

AABB / CAP Assessments

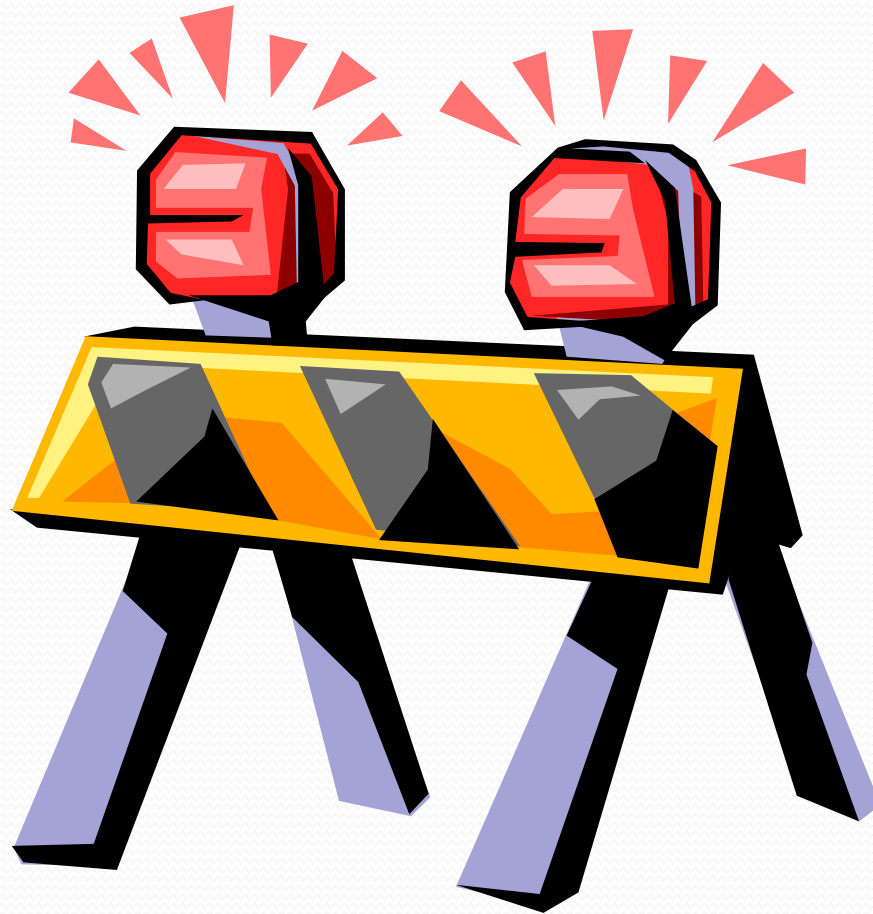
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Common Nonconformances

- Data presented at 2009 AABB Annual Meeting
- Assessor experience

DISCLAIMER!



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- Neither one of us are official representatives of these organizations.
- We are just sharing information either presented at educational sessions or from assessment experience!

OBJECTIVES

- Present most common nonconformances from AABB & CAP Inspections 2008-2009
- Present new AABB & CAP Standards
- Have group discussion on inspection experiences

Most Common Nonconformances

- AABB BBTS 25th Edition of Standards
- 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.

Nonconformances, cont.

- 5.0: The blood bank or transfusion service shall have policies, and validated processes and procedures that ensure the quality of the blood, components, tissue, derivatives, and service. The blood bank or transfusion service shall ensure that these policies, processes, and procedures are carried out under controlled conditions.
- 6.0: The blood bank or transfusion service shall have policies, processes, and procedures to ensure that documents are identified, reviewed, approved, and retained and that records are created, stored, and archived in accordance with record retention policies.

Nonconformances, cont.

- 5.1.6.3.1: (General Labeling Requirements) The following requirements shall apply:
 - 1) Labeling of blood and component containers shall be in conformance with the most recent version...of ISBT 128,
 - 2) The original label and added portions...shall be in clear, eye-readable format. Additionally, the ABO/Rh, donation identification number, product code, and facility identification shall be in machine-readable format.

Personal Experience

- Disaster plans – Localized to only the lab / blood bank
- Computer back-up “tapes”
 - Off-site storage
 - Functionality
- Labeling facility prepared products (pools, aliquots)
- Supplier agreements
- Implementation plan of new standards and requirements
- Anonymous reporting to AABB
- TRALI

New AABB Stds. 26th Edition

- 1.5: Communication of Concerns – anonymous reporting to executive management and/or AABB
- 4.2.2: Agreement Review – Definition of responsibility for multi-facility involvement
- 5.1.8.2.1: Transportation – Containers for blood products must be qualified and the process validated
- 5.6.7.1: Therapeutic Phlebotomy and Apheresis – Units MAY be used for allogeneic transfusions IF donor meets all requirements

New Stds., cont.

