommend better ways to document training, competency and educational requirements

Agenda

1. Training Requirements
2. Competency and Educational Requirements
3. Common Questions

Training Requirements

Training is Different than Initial Competency

Competency is **NOT**
the same as performance evaluation, proficiency testing, or training

Who Approves Training?

Laboratory Director/Technical Consultant

- The vendor can help the technical consultant with the initial training, but the facility's technical consultant(s) would have to sign off on the training

Revised CAP Checklist POC.06800 Authorized POCT Personnel

Current list of POCT personnel that delineates the specific tests and methods (waived and nonwaived) that each individual is authorized to perform.

Covers (GEN.54750) and personnel records (GEN.54400) are found in the Laboratory General Checklist.

CAP – How Long Do You need to Keep Training Records?

Revised POC.06850 Personnel Training

There are records demonstrating that all POCT personnel INCLUDING WAIIVED TESTING have satisfactorily completed training on all instruments, methods, and specimen collection techniques applicable to the point-of-care testing that they perform.

The records must cover all testing performed by each individual. Training records must be maintained for a minimum of two years . After the initial two year period, records of successful ongoing competency assessment may be used to demonstrate compliance with this requirement. Written procedure for training is required.

Retraining must occur when problems are identified with personnel performance.

CAP POC.09500 Training of Providers

There are records demonstrating that all providers have satisfactorily completed initial training on the performance of the specific tests performed.

NOTE: Medical staff credentialing is not an acceptable record of training.

CAP, TJC and COLA Specimen Collection Training Pre-Analytical

There are records that all personnel collecting patient specimens have been trained in collection techniques and in the proper selection and use of equipment/supplies and are knowledgeable about the contents of the specimen collection procedures.

- NOTE: This applies to all personnel who work under a single CLIA license.

All types of specimen collection techniques (e.g. phlebotomy, capillary, arterial, in-dwelling line, phlebotomy during intravenous infusion), as well as non-blood specimens, must be included in the training in accordance with the individuals' duties.

Specimen collection for TJC is done initially(training), and then assessed and documented every 2 years. HR.01.06.01 Assessing phlebotomy staff competency

COLA includes an initial training, 6 month competency first year, and every year.

Competency and Educational Requirements

Why are Competency Requirements Confusing?

CLIA regulations for competency assessment have not changed

- Vague language
- Misinterpretation
- Various related requirements are interspersed throughout the CLIA regulations
- Requirements are not the same amongst the different inspecting groups

