

Common AABB Assessment Findings

Linda Sigg, MT(ASCP)SBB, CQA(ASQ)
Staff Lead Assessor,
Accreditation and Quality
AABB

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Introduction

- Your Performance Review
- AABB Assessment Objective
- Process Improvement Opportunities
- Most Common Nonconformances/Objective Evidence
- Root Cause Analysis
- Summary



Performance Review

- Overall the blood banking industry is doing well embracing quality concepts
- Facilities are recognizing benefits from implementation of quality systems
- Follow through with root cause analysis is important
- There is always room for improvement



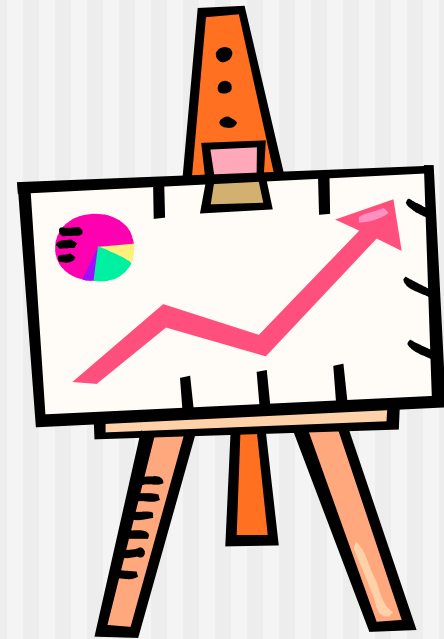
Assessment Objective

- To verify conformance with stated accreditation requirements
 - BB/TS Standards, 25th edition
 - Immunohematology Reference Laboratory Standards, 5th edition
 - Cellular Therapy Standards, 3rd edition
 - Perioperative Standards, 3rd edition
 - Relationship Testing, 8th edition

