Community Blood Center

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Saint Luke's

Hospital of Kansas City

Where's the caffeine?

OR

You want me to stay awake during talk on Assessments & Standards?

Sharon Rice, MLS^{CM}
St. Luke's Hospital

Mary Kowalski, MT(ASCP)SBB
Community Blood Center

ODE TO AN AABB STANDARD

- Inspections are out and assessments are in
- Oh when did these AABB Standards begin?
- I just closed my eyes and then with a start
- We're morphing molecular, what future this art
- Of shaking those cross linked red blood cells apart?

- From BBTS it changed and it grew
- And now we've Molecular standards too
- Cellular Therapy, Relationship Testing
- And Perioperative Autologous Blood, I'm truly not jesting
- With organization, equipment and records
- Kept for indefinite periods with efforts
- Of many who labor in dungeons of records

- Of assessments and standards we've been given the mission
- To speak of items requiring attention
- And if you're awake when we are through
- Just one more stanza awaits your review…

The Scoop on this Talk

- What are assessors looking for?
- Most common nonconformances
  - IRL Standards
  - BBTS Standards
- Case Studies

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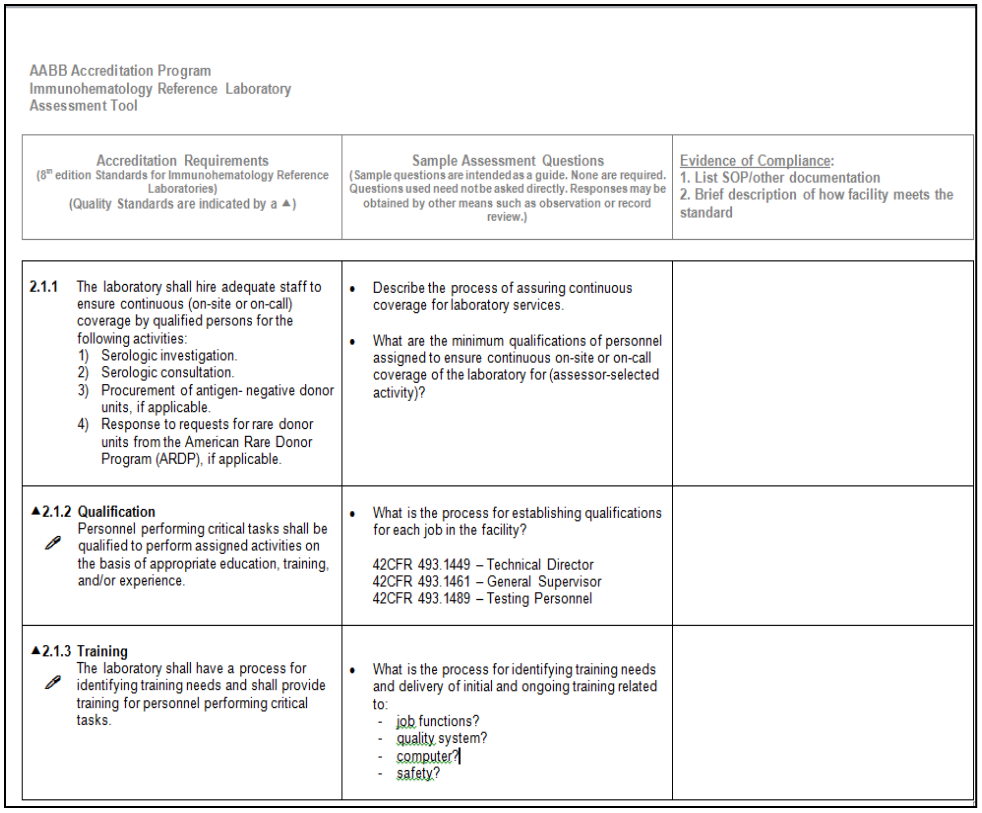
ASSESSMENT TOOLS FOR FACILITIES
Available on AABB website

