Association for the Advancement of Blood & Biotherapies

# The AABB Experience with Addressing Common Nonconformances and How to Prevent Them

**Clinical Laboratory Improvement Advisory Committee**
**Wednesday, November 8, 2023**

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**AABB**

# CMS TOP TEN DEFICIENCIES 1-5

| Rank | Description | Regulatory Citation | D-Tag | Number of Times Cited | Percentage of Citations* |
|---|---|---|---|---|---|
| 1 | Personnel Competency Assessment (Standard-Level) | § 493. 1235 | D5209 | 1,195 | 3.2% |
| 2 | General Lab Systems: Twice a year Accuracy Verification (Standard-Level) | § 493. 493.1236(c)(1) | D5217 | 1,057 | 2.9% |
| 3 | Analytic Systems: Reagent and specimen storage (Standard-Level) | § 493.1252(b) | D5413 | 1,036 | 2.8% |
| 4 | Analytic Systems: Procedure manual requirements (Standard-Level) | § 493. 1251(b) | D5403 | 927 | 2.5% |
| 5 | Analytic Systems: Verification of Performance Specifications (Standard-Level) | § 493. 1253(b)(1) | D5421 | 775 | 2.1% |

# Top 5 AABB Non-Conformances

CLIA

CLIA

| | | |
|---|---|---|
| **BBTS 2.1.3** | **5.6%** | **Evaluations of competence shall be performed before independent performance of assigned activities and at specified intervals.** |
| BBTS 1.3 | 5.6% | Quality and operational policies, processes, and procedures shall be developed and implemented to ensure that the requirements of these BB/TS Standards are satisfied. All such policies, processes, and procedures shall be in writing or captured electronically and shall be followed. Standard 5.1.1 applies. |
| CT 5.0 | 4.8% | The facility shall identify, design, modify, and validate the policies, processes, and procedures that affect the quality of cellular therapy products, services, and patient care. |
| BBTS 5.0 | 4.3% | The BB/TS shall have policies and validated processes and procedures that ensure the quality of the blood, blood components, tissue, derivatives, and services. The BB/TS shall ensure that these policies, processes, and procedures are carried out under controlled conditions. |
| BBTS 3.5 | 3.3% | The BB/TS shall have a process for scheduled monitoring and maintenance of equipment that at a minimum is in accordance with manufacturer's written instructions. The process shall include frequency of checks, check methods, acceptance criteria, and actions to be taken for unsatisfactory results. |

# Examples of actual Nonconformance Statements for BBTS Standard 2.1.3

Standards 2.1.3: Evaluations of competence shall be performed before independent performance of assigned activities and at specified intervals.*
*42 CFR 493.1235 and 42 CFR 493.1451(b)(8)(9).

