

AABB : Its an Assessment not an Inquisition

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WHY AABB?



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Purpose of Assessment

- To determine compliance with established Standards
- Peer review
- Education



Expectation

You are always
 prepared
 for an assessment



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Why Unannounced?



- To increase public trust in assessment process
- GAO report expressed concerns about integrity of inspections where facility receives prior notification of date
- CMS has placed restrictions on accrediting organizations regarding scheduling of assessments/inspections

AABB Standards

- Revised every two years
- 4-month implementation period
- Begin assessing on effective date of applicable Standards

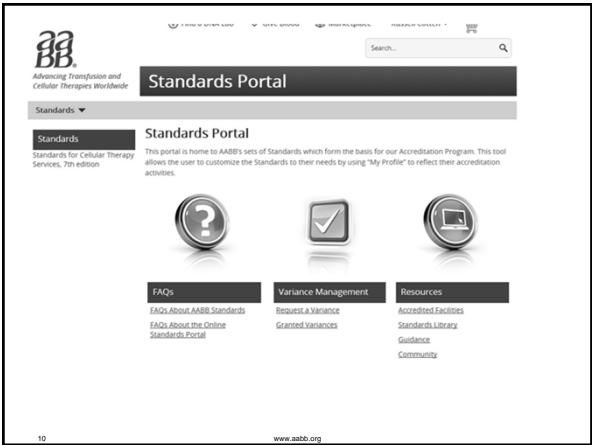


How Do I Get Ready?



Tools To Prepare For Assessments

- Standards for activities to be assessed
- AIM - Accreditation Information Manual
- Assessment Tools
- www.aabb.org



Standards Portal Cont...

- Benefits of the Standards Portal include
 - Customizable profiles based on your accredited activities.
 - Guidance to most standards (including significant changes to this edition).
 - Seamless integration of interim standards when they become effective
 - Ability to print the entire set of Standards on demand.
 - Discounted pricing structure for facilities or individuals who wish to purchase multiple licenses

Assessment Tool

Accreditation Requirement	Sample Assessment Questions	Evidence of Compliance
▲ 1.3 Policies, Processes, and Procedures Quality and operational policies, processes, and procedures shall be developed and implemented to ensure that the requirements of these <i>BB/TS Standards</i> are satisfied. All such policies, processes, and procedures shall be in writing or captured electronically and shall be followed. Standard 5.1.1 applies	What is the process to ensure that the requirements of AABB Standards and of regulatory agencies are incorporated into your documents and practices?	

Getting Ready: Helpful Hints

- Have a plan!
 - Activities
 - Timeline
- Involve your staff
 - To develop policies, processes, and procedures
 - To find areas of nonconformance



Who Are These Assessors?

- Staff assessors
 - Lead assessments for blood centers, cellular therapy labs, cord blood banks, perioperative services, molecular testing and relationship testing labs
 - Conduct and manage audits
 - Expertise in quality systems
 - Trained in CMS regulations
- Volunteer assessors
 - Knowledge of and experience in activity to be assessed
 - Trained as assessors

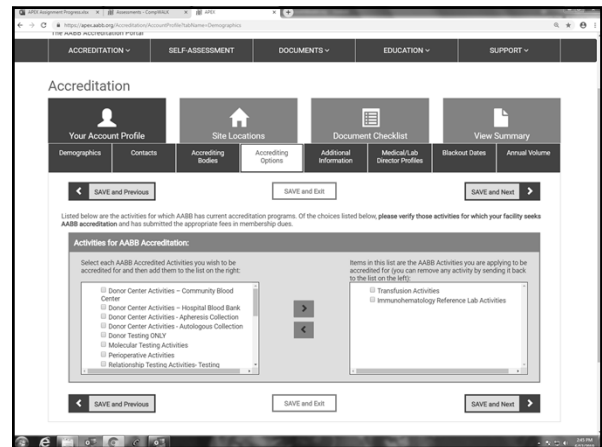
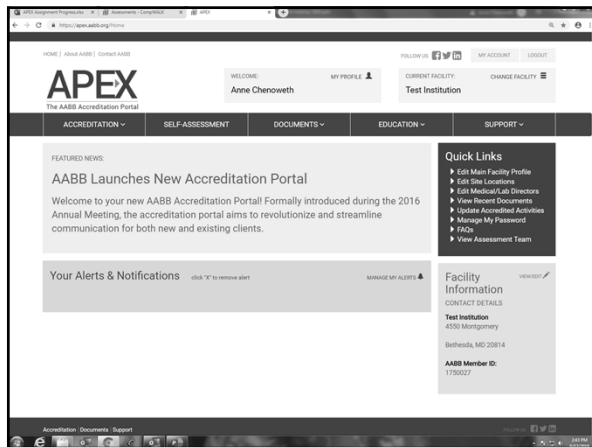


