2014 Continuing Compliance Master Series
The Truth About Personnel Competency

Denise Driscoll, MS, MT(ASCP)SBB
August 20, 2014
Today’s Presenter

Denise K. Driscoll, MS, MT(ASCP)SBB

Ms. Driscoll is the Director for Accreditation and Regulatory Affairs for the College of American Pathologists (CAP) Accreditation Programs. As a Regulatory Analyst for the CAP in 1995, she managed complaint investigations and state and regulatory affairs before becoming the Accreditation Director in 1998, responsible for core operational processes to inspect and accredit 6600 laboratories.

Denise received a BS in Medical Technology from Auburn University and is an ASCP-certified Medical Technologist with an SBB specialty in Blood Bank. She has a MS in Clinical Laboratory Science from the University of Alabama at Birmingham. Blood Bank, Hematology, and Coagulation are her areas of laboratory practice, and she managed the Blood Bank and Apheresis at the University of Alabama Hospital in Birmingham. Her work history also includes being a sales representative for Immucor, Inc. where she was responsible for sales, marketing, and technical support of blood bank reagents and instruments.

Denise has performed many inspections of blood banks for both the CAP and the American Association of Blood Banks.
Objectives

- Describe how to become compliant with CMS and CAP competency assessment requirements.
- Define test systems in your laboratory.
- Differentiate training from competency.
- Identify appropriate personnel to assess competency.
Most Commonly Cited Deficiencies in 2013

- Competency
- Activity Menu
- Document Control
- PT Evaluation
- Procedure Manual
- Attestation Page
- Procedure Review
- Reagent Labeling
- Reagent Storage
- Personnel Records
Competency Requirement GEN.55500

GEN.55500  Competency Assessment of Testing Personnel
Phase II

The competency of each person performing patient testing to perform his/her assigned duties is assessed.
GEN.55500 – Requirement

- Initial Training
- Assessment Frequency
  - Waived Testing
  - Non-Waived Testing
    - Employee performing testing < one year
    - Employee performing testing > one year
- Competency Assessment Elements
- Test Systems
- Examples of how to assess
- Who may assess competency
  - High Complexity Testing
  - Moderate Complexity Testing
GEN.55450 Initial Training Phase II

There is documentation that all staff have satisfactorily completed initial training on all instruments/methods applicable to their designated job.

NOTE: The records must show that training specifically applies to the testing performed by each individual.

Retraining must occur when problems are identified with employee performance.

REFERENCES

# Training vs. Competency

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Competency Assessment - Waived Testing

• Must be performed at least one year after training is complete
• Reassessed annually
• Does not require use of all six elements
• Laboratory Director and staff decide which elements are appropriate
Competency Assessment Frequency – Non-waived Testing

• During first year of patient testing must be assessed semiannually after training is complete and employee is performing testing on his/her own during the first year.
• Reassessed at least annually.
• Requires all six elements of competency be assessed when applicable for each test system.
Test Systems

- Definition - the process that includes pre-analytic, analytic, and post-analytic steps used to produce a test result or set of results. A test system may be manual, automated, multi-channel or single use and can include reagents, components, equipment or instruments required to produce results.

- May encompass multiple identical instruments or devices.

- Tests performed on the same instrument or device may be defined as a single test system.

- Any tests with unique aspects, problems or procedures within the same testing platform (e.g., pretreatment of samples prior to analysis), competency must be assessed as a separate test system to ensure staff are performing those aspects correctly.
## MICROBIOLOGY - FULL SERVICE EXAMPLE - Appropriate Test System Delineation

### Competency elements:
1. **Direct observations of routine patient test performance**, including, as applicable, patient identification and preparation; and specimen collection, handling, processing and testing
2. **Monitoring the recording and reporting of test results**, including, as applicable, reporting critical results
3. **Review of intermediate test results or worksheets**, quality control records, proficiency testing results, and preventive maintenance records
4. **Direct observation of performance of instrument maintenance and function checks**
5. **Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency samples**
6. **Evaluation of problem-solving skills**

### Method of assessment key:
- **DO**: Direct Observation
- **RR**: results review
- **WR**: worksheet review

### Test System Delineation

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© 2014 College of American Pathologists. All rights reserved.
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**MICROBIOLOGY - FULL SERVICE EXAMPLE - POOR TEST SYSTEM**

**DELIBERATION**

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Six Elements - Documenting through day to day operations

