Addressing Common Citations from AABB and CAP
Program #144808
Tuesday, December 2, 2014
2:00 pm-3:30 pm (ET) ~ 7:00 pm-8:30 pm (GMT)

The AABB and the College of American Pathologists (CAP) accreditation programs provide assessment teams to assist in the continual improvement of laboratory quality, safety and operations. This teleconference will present common citations encountered by AABB and CAP assessors and provide suggestions on how to avoid noncompliance. Experts will help you identify best practices based on accreditation standards to maintain and enhance your blood bank’s technical performance.

Objectives:
- Identify ways to correct common citations and attain compliance.
- List the most common deficiencies to CAP checklist requirements noted by CAP assessors in 2014.
- List the most common nonconformances to AABB Standards (29th Edition) noted by AABB assessors.

Director/Moderator:
Nancy Dunbar, MD
Assistant Professor of Pathology and of Medicine
Dartmouth-Hitchcock Medical Center

Faculty:
Brynna Gates, MLS(ASCP)CM, CQA(ASQ)
AABB Technical Specialist
Accreditation and Quality

Ljiljana Petkovic, MT(ASCP)BB,SBB
Technical Specialist, CAP Accreditation Programs
College of American Pathologists
In accordance with AABB Policy on Disclosure of Faculty Relations, the faculty for this event have signed a conflict of interest form in which they have disclosed any significant financial interests or other relationships with industry relative to the topics that they will discuss at this program. Such disclosures allow you to better evaluate the objectivity of the information presented in the lectures.

**Director/Moderator:**
**Nancy Dunbar, MD**  
Assistant Professor of Pathology and of Medicine  
Dartmouth-Hitchcock Medical Center  
**Disclosures:** No disclosures given

**Faculty:**
**Brynna Gates, MLS(ASCP)CM, CQA(ASQ)**  
AABB Technical Specialist  
Accreditation and Quality  
**Disclosures:** No disclosures given

**Ljiljana Petkovic, MT(ASCP)BB,SBB**  
Technical Specialist, CAP Accreditation Programs  
College of American Pathologists  
**Disclosures:** No disclosures given

<table>
<thead>
<tr>
<th>Name/Role in Content Planning</th>
<th>Disclosure</th>
<th>Nature of relationship</th>
<th>Manufacturer/Provider</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colleen Aronson, planning committee member</td>
<td>none</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Robert Braun, planning committee member</td>
<td>none</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nancy Dunbar, planning committee member</td>
<td>none</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Jennifer Ford, planning committee member</td>
<td>none</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Michele Hayes, planning committee member</td>
<td>yes</td>
<td>Professional</td>
<td>GASCO Eastern District Federal Credit Union - Chair of Supervisory Committee</td>
</tr>
<tr>
<td>Nora Hirschler, board representative</td>
<td>yes</td>
<td>Professional</td>
<td>ABC Member</td>
</tr>
<tr>
<td>Gail Moskowitz, planning committee member</td>
<td>yes</td>
<td>Professional</td>
<td>Board of Directors, Guide to Cord Blood Foundation</td>
</tr>
<tr>
<td>Jayanna Slayten, planning committee member</td>
<td>none</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Linda Stefaniak, planning committee member</td>
<td>none</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kristina Williams, planning committee member</td>
<td>none</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sharon Moffett, staff member</td>
<td>none</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lauren Rohde, staff member</td>
<td>none</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alyson Wagner, staff member</td>
<td>none</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Accessing your Continuing Education Credits Online!