Standards and Accreditation> Accreditation Member Tools> Facilities



AABB Accreditation Program
Immunohematology Reference Laboratory
Assessment Tool

Accreditation Requirements (8th edition Standards for Immunohematology Reference Laboratories) (Quality Standards are indicated by a ▲)	Sample Assessment Questions (Sample questions are intended as a guide. None are required. Questions used need not be asked directly. Responses may be obtained by other means such as observation or record review.)	Evidence of Compliance: 1. List SOP/other documentation 2. Brief description of how facility meets the standard
2.1.1 The laboratory shall hire adequate staff to ensure continuous (on-site or on-call) coverage by qualified persons for the following activities: 1) Serologic investigation. 2) Serologic consultation. 3) Procurement of antigen- negative donor units, if applicable. 4) Response to requests for rare donor units from the American Rare Donor Program (ARDP), if applicable.	• Describe the process of assuring continuous coverage for laboratory services. • What are the minimum qualifications of personnel assigned to ensure continuous on-site or on-call coverage of the laboratory for (assessor-selected activity)?	
▲2.1.2 **Qualification** Personnel performing critical tasks shall be qualified to perform assigned activities on the basis of appropriate education, training, and/or experience.	• What is the process for establishing qualifications for each job in the facility? 42CFR 493.1449 – Technical Director 42CFR 493.1461 – General Supervisor 42CFR 493.1489 – Testing Personnel	
▲2.1.3 **Training** The laboratory shall have a process for identifying training needs and shall provide training for personnel performing critical tasks.	• What is the process for identifying training needs and delivery of initial and ongoing training related to: - job functions? - quality system? - computer? - safety?	

YOU CAN KNOW EXACTLY

- Questions you will be asked
- Documentation you will be asked to produce

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AABB Assessments NOT Inspections

- Don’t need (or want) to see every record
- Policies, Processes and Procedures that support adherence to Standards
  - Describe the process for…
  - What is the process for…
  - How do you ensure that…
  - What is the evidence that…

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AABB Assessments NOT Inspections

- Policies, Processes and Procedures must be in writing
  - Reviewed
  - Approved
  - Controlled
- "We always do …"
  - Not sufficient

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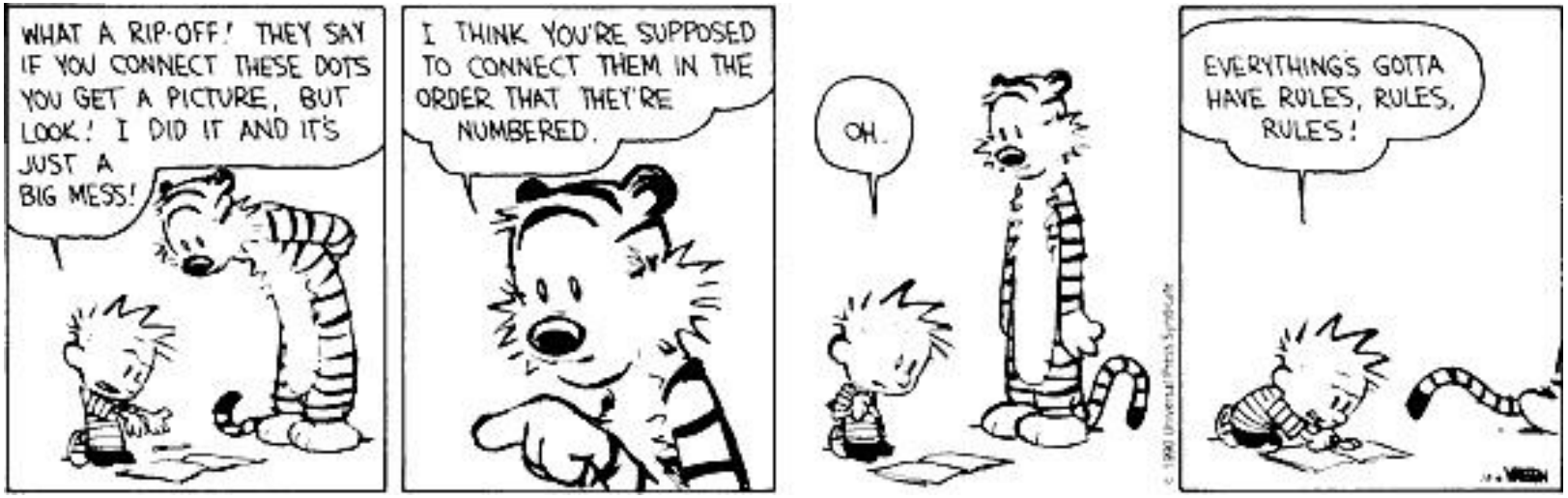
AABB Assessments NOT Inspections

