

Getting The Most From Your AABB Assessment

SEABB Meeting
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Then Medical Symbol From Ephesus - Ancient Turkey



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Assessment -Opportunity Taken or Lost

Develop strategies to elicit and capture ideas while the AABB assessment team is on site to maximize the value from the assessment process and team.

Translated = Educational Opportunities



Assessments



- AABB
- FDA
- CAP
- Joint Commission
- Vendor Supplier
- CLIA



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Educational Value Earned

Non Conformance

→ **Understanding**

→ **Knowledge**



Treasure of Wealth



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Interaction ???????



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How Do You Participate?

- Drop off records – run to office and hide



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Breeze in & out of conference room & hope assessors don't speak to you



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Sit with the assessor and dream of the beach and margaritas



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Sit with assessors, with pen and paper to take notes



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How Do You Participate?

- Sit with assessors, with pen and paper in hand taking notes
-ready to ask questions and discuss



The Questions

- Why- Don't you think we meet the standard?
- What- Do you think the standard means?
- How- Have you seen the standard met?
- Documentation- What kind is needed?



Value Derived Assessment

Assessors = All trained in our field

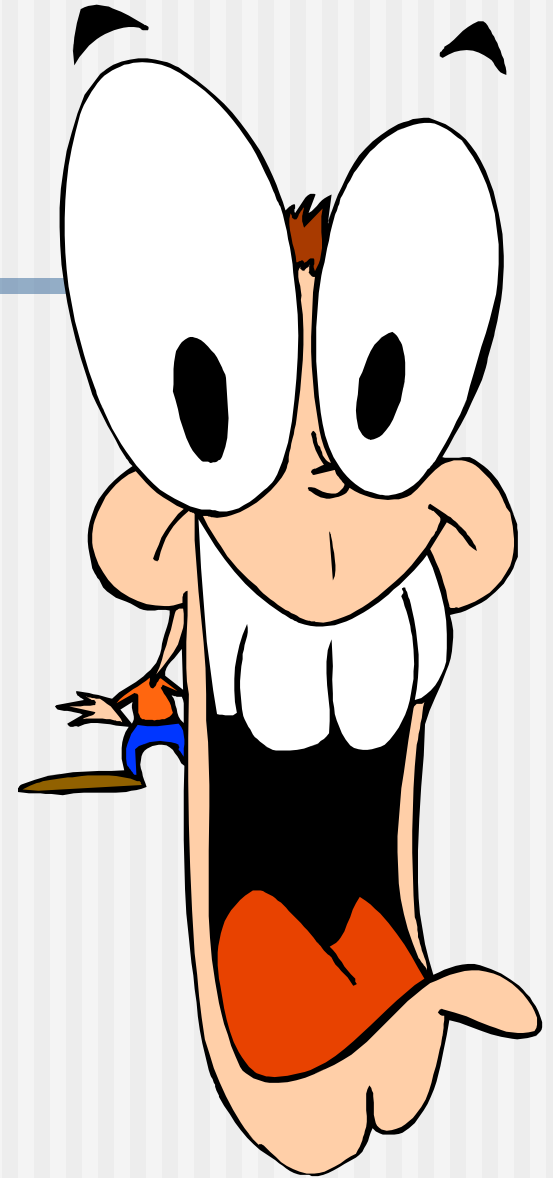
Assessment Team = Outside eyes

Reviewing: Policies, processes &
procedures



What Do We See

- Forms
- Procedures
- Training
- Computer



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42 CFR 493.1451 (b) (8)

- Competency Elements
 - Direct Observations
 - Patient testing
 - Instrument maintenance/function checks
 - Monitor recording and reporting of test results
 - Review of QC records, PT results, PM results
 - Assessment of test performance
 - Assessment of problem solving skills



2.0 Resources cont...

- 2.1.4 Personnel records for each employee shall be maintained.
 - Missing inclusive dates of employment
 - Missing diploma or transcript



3.0 Equipment

- 3.0...shall identify equipment that is critical...
- 3.4 ...equipment shall have unique identification
- No record of what is considered critical equipment
- Equipment lacking unique identification