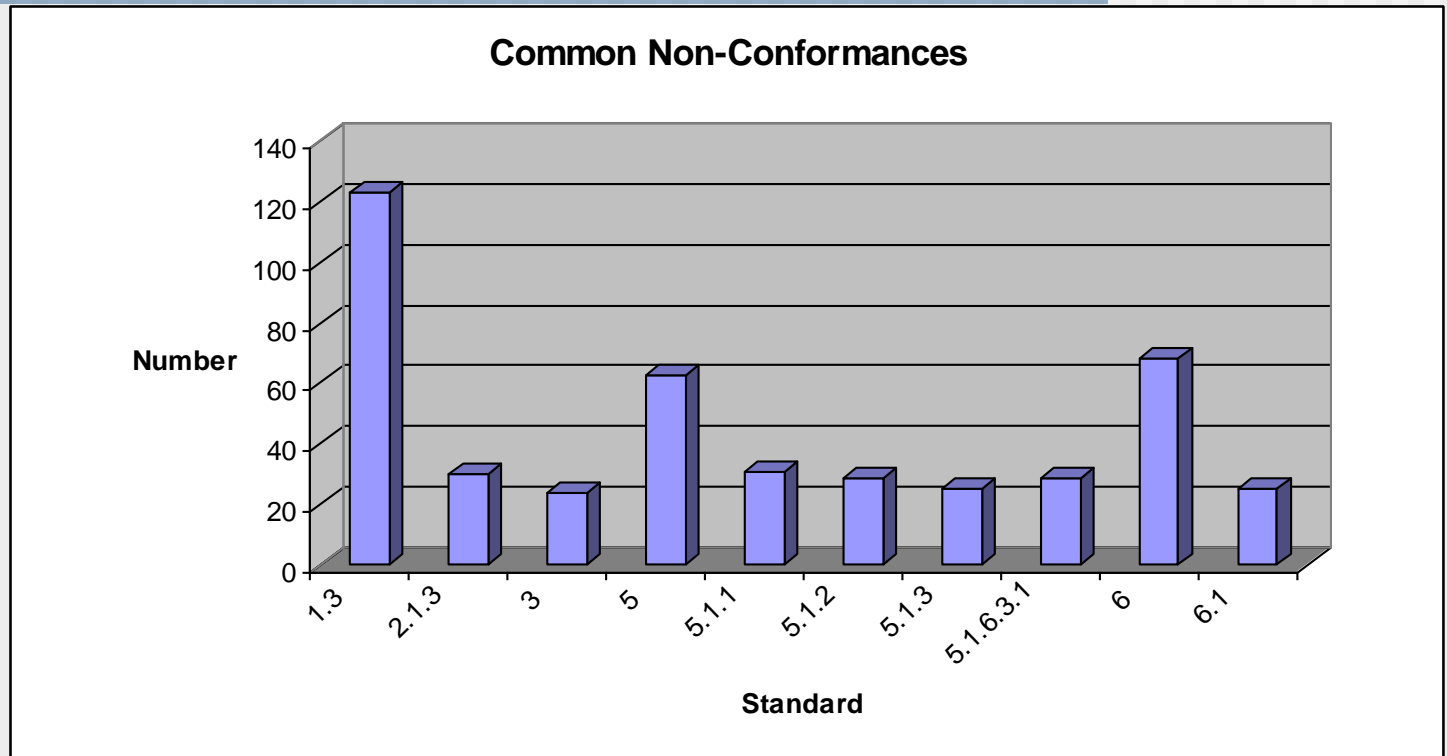


Process Improvement Opportunities

- Analysis of occurrence reports
- Findings from quality indicators
- Reports of customer complaints
- Review of selected processes (internal assessments)
- External assessment report findings



Common Non Conformances 4-08



1. Organization

- 1.3 Quality and operational policies, processes and procedures shall be **developed...in writing...and followed**
- Processes are not written
- Sops are not followed as written



1. Organization

- **1.4 ...shall have** emergency operation policies, processes and procedures to respond to the effects of disasters
- Emergency plans do not include what to do if you have an internal disaster
- Where does the blood bank move if the primary location is inoperable?



2.0 Resources

- 2.1.2 Training

The blood **bank...shall have a** process for identifying training needs and shall provide **training ...**

- Training records are incomplete, not reviewed. not signed off



2. Resources

2.1.3 Competence – Evaluations of competence shall be **performed** ... at specified intervals.

- A review of competency records showed that five staff members had no annual competency assessment performed.
- Competency assessment not done twice in the first year.



3. Equipment

- **3.0 ...shall identify equipment that is critical...**
- There is no record of what equipment is considered critical



4.0 Supplier and Customer Issues

- 4.3 Incoming receipt and inspection

Incoming blood, components, tissue, derivatives and critical materials shall be received, inspected and tested

- SOP does not define inspection criteria
- SOP does not define action to take if product fails inspection
- There is not documentation of acceptance



4.0 Supplier and Customer Issues

- 4.1.1 When a supplier fails to meet specified requirements it shall be reported to the management with contracting authority.
- There is no SOP or written process for employees to relay information about vendor/supplier problems.



5. Process Control

- 5.0 Process Control
...shall have policies and validated processes and procedures that **ensure the quality...**
- 5.1.1 **...shall have a** process to develop new processes and procedures or change **existing ones...**
- There is no documentation of process validation
- There is incomplete documentation of changes made to existing processes



5. Process Control

- 5.1.2 ...shall participate in a proficiency program...
- 5.1.3 A program of quality control shall **be established...** Results shall be reviewed and corrective action taken...
- When PT is not available there is no process to determine accuracy and reliability of test.

Review of QC results is not always done in a timely manner or at all

- Corrective action for out of range results is not always documented www.aabb.org



General Labeling Requirements

- 5.1.6.3.1 The following requirements shall apply:
 1. Shall be in conformance **withISBT 128.....**
 2. Original label and added portions shall be attached to the container **..... ABO/RH, id #,** product code, & Facility id shall be in machine-readable format
- Variances had not been applied for from AABB
- No process in place for machine readable labels or were not attached to the container properly.



6. Documents and Records

- **6.0 ...shall have** policies, processes and procedures to ensure that documents are identified, reviewed, approved, and retained...
- Policies, processes and procedures for document control are not complete



6. Documents and Records

- 6.1.1 A master list of **documents**.....
- 6.1.4 Annual review and approval
- 6.1.5 Use of only current and valid documents
- No list of forms, labels
- No review or authorized individual not delegated
- Using outdated references or no process for review of current references



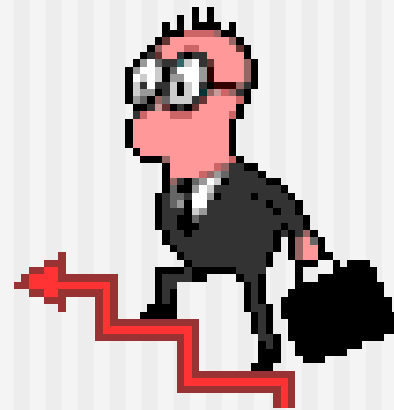
7.0 Deviations, Nonconformances and Adverse Events

- 7.0 The blood **bank...shall have** policies, processes and procedures to ensure the capture, assessment, investigation and monitoring of **deviations...**
- Shall be reported to **outside agencies...**
- No process to report BPDs to the FDA



What Next?