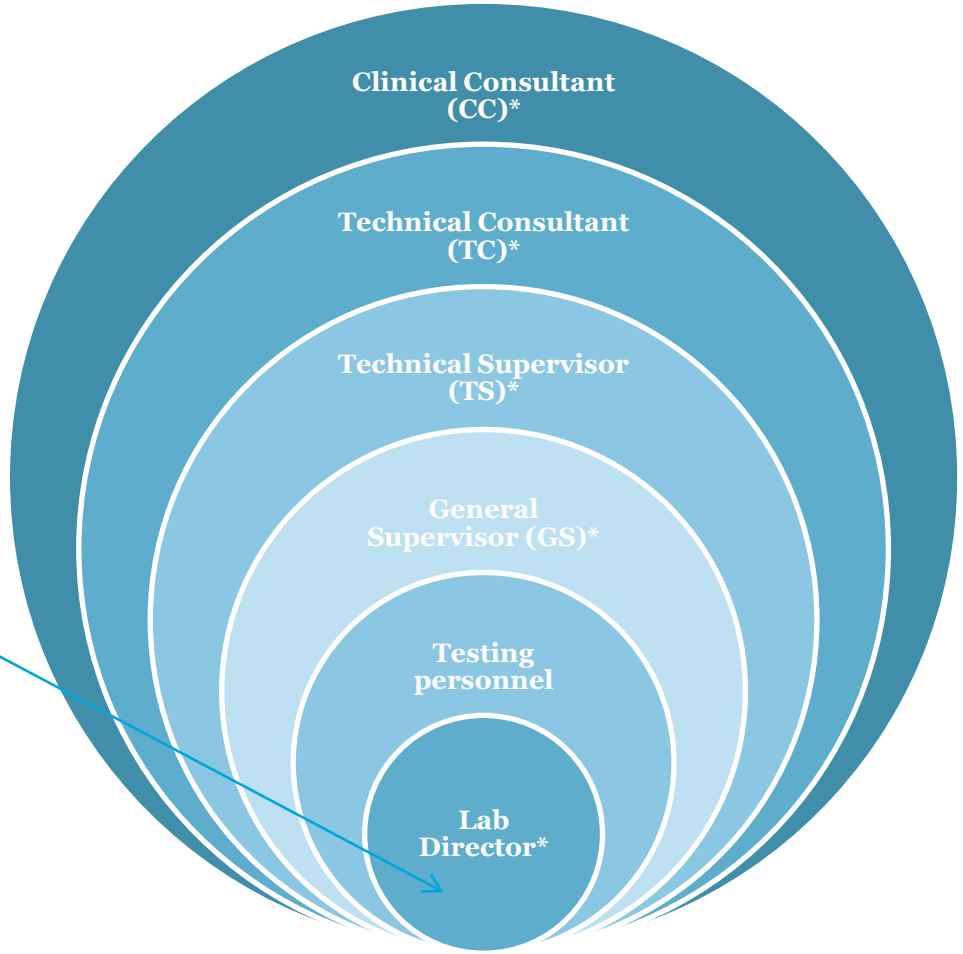
Who needs a Competency Assessment?

Who?	
	ANYONE that performs the testing
	Pathologists
	PhDs

Which staff members should be assessed by whom?

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

The qualifications of individuals assessing competency of waived testing personnel shall be determined by the laboratory director.



*In addition to the six required assessments for testing performed, must also assess for competency based on their federal regulatory responsibilities.

Example Competency Assessment for TC, TS, and GS

Assures that performance specifications are established or verified for necessary tests

Example Competency Assessment for TC, TS, and GS

Enrollment in an approved HHS approved proficiency testing program for each test requiring proficiency testing (PT)?

How well does the laboratory perform PT?

Review of PT results

Example Competency Assessment for TC, TS, and GS

Ensure that a Quality Control (QC) program is in effect and is adequate for the laboratory's testing

Example Competency Assessment for TC, TS, and GS

Resolves technical problems and ensures remedial actions are taken

Example Competency Assessment for TC, TS, and GS

Ensures patient test results are not reported until all corrective actions have been taken and the test system is functioning properly

