



## CLINICAL STAFF COMPETENCY ASSESSMENT POLICY

POLICY #:

Effective Date:

### POLICY

1. Competency is the ability of personnel to apply their skill, knowledge, and experience to perform their laboratory duties correctly. Competency assessment is used to ensure that the laboratory personnel are fulfilling their duties as required by federal legislation.
2. Competency must be assessed a minimum of twice in the first year of employment for testing personnel and annually thereafter. Competency must also be assessed, prior to reporting results, whenever there are test methodology or instrumentation changes. Competency assessment can be done throughout the entire year by coordinating it with routine practices and procedures to minimize impact on workload.
3. Competency will be documented in writing with additional supporting documentation when indicated. These records may be maintained electronically or on paper. An annual Competency Assessment Summary Form must be completed for each person indicating the dates of assessment, procedure, method of assessment, identity of person assessing competency, and dates of review. See Attachment A.
4. Competency assessments will be performed by senior personnel who have documented competency and are proficient in the area assessed. Personnel performing the assessment must at minimum meet the CLIA requirements of general supervisor, but need not be in a supervisory position.
5. The procedures for assessing clinical staff competency must include, but are not limited to:
  - Direct observation of routine patient test performance, including specimen handling, processing, and testing;
  - Monitoring the recording and reporting of test reports;
  - Review of intermediate test results or worksheets, quality control records, proficiency testing (PT) results, and preventative maintenance records;
  - Direct observation of performance of instrument maintenance and function checks;
  - Assessment of test performance through testing of previously analyzed samples, internal blind testing samples or external PT samples
  - Assessment of problem solving skills.
6. Competency assessment, which includes the six procedures above, must be performed on testing personnel for each test that the individual is approved to perform. Exception: If multiple tests are performed simultaneously on the same testing platform and there are no unique aspects, problems or procedures within the same testing platform, the assessment can be performed on the testing system (examples: GSP, Architect).
7. Each testing person will have a notebook where training and competency documentation will be filed for a minimum of 2 years. Older documentation can be moved to file drawers.
8. Supervisors who perform testing on patient specimens are required to have the six required procedures in their technical competency assessment in addition to a competency assessment based on their federal regulatory responsibilities.

<b>CLINICAL STAFF COMPETENCY ASSESSMENT POLICY</b>	
<b>POLICY #:</b>	<b>Effective Date:</b>

9. Unit managers, who fill the CLIA role of technical supervisor, are required to have a competency assessment on the federal regulatory responsibilities and additional responsibilities that have been delegated to them from the laboratory director. These delegated responsibilities must be in writing.

### **COMPETENCY PROCEDURE FOR TESTING PERSONNEL**

1. The laboratory manager will ensure that a Competency Assessment Summary Form (Appendix A) is filled out for each testing person. The form will list all procedures for which competency is required and the date training was completed. For each procedure, a competency plan will be documented indicating when each of the 6 procedures will be assessed.
2. Perform the following steps when planning a competency assessment:
  - a. Discuss with the individual what tasks will be assessed and determine a mutually agreed date and time for the assessment.
  - b. Provide a copy of the checklist for technical areas or a list of the items to be evaluated to the technologist.
  - c. Determine from the technologist if there are any areas of uncertainty that need training or review before the assessment takes place and provide that information.
3. When observing performance of laboratory testing, monitor the following:
  - a. Observe specimen handling and processing
  - b. Look for application and adherence to all elements of the test method/instrumentation procedure
  - c. Observe the assessment of QC results and documentation
  - d. Look at reagent preparation and calibrations, if applicable
  - e. Monitor the recording and reporting of test results
  - f. Observe for compliance with safety protocols
  - g. Observe any instrument maintenance and function checks
  - h. Evaluate any problems-solving skills if they occur
3. Assessment of problem solving skills can be documented by recording instances when employees report to supervisor the correct solutions to problems such as handling mis-labeled specimens, customer complaints, and instrument malfunctions. An example of a problem-solving documentation form is included in Appendix B. Problems can also be posed in the form of a written test that staff members can solve on paper. If choosing this type of problem-solving exercise, make clear to staff that problems must be solved according to written policies and procedures or instrument manuals. These types of written exercises should be "open-book" since staff would have access to materials during a routine workday.
4. If using proficiency testing (PT) samples as unknowns to assess competency, they should be used only after the results have been returned from the PT agency. Successful performance of PT samples cannot be the only means of documenting competency assessment.

<b>CLINICAL STAFF COMPETENCY ASSESSMENT POLICY</b>	
<b>POLICY #:</b>	<b>Effective Date:</b>

5. When reviewing records as part of the competency assessment, document which records were reviewed, don't just place a checkmark on the form. For example: "reviewed worksheet # from date "xx/xx/xx" or "workflow for specimen #."
6. If the competency assessment is unsuccessful and the individual needs further training, consideration must be given to the nature of the errors observed and the testing assignment must be adjusted accordingly. Document if re-training, re-evaluation, reviews, and/or future monitoring are required. The summary form includes a place for corrective actions on the last page.
7. When all competency assessments are complete for the year, review the summary form with the testing person and both the employee and supervisor signs the last page.
8. Contact the laboratory QA Office for assistance with developing competency assessment checklists.

### **COMPETENCY PROCEDURE FOR TECHNICAL AND GENERAL SUPERVISORS**

A competency assessment is required for any duties that the laboratory director has delegated to the supervisor as well as requirements that are specified in the CLIA regulations for this position. The Unit Manager (technical supervisor) can perform and sign off on the competency assessment for the general supervisor. The laboratory director must sign off on the competency assessment for the technical supervisors.

This competency assessment must be completed annually.

See Appendices C and D for examples of general supervisor and technical supervisor competency assessment forms.

### **REFERENCES**

1. APHL Teleconference: *2012 CLIA Update: Mission Possible – Competency Assessments*, presented by Diana Fairbanks, Nancy Grove and Kristine Rotzoll on 3/27/2012.
2. *Appendix C. Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services*; Centers for Medicare and Medicaid Services; State Operations Manual, Rev. 140, May 29, 2015.
3. CMS Center for Clinical Standards and Quality/Survey and Certification Group; S&C:15-17-CLIA, 1/9/2015.
4. Clinical Laboratory Standards Institute (2009); Training and Competency Assessment; Approved Guideline – Third Edition. CLSI Document GP21-A3. CLSI, Wayne, PA.

<b>CLINICAL STAFF COMPETENCY ASSESSMENT POLICY</b>	
<b>POLICY #:</b>	<b>Effective Date:</b>

**APPENDICES**

Appendix A: Competency Assessment Summary Form

Appendix B: Form for Competency Assessment of Problem Solving Skills

Appendix C: Example Competency Form for General Supervisors

Appendix D: Example Competency Form for Technical Specialists