Competency Assessment Who, What, When, Why and How

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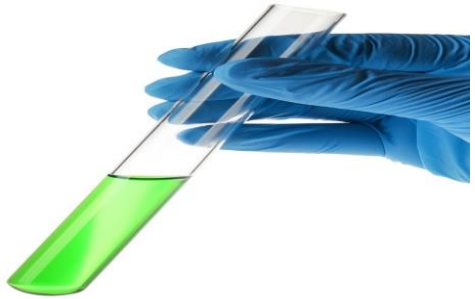
Learning Objectives

- Define Competency
- Explain difference between training and competency
- List the elements required for competency assessment
- Discuss who can perform competency assessments

Competency

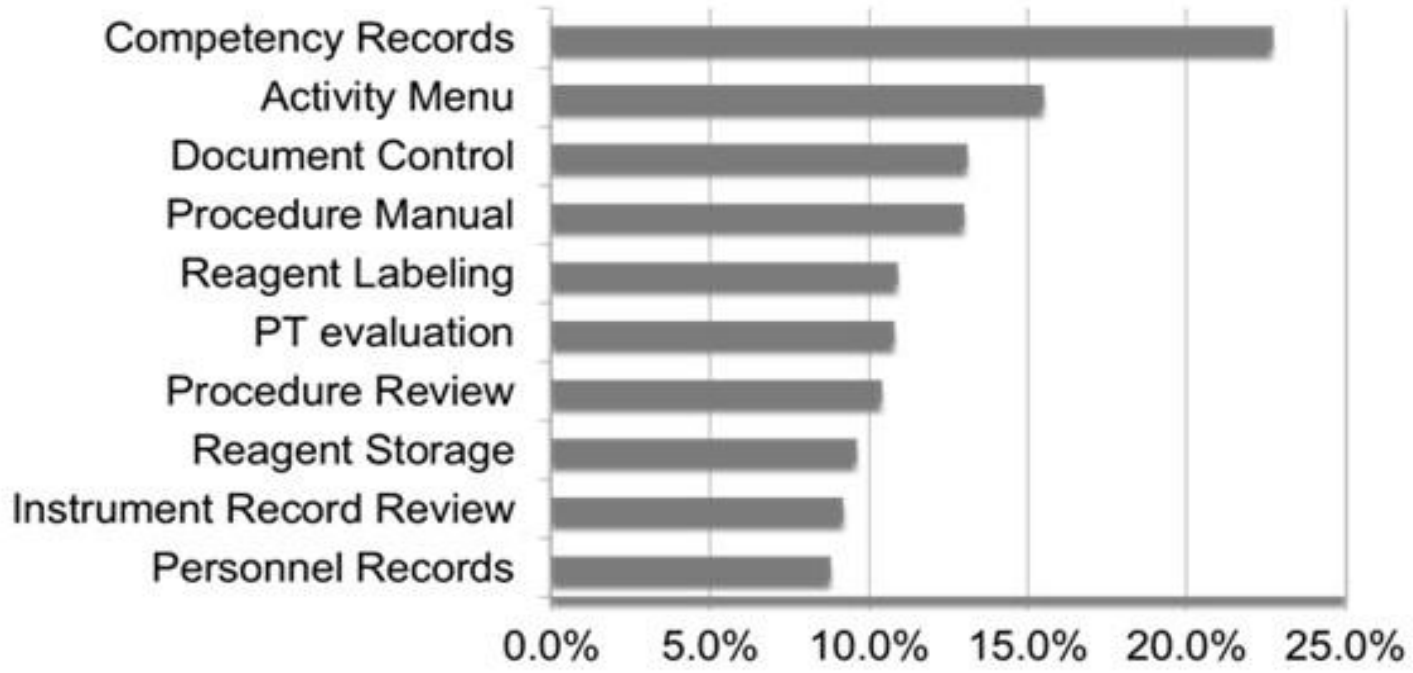
- See one

- Do one



- Teach one!

Most Commonly Cited Deficiencies



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Quality Management System

- QSE: Personnel

"Obtaining and retaining an adequate number of qualified, well trained, and competent laboratory staff to perform and manage the activities of the laboratory."