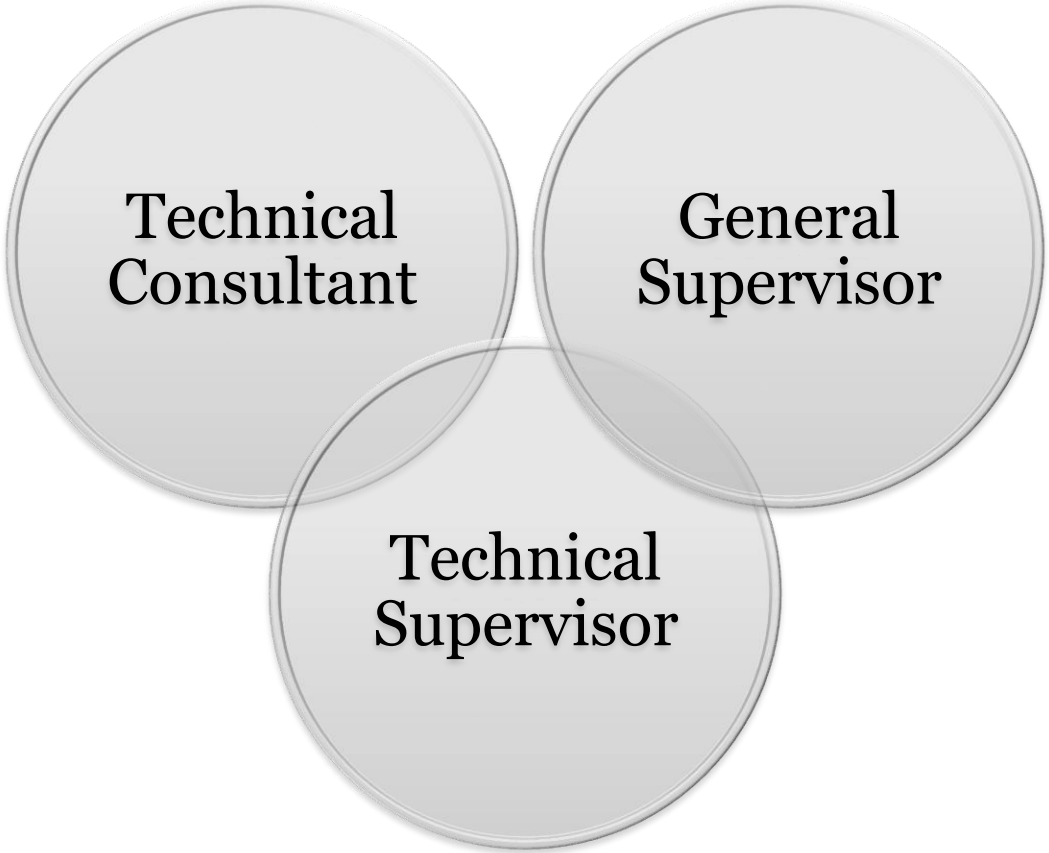
Example Competency Assessment for TC, TS, and GS

Identifies training needs and assures that each individual performing tests receives regular in-service training and education appropriate for the tests they are to perform

Example Competency Assessment for TC, TS, and GS

Evaluates the competency of the testing personnel and assure that all staff members maintain their competency to perform tests accurately, report results promptly, accurately and proficiently

Who Can Perform the Assessments?



Peer Testing Personnel (TP) cannot be designated to perform competency assessment if they do not qualify as General Supervisor (GS), Technical Consultant (TC), Technical Supervisor (TS)

Who Can Perform Competency Assessments for High-Complexity Testing?

Section Director (CC)	
Technical Supervisor	• Bachelor's degree and 4 years training or experience in high-complexity testing
General Supervisor (Delegated in writing by Section Director)	• Associate degree and 2 years of high complexity testing training or expertise. For technologists who've been working in the lab longer, the regulation makes an exception for those previously qualified as a general supervisor under federal regulations on or before Feb. 28, 1992. Also, someone at least meeting the minimum qualifications for a general supervisor.

Who Can Perform Competency Assessments for Moderate-Complexity Testing?

Technical Consultant	• Bachelor's degree and 2 years of laboratory training or experience with non-waived testing. The experience should be in the designated specialty or subspecialty in which the testing takes place
Trained Nurses (Delegated by LD)	• Bachelor's degree and 2 years of training or experience with non-waived testing. In addition, the laboratory director must delegate this task to a nurse in writing beforehand

2 year-degree RN, anesthesia tech, respiratory tech etc. CANNOT assess moderate complexity testing, even if delegated by the Lab Director

New CAP Checklist POC.06920 Qualifications of Individuals Assessing Competency

Individuals responsible for competency assessments have the education and experience to evaluate the complexity of the testing being assessed.

High complexity testing: Section director (technical supervisor) or individual meeting general supervisor qualifications

Moderate complexity testing: Technical consultant or individual meeting those qualifications

Waived testing: May be determined by the laboratory director

EVIDENCE OF COMPLIANCE:

- Policy or statement signed by the laboratory director authorizing individuals by name or job title to perform competency assessment **AND**
- Records of competency assessments performed by qualified individuals

CLIA Competency Assessment Policy

Annual CA is required for all technical, supervisory & testing personnel.

Current staff need CA before patient testing when new methods or instruments are added.

Various related requirements are interspersed throughout regulations.