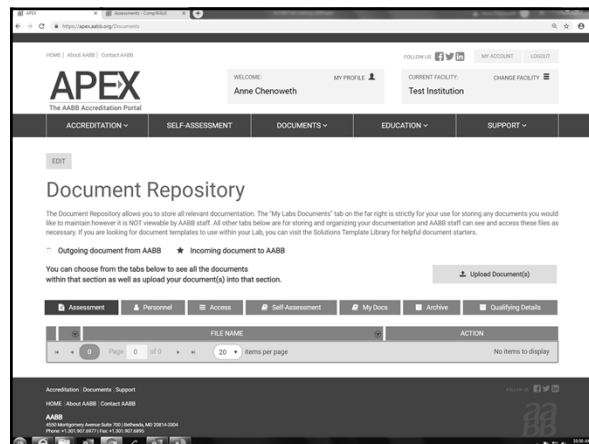
Why AABB

- Quality system assessment vs checklist



Risk Mitigation





- 1.1 ...shall have a defined executive management
- Evidence of participation in quality reviews are missing
- 1.3 quality and operational policies, processes and procedures shall be developed and implemented to ensure requirements...are met.
- Processes are not written
- SOPs are not followed as written

- 2.1.3 Competence
 - Evaluation of competence shall be performed... at defined intervals
 - Missing annual competence
 - Competence assessment not performed twice within the first year of employment
 - Competency assessments do not include all CLIA requirements

- Direct observations of routine patient test performance, including patient preparation, specimen handling, processing and testing
- Monitoring the recording and reporting of test results
- Review of intermediate test results or worksheets, quality control records, proficiency test results and preventive maintenance records
- Direct observations of performance of instrument maintenance and function checks
- Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external PT samples
- Assessment of problem solving skills

Competency assessment, including the 6 elements, must be performed for testing personnel for each test that the individual is approved by the lab director to perform.

3.0 Equipment

- 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



Proficiency Testing (PT)

- Required for the test system used as the primary method for patient / donor testing



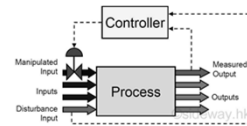
Proficiency Testing: Analytes Requiring PT

- Laboratory must enroll in a CMS approved PT program
- PT testing must be rotated among staff
- PT samples must be treated the same as patient samples



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



Continual Readiness



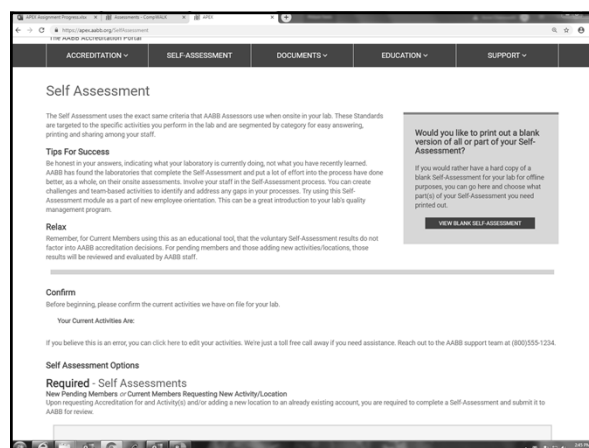
Staying Ready for Assessments

- Implementation and monitoring of CAPlan
- Introduction of New Standards
 - Comment period
 - Make your thoughts known!
- 4 month implementation period
 - Develop a plan
 - Implement
- Internal assessments
- Process improvement



Available tools

- www.aabb.org
 - AABB assessment tools
 - Commendable Practices Library
 - Facility Guide Through the Assessment Process
 - AABB HUB
 - Accreditation and Quality Department
 - accreditation@aabb.org
 - 301-215-6492



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In Summary...

- **Empower Facilities** to have control over their AABB Accreditation information, eliminate completing and submitting forms from scratch every two years – significantly reduce the amount of time and paper
- Automate manual, often repetitive tasks so you can **focus** on the things that truly need more attention
- **Centralize** and **Document** communication between Facilities and AABB, eliminating potential disjointed back and forth (email chains, waiting on a fax, calling AABB)
- Communications become **proactive** rather than reactive, alerts and notifications help to guide you efficiently through the process



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