GP26-A4

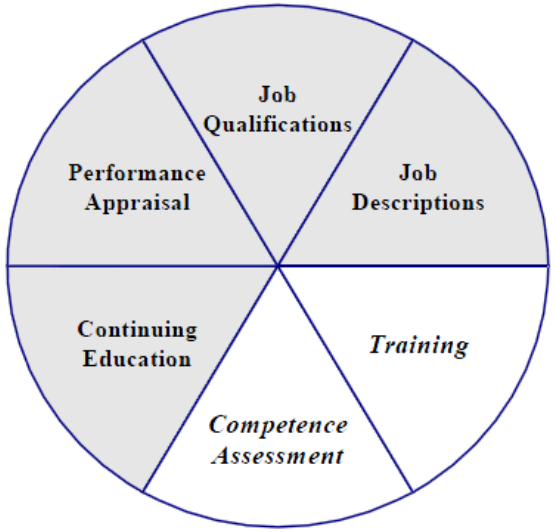

Figure 2. Key Elements of QSE: Personnel

Quality Management System

- The effectiveness of training and competence directly affects the laboratory's ability to meet it's quality goals and objectives.
- Competence – ongoing assessment is required to verify job performance
- Must be documented and different from training

Why?

Prevent: Errors

- Non-Standard work
- Complacency
- Not following SOP – short cuts developed by personnel

Caused by:

- Loss of familiarity of processes or SOP's
- Rotation through other labs
- Working in only one section of the lab

Who Requires Competency Assessment?
Everyone!

- CMS
- CAP
- State regulations
- AABB
- FDA
- FACT
- Joint Commission

CLIA

- Considered a minimum set of guidelines for quality
- All clinical labs in the USA must meet these guidelines in order to receive Medicare and Medicaid re-imbursement
- Most labs try to take beyond and have a Quality Management System

Define

- **Competency** – The ability of personnel to apply their skill, knowledge and experience to perform their laboratory duties correctly.

- **Assessment** – Is used to ensure that the laboratory personnel are fulfilling their duties as by federal regulation.

Centers for Medicare and Medicaid Services

Proficiency Testing vs. Performance Appraisal

- **Proficiency Testing (PT)** Assesses the laboratory's ability to perform accurate and reliable testing by the testing of unknown samples sent to the lab by a CMS approved PT program.

- **Performance appraisal** evaluates general job/position performance and is more subjective. May include competency
- Competency assessment ensures conformance to standard procedures and is objective and binary (e.g. competence observed or not).

Why?

“One thing worse than training employees and losing them… is not training them and keeping them.”

-Ed Metcalf

What Are the Requirements?

- GEN.55500 = The competency of each person to perform his/her assigned duties is assessed.
- **Evidence of Compliance:**
- Records of competency assessment for new and existing employees reflecting the specific skills assessed, the method of evaluation.
- *A laboratory must evaluate and document the competency of all testing personnel for each **test system**. A TEST SYSTEM is the process that includes pre-analytic, analytic, and post-analytic steps used to produce a test result or set of results..*
- *Documentation of these elements, including observation of test performance, results reporting, instrument maintenance, review of worksheets, recording QC, performance of PT, and demonstration of taking appropriate corrective actions are examples of daily activities that can be used to demonstrate competency.*
- *If elements of competency are assessed by routine supervisory review, the competency procedure must outline how this routine review is used to evaluate competency. Competency assessment by routine supervisory review may be documented by a checklist.*
- *For nonwaived test systems, six elements must be assessed annually. For waived test systems, the laboratory may select which elements to assess.*

Waived tests

- Waived tests require minimal technical competency and they yield low risk in the event of an erroneous result.
- Any individual can perform a waived test in a physician office or their home and no educational or professional training is required.
- If the test is performed in a physician's office, the office must apply for a CLIA certificate and the facility that performs the test must comply with all the manufacturer recommendations.
- CLIA doesn't demand any other regulations for waived tests.