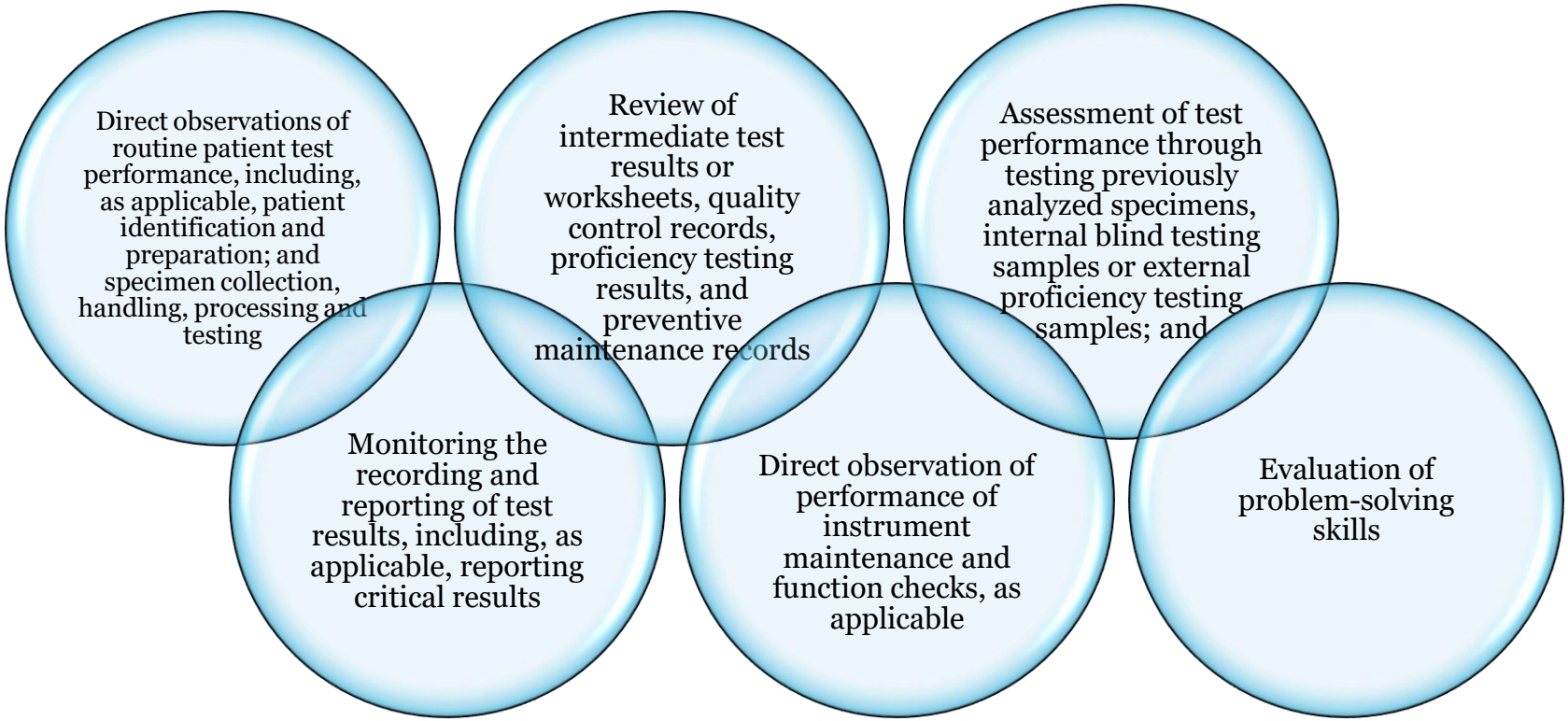
New staff have CA semiannually.

Six elements are necessary for all who perform non-waived testing, for all tests performed.

CA must be documented.

Operator training prior to testing is critical & required.

Six Elements for Non-waived Testing



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Documentation of Competency

Records of competency assessment may be retained centrally within a healthcare system, but must be available upon request. Competency of nonwaived testing personnel **must be assessed at the laboratory where testing is performed** (CAP/CLIA number). If there are variations on how a test is performed at different test sites, those variations must be included in the competency assessment specific to the site or laboratory.