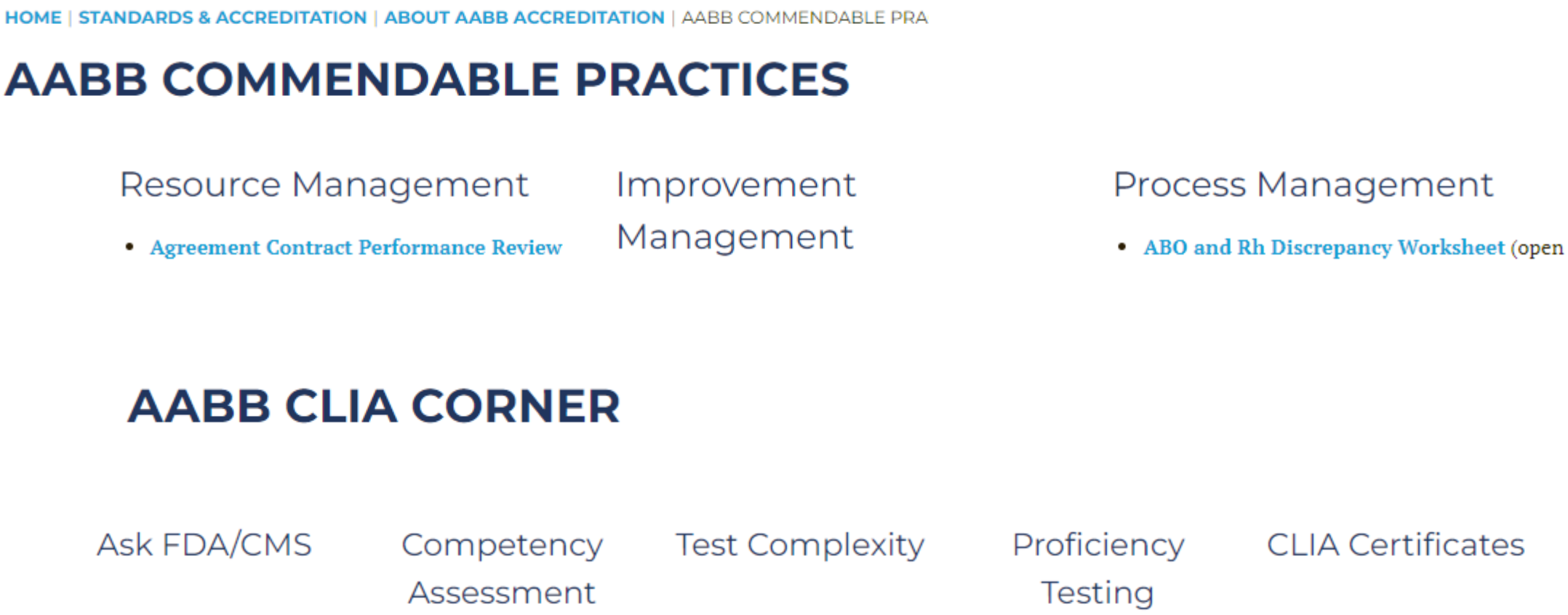
| Documented Nonconformance |
| --- |
| Competency assessment does not include the requirement of Direct observation of performance of instrument maintenance and function checks. |
| Annual competency training for bedside nurse performing blood administration was also requested but not provided. |
| During an observation of a blood product administration on unit 4 East, nurse FH training records for blood administration was reviewed and it was found that she had not completed the annual requirement since 2020 |
| No record of competency assessment for staff located for 2021 or 2022. The documents for 2020 were reviewed and acceptable. Facility is in transition with staff overturn and recent retirement of their blood bank manager, so the competency may have been done, however the records could not be located. |

# Examples of actual Nonconformance Statements for BBTS Standard 1.3

Quality and operational policies, processes, and procedures shall be developed and implemented to ensure that the requirements of these BB/TS Standards are satisfied. All such policies, processes, and procedures shall be in writing or captured electronically and shall be followed.
Standard 5.1.1 applies.

| Documented Nonconformance |
| --- |
| The Component Preparation Log SOP refers to acceptable product volumes for a 450ml bag and was not updated to reflect the acceptable volumes for the 500ml bag. The BDR is used to document volume of blood collected, however, the space used to record this is labeled grams instead of milliliters. |
| TR 615.6 Hemotemp II Indicators procedure does not follow manufacture's instruction for use |
| SOP # 1657: Polyethylene Glyco PEG Procedure 1.d. says "add two drops of patient's plasma to each testing tube" and Procedure 1.e. say "add the red cells to each testing tube" step-wise. Staff was observed and verbally confirmed of adding the red cells first and then adding the two drops of plasma to each of the testing tube in reverse order |

# AABB Efforts to Mitigate these Common Nonconformances



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## AABB COMMENDABLE PRACTICES

Resource Management

- Agreement Contract Performance Review

Improvement Management

Process Management

- ABO and Rh Discrepancy Worksheet (open

## AABB CLIA CORNER

Ask FDA/CMS

Competency Assessment

Test Complexity

Proficiency Testing

CLIA Certificates

# AABB Efforts to Mitigate these Common Nonconformances

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## AABB COMMENDABLE PRACTICES

### Resource Management

- Agreement Contract Performance Review
- Assessment of Problem-Solving Skills
- Blood Bank Competency Checklist (open to non-members)