Certificate of Waiver (CoW)

- Enroll in the CLIA program
- Pay biennial certificate fees
- Only perform tests categorized as waived
- Not subject to routine inspections
- Must follow manufacturer's instructions

Issues with waived testing

- In the waived test environment, the methodology or the instrument used is very good.
- It's in the preanalytic and postanalytic phases—for example, human errors that occur while the test sample is being gathered, or after the test has been run—that industry-wide, no matter what the test classification is, there are issues involved with quality.
- Most laboratories in the United States now are using waived testing devices that have pre-analytic and post-analytic problems
- These sites are generating problem data that are being used in the diagnosis and treatment of patients.

If my laboratory only performs waived testing, do I need written policies for assessing personnel competency?

- CLIA does not require policies for assessing personnel competency for waived testing.
- Even though CLIA has no specific requirements for personnel performing waived testing, you need to ensure that patient testing results are correct to assist in making an accurate patient diagnosis.
- You will need to ensure that testing **personnel are following all manufacturers' instructions.**
- Testing personnel who are properly trained and performing the test correctly will aid the physician/provider in making an accurate patient diagnosis.
- If your laboratory is accredited, you may need to consult your accrediting organization's standards.

Non waived tests

- Non-waived tests are defined as either moderate or high complexity.
- Unique educational and professional experience are required to perform non-waived tests. CLIA and the Food and Drug Administration (FDA) determines the complexity of the test, using specific criteria.
- Healthcare facilities that perform non-waived tests must obtain a CLIA certificate and abide by CLIA regulations.
- In addition, the facility must be inspected periodically and provide proof that they comply with the CLIA quality requirements.
- All Laboratory Developed Tests (LDT), and non-FDA approved tests are classified as high complexity tests and CLIA requirements are more rigorous for these kinds of tests.

What happens when you adjust how a test is performed.

- Devices used outside of the manufacturer's requirements are considered to be **test modification/off label use.**
- This is not a new CLIA regulation!
- **Test modification/off label use**
- Any change to a test system/device or manufacturer's instructions or intended use that affects the test's performance specifications for accuracy, precision, sensitivity or specificity.
- Modified tests become high complexity tests under CLIA

Competency Requirements

The following 6 elements are the minimal requirements

1. Direct observation (handling, preparation, processing, testing)
2. Monitoring the recording and reporting of testing
3. Review of intermediate test results or worksheets, QC, records, PT results, and PM records
4. Direct observation of performance of instrument maintenance and function checks
5. Assessment of problem solving skills, case studies, quizes
6. Assessment of test performance using previously tested specimens, blind specimens and external proficiency samples

New York State: (in case you perform testing from NYS)

7. NYS has added a 7th. Requirement of observation of compliance with safety protocols
8. “Assessment of competency of any delegated supervisory functions” – recently added by NYS

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 competency assessment elements

Competency

- Occurs after independent patient testing begins
- Does require use of six competency assessment elements for non-waived testing

Training Checklist

TRAINING Leukocyte Alkaline Phosphatase (LAP)
NAME:_____
DATE:_____
TRAINER:_____
Training completed:_____ by _____
I understand the procedure and feel confident to perform the testing.
Sign_____Date_ _____

Training	Trainee	Trainer
Understands the intended use of the test.		
Overview of principle of procedure		
Specimen requirements: collection and storage		
PPE requirements		
Reagent preparation		
Pull pending log and worksheet		
Additional materials required		
Review of the SOP		
Quality control samples		
Preparation of blood smear		
Storage and stability of smears		
Drying the smear		
Fixing the smears		
Staining the smears		
Using the microscope		
Identifying the granules		
Scoring the samples		
Reference range		
Recording of results		
Interpretation of Results		
Reporting results in Cerner		

New York-Presbyterian Hospital / Columbia University Medical Center
DEPARTMENT OF CLINICAL LABORATORIES

ANNUAL COMPETENCY ASSESSMENT CHECKLIST

Employee Name: Test Employee **Dept:** Laboratory **Year:** **Policy:** HR-9i

Competency Assessment is used to ensure that the laboratory personnel are fulfilling their duties as required by the department and federal regulation.