Stating that the six elements are being utilized for assessment in the competency policy is not sufficient documentation

- Direct Observation patient testing
- Recording and Reporting of test results
- Review of worksheets, quality control, proficiency testing results and maintenance records
- Direct observation of maintenance and function checks
- Previously analyzed samples, proficiency testing materials or internal blind samples
- Problem solving
How to incorporate the six competency elements into daily workload - Round Table Discussion

The discussion will be by the panel members describing ways that they have seen or assessed the six elements of competency.
Who May Assess Competency

- **High Complexity Testing** - Testing personnel performing high complexity testing must be assessed by the section director/technical supervisor, or individual meeting general supervisor requirements for high complexity testing if delegated in writing by the section director/Technical Supervisor.

- **Moderate Complexity Testing** - Testing personnel performing moderate complexity testing, must be assessed by an individual meeting the qualifications of a technical consultant for moderate complexity testing.
Technical Supervisor/Section Director

- The section director/technical supervisor in each high complexity laboratory section can be a licensed MD or DO with certification in anatomic and/or clinical pathology, or qualifications equivalent to those required for board certification.

- Responsible person for anatomic pathology must be an MD or DO certified in anatomic pathology or possess qualifications equivalent to those required for certification.

- The responsible person for clinical pathology must be an MD or DO certified in clinical pathology or possess qualifications equivalent to those required for certification; or may be an individual who meets the alternate qualifications for the specialties supervised.

- If the section director is responsible for both anatomic and clinical pathology, then he/she must be certified in both anatomic and clinical pathology or possess qualifications equivalent to those required for certification.
Technical Supervisor (Cont)

- Additional requirements for the section directors of the clinical cytogenetics, histocompatibility, and transfusion medicine services are found in the Cytogenetics, Histocompatibility, and Transfusion Medicine Checklists, respectively.

- For laboratories subject to US regulations, alternate qualifications for the following specialty areas can be found in Fed Register. 1992(Feb 28): 7177-7180 [42CFR493.1449]: bacteriology, mycobacteriology, mycology, parasitology, virology, diagnostic immunology, chemistry, hematology, cytology, ophthalmic pathology, dermatopathology, oral pathology, radiobioassay, immunohematology.

- Minimum requirement – bachelor’s degree and 4 years of experience in high complexity testing in the specialty, however a few specialties require a physician.

- See 493.1449 for specific specialty requirements.
## CAP Personnel Requirements by Testing Complexity for Technical Supervisor

### Technical Supervisor

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<th>Moderate Complexity Testing</th>
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1. MD or DO with a current medical license\(^1\) and board-certification in Anatomic and Clinical Pathology or possess qualifications equivalent to those required for certification; OR
2. MD or DO with a current medical license\(^1\) and board-certification in Anatomic or Clinical Pathology or possess qualifications equivalent to those required for certification
   - Technical supervisors overseeing anatomic pathology services must have board-certification in anatomic pathology or equivalent qualifications
   - Technical supervisors overseeing a clinical pathology specialty must have board-certification in clinical pathology or equivalent qualifications; OR
3. MD or DO with a current medical license\(^1\) and 1 year training and experience in high-complexity testing in the respective specialty; OR
4. Doctoral degree in clinical laboratory science, chemical, physical or biological science with 1 year training and experience in the respective specialty; OR
5. Master’s degree in medical technology, clinical laboratory science, or chemical, physical or biological science and 2 years training and experience in high-complexity testing in the respective specialty; OR
6. Bachelor’s degree in medical technology, clinical laboratory science, or chemical, physical or biological science and 4 years training and experience in high-complexity testing in the respective specialty

**Exception:** CLIA requires special qualifications for Technical Supervisor for the specialties of Transfusion Medicine, Cytology, Cytogenetics, Histopathology, Oral pathology, Histocompatibility. For these specialties, the Technical Supervisor must be a physician and/or doctoral scientist, and have specific training/experience. Refer to the CLIA regulation (42CFR493.1449) or inspection checklist for further details. For these specialties, the Technical Supervisor may be referred to as the section director.
Section Supervisor/General Supervisor

- Bachelor’s degree in a chemical, physical, biological or clinical laboratory science or medical technology with at least one year experience with high complexity testing, or

- Associate degree in a laboratory science or medical technology program with at least two years experience with high complexity testing, or

