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I fought the law…

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Let's talk Regulations

- Standards
- Regulations
- Assessments
- Audits
- Laws
- Reactions
- Action Plans

How many IRLs?

- AABB website lists 66 accredited facilities internationally
- Assessed every 2 years
- Divided almost equal between odd and even years

- CAP accredited…fewer? Some with both.

#1 most common AABB citation

- 2.1.4 Competence

  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)

How can we avoid this common citation

- Pre-assessment review
- Internal audits
- Frequent review of competency program

- Have a solid SOP for competency assessment?
- Are you following SOP?
- Does your documentation reflect this clearly?

Next 9 most common in order of frequency (#2)

- 1.3 Policies, Processes, and Procedures

  Quality and operational policies, processes, and procedures shall be developed and implemented to ensure that the requirements of the IRL Standards are satisfied. All such policies, processes, and procedures shall be in writing or captured electronically and shall be followed.

5.1.6.1 Results and Reports (#3)

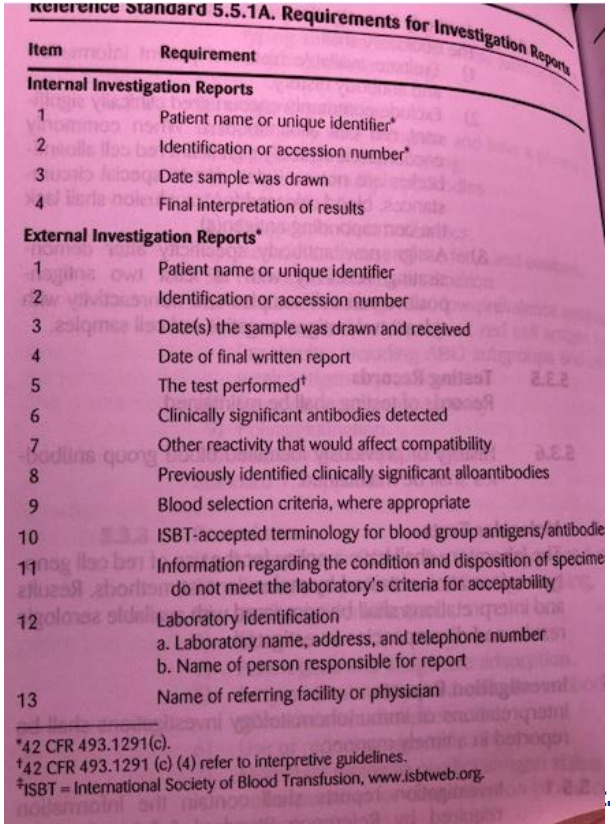
- The laboratory shall have a process to ensure that test results and reports are reviewed for acceptability before distribution, issue, or delivery.

5.0 Process Control (#4)

- The laboratory shall have policies and validated processes and procedures that ensure the quality of immunohematology reports and testing services. The laboratory shall ensure that these polices, processes, and procedures are carried out under controlled conditions.

5.5.1A Requirements for Investigation Reports (#5)

Long list, must be on each report.



Reference Standard 5.5.1A. Requirements for Investigation Reports

Item	Requirement
Internal Investigation Reports	
1	Patient name or unique identifier*
2	Identification or accession number*
3	Date sample was drawn
4	Final interpretation of results
External Investigation Reports*	
1	Patient name or unique identifier
2	Identification or accession number
3	Date(s) the sample was drawn and received
4	Date of final written report
5	The test performed†
6	Clinically significant antibodies detected
7	Other reactivity that would affect compatibility
8	Previously identified clinically significant alloantibodies
9	Blood selection criteria, where appropriate
10	ISBT-accepted terminology for blood group antigens/antibodie
11	Information regarding the condition and disposition of specime do not meet the laboratory's criteria for acceptability
12	Laboratory identification a. Laboratory name, address, and telephone number b. Name of person responsible for report
13	Name of referring facility or physician

*42 CFR 493.1291(c).
†42 CFR 493.1291 (c) (4) refer to interpretive guidelines.
‡ISBT = International Society of Blood Transfusion, www.isbtweb.org.

