



cap
Advancing Excellence

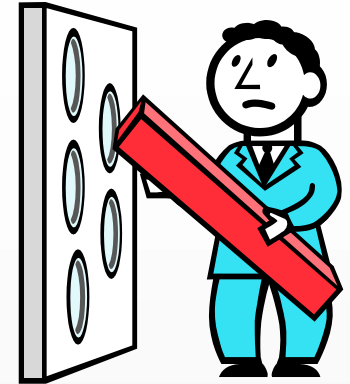
Is Your Lab's Competency Assessment a Competent Assessment?

Every
number
is a life.

Presented by
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Objectives...

- Understand the reasons for World-Class Competency Assessment
- Review CAP's requirements
- Answer...



- When must Competency be assessed?
- What must be assessed?
- Who must be assessed?
- How must we assess competency?

Two things to know...

- Do you produce quality results?
- Do your people know what they are doing?



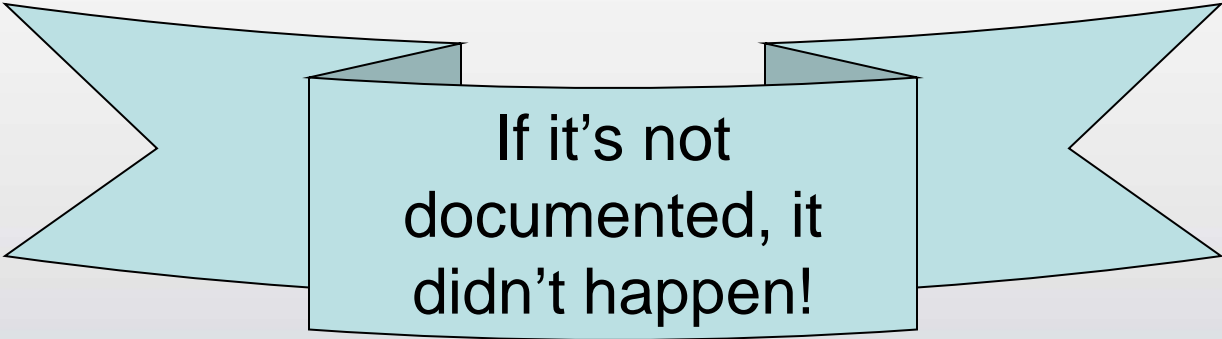
Do you produce quality results?

- ✓ QC
- ✓ QM/QI/PI/XYZ
- ✓ Calibration/AMR
- ✓ Comparisons
- ✓ QMS
- ✓ Audits
- ✓ Maintenance, Temperature monitoring, Etc, Etc!



Do your people know what they are doing?

- ✓ Training
- ✓ Proficiency Testing
- ✓ Competency Assessment
- ✓ Continuing Education



**If it's not
documented, it
didn't happen!**

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.

*Other elements of competency may be assessed, as applicable. 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. A test system may be manual, automated, multi-channel or single use and can include reagents, components, equipment or instruments required to produce results. A test system may encompass multiple identical analyzers or devices. Different test systems may be used for the same analyte.*

The laboratory must identify the test systems that an employee uses to generate patient test results. Many of the elements of competency assessment are performed during routine supervisory review of an employee. 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, all the above six elements must be assessed annually (unless any are not applicable to the test system). For waived test systems, the laboratory may select which elements to assess.

What is a 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. A test system may be manual, automated, multi-channel or single use and can include reagents, components, equipment or instruments required to produce results.

Who has to perform Competency Assessment?



A laboratory must evaluate and document the competency of all testing personnel for each test system.

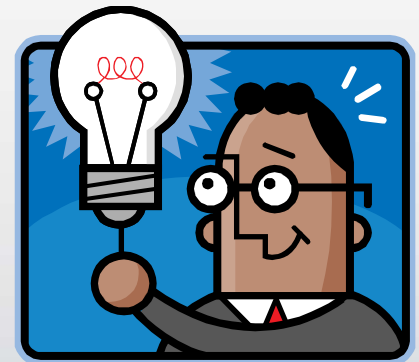
- ✓ *Any personnel whose work is part of the testing process (includes pre-analytical!)*
- ✓ *Identify which test systems each person uses*

FAQs....

Do I have to do competency assessment on non-laboratory employees?

Answer = If they are performing testing, they need to know what they are doing SO....

Yes, they need to have competency assessment.



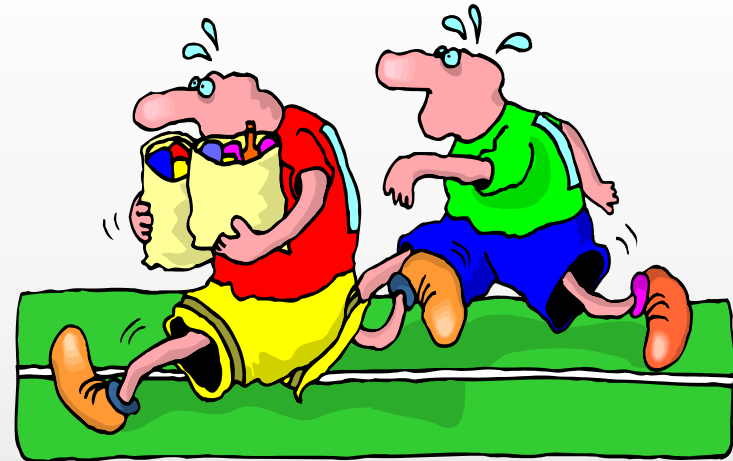
How do you document Competency for all those test systems?!?!?