CAP Definition of Test System for Competency Assessment

A TEST SYSTEM is the process that includes pre-analytic, analytic, and post-analytic steps used to produce a test result or set of results.

A test system may be manual, automated, multi-channel or single use and can include reagents, components, equipment or instruments required to produce results. A test system may encompass multiple identical analyzers or devices. Different test systems may be used for the same analyte.

In many situations, tests performed on the same analyzer may be considered one test system; however, if there are any tests with unique aspects, problems or procedures within the same testing platform (pretreatment of samples prior to analysis), competency must be assessed as a separate test system to ensure personnel are performing those aspects correctly.

Does CLIA Require Competency for Waived Testing?

NO COMPETENCY ASSESSMENT is required for personnel who only perform waived testing in a CLIA laboratory

Personnel involved in pre- or post-analytical processes are not required to undergo competency assessment

Waived testing personnel, non-testing pre/post analytic personnel & those not in regulatory positions aren't subject to competency assessment

CAP Waived Testing Competency

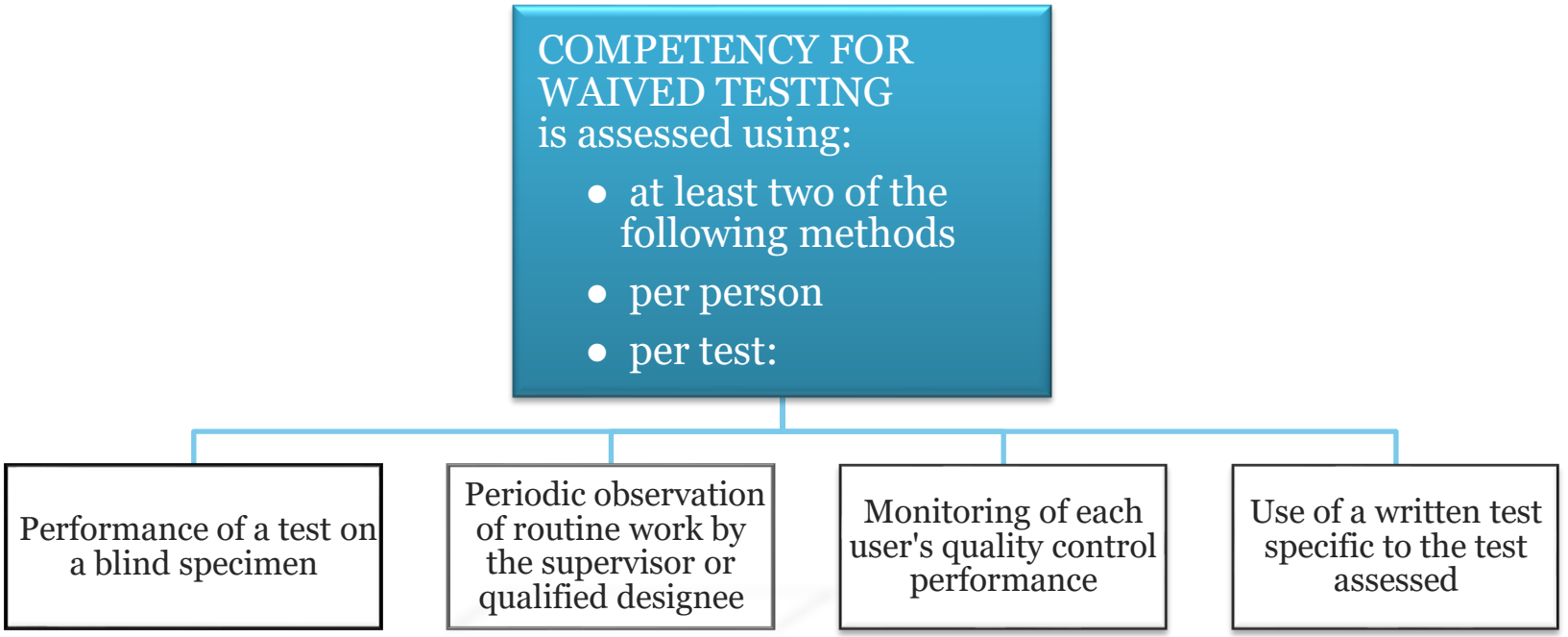
It is not necessary to assess all 6 elements for each assessment event: The **POC program may select which elements to assess.** Selected elements of competency assessment include but are **not limited to the six elements** required for non-waived testing

