

CLIA Corner

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Iowa CLIA Surveyors:

Nancy Grove, BS, MT(ASCP)

Kristine Rotzoll, BS, MT(ASCP)

Melinda Bochmann, BA, MT(AMT)



In This Issue of the CLIA Corner we address:

- ***The CLIA Six Competency Assessment Criteria and the Why, Who, When, What and How of Competency Assessments***

WHY

Competency assessments must be performed and documented to ensure that laboratory personnel are competent to process specimens, perform test procedures, and report test results promptly and accurately. The competency assessment monitors and assesses the individual's competency to perform and report laboratory tests and examinations.

Do not confuse competency assessments with training and/or performance evaluations. Training is the process of providing and developing knowledge and skills; whereas, competency is the application of the attained knowledge and skills. Performance evaluations may include the assessment of competency, but they also evaluate other behaviors and attributes as they relate to the personnel's position and job (e.g. internal and external customer relations, initiative, etc.).

WHO

Competency assessments are required for individuals fulfilling the following personnel responsibilities outlined in Subpart M of the CLIA regulations: clinical consultant, technical consultant, technical supervisor, general supervisor and testing personnel. Clinical consultants, technical consultants, technical supervisors and general supervisors who perform testing on patient specimens are required to have competencies based upon the six criteria for testing personnel, in addition to, competencies based on their supervisory responsibilities (listed in Subpart M of the CLIA regulations.)

The laboratory director is responsible for ensuring that laboratory personnel are trained and competent to perform test procedures and report test results promptly and accurately prior to reporting patient test results. The laboratory director may delegate this responsibility, in writing, to the technical consultant for moderate complexity testing personnel (TP) and to the technical supervisor and/or general supervisor for high complexity TP.

WHEN

Competency assessments are to be performed:

- At least semiannually during the first year of employment;
- Annually thereafter; and
- When there are test methodology or instrumentation changes, and with the addition of new test systems.

Competency assessments may be performed throughout the entire year by coordinating them with routine laboratory practices and procedures.

WHAT

The overall competency assessment must include:

- Each non-waived instrument and analyzer the individual is responsible for operating;
- Each non-waived test system or kit the individual is responsible for performing; and
- Each non-waived manual test the individual is responsible for performing (e.g. Gram stains, manual differentials, wet mounts, etc.)

For competency purposes, all tests performed simultaneously on the same test platform may be combined, as long as there are no unique aspects, problems or procedures associated with any of the tests.

CLIA does not require competency assessment for waived testing; however, it is considered a good laboratory practice.

HOW

After determining that testing personnel have received the appropriate training, their competency must be assessed. The competency assessments must address the **six criteria** listed below.

Criteria 1 - Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing.

Over time, testing personnel may create shortcuts, omit certain steps or even maintenance thinking they are saving time or cutting laboratory costs. In reality, invalidated changes to procedures may lead to problems with patient test results. Without direct observations, these omissions will never be identified as a potential problem.

While performing the direct observation of routine patient test performance ensure personnel:

- Apply and adhere to all elements of test method and instrument procedures:
 - Does the laboratory personnel follow procedures and access operator's manual or package insert as needed?
- Collect sufficient patient sample and correctly process the specimen used for testing:
 - Does the laboratory personnel maintain positive identification of the specimen throughout all phases of testing?
 - Does the laboratory personnel identify specimen type and storage requirements?
 - Does the laboratory personnel understand specimen rejection criteria?
 - Does the laboratory personnel review the test requisition for completeness?
 - Does the laboratory personnel adhere to correct specimen collection techniques and specimen labeling criteria?
- Prepare reagents and control materials (including verification of lot number, expiration date) and controls adequately, and perform the testing appropriately:
 - Does the testing personnel follow labeling criteria for both reagents and controls?
 - Does the testing personnel perform the test correctly by adding the proper amount of patient specimen and reagent(s) in the correct order?
 - Does the testing personnel correctly interpret test reactions and results?

- Utilize and demonstrate appropriate laboratory skills and practices. Examples include reading a meniscus, demonstrating manual dexterity and performing accurate measurements, such as pipetting.
- Adhere to safety requirements, including:
 - Does the testing personnel wear appropriate personal protective equipment?
 - Does the testing personnel dispose of waste supplies appropriately?
 - Does the testing personnel follow safe laboratory practices?

Criteria 2 – Direct observation of performance of instrument maintenance and function checks.

While performing the direct observation ensure personnel:

- Operate the instrument as required by the manufacturer, including:
 - Does the testing personnel perform all the required instrument maintenance?
 - Does the testing personnel adhere to the laboratory's policies for instrument calibration and calibrate as required by the manufacturer?
 - Does the testing personnel understand instrument software and operating error messages?
 - Does the testing personnel follow troubleshooting instructions?