1. Log into the Live Learning Center from the www.aabb.org website

2. Go to “Professional Development”

3. Click on red link that says “AABB Live Learning Center” on the left side of the page

4. Click on red link that says “AABB Live Learning Center” in the center of the page

5. Click the “My Account” link at the top of the page.

6. Log in using your e-mail address and password.

7. Click on the link that says “My Transcripts”

8. Go to the “Select Conference” drop down menu and select 2014 Audioconference Series

9. Choose the appropriate audioconference title.
Top AABB Nonconformances

Brynna Gates, MLS(ASCP)CM, CQA(ASQ)
Technical Specialist
Accreditation and Quality
AABB

Introduction

- AABB Assessment Objective
- Most Common Nonconformances/Objective Evidence
- Corrective Action Plans
- Root Cause Analysis
- System Improvements and Monitoring CA Plans

Assessment Objective

- Verify conformance with stated accreditation requirements
- Improve and maintain the quality and safety of laboratory operations and patient care
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. Resources

2.1.3 Competence – Evaluations of competence shall be performed ... at specified intervals.
- No annual competency assessment performed
- Competency assessment not done twice in the first year
- Competency assessment does not include all CLIA elements

42 CFR 493.1451(b)(8) Competency Elements

- Direct observations
- Patient testing
- Instrument maintenance/function checks
- Monitoring recording and reporting of test results
- Review of QC records, PT results and PM records
- Assessment of test performance (PT, etc.)
- Assessment of problem solving skills
3. Documents and Records

- 6.0 ...shall have policies, processes and procedures to ensure that documents are identified, reviewed, approved, and retained...
- Processes and procedures for document control are not complete
- Reviews are incomplete or not timely

- 6.1.1 A master list of documents including labels, and forms
- 6.1.4 Biennial 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

4. Process Control

- 5.0 Process Control ...shall have policies and validated processes and procedures that ensure the quality...
- No documentation of process validation
- Incomplete documentation of changes made to existing processes
- Change control process not followed
4. Process Control

5.1.2 Proficiency Testing...shall participate in a proficiency testing program, if available, for CLIA regulated testing performed by the facility.

5.1.2 Proficiency Testing...shall participate in a proficiency testing program, if available, for CLIA regulated testing performed by the facility.

There is no process to determine if PT is performed for each CLIA regulated test.

5.1.3 A program of quality control shall be established... Results shall be reviewed and corrective action taken...

5.1.3 A program of quality control shall be established... Results shall be reviewed and corrective action taken...

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.

5.1.4 All materials...shall be stored and used in accordance with manufacturer's written instructions...

5.1.4 All materials...shall be stored and used in accordance with manufacturer's written instructions...

Storage of reagents (2-8C)

Failure to follow manufacturer's instructions.
5. Equipment

- 3.0 ...shall identify equipment that is critical...
- 3.5 ...process for scheduled monitoring and maintenance of equipment

- No record of what equipment is considered critical
- Do not follow manufacturer’s instructions
- No evidence of follow up

5. Equipment

- 3.5 Equipment Monitoring and Maintenance

- No documentation of scheduled maintenance or alarm checks
- No review of maintenance done by biomedical staff
- Blood Warmers!

How Can You Prepare?

- 4 month implementation period prior to effective date of Standards
- Use the crosswalk to identify new and revised standards
- Revise policies, processes, and procedures
- Make sure documentation is accurate and up to date
Assessment Tools

- AABB Web site
- Standards and Accreditation > Accreditation Member Tools > Facilities
- Available in Word format

Assessment Tool

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

What Next?

- Corrective Action
- Root Cause Analysis
- Process Improvement
Corrective Action Plans

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

What to Correct?

- Goal of Corrective Action: to prevent the reoccurrence of the same or similar situation
- Determine steps to be taken to correct the problems identified in root cause analysis
- Is the planned corrective action relevant to the problem?
Corrective Action Plans

Remedial (Immediate) Action
- Immediate
- Corrects specific incidence of nonconformance
- "Band-aid"

Corrective Action Plans

Root Cause Analysis
- Identification of the underlying factors causing the problem
- Eliminates being blindsided by the same problem

Root Cause Analysis Is NOT
- A restatement of the objective evidence
  - Objective evidence: "No process exists for evaluating the competency of testing personnel."
  - Root cause analysis: "We never developed a process for evaluating the competency of testing personnel."
  - Meant to be applied to each piece of objective evidence
Look for Common Threads

- Is it a document development issue?
- Is there a problem with the review process?
- Is it a document control issue?
- Is there a problem with the training process?

