32nd Edition of the *AABB Standards for Blood Banks and Transfusion Services*

32nd Edition of the *AABB Standards for Blood Banks and Transfusion Services* are effective April 1, 2020. The following is a summary of the significant changes as they relate to Transfusion Services.

****Note**: not every change is included in this summary. Refer to the "Crosswalk between the 31st & 32nd Editions of Standards" for a complete list of changes & identification of new standards (beginning of pg 109 of 32nd Edition of *AABB Standards for Blood Banks and Transfusion Services*).

Bold indicates (new) added verbiage to the standard

1.0 Organization

- 1.4 Transfusion service shall have continuity plans for potential events that place operations at risk. (New)
- 1.4.1 Transfusion service shall have a policy to address product inventory shortages. (New)

3.0 Equipment

- 3.5.2 #4 Investigation of the malfunction, failure, or adverse event, and **a determination** if other equipment is similarly impacted.
- 3.9.6 A process shall be in place to ensure that the facility has measures in place to minimize the risk of an internal or external data breach. (New)

5.0 Process Control

- 5.8.5 – 5.8.7 have been expanded to include the requirement to perform Zika Virus RNA & nucleic acid testing (NAT) for Babesia. Note: Babesia requirement is effective May 10, 2020 & applies to donations collected in states specified by FDA.
- 5.1.8A: Requirements for Storage, Transportation, and Expiration. Table was reorganized to add Platelets Cold Stored, Pathogen Reduced Apheresis Platelets, and Pathogen Reduced Plasma.
- 5.14.2 …If a discrepancy is detected and transfusion is necessary before resolution, only Rh negative Red Blood Cells shall be issued to ~~**females**~~ **patients** of childbearing potential.
- 5.14.5 There shall be two determinations of the recipient's ABO group as specified in 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 using a validated electronic identification system ~~or another process validated to reduce the risk of misidentification~~.

  *Note: 5.14.1 includes testing the serum or plasma for expected antibodies with A_1 & B reagent red cells
- 5.15.2.1 The transfusion service shall have a policy for the use of Rh-positive red-cell-containing components in Rh-negative recipients **including during times of critical inventory levels**. **Standards 1.4 & 1.4.2 apply.**
- 5.16.2.1.1 For facilities subject to United States laws and regulations, the computer system shall be an FDA 510(k) cleared medical device. (New)
- 5.19.3 BB/TS shall have a policy regarding the use of washed cellular products. (New)

- 5.19.7 BB/TS shall have a policy regarding indications for specially selected platelet requirements, where applicable, including but not limited to:
    1) HLA-matched, crossmatch-compatible, HLA antigen-negative, and HPA antigen-negative platelets.
    2) The use of cold stored platelets.
- 5.22 The BB/TS shall have a policy for the **visual** inspection of blood, blood components, tissue, and derivatives at the time of issue.
- 5.27.1.1 If low-titer group O Whole Blood is used, the BB/TS shall define low-titer group O Whole Blood and shall have policies, processes and procedures for:
    1) The use of low-titer group O Whole Blood.
    2) The maximum volume/unites allowed per event.
    ~~3) Patient monitoring for adverse effects.~~
- 5.28.7 Specific written instructions concerning possible adverse events**, including emergency medical care contacts**, shall be provided to the patient or a responsible caregiver when direct medical observation or monitoring of the patient will not be available after transfusion.
- 5.29.1 The patient's medical record shall include the transfusion order, documentation of patient consent, the component name, the donation identification number, the donor ABO/Rh type, the date and time of transfusion, **vital signs taken at facility defined intervals including** pre, **during** and post-transfusion, ~~vital signs~~ the amount transfused, the identification of the transfusionist, and , if applicable, transfusion-related adverse events.

8.0 Assessments: Internal and External

- 8.2 Transfusing facilities shall have a peer-review program that monitors and addresses transfusion practices for all categories of blood and blood components. The following shall be monitored:
    7) **Appropriateness of use, including the use of group O/O Rh (D)-negative RBCs and AB plasma.** (consistent with the AABB Bulletin #19-02)

10.0 Facilities and Safety

- 10.1.1 Where liquid nitrogen is stored, specific hazards shall be addressed. (New)
- 10.1.1.1 Blood banks and transfusion services with liquid nitrogen tanks shall have a system in place to monitor oxygen levels and an alarm system set to activate under conditions that will allow action to be taken. (New)
- 10.1.1.1.1 Oxygen alarm activation shall require personnel to investigate and document the condition activating the alarm and to take immediate corrective action as necessary. (New)