- Have previously qualified or could have qualified as a general supervisor prior to 2/28/1992
### CAP Personnel Requirements by Testing Complexity for General Supervisor

<table>
<thead>
<tr>
<th>Waived Testing</th>
<th>Moderate Complexity Testing</th>
<th>High Complexity Testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td></td>
</tr>
</tbody>
</table>

1. Qualified as a Director for high-complexity testing; OR
2. Qualified as a Technical Supervisor for high complexity testing; OR
3. Doctoral degree in clinical laboratory science or chemical, physical or biological science with 1 year training and experience in high-complexity testing; OR
4. Master's degree in clinical laboratory science, medical technology or chemical, physical or biological science and 1 year training and experience in high-complexity testing; OR
5. Bachelor's degree in clinical laboratory science, medical technology or chemical, physical or biological science and 1 year training and experience in high-complexity testing; OR
6. Associate degree in medical laboratory technology (or pulmonary function) and 2 years laboratory (or blood gas analysis) training or experience, or both, in high complexity testing

Refer to the CLIA regulation 42CFR493.1461 for additional qualifications.

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MD, DO, or DPM, licensed to practice in the jurisdiction where the laboratory is located (if required), with at least 1 year of training and/or experience in non-waived testing; or

Doctoral or masters degree in a chemical, physical, biological or clinical laboratory science with at least 1 year of training and/or experience in non-waived testing; or

Bachelor's degree in a chemical, physical, biological, or clinical laboratory science or medical technology with at least 2 years of experience in non-waived testing.

The technical consultant's training and experience must include the disciplines in which the individual is providing consultation.
<table>
<thead>
<tr>
<th>Waived Testing</th>
<th>Moderate Complexity Testing</th>
<th>High Complexity Testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Applicable</td>
<td>A Technical Consultant is only required if the director is not qualified as a high complexity director.</td>
<td>Not Applicable</td>
</tr>
<tr>
<td></td>
<td>1. MD, DO, or DPM with a current medical license(^1) with at least 1 year of training and/or experience in nonwaived testing in the designated specialty/subspecialty area; OR</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2. Doctoral or Master’s degree in a chemical, physical, biological or clinical laboratory science with at least 1 year of training and/or experience in nonwaived testing in the designated specialty/subspecialty area; OR</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3. Bachelor’s degree in a chemical, physical, biological or clinical laboratory science or medical technology with at least 2 years of experience in nonwaived testing in the designated specialty/subspecialty area</td>
<td></td>
</tr>
</tbody>
</table>
What if an Employee Fails Competency?

GEN.57000  Competency Corrective Action  Phase II

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.

NOTE: If it is determined that there are gaps in the individual's knowledge, the employee should be re-educated and allowed to retake the portions of the assessment that fell below the laboratory's guidelines. If, after re-education and training, the employee is unable to satisfactorily pass the assessment, then further action should be taken which may include, supervisory review of work, reassignment of duties, or other actions deemed appropriate by the laboratory director.

Evidence of Compliance:

Records of corrective action to include evidence of retraining and reassessment of competency.
New Requirement GEN.55525

GEN.55525  Performance Assessment of Supervisors/Consultants Phase II

The performance of section directors/technical supervisors, general supervisors, and technical consultants is assessed and satisfactory.

NOTE: All responsibilities of section directors (as technical supervisors in laboratories performing high complexity testing) and technical consultants (in laboratories performing moderate complexity testing, but not high complexity testing) must be delegated by the laboratory director in writing. Unsatisfactory performance must be addressed in a corrective action plan.
GEN.55525 (Cont)

- The assessment may take the form of a check off list or other written documentation of performance of responsibilities, as defined by the individual's job description.
- If the individuals in these roles are also performing non-waived patient testing, competency assessment requirements for testing personnel (GEN.55500) also apply, including all six elements of competency.

Evidence of Compliance:
- Job descriptions that list regulatory responsibilities AND
- Records of performance assessment
GEN.55525 What Needs to be Done?

- Laboratory Director must delegate responsibilities in writing
- Perform and document the performance assessment
- Document all corrective action required
- If the individual is performing non-waived testing must document competency assessments including the six elements
- Recommend including all regulatory responsibilities in the individual's job description
- Please see an example assessment in the included toolkit.
The laboratory director ensures the professional competency of pathologists who provide interpretive services to the anatomic pathology laboratory.

