Significant Changes and Response to Comments Received to the 33rd edition of Standards for Blood Banks and Transfusion Services

Please note that public comments that were submitted address the proposed 33rd edition of BBTS Standards, and not the final version. The changes are best understood when the proposed Standards are compared to the final published version. The committee has elected to make the substance of public comments that were submitted a part of this document. Guidance that appears with the 33rd edition of BBTS Standards in the Standards Portal provides a more in-depth look at the additions, deletions and changes and the rationales behind those decisions that what appears below.

Standard	SC/RC	Comment	Change made?	Outcome
1.1.1	SC	NA	NA	The committee added the clause "facility defined" to the standard as it related to continuing education for clarity. This addition is in line with what is occurring already in accredited facilities and in practice closes a gap not addressed in the Standards.
1.7	SC	NA	NA	The committee added a cross-reference to standard 4.2 for completeness. Standard 4.2 requires that all agreements include defined customer expectations, which is the focus of standard 1.7.
3.5.2, #6	SC	NA	NA	The committee added a reference to 21 CFR 803.30 to subnumber 6 of the standard for completeness. This requirement details what information concerning medical devices need to be reported to the FDA.
3.8	SC	NA	NA	The committee added a record retention requirement to this standard, and an according entry in Reference Standard 6.2C for completeness. This new record retention requirement ensures that the records surrounding warming devices are maintained. The committee also added a cross-reference to standard 3.5 to this standard. Standard 3.5 is being included as it requires that all equipment be monitored and maintained in accordance with manufacturer's instructions.

3.9.2	SC	NA	NA	The committee expanded standard 3.9.2 to better reflect the realities of current BB/TS operations by including a requirement that "any required forms…be readily available" on site. Having required forms available ensures continuous operations with no significant delay.
3.9.6	SC	NA	NA	The committee edited standard 3.9.6 to ensure that the language included therein parallels the content of the same standard in other AABB Standards. The intent of the standard has not changed.
Chapter 4, 4.0	SC	NA	NA	The title of chapter 4 and standard 4.0 were changed from "Supplier and Customer Issues" to "Suppliers and Customers." The committee felt that the term "Issues" did not reflect the content of the standard.
4.0	SC	NA	NA	The committee edited standard 4.0 for clarity, removing the clause, "…to evaluate the ability of suppliers of critical materials, equipment, and services to consistently meet specified requirements." as it fit more appropriate in standard 4.1. The committee also added a cross-reference to standard 1.7, "customer focus" for completeness.
4.0	RtC	The original meaning of standard 4.0 has been lost with the proposed changes. The primary focus of section 4.0 is on supplier controls. Only 4.2, Agreements, is related to customers. The current standard states "The BB/TS shall have policies, processes, and procedures to evaluate the ability of suppliers … to consistently meet specified requirements." The expectation that suppliers meet specified requirements was moved to standard 4.1, the bolded text was not. Having processes to evaluate the ability and capability of suppliers is the key requirement. Revise standard 4.0 - The BB/TS shall have policies, processes, and procedures to evaluate the ability of suppliers to consistently meet specified requirements and to specify customer expectations.	NO	The committee reviewed this comment and did not feel that a change was needed at this time. The committee feels that the change incorporated does allow for both the customer and supplier to have expectations and that those expectations are met.

4.1.1 (4.1)	SC	NA	NA	The committee elected to remove the clause, "…shall be evaluated to determine their ability to…" from standard 4.2 as a part of the creation of this standard that previously appeared as the second sentence of standard 4.1. The decision once the creation of standard occurred was for completeness.
4.2	SC	NA	NA	The committee edited standard 4.2 for clarity by removing extraneous verbiage. The committee feels that changes would be included as a part of agreements themselves. The second clause, "and shall reflect agreement" was removed as it was deemed extraneous.
5.1.5.2	SC	NA	NA	The committee added the clause, "…stored at 20 – 24 C" at the end of the standard reflecting the content that exists in reference standard 5.1.8A and the understanding that facilities are using cold stored platelets that are not addressed in the FDA Guidance. The inclusion of the FDA Guidance, "FDA Guidance for Industry, Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion (Updated December 17, 2020)" was included for completeness.
5.1.5.2	RC	The standard reads that a TS shall have these methods in place even though most TS rely on their blood providers to have these methods. Can the standard be worded in a manner that incorporates this? Or can the standard be worded in a manner that this standard only applies to TS that collect and process platelet components?	NO	The committee noted this comment but did not feel that a change was needed at this time. The committee notes that there are facilities that perform both functions, blood bank and transfusion service activities. If a facility does not perform this function as a transfusion service, this should be covered in the agreement between the facility and the associated transfusion service. The committee will expand upon this in the next edition of guidance.

5.1.5.2.1	SC	NA	NA	The committee edited standard 5.1.5.2.1 for clarity. The committee removed content from the standard that was deemed redundant to the content in the first sentence of the standard.
5.1.6.3, 5.1.6.3.1	RtC	AABB BB/TS Standards do not address the need to modify and shorten the expiration date of ACD-A/ADSOL (AS-1) units irradiated with a CD ≥ 3000 cGy to 28 days from the date of collection. Hospital facilities irradiating products would not be aware of these special caveats outlined in the collection operator's manuals and direction inserts. Failure to modify the expiration date could result in the transfusion of products with a mean red blood cell recovery below the 75% recovery level required by FDA. Suggestions: 5.1.6.3 General Labeling Requirements 5.1.6.3.1 2) The original label and added portions… The label shall include the applicable items required in Reference Standard 5.1.6A, Requirements for Labeling Blood and Blood Components and be in accordance with the collection set manufacturer's written instructions. 5.7.3.2 Irradiation 5.7.3.2.1 Verification of dose delivery… 5.7.3.2.2 The dose delivery should be evaluated in accordance with the collection set manufacturer's written instructions concerning irradiation of products and appropriate modifications made to expiration dating based on the dosimetry results. Reference Standard 5.1.8A—Requirements for Storage, Transportation, and Expiration Item No Component Storage Transport Expiration Additional Criteria 7 RBCs Irradiated 1-6 C 1-10 C Original expiration or 28 days from date of irradiation, whichever is sooner. ACD-A/ADSOL (AS-1) units irradiated at CD ≥ 3000 cGy, 28 days from date of collection. New RBCs Leukocytes Reduced Irradiated 1-6 C 1-10 C Original expiration or 28 days from date of irradiation, whichever is sooner.	NO	The committee noted this comment but did not feel that a change was needed at this time. The committee notes that standards are not updated when only one product is available to ensure that compliance with the standards is possible. As noted in the comment, the ALEX package insert does provide instructions that are more stringent than what is currently required in the standards, which if individuals follow would allow them to meet to ensure compliance with the existing standards.