- 5.7.5.16: Thawed Plasma Cryoprecipitate Reduced – Preparation (Donor Center)
- 5.18.2.1: Issue of Tissue and Derivatives – Requires verification of package insert, product name and quantity, date and time of issue, and recipient's 2 independent identifiers

Update to Std. 1.5

- This was just posted to the AABB web site last week:
 - http://www.aabb.org/Documents/Members_Area/Members_Area_Accreditation/Facilities/accredwhistleblower.pdf

The logo features the letters 'aabb' in a stylized, lowercase, blue font with a slight shadow effect, followed by the word 'Accredited' in a larger, bold, blue, sans-serif font.

This blood bank is accredited by AABB.

If you are concerned about the quality with which this facility operates or if safety measures are not being followed, please contact AABB.

Your identity will be kept confidential.

Please contact us at:
+1.301.215.6492 or accreditation@aabb.org

www.aabb.org

VALUABLE RESOURCE!

CROSSWALK
BB/TS 26TH ED – CAP TRANSFUSION MEDICINE AND GENERAL
LABORATORY CHECKLISTS
(CAP checklist date 6/15/09)
(RED: NEW; BLUE: REVISED)

<i>AABB Standard Blood Banks and Transfusion Services 26th Edition</i>	<i>CAP Checklist Questions 6/15/09</i>
AABB 1.0	GEN.54000
AABB 1.1	TRM.30000; TRM.33300; TRM.45050; TRM.50050 GEN.20374
AABB 1.1.1	TRM.30000; TRM.31155; TRM.42195; TRM.42245; TRM.42290; TRM.45255; TRM.50050
AABB 1.2	TRM.20000 GEN.13806; GEN.16902
AABB 1.2.1	
AABB 1.2.2	GEN.20369;
AABB 1.3	TRM.31190; TRM.43500; TRM.45190; TRM.45264; TRM.47350 GEN.30000; GEN.54100
AABB 1.3.1	TRM.31160; TRM.50100

College of American Pathology

CAP Mission Statement: The College of American Pathologists, the leading organization of board-certified pathologists, serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine

Laboratory Accreditation requires inspection every 2 years.

Inspection Deficiencies: 2 Types

Phase I: Requires a written response indicating corrective action taken.

Phase II: Requires a written response and supporting documentation demonstrating compliance.

CAP NONCONFORMANCES

Most frequent nonconformance:

TRM. 31150 Phase II

Is there documentation of at least annual review of all policies and procedures by the current laboratory director or designee?

CAP NONCONFORMANCES

Second most common nonconformance:

Any **new** Checklist Item

CAP New Checklist Items

- TRM 41025 Are personnel involved in transfusion trained in identification of transfusion recipients and blood components, and in observation of recipients during and after transfusion, with in-service education at least annually? (II)
- TRM 31450 If the laboratory uses more than one instrument/method for a given analyte, are the instruments/methods checked against each other at least twice a year for correlation of results? (II)

TRM 31450: Reference Article

METHOD CORRELATION OR MADNESS?

By Suzanne H. Butch, MA, MT(ASCP)SBB

<http://www.bloodbanktalk.com/forum/showthread.php?t=3366&page=2>

(Accessed 2/25/10)

- “The rationale ... is that correlation studies are required by CLIA regulation. This appears to be an unintended consequence of the most recent revision of the CLIA quality control regulations where individual laboratory requirements were eliminated in favor of a single set of requirements.”
- Contact Information: Judy Yost, Director, Center for Laboratories US Dept of Health & Human Services Commission on Medicare & Medicaid Baltimore, MD or CLIA staff at (410) 786-3407 or (410) 786-3531. Her e-mail is Judith.yost@cms.hhs.gov

CAP New: Therapeutic Apheresis

- TRM 42246 Records maintained of specified items (II)
- TRM 42255 Medical personnel qualified to perform or supervise procedure (I)
- TRM 42260 Policy for timely evaluation and approval of requests for procedure (I)
- TRM 42265 Process to evaluate requests for procedure
- TRM 42270 Placement of venous access device verified by operator prior to use (I)
- TRM 42275 Time Out prior to start of procedure (I)
- TRM 42280 SOP discusses evaluating patient risk and monitoring/treatment for adverse reaction (I)

CAP New: Therapeutic Phlebotomies

- TRM 42290 If performed by BB staff, has qualified physician accepted responsibility (II)
- TRM 42295 Procedures provide patient protection (I)
- TRM 42305 Physician develops therapeutic patient plan with clearly defined goals (I)
- TRM 42310 Physician's order must include frequency, volume to be removed, and laboratory values to be monitored (I)
- TRM 42315 Physician reviews indications for procedure prior to initiation & at least every 12 months thereafter (II)

CAP New: General Checklist

GEN 20425 Does the laboratory have a policy to ensure that all records, slides, blocks, and tissues are retained and available for appropriate times should the laboratory cease operation? (I)

(42 CFR 482.27 Condition of Participation: Laboratory Services: “The hospital must maintain---a **fully funded** plan to transfer records to another hospital or other entity if such hospital ceases operation for any reason.”)

CAP Questions to ponder-----

- Does your facility have a written, documented schedule for annual review?
- Does your facility have a written, documented process for correlation of testing methodologies?
- Does your facility have a written, documented process for implementation of new/revised inspection checklists?
- Does your facility have a fully funded plan to transfer records to another hospital or entity should it cease operations?