Association for the Advancement of Blood & Biotherapies

Changes to the 33rd Edition of the AABB Standards for Blood Banks and Transfusion Services

Presentation to the Massachusetts Association of Blood Banks

May 24, 2022

Faculty Disclosure

- Dewayne Defee, AABB Staff Lead Assessor
- No disclosures

Association for the Advancement of Blood & Biotherapies

Mission

Improving lives by making transfusion medicine and biotherapies safe, available, and effective worldwide.

Vision

A connected community dedicated to advancing transfusion medicine and biotherapies. From donor to patient. From lab to bedside.

Learning Objectives

At the completion of this lecture, the attendee will be able to:

- Demonstrate knowledge of the changes and updates to the 33rd Edition of the AABB Standards for Blood Banks and Transfusion Services
- Explain the rationale for the changes/updates
- Implement the updates/changes at their facilities

The BBTS Standards Committee

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Plasma Protein Therapeutics Association—Larisa Cervenakova, MD, PhD
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Timeline for the 33rd edition

January 2021	Submit request for comments for 33rd edition
February 2021	Online document review in Work Groups
March 2021	Online meeting in place of face to face meeting to prepare proposed 33rd edition for comment
April 2021	Technical, Legal, and Regulatory review
April 2021	SPC/BBTS SC review
April 2021	BoD review
May – June 2021	60 day Public Comment Period
July 2021	Comment review in Work Groups
August 2021	Online meeting in place of face to face meeting to prepare final 33rd edition for comment
August 2021	Technical, Legal, and Regulatory review
August 2021	SPC/BBTS SC review
August 2021	BoD review
August 2021	Standards sent to Publications
September 2021	Complete guidance creation and review
January 2022	Standards Mailed
February, 2022	Significant Changes to the 33rd edition of BBTS Standards Audioconference
April 1, 2022	33rd edition of BBTS Standards become effective

Comment Periods

- **In the draft pre online meeting comment period the committee received 13 comments from 10 individuals or institutions.**
- **In the proposed comment period, the committee received 54 comments from 20 individuals or institutions.**
  - This was lower than usual, potentially reflecting the time individuals had to give to a review due to the ongoing COVID19 pandemic.

Chapter 1 - Organization

1.1.1

Medical Director Qualifications and Responsibilities

The BB/TS shall have a medical director who is a licensed physician, qualified by training, experience, and ***facility-defined*** relevant continuing education in activities required by these BB/TS Standards for which the facility is accredited. The medical director shall have responsibility and authority for all medical and technical policies, processes, and procedure —including those that pertain to laboratory personnel and test performance—and for the consultative and support services that relate to the care and safety of donors and/or transfusion recipients. The medical director may delegate these responsibilities to another qualified physician; however, the medical director shall retain ultimate responsibility for medical director duties.*

*42 CFR 493.1445.

Rationale

The committee added the clause "facility defined" to the standard as it related to continuing education for clarity. This addition is in line with what is occurring already in accredited facilities and in practice closes a gap not addressed in the Standards

Chapter 3 – Equipment

3.8

Warming Devices for Blood and Blood Components

Warming devices shall be equipped with a temperature-sensing device and a warning system to detect malfunctions and prevent hemolysis or other damage to blood or blood components. ***Standard 3.5 applies.***

Rationale

The committee added a record retention requirement to this standard, and a corresponding entry in Reference Standard 6.2C for completeness. This new record retention requirement ensures that the records surrounding warming devices are maintained. The committee also added a cross-reference to standard 3.5 to this standard. Standard 3.5 is being included as it requires that all equipment be monitored and maintained in accordance with manufacturer's instructions

Chapter 3 - Equipment

3.9.2

An alternate system, including ***any required forms***, shall ***be maintained and readily available*** for use to ensure continuous operation in the event that computerized data and computer-assisted functions are unavailable. The alternate system shall be tested at defined intervals. Processes and procedures shall address mitigation of the effects of disasters and include recovery plans.