- Policies, Processes and Procedures must be FOLLOWED



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Quality, Standards, and Accreditation

Quality: a high level of value or excellence

Standard: something set up and established by authority as a rule for the measure of quantity, weight, extent, value, or ***quality.***

Accreditation: the granting of approval to an institution by an official review board after the institution has met specific requirements or ***standards.***

Common laboratory accreditation agencies:

- Joint Commission
- College of American Pathologists
- COLA
- American Association for Laboratory Accreditation
- AABB

Assessment Objective

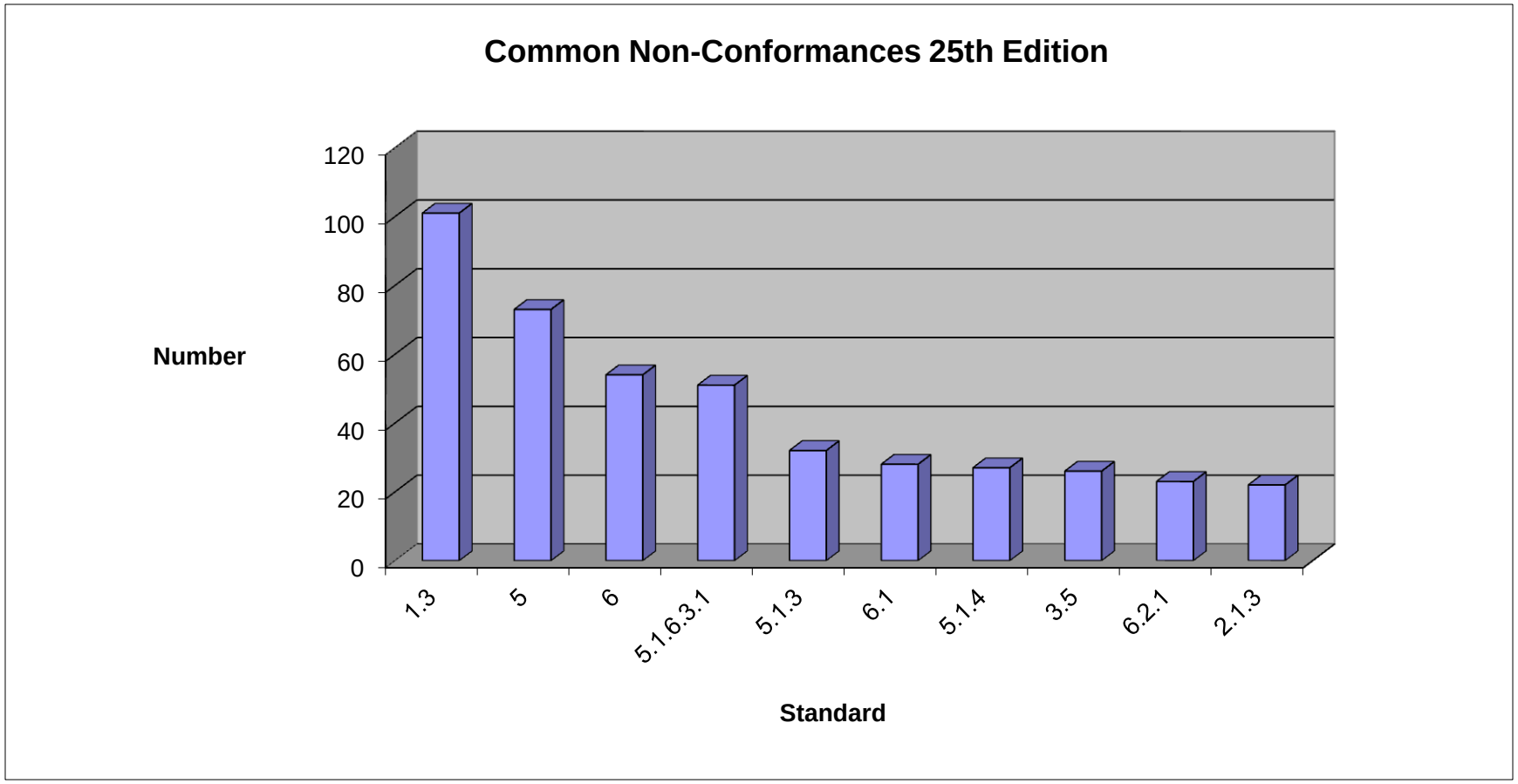
What an assessment is:

- A process
- About collecting information
- A way to demonstrate laboratory effectiveness
- To verify conformance with current standards

What an assessment is NOT:

- Useless
- An end goal
- The only information considered when creating policies/procedures

BB/TS Common Non-Conformances



In first place…
BB/TS Standard 1.3

- **1.3 Policies, Processes, and Procedures**
  - 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
- CAP TRM.42295; TRM.42950; TRM.43500; TRM.43650; TRM.45252; TRM.47350
- CAP COM.04150; COM.30575

Processes need to be written and followed!

Second Place…
BB/TS Standard 5.0 Process Control

- **PROCESS CONTROL**
  - The blood bank or transfusion service shall have policies and validated processes and procedures that ensure the quality of the blood, blood components, tissue, derivatives, and services. The blood bank or transfusion service shall ensure that these policies, processes, and procedures are carried out under controlled conditions
- TRM.30550; TRM.42212

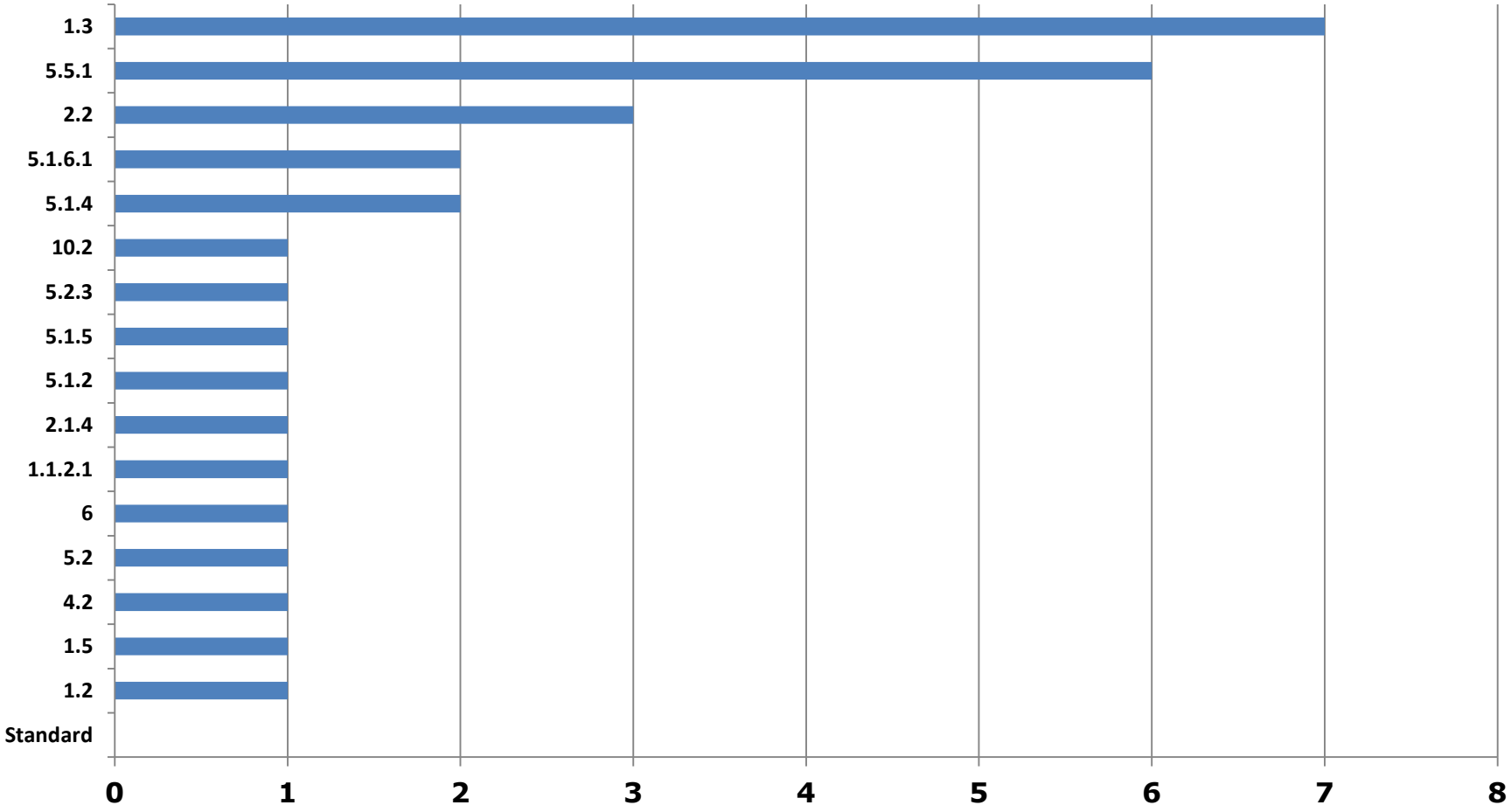
Participate in PT, follow manufacturer's instructions, take corrective action!

