



Advancing Transfusion and
Cellular Therapies Worldwide

AABB : Its an Assessment not an Inquisition

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Accreditation and Quality

AABB

WHY AABB?



Purpose of Assessment

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



Expectation

You are always
prepared
for an assessment



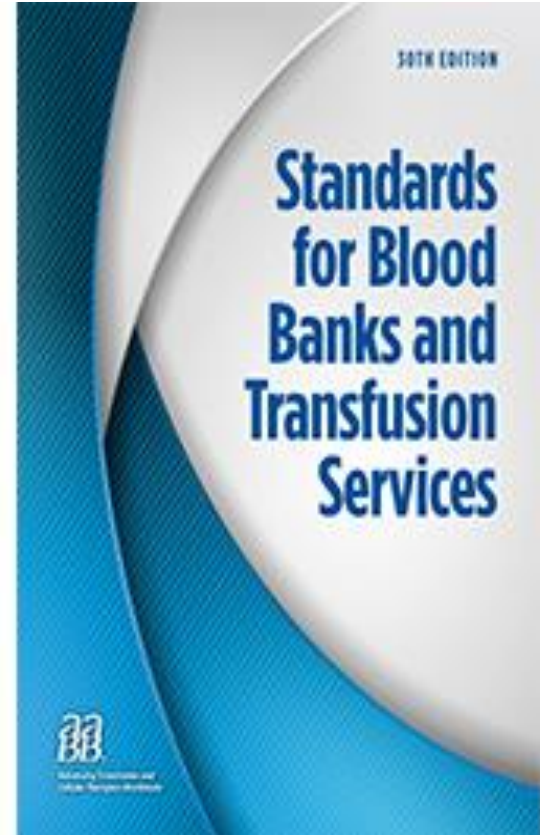
Why Unannounced?



- 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





Advancing Transfusion and
Cellular Therapies Worldwide

Find a DNA Lab

Give Blood

Marketplace

Register/Login



Search...



Standards Portal

Standards ▼

Standards

Standards for Cellular Therapy
Services, 7th edition

Standards Portal

This portal is home to AABB's sets of Standards which form the basis for our Accreditation Program. This tool allows the user to customize the Standards to their needs by using "My Profile" to reflect their accreditation activities.



FAQs

[FAQs About AABB Standards](#)

[FAQs About the Online
Standards Portal](#)



Variance Management

[Request a Variance](#)

[Granted Variances](#)



Resources

[Accredited Facilities](#)

[Standards Library](#)

[Guidance](#)

[Community](#)



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
<p>▲ 1.3 Policies, Processes, and Procedures</p> <p>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</p> <p>All such policies, processes, and procedures shall be in writing or captured electronically and shall be followed. Standard 5.1.1 applies</p>	<p>What is the process to ensure that the requirements of AABB Standards and of regulatory agencies are incorporated into your documents and practices?</p>	

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





WELCOME:

Anne Chenoweth

MY PROFILE 

CURRENT FACILITY:

Test Institution

CHANGE FACILITY 

ACCREDITATION ▾

SELF-ASSESSMENT

DOCUMENTS ▾

EDUCATION ▾

SUPPORT ▾

FEATURED NEWS:

AABBS Launches New Accreditation Portal


Welcome to your new AABBS Accreditation Portal! Formally introduced during the 2016 Annual Meeting, the accreditation portal aims to revolutionize and streamline communication for both new and existing clients.

Quick Links

- ▶ Edit Main Facility Profile
- ▶ Edit Site Locations
- ▶ Edit Medical/Lab Directors
- ▶ View Recent Documents
- ▶ Update Accredited Activities
- ▶ Manage My Password
- ▶ FAQs
- ▶ View Assessment Team

Your Alerts & Notifications

click "X" to remove alert

MANAGE MY ALERTS 

Facility Information

[VIEW/EDIT](#) 

CONTACT DETAILS

Test Institution


4550 Montgomery


Bethesda, MD 20814


AABBS Member ID:


1750027

Accreditation


Your Account Profile


Site Locations


Document Checklist


View Summary

Demographics

Contacts

Accrediting Bodies

Accrediting Options

Additional Information

Medical/Lab Director Profiles

Blackout Dates

Annual Volume

◀ SAVE and Previous

SAVE and Exit

SAVE and Next ▶

Listed below are the activities for which AABB has current accreditation programs. Of the choices listed below, **please verify those activities for which your facility seeks AABB accreditation** and has submitted the appropriate fees in membership dues.