Criteria 3 – Monitor the recording and reporting of test results.

While reviewing patient testing records ensure testing personnel:

- Adhere to the laboratory's policies for recording patient test results:
 - Does the laboratory personnel correctly document results on patient logs?
 - Does the laboratory personnel document and notify appropriate personnel about clinically significant or unusual test results (i.e. lead tech, supervisor or manager)?
 - Does the laboratory personnel alert the authorized/appropriate individual or entity when any test results indicate an imminently life-threatening condition, or critical or panic value results?
 - Does the laboratory personnel document the notification with date, time, test results and person to whom the test results were reported?
- Demonstrate laboratory information system (LIS) knowledge and application, including: tracking samples, reviewing and validating patient results, looking up patient information and test results, and creating pending test logs and other reports if part of job responsibilities.

Criteria 4 – Review of intermediate test results or worksheets, quality control (QC) records, proficiency testing (PT) results and preventive maintenance records.

While reviewing test results or worksheets, QC records, proficiency testing results and preventive maintenance records, ensure testing personnel:

- Review QC results:
 - Does the laboratory personnel understand, utilize and adhere to QC acceptance criteria, including the appropriate corrective action to be taken when results are not acceptable?
 - Does the laboratory personnel review QC results, charts or graphs by paper or LIS methods?

- Treat proficiency testing samples in the same manner as patient specimens and maintain appropriate records:
 - Does the testing personnel adhere to the laboratory’s policies for performing PT testing?
 - Does the testing personnel appropriately fill out the PT records, including signing the attestation statement?
- Document the performance of maintenance appropriately:
 - Does the testing personnel appropriately complete the maintenance logs as required by the manufacturer (including weekly, quarterly and annual maintenance)?

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

As part of competency assessment, testing personnel must partake in proficiency testing or assessment of test performance through a different means (i.e. internal blind samples or previously analyzed specimens). Depending on the type of samples tested, there are advantages and disadvantages:

SAMPLE TYPE	ADVANTAGE	DISADVANTAGE
Previously analyzed specimens	Budgetary savings	Only assesses analytic phase of testing
Internal blind samples	Integrated into workflow so TP are unaware. Assesses routine performance and identifies problems within all phases of testing	Feasibility is not the easiest. Sample preparation and the inadvertent reporting of results may cause problems.
External proficiency testing (PT) samples	Assessment compared with other labs with same method(s). Results are unknown until PT program grades/scores.	Only assesses analytic phase of testing
Previously analyzed external PT samples	Budgetary savings. IMPORTANT: Before using these samples to assess additional TP, be sure the results have been sent to the PT program & grades/scores have been received.	Samples are tested prior to original results sent to PT program and/or grades/scores are received from PT program. NEVER send PT samples to another lab for ANY REASON including determination of competency.

Criteria 6 – Assessment of problem solving skills.

Finally, competency assessments must include the assessment of problem solving skills. This can be accomplished through a variety of different ways:

- Case studies use real problems that have occurred in the past to ensure competency and consistency among personnel.
- Theoretical questions assess knowledge of background information (e.g., describe the test method of a specific test).
- Technique questions assess knowledge of an important step in a procedure (e.g. explain the order of performing a specific test).
- Interpretation questions assess the ability to arrive at the correct conclusion for a given set of information (e.g., explain how to handle tests results that are inconsistent with the patient’s current condition).
- Problem solving questions assess ability to think critically (e.g., explain the action to be taken if calibration fails for a specific analyte).

Summary

The laboratory must establish and follow written policies and procedures to monitor and assess each individual's competency and to identify remedial training or continuing education needs. This encompasses all laboratory personnel, including consultants and supervisors.

The laboratory must have a way to document and track competency assessments. This documentation should include who performed the assessment, outcomes of any written problem solving questions, and review of records and reports.

The use of electronic records is acceptable for maintaining this documentation. The system must be secure and provide for the individual's privacy and confidentiality.

Here is a quick checklist of "tips":

- ✓ Evaluate/assess only what the laboratory personnel is responsible for;
- ✓ Utilize checklists or forms to collate information;
- ✓ Designate what was and will be observed;
- ✓ Collect copies/scan examples of corrective actions for solved problems; and
- ✓ Collect data and document (paper or electronically) throughout the year and maintain these records in each individual's personnel file (i.e. review of quality control records, proficiency testing records and results, patient testing records and reports, and preventive maintenance records).

References

- State Operations Manual; Appendix C – Survey Procedures and Interpretative Guidelines for Laboratories and Laboratory Services; Rev. 166, 02-03-17.
- 2012 CLIA Update: Mission Impossible-Competency Assessments; Association of Public Health Laboratories and State Hygienic Laboratory at the University of Iowa; 03-27-12.
- CLIA Brochure #10 – “What Do I Need to Do to Assess Personnel Competency?”