**Blood Bank Competency Checklist**

Name:_____ Laboratory Site:_____ Year_____ □ 6-Month □ Annual

| Test System:_____ | Element | Documentation Supplied-Meditech | Documentation Supplied-Pathnet | Date | Assessor Initials |
|---|---|---|---|---|---|
| Observe routine test performance, including, as applicable, patient identification and preparation, and specimen collection, handling, processing and testing. | 1 | Direct observation | Direct observation | | |
| Reporting of Test Results | 2 | Internal Inquiry | Screen print of test result | | |
| Review of QC records | 3 | Recorded on Direct Observation | Copy of QC Form | | |
| Observe Instrument Maintenance (if applicable) | 4 | Recorded on Direct Observation | Copy of QC Form | | |
| Assess Proficiency Testing **or** Blind sample | 5 | Report from original and test patient | Report from original and test patient | | |
| Demonstrate Problem-Solving Skills | 6 | Problem solving case study | Problem solving case study | | |

I have had the opportunity to review and ask questions about policies and procedures related to equipment and testing above. Associate Signature:_____ Date:_____

This associate is deemed to be competent to perform unsupervised patient testing in the above test systems. CLIA Medical Director/Designee Signature:_____ Date:_____

## AABB CLIA CORNER

Ask FDA/CMS | Competency Assessment | Test Complexity | Proficiency Testing | CLIA Certificates

- CLIA proficiency testing and PT referral booklet
- Failed proficiency test report form
- PT report example
- CLIA Corner PT attestations
- Twice Annual Verification nonconformances

**AABB Standard 5.1.2**
**Proficiency Testing Program**
The BB/TS shall participate in a proficiency testing program, if available, for testing regulated by the Clinical Laboratory Improvement Amendments and performed by the facility.* When a CMS-approved program is not available, there shall be a system for determining the accuracy and reliability of test results. Results shall be reviewed and when expected results are not achieved, investigation and corrective action shall be taken where appropriate.
*42 CFR 493.1236.

Per AABB, Chapter 5 Process Control) is frequently cited. See the chart below for examples of the documented objective evidence that was found during assessments.

| Standard | Objective Evidence |
|---|---|
| 5.1.2 | In 2019 only 1 eluate sample was present in an AABB IRL proficiency sample therefore twice annual verification was not performed. |
| 5.1.2 | The facility does have a process for a twice annual verification, but the assessor did not see any results |
| 5.1.2 | Proficiency testing for Microbial detection and flow cytometry CD34 testing has not been performed twice a year at a minimum in 2020. There were also gaps in 2019. |

# AABB Efforts to Mitigate these Common Nonconformances

Participation in

**Workforce Action Alliance**

Sponsored by:

COLA

Educational Offerings:

**Addressing Common Nonconformances from AABB: Deep Dive (23EL-894)**

*12/6/2023*

This program is a continuation of the conversation from the September 13th AABB eCast, Addressing Common Nonconformances from AABB and How to Prevent Them.

