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# Competency Assessment

Is Your Lab's Competency Assessment  
a Competent Assessment?

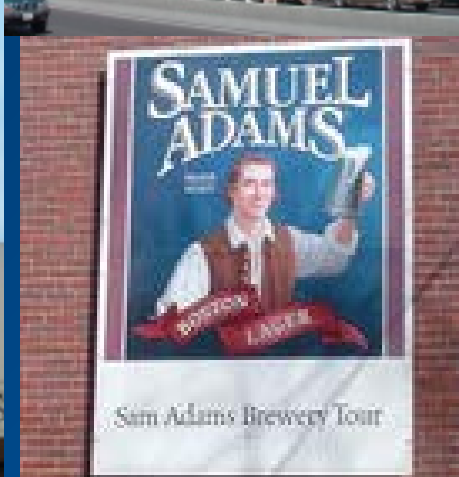
Presented by:

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June 16<sup>th</sup>, 2015

Oh...the places we've been...

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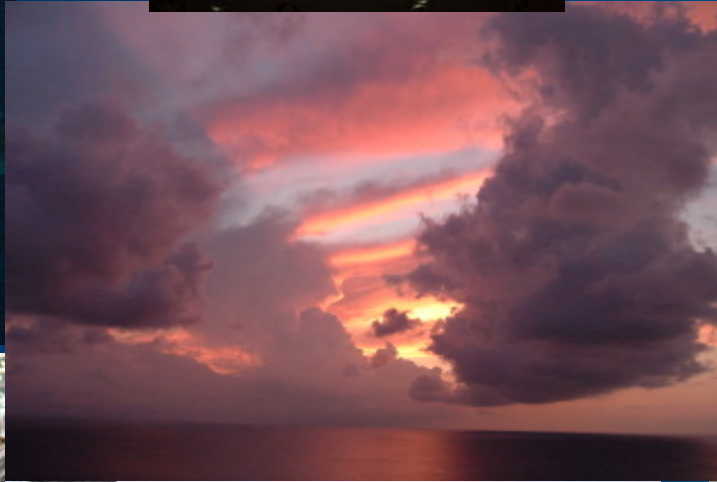
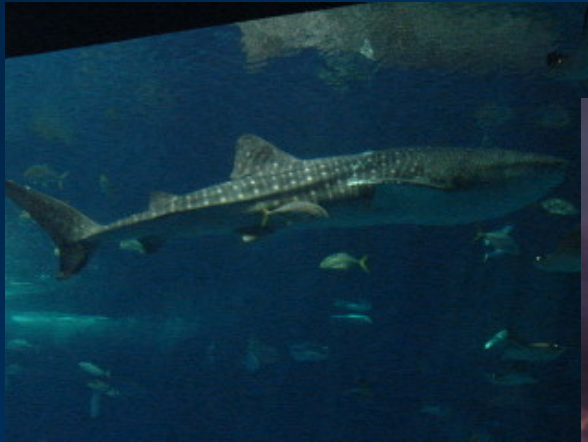




Oh...the things we've seen...



← CONTROL PANEL...FOR A TOILET



# Objectives

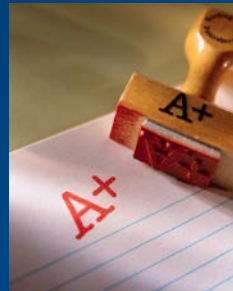
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- Define competency, training, education and know the differences
- Establish appropriate “Test Systems”
- Explain CAP’s requirements for who can assess and how assessments need to be documented

# Two things to know...

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



# Do you produce quality results?

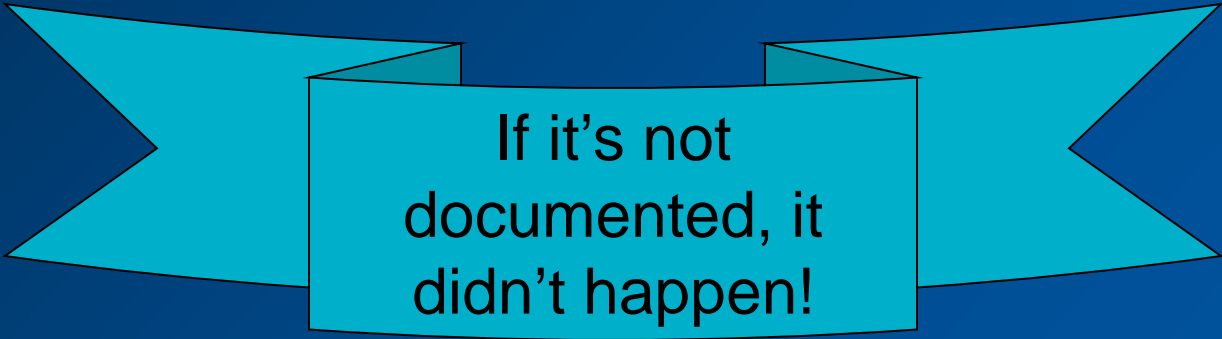
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- ✓ QC
- ✓ QM/QI/PI/XYZ
- ✓ Calibration/AMR
- ✓ Comparisons
- ✓ QMS
- ✓ Audits
- ✓ Maintenance, Temperature monitoring, Etc, Etc!

# Do your people know what they are doing?

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



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

# First...Do you know what Competency Assessment is? And what it isn't?

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- What is Training?
- What is Competency Assessment?
- What is Continuing Education?



# What Are the Requirements?

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- GEN.55500 = The competency of each person performing patient testing 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.
  - Written Procedure defining the method and frequency of competency assessments

# What is a Test System?

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- *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?

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- 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....