- Three kinds of programs:
 - Home grown
 - Commercially available
 - Hybrid



Home Grown

- This is okay...if it's comprehensive and trackable.
 - Quizzes
 - Observation
 - Record review
 - Demonstration
 - Trouble-shooting



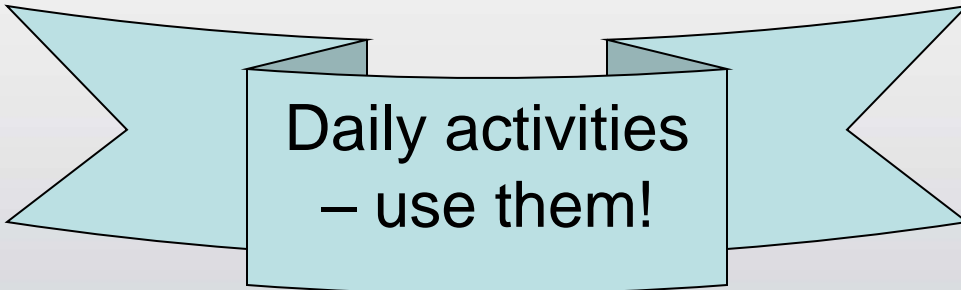
WHAT must be assessed?

- *Direct observations*
 - *Maintenance*
 - *Test performance*
- *Monitoring test results,*
- *Review of QC, PT and Maintenance*
- *Unknowns*
- *Troubleshooting*



Here's a TIP for you!

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.



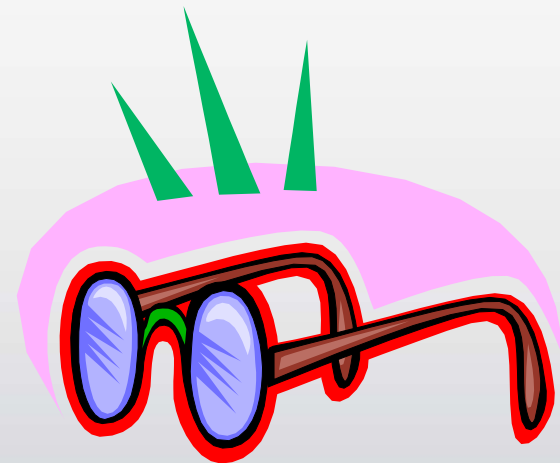
**Daily activities
– use them!**

FAQs...

Do I have to **observe** EVERY employee?

Answer = Depends. If they are performing
NON-WAIVED testing, Yes.

If they are performing Waived, then you can
CHOOSE to or NOT.



Non-Waived vs. Waived



So, how do you KNOW if a test is Waived or Non-Waived?

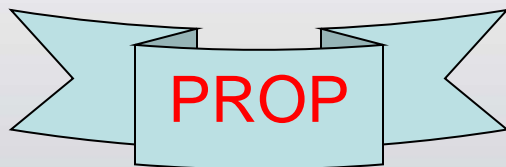
- ✓ FDA website
- ✓ Kit box or insert
- ✓ Manufacturer website
- ✓ Call manufacturer



What's the difference?

Non-Waived:

- ✓ ALL of the Big Six
 - ✓ Proficiency Testing
 - ✓ Record review
 - ✓ Test results
 - ✓ Worksheets, QC, PT, Maintenance
 - ✓ Observation
 - ✓ Testing
 - ✓ Maintenance
 - ✓ Problem Solving Skills



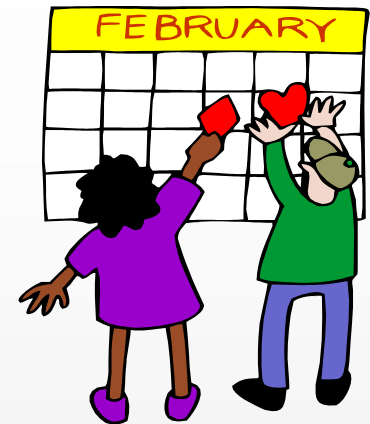
Waived:

- ✓ Pick what you want!



WHEN must competency be assessed?

- The competency of each person to perform the duties assigned must be assessed following training before the person performs patient testing. Thereafter, during the first year of an individual's duties, competency must be assessed at least semiannually.



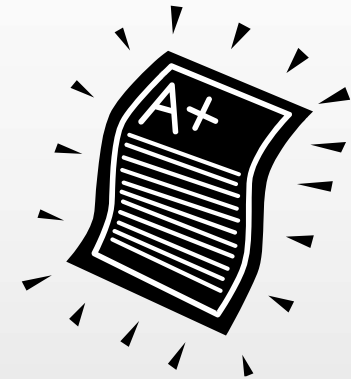
FAQs...

If I assess the employee at the end of training, that counts as one of my semiannual competencies for that first year...right?

Answer = NO. Does not count.

Question for YOU...

What do you consider “passing” for competency assessment?





Don't forget....

GEN.57000 = 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

GEN.58500 = There is documentation of retraining and reassessment for employees who initially fail to demonstrate satisfactory performance on competency assessment.



Requirements - POC

POC.06900 = There is a documented program to ensure that each person performing POCT maintains satisfactory levels of competence.

- ✓ For EACH test system
- ✓ For ALL testing personnel



RECAP...

- Did we master all of the objectives?



WHO?
WHAT?
WHEN?
HOW?

QUESTIONS?



Please feel free to type in your questions
in "Chat"

You can also phone in and pose your
questions...remember to use your code...





...To all the laboratorians who work tirelessly to provide the best testing possible daily. No one understands, except another laboratory professional, how much goes into ensuring those quality results. From those who do, on behalf of your patients...THANK YOU!