Rationale

The committee expanded standard 3.9.2 to better reflect the realities of current BB/TS operations by including a requirement that "any required forms…be readily available" on site. Having required forms available ensures continuous operations with no significant delay.

Chapter 4 – Suppliers and Customers

4.0

Suppliers and Customers
The BB/TS shall have policies, processes, and procedures that define supplier and customer expectations.
Standard 1.7 applies.

Rationale

The title of chapter 4 and standard 4.0 were changed from "Supplier and Customer Issues" to "Suppliers and Customers." The committee felt that the term "Issues" did not reflect the content of the standard.

Chapter 4 – Suppliers and Customers

4.1.1

Suppliers of critical materials, equipment, and services shall be evaluated to determine their ability to meet specified requirements.

Rationale

The content of standard 4.1.1 previously existed as a part of standard 4.0. The content did not fit with both suppliers and customers. The content fit with suppliers and hence the creation of the new standard.

Chapter 5 – Process Control

5.1.5.2

The BB/TS shall have methods to detect bacteria or use pathogen reduction technology in all platelet components ***stored at 20-24 C.****

*21 CFR 606.145.
FDA Guidance for Industry, Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion (Updated December 17, 2020).

Rationale

The committee added the clause, "…stored at 20 – 24 C" at the end of the standard reflecting the content that exists in reference standard 5.1.8A and the understanding that facilities are using cold stored platelets that are not addressed in the FDA Guidance. The inclusion of the FDA Guidance, "FDA Guidance for Industry, Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion (Updated December 17, 2020)" was included for completeness.

Chapter 5 – Process Control

5.1.6.5.2

If a transfusing facility or an intermediate shipping facility receives ***blood or a blood component*** labeled with a ***non ISBT 128*** donation identification number, an ISBT 128 Donation Identification Number shall be assigned. The label shall be affixed to the container and shall identify the facility assigning the identification. Standard 5.1.6.2 applies.

Rationale

The committee replaced the term "unit" with "blood or a blood component" for clarity, noting that these labels apply to blood and blood components. The committee removed the term "Codabar" and replaced it with "non ISBT 128" understanding that facilities may not use ISBT 128 specific labels, but in that case they will no longer be using Codabar.

Chapter 5 – Process Control

5.1.8.1.2

Tissue, derivatives, ***and reagents*** shall be stored in accordance with the manufacturer's written instructions.

Rationale

The committee added the term "reagents" to standard 5.1.8.1.2 for completeness and accuracy.

Chapter 5 – Process Control

5.5.2.4

A plasma product derived from collection of a platelet product stored in platelet additive solution ***is not considered a concurrently collected plasma product, and therefore*** shall not affect the determination of plasmapheresis frequency, when the plasma volume derived from the collection is equivalent to the volume of additive solution added.

Rationale

The committee added the clause, "…is not considered a concurrently collected plasma product, and therefore" while removing "…the plasma loss" from the standard for clarity.

Chapter 5 - Process Control

5.5.3.1

The interval between procedures for platelet, granulocyte, and leukocyte donors shall be at least 2 days, and the total volume of plasma collected shall not exceed the volume of plasma cleared by the FDA for the instrument. A donor shall undergo the procedure a maximum of two times in a 7-day period. When ***greater than or equal to 6 × 10^{11} platelet*** collection is performed, the donor shall undergo the procedure a maximum of once in 7 days. Procedures shall not exceed 24 times in a rolling 12-month period, except in unusual circumstances as determined by the medical director. Standard 5.4.3.3 applies.*

*21 CFR 640.21(e).
FDA Guidance for Industry and FDA Review Staff: Collection of Platelets by Automated Methods (December 17, 2007).

Rationale

The committee replaced the former language that referred to double and triple collections with the numerical platelet content to be consistent with the wording in the CFR. This change was also made to standard 5.5.3.4.1.

Chapter 5 – Process Control

5.6.7.1

Units drawn as therapeutic phlebotomies shall not be used for allogeneic transfusion unless the individual undergoing the therapeutic phlebotomy meets all allogeneic donor criteria with the exception of donation interval.