		ACD-A/ADSOL (AS-1) units irradiated at CD ≥ 3000 cGy, 28 days from date of collection.		
5.1.6.3.1, #6	SC	NA	NA	The committee removed the clause, "as appropriate" from the subnumber as the inclusion did not provide a benefit to the standard.
5.1.6.5.2	SC	NA	NA	
5.1.6.5.2	RtC	Addition of 'blood or a blood component' - remove the 'a' before 'blood component' to be consistent with the 'a' crossed out before.	YES	The committee noted this comment and made the adjustment, which was a grammatical issue.
5.1.8.1.2	SC	NA	NA	The committee removed the requirement concerning "reagents" from standard 5.1.8.1.3 (more information below) and added it to standard 5.1.8.1.2 for completeness and accuracy.
5.1.8.1.3	RtC/SC	The addition of reagents into the requirement for continuous monitoring is a significant departure from previous standards requirements. We already perform quality control checks on the reagents, and we validate the storage equipment to maintain temperatures. Continuous monitoring of reagents is not required by CAP or CLIA and other AABB standards do not have this requirement. What is the rational for this change? What is the benefit?	YES	In the proposed edition of the 33rd edition of Standards for Blood Banks and Transfusion Services, the committee elected to add, "reagents, tissues and derivatives" to standard 5.1.8.1.3 to mirror the construction of proposed 5.1.8.1.2. However, based on the comment received, noting that all three of these products are not continuously monitored the change was reversed. Reagents has since been added to standard 5.1.8.1.2 and standard 5.1.8.1.3 has since been revised to focus solely on blood and blood components.
5.1.8.1.2, 5.1.8.1.3	RtC	Can these two standards be combined into one? For storage of blood or blood components, reagents, tissues or derivatives, temperature monitoring of the storage equipment as well as open ambient storage areas shall be monitored continuously and recorded at least every 4 hours. Could probably use more thought in crafting it however, something to that nature. I usually review the revisions and make notes over a period of time then get distracted by the day to day operations and unexpected events then forget to submit it. This time I decided to spend the time to do a review and submit what	NO	The committee reviewed this comment but did not feel that a change was appropriate at this time. The committee notes that the content of both standards relate to two distinct concepts, specifically based on where the product in question is stored. In one case a device that has continuous monitoring and the other where it is

		I had on the first go round. My submission wasn't about changes to content or wording but more clerical. I agreed with the updates and reasoning behind them.		stored at ambient storage temperatures and maintained for different time periods.
5.1.8.1.3.1	SC	NA	NA	The committee removed the cross-reference to standard 3.7 that had previously appeared with this standard. The standard included was not relevant in this case.
5.1.8.2.2	RtC	Please add requirements for Transfusion Services who provides blood for ambulance or helicopter emergency service that transfuse, but patient ends up at a different hospital system.	NO	The committee noted this comment but did not feel that the change and creation of these requirements would be too significant to put forth without public and member comment. The committee will consider an addition in the 34th edition of Standards for Blood Banks and Transfusion Services.
5.3.1	SC	NA	NA	The committee added a reference to the 21 CFR 606.40(a)(1), which details what is required to be included in the donor qualification process. The addition was added for completeness.
5.4.4.2	SC	NA	NA	The committee removed the requirement that previously appeared in the standard "Blood obtained by earlobe puncture shall not be used for this determination." This requirement was removed as this is now an understood action and no longer in practice. The committee feels it is important to include activities that are required and not activities to not perform. The removed sentence will be included in guidance going forward as an assist to users.
5.4.4.4	SC	NA	NA	The committee elected to replace the clause "he or she" with the term "they" when discussing a donor's gender and identity. This is as a part of an effort to ensure that the Standards can achieve gender neutrality.

5.4.4.4	RtC	It is recommended to retain the term "An Autologous donor" rather than "Autologous donor*s*" as the standard is easier to understand when it relates to one donor rather than many. Additionally, the singular usage is consistent with the standards under 5.4.4. *Examples:* *Excerpt from the Trima Operator's Manual (v.7.0) –* If the displayed Plasma replaced by PAS product volume on the End of run summary screen does not show the yellow diamond and exceeds the volume of PAS by 5 mL or more, the donor should be deferred from plasma donations for at least 4 weeks. *Excerpt from Amicus Operator's Manual (v.4.3) -* If the actual absolute plasma product volume exceeds the volume of absolute plasma replaced by InterSol by 5 mL the donor should be deferred for at least 4 weeks as an infrequent plasma donor. In order to meet this criterion, we suggest you consider programming your device to collect a plasma product volume that is 90% of the plasma volume replaced by InterSol.	NO	The committee noted this comment but did not feel that a change was needed at this time. The committee made the change to the standard as noted above.
5.5.2.4	SC	NA	NA	The committee edited standard 5.5.2.4 for clarity. The committee added the clause, "…is not considered a concurrently collected plasma product, and therefore" while removing "…the plasma loss" from the standard for clarity.
5.5.2.4	RtC/SC	"*The absolute plasma volume removed from the platelet must not exceed the amount of platelet additive solution added to the platelet by more than 5 mL."* If so, it will affect the determination of plasmapheresis frequency. Recommend being more specific so it is understood plasmapheresis frequency determination is not affected if the plasma volume is equivalent to the volume of additive solution added.	YES	The committee edited the standard based on this comment. Based on the comment, the committee added the clause, "…when the plasma volume derived from the collection is equivalent to the volume of additive solution added." for clarity. The addition ensures plasmapheresis frequency is not affected if the plasma volume is equivalent to the additive solution added. The standard now reads as follows, "A plasma product derived from collection of a platelet product stored in platelet additive solution is not considered a concurrently collected plasma product, and therefore shall not affect the determination of plasmapheresis frequency, when the plasma volume derived