And finally in Third Place…

- 6.0 Documents and Records
  - …shall have policies, processes and procedures to ensure that documents are identified, reviewed, approved, and retained…
- TRM.45190 ,GEN.20375; GEN.20377; GEN.43900

Complete documentation! Review Documentation! Keep Documentation!

Nonconformance (NC) by IRL Standard
56 Facilities; 31 NC issued



AND THE WINNER IS… Standard 1.3

Policies, Processes and Procedures shall be Developed and Implemented…

- Always the winner
- Many observations/objective evidence can be grouped under this standard for one nonconformance.
  - No document
  - Document doesn't fulfill requirement of standard
  - Document in use not current version
  - Not following written procedure
    - Many standards require a policy or process
    - Content not dictated
    - Practice what you "preach", or write
  - No review of documents

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AND THE WINNER IS... Standard 1.3

Policies, Processes and Procedures shall be Developed and Implemented...

- No policy for use of red cell genotype information by molecular methods
- No process for corrective action of near miss events
- References to non-existent procedures in current documents
- No policy for the use of outdated reagent red cells
- No process for review of QC
- No process/procedure for investigating reagent dependent reactivity or HDFN

1st Runner up is 5.5.1

Requirements for IRL Investigative Reports

- ISBT-accepted terminology (5)
  - Anti-Fy^{a} or FY:1, not Fya or FYA…
- No system to report unacceptable samples that were not tested

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2nd Runner Up: Standards 2.2

Inventory Resources

- Missing required inventory or rare cells, antisera, reagents
- Source, specificity, reactivity undocumented (5.1.5.3)

- **98% Reference Standard 2.2A**
- **50% Reference Standard 2.2B**

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Tied for 4th

- **5.1.6.1:** Process to ensure results/reports reviewed for acceptability **BEFORE** distribution, issue or delivery
- Many ways to fulfill
  - 2nd person review required by institution's SOP
  - SOP Not followed
- 2nd person review ideal, but not required by IRL Standards
  - Self review ok
    - Tool or checklist is helpful, but not required
  - Includes preliminary results/reports
    - If released, it must be reviewed

PRACTICE WHAT YOU PREACH

- Follow your policy
  - If you say results/reports only released after 2nd person review
  - Must follow policy
  - Considerations when developing process
    - 2nd, 3rd shifts, on-call, weekends??
    - Life threatening situations?
    - Short staffed?

