EDUCATIONAL COMMENTARY – COMPETENCY ASSESSMENT IN THE CLINICAL LABORATORY: DEVELOPING A COMPETENCY ASSESSMENT PROGRAM

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LEARNING OBJECTIVES

On completion of this exercise, the participant should be able to

- explain the importance of competency assessment in fulfilling federal regulations.
- describe who is responsible for competency assessment, who must have their competency assessed, and the frequency of the assessment.
- use examples to explain the 6 methods of competency assessment.
- define a test system in accordance with federal regulations for competency assessment.
- describe the elements of a competency assessment program.

Introduction

Competency is the ability to accomplish a task successfully. In the laboratory, this means testing the right sample in the correct way to produce the best result possible for patient care. Competency must encompass all phases of testing: preanalytic, analytic, and postanalytic. Assessing staff for competency can be challenging, but with a comprehensive competency assessment program, the task can be a little less daunting. Through regulations set forth by the U.S. federal government, it is possible for each individual laboratory to develop an effective competency program.

The Centers for Medicare & Medicaid Services (CMS) regulates all laboratory testing (except research) performed on humans in the U.S. through the Clinical Laboratory Improvement Amendments (CLIA). In total, CLIA covers approximately 225,000 laboratory entities. The Division of Laboratory Services, within the Survey and Certification Group, under the Office of Clinical Standards and Quality (OCSQ), has the responsibility for implementing the CLIA Program.¹

As recorded in the Code of Federal Regulations (CFR) Title 42, Part 493, Subpart M, the Clinical Laboratory Improvement Amendments of 1988 (CLIA ’88) specify standards that laboratories must follow to ensure the competency of staff and, therefore, the ultimate quality of the final test result. These
EDUCATIONAL COMMENTARY – COMPETENCY ASSESSMENT IN THE CLINICAL LABORATORY: DEVELOPING A COMPETENCY ASSESSMENT PROGRAM (cont.)


Clinical laboratories must establish a competency assessment program that meets the federal requirements for a certified laboratory as stated in CLIA ‘88, as well as the standards of other CMS-approved accrediting agencies such as The Joint Commission, CAP (the College of American Pathologists), and COLA. These agencies refer directly to CLIA ‘88 regulations for competency assessment and may have additional requirements unique to their accreditation. The goal of these regulatory and certifying standards is to “ensure that prior to testing patients’ specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.”

Current regulatory and certifying standards prescribe the following:

- How competency will be assessed and the methods that must be used,
- Personnel responsible for overseeing competency,
- The individuals who must have their competency assessed and the frequency of that assessment,
- The test systems that fall under the regulation for competency assessment.

How Competency Will Be Assessed and the Methods That Must Be Used

Six methods are required by CLIA ‘88 federal regulation to be used to assess competency.

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

   This method requires a specified individual to observe staff members performing the preanalytic and analytic phases of testing according to written procedures. These procedures can be summarized in a direct observation checklist that addresses the critical steps of a specific procedure to help the observer evaluate each procedure.

2. “Monitoring the recording and reporting of test results.”

   This can be accomplished by reviewing patient records in a laboratory information system, hard copy reports, or patient medical records. Specific elements, such as critical value documentation, accurate reference ranges, corrected reports, and accurate patient demographics are important to the quality of patient data and should be monitored.
EDUCATIONAL COMMENTARY – COMPETENCY ASSESSMENT IN THE CLINICAL LABORATORY: DEVELOPING A COMPETENCY ASSESSMENT PROGRAM (cont.)

3. “Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records;”

A method to document the review of the elements mentioned in the standard must be used to ensure that all staff are maintaining quality in the laboratory. The routine review of quality control records and preventive maintenance records should be part of every laboratory’s quality assurance plan. Proficiency test results are reviewed by performing personnel as well as by the laboratory director. Intermediate test results can be reviewed by specified personnel before patient results are reported to look for documentation such as manufacturer kit lot number and expiration date, the date testing was performed, the initials of staff performing the testing, and documentation of kit performance by quality controls.

4. “Direct observation of performance of instrument maintenance and function checks;”

In addition to the review of documentation, a specified individual is also responsible to watch staff perform instrument maintenance and function checks, which are critical to analyzer performance. This method of competency assessment ensures that all steps are performed according to the written procedures. Again, an observation checklist with the critical steps summarized is an effective tool for documentation of this method.

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

This method can be time consuming if there are several staff members to assess. This requires the assessor to prepare unknown samples to be incorporated into the daily workload. As stated, these can be proficiency samples, blind samples, or previously analyzed samples. The number of blind samples assigned to each staff member can be determined by the assessor. The other component of this method is setting an acceptable performance limit. Acceptable standard deviation, coefficient of variation, or CLIA ‘88 proficiency limits for the test that is assessed are valid methods for setting the acceptable performance limits.

6. “Assessment of problem solving skills.”

Although problem solving skills can be difficult to assess, they are used by laboratory staff every day. Problems encountered include inadequate or mislabeled specimens, troubleshooting instrumentation or reagent performance, and customer complaints. Documentation of these common problems can be used to fulfill this assessment. Other methods that can be used include a case study with questions that relate to laboratory-specific written policies and procedures, a mock demonstration of a written policy, or online continuing education that relates to the test system that is being assessed. It may be beneficial to ask the
instrument or reagent manufacturer if they provide tools to assess competency, as this is an added value to the laboratory customer.

Personnel Responsible for Competency Assessment

The laboratory director is ultimately responsible for the oversight of competency; the director authorizes specific responsibilities and duties of supervisors and consultants, and ultimately, of all staff who are involved in all phases of testing. This can be accomplished by means of written job descriptions. The director is also responsible for “ensur[ing] that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.”