				from the collection is equivalent to the volume of additive solution added."
5.5.3, 5.5.3.1	RtC/SC	We recommend that this statement be consistent with the regulations including the exceptions allowed under 21 CFR 640.21 e(4). You may include the appropriate regulatory cites under 21 CFR 640.21 in addition to the 2007 FDA Guidance for Industry: Collection of Platelets by Automated Methods as reference.	YES	The committee noted this comment and agreed with the intent. To meet the request, the committee has added the suggested reference " 21 CFR 640.21(e)" to the standard. In line with this change, the committee replaced the former language that referred to double and triple collections with the numerical designation that becomes effective with the exception language for individuals not being able to donate for a 7 day period. The standard reads as follows: 5.5.3.1 The interval between procedures for platelet, granulocyte, and leukocyte donors shall be at least 2 days, and the total volume of plasma collected shall not exceed the volume of plasma cleared by the FDA for the instrument. A donor shall undergo the procedure a maximum of two times in a 7-day period. When greater than or equal to 6 x 10^{11} ~~a double or triple~~ platelet collection is performed, the donor shall undergo the procedure a maximum of once in 7 days. Procedures shall not exceed 24 times in a rolling 12-month period, except in unusual circumstances as determined by the medical director. Standard 5.4.3.3 applies." This should assist users outside the United States who may use a platelet dose other than 3.0 x 10^{11} with compliance with the standard and ensures that there is exception language for donors who are not able to donate within the 7 day deferral period.
5.5.3.4.1	SC	NA	NA	Based on the change made to standard 5.5.3.1 (as noted above), the committee has edited the

				standard to remove the colloquial "triple collections" and included the exact content number requirement, which is "9.0 x 10^{11} or more."
5.5.4	SC	NA	NA	The committee added the clause, "…or Competent Authority.." for completeness and parallel structure for facilities outside of the US. This change is similar to others put forth in all sets of AABB Standards where a regionally specific regulatory authority is noted.
5.6.2	SC	NA	NA	The committee felt it was time to retire the clause from the standard, "Green soap shall not be used" as it is no longer used. The committee feels it is important to include activities that are required and not activities to not use. The removed sentence will be included in guidance going forward as an assist to users.
5.6.7	SC	NA	NA	The committee removed the term "physician" from the standard as it was felt that the term "authorized health professional" would satisfy this requirement adequately.
5.6.7.1, 5.6.7.1.1 (5.6.7.1)	SC	NA	NA	The committee edited standard 5.6.7.1 by splitting the standard into two separate standards for clarity. Standard 5.6.7.1 now reads as follows: "Units drawn as therapeutic phlebotomies shall not be used for allogeneic transfusion unless the individual undergoing the therapeutic phlebotomy meets all allogeneic donor criteria with the exception of donation interval." For new standard 5.6.7.1.1, the elements that previously appeared in subnumber 1 now appear in the stem of the new standard. With the revisions to the standard, the elements that now appear in subnumber 1 previously

				appeared as former subnumber 3. The elements of new subnumber 1 previously appeared as subnumber 2. The decision to remove the clause concerning "no charge" from subnumber 1 (formerly 2) was made as this applies to more than just hereditary hemochromatosis. **The standard now reads as follows:** The container label shall conspicuously state the disease or condition of the donor that necessitated phlebotomy. However, labeling for the disease or condition is not required if: 1) The phlebotomy is for hereditary hemochromatosis or for a condition for which the collection procedure has been approved by the Competent Authority*, and 2) The phlebotomy is performed for no charge for all individuals with that disease or condition. *21 CFR 630.15(a)(2)
5.7.2.1.1	SC	NA	NA	The committee elected expand the content of the standard by adding the clause concerning "…or Competent Authority" for completeness and parallel structure for facilities outside of the US. The standard now reads as follows: If the integrity of the weld is complete, the component shall have an expiration date/time assigned in accordance with FDA or Competent Authority approved package insert for the storage container.
5.7.2.1.1, 5.7.2.1.3 (5.7.2.1.1)	RtC	The standard as revised seems to direct manufacturers of product storage containers to include explicit language for the expiration time of the product after a sterile weld is complete. Research of various manufacturers inserts for product containers revealed, in most cases, there is no such language that would meet this standard. Without such language in container manufacturer's package inserts, there would	YES	The committee reviewed this comment and agreed with the intent. In the proposed 33rd edition, the committee had included a second sentence in standard 5.7.2.1.1 and based on this comment created new standard 5.7.2.1.3. Standard 5.7.2.1.3 reads as follows:

		be a significant unintended consequence of limiting component shelf life to 4 hours rather than retaining the original expiration. If the integrity of the weld is complete, the component shall retain original expiration dates or have an expiration date/time assigned in accordance with the FDA or Competent Authority approved package insert for the storage container if specified.		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 original container.
5.7.2.1.1, 5.7.2.1.3 (5.7.2.1.1)	RtC	What is the rational for this change? Why wouldn't cold products be 24 hours like an open system if a seal is unacceptable? Does 5.1.8A still apply for open systems?	YES	The committee reviewed this comment and agreed with the intent. In the proposed 33rd edition, the committee had included a second sentence in standard 5.7.2.1.1 and based on this comment created new standard 5.7.2.1.3. Standard 5.7.2.1.3 reads as follows: 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 original container.
5.7.2.1.3 (5.7.2.1.1)	SC	NA	NA	The committee removed the second sentence from standard 5.7.2.1.1 as the initial change to the standard. This adjusted the intent of the standard, that may not have been clear in its original presentation. New standard 5.7.2.1.3 has been created and edited with the understanding that weld integrity is not considered when there is no time limit specified in the package insert, if included. Standard 5.7.2.1.3 reads as follows: 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 original container.
5.7.3	RtC	To be consistent, they should, for example, include either December 2007 or December 17, 2007. This also applies to other dates.	YES	The committee noted this comment and has adjusted the way FDA guidances are presented to be consistent throughout the edition.