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Tied for 4th

- **5.1.4.2:** Laboratory prepared reagents used in lieu of FDA licensed product must meet or exceed FDA criteria
- Many reagent not available as licensed reagents
- If FDA-licensed available, in-house reagent must meet FDA requirements
  - Labeling issues
  - Reagent not prepared to meet or exceed FDA criteria

It's your chance
YOU ARE THE ASSESSOR

IRL Case 1
Assessment at XYZ Blood Center

- A technologist observed performing antigen typing of donor cells.
- "How do you determined the incubation times and temperatures etc. for the antiserum being used?"
- The technologist pulled a chart from the drawer that listed different specificities (e.g., E, K, Jk^a) with temperatures, incubation times, centrifugation times.
- Is this a nonconformance?

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BACKGROUND

- IRL Standard 5.1.4: All materials …shall be used in accordance with manufactures' written instructions…
  - Scads, loads, many, lots… antigen typing performed in IRLs
  - Must have a written process to support 5.1.4
- Is a chart necessary??
  - No – process chosen by laboratory
  - SOP could state to refer to the current package insert.

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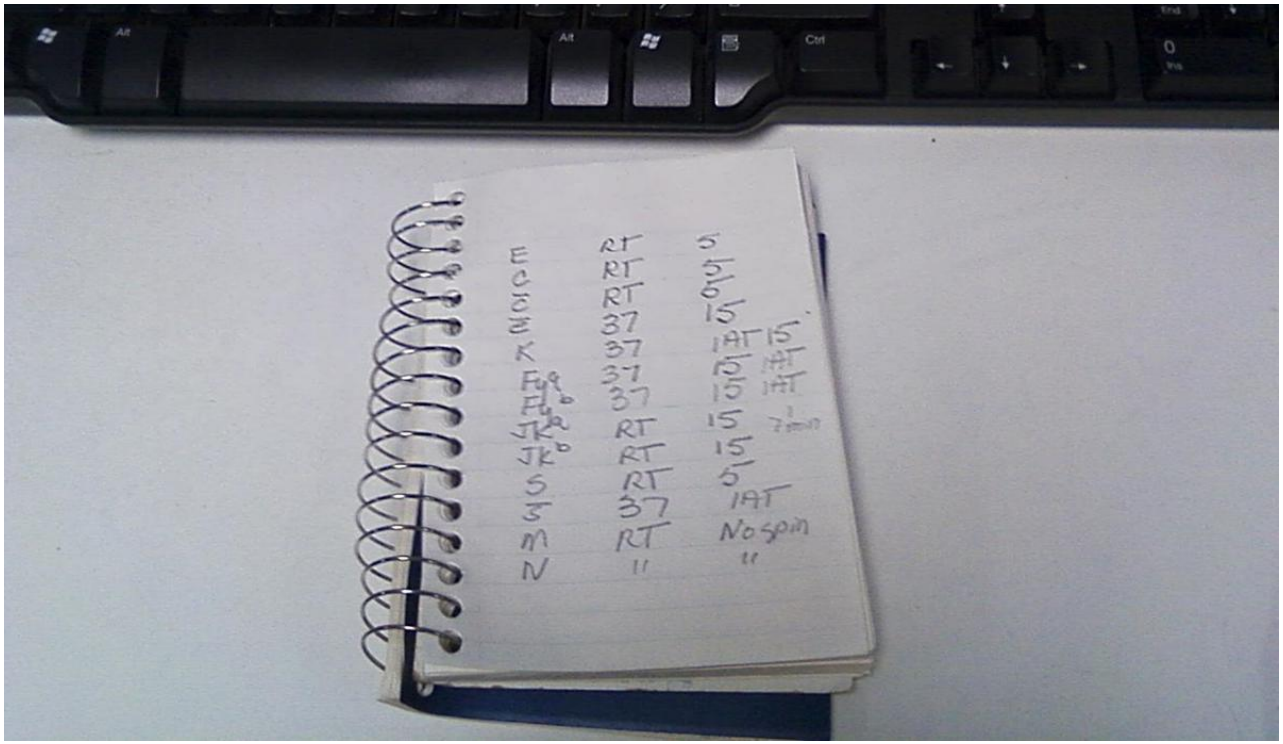
Case 1: Is this a NC?

