



Advancing Transfusion and
Cellular Therapies Worldwide

Association Bulletin #16-05

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To: AABB Members

From: Donna Regan, MT(ASCP)SBB – President
Miriam A. Markowitz – Chief Executive Officer

Re: Changes to the 30th edition of *Standards for Blood Banks and Transfusion Services*

Association Bulletins, which are approved for distribution by the AABB Board of Directors, may include announcements of standards or requirements for accreditation, recommendations on emerging trends or best practices, and/or pertinent information. This bulletin describes three changes to the 30th edition of *Standards for Blood Banks and Transfusion Services (BBTS Standards)*. These changes are:

- 1) Revisions to Requirements for Prevention of Transfusion-Associated Graft-vs-Host Disease
- 2) Extended Expiration Date for Apheresis Platelets Leukocytes Reduced
- 3) Adjusted Effective Date for Standards Affected by FDA Final Rule (issued May 22, 2015)

Items 1 and 2 above were presented to the membership as proposed interim standards and underwent a public comment period from January 29 – February 29, 2016. They are now approved by the AABB Board of Directors and are effective April 1 for the 30th edition of *BBTS Standards*. Item 3 reflects the Board's approval to extend the implementation date to May 23 for specific standards affected by the FDA Final Rule. Item 3 highlights standards for which the implementation date has been adjusted; these standards have a new effective date of May 23, 2016.

1) Revisions to Requirements for Prevention of Transfusion-Associated Graft-vs-Host Disease

Summary

Standard 5.19.3 has been expanded and a new Standard 5.19.3.1 has been added. The newly renumbered Standard 5.19.3.2 (formerly 5.19.3.1) has been expanded. These changes are intended to allow for the use of certain pathogen reduction technologies to prevent transfusion-associated graft-vs-host disease.

The standards read as follows:

5.19.3 ~~Irradiation~~ Prevention of Transfusion-Associated Graft-vs-Host Disease

The BB/TS shall have a policy regarding the ~~transfusion of irradiated components~~ **prevention of transfusion-associated graft-vs-host disease**.

5.19.3.1 **Methods known to prevent transfusion-associated graft-vs-host disease shall be used, and include either irradiation or the use of a pathogen reduction technology that is known to inactivate residual leukocytes and is cleared or approved by the FDA or Competent Authority.**

5.19.3.2 At a minimum, cellular components shall be ~~irradiated when~~ **prepared by a method known to prevent transfusion-associated graft-vs-host disease when:**

- 5.19.3.2.1 A patient is identified as being at risk for transfusion-associated graft-vs-host disease.
- 5.19.3.2.2 The donor of the component is a blood relative of the recipient.
- 5.19.3.2.3 The donor is selected for HLA compatibility, by typing or cross-matching.

Background

The BBTS Standards Program Unit, or BBTS SPU, reviewed the effectiveness of certain pathogen reduction technologies and determined that they would be as effective as traditional irradiation and that expanding standard 5.19.3 and creating new standard 5.19.3.1 would ensure that the BB/TS Standards remained in line with the AABB’s membership’s thinking on the matter.

2) Extended Expiration Date for Apheresis Platelets Leukocytes Reduced

Summary

A revision to Reference Standard 5.1.8A in the 30th edition of *BBTS Standards* allows facilities to extend the expiration date for Apheresis Platelets Leukocytes Reduced to 7 days. Additional criteria in order to extend the expiration date for this component are explained in a footnote.

The standard reads as follows:

Reference Standard 5.1.8A—Requirements for Storage, Transportation, and Expiration ¹					
Item No.	Component	Storage	Transport	Expiration ²	Additional Criteria
Platelet Components					
21	Apheresis Platelets Leukocytes Reduced	20-24 C with continuous gentle agitation	As close as possible to 20-24 C ³	Open system: within 4 hours of opening the system Closed system: 5 days or 7 days⁴	Maximum time without agitation: 24 hours

¹Products may be pathogen reduced if approved by the FDA.

