

Objectives

- Discuss requirements related to competency assessment
- Describe what assessors, inspectors, and surveyors look for as evidence of compliance
- Identify methods to meet requirements for competency assessment

Blood Systems

What Is Competency and Competency Assessment?

- 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 regulation.

Centors for Medicare and Medicaid Services

Blood Systems

**Once Competent, Always Competent,
Right?**

Not Necessarily!

- **Dedicated Staff**
 - Complacency
 - SOP drift
- **Rotating Staff**
 - Loss of familiarity
 - Infrequent activities



**What Drives Competency Assessment
for Laboratory Staff**

**It's the right thing
to do!!!!**

**It's required by
regulation!**



**CLIA Competency Assessment Key
Requirement**

493.1413(b)(8)(9) & 1451(b)(8)(9)

Technical Consultant/Supervisor Responsibilities

- **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**



Competency Elements

- Direct observation of performance
- Direct observation of instrument maintenance/function checks
- Monitoring recording and reporting of test results
- Review of worksheets, QC records, PT results, PM records
- Testing of previously analyzed specimens
- Assessment of problem solving skills

Frequency

- At least semiannually during the first year the individual tests patient specimens
- At least annually thereafter unless test methodology or instrumentation changes
 - Prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the now test methodology or instrumentation

CAP

GEN.55500 Competency Assessment

- The competency of each person to perform his/her assigned duties is assessed
- CLIA elements cited

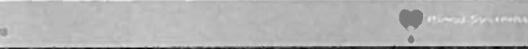
NOTE: The competency of each person to perform the duties assigned must be assessed following training before the person performs patient testing.

CAP

GEN.57000 Competency Corrective Action

- If an employee fails to demonstrate satisfactory performance on the competency assessment, the laboratory has a plan of corrective action to retrain and reassess the employee's competency.

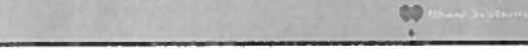
- Evidence of Compliance:
Records of corrective action to include evidence of retraining and reassessment of competency



What Drives Competency Assessment for Other Staff

It's the right thing to do!!!

It's required by Standards!



AABB

STD 2.1.2 Training

- The blood bank or transfusion service shall have a process for identifying training needs and shall provide training for personnel performing critical tasks.

Not Just Testing Personnel!



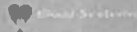
AABB

STD 2.1.3 Competence

- Evaluations of competence shall be performed before independent performance of assigned activities and at specified intervals.
- 2.1.3.1 Action shall be taken when competence has not been demonstrated



What Do Assessors / Inspectors / Surveyors Look For?



First Things First

- Is there a Policy, Process or Procedure Addressing Training and Competency?
 - Laboratory
 - General policies
 - CLIA elements incorporated
 - Blood Bank
 - SOPs specific for the testing performed



The Next Steps

- How is competency determined?
 - Who can assess competency?
 - Is it defined?
 - No self-assessments allowed!!!
 - What constitutes an assessment?
 - 3 P's, Tools, Checklists, Guidance
 - What tests are being evaluated?
 - All tests individual is approved to perform
 - Can't pick and choose
 - How is it documented?
 - Does practice match SOPs?



Beware the Regulations!

- Testing Personnel
 - All routine tests
 - All CLIA elements MUST be used for evaluation
- Other Personnel
 - Facility-specified



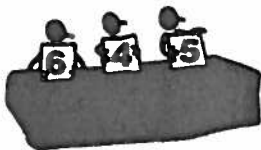
Considerations

- New employees
 - Competency assessment separate from training
 - Assessed twice in the first year
- Incumbents
 - Annual assessment
- Documentation for staff that work on all shifts
- Tests being evaluated
 - Is there any distinction made for testing that may be provided on day shift vs after hours
 - Special testing



Competent or Not?

- Statement of competency
- If not competent, what was done?
 - Does practice match SOP?



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I Don't Have Time for This!!



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Let's Go Back to Basics

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Direct Observation

- The observation must be documented
 - Create a checklist from the procedure


Don't forget this is a good time to critique procedures

Creating a checklist = an internal audit!




Direct Observation Checklist

- SOP in checklist form
- Performed at conclusion of training on that SOP
- Future use:
 - Semi-annual competency assessment
 - Annual competency assessment



Instrument Maintenance

- Direct observation of performance of instrument maintenance and function checks
- Which instruments?
- Who does it?



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Aren't You Doing This Already?! *

- Include as part of the competency policy
- Include as part of direct observation
 - Recording and reporting of test results
 - QC records
 - Preventive maintenance records
 - Worksheets
- Document!

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Previously Analyzed Specimens

- Patient samples
- Competency programs
- Proficiency testing samples
 - Must be rotated among all individuals performing testing
 - Document as part of competency assessment

Danger, Danger, Will Robinson!!!