A laboratory must evaluate and document the competency of all testing personnel for each test system

Any personnel whose work is part of the testing process (includes pre-analytical) CAP Qprobe QP174

Identify which test systems each person uses

TJC Waived Testing Competency



COLA Waived Competency Assessment

Should include Pre-analytical, Analytical, and Post- analytical of each test performed

Initial Competency

6 Months Later after initial competency, and annually thereafter

CAP Provider Performed Testing

Competency Assessment Required:

- PPT is performed under the same CLIA number as the laboratory, and
- The laboratory director is responsible for competency assessment of the physicians and midlevel practitioners.

Competency Assessment NOT Required

- PPT is performed (waived testing only) under the same CLIA number as the laboratory, and
- The institutional medical staff has established the competency of physicians and mid level practitioners through the credentialing process.

TJC states if PPT does not involve an instrument, waived PPT may use medical staff credentialing for training and competency. WT.03.01.01 EP6

Common Questions

CLIA Q&A

If my laboratory only performs waived testing, do I need written policies for assessing personnel competency?

- CLIA DOES NOT require policies for assessing personnel competency for waived testing.
- Even though CLIA has no specific requirements for personnel performing waived testing, you need to ensure that patient testing results are correct to assist in making an accurate patient diagnosis.
- You will need to ensure that testing personnel are following all manufacturers' instructions.
- Testing personnel who are properly trained and performing the test correctly will aid the physician/provider in making an accurate patient diagnosis. If your laboratory is accredited, you may need to consult your accrediting organization's standards.

CLIA/CAP Q&A

What are the educational requirements to qualify as the TC?

- A TC needs at least a bachelor's degree in the applicable area (chemical, physical, biological science or medical technology) as well as two years of training/experience in the specialty or subspecialty for which they are responsible in order to quality as a technical consultant. Please note that CLIA does not require laboratory personnel titles to be the same as the personnel outlined in the CLIA regulations (subpart M); however, if an individual is designated on the Accreditation Organization (AO)/CLIA personnel form as one of the individuals found in subpart M, they must meet the regulatory requirements/AO standards. The AO standards may be more stringent than CLIA.

- CAP stated additionally : There are no requirements for courses or hours or semesters. We leave this to the discretion of the laboratory director.

COLA Q&A

Who should perform the competency assessment on the Technical Consultant?

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

Who evaluates competency of LD or Clinical Consultant?

- 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.

Is a competency assessment needed for specimen collection and processing personnel?

- YES

COLA Q&A

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

- "Lab Manager" is not a CLIA defined position. The Lab Manager must have minimum qualifications of a TC, TS or GS.

Should the Lab Director sign all competency evaluations?

- No, not necessarily. The TC, TS, or GS can sign the competency evaluations. This should be defined in the competency assessment procedures.

COLA Q&A

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?

- The TP/GS could plan to do a self-evaluation in the presence of the LD/TS – and gather and review the documentation together.

CLIA Q&A

What must I include in the personnel assessment for a mid-level practitioner (PPM)?

- The competency assessment for mid-level practitioners must include the six procedures. Some things to consider for the competency assessment for all tests performed by that individual can:
  - Is the test actually performed during the patient's visit?
  - Is the correct microscope type used (limited to brightfield or phase/ contrast)?
  - Is the patient specimen processed correctly and timely?
  - Does the mid-level practitioner perform the test and report results according to the laboratory's procedure?

