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The Truth About Personnel Competency

What's Changing and the Secrets to More Effectively Engage Staff and Physicians

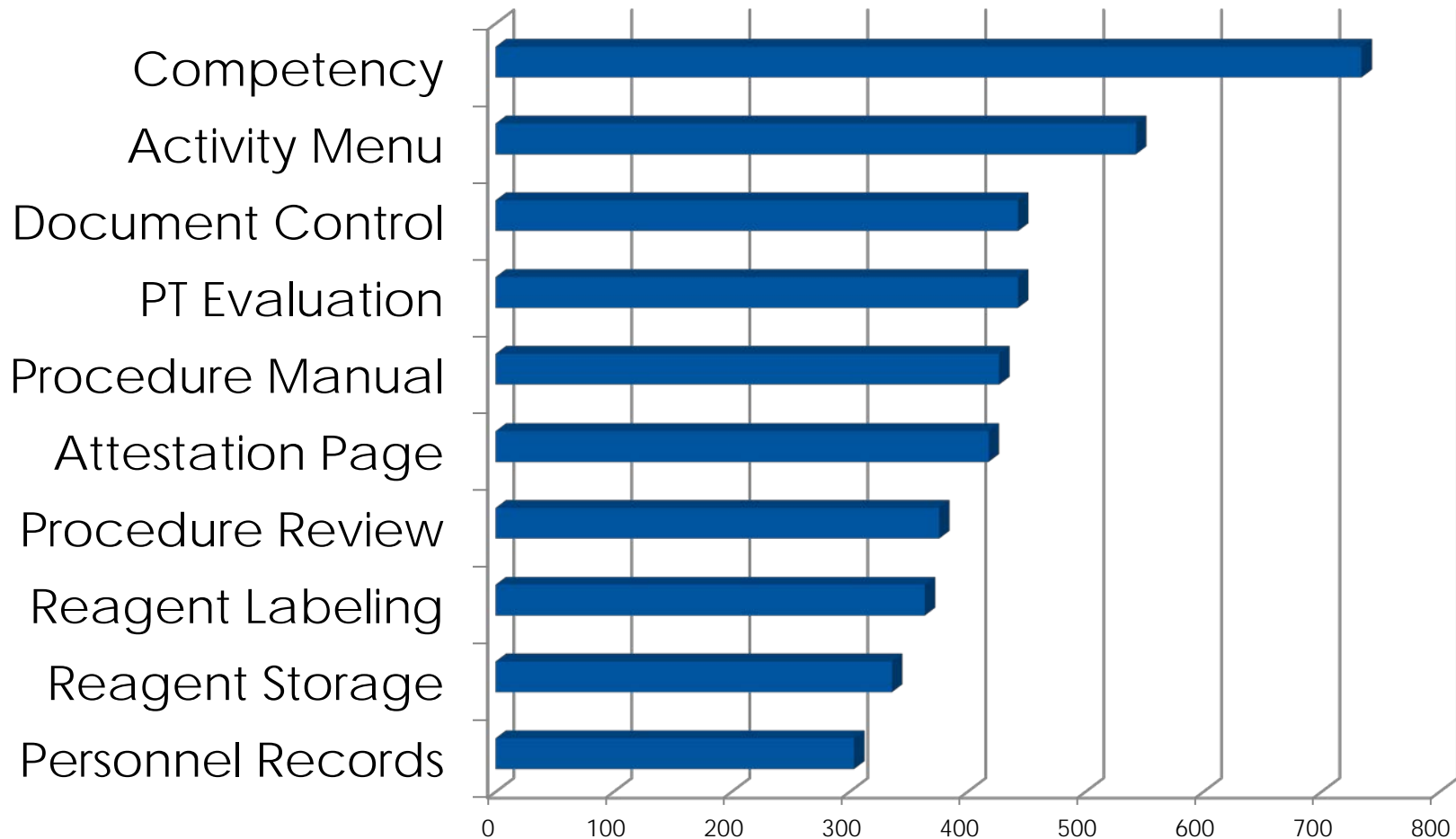
PRESENTED BY
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Objectives

- Describe how to engage staff to become compliant with CMS and CAP competency assessment requirements.
- Understand test systems in your laboratory.
- Differentiate training from competency.
- Identify appropriate personnel to assess competency.

Most Commonly Cited Deficiencies in 2013



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

Training Requirement GEN.55450

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

1) Clinical and Laboratory Standards Institute (CLSI). *Training and Competence Assessment; Approved Guideline—Third Edition*. CLSI Document GP21-A3. (ISBN 1-56238-691-3). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA, 2009.

Training vs. Competency

Training

- Occurs before patient testing begins
- Usually once unless employee fails successful demonstration of skill to trainer and retraining required
- Does not require use of six elements

Competency

- Occurs after patient testing begins
- Ongoing assessments
- Does require use of six elements for non-waived testing

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 (eg, 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	W=waived NW=non waived or LDT	1	2	3	4	5	6	Method: DO, RR, WR	Competent date/assessor	Retrain/corrective action date/assessor
<i>Bacteriology</i>										
<i>Specimen processing</i>										
Gram stain										
Aerobic culture reading										
Spot tests										
Streptococcal grouping										
Serologic typing (eg Salmonella, Shig)										
Automated ID system										
Automated susc system										
Manual susc										
Anaerobic cultures										
<i>Direct Antigen Kit tests</i>										
Group A Streptococcus										
Legionella Antigen										
Clostridium difficile										
<i>Mycology</i>										
<i>Specimen processing</i>										
KOH										
Calcoflour white										
Fungal cultures										

MICROBIOLOGY - FULL SERVICE EXAMPLE – POOR 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

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TEST SYSTEM	W=waived NW=non waived or LDT	1	2	3	4	5	6	Method: DO, RR, WR	Competent date/assessor	Retrain/corrective action date/assessor
<i>Bacteriology</i>										
Gram stain										
Culture reading										
Automated ID/susc system										
<i>Direct Antigen Kit tests</i>										
<i>Mycology</i>										
KOH/Calcofluor										
Fungal cultures										
Automated yeast ID										
Cryptococcal Antigen										
<i>Mycobacteria</i>										
AFB stain										
AFB cultures										
AFB ID										
AFB susc										
<i>Parasitology</i>										
stain										
O/P										
EIA for Crypto/Giardia										
Arthropod ID										
<i>Virology</i>										
Viral cultures/ID										
Direct Antigen Kit tests										
<i>Molecular Microbiology</i>										
Single Test Cartridge										
Array										
Home brew										
MALDI-TOF										

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

Practical ways to assess competency utilizing routine workload processes

- Utilize Laboratory Information System reports such as secondary review or approval, critical value, delta check, quality control and result correction.
- Perform direct observation while testing patient samples in the laboratory or observe when performing other activities such as inventory or stocking supplies.
- Document throughout the year as opposed to trying to pick one day to assess and document competency.
- Keep competency documents readily available so they are easy to access. Electronic forms such as Excel Spreadsheets work well for documenting competency.
- The use of a quiz that encompasses all of the test systems can aid in addressing problem solving.
- Get the entire staff involved. Those that qualify to assess competency should be utilized for this function.

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.

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 individuals job description
- Please see an example assessment in the included toolkit.

Pathologist Competency

****NEW**** 04/21/2014

ANP.10255 Professional Competency Phase II

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

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

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

- **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.**
- *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
 - Denise Driscoll