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1.1.2.2 Supervisor Qualifications and Responsibilities (#6)

- When the individual does not possess one of these* qualifications, exceptions shall be considered on a case-by-case basis by the Immunohematology Reference Laboratory Accreditation Committee.

*1.1.2.1 SBB or equivalent OR doctorate in immunohematology-related field, OR medical license and certification in BB/TM by American Board of Pathology or equivalent non-US agency

4.3 Incoming Receipt, Inspection, and Testing of Materials (#7)

- Incoming materials shall be received, inspected, and tested, as necessary, before acceptance or use.

5.1.2 Proficiency Testing Program (#8)

- The laboratory shall participate in a proficiency testing program for <u>each analyte</u> tested by the laboratory. Results shall be reviewed and corrective action taken, where appropriate, when expected results are not achieved.

COM.01500

- Analytes lacking PT need in-house competency 2x/year
  - Examples: Weak/Partial D, Donath Landsteiner, Drugs, Lectins
- **Semiannual** requirement means **every 6 months** (not twice a year)

5.1.6 Inspection (#9)

- The laboratory shall ensure that immunohematology reports, critical materials, samples, blood, components, and test results are inspected at laboratory-defined stages to verify that specified requirements are met.

5.3.2 Serologic Capabilities (#10)

- The lab shall recognize and have a process to investigate each of the following:

Single and multiple Ab
Autoantibodies
Drug-dependent Ab
HDFN
Hemolytic Tx Reaction
Ab to high- and low-prevalence Ag

Aberrant and/or discrepant red cell Ag typing results (including ABO subgroups and other weak Ag expression)
Reagent-dependent reactivity
Polyagglutination
Interfering therapeutic agents

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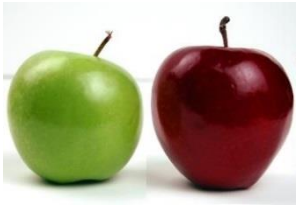
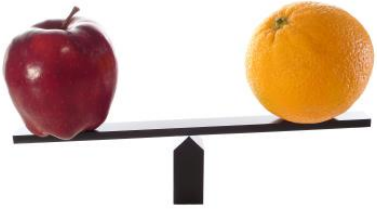
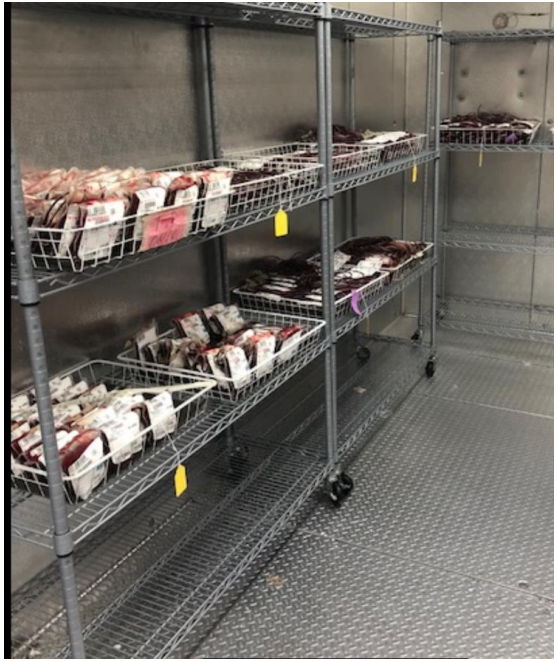


- Instrument to instrument comparison of testing
  - For each instrument of which there are duplicates
- What about different instruments (methods) doing same testing (similar AABB standard)
  - Example: How do you compare PeG to saline to SPRCA?



TRM.42600

- How many probes are needed in various size refrigerators/freezers
- Define “large”



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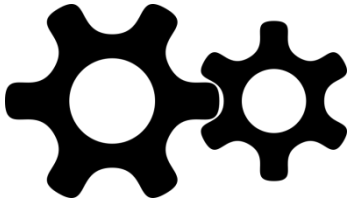
Switch gears



- I fought the law…
- Ever feel you got "busted"? We are supposed to learn from audits.