Activities for AABB Accreditation:

Select each AABB Accredited Activities you wish to be accredited for and then add them to the list on the right:

- ☐ Donor Center Activities – Community Blood Center
- ☐ Donor Center Activities – Hospital Blood Bank
- ☐ Donor Center Activities - Apheresis Collection
- ☐ Donor Center Activities - Autologous Collection
- ☐ Donor Testing ONLY
- ☐ Molecular Testing Activities
- ☐ Perioperative Activities
- ☐ Relationship Testing Activities- Testing



Items in this list are the AABB Activities you are applying to be accredited for (you can remove any activity by sending it back to the list on the left):

- ☐ Transfusion Activities
- ☐ Immunohematology Reference Lab Activities

◀ SAVE and Previous

SAVE and Exit

SAVE and Next ▶

ACCREDITATION ▾

SELF ASSESSMENT ▾

DOCUMENTS ▾

EDUCATION ▾

SUPPORT ▾

Accreditation



AABB Account Profile



Site Locations



Document Checklist



View Summary

Demographics

Accrediting Bodies

Accrediting Options

Additional
InformationMedical/Lab Director
Profiles

Blackout Dates

Annual Volume

SAVE & Exit

SAVE & Next



Please complete the information below. The Accreditation Contact will be the first point of contact for most accreditation communication. ALL contacts will be notified on Friday the week prior to the scheduled assessment date UNLESS your facility is BOTH Joint Commission and CAP accredited.

Physical Address

Please review the addresses we have on file for your lab for correctness. No PO Box; must be actual location where assessor(s) will visit

COUNTRY*:

UNITED STATES ▾

FACILITY NAME*:

ADDRESS: (NO PO BOXES)

SUITE:

ADDRESS 2:

CITY*:

STATE*:

ZIP*:

PHONE*:

FAX*:

ORGANIZATION WEBSITE ADDRESS*:

CEO/President:

FIRST NAME*:

LAST NAME*:


SALUTATION*:


MR ▾

GENDER*:

☒ Male☐ FemaleCheck here if Facility **billing** address differs from physical address.



WELCOME: MY PROFILE 
Anne Chenoweth

CURRENT FACILITY: CHANGE FACILITY 
Test Institution

- ACCREDITATION ▾
- SELF-ASSESSMENT
- DOCUMENTS ▾
- EDUCATION ▾
- SUPPORT ▾


EDIT








Document Repository

The Document Repository allows you to store all relevant documentation. The "My Labs Documents" tab on the far right is strictly for your use for storing any documents you would like to maintain however it is NOT viewable by AAB B staff. All other tabs below are for storing and organizing your documentation and AAB B staff can see and access these files as necessary. If you are looking for document templates to use within your Lab, you can visit the Solutions Template Library for helpful document starters.

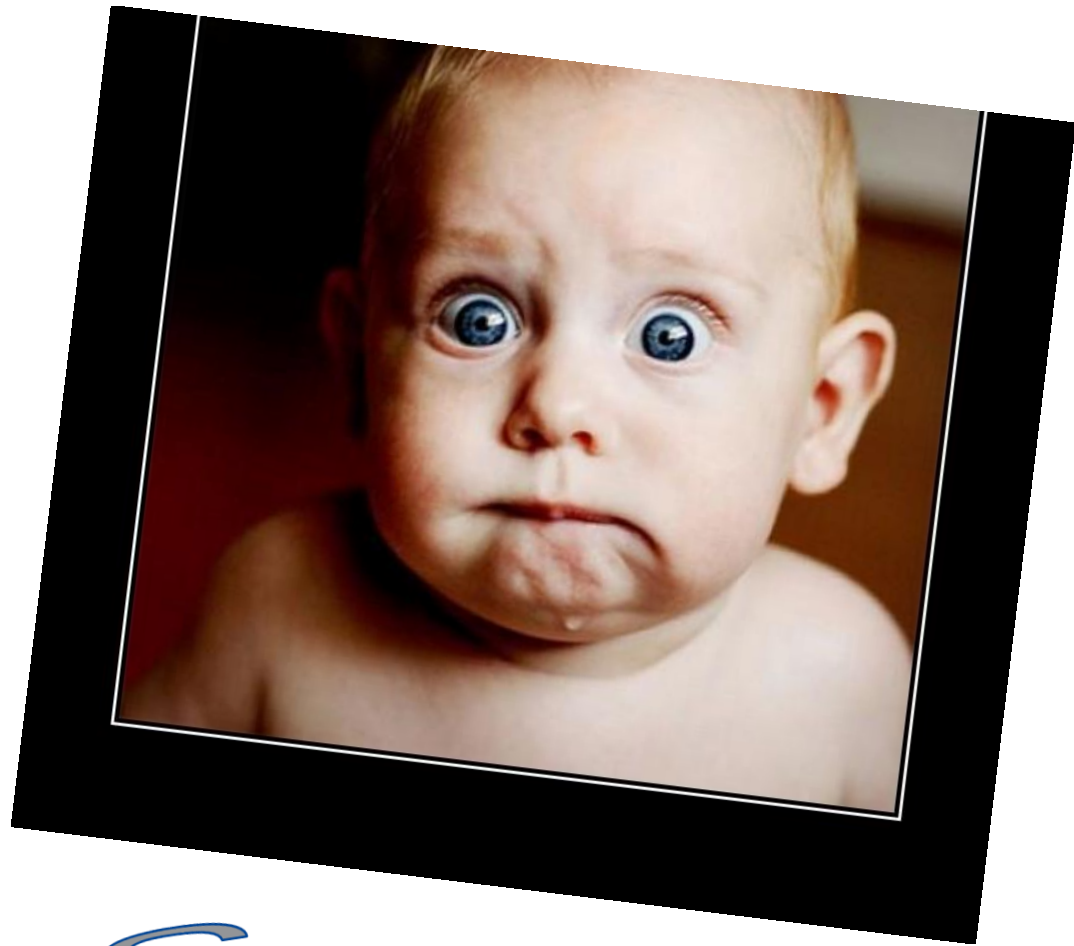
- ☐ Outgoing document from AAB B
- ☒ Incoming document to AAB B