Method of assessment:

1) direct observation;
2) observation for compliance with safety protocols;
3) periodic review of work product for compliance with standard operating procedures and applicable workload limits;
4) monitoring the recording and reporting of test results;
5) direct observation of performance of instrument maintenance and function checks;
6) assessment of test performance through testing of previously analyzed specimens, internal blind or external proficiency testing samples;
7) assessment of problem solving skills.
8) assessment of delegated functions

Evaluate the competency of staff for all tasks for which he/she is responsible. Indicate evaluation for each task as: YES (competent) or NO (not competent). Areas that the employee is not responsible will be marked NA (not applicable). If the staff is not competent, a corrective or remedial action should be initiated and documented and filed with this document.

Roche Analyzer		1) Direct Observation	2) Safety Compliance	3) Compliance w/ SOP	4) Review test results	5) Instrument Maintenance	6) Unknown/PT Samples	7) Problem Solving	8) Delegated functions
[ ] Check If Task Is Not Applicable	Specimen requirements.	[X] YES [ ] NO		[X] YES [ ] NO		[X] YES [ ] NA		[X] YES [ ] NO	
	Sample Handling and Stability	[X] YES [ ] NO		[X] YES [ ] NO		[X] YES [ ] NA		[X] YES [ ] NO	
Assessed	Processing	[X] YES [ ] NO		[X] YES [ ] NO		[X] YES [ ] NA		[X] YES [ ] NO	
	Measurement methodology	[X] YES [ ] NO		[X] YES [ ] NO		[X] YES [ ] NA		[X] YES [ ] NO	
By:	Quality Control	[X] YES [ ] NO		[X] YES [ ] NO		[X] YES [ ] NA		[X] YES [ ] NO	
	Reporting Results	[X] YES [ ] NO	[X] YES [ ] NO	[X] YES [ ] NO	[X] YES [ ] NA If YES, date of event: Accession #:	[X] YES [ ] NA	[ ] YES [ ] NA If YES, date of event _____ score: _____	[X] YES [ ] NO	
Date:	Reagent Handling and Storage	[X] YES [ ] NO		[X] YES [ ] NO		[X] YES [ ] NA		[X] YES [ ] NO	
	Maintenance	[X] YES [ ] NO		[X] YES [ ] NO		[X] YES [ ] NA		[X] YES [ ] NO	
	Delegated QC Review								[X] YES [ ] NA
	Delegated Staff Training								[X] YES [ ] NA
	Delegated Regulatory Tasks								[X] YES [ ] NA
	Delegated Scheduling								[X] YES [ ] NA
Radiometer ABL 800 Blood Gas Analyzer		1) Direct Observation	2) Safety Compliance	3) Compliance w/ SOP	4) Review test results	5) Instrument Maintenance	6) Unknown/PT Samples	7) Problem Solving	8) Delegated functions
[ ] Check If Task Is Not Applicable	Specimen requirements.	[ ] YES [ ] NO		[ ] YES [ ] NO		[ ] YES [ ] NA		[ ] YES [ ] NO	
Assessed	Sample Handling and Stability	[ ] YES [ ] NO		[ ] YES [ ] NO		[ ] YES [ ] NA		[ ] YES [ ] NO	
	Processing	[ ] YES [ ] NO		[ ] YES [ ] NO		[ ] YES [ ] NA		[ ] YES [ ] NO	
By: _____	Measurement methodology	[ ] YES [ ] NO		[ ] YES [ ] NO		[ ] YES [ ] NA		[ ] YES [ ] NO	
	Quality Control	[ ] YES [ ] NO		[ ] YES [ ] NO		[ ] YES [ ] NA		[ ] YES [ ] NO	
Date: _____	Reporting Results	[ ] YES [ ] NO	[ ] YES [ ] NO	[ ] YES [ ] NO	[ ] YES [X] NA If YES, date of event: _____ Accession #: _____	[ ] YES [ ] NA	[ ] YES [ ] NA If YES, date of event _____ score: _____	[ ] YES [ ] NO	
	Reagent Handling and Storage	[ ] YES [ ] NO		[ ] YES [ ] NO		[ ] YES [ ] NA		[ ] YES [ ] NO	
	Maintenance	[ ] YES [ ] NO		[ ] YES [ ] NO		[ ] YES [ ] NO		[ ] YES [ ] NO	
	Delegated QC Review								[X] YES [ ] NA
	Delegated Staff Training								[X] YES [ ] NA
	Delegated Regulatory Tasks								[X] YES [ ] NA
	Delegated Scheduling								[X] YES [ ] NA
Miscellaneous Tasks	**Task/Element**	1) Direct Observation	2) Safety Compliance	3) Compliance w/ SOP	4) Review test results	5) Instrument Maintenance	6) Unknown/PT Samples	7) Problem Solving	8) Delegated functions
Centrifuges	Operation	[X] YES [ ] NO	[X] YES [ ] NO	[X] YES [ ] NO	NA	[X] YES [ ] NA	NA	[X] YES [ ] NO	[X] YES [ ] NO
Pipettes	Operation	[X] YES [ ] NO	[X] YES [ ] NA	[X] YES [ ] NO	NA	[X] YES [ ] NA	NA	[X] YES [ ] NO	[X] YES [ ] NO