5.7.4	SC	NA	NA	The committee edited the title of the standard to read as follows, “Preparation of Blood and Blood Components”. The committee removed “specific” and replaced the term with “blood and blood” for clarity.
5.7.4.1	SC	NA	NA	The committee elected to edit standard 5.7.4.1 (and others listed below) to mirror the language included in the FDA Guidances cited with the standard. The committee felt (and based on comments received) that the understanding of confidence intervals is now universal and that the AABB membership is ready to enact these requirements in their facilities. These changes should also assist users in facilities outside of the United States who have at times had a difficult time understanding the previous wording. The committee also removed the clause “at the end of allowable storage” that appeared in the standard to match the current FDA Guidances. The standard now reads as such: **5.7.4.1 WHOLE BLOOD LEUKOCYTES REDUCED** Whole Blood Leukocytes Reduced shall be prepared by a method known to retain at least 85% of the original whole blood content. The sampling plan shall confirm with 95% confidence that more than 95% of units contain $<5 \times 10^6$ leukocytes. FDA criteria apply*. Standard 5.7.3.1 applies. *FDA Guidance for Industry: Pre-Storage Leukocyte Reduction of Whole Blood and Blood Components Intended for Transfusion (September 2012)
5.7.4.7	SC	NA	NA	The committee elected to edit standard 5.7.4.7 (and others listed below) to mirror the language

				included in the FDA Guidances cited with the standard. The committee felt (and based on comments received) that the understanding of confidence intervals is now universal and that the AABB membership is ready to enact these requirements in their facilities. These changes should also assist users in facilities outside of the United States who have at times had a difficult time understanding the previous wording. The committee also removed the clause "at the end of allowable storage" that appeared in the standard to match the wording in the current FDA Guidances. The standard now reads as such: **5.7.4.7 RED BLOOD CELLS LEUKOCYTES REDUCED** Red Blood Cells Leukocytes Reduced shall be prepared by a method known to retain at least 85% of the original red cells. The sampling plan shall confirm with 95% confidence that more than 95% of units contain $<5 \times 10^6$ leukocytes. FDA criteria apply*. Standard 5.7.3.1 applies. *FDA Guidance for Industry: Pre-Storage Leukocyte Reduction of Whole Blood and Blood Components Intended for Transfusion, September 2012
5.7.4.9.1	SC	NA	NA	The committee elected to edit standard 5.7.4.9.1 (and others listed below) to mirror the language included in the FDA Guidances cited with the standard. The committee felt (and based on comments received) that the understanding of confidence intervals is now universal and that the AABB membership is ready to enact these requirements in their facilities. These changes should also assist users in facilities outside of

				the United States who have at times had a difficult time understanding the previous wording. The committee also removed the clause "at the end of allowable storage" that appeared in the standard to match the current FDA Guidances. The standard now reads as such: **5.7.4.9.1 APHERESIS RED BLOOD CELLS LEUKOCYTES REDUCED** Apheresis Red Blood Cells Leukocytes Reduced shall be prepared by a method known to ensure a final component containing a mean hemoglobin of ≥51 g (or 153 mL cell volume). The sampling plan shall confirm with 95% confidence that more than 95% of units contain $<5 \times 10^6$ leukocytes. At least 95% of units sampled shall have >42.5 g of hemoglobin (or 128 mL red cell volume). Validation and quality control shall demonstrate that these criteria or the criteria specified in the operator's manual are met. FDA criteria apply.* Standards 3.3 and 5.7.3.1 apply. FDA Guidance for Industry: Pre-Storage Leukocyte Reduction of Whole Blood and Blood Components Intended for Transfusion (September 2012)
5.7.4.16.1 (New)	SC	NA	NA	The committee created new standard 5.7.4.16.1 recognizing that there are components prepared from pathogen reduced plasma that are processed and stored per manufacturer's instructions. The terms in parentheses are the industry terms used to describe these components. Please see the new standard below: **5.7.4.16.1** Components prepared from pathogen reduced plasma, (including but not limited to,

				thawed plasma, cryoprecipitated fibrinogen complex, plasma cryoprecipitated reduced), shall be processed and stored as per manufacturer's written instructions.
5.7.4.17	RtC/SC	This ("a minimum") is inconsistent with the language in the 2nd line of the paragraph stating "an average content" of at least 150mg. Need for harmonization of language.	YES	The committee reviewed this comment and the change was made. The committee removed the clause, "the minimum" and has replaced it with "at least." we'll update the guidance to include tables to show how much is needed in each pool based on the content. The standard now reads as such: **5.7.4.17 CRYOPRECIPITATED AHF** Cryoprecipitated AHF shall be prepared by a method known to separate the cold insoluble portion from Fresh Frozen Plasma and result in an average content of at least 150 mg of fibrinogen and 80 IU of coagulation Factor VIII per container or unit. In tests performed on prestorage pooled components, the pool shall contain at least 150 mg of fibrinogen and 80 IU of coagulation Factor VIII per component in the pool.* *21 CFR 606.122, 21 CFR 640.54, and 21 CFR 640.56
5.7.4.21	SC	NA	NA	The committee elected to edit standard 5.7.4.21 (and others listed below) to mirror the language included in the FDA Guidances cited with the standard. The committee felt (and based on comments received) that the understanding of confidence intervals is now universal and that the AABB membership is ready to enact these requirements in their facilities. These changes should also assist users in facilities outside of the United States who have at times had a difficult time understanding the previous

				wording. The committee also removed the clause "at the end of allowable storage" that appeared in the standard to match the current FDA Guidances. The standard now reads as such: **5.7.4.21 PLATELETS LEUKOCYTES REDUCED** Validation and quality control of Platelets Leukocytes Reduced shall demonstrate that at least 75% of units sampled contain $\geq 5.5 \times 10^{10}$ platelets and at least 90% of units sampled have a pH ≥ 6.2 at the end of allowable storage. The sampling plan shall confirm with 95% confidence that more than 95% of units contain $< 8.3 \times 10^{5}$ leukocytes. FDA criteria apply.^ ^21 CFR 640.25(b). FDA Guidance for Industry: Pre-Storage Leukocyte Reduction of Whole Blood and Blood Components Intended for Transfusion (September 2012)
5.7.4.22	SC	NA	NA	The committee elected to edit standard 5.7.4.22 (and others listed below) to mirror the language included in the FDA Guidances cited with the standard. The committee felt (and based on comments received) that the understanding of confidence intervals is now universal and that the AABB membership is ready to enact these requirements in their facilities. These changes should also assist users in facilities outside of the United States who have at times had a difficult time understanding the previous wording. The committee also removed the clause "at the end of allowable storage" that appeared in the standard to match the current FDA Guidances.

