



Association Bulletin #23-05

Date: December 21, 2023

To: AABB Members

From: Aaron A. R. Tobian, MD, PhD – AABB President
Debra BenAvram – Chief Executive Officer

Re: Interim Standards for the 33rd edition of *Standards for Blood Banks and Transfusion Services*

Association Bulletins provide a mechanism for the publication of documents that the Board of Directors has approved for distribution to individual and institutional members, such as:

- Standards adopted after the publication of the most recent edition of *Standards*.
- Statements of AABB policy intended for distribution to members.
- Guidance, recommendations, and reports that have been developed by AABB Committees or National Office staff for distribution to members.

Summary

This bulletin describes updates to the 33rd edition of *Standards for Blood Banks and Transfusion Services* based on the Food and Drug Administration (FDA) Guidance for Industry, “Alternative Procedures for the Manufacture of Cold-Stored Platelets Intended for the Treatment of Active Bleeding when Conventional Platelets Are Not Available or Their Use Is Not Practical” issued June 23, 2023. It includes updating Standard 5.6.5.1; creating new Standards 5.6.5.2, 5.6.5.2.1, 5.6.5.2.2, and 5.6.5.2.2.1; and providing updates to Reference Standard 5.1.8A, Requirements for Storage, Transportation, and Expiration. To read more on the FDA Guidance for Industry, [please click on this link](#).

Background

The FDA Guidance for Industry provides information surrounding the manufacture, process validation, quality control, storage and handling of these products.

These interim standards were made available for 30-day public and member comment from September 13 to October 13, 2023.

The updates to the 33rd edition of *Standards for Blood Banks and Transfusion Services* are listed below, including the rationale for their creation.

Please note that the edited standards are indicated by strike-through and bold formatting.

Final Interim Standards

5.6.5.1 Whole Blood ~~and Apheresis Platelets~~ intended for room temperature processing ~~and Apheresis Platelets~~, shall be transported ~~and stored~~ in a manner intended to cool the blood and Apheresis Platelets toward a temperature range of 20 to 24 C.

5.6.5.2 Apheresis platelets intended for cold storage without pathogen reduction shall be placed at 1-6 C within 4 hours from the end of collection.*

*FDA Guidance for Industry, Alternative Procedures for the Manufacture of Cold-



Stored Platelets Intended for the Treatment of Active Bleeding when Conventional Platelets Are Not Available or Their Use Is Not Practical (June 2023)

- 5.6.5.2.1** **If the apheresis product intended for cold storage without pathogen reduction will arrive at the processing facility within 4 hours of collection, the product may be transported in a manner intended to cool the blood and Apheresis Platelets toward a temperature range of 20 to 24 C.**
- 5.6.5.2.2** **If the apheresis product intended for cold storage without pathogen reduction will not arrive at the processing facility within 4 hours of collection, the product shall be placed at 1-6 C within 4 hours from the end of collection.**
- 5.6.5.2.2.1** **If the apheresis product intended for cold storage without pathogen reduction has been placed at 1-6 C, it shall be transported in a qualified container having sufficient refrigeration capacity to maintain a temperature range of 1 to 10 C.**

Summary of Changes and Additions to Standards 5.6.5.1 – 5.6.5.2.2.1

Standard 5.6.5 and the standards that follow cover the requirements for temperature during transport from the collection site to the processing site. The intent of the new wording for 5.6.5.1 is that whole blood and apheresis platelets that are intended for room temperature processing should be cooled toward a temperature range of 20-24C. This category includes apheresis platelets intended for processing by the Intercept pathogen reduction process, which is performed at room temperature.

The intent of the new Standards 5.6.5.2.1 and 5.6.5.2.2 is to clarify that apheresis platelets intended for cold storage without pathogen reduction must be placed at 1-6 C within 4 hours of collection wherever they are at that time, and thereafter must be kept cold. Some collection facilities may be able to transport these products to their processing facilities within 4 hours of collection. Facilities that cannot ensure the products will be at their processing facility within 4 hours will need to refrigerate the products at their collection site before transporting the products to the processing facility. The Blood Banks/Transfusion Services Standards Committee created these new standards to clarify the requirements:

1. If a product will be transported to the processing facility within the 4-hour time frame, it would be permissible to use the target temperature range of 20-24C that is used for standard platelet products (Standard 5.6.5.2.1).
2. If the product would not be transported to the processing facility within the 4-hour time frame, the product should be placed at 1-6 C within the 4 hours, (Standard 5.6.5.2.2).
3. When the products that have been placed at 1-6 C at the collection site are subsequently transported, the transport temperature shall be maintained within the range of 1-10 C (Standard 5.6.5.2.2.1)

**Reference Standard 5.1.8A—Requirements for Storage, Transportation, and Expiration¹**

Item No.	Component	Storage	Transport ²	Expiration ³	Additional Criteria
14 23	Apheresis Platelets Cold Stored ⁹	1-6 C (agitation optional)	1-10 C	14 days	<u>Suspended in 100% Plasma or platelet additive solution</u>
24	<u>Apheresis Platelets Pathogen Reduced Cold Stored⁹</u>	<u>1-6 C (agitation optional)</u>	<u>1-10 C</u>	14 days	<u>Suspended in 100% Plasma or platelet additive solution</u>
25	<u>Whole-Blood-Derived Platelets Cold Stored</u>	<u>1-6 C (agitation optional)</u>	<u>1-10 C</u>	<u>As specified in the instructions for use by the blood collection, processing, and storage system approved or cleared for such use by FDA or Competent Authority</u>	

¹For blood pressure, see 21 CFR 630.10(f)(2); for pulse, see 21 CFR 630.10(f)(4).

²FDA Guidance for Industry and FDA Review Staff: Collection of Platelets by Automated Methods (December 2007).

³Medication Deferral List current version at <https://www.aabb.org/news-resources/resources/donor-history-questionnaires/blood-donor-history-questionnaires>.

⁹**FDA Guidance for Industry: Alternative Procedures for the Manufacture of Cold-Stored Platelets Intended for the Treatment of Active Bleeding when Conventional Platelets Are Not Available or Their Use Is Not Practical (June 23, 2023)**

~~Applies to modified, unmodified, apheresis, and whole blood derived platelet products~~

Summary of Changes and Additions to Reference Standard 5.1.8A

Reference Standard 5.1.8A provides storage and transport requirements for products after receipt by the processing facility. This standard has been edited where appropriate based on the changes and additions to Standards 5.6.5.1 – 5.6.5.2.2.1.

Entry #14 has been moved to appear as new #23 with new entries #24 and #25.

Entry #23's component nomenclature has been updated to mirror the language in the edited and added standards cited above. The expiration time and additional criteria for apheresis platelets mirror the language in the recently released FDA Guidance.



Entry #24 reflects specifications for pathogen reduced cold stored apheresis platelets in the FDA Guidance.

Entry #25 is included to address regions that have storage bags approved for cold storage of whole blood derived platelets.

Conclusion

The interim standards listed above will be updated in the AABB Standards Portal and should be implemented by AABB-accredited facilities immediately.

Please note, facilities that do not collect, use, store, or transport Cold Stored Platelets are not required to implement these standards, nor will they be assessed against them. These standards have also been included in the forthcoming 34th edition of Standards for Blood Banks and Transfusion Services.

Facilities that have any questions concerning the interim standards, or their implementation can be directed via email to standards@aabb.org.