DO NOT share PT samples with other staff until **AFTER** the results have been received from the PT provider



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Assessment of Problem Solving Skills

- Written test or quiz
- Case Studies
- Scenarios: What would you do if...?
- Staff narrative

Unsuccessful Result


- Process for Remediation
 - Actions to take
 - Removing employee from testing until competency is demonstrated
 - Documentation
 - Recurrence
 - Re-assessment
 - Determination
 - Completion at end of each assessment

Documentation

- Trackable and Traceable
 - Checklist not sufficient
 - Each assessment requirement must be documented
 - Direct observation checklists
 - Title and date of record review
 - Title, date, sample ID if using PT
 - Graded test/quiz
 - Assessor name(s) and dates
 - Employee name

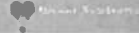
Documentation

- Determination of competency
 - Signature/date of supervisor
 - Signature/date of individual performing competency assessment if different from the supervisor
 - Signature/date of employee
 - Include a statement of competency by the supervisor and the employee



Example Competency Statements

- (employee sign/date) _____ certify that I am fully trained and competent to perform the roles listed above
- (assessor sign/date) _____ attest that the staff member listed above is fully trained and competent to perform the roles listed above






I'm Done! Right?

NO!!



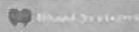
New Procedures



- Changes in test methods or instrumentation
- Prior to reporting patient test results, the individual's performance must be re-evaluated to include the use of the new test methodology or instrumentation




Revised Procedures

- Determine type of Training
 - Read SOP and sign
 - Perform in service and read & sign
 - Full training and competency assessed
 - Trainer requirements/Trainee requirements/DO and Evaluation




What Do I Need to Do to Assess Personnel Competency?



HOT OFF THE PRESS!!!

<http://cms.hhs.gov/Regulationsand-Guidance/Legislation/CLIA>


CLIA Brochures



Who Is Required to Have a Competency Assessment?


- Anyone who performs testing on patient specimens
- Clinical Consultant
- Technical Consultant
- Technical Supervisor
- General Supervisor

Competency assessment based on their federal regulatory responsibilities



Technical Supervisor for Immunoematology


- MD or DO certified in clinical pathology
- MD or DO with at least one year of lab training or experience in immunoematology



TC/TS Regulatory Responsibilities

- Available to provide consultation
- Select appropriate test methods
- Assure performance specifications are established
- Ensure enrollment and participation in PT
- Ensure QC program is in effect and adequate
- Resolve technical problems
- Identify training needs
- Evaluate competency of testing personnel

Remember: applies to moderate AND high complexity testing!



General Supervisor Responsibilities

- Accessible to testing personnel
- Provides day-to-day supervision
- Monitoring tests analyses and specimen examinations
- Delegated responsibilities
 - Remedial actions taken when deviations occur
 - Ensure test results not reported until CAPA has been performed
 - Provide orientation to testing personnel
 - Annually evaluate and document performance of testing personnel

Competency Assessment for TC, TS and GS

Personnel evaluations do not satisfy the requirement for competency assessment

Who is Responsible for Performing Competency Assessment?

- Technical Consultant – moderate complexity testing
 - Can be performed by other personnel meeting TC qualifications
- Technical Supervisor – high complexity testing
 - Can be delegated, in writing, to a General Supervisor meeting qualifications as GS for high complexity testing

“Peer testing personnel who do not meet the regulatory qualifications of a TC, TS, or GS cannot be designated to perform competency assessments.”

Qualifications

- **Technical Consultant**
 - Bachelor's degree in chemical, physical or biological science or medical technology AND
 - Have at least 2 years of laboratory training or experience, or both, in non-waived testing
- **General Supervisor**
 - Qualify as testing personnel under 42CFR493.1489(b)2 AND
 - Have at least 2 years of laboratory training or experience, or both, in high complexity testing

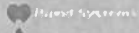
Remember Those 6 Competency Elements?

- Direct observation of performance
- Direct observation of instrument maintenance/function checks
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"All six procedures must be addressed for personnel performing testing for all tests performed."


Do all six procedures of competency assessment need to be performed at the same time each year?

"No, competency assessment can be done throughout the entire year. The laboratory may coordinate the competency assessment with its routine practices and procedures to minimize impact on workload."



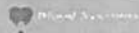
Proficiency Testing and Competency

- PT performance may be used as part of competency
- PT is not sufficient to meet all six required elements



Training
≠
Competency Assessment

"Documentation of training does not satisfy the requirement for documented competency assessment."



Why Do We Care About This?

- Accrediting Organizations have 'deemed status' for CLIA
- Accrediting Organizations are judged by results of validation surveys
- A new brochure often indicates a new CMS "hot button"
- When CMS speaks... Accrediting Organizations listen!

Words of Wisdom

In a hierarchy, every employee tends to rise to his level of incompetence.

Work is accomplished by those employees who have not yet reached their level of incompetence.

- Laurence J Peter

Certificate of Participation

- Available on E-learning
 - <http://bloodsystemseducation.org/programs/index.php>
 - Must register (valid email address and account number)
 - Program is NOT PACE accredited

Encore Webinar and Recording

- **Encore presentation will be offered. Watch for email invitation.**
- **Recording**
 - Watch your email for notification of recording availability