²If the seal is broken during processing, components stored at 1 to 6 C shall have an expiration time of 24 hours, and components stored at 20 to 24 C shall have an expiration time of 4 hours, unless otherwise indicated. This expiration shall not exceed the original expiration date or time.

³ 21 CFR 600.15(a)

⁴ **May be stored for 7 days only if: 1) storage containers are cleared or approved by FDA for 7-day platelet storage and 2) labeled with the requirement to test every product stored beyond 5 days with a bacteria detection device cleared by FDA and labeled as a “safety measure.”**

Background

This revised expiration timeframe is consistent with the recent availability of FDA-cleared or -approved safety measures and collection/storage bags that allow for an outdate of 7 days for Apheresis Platelets Leukocytes Reduced. Currently culture-based bacterial detection devices labeled as a “safety measure” for the extension of dating beyond day 5 are not available. Facilities planning to extend the outdate for this component should contact their FDA consumer safety officer to ensure they are using the appropriate implementation route/reporting category.

3) Adjusted Effective Date for Standards Affected by FDA Final Rule

Summary

The AABB Board of Directors has approved a recommendation from the BBTS SPU to delay the effective date for certain requirements in the 30th edition of *BBTS Standards* that are directly affected by the FDA’s forthcoming “Final Rule for Requirements for Blood and Blood Components Intended for Transfusion or for Further Manufacturing Use.” The Final Rule goes into effect on May 23, 2016, whereas the *BBTS Standards* goes into effect on April 1, 2016. The AABB Board of Directors approved a delay of the effective date for the following standards until May 23, 2016.

5.4.1.1 If the donor is deferred or if the donation is determined to be unsuitable, the donor’s record will identify the donor as ineligible to donate and the donor will be notified of the reason for deferral.

5.4.2.1 If the collection facility determines that additional clarification or information is needed to evaluate donor eligibility, this information shall be obtained within 24 hours of collection.

5.5.2.3 Plasmapheresis donors shall be weighed at each donation.

5.6.7.1 Units drawn as therapeutic phlebotomies shall not be used for allogeneic transfusion unless:

- 2) The collection is for hereditary hemochromatosis or a condition with a collection procedure that has been approved by the FDA.

Reference Standard 5.1.6A—Requirements for Labeling Blood and Blood Components				
Item No.	Labeling Item	Collection or Preparation	Final Component	Pooled
12	For whole blood platelet, name of drug taken by donor that adversely effects platelet function ⁸	NR	R	R

⁸ 21 CFR 640.21 (c)

Reference Standard 5.4.1A—Requirements for Allogeneic Donor Qualification		
Category	Criteria/Description/Examples	Deferral Period
5) Hemoglobin/ Hematocrit	<ul style="list-style-type: none"> • ≥ 12.5 g/dL, $\geq 38\%$ women; 13.0 g/dL, $\geq 39\%$ men; blood obtained by earlobe puncture shall not be used for this determination • For double Red Blood Cell collections, follow instrument operator’s manual 	
6) Weight	<ul style="list-style-type: none"> • All donors shall weigh a minimum of 50 kg (110 lb) • For plasmapheresis collections, the donor shall be weighed. • For all other product collections, self-reported weight is acceptable. 	
11) Xenotransplantation	Receipt of any cells, tissues, or organs from a nonhuman animal source. Note: Nonliving biological products or materials from nonhuman animals, such as porcine or bovine heart valves and porcine insulin, are acceptable.	Permanent

Background

In May 2015, FDA issued a final rule that updated Part 600 of Title 21, the Code of Federal Regulations, dealing with blood collection and manufacturing. The Final Rule becomes effective on May 23, 2016. Most of the changes necessary to meet the new regulations are reflected in the 30th edition of AABB's *BBTS Standards*, which has an effective date of April 1, 2016.

Due to the operational issues associated with implementation and to allow for consistency with the FDA implementation date, AABB will extend the effective date for the standards listed under item (3) in this Association Bulletin to the May 23, 2016 date. All other standards in the 30th edition become effective on April 1, 2016.

Facilities assessed between April 1 and May 23, 2016 may be asked by AABB assessors to provide a plan for the implementation of these standards by May 23.