



Association Bulletin #23-04

Date: September 1, 2023

To: AABB Members

From: Brian Gannon, MBA – President
Debra BenAvram – Chief Executive Officer

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

Association Bulletins provide a mechanism for the publication of documents 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 developed by AABB Committees or National Office staff for distribution to members.

Summary

This bulletin describes emergent standards to Reference Standard 5.4.1A, Donor Qualification, in the 33rd edition of *Standards for Blood Banks and Transfusion Services (BB/TS Standards)*, for donor eligibility criteria and associated donor deferrals related to hepatitis risk assessment. The update to entry 15 of the Reference Standard 5.4.1A shifts the deferral period from 12 months to 3 months for donors who have lived with or had sexual contact with an individual with acute or chronic hepatitis B or symptomatic hepatitis C. This change was made in accordance with shortened FDA deferral periods.

Background

During the revision and review process for the Donor History Questionnaire, version 4.0 (DHQ v4.0), FDA shortened the deferral period, confirming “that revising the deferral periods for hepatitis risk factors to 3 months, consistent with deferrals for HIV risk factors, is expected to maintain the safety of blood components because nucleic acid testing for HBV and HCV can detect the viruses well within a 3-month period following initial infection.” This decision was formalized by [FDA’s May 2023 Level 2 guidance](#) recognizing DHQ v4.0 as “acceptable for use in screening donors of blood and blood components. These documents are consistent with FDA requirements and recommendations for donor eligibility.”

AABB notes that this change in deferral period is possible because all regulatory references to a 12-month deferral for hepatitis risk were removed in 2015. FDA removed the regulations in 21 CFR 640.3 in the [May 2015 final rule](#). Since the final rule became effective in May 2016, FDA has not issued recommendations specifying the deferral period for hepatitis risk. Regulations in



[21 CFR 630.10\(e\)\(1\)\(v\)](#) require donor assessment for intimate contact with risk for relevant transfusion-transmitted infections but do not establish specific deferral timeframes. This change also should assist facilities currently implementing (DHQ v4.0).

To facilitate this change, the AABB is issuing this update to Reference Standard 5.4.1A, line 15.

Please note that the edited standard is indicated by strike-through and bold formatting.

33rd Edition of *Standards for Blood Banks and Transfusion Services*
Additions and Update

Category	Criteria/Description/Examples	Deferral Period
15) Relevant Transfusion-Transmitted Infections ⁷	<ul style="list-style-type: none"> • Sexual contact or lived with an individual who: <ul style="list-style-type: none"> - Has acute or chronic hepatitis B (positive HBsAg test, HBV NAT) - Has symptomatic hepatitis C 	12 3 months

To assist facilities in their implementation of the updated *Standards for Blood Banks and Transfusion Services*, as well as the Donor History Questionnaire version 4.0 and Accompanying Materials, AABB has launched an Individual Donor Assessment Library on the [AABB website](#) and created an [Individual Donor Assessment and DHQ v4.0 Implementation Toolkit](#).