5 Whys

- Determine the starting point (either a problem or an identified cause that needs to be further analyzed)
- Use brainstorming, brainwriting, etc. to generate causes; record ideas as a chain or sequence of events
- At each level, ask: "Why is this a cause of the identified problem?"
- For each new answer, ask the question again.
- Rule of thumb: This method often requires 5 rounds of the question "Why?"
- Result will most likely be the root cause of the problem.

Corrective Action Plans

System Improvements

- Description of the action taken to prevent recurrence of same or similar nonconformance
- Timeline for the completion of the action
- Individuals responsible for overseeing the completion of the action
Plan for Monitoring CA

- Monitoring the effectiveness of CA is critical for ensuring that the causative factors of the incident have been identified and corrected
- Indicator tracking
- Error tracking
- Direct observation
- Paperwork review
- Focused audits
- Combination of these

Additional Resources

- www.aabb.org
  - AABB Assessment Tools
  - Commendable Practices Library
  - Facility Guide Through the Assessment Process
  - AABB Community

AABB Department of Accreditation and Quality
301-215-6492
accreditation@aabb.org
Thank You!

www.aabb.org
Today’s presentation will review:

- Most common checklist deficiencies
  - Lab General
  - All Common
  - Transfusion Medicine
- Checklist Challenges
  - Interpretation of requirements
  - New requirements

**LAB GENERAL CHECKLIST**

- GEN.55500 Competency Assessment
  - Each non-waived test system – to include all 6 required elements
  - Waived test systems – elements can be selected
  - Semiannually during first year of duties for new employees (non-waived)
  - Annually thereafter
  - Performed by Technical Supervisor or qualified designee (in writing)
Lab General (cont.)

- GEN.20375 Document Control System
  - Policies and procedures are current
  - Personnel are knowledgeable – including defined process for introduction of new or revised documents (sign-off sheets, electronic, meeting minutes)
  - Signed by Laboratory Director before implementation
  - Procedures reviewed per laboratory policy by director or designee (at least biennially)
  - Discontinued policies/procedures removed

Lab General (cont.)

- GEN.75400 Annual Fire Drill
  - All staff must participate annually (records required)
  - Paper or computerized
  - Physical evaluation of escape routes must be performed

  - New for 2014 – annual in-service for all. exit fire drill recommended, not required

Lab General (cont.)

- GEN.77400 Eyewash
  - Accessible – time/distance
  - Accessible – NOT blocked
  - Eyewash check documented weekly
  - Tepid temperature (not required to take actual temperature reading of water but temperature should be between 60-100 degrees F)
Most Common Deficiencies – All Common Checklist

• COM.01400 PT Attestation Page
  o Written signature of Lab Director or designee (even if submitted electronically) and individuals performing test
  o Designee must be in writing
• COM.01700 PT Evaluation
  o Prompt evaluation
  o All unacceptable results
  o Includes follow-up/corrective action

All Common Checklist (cont.)

• COM.10000 Procedure Manual
  o Complete and current (outdated retired)
• COM.10100 Procedure Manual Review
  o Per laboratory policy (at least biennially)
  o At individual procedure level OR multiple signatures on a list of procedures
  o Electronic OR written signature acceptable
  o Laboratory Director or designee (in writing)

All Common Checklist (cont.)

• COM.30300 Reagent Labeling – revised expiration date must be recorded on container or log
• COM.30350 Reagent Storage
  o per manufacturer requirements
  o Temperatures recorded daily
• COM.30400 Reagent Expiration Date – used within expiration date
• COM.30450 New Lot/Shipment – confirmation of acceptability
Most Common Deficiencies – Transfusion Medicine Checklist

- TRM.31450 (now COM.04250) Comparability of Instrument/Method
  - Non-waived instruments/methods; e.g., Gel vs. tube method, multiple instruments, etc.
  - Twice/year
  - Acceptability criteria defined
  - Documented review

Most Common Deficiencies – Transfusion Medicine Checklist

- TRM.41025/41650 Transfusionist Training and Transfusion Reaction Recognition – annual education required for ALL transfusionists
- TRM.31227 Package Inserts
  - Current
  - Process defined to ensure current and no changes

Transfusion Medicine Checklist (cont.)