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- 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?!?!?

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



# Home Grown

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

# Commercially available

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- The CAP Competency Assessment Program
  - Over 150 automated test systems
  - Customizable
  - Affordable/Time Saver
  - Format for documentation
  
  - Must be supplemented by direct observations

# WHAT must be assessed?

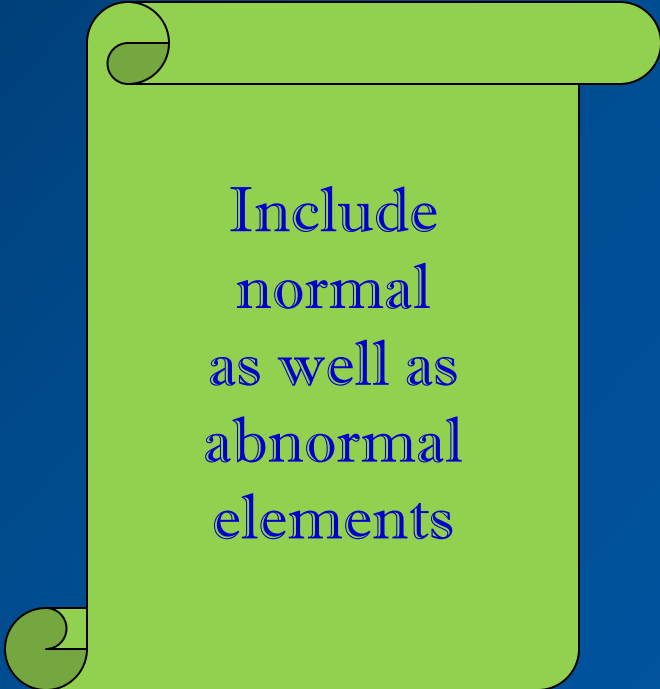
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- Direct observations
  - Maintenance
  - Test performance
- Monitoring test results,
- Review of QC, PT and Maintenance
- Unknowns (proficiency testing or blind samples)
- Troubleshooting

# Don't forget Morphologic Consistency!

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- It's part of your Competency Assessment
- Criteria for acceptability
- Use it as "Blind Sampling"

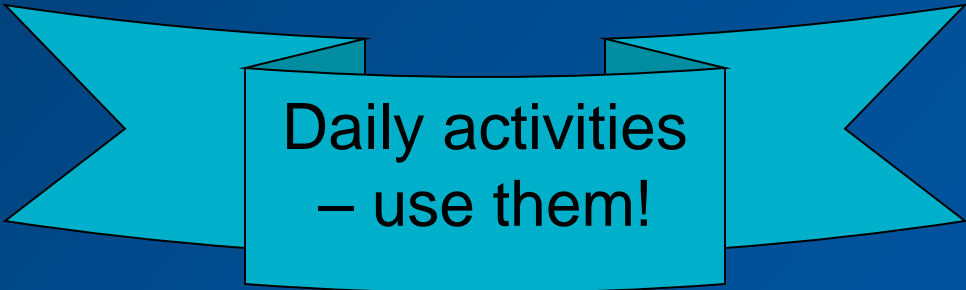


Include  
normal  
as well as  
abnormal  
elements

# Here's a TIP for you!

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- *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...

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- 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.

# WHO can assess competency?

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- High Complexity
  - Technical Consultant but can delegate to General Supervisor
- Moderate Complexity
  - Must qualify as a Technical Consultant under CLIA
- Waived Complexity

# Non-Waived vs. Waived

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

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



# What's the difference?

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- 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?

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- NON-waived:
- 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.

# WHEN must competency be assessed?

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- **WAIVED:**
- **NO** requirement for semiannual assessment within the first year of testing duties
- **Annual** assessment required

## FAQs...

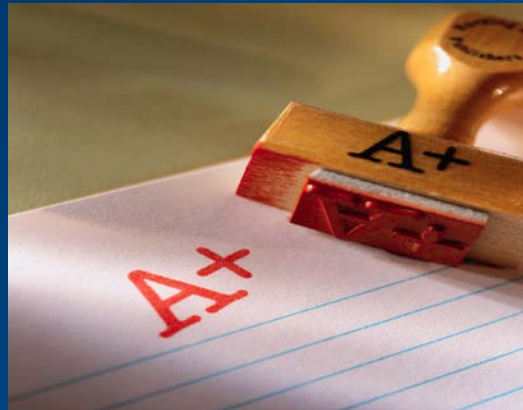
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- If I assess the employee at the end of training, that counts as one of my semiannual competencies for that first year...right?
- Answer = NO. Does not count.

# Question for YOU...

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- What do you consider “passing” for competency assessment?



# Don't forget....

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- 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



# Requirements - POC

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## POC.06875 Competency Assessment – Waived Testing

There is a documented program to ensure that each person performing waived testing maintains satisfactory levels of competence.

## POC.06910 Competency Assessment – Non-waived Testing

There is a documented program to ensure that each person performing non-waived testing maintains satisfactory levels of competence.

# RECAP...

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- Did we master all of the objectives?

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- 
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WHO?

WHAT?

WHEN?

HOW?



# One more requirement...

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- **GEN.55525 Performance Assessment of Supervisors/Consultants**
  - The performance of section directors/technical supervisors, general supervisors, and technical consultants is assessed and satisfactory.
  - Evidence of Compliance
    - Job Descriptions that list regulatory responsibilities
    - Records of performance assessment

# QUESTIONS?

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- Please feel free to type in your questions in “Chat”
- You can also phone in and pose your questions...remember to use your code...



# Thank You!

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...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 know, on behalf of your patients...**THANK YOU!**





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