



Association Bulletin #23-03

Date: June 9, 2023

To: AABB Members

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

Re: Emergent 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.

This bulletin describes updates and changes requirements to Reference Standard 5.4.1A, Donor Qualification, in the 33rd edition of *Standards for Blood Banks and Transfusion Services (BB/TS Standards)*, updating the requirements concerning reducing the risk of human immunodeficiency virus (HIV) transmission. **The updates and changes to Reference Standards 5.4.1A that appear below are emergent standards and may be implemented immediately. However, to remain in conformance with the 33rd edition of *Standards for Blood Banks and Transfusion Services*, the changes listed below must be in place by January 1, 2024.**

On Thursday, May 11, 2023, the Food and Drug Administration (FDA) issued new guidance, “FDA Guidance for Industry: Recommendations for Evaluating Donor Eligibility Using Individual Risk-Based Questions to Reduce the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products,” which supersedes the previous guidance issued by the FDA in August of 2020, “FDA Guidance Industry: Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products.” To read more on the FDA’s review of the available science and decision to update the guidance, please [click on this link](#).

Based on the newly released FDA Guidance update concerning individual donor risk assessment, AABB is making changes to the *BB/TS Standards* to add requirements to the drug therapy and specific medication section (row 9) of Reference Standard 5.4.1A, as well as the relevant transfusion-transmitted infections section (row 15). In addition, the language for some standards related to blood contact, tattoos, skin piercing, and drug injection was modified to align with wording in the Donor History Questionnaire v4.0 (DHQ v4.0) recently accepted by FDA and consistent with the [new donor eligibility recommendations](#).

These changes fall into the following categories:

- 1) Deferrals associated with individuals who have taken medications to prevent or treat HIV infection.
- 2) Deferrals based on sexual contact history.



- 3) Revisions to the language for deferrals related to blood contact, tattoos, skin piercing, and drug injection.

Summary of Additions to Reference Standard 5.4.1A

1) The updates in the reference standard communicated in this Association Bulletin add deferral periods for the use of medication to prevent or treat HIV infection.

- Potential donors who take oral medications to prevent HIV infection (ie, PrEP or PEP) are now deferred from donation for 3 months.
- Potential donors who have injected medication to prevent HIV infection (ie, long-acting antiviral PrEP or PEP) are now deferred from donation for 2 years.
- Potential donors who have taken any medication to treat HIV infection will remain permanently deferred from donation.
- Potential donors who have ever had a positive test result for HIV infection are now permanently deferred, whereas previously donors were deferred for an indefinite period.

2) The updates in the reference standard communicated in this Association Bulletin add deferral periods based on sexual contact history as indicated below:

- Potential donors who have had sexual contact with a new sexual partner in the past 3 months **and** anal sex in the past 3 months are now deferred for 3 months.
- Potential donors who have had sexual contact with more than one sexual partner in the past 3 months **and** have had anal sex in the past 3 months are now deferred for 3 months.
- Potential donors who have had sexual contact with an individual who, in the past 3 months, has received money, drugs, or other payment for sex are now deferred for 3 months.
- Potential donors who have had sexual contact with an individual in the past 3 months and have used needles to inject drugs, steroids, or anything not prescribed by their doctor in the past 3 months are now deferred for 3 months.

3) The updates in the reference standard communicated in this Association Bulletin revise the criteria for individuals who have had ear or body piercing.

- Potential donors who have had contact with the blood of another individual through percutaneous inoculation, such as a needlestick or contact with a donor's open wounds, remain deferred for 3 months.
- Potential donors who have gotten ear or body piercings continue to be able to donate blood with no deferral if the piercing was done using single-use equipment.
 - Donors who do not meet the criteria above are deferred for 3 months.

Note, the updates and changes to Reference Standards 5.4.1A that appear below are emergent standards and may be implemented immediately. However, to remain in conformance with the 33rd edition of *Standards for Blood Banks and Transfusion Services*, the changes listed below must be in place by January 1, 2024.



In line with the new FDA guidance and changes to the *BB/TS Standards*, AABB’s DHQ version 4.0 and Accompanying Materials have been recognized by the Food and Drug Administration and can be [accessed here](#).

To assist facilities in their implementation of the updated *BB/TS Standards* and 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](#).

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

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

Reference Standard 5.4.1A Requirements for Allogeneic Donor Qualification

Category	Criteria/Description/Examples	Deferral Period
9) Drug Therapy	<ul style="list-style-type: none"> • <u>Taken any medication by mouth (oral) to prevent HIV infection (i.e., PrEP or PEP)</u> 	<u>3 months</u> ⁴
	<ul style="list-style-type: none"> • <u>Received any medication by injection to prevent HIV infection (i.e., long-acting antiviral PrEP or PEP)</u> 	<u>2 years</u> ⁴
	<ul style="list-style-type: none"> • <u>Taken any medication to treat HIV infection</u> 	<u>Permanent</u> ⁴

Category	Criteria/Description/Examples	Deferral Period
15) Relevant Transfusion-Transmitted Infections ⁷	<ul style="list-style-type: none"> • Present or past clinical or laboratory evidence of infection with HIV, HCV,¹² HTLV, or <i>T. cruzi</i> or as excluded by current FDA regulations and recommendations for the prevention of HIV transmission by blood and components¹³ 	Indefinite
	<ul style="list-style-type: none"> • <u>Ever had a confirmed positive test result for HIV infection</u>⁴ 	<u>Permanent</u>
	<ul style="list-style-type: none"> • Use of a needle to administer inject drugs, 	3 months



	<p><u>steroids or anything not prescribed by their doctor</u></p>	
	<ul style="list-style-type: none"> • <u>Contact with blood of another individual through percutaneous inoculation such as a needle stick or through contact with a donor's open wound or mucous membranes exposure to blood.</u> 	3 months
	<ul style="list-style-type: none"> • Nonsterile skin penetration <ul style="list-style-type: none"> — With instruments or equipment contaminated with blood or body fluids other than the donor's own - Includes tattoos or permanent make-up unless applied by a state-regulated entity with sterile needles and ink that has not been reused • Tattoo, ear, or body piercing <ul style="list-style-type: none"> - For tattoos, no deferral if the tattoo was applied by a state-regulated entity with sterile needles and non-reused ink. - <u>For ear or body piercings, no deferral if the piercing was done using single-use equipment.</u> 	3 months
	<ul style="list-style-type: none"> • Sexual contact with an individual with <u>who ever had a positive test result for HIV infection or at high risk of HIV infection</u> 	3 months ⁴
	<ul style="list-style-type: none"> • <u>Sexual contact with an individual who in the past 3 months:</u> <ul style="list-style-type: none"> -has received money, drugs, or other payment for sex. -has used needles to inject drugs, steroids or anything not prescribed by their doctor. 	<u>3 months</u> ⁴
	<ul style="list-style-type: none"> • <u>Received money, drugs, or other payment for sex.</u> 	<u>3 months</u> ⁴



	<ul style="list-style-type: none"> • <u>Have had a new sexual partner in the past 3 months and have had anal sex in the past 3 months.</u> 	<u>3 months</u> ⁴
	<ul style="list-style-type: none"> • <u>Have had more than one sexual partner in the past 3 months and have had anal sex in the past 3 months.</u> 	<u>3 months</u> ⁴

⁴ **FDA Guidance for Industry: Recommendations for Evaluating Donor Eligibility Using Individual Risk-Based Questions to Reduce the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products** ~~Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products (May 2023 August 2020)~~