5.6.7.1.1

The container label shall conspicuously state the disease or condition of the donor that necessitated phlebotomy. However, labeling for the disease or condition is not required if:

1. The phlebotomy is for hereditary hemochromatosis or for a condition for which the collection procedure has been approved by the Competent Authority*, and
2. The phlebotomy is performed for no charge for all individuals with that disease or condition.

*21 CFR 630.15(a)(2).

Rationale

The committee edited standard 5.6.7.1 by splitting the standard into two separate standards for clarity. Standard 5.6.7.1 now reads as follows: "Units drawn as therapeutic phlebotomies shall not be used for allogeneic transfusion unless the individual undergoing the therapeutic phlebotomy meets all allogeneic donor criteria with the exception of donation interval." For new standard 5.6.7.1.1, the elements that previously appeared in subnumber 1 now appear in the stem of the new standard. With the revisions to the standard, the elements that now appear in subnumber 1 previously appeared as former subnumber 3. The elements of new subnumber 1 previously appeared as subnumber 2. The decision to remove the clause concerning "no charge" from subnumber 1 (formerly 2) was made as this applies to more than just hereditary hemochromatosis.

Chapter 5 – Process Control

5.7.2.1.1

If the integrity of the weld is complete, the component ***shall have an expiration date/time assigned in accordance with the FDA- or Competent-Authority-approved package insert for the storage container.***

5.7.2.1.3

Regardless of the integrity of the weld, if no storage time limit is specified in the package insert or the package insert is not available, the component shall have an expiration time of 4 hours after transfer from original container.

Rationale

The committee modified 5.7.2.1.1 to indicate that if the integrity of the weld is complete, the expiration date/time is assigned in accordance with the package insert for the storage container. A new standard, 5.7.2.1.3, was added to indicate that if there is no storage time limit specified in the package insert for the new container or if a package insert indicating a storage limit is not available, the component shall be given an expiration time of 4 hours after transfer from the original container to that new container.

Chapter 5 – Process Control

5.7.4.1

WHOLE BLOOD LEUKOCYTES REDUCED

Whole Blood Leukocytes Reduced shall be prepared by a method known to retain at least 85% of the original whole blood content. The sampling plan shall confirm with 95% confidence that more than 95% of units contain <5 × 10^6 leukocytes. FDA criteria apply.* Standard 5.7.3.1 applies.

*FDA Guidance for Industry: Pre-Storage Leukocyte Reduction of Whole Blood and Blood Components Intended for Transfusion (September 2012).

Rationale

The committee elected to edit standard 5.7.4.1 (as well as 5.7.4.7, 5.7.4.9.1, 5.7.4.21, 5.7.4.22, 5.7.4.23, 5.7.4.24, and 5.7.4.25) to mirror the language regarding statistical confidence that is included in the FDA Guidances cited with the standards. The committee felt (and based on comments received) that the AABB membership is positioned to accept this concept now. These changes should also assist users in facilities outside of the United States who have at times inquired regarding QC sampling requirements. The FDA guidances cited contain examples of sampling plans.

Chapter 5 – Process Control

5.7.4.16.1

Components prepared from pathogen-reduced plasma (including, but not limited to, thawed plasma, cryoprecipitated fibrinogen complex, plasma cryoprecipitate reduced) shall be processed and stored per the manufacturer's written instructions.

Rationale

The committee created new standard 5.7.4.16.1 recognizing that there are components prepared from pathogen reduced plasma that are processed and stored per manufacturer's instructions.

Chapter 5 – Process Control

5.7.4.23.1

Apheresis Platelets containing <3.0 × 10^{11} platelets shall have the platelet content included on the label.

5.7.4.24.1

Apheresis Platelets Leukocytes Reduced containing <3.0 × 10^{11} platelets shall have the platelet content included on the label.

5.7.4.25.1

Apheresis Platelets Platelet Additive Solution Added Leukocytes Reduced containing <3.0 × 10^{11} platelets shall have the platelet content included on the label.

