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Association for the Advancement of Blood & Biotherapies

Association Bulletin #22-04

Date: September 9, 2022

To: AABB Members

From: Dana Devine, PhD – 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 have been approved by the Board of Directors for distribution to individual and institutional members, such as:

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

This bulletin describes updated requirements included in Standard 5.7.2.1.1, new Standard 5.7.2.1.1.1, and the deletion of Standard 5.7.2.1.3 in the 33rd edition of *Standards for Blood Banks and Transfusion Services* (*BB/TS Standards*).

On April 11, 2022, the AABB issued interim standards for a 30-day public comment period through May 2, 2022. During that initial comment period, the Blood Banks/Transfusion Services Standards Committee (BB/TS SC) received a number of comments that required the committee to consider edits to the interim standards presented, which would require further public and member input. With that, the AABB issued a revised version of the interim standards on June 2, 2022, for an additional 30-day public comment period, which concluded on July 2, 2022. Following the comment periods, the BB/TS SC reviewed the comments received and adjusted the interim standards where appropriate.

Background

When the 33rd edition of *BB/TS Standards* became available to the membership in the Standards Portal, the Standards Department began to receive queries concerning new Standard 5.7.2.1.3. The queries articulated the reality that due to a lack of expiration times included in some manufacturers' instructions for certain storage containers (including but not limited to bags and transfer packs), many products would have to be discarded because of the 4-hour expiration requirement.

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In creating this new standard, the BB/TS SC intended to close a loophole whereby products such as platelets are aliquoted into a container not approved for storage of this component (such as a syringe) before administration to the patient. The BB/TS SC reasoned that in the absence of labeling indicating the container had been approved for storage of the component and lacking manufacturer's instructions indicating expiration time for this use (storage), adding a 4-hour expiration time would be appropriate.

Rationale
During the initial 30-day comment period on the proposed interim standards, the committee heard from many members that further clarity was needed surrounding the expiration date/time. The committee, as a result, rewrote Standard 5.7.2.1.1 in a manner that requires that facilities follow the expiration date and time set by the FDA or Competent Authority before welding begins if the container is approved for storage of the specific component. "Standard 5.1.4 applies" refers to the requirement that facilities follow manufacturers' instructions; for example, instructions for platelet storage containers may include volume and/or content constraints. In addition, facilities are encouraged to communicate with their container suppliers to obtain any component storage recommendations for the container.

The committee also created new Standard 5.7.2.1.1.1 to ensure that in situations where individuals are using a container that is not approved for storage by the FDA or Competent Authority, that expiration time for the component be either 4 hours or a time defined and validated by the facility. Again, comments received indicated that clarity was needed in this case. Finally, the BB/TS SC deleted Standard 5.7.2.1.3, which required an expiration time of 4 hours in the case where no storage time was specified in the package insert, or where a package insert was not available.

5.7.2.1.1 If the integrity of the weld is complete, **and** the **container in use is approved for storage of the specific blood component by the FDA or Competent Authority, then** the expiration date/time **before welding shall apply**. ~~assigned in accordance with the FDA- or Competent Authority-approved package insert for the storage container.~~

Standard 5.1.4 applies.

5.2.7.1.1.1 If the container in use is not approved for storage of the component by the FDA or Competent Authority, the component shall have an expiration time of 4 hours or as defined and validated by the facility.

5.7.2.1.2 If the integrity of the weld is incomplete, the container shall be considered an open system and may be sealed and used with a

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component expiration as indicated in Reference Standard 5.1.8A, Requirements for Storage, Transportation, and Expiration.

~~**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 the original container.~~

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

In the case where your facility may have any questions concerning the interim standards, or their implementation can be directed via email to standards@aabb.org.