- TRM.30000 Ongoing Record Evaluation (name changed to “Monthly QC Review”)
  - Pertains to all Quality Control data
  - Review must be documented and include follow-up for outliers, trends, etc.
  - Temperature checks now moved to COM.30750
- TRM.32000 Routine Maintenance Schedule now moved to (new) checklist, COM.30600 Maintenance/Function checks
  - All instruments/ equipment
  - As specified by manufacturer (at a minimum)
  - Reviewed monthly
  - No longer states equipment performance to be validated on receipt; new checklist, COM.30550 Instrument/Equipment Performance Validation addresses new equipment requirements
Transfusion Medicine Checklist (cont.)

- TRM.42850 Alarm Sensors To Trigger Action Needed
  - Set to alarm prior to falling out of range
  - Corrective action documented
  - Review documented

- TRM.42470 Acceptance Back Into Inventory
  - Process documented
  - Criteria defined

- TRM.30866 Service Agreement – approved, written agreement or understanding defining transfusion support services to all clinical areas served

Checklist “Challenges”

- Interpretation of requirements - sources
  - Participants - calls/accred@cap.org questions
  - Inspectors
  - Deficiency challenges

- Checklist changes

Interpretation “challenges”

- GEN.54400/54750 Personnel Records
  - Personnel license alone acceptable only if required by your state
  - Copy of diploma or transcript required if state licensure not applicable
    - Must include course of study, eg, Bachelor of Science in Medical Technology, Biology, etc.
  - Non-US degrees require foreign equivalency evaluation; eg, NACES, AICE and others
  - Certification – copy needed only if required by state or employer; eg, ASCP

© 2014 College of American Pathologists. All rights reserved.
Interpretation “challenges” (cont.)

• COM.30450 New Reagent Lot Verification
  o Applicable to all reagents/antisera/kits
  o Requires documentation and review

• COM.10600 Manufacturer Instructions
  o Any change to instructions requires verification
  o Change in waived test instructions makes test high complexity (and changes personnel requirements)

Interpretation “challenges” (cont.)

• TRM.30575 Misidentification Risk – documented action or plan to reduce misidentification risk (will be changed to Phase II in 2015)
• TRM.31900 Serologic Centrifuge Checks – RPM and mechanical timer checks required each 6 months
• TRM.42110 TRALI - documented program or agreement with blood supplier for measures to reduce the risk of TRALI (will be more robust in 2015)

Interpretation “challenges” (cont.)

• TRM.41525/ 41550/ 41600 Perioperative/ Intraoperative Blood Programs
  o Defined responsibility of Laboratory Director and laboratory in perioperative and intraoperative programs
  o Documented Laboratory Director involvement in policies and procedures
• TRM.30950 CBER Notification
  o FDA biological product deviation reporting requirements (website: www.fda.gov/cber)
  o Includes testing, component prep, labeling, storage, and distribution of units
Checklist requirement update

New/Revised requirements – 2014

- TRM.45165 Blood Vessel Storage – requires procedures and records in accordance with US Organ Procurement and Transplantation Network (OPTN)
- TRM.42750/42800 Storage Unit Alarms
  - Combined into one requirement
  - Requires quarterly checks
- Separate Donor Apheresis and Therapeutic Apheresis sections; however, no “new” requirements