Atttestation and Signatures

"I have read the above competency assessment. I understand that by signing this statement, I agree that I have been trained in the areas noted in this assessment and I am approved to perform the tests/procedures independently. I also feel competent to perform this list of tests/procedures, and processes independently as indicated by the above assessment."

_____ _____
Employee Signature Date

_____ _____
Employee Signature / Date Supervisor Signature / Date

Requirements:

- Direct observation of routine patient testing --

  Watch employee perform routine work processes and procedures including patient preparation, specimen handling, processing, and testing.

  use of a checklist as guidance for evaluation and to document that all required procedural steps are completed.

- **Monitoring the recording and reporting of test results** --

  Review worksheets, computer printouts, or manual test logs for results or entries that are incorrect or incomplete.

  The worksheets, logs, and printouts should be compared to final test reports, evaluated turnaround times, and for compliance with policies and procedures.

Requirements

- Review of intermediate test results, records, and proficiency testing results --

  Review testing documentation, to include test results or worksheets, documentation forms, QC logs, proficiency testing documentation, and other applicable documentation for completion of proper policies and procedure. Documentation of review will include follow up of corrective action related to problems in the laboratory.

- Direct observation of instrument maintenance and function checks --

  Watch employee perform instrument maintenance and function checks as compared to documentation for completeness and correctness of process and expected outcome.

  Record observations on checklist for documentation of inclusion and completion of all steps.

Requirements:

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

  Assessment of previously tested samples; internal blind samples or external proficiency testing samples.

  Use of checklist for documentation of blind sample performance.

- **Assessment of problem solving skills** --

  Include review of problem logs, incident reports, and QC failures; Review corrective actions employed to resolve the problem. Personnel interviews (staff narrative) may also be included for documentation.

  Exams (include pre-analytical, analytical and post analytical)

In God we trust, all others must provide data

- The easiest way to document problem solving is with a quiz
- It should cover the elements of specimen requirements, sample handling and stability, processing, methodology, QC and reporting results
- Case studies work very well

Frequency

- At least semiannually during the first year the individual tests patient specimens
- At least annually thereafter unless test methodology or instrumentation changes – then 6 months and annually
- Prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation

What is the timeline?

- If you are hired on January 1-
- You are trained in hematology from January 2- March 2
- And you are assessed competency on performing a CBC on March 3rd
- When is your 6 month competency assessment performed:
  a. June 1
  b. June 3
  c. September 3
  d. Anytime before the end of the year

Answer: C September

New employees

- Competency assessment separate from training
- Assessed twice in the first year

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

Case study

- An employee goes out on maternity leave and is gone for a period of 6 months
- She comes back and immediately begins working on the bench and reporting out results
- Is this acceptable?
- She has worked in her position previously for 10 years

What do the regulations say?

- Not much
- There are currently no defined regulatory or accreditation requirements for this situation
- It is a defined laboratory policy-whatever you state in your policy, you must follow
- NYP defines this as 3 months:
  1. Re-assess competency
  2. if there is a failure, person will be retrained
  3. then re-assessment of competency
- If an employee has minimal previous experience, or they are uncomfortable at their workstation, a full training and competency should be performed.