				The standard now reads as such: **5.7.4.22 POOLED PLATELETS LEUKOCYTES REDUCED** Pooled Platelets Leukocytes Reduced shall be prepared by a method known to result in a 95% confidence that more than 95% of units contain $<5 \times 10^6$ leukocytes and at least 90% of units sampled have a pH $\geq$6.2 at the end of allowable storage. Standard 5.7.4.21 applies.
5.7.4.23	RtC	The proposed standard does not align with the referenced FDA guidance document. The guidance document indicates that for validation and QC monitoring, a statistical sampling plan should be developed. The standard does not specify the confidence level (e.g. 95%) for the percentage of units that must meet each specified criterion for platelet yield and pH, as is stated in the guidance document and as is required in statistical sampling. Furthermore, the standard's stated percentages differ from the guidance document's stated percentages. For platelet yield, the standard specifies 90%, but the guidance document specifies 95%/75% (95% confidence that greater than 75% of the components meet the specification). For pH, the standard specifies 90%, but the guidance document specifies 95%/95%.	YES	The committee agreed with this comment. The committee has edited the standard to mirror the language included in the FDA Guidance as suggested. This change will mirror other changes included in this edition cited above and below. The standard now reads as follows: **5.7.4.23 APHERESIS PLATELETS** Validation and quality control of Apheresis Platelets shall demonstrate with 95% confidence that greater than 75% of units contain $\geq 3.0 \times 10^{11}$ platelets and shall demonstrate with 95% confidence that greater than 95% of units have a pH $\geq$6.2 at the time of issue or within 12 hours after expiration. FDA criteria apply.* *21 CFR 640.25(b). FDA Guidance for Industry and FDA Review Staff: Collection of Platelets by Automated Methods (December 17, 2007)
5.7.4.23	SC	NA	NA	The committee elected to edit standard 5.7.4.23 (and others listed below) to mirror the language included in the FDA Guidances cited with the standard. The committee felt (and based on comments received) that the understanding of confidence intervals is now universal and that the AABB membership is ready to enact these requirements in their facilities. These changes

				should also assist users in facilities outside of the United States who have at times had a difficult time understanding the previous wording. The committee also removed the clause "at the end of allowable storage" that appeared in the standard to match the current FDA Guidances. The standard now reads as such: **5.7.4.23 APHERESIS PLATELETS** Validation and quality control of Apheresis Platelets shall demonstrate with 95% confidence that greater than 75% of units contain $\geq 3.0 \times 10^{11}$ platelets and shall demonstrate with 95% confidence that greater than 95% of units have a pH ≥ 6.2 at the time of issue or within 12 hours after expiration. FDA criteria apply.* *21 CFR 640.25(b). FDA Guidance for Industry and FDA Review Staff: Collection of Platelets by Automated Methods (December 17, 2007)
5.7.4.23.1 (New)	SC	NA	NA	The committee created this new standard to add requirements for products that would be considered "low yield." This ensures that these products are labeled appropriately when stored and utilized in AABB accredited facilities. The standard reads as such: **5.7.4.23.1** Apheresis Platelets containing $< 3.0 \times 10^{11}$ platelets shall have the platelet content included on the label.
5.7.4.23.1 (New)	RtC	The new standard adds requirements for products that would be considered "low yield" to ensure these products are labeled appropriately. We recommend the AABB Standards Committee consider adding clarifying language regarding the inclusion of the platelet yield on an attached container tie tag.	YES	The committee reviewed this comment and agreed with the intent. The committee noted that reference standard 5.1.8A includes directions for what should be included on a low yield product label.

5.7.4.24	SC	NA	NA	The committee elected to edit standard 5.7.4.24 (and others listed below) to mirror the language included in the FDA Guidances cited with the standard. The committee felt (and based on comments received) that the understanding of confidence intervals is now universal and that the AABB membership is ready to enact these requirements in their facilities. These changes should also assist users in facilities outside of the United States who have at times had a difficult time understanding the previous wording. The committee also removed the clause "at the end of allowable storage" that appeared in the standard to match the current FDA Guidances. The standard now reads as such: **5.7.4.24 APHERESIS PLATELETS LEUKOCYTES REDUCED** Validation and quality control shall demonstrate with 95% confidence that greater than 75% of units contain $\geq 3.0 \times 10^{11}$ platelets and shall demonstrate with 95% confidence that greater than 95% of units, have a pH ≥ 6.2, at the time of issue or within 12 hours after expiration. The sampling plan shall confirm with 95% confidence that more than 95% of units contain $< 5 \times 10^{6}$ leukocytes. FDA criteria apply.‡ ‡21 CFR 640.25(b) FDA Guidance for Industry and FDA Review Staff: Collection of Platelets by Automated Methods (December 17, 2007) FDA Guidance for Industry: Pre-Storage Leukocyte Reduction of Whole Blood and Blood Components Intended for Transfusion (September 2012)