- Corrective Action
- Root Cause Analysis



Corrective Action Plans

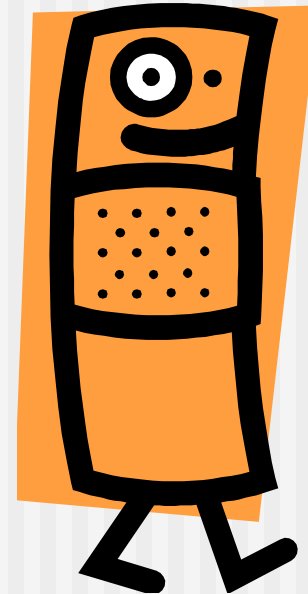
- Restatement of nonconformance and objective evidence
- Remedial action
- Root cause analysis
- System improvement



Corrective Action Plans

Remedial Action

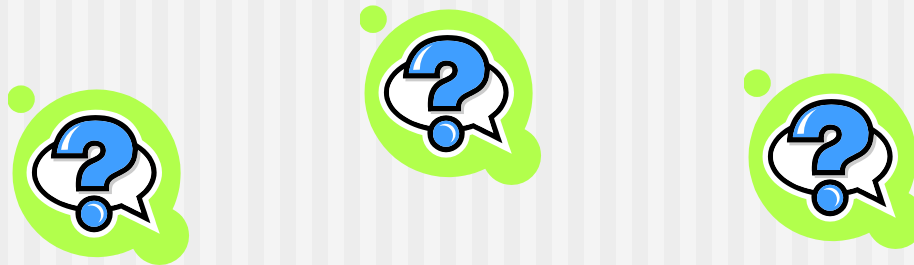
- Immediate
- Corrects specific incidence of nonconformance
- “Band-aid”



Corrective Action Plans

Root Cause Analysis

- Identification of the underlying factors causing the problem
- Why, Why, Why, Why, Why?



Corrective Action Plans

System Improvements

- Changes to the system or process needed to prevent recurrence of the same or similar nonconformance



How Do I Know It Worked??

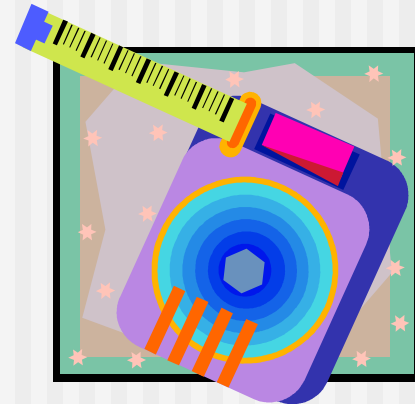


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Evaluating Effectiveness

- Define and track measurements of success
- Periodic audits
- Self-assessments



Additional Resources

- AABB Assessment Tools
 - Quality System
 - Transfusion Service
 - Donor Center
 - Cellular Therapy
 - IRL
 - Relationship Testing
 - Perioperative Services

- Commendable Practices Educational Resource Files
 - Organized by QSE
 - Forms
 - Checklists
 - SOPs
 - Flow charts
 - Reports
 - Master Lists



Additional Resources

AABB Department of Accreditation
and Quality

301-215-6492

accreditation@aabb.org



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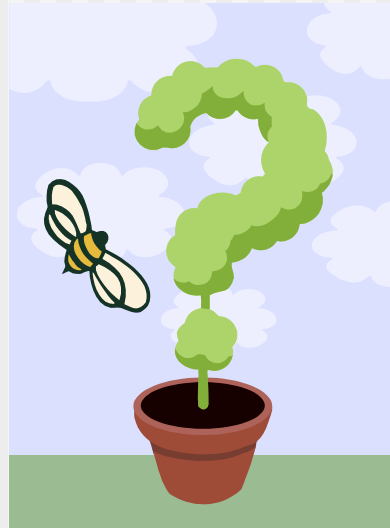
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Summary

- Examples of most common nonconformances
- Common thread in all areas is process control
- There should be a process to review new standards and determine compliance prior to implementation
- Corrective action and root cause
- Keep up the good work!



Thank You!



Questions?



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