NOTE: The mechanism for competency assessment must be pertinent to the type of interpretive services provided. There must be a written policy for assessing professional competency, criteria for the assessment, and records of the assessment must demonstrate review by the laboratory director.
Pathologist Competency (Cont)

Evidence of Compliance:

• Policy for assessing professional competency AND
• Participation in a peer educational program (eg, CAP Educational Anatomic Pathology Programs) or intra-departmental or inter-institutional peer review program OR
• Metrics developed from diagnostic quality management reports (ANP.10100, ANP.10150, ANP.12075, etc.) OR
• Quality management records (internal audits, error reports, etc.) OR
• Individual assessment according to defined criteria
Phlebotomist Competency

- If not performing patient testing, not required but must follow laboratory competency policy if institution requires phlebotomist competency assessments.
- Assessment interval the same if performing patient testing.
- Six elements must be used if performing non-waived testing.
GEN.54400 Personnel Records

GEN.54400 Personnel Records Phase II

Personnel files are maintained on all current technical personnel and personnel records include all of the following:

- Copy of academic diploma or transcript
- Laboratory personnel license, if required by state, province, or country
- Summary of training and experience
- Certification, if required by state or employer
GEN.54400 Personnel Records (Cont.)

- Description of current duties and responsibilities as specified by the laboratory director: a) Procedures the individual is authorized to perform, b) Whether supervision is required for specimen processing, test performance or result reporting, c) Whether supervisory or section director review is required to report patient test results
- Records of continuing education
- Records of radiation exposure where applicable (such as with in vivo radiation testing), but not required for low exposure levels such as certain in-vitro testing
- Work-related incident and/or accident records
- Dates of employment
Provider Performed Testing (PPT)

- CAP accreditation for provider-performed testing (PPT) is limited to the following tests:
  - pH, body fluids*
  - Vaginal pool fluid smears for ferning
  - Fecal leukocytes
  - Gastric biopsy urease*
  - Nasal smears for eosinophils
  - Occult blood, fecal and gastric*

*Waived test methodologies

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Provider Performed Testing (PPT)

- Pinworm examination
- Post-coital mucus examination
- Potassium hydroxide (KOH) preparations
- Semen analysis, qualitative
- Urine dipstick*
- Urine sediment microscopy
- Wet mount preparations for the presence or absence of bacteria, fungi, parasites, and human cellular elements

* Waived test methodologies
PPT Competency Assessment

- POC.09600  PPT Competency Assessment - Non-waived Testing Phase II

- There is a documented program to ensure that all providers performing nonwaived PPT maintain satisfactory levels of competence.

- NOTE: During the first year of non-waived testing, competency must be assessed at least semiannually. After a provider has performed non-waived testing duties for one year, competency must be assessed annually. Retraining and reassessment of provider competency must occur when problems are identified with test performance.

- Competency assessment must include all six elements described below for each test system during each assessment period, unless an element is not applicable to the test system. Elements of competency assessment include but are not limited to:
  
  - Direct observations of routine patient test performance, including, as applicable, patient identification and preparation; and specimen collection, handling, processing and testing.
  
  - Monitoring the recording and reporting of test results, including, as applicable, reporting of critical results.
PPT Competency Assessment (Cont.)

- Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

- Direct observation of performance of instrument maintenance and function checks, as applicable.

- Assessment of test performance through testing previously analyzed specimens, internal blind testing samples of external proficiency testing samples; and

- Evaluation of problem-solving skills.

- Competency may be assessed by the director of the POCT program or delegated to an individual meeting the technical consultant qualifications for moderate complexity testing.

- This requirement does not apply to waived PPT. The laboratory director may determine how competency is determined.
Key Points

- Competency assessments – non-waived testing – semiannually first year of duties and annually thereafter
- Training initially and retraining if employee failed competency
- Competency Assessments – non-waived – use six elements
- Competency Assessments - waived - laboratory decides
- Competency assessor – High Complexity – person who qualifies as a Section Director/Technical Supervisor or General Supervisor
- Competency assessor – Moderate Complexity – a person who qualifies as a Technical Consultant
Thank You

• Thank you to our presenter
  o Denise Driscoll

• Thank you to our roundtable / panel members
  o Jean Hood
  o Jean Ball
  o Rodney Stewart
  o Kim Merrick
  o Wilson Kung
  o Joan Rose
  o Carolyn Gandy

• Thank you to our participants for their time.

• Keep in mind the tool kit is available with the link your site coordinator has received
Questions?