Checklist requirement update

New/Revised requirements – 2014

- Most instrument/equipment requirements moved to All Common Checklist; TRM-specific requirements only remain in TRM
- TRM.31250 Reagent Expiration Dates
  - Written policy required
  - Documented attempts to procure reagents (being re-evaluated for 2015)
- TRM.42500 Blood/Component Storage Monitoring
  - Specific addition of applicability to storage outside of Transfusion Service, eg. surgery, nursing, dialysis
- TRM.32250 Record Retention
  - Added Retyping of donor units to Quality Control Records section for 10 years

Checklist requirement update

DONOR APHERESIS

- TRM.42214 Donor Eligibility
  - Policy defining donor eligibility criteria
  - Documented evaluation of criteria
- TRM.42222 Donor Informed Consent – signed consent must be maintained
- TRM.42224 Adverse Reaction – documented procedure for the recognition, treatment, tracking, and trending of adverse reactions
Topics of Discussion with TRMC for 2015

• TRM.31250 Reagent Expiration Dates – proposal to remove requirement to document attempts to obtain in-date reagents
• TRM.40700 Whole Blood/Red Cells/Plasma - clarify use of plasma products
• TRM.42110 TRALI - change to Phase II; require labs to have protocols for investigation of suspected TRALI cases

Special Thanks

• Kathleen Passerelli, MT(ASCP)SBB
• Lyn Wieglos, MT(ASCP)
• James Rasch, MT(ASCP)
• Theresa Sarni

Resources

• Phone: 1-800-323-4040 (CAP Customer Contact Center)
• E-mail: accred@cap.org
• cap.org/e-LAB Solutions
  Connect tools:
  • Personnel
  • Proficiency Testing
  • Change forms
  • Master and Custom Checklists (eg, references, Word documents, and Excel spreadsheets)
The methods of transporting blood for storage and the physical storing of blood outside of the blood bank can be achieved in many ways. Is transporting blood for storage the same as transporting blood for transfusion? This can sometimes be misinterpreted, understanding the requirements and the standards in this area may help strategizing best practice and dispel controversies.

Objectives:

- Understand the requirements for storing and transporting blood outside of the Blood Bank.

Intended Audience: Physicians, Nurses, Technologists, Managers/Supervisors, Perfusionists

Event Level: Intermediate

Director/Moderator:
Robert Braun, MT(ASCP)SBB
CPC Consulting

Faculty:
Ricardo Sumugod, MS, MT(ASCP)SBB
Operations Coordinator
Blood Bank
Northwestern Memorial Hospital and Northwestern Medicine Lake Forest Hospital
AABB would like to thank the members of the AABB Distance Learning Program Unit for their assistance in developing these programs:

**2014 Distance Learning Program Unit**

**CHAIR**
**Kristi Williams, MT(ASCP)SBB, CQA, CQIA(ASQ)**
Manager, Biomedical Headquarters IRL Operational Support, American Red Cross
Washington, IL

**Colleen Aronson, MT(ASCP)SBB**
Quality Programs Coordinator, Northshore University Healthsystem
Evanston, IL

**Meghan Delaney, DO, MPH**
Assistant Medical Director, Puget Sound Blood Center
Seattle, WA

**Nancy Dunbar, MD**
Assistant Professor, Dartmouth-Hitchcock Medical Center
Hanover, NH

**Michele Hayes, MT(ASCP)SBB**
Director of Immunohematology Reference Laboratory, American Red Cross
Johnstown, PA

**Nora Hirschler, MD**
CEO, Blood Centers of the Pacific
San Francisco, CA

**Drew Minardi,**
Director of Education for School of Medical Laboratory Science, Atlantic Health
Saddle Brook, NJ

**Sharon Moffett, CAE**
Director of Education and Professional Development, AABB
Bethesda, MD

**Gail Moskowitz, MD**
Independent Consultant
New York, NY

**Lauren Rohde**
Programs Manager, AABB
Bethesda, MD

**Jayanna Slayten, MS, MT(ASCP)SBB**
Reference Laboratory Supervisor, Indiana Blood Center
Indianapolis, IL

**Alyson Wagner**
Cellular Therapy Program Manager, AABB
Bethesda, MD