5.7.4.24	RtC	The proposed standard removes the term "sampled" for yield criteria yet retains the term "sampled" for residual leukocyte criteria. This is inconsistent.	YES	The committee reviewed this comment and agreed with the intent. The committee has adjusted the standard to reflect the comment and the referenced FDA Guidances. The standard now reads as such: **5.7.4.24 APHERESIS PLATELETS LEUKOCYTES REDUCED** Validation and quality control shall demonstrate with 95% confidence that greater than 75% of units contain $\geq 3.0 \times 10^{11}$ platelets and shall demonstrate with 95% confidence that greater than 95% of units, have a pH ≥ 6.2, at the time of issue or within 12 hours after expiration. The sampling plan shall confirm with 95% confidence that more than 95% of units contain $< 5 \times 10^{6}$ leukocytes. FDA criteria apply.‡ ‡21 CFR 640.25(b) FDA Guidance for Industry and FDA Review Staff: Collection of Platelets by Automated Methods (December 17, 2007) FDA Guidance for Industry: Pre-Storage Leukocyte Reduction of Whole Blood and Blood Components Intended for Transfusion (September 2012)
5.7.4.24	RtC	Why wouldn't the word "sampled" be removed from the residual leukocyte criteria, if the word sampled is being removed from the platelet content criteria.	YES	The committee reviewed this comment and agreed with the intent. The committee has adjusted the standard to reflect the comment and the referenced FDA Guidances. The standard now reads as such: **5.7.4.24 APHERESIS PLATELETS LEUKOCYTES REDUCED** Validation and quality control shall demonstrate with 95% confidence that greater than 75% of units contain $\geq 3.0 \times 10^{11}$ platelets and shall demonstrate with 95% confidence that greater than 95% of units, have a pH ≥ 6.2, at the time of issue or within 12 hours after

				expiration. The sampling plan shall confirm with 95% confidence that more than 95% of units contain <5 x 10^6 leukocytes. FDA criteria apply.‡ ‡21 CFR 640.25(b) FDA Guidance for Industry and FDA Review Staff: Collection of Platelets by Automated Methods (December 17, 2007) FDA Guidance for Industry: Pre-Storage Leukocyte Reduction of Whole Blood and Blood Components Intended for Transfusion (September 2012)
5.7.4.24	RtC	In order to increase platelet availability, a blood center may intentionally make leukocyte reduced apheresis platelets with a content of less than 3 x 10^{11} and label the unit with the yield since some hospital transfusion services will accept PLTs with a yield of less than 3 x 10^{11} . A recent US hospital survey showed that approximately 40% of hospitals surveyed reported using platelets with a yield of < 3 x 10^{11} platelets either routinely or in times of shortage.[1] Often the hospital and Blood Center will still have a minimum yield criteria for these low yield platelets, for example 2.5 x 10^{11}. If the apheresis platelet yield falls between that minimum (e.g. 2.5 x 10^{11}) and 3 x 10^{11}, then the platelet is acceptable for distribution. The intentional production of < 3 x 10^{11} yield platelets may become more common practice at Blood Centers after large volume delayed sampling is implemented (an option in the FDA guidance to mitigate bacterial contamination risk) in order to maintain PLT split rate and minimize impact to platelet production.[2] When a blood supplier (in partnership with transfusion services who will accept PLTs with < 3 x 10^{11} platelets) determines to intentionally make a certain portion of their apheresis platelets with a yield of < 3 x 10^{11} platelets these should not be included in the QC requirement of ≥90% of units sampled having the yield of > 3 x 10^{11} platelets and counted against the center in meeting QC. The requirement that 90% of QCed PLTs contain > 3 x 10^{11} platelets is to ensure that the routine process does not result in inadvertent collections failures or manufacturing losses. PLTs that are made following the routine process should be expected to meet this 90% requirement. However, for those apheresis platelet units that the blood center specifically identifies ahead of time in the manufacturing process to split and label as units that are < 3 x 10^{11} to be provided to accepting hospitals, the center should be permitted to exclude these from routine QC for yield of > 3 x 10^{11}. There should, however, still be yield	NO	The committee reviewed this comment but did not make a change at this time as it was not deemed appropriate. Based on feedback from the Food and Drug Administration, this change cannot be made at this moment. The change would also require feedback from the public or membership as well. The committee will consider this for the next edition.

		related QC performed on these "low yield" units but they should be placed in a separate QC bucket and the center determines how best to QC yield based on the center's specific criteria established for these units. For example, lets say a blood center has a few hospitals that will routinely accept PLT units with a < 3 x 10^{11} platelet yield so they have decided that they will intentionally produce ~15-25% of their apheresis PLT components with a < 3 x 10^{11} platelet yield. This will allow the blood center to maintain/increase overall PLT availability. Their procedures note that yield must still be above 2.5 x 10^{11} as agreed upon with the partnering hospitals. So if in a given month the center collects 1000 platelets and 150-250 a month will have < 3 x 10^{11} platelets, the center may fail monthly QC depending on which units end up being sampled even though the production of those 150-250 platelets with a < 3 x 10^{11} yield was pre-planned. The better approach in this type of scenario is those 150-250 apheresis units that were intentionally produced to have a yield between 2.5 and 3.0 x 10^{11} should be Qced in a separate bucket. For example, a sampling could be taken form that group and > x percent (e.g. 75% or 90%, percent would be set by center procedure) needs to have a yield greater than the minimum set by the center for those "low yield" platelets (in this example 2.5 x 10^{11}). Adding language to standard 5.7.4.24 that addresses this specific scenario would provide clarity to those blood centers who currently are intentionally producing (or plan to produce) apheresis platelets with a yield of < 3 x 10^{11} platelets given acceptance of these platelets by some hospitals and the need to increase PLT production. As the current standard revision has added (and CFR require), apheresis PLT units with < 3 x 10^{11} yield would all be labeled with the platelet yield. Below is some suggested wording that can help address this: 5.7.4.24 APHERESIS PLATELETS LEUKOCYTES REDUCED Validation and quality control shall demonstrate that 90% of units sampled contain >3.0 x 1011 platelets and, at the end of allowable storage or at the time of issue, have a pH >6.2 Apheresis platelets intentionally produced to have a yield of less than 3 x 10^{11} can be excluded from the above monthly quality control requirements for platelet yield but shall have a separate facility defined QC requirement.		
5.7.4.24.1 (New)	SC	NA	NA	The committee created this new standard to add requirements for products that would be considered "low yield." This ensures that these products are labeled appropriately when stored and utilized in AABB accredited facilities.