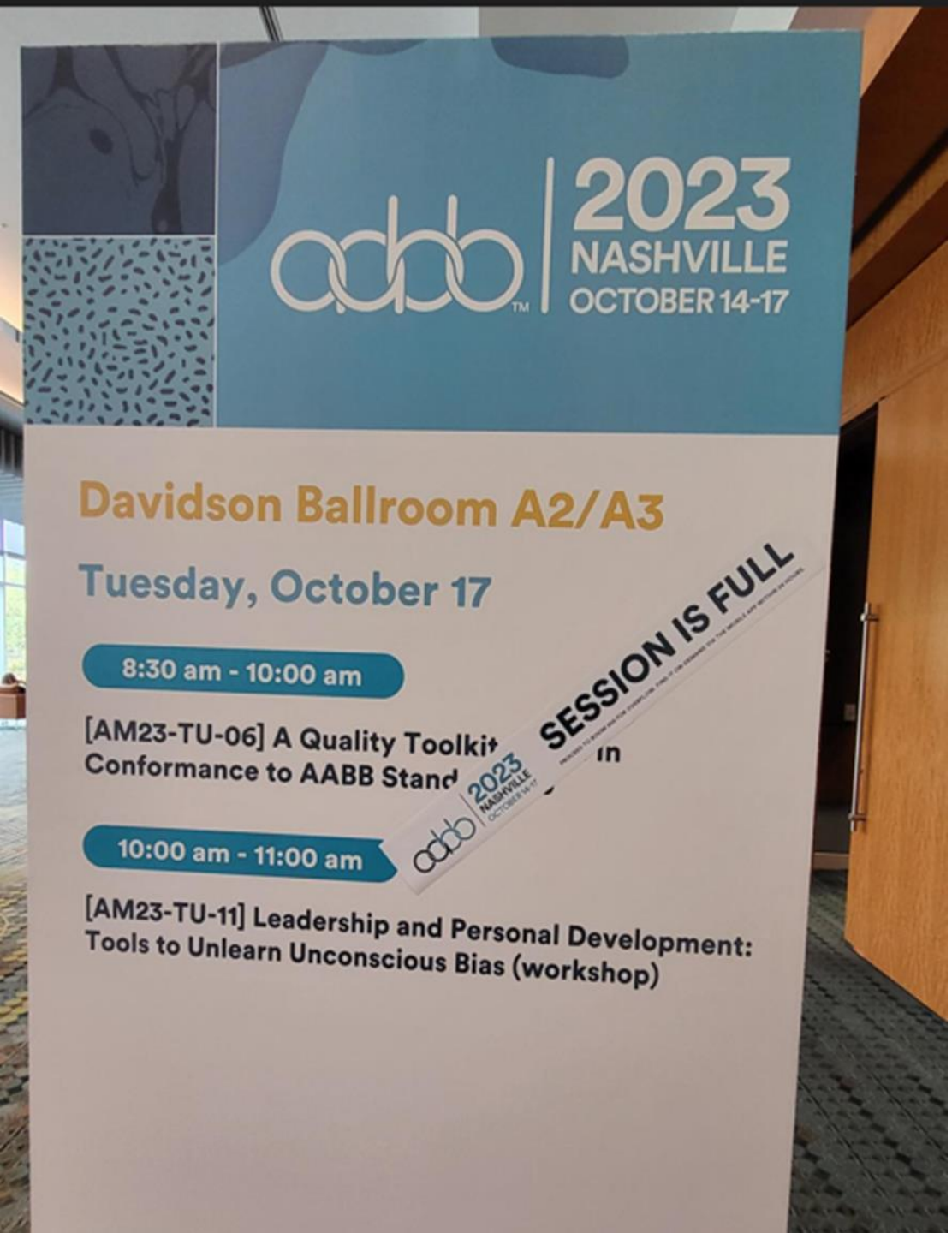
https://www.aabb.org/education/calendar/event/2023/12/06/aabb-ecast/addressing-common-nonconformances-from-aabb-deep-dive-23el-894

**Addressing Common Nonconformances from AABB and How to Prevent Them (21EL-694)**

*11/17/2021*

Open discussion with case studies to be presented by AABB's accreditation team. AABB standards and interpretations that resulted in nonconformances will be highlighted. The speakers will then expand discussion on selected items...

https://www.aabb.org/education/calendar/event/2021/11/17/aabb-ecast/addressing-common-nonconformances-from-aabb-and-how-to-prevent-them-21el-694




# 2023 AABB Annual Meeting Session: A Quality Toolkit to Aid in Conformance to AABB Standard 5.0

The AABB Accreditation Staff will introduce the tools and use these quality concepts, and will dissect actual objective evidence cited for non-conformance to Standard 5.0: Process Control

Current Quality Tools to Aid in Conformance

| | | | |
|---|---|---|---|
| Process Improvement Check Sheet | Pareto Chart to Identify "Vital Few" Improvements | Root Cause Analysis Fishbone Diagram | Process Sequencing Flowchart |
| Process Pattern Analysis Histogram | Control Chart to Determine Statistical Variation | 5 Whys to Identify a Root Cause and Solution | Affinity Diagram to Organize Ideas |
| Interrelationship Diagram to Identify Root Causes | Process Sequencing Tree Diagram | Regulatory Toolkits | |

# Thank you!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