- Constant changes/additions/updates
- Sometimes struggle to "meet intent"
- Quick review of recent changes – both easy and challenging

New in the 10th Ed. IRL

- **1.3.1** Any exceptions to policies, processes, and procedures warranted by clinical situations shall require justification and preapproval by the medical director.

  (Chapter 7, Deviations, Nonconformances, and Adverse Events, applies.)

New in the 10th Ed. IRL

- **2.3** The laboratory shall have a written plan for the implementation of allele determinations for *RHCE* variants.
- Labs shared concerns over the intent and how to meet it

New in the 10th Ed. IRL

- **3.6.3.1** There shall be a process in place to ensure that action is taken if liquid nitrogen reaches an unacceptable level or temperature.
- **3.7.2** The alarm system in liquid nitrogen freezers shall be activated before the contained liquid nitrogen reaches an unacceptable level.

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We connect donors and the lives they impact.

New in the 10th Ed. IRL

- **4.1.2.2** Testing by facilities outside of the United States shall be performed by a laboratory authorized as a testing center by the Competent Authority.

New in the 10th Ed. IRL

- **4.4.1** When a sample has been rejected and is unsuitable for testing, documentation of customer notification shall be maintained. *

- *42 CFR 493.1242(a)(7)

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We connect donors and the lives they impact.

New in the 10th Ed. IRL

- **5.1.5.2.1** For laboratories that accept verbal requests, a written or electronic authorization shall be requested within 30 days. If the requested written or electronic authorization is not provided, the laboratory shall maintain evidence of efforts to obtain the authorization.

New in the 10th Ed. IRL

- **5.2.1** Donor Center based laboratories shall also register at least 10 donors in the ARDP on an annual basis. Standard 5.2 applies.

Whaaaat??

Challenges we have faced

- BBTS
- IRL
- CAP
- CLIA
- FDA

CLIA

- Every 2 years, independent audit if not deemed thru another agency
- They can visit independently anyway
  (And they do)
- Diploma citations – shared by several
  - Keep them on file in HR for your testing personnel

31st edition BBTS

- **5.14.5**
- Impact of new 2nd ABO requirement
- Is this requirement more challenging for reference labs?
- Do you act as the TS? Does this change your response/action plan? Or does the burden remain with hospital/LTAC/etc?

AABB Calendar Challenge?

3.5.1 Calibration of Equipment

Calibration and/or adjustments shall be performed using equipment and materials that have adequate accuracy and precision. At a minimum, calibrations and/or adjustments shall be performed:

- Before use
- After activities that may affect the calibration
- At prescribed intervals

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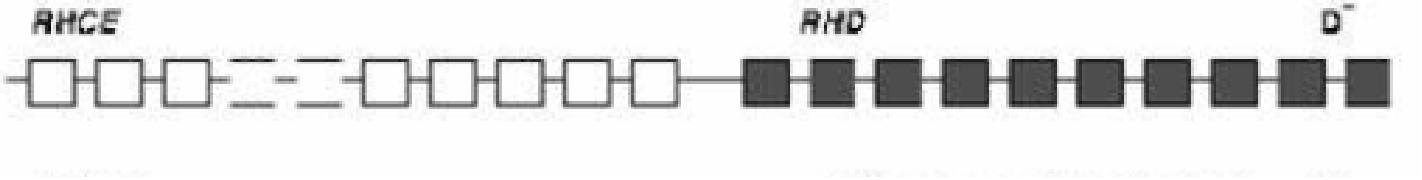
- **2.3** The laboratory shall have a written plan for the implementation of allele determinations for *RHCE* variants.



Labs shared concerns over the intent and how to meet it

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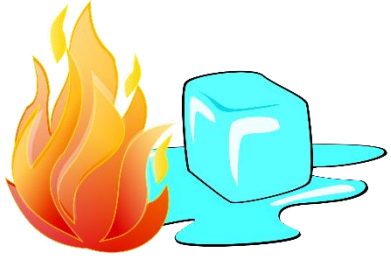
- **3.7 Alarm Systems**



- Remote monitoring systems
- Manufacturer installation Fire/Ice
- Who is responsible after that?
- Routine Fire/Ice or/plus (?) routine quarterly "checks"


IT'S
BEEN
LOVELY
BUT
I HAVE TO
SCREAM
NOW