				The standard reads as such: **5.7.4.24.1** Apheresis Platelets Leukocytes Reduced containing < 3.0 x 10^{11} platelets shall have the platelet content included on the label.
5.7.4.24.1 (New)	RtC	The new standard adds requirements for products that would be considered "low yield" to ensure these products are labeled appropriately. We recommend the AABB Standards Committee consider adding clarifying language regarding the inclusion of the platelet yield on an attached container tie tag.	YES	The committee reviewed this comment and agreed with the intent. The committee noted that reference standard 5.1.8A includes directions for what should be included on a low yield product label.
5.7.4.25	SC	NA	NA	The committee elected to edit standard 5.7.4.25 (and others listed below) to mirror the language included in the FDA Guidances cited with the standard. The committee felt (and based on comments received) that the understanding of confidence intervals is now universal and that the AABB membership is ready to enact these requirements in their facilities. These changes should also assist users in facilities outside of the United States who have at times had a difficult time understanding the previous wording. The committee also removed the clause "at the end of allowable storage" that appeared in the standard to match the current FDA Guidances. The standard now reads as such: **5.7.4.25 APHERESIS PLATELETS PLATELET ADDITIVE SOLUTION ADDED LEUKOCYTES REDUCED** Apheresis Platelets Platelet Additive Solution Added Leukocytes Reduced shall be collected by apheresis and suspended in variable amounts of plasma and an approved platelet additive solution. Validation and quality control shall demonstrate with 95% confidence that greater than 75% of units contain ≥3.0 x 10^{11} platelets and shall demonstrate with 95% confidence that

				95% of units have a pH $\geq$6.2 at the time of issue or within 12 hours after expiration. The sampling plan shall confirm with 95% confidence that more than 95% of units contain <5 x 10^6 leukocytes. FDA criteria apply.* * FDA Guidance for Industry and FDA Review Staff: Collection of Platelets by Automated Methods (December 17, 2007) FDA Guidance for Industry: Pre-Storage Leukocyte Reduction of Whole Blood and Blood Components Intended for Transfusion (September 2012)
5.7.4.25	RtC	The proposed standard does not align with the referenced FDA guidance document. The guidance document indicates that for validation and QC monitoring, a statistical sampling plan should be developed. The standard does not specify the confidence level (e.g. 95%) for the percentage of units that must meet each specified criterion for platelet yield, pH, and residual leukocyte count, as is stated in the guidance document and as is required in statistical sampling. Furthermore, the standard's stated percentages differ from the guidance document's stated percentages. For platelet yield, the standard specifies 90%, but the guidance document specifies 95%/75% (95% confidence that greater than 75% of the components meet the specification). For pH, the standard specifies 90%, but the guidance document specifies 95%/95%. For residual leukocyte count, the standard specifies 95%, but the guidance document specifies 95%/95%. Retaining the term "sampled" for yield criteria is inconsistent with standards 5.7.4.23 and 5.7.4.24.		The committee reviewed this comment and as noted above, the standard has been adjusted to now include confidence levels with regard to platelets and leukoreduced platelets. The standard now reads as such: **5.7.4.25 APHERESIS PLATELETS PLATELET ADDITIVE SOLUTION ADDED LEUKOCYTES REDUCED** Apheresis Platelets Platelet Additive Solution Added Leukocytes Reduced shall be collected by apheresis and suspended in variable amounts of plasma and an approved platelet additive solution. Validation and quality control shall demonstrate with 95% confidence that greater than 75% of units contain $\geq$3.0 x 10^{11} platelets and shall demonstrate with 95% confidence that 95% of units have a pH $\geq$6.2 at the time of issue or within 12 hours after expiration. The sampling plan shall confirm with 95% confidence that more than 95% of units contain <5 x 10^6 leukocytes. FDA criteria apply.* * FDA Guidance for Industry and FDA Review Staff: Collection of Platelets by Automated Methods (December 17, 2007)

				FDA Guidance for Industry: Pre-Storage Leukocyte Reduction of Whole Blood and Blood Components Intended for Transfusion (September 2012)
5.7.4.25	RtC	If "sampled" is being removed from standard 5.7.4.24 why isn't it being removed from 5.7.4.25?	YES	The committee reviewed this comment and as noted above, the standard has been adjusted to now include confidence levels with regard to platelets and leukoreduced platelets. The standard now reads as such: **5.7.4.25 APHERESIS PLATELETS PLATELET ADDITIVE SOLUTION ADDED LEUKOCYTES REDUCED** Apheresis Platelets Platelet Additive Solution Added Leukocytes Reduced shall be collected by apheresis and suspended in variable amounts of plasma and an approved platelet additive solution. Validation and quality control shall demonstrate with 95% confidence that greater than 75% of units contain $\geq 3.0 \times 10^{11}$ platelets and shall demonstrate with 95% confidence that 95% of units have a pH ≥ 6.2 at the time of issue or within 12 hours after expiration. The sampling plan shall confirm with 95% confidence that more than 95% of units contain $< 5 \times 10^{6}$ leukocytes. FDA criteria apply.* * FDA Guidance for Industry and FDA Review Staff: Collection of Platelets by Automated Methods (December 17, 2007) FDA Guidance for Industry: Pre-Storage Leukocyte Reduction of Whole Blood and Blood Components Intended for Transfusion (September 2012)
5.7.4.23, 5.7.4.24, 5.7.4.25	RtC	Please revise these 3 standards for platelet content from 90% to match FDA guidance (95%/75%).	YES	The committee reviewed this comment and as noted above, the standard has been adjusted to now include confidence levels with regard to platelets and leukoreduced platelets.