- That depends
- Need more information
- Questions
  - Is there a process to keep the “chart” updated with package insert changes? (Is the update process controlled?)
  - Is the process in writing?
  - Does the lab have more than one supplier of antisera? Does chart information reflect this?

Case 1 – Objective Evidence A

"This is updated when we receive new antisera"



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Case 1 – Objective Evidence B

IRL Antisera Testing Job Aid IMM.03.0122 v 8.0							
Anti-	E	E	C	c	Jka	Jka	Jka
Manufacturer	BR	IM	BR	BR	OR	IM	BR
Temp.	RT	37	RT	RT	RT	37/IAT	37
Time	5	15	5	5	5	15	15
Spin time, if AP.	NA	NA	NA	NA	NA	NA	60
Lot #	80133152 80134157	45012	80107917	7931245 7932256	JBB1946	45126	80314652
Pk Insert Rev.	Oct-14	Jul-13	Oct-14	Oct-14	Jun-12	Jul-13	Oct-14
Rev: jkr 10/5/14							

- " This chart is updated when we receive new antisera. The SOP states to update for new suppliers or when a revised package insert is received…"
  - Process in writing (1.3)
  - Accommodates new supplier and package insert updates.
    - Should include process to assure old versions not in use (6.1.5)
  - Assures use in accordance with manufacturer's instructions (5.1.4)

Case 1

Example A is a nonconformance

Example B is not

BBTS CASE Study #1

- Blood Administration process
  - Nursing process
  - Product return to inventory

- The assessor asks to see the lab policy on return/re-issuing blood products.

CASE Study #1…continued…

The policy provided included a statement…

- *Red cell products returned to the lab may be re-issued only if the temperature of the unit has not exceeded 10° C as evidenced by the irreversible portion of the attached temperature indicator. If storage conditions are undocumented, or unacceptable storage is suspected, fold donor unit around a certified Blood Bank thermometer to check the unit temperature. The 10° C temperature limit is usually exceeded if the unit is at room temperature for more than 30 minutes. Units are also unacceptable for re-issue if they have been entered or stored in unmonitored nursing unit refrigerators. When units do not meet criteria for re-issue, the unit must be discarded.*

CASE Study #1…Assessors findings

- However, when the assessor reviewed the unit returned, there was not a temperature indicator on it and the tech did not make the temperature using the alternative method outlined in the policy. When asking the tech about how it was determined the unit was acceptable for re issue, he stated, it had been less than 30 minutes.
- Is this a non-conformance??

- YES
  - Non-conformance issued for CAP TRM 42470 and BB/TS 1.3 and 5.26

IRL Case 2

- The ABC Blood Center's IRL antibody identification procedure states…
- Antibodies shall be identified by demonstrating reactivity with 3 antigen-positive cells and nonreactivity with 3 antigen-negative cells.

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ANTIBODY INVESTIGATION BACKGROUND

- IRL 5.3.3 " Assign specificity (IDENTIFY) after demonstrating reactivity with 2 antigen-positive red cells and nonreactivity with 2 antigen-negative red cells."
- "Exclude common clinically significant red cell alloantibodies….if not excluded…blood released for transfusion shall lack corresponding antigen."

Case 2 Objective Evidence

- Example cases, the following was observed.
  - Anti-Vel was identified. 3 Vel+ cells were reactive and 3 Vel- cell were nonreactive.
  - Additional commonly encountered clinically significant red cell antibodies were excluded with 3 antigen-positive, Vel- cells, except anti-K.
  - Only 2 Vel-, K+ cells were nonreactive with the patient's plasma. K negative units were not provided.

Case 2: Is this a nonconformance??

Yes?

No?

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IRL Case 2 cont.