You can choose from the tabs below to see all the documents within that section as well as upload your document(s) into that section.

 Upload Document(s)

-  Assessment
-  Personnel
-  Access
-  Self-Assessment
-  My Docs
-  Archive
-  Qualifying Details

	FILE NAME	ACTION
<div>◀ 0 Page 0 of 0 ▶ 20 items per page No items to display</div>		



OOPS...

aa
BB®

1.0 Organization

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

2.0 Resources

- 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

Minimal regulatory 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

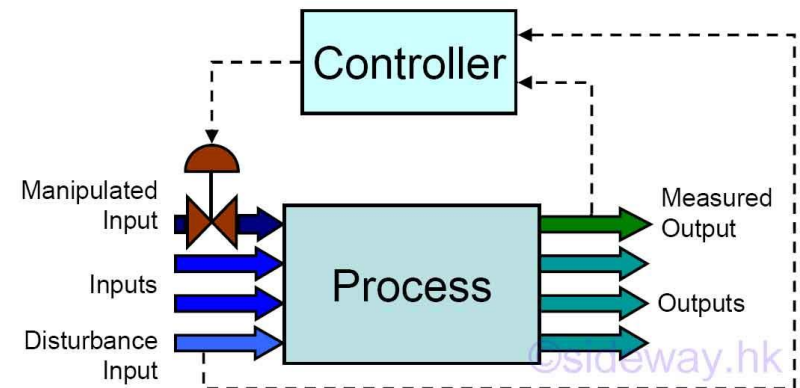
- Laboratory must enroll in a CMS approved PT program
- PT testing must be rotated among staff
- PT samples must be treated the same as patient samples



**PROFICIENCY
TESTING**

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



Self Assessment

The Self Assessment uses the exact same criteria that AABBS Assessors use when onsite in your lab. These Standards are targeted to the specific activities you perform in the lab and are segmented by category for easy answering, printing and sharing among your staff.

Tips For Success

Be honest in your answers, indicating what your laboratory is currently doing, not what you have recently learned. AABBS has found the laboratories that complete the Self-Assessment and put a lot of effort into the process have done better, as a whole, on their onsite assessments. Involve your staff in the Self-Assessment process. You can create challenges and team-based activities to identify and address any gaps in your processes. Try using this Self-Assessment module as a part of new employee orientation. This can be a great introduction to your lab's quality management program.

Relax

Remember, for Current Members using this as an educational tool, that the voluntary Self-Assessment results do not factor into AABBS accreditation decisions. For pending members and those adding new activities/locations, those results will be reviewed and evaluated by AABBS staff.

Would you like to print out a blank version of all or part of your Self-Assessment?

If you would rather have a hard copy of a blank Self-Assessment for your lab for offline purposes, you can go here and choose what part(s) of your Self-Assessment you need printed out.

[VIEW BLANK SELF-ASSESSMENT](#)

Confirm

Before beginning, please confirm the current activities we have on file for your lab.

Your Current Activities Are:

If you believe this is an error, you can [click here](#) to edit your activities. We're just a toll free call away if you need assistance. Reach out to the AABBS support team at (800)555-1234.

Self Assessment Options

Required - Self Assessments

New Pending Members or Current Members Requesting New Activity/Location

Upon requesting Accreditation for and Activity(s) and/or adding a new location to an already existing account, you are required to complete a Self-Assessment and submit it to AABBS for review.



ABC Medical Laboratory
Facility Profile
Summary Report



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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