

# **CLIA Updates: Competency Assessment, Personnel**

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# Today's Topics for Discussion

- Definition & Introduction
- Regulations
- Rationale
- Competency Assessment Policies
- Tips
- Frequently Asked Questions
- Personnel Requirements: PPM, Testing Personnel

# CLIA Competency Assessment Definition

Competency is the ability of laboratory personnel to apply their skill, knowledge, & experience to perform their duties correctly.

# CLIA Competency Assessment Introduction

Competency assessment is used to ensure that laboratory personnel are fulfilling their duties, as required by Federal regulations.

# CLIA Competency Assessment- Key Regulation

## 493.1413(b)(8) & 1451(b)(8)

### Technical Consultant/Supervisor

- Evaluating the competency of all testing personnel & assuring that the staff maintain their competency to perform test procedures & report test results promptly, accurately, & proficiently
- Includes 6 required procedures

# CLIA Competency Assessment- Key Regulation

## 493.1413(b)(8) & 1451(b)(8)

### Technical Consultant/Supervisor

Evaluating and document competency

- Semiannually the first year
- Annually thereafter
- Reevaluated with new test methodology or instrumentation

# Regulatory Requirement

Individual conducting competency assessments must be qualified as TC or TS/GS

# Provider-Performed Microscopy (PPM)

Competency assessment must be done for Provider-Performed Microscopy (PPM) individuals.



# Training vs. Competency

Training	Competency
<b>Development</b> of skill, knowledge, experience	<b>Application</b> of skill, knowledge, experience
<b>Prior</b> to reporting patient test results	<b>After</b> training (initial and changes in testing)
No specific regulatory intervals	Specific regulatory intervals

# CLIA Competency Assessment Rationale

- ▶ Confirms training effectiveness
- ▶ Helps to ensure performance of test procedures remains consistent
- ▶ Part of overall quality management system

# CLIA Competency Assessment Rationale

- ▶ Studies indicate that more education and training produce higher quality results
- ▶ Survey experience indicates problems caused by human errors can have patient impact
- ▶ Routine CA can help prevent errors

# CLIA Competency Assessment Policy

- ▶ Documented competency is required for all technical, supervisory & testing personnel
- ▶ Six procedures are necessary for all who perform non-waived testing for all tests performed
- ▶ CA must be documented

# CLIA Competency Assessment Policy – Laboratory Director

- ▶ Must demonstrate competency based on regulatory responsibilities
- ▶ Checked on survey
- ▶ 1 MD practice
  - 6 procedures not required
  - Must show competency (e.g., peer review, PT)

# Required Procedures – Direct Observation of Testing

(#1) Direct observation of routine patient test performance, including patient preparation, if applicable, specimen handling, processing & testing.



# Required Procedures – Monitoring Test Results

(#2) Monitoring the recording & reporting of test results



# Required Procedures – Review of Records

(#3) Review of intermediate test results or worksheets, QC records, PT results, & preventive maintenance records



# Required Procedures – Direct Observation of PM/Fxn Checks

(#4) Direct observation of performance of instrument maintenance & function checks



# Required Procedures – Previously Analyzed Specimens

(#5) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external PT samples



# Required Procedures – Problem Solving Skills

(#6) Assessment of problem solving skills



# CLIA Competency Assessment Tips

- ▶ Competency is not PT...but it is a good tool
- ▶ Pathologists should be evaluated by the laboratory director as technical supervisors
- ▶ Competency is NOT the same as performance evaluation or training
- ▶ Pictures/double-headed scopes work well for PPM testing

# CLIA Competency Assessment Tips

- ▶ Check job duties to ensure CA covers all testing, reporting, PM, calibration, etc.
- ▶ When observing test performance, use the SOP, package insert (PI) to ensure procedure is current and being performed correctly
- ▶ It is important to document who performs the CA as well as when it was performed – surveyors will ask for this information

# CLIA Competency Assessment Tips

- ▶ Can use competency assessment for QA when confirming tests result printouts match reported/charted results
- ▶ Personnel performing waived tests, pre & post analytic activities & not in regulatory positions are not subject to competency, but it's good QA
- ▶ Break Microbiology down into component parts

# CLIA Competency Assessment Tips

- ▶ Follow up on QC corrective actions will demonstrate problem-solving ability
- ▶ Don't have to do CA all at one time
- ▶ Build CA into existing quality practices, procedures (Quality System)
- ▶ Can often combine analytes tested on the same platform

# CLIA Competency Assessment Tips

- ▶ If lab has a service contract for PM, it's ok to review maintenance records
- ▶ If test methods are added or changed, competency must be re-evaluated prior to reporting test results
- ▶ Sole practitioners performing their own testing must show they are competent

# Frequently Asked Questions

Is it acceptable under CLIA for nurse manager to perform CA for POCT testing personnel?

Yes, as long as the nurse manager meets the regulatory requirements to qualify as a TC + delegated in writing

# Frequently Asked Questions

Do the CA requirements differ for high and moderate complexity testing?

No, the six required procedures are the same for all non-waived testing.

# Frequently Asked Questions

May I use training and personnel evaluations to assess competency?

No, training/personnel evaluations are not the same as competency testing.

# Frequently Asked Questions

Who is responsible for performing the competency assessment?

The TC is responsible for moderate complexity testing; the TS/GS is responsible for high complexity testing.

# Personnel Requirements: PPM, Testing Personnel

# Provider-Performed Microscopy (PPM)

Required personnel:

- Laboratory Director
- Testing Personnel
  - Physician
  - Midlevel practitioner
  - Dentist

# Testing Personnel Qualifications: Moderate Complexity

- State licensure, if required
- MD, DO
- PhD, Masters, Bachelors
  - Chemical, physical, biological science
  - Clinical Laboratory Science
  - Medical Technology

# Testing Personnel Qualifications: Moderate Complexity

- Associates Degree (AA)
  - Chemical, physical, biological science
  - Medical Laboratory Technology
- High school graduate or equivalent with successful completion military program
- High school diploma or equivalent + appropriate training

# Testing Personnel Qualifications: High Complexity

- State licensure, if required
- MD, DO
- PhD, Masters, Bachelors
  - Chemical, physical, biological science
  - Clinical Laboratory Science
  - Medical Technology

# Testing Personnel Qualifications: High Complexity

- Associates Degree (AA)
  - Laboratory science or medical laboratory technology; **OR**
- Education and training equivalent to AA
  - 60 semester hours (specified) + 3 months of training
- Qualified or could have qualified as technologist prior to 2/28/92

# Testing Personnel Qualifications: High Complexity

- Blood gas analysis
  - Qualify as HC TP
  - Bachelors degree in respiratory therapy or cardiovascular technology
  - Associates degree related to pulmonary function
- Histopathology
  - Qualify as a Technical Supervisor

# Testing Personnel Qualifications: High Complexity, Grandfathering

- On or before 4/24/95:
  - HS graduate or equivalent and have graduated from clinical laboratory training program or military medical laboratory program training course
- Until 9/1/97:
  - HS diploma or equivalent AND appropriate documented training

# Where to Obtain Information

**CMS/CLIA Web site:**

**[www.cms.hhs.gov/clia/](http://www.cms.hhs.gov/clia/)**

Interpretive Guidelines, Brochures #10

**CMS CLIA Central Office:**

410-786-3531

**email: [sarah.bennett1@cms.hhs.gov](mailto:sarah.bennett1@cms.hhs.gov)**

**THE END**

**Thank You  
Questions?**