Rationale

The committee created these new standards to add requirements for products that would be considered "low yield" to be consistent with FDA guidance and to enable customers to be aware if a product is a low yield product.

Chapter 5 – Process Control

5.14.8

Pretransfusion Testing for Allogeneic Transfusion of Whole Blood, Red Blood Cell, and Granulocyte Components

There shall be two determinations of the recipient's ABO group as specified in Standard 5.14.1. The first determination shall be performed on a current sample, and the second determination by one of the following methods:

1.Comparison with previous records.

2.Testing a second sample collected at a time different from the first sample, including a new verification of patient identification.

3.Retesting the same sample if patient identification was verified at the time of sample collection using an electronic identification system.

Standards 3.2, 5.11, and 5.27.1 apply.

Rationale

The committee removed the clause "validated" from subnumber 3 as its inclusion in the standard was resulting in many questions, confusion and a misunderstanding of the intent of the standard for the membership. The committee also added the clause, "at the time of sample collection" to the entry for clarity and based on queries received from the membership. The committee also added a crossreference to standard 3.2 to the standard as it relates to qualification of equipment which will ensure that electronic identification systems in use are qualified to do so.

Chapter 5 – Process Control

5.15.1

Recipients shall receive ABO group-compatible Red Blood Cell components, or ABO group-specific Whole Blood. Standard 5.15.4 applies.

The verbiage “or low titer group O Whole Blood (for non group O recipients or for recipients whose ABO group is unknown)” was removed.

Rationale

The committee elected to edit standard 5.15.1 to ensure that it was understood that the use of group O Whole Blood should only be in trauma or emergent situations. As previously written, the standard could be interpreted to state that this product could be used at all times. The section of standards 5.27 that discusses low titer group O Whole Blood has also been edited.

Chapter 5 – Process Control

5.27.2

If low-titer group O Whole Blood is used, the BB/TS shall have policies, processes, and procedures to define:

1.Low-titer threshold.

2.Use of low-titer group O Whole Blood.

3.Maximum volume/units allowed per event.

Standard 5.15.4 applies.

Rationale

The committee elected to create a new subnumber 1 for standard 5.27.2 which requires blood banks and transfusion services define "low titer threshold" for the use of group O whole blood.

Chapter 5 – Process Control

5.28.2

Transfusions shall be prescribed and administered under medical direction by an ***authorized health professional***.

Rationale

The committee edited this standard for clarity as there is an expanding scope of providers beyond medical doctors who can prescribe and administer blood products.

Chapter 5 – Process Control

Reference Standard 5.1.6A

Item # 22 added which requires the labeling of an apheresis platelet with the actual platelet content when the product contains <3.0 x 10^11 platelets.

Rationale

The committee created new entry #22 for completeness. This was included to mirror the requirements in the component section of chapter 5 (standards 5.7.4 through 5.7.4.26) and to ensure that if platelets are released for transfusion with a count of < 3.0 x 1011 that the actual platelet count be displayed.

Chapter 5 – Process Control

Reference Standard 5.1.8A

Items #30 and #31 were created for Pathogen Reduced Cryoprecipitated Fibrinogen Complex and Pathogen Reduced Cryoprecipitated Fibrinogen Complex (after thawing).

Chapter 5 – Process Control

Reference Standard 5.4.1A

The committee created a new entry specifically geared around the inclusion of the new monkeypox and smallpox vaccines.

Chapter 5 – Process Control

Reference Standard 5.4.1A

The committee added a new entry to reference standard 5.4.1A concerning the receipt of SARS COV2 vaccines and any associated deferrals for clarity. The content of the entry matches the requirements set forth by the FDA in September 2020 that was also included as a separate guidance released by the committee in September 2020. The guidance can be found on the AABB website.

Chapter 7 – Deviations, Nonconformances, and Adverse Events

7.5.2.2

The BB/TS shall have a process for evaluation for suspected nonhemolytic transfusion reactions including, but not limited to, febrile reactions, possible bacterial contamination, and ***pulmonary reactions*** (including TRALI and TACO).