Case Study

- Inspector is conducting a tracer audit of a sample performed on April 10, 2019
- Notes that the technologist that performed and signed off on the testing is a relatively new employee
- Asked to see their files
- Competency for this procedure was assessed on April 29, 2019- employee was trained on April 1, 2019
- Is this within compliance

NO! CAP/CLIA requirement

Gen. 55500 competency assessment – the competency of each person to perform his/her assigned duties is assessed. This must be addressed following training before the person performs patient testing.

College of American Pathologists - ref. CLIA elements

Case study

- In the Special Coagulation laboratory, the Star Evolution and the Sta-Max are used for testing
- The technologists are assessed for competency on factor assays, AT testing, von Willebrand testing, mixing studies
- Since they are on the same platform is this necessary?

Yep!

- May I combine for competency purposes, all tests performed simultaneously on the same testing platform?

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

- ***However, any test with unique aspects, problems or procedures within the same testing platform should be assessed separately to ensure that staff maintain their competency to report test results promptly, accurately and proficiently.***

So: Factor assays are clot based

AT is a chromogenic assay

Mixing study requires intervention; incubation; manual dilution

Von Willebrand testing is complex and immunoturbidimetric assay

All different methodologies but on the same platform!

Case study

- Inspector is reviewing competency assessment for unknown or proficiency testing sample
- It is filled out as: Yes

  August 12, 2019

  100% score
- The inspector doesn’t want to accept this
- All the boxes are filled out
- What is wrong

If it’s not documented it’s not done!

- Insufficient information
- ***Information must be retrievable***
- “Documentation of the event used for the assessment of the staff’s test performance must contain enough specific detail so that the evaluation can be substantiated”
- Should have PT name (challenge 1,2 or 3) date testing was performed/signed by tech and score.
- Or if a previously analyzed specimens were used- must indicate the date and the result of both the original testing and testing performed by the staff member.
- ***If no supporting data is attached to the document***
- This documentation shows the directive was fulfilled

What happens if it doesn’t match

- You cannot accept it as a fulfillment of that requirement
- Check for error due to sample instability
- Repeat the exercise
- If results still do not match what do you do?
- **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**

Case study

- Annual competency is due for a technologist
- The analyzer working that she needs to be evaluated on is not really well understood by the supervisor
- Another technologist who is familiar with the procedure does the competency assessment
- Is this allowed

Who can assess competency?

- Competency must be assessed by a supervisor (person must meet supervisor qualifications- make sure they are competency assessed as a supervisor!)
- It is no longer train the trainer
- Can another tech train people?
- Yes, as long as they are competent on that procedure- they can train
- They cannot assess competency

Who is required ??

All individuals fulfilling the duties as outlined in Subpart M of CLIA regulations: (Anyone who performs testing on patient specimens)

1. CC Clinical Consultant
2. TC Technical Consultant
3. TS Technical Supervisor
4. GS General Supervisor
5. TP Testing Personnel

Who is Responsible for Performing Competency Assessment ?

- **Technical Consultant** – Moderate complexity

  Responsible for performing and documenting but can also be others who meet the TC requirements.

- **Technical Supervisor** – high complexity

  Responsible for performing and documenting but can be delegated in writing to a GS as long as they meet the regulatory requirements as a GS for high complexity testing.

Who is Responsible for Performing Competency Assessment ?

- General Supervisor – High complexity

  Provides day to day supervision and has access to personnel, monitors analyses and examinations, take remedial actions, report deviations, provide orientation to personnel, and annually evaluate performance of testing personnel.

Who, con't.

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

Ultimately, the Lab Director is responsible to ensure all testing personnel are competent and maintain competency.

Who is required to have competency assessed??

All individuals fulfilling the duties as outlined in Subpart M of CLIA regulations: (Anyone who performs testing on patient specimens)

1. Clinical Consultant
2. Technical Consultant
3. Technical Supervisor
4. General Supervisor
5. Testing Personnel

BUT ALSO:

1. Managers
2. Quality Managers
3. Directors
4. Lab attendants
5. IT personnel

Supervisor done by manager, manager by director

COMPETENCY ASSESSMENT
SUPERVISORY STAFF
❑ **Initial**

❑ **Six Months Post Hire Date** ❑ **Annual**

Staff Name: _____ **Job Title:** _____

Supervisory Functions Assessed:

- ❑ Day-to-day supervision of test performance by testing personnel;
- ❑ Monitoring examinations to ensure the acceptable levels of analytic performance are maintained;
- ❑ Assuring that all remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications;
- ❑ In the event of non-conformances, ensuring that results of test examinations are not reported until all corrective actions have been taken and the test system is properly functioning;
- ❑ Providing training to personnel;
- ❑ Evaluating and documenting the performance of all testing personnel annually;
- ❑ Compliance with policies and procedures;
- ❑ Communication, including bringing problems and non-conformities to the attention of the laboratory upper management team;
- ❑ Leadership and problem-solving capabilities;
- ❑ Allocation of resources; maintaining staff schedules, equipment and supplies providing effective and efficient workflow;
- ❑ Personnel management.

Method of Assessment:

- ❑ Direct observation of performance of duties
- ❑ Periodic review of work product for compliance w/ SOP

Evaluation:

- ❑ Met (The staff is competent and can perform his/her task(s) independently)
- ❑ Partially Met (The staff requires additional training)
- ❑ Not Met (Re-education/In-service required)

Comments:

Staff Signature: _____ Date: _____

Evaluator/Observer Signature: _____ Date: _____

What to look at

- Phlebotomist:

  Assessment of blood sample collection; processes & procedures
- Technician in sample receiving:

  data entry, sample processing
- Transcriptionist

  pathology report process, accuracy and timeliness of report

Competency Testing during COVID

- While the rest of the country was on pause- that was not the case for laboratories
- Still need to be in compliance with all regulatory issues
- How do you deal with this – personnel being out, scheduling issues, performing less testing, performing different testing, implementing new testing
- How do you train and social distance?
- What did we do?

New York Presbyterian- Columbia Hot Spot- 1st hospitalized COVID patient

- First we had an extreme slow down in testing- we used this time to make sure our regulatory issues were up to date- including instrument correlations, linearity, carry over.
- Prepared all of the competency quizzes for personnel to perform
- Because staff is assessed throughout the year for so many tests, we worked with folders, for personnel to keep test results, any unknowns, and proficiency testing results.
- Assigned unknowns during this time and also tried to align annual assessment to a period of 3 months, instead of throughout the year.

Phase II- testing increased to align with 100% COVID patients

- **Blood Gases: Increase 100%**
- **Ferritin: Increase 210%**
- **Procalcitonin: Increase 116%**
- **Hepatic Panel: Increase 135%**
- **Metabolic Panel: 480%**
- **Respiratory Panel: 257%**
- **CBC = 244%**
- **CBC with Diff= 244% increase**
- **Manual Diff: = 311%**
- **ESR: Increase of 258%**
- **D-dimer: 5 fold increase in testing**
- **Fibrinogen: 3.5 fold increase in testing**
- **PT= 2.5 fold increase in testing**
- **aPTT= 2.3 fold increase in testing**
- **AT= 2.0 fold increase in testing**

What happened?

- During this surge time, we went to 3/12 hour days – to decrease amount of time people had to travel to the hospital- most people use public transportation
- Actually worked well, if we had staff out, we would follow specific emergency testing, but they had long days to complete testing.
- They could also integrate unknowns as part of validation protocols- since we had to do additional lot to lot validations because of reagent utilization
- Opportunity to also complete the quizzes for the problem solving section of competency

Phase III- implementation of New Testing: PCR, ELISA, Anti-body testing

- Remember in the beginning of March, we had no testing. We were then charged with the task of bringing these tests up rapidly. Some were LDT's additionally had to be submitted to NYS, others had EUA.
- Regardless, they had to perform, had to have all of the requirements to demonstrate robustness, and sensitivity and specificity.
- In NYS only licensed technologists can perform testing, our Governor signed a bill allowing other science professionals to perform COVID testing.
- Now, all of these people had to have documentation of both training and competency.
- Be aware, these will be the tests that inspectors will review documentation for-
- Training, competency (initial), 6 months, and annual.

Conclusion

- Competency assessment is complicated
- It needs to be done
- Try to incorporate it into the work load as much as possible
- The only basis to make sure things are being performed correctly
- Use quizzes as an easy problem solving tool
- Stick to the time intervals
- ***This is all part of a quality system!***