3.0 Equipment cont...

- 3.5 ...process for scheduled monitoring and maintenance of equipment
- 3.7 The alarm shall be set to activate under conditions that will allow action to be taken before...reach unacceptable conditions.
- Manufacturer's instructions are not followed
- No evidence of corrective action if equipment is not functioning correctly
- Alarms set outside acceptable limits



4.0 Supplier and Customer Issues

- 4.3 ...incoming ...critical materials shall be received, inspected and tested ...before acceptance or use
- No documentation of inspection upon receipt



5.0 Process Control

- 5.0 Process control...shall have policies, and validated procedures that ensure the quality...
- 5.1.1 ...shall have a process to develop new processes and procedures of change existing ones...
- No documentation of validation process
- Incomplete documentation of changes made to existing procedures
- Change control process not followed



5.0 Process Control cont...

- 5.1.2 Proficiency Testing...shall participate in a proficiency testing program, if available, for CLIA regulated testing performed by the facility.
- 5.1.3 A program of quality control shall be established...and methods performed as expected.
- No evidence of a process to determine if all appropriate PT is performed
- Review of qc results are not performed in a timely manner or not done at all.
- Corrective action for out of range results are not documented



6.0 documents and Records



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6.0 Documents and Records

- 6.0 ...shall have policies, processes and procedures to ensure that documents are identified, reviewed, approved and retained
- 6.1.1 A master list of documents
- Processes and procedures for document control are not complete
- Reviews are incomplete or not timely
- Labels and forms are not included in the master document list



6.0 Documents cont...

- 6.1.4 Annual review of each policy, process and procedure by an authorized individual
- 6.1.5 Use of only current and valid documents
- Missing annual review
- Using outdated references
- No process for review of current references



9.0 Process Improvement Through Corrective Action

- 9.1 ...shall have a process for corrective action of deviations, nonconformances and complaints...
- Documentation of evaluation to ensure corrective action taken is effective



Proactive Approach – Be Ready!



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Proactive Approach

- Analysis from occurrence reports
- Findings from quality indicators
- Customer complaints
- Internal assessments
- Implementation period for new standards (approx 4 months)
- Use the crosswalk to identify new or changed standards
- Commendable Practices (www.aabb.org>Standards and accreditation>member tools)



“Small Opportunities are Often the Beginning of Great Enterprises”

Demosthenes 4th Century BC



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THANK YOU

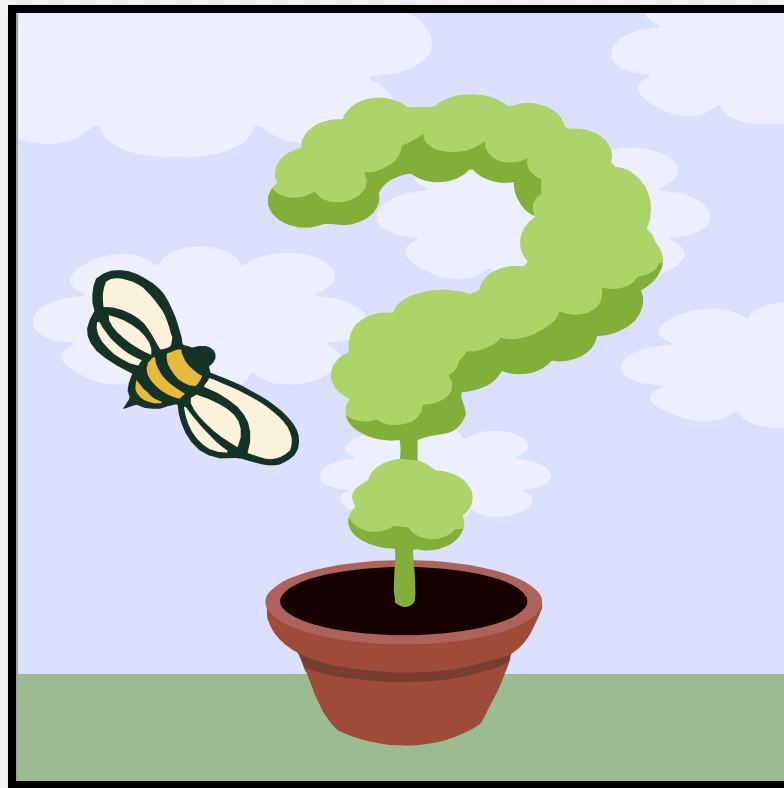


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