COLA Q&A

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

- 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 TC in a small lab and performs some testing, who evaluates the Director?

- It is not required for the Lab Director to undergo competency assessment for the positions that he/she holds, including testing personnel.

COLA Q&A

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

- 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.

AACC POC List Serve

Date: Sun, 29 Jan 2017 15:37:36 +0000
From: "Mann, Peggy" <pmann@UTMB.EDU>
To: "'aacc-poct-div@aacclists.org'" <aacc-poct-div@aacclists.org>
Cc: "Michelle.Reeves@uchealth.org" <Michelle.Reeves@uchealth.org>
Subject: Re: [Aacc-poct-div] provider performed microscopy
Message-ID: <824574EF1D992F42940CC2C14216D6C9CB0244FE@GRMBX4.utmb.edu>
Content-Type: text/plain; charset="us-ascii"

Hi Michelle,
We by NO means 'have PPMP under 'control''. I threw caution to the wind, however, and tried to respond to your questions:

<Can I get a brief overview of everyone's structure for this?>
Our non-hospital clinics have CLIA PPMPs held by an MD within the department.
The POC lab has set up the competency assessment via an online 'test' with images, case studies. Departments using those competency assessment onlines are given input to the images used, case studies created. The onlines are done through the health system's compliance online testing system which sort of makes the 'who took it' assessment 'trackable' but completing the circle of having all the elements met and knowing who ALL are using the microscope/documenting in EMR is a gap (worse yet, who is failing to document) and s not where it needs to be for 100 compliance. The observation element has to be performed/conducted by faculty within the department holding the CLIA PPMP (eg Derm, Fam Med, Pedi).

<We are suddenly getting HUGE push back from our providers about having to do training, direct observations, comp assessments, etc. Has anyone else encountered this?>
Yes although for us it's been more constant over last 15 years. Never 'suddenly' a problem.

<How did you overcome that?>
I don't feel we in POCT have overcome resistance. I don't feel the health system (particularly the medical staff upper echelon) has been supportive enough, has not built in as yet the accountability required on the side of the departments holding the CLIAs.

Good Luck in your endeavor and be sure to post if you 'solve this' within your organization, Peggy

Question for CAP email accred@cap.org

Hi Jane,

The inspectors instructions are correct, the competency assessment must be performed at each location, even if everything is identical.

Some helpful ideas might be using the same form for the assessment and indicating on the form the site. Also keeping the records electronically might help with the organization and allow easy access or a more proficient check to see if any elements or sites have not been assessed. One facility had testers listed along with the sites they performed testing at, and even included hyperlinks to the documentation at each location.

I hope this helps!
Sincerely,
Jean Hood
Team Lead Inspection Services
Laboratory Accreditation Program

---- Original Message ----
Hello CAP Technical Services,
Can you advise on this question? I would like to inquire more specifically about competency assessment for EPOC operators who work at multiple CLIA locations. We have a sizeable group of EPOC operators who work at the main hospital and satellite NICUs at three other CLIA locations run by us, but located within other regional hospitals. An inspector indicated that operators would have to complete and document annual competency assessments at all 4 locations each year, even though the tests are performed and overseen identically at all 4 locations under one shared set of written procedures. With the specifics of our situation in mind, have you had any experience with a customer faced with this challenge? Because it would be logistically challenging to pull off assessments of each individual at 4 locations, I am wondering if you have heard how of any strategies that any other labs have used to meet this requirement.
Best regards,
Jane

For More Information

CAP	accred@cap.org
TJC	https://web.jointcommission.org/sigsubmission/sigquestionform.asp
COLA	info@cola.org
CLIA	LabExcellence@cms.hhs.gov

References

CAP Checklists 8/22/2018
http://elss.cap.org/elss/ShowProperty?nodePath=/UCMCON/Contribution%20Folders/DctmContent/education/OnlineCourseContent/2017/LAP-TLTM/checklists/cl-com.pdf
TJC Standards 2018
COLA Criteria 2016

QUESTIONS?

Abbott