Rationale

The committee has expanded standard 7.5.2.2 by including the clause "pulmonary reactions" to the content. These reactions, specifically TRALI and TACO are becoming far more frequent and the committee wishes to recognize this.

Chapter 7 – Deviations, Nonconformances, and Adverse Events

7.5.2.2.1

The BB/TS shall have policies, processes, and procedures for referral for microbial testing for bacterial contamination.

Rationale

The committee created new standard 7.5.2.2.1 which was included for completeness. This standard ensures the Standards are consistent with the most recent FDA guidance on microbial testing for bacterial contamination.

Chapter 10 – Facilities and Safety

10.3

Handling **of Blood, Components, Tissue, and Derivatives**

Blood, blood components, tissue, and derivatives shall be handled and discarded in a manner that minimizes the potential for human exposure to infectious agents.

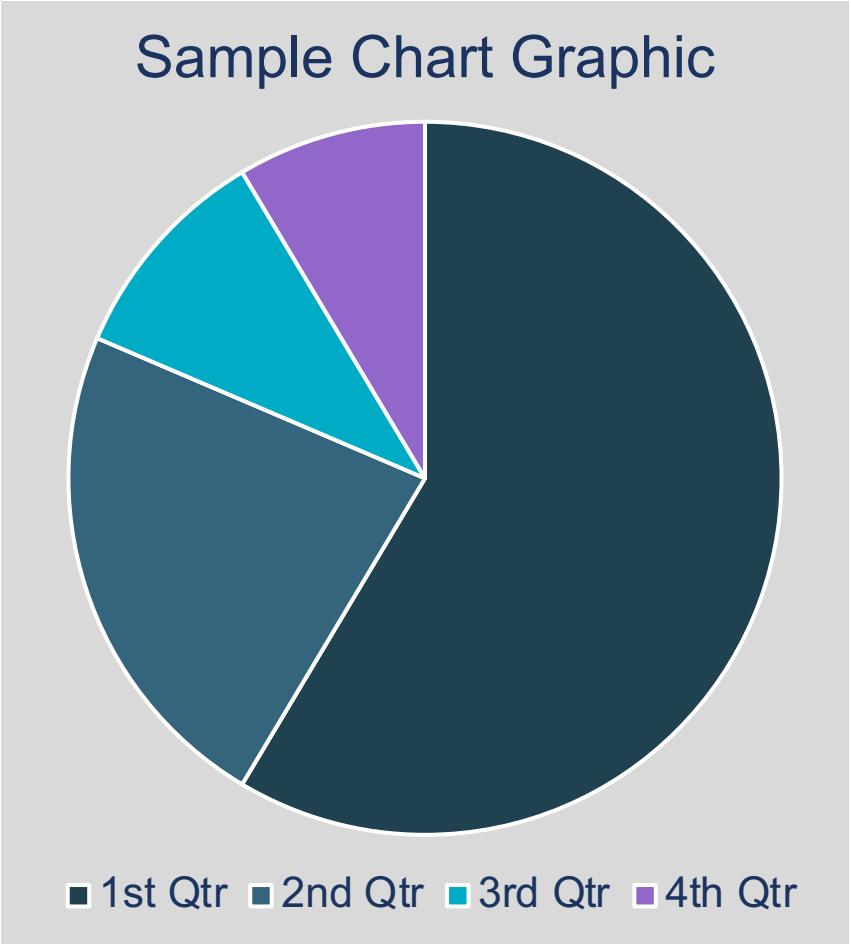
Rationale

The committee edited the title of this standard by replacing the term "discard" with "handling". The committee feels that this term better reflects the content of the standard. The committee felt that the term "discard" did not accurately represent the content of the standard.

Questions?

Additional questions can be directed to standards@aabb.org.

THANK YOU!!


Sample Chart Graphic
1st Qtr
2nd Qtr
3rd Qtr
4th Qtr