- There is no Standard for antibody exclusion, only antibody identification.
- IRL 5.3.3 only requires antigen positive and 2 antigen negative cells for antibody ID.
  - ABC's IRL Antibody ID procedure was more stringent
    - 3+3 rule
  - Procedure followed in this case
  - Not a nonconformance
- Does procedure state antibody exclusion policy?
  - Check for compliance

BBTS Case Study #2

- How new lots of reagents are handled?
- Observes processes for anti-A
  - Lab specific QC documentation
  - Reactions are reviewed against the previous lot number
  - Review was documented on the QC sheet.

The assessor was IMPRESSED! Great job!

Case Study #2…continued…

- Know when to stop talking
- Tech related to FDA reportable events in the past
- Investigation by assessor…

CASE Study #2…continued…

The policy provided included:

Internal Assessments

- Assessments of all transfusion related processes are performed as a part of the Quality Program of the Blood
- Transfusion Service. Internal assessments consist of record review and data collection or direct observation of the
- activity with documentation of required information. Trends observed are reported to the Lab CQI Coordinator,
- Quality and Utilization Management Review department and the Lab Utilization Review Committee for the purpose
- of evaluating the need for corrective actions, system or procedure change or to initiate process improvement
- activities. Special focused audits may be devised and performed on the recommendation of the Quality and
- Utilization Management Review department, the Blood Transfusion Service, the Lab Utilization Review Committee
- or the Medical Director of the Blood Transfusion Service as a component of process improvement.

Process Improvement

- Personnel are trained in the use of problem-solving methods and tools as part of Hospital Orientation.
- Laboratory QAIPI Committee and the Blood Transfusion Service utilizes the "PMAAR" model (Plan, Measure,
- Analyze, Act, Review) for process improvement. Ad hoc groups composed of the appropriate staff will address negative trends, adverse events and problems according to the following procedure:
  - Investigate, analyze and define the problem or adverse event, or evaluate data gathered through system check audits to identify patterns, trends and the need for additional data collection/audit.
  - Define corrective actions and preventive actions to improve the process being evaluated.
  - Devise a plan for implementation of corrective action and preventative actions. A Change Control form will be initiated according to policy #123456.
  - Report plan to oversight Committee or Quality and Compliance Director as appropriate.
  - Data collected from system checks or focused audits will be used to monitor the effectiveness of the action taken.
  - Process improvement will be reinitiated when the corrective and/or preventative actions are determined to be ineffective or insufficient based on results of follow-up audits and routine system checks.

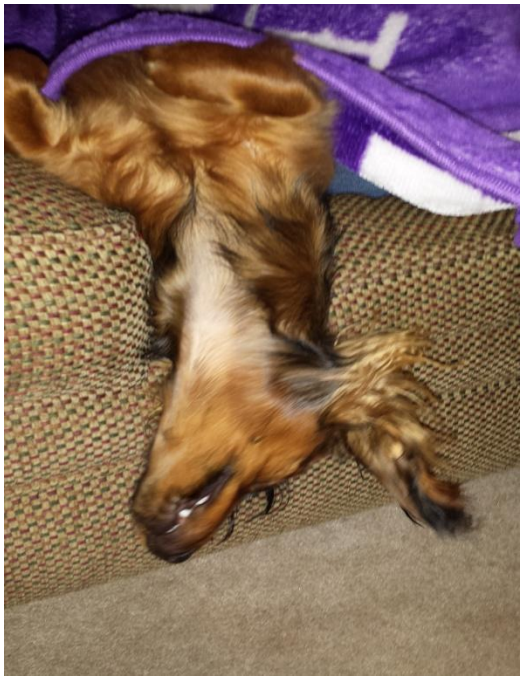
CASE Study #2…Assessors findings

- The supervisor was able to provide all appropriate documentation related to the event the tech opened her mouth about including the corrective action and staff education.
- Was this a non-conformance?

- No
- Conformance met for CAP TRM 30700 and TRM 40140, COM 30450 and BB/TS 5.0 and 9.0

And at the end of the day….

- We all do our best to conform to the standard and let the assessor do the rest!



Ode to an AABB Standard

- The final slide has passed by your eyes
- And if you're awake, it must truly imply
- A very large caffeine supply
- Or super human interest
- In facts most dry, a true means test
- You've missed your calling, could it be
- You should be part of Quality!

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