While the policy may be developed and/or approved by the laboratory director, a Technical Supervisor or Technical Consultant is the individual responsible for assessing and documenting competency. Specifically, the technical supervisor and technical consultant are responsible for “identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed” as well as “evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.” This may be done directly or by means of delegation to staff. Staff who have been identified as technical leads in a specific area must meet the federal qualifications for a Technical Consultant, Technical Supervisor, or General Supervisor, as described in subpart M of 42CFR 493.

Staff Members Assessed and Frequency of Assessment

Competency assessment must be documented for all testing personnel. All staff members who perform testing using methods that are defined as non-waived testing under 42 CFR must have their competency assessed at least semiannually during the first year the individual performs patient testing and annually thereafter. If there is a new test method or change in instrumentation, all testing personnel must be reevaluated before reporting patient results.

Test Systems to Be Assessed

Any non-waived test system under 42 CFR must be addressed in a competency program. This includes provider-performed microscopy and moderate- and high- complexity testing. A test system may be a single test or an instrument. An instrument that performs multiple tests can be assessed under one
EDUCATIONAL COMMENTARY – COMPETENCY ASSESSMENT IN THE CLINICAL LABORATORY: DEVELOPING A COMPETENCY ASSESSMENT PROGRAM (cont.)

... competency assessment that includes all six elements described above, as long as the tests are assayed in a similar way. If a single test requires manual manipulation before testing or any other unique procedure associated with testing on an automated platform, it may be considered a separate test system.³

Waived testing is not considered a test system that requires annual competency assessment with all six elements. Still, it is essential to patient care that testing personnel are properly trained and perform testing according to the manufacturer's instructions to provide accurate results. Annual competency assessment can be a tool to accomplish this goal.³

Developing a Competency Program

Now that each element of the competency assessment program has been described, the next step is to develop a competency program specific to each laboratory by establishing policies and procedures. The Table (next page) summarizes elements that are essential to a successful competency program.

Summary

A formal competency program is an essential part of ensuring quality in the clinical laboratory as well as of maintaining regulatory compliance. Maintaining a schedule and documentation of competency activities will assist all staff, from the laboratory director to testing personnel, in the successful completion of required annual competency. Competency assessment should be tailored to fit the needs of each testing laboratory within the guidelines set forth by CLIA '88 in 42 CFR or the individual laboratory's accrediting agency.
EDUCATIONAL COMMENTARY – COMPETENCY ASSESSMENT IN THE CLINICAL LABORATORY: DEVELOPING A COMPETENCY ASSESSMENT PROGRAM (cont.)

Table. Ways to Document Elements of a Competency Assessment Program.

<table>
<thead>
<tr>
<th>Who</th>
<th>All testing personnel</th>
</tr>
</thead>
<tbody>
<tr>
<td>Determine who will be assessed</td>
<td>List personnel who have the qualifications of a Technical Consultant, Technical Supervisor, or General Supervisor</td>
</tr>
<tr>
<td>Determine who will perform the assessments</td>
<td>List test systems and individual tests to be assessed that are considered moderate or high complexity</td>
</tr>
<tr>
<td>Is this a single analyte or an analyzer that performs several tests using a similar process?</td>
<td>List instrumentation and each test performed on the platform</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>What</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Define each test system for which competency must be assessed</td>
<td>Establish a schedule so the assessments are not a burden to the staff who are assessed or to those who will perform the assessments</td>
</tr>
<tr>
<td>Is this a single analyte or an analyzer that performs several tests using a similar process?</td>
<td>Training and competency assessment are different processes; ensure that separate documentation is maintained</td>
</tr>
</tbody>
</table>

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<tr>
<th>When</th>
<th></th>
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<tbody>
<tr>
<td>All testing personnel are assessed on an annual basis</td>
<td>Establish a schedule for installation that will require training and competency assessment before patient testing</td>
</tr>
<tr>
<td>Determine how the schedule will be maintained</td>
<td>Use a schedule that the assessor and staff being assessed can understand</td>
</tr>
<tr>
<td>New staff have competency assessed semiannually during the first year of testing patient specimens</td>
<td>Training and competency assessment are different processes; ensure that separate documentation is maintained</td>
</tr>
<tr>
<td>Current staff need competency assessed before patient testing when new test methods or instruments are added</td>
<td>Establish a schedule for installation that will require training and competency assessment before patient testing</td>
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<table>
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<tr>
<th>How</th>
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<tbody>
<tr>
<td>Mechanism for monitoring outcomes</td>
<td>Each assessment method is required; describe how each method is addressed for the test system being assessed</td>
</tr>
<tr>
<td>Defining and measuring acceptable performance</td>
<td>Use acceptable test performance measures as a guide such as SD, CV, and CLIA acceptable performance for regulated analytes</td>
</tr>
<tr>
<td>Documentation of review of records</td>
<td>A scheduled review of records and documentation by the lab director or designee will accomplish the majority of this assessment method</td>
</tr>
<tr>
<td>Direct observation checklists</td>
<td>Create direct observation checklists with critical tasks obtained from the written procedure for documentation by the observer.</td>
</tr>
<tr>
<td>Plan for unsuccessful outcomes/correct problems</td>
<td>When competency is not demonstrated, documentation of corrective action is necessary</td>
</tr>
</tbody>
</table>

**Abbreviations:** CLIA (Clinical Laboratory Improvement Amendments); CV (coefficient of variance); and SD (standard deviation).
EDUCATIONAL COMMENTARY – COMPETENCY ASSESSMENT IN THE CLINICAL LABORATORY: 
DEVELOPING A COMPETENCY ASSESSMENT PROGRAM (cont.)

References


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