				The standard now reads as such: **5.7.4.25 APHERESIS PLATELETS PLATELET ADDITIVE SOLUTION ADDED LEUKOCYTES REDUCED** Apheresis Platelets Platelet Additive Solution Added Leukocytes Reduced shall be collected by apheresis and suspended in variable amounts of plasma and an approved platelet additive solution. Validation and quality control shall demonstrate with 95% confidence that greater than 75% of units contain $\geq 3.0 \times 10^{11}$ platelets and shall demonstrate with 95% confidence that 95% of units have a pH ≥ 6.2 at the time of issue or within 12 hours after expiration. The sampling plan shall confirm with 95% confidence that more than 95% of units contain $< 5 \times 10^{6}$ leukocytes. FDA criteria apply.* * FDA Guidance for Industry and FDA Review Staff: Collection of Platelets by Automated Methods (December 17, 2007) FDA Guidance for Industry: Pre-Storage Leukocyte Reduction of Whole Blood and Blood Components Intended for Transfusion (September 2012)
5.7.4.23, 5.7.4.24, 5.7.4.25	RtC	75% in FDA 2007 Guidance, with 95% confidence. AABB may elect to go with 90% but then they should not state at the end of the paragraph that "FDA criteria apply".		The committee reviewed this comment and as noted above, the standard has been adjusted to now include confidence levels with regard to platelets and leukoreduced platelets. The standard now reads as such: **5.7.4.25 APHERESIS PLATELETS PLATELET ADDITIVE SOLUTION ADDED LEUKOCYTES REDUCED** Apheresis Platelets Platelet Additive Solution Added Leukocytes Reduced shall be collected by apheresis and suspended in variable amounts of plasma and an approved platelet additive solution. Validation and quality control shall demonstrate with 95% confidence that greater

				than 75% of units contain $\geq 3.0 \times 10^{11}$ platelets and shall demonstrate with 95% confidence that 95% of units have a pH ≥ 6.2 at the time of issue or within 12 hours after expiration. The sampling plan shall confirm with 95% confidence that more than 95% of units contain $< 5 \times 10^{6}$ leukocytes. FDA criteria apply.* * FDA Guidance for Industry and FDA Review Staff: Collection of Platelets by Automated Methods (December 17, 2007) FDA Guidance for Industry: Pre-Storage Leukocyte Reduction of Whole Blood and Blood Components Intended for Transfusion (September 2012)
5.7.4.25.1 (New)	SC	NA	NA	The committee created this new standard to add requirements for products that would be considered "low yield." This ensures that these products are labeled appropriately when stored and utilized in AABB accredited facilities. The standard reads as such: **5.7.4.25.1** Apheresis Platelets Platelet Additive Solution Added Leukocytes Reduced containing $< 3.0 \times 10^{11}$ platelets shall have the platelet content included on the label.
5.7.4.25.1 (New)	RtC	Is the expectation that the product code should also be changed to reflect the "low yield" in addition to having the platelet content on the label?	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The committee feels that this should be discussed with the Food and Drug Administration. Note, Reference Standard 5.1.6A discusses labeling requirements in terms of low yield products.
5.7.4.26.1 (New)	SC	NA	NA	The committee new standard 5.7.4.26.1 to add requirements for products that would be considered "low yield." This ensures that these products are labeled appropriately. The FDA

				Guidance cited that previously appeared with standard 5.7.4.26, has now been moved to standard 5.7.4.26.1. The standard reads as follows: **5.7.4.26.1** Pathogen-Reduced Platelets containing <3.0 x 10^{11} platelets shall have the platelet content included on the label. Standards 5.7.4.24 and 5.7.4.25 apply. # # FDA Guidance for Industry and FDA Review Staff: Collection of Platelets by Automated Methods (December 17, 2007)
5.8.5	SC	NA	NA	The committee removed the required infectious disease test for "Zika virus RNA" and associated reference to the FDA Guidance from July 2018 from the 33rd edition in accordance with the decision by the FDA to withdraw this guidance as of Tuesday, May 11, 2021 and as noted in AABB Association Bulletin #21-03.
5.8.5	RtC	In Standard 5.8.5 (Tests Intended to Prevent Disease Transmission by Allogeneic Donations) there is no mention of a requirement for a bacterial testing strategy. Why is the requirement not listed here?	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The committee feels that the existing section based on bacterial testing earlier in chapter 5 discusses the issue in a sufficient manner.
5.8.6	SC	NA	NA	The committee elected to add the phrase, " For other relevant FDA Guidance concerning testing of donor blood, standard 5.8.5 applies" to cover all of the FDA guidances from standard 5.8.5 that applies to donors without having to relist the associated FDA guidances.
5.8.7	SC	NA	NA	The committee has added the new FDA Guidance concerning HTLV I/II from February 2020 as seen below: FDA Guidance for Industry: Use of Serological Tests to Reduce the Risk of Transfusion-Transmitted Human T-Lymphotropic Virus Types I and II (HTLV-I/II) (February 2020)

5.14.4 (5.14.3.2)	SC	NA	NA	The committee elected to edit this standard for clarity. The committee added the clause "new" when discussing a sample, and have added the clause "prior to" in place of "of the scheduled." The standard now reads as such: **5.14.4** A new sample shall be obtained from the patient within 3 days prior to transfusion in the following situations: 1) If the patient has been transfused in the preceding 3 months with blood or a blood component containing allogeneic red cells. 2) If the patient has been pregnant within the preceding 3 months. 3) If the history is uncertain or unavailable. Day 0 is the day of draw.
5.14.5 (5.14.3.3)	RtC	Are standards 5.14.3.3 and 5.14.3.4 truly subsets of 5.14.4? Or should these be changed to appear as standards "5.14.5" and "5.14.6" and subsequent Standards re-numbered as well?	YES	The committee agreed with this comment and made the change. The subsequent standards were renumbered accordingly.
5.14.6 (5.14.3.4)	RtC	Are standards 5.14.3.3 and 5.14.3.4 truly subsets of 5.14.4? Or should these be changed to appear as standards "5.14.5" and "5.14.6" and subsequent Standards re-numbered as well?	YES	The committee agreed with this comment and made the change. The subsequent standards were renumbered accordingly.
5.14.8, #3 (5.14.5, #3)	SC	NA	NA	The committee removed the clause "validated" from subnumber 3 as its inclusion in the standard was resulting in many questions, confusion and resulted in a misunderstanding of the intent of the standard for the membership. The committee also added the clause, "at the time of sample collection" to the entry for clarity and based on queries received from the membership. The committee also added a cross-reference to standard 3.2 to the standard as it relates to qualification of equipment which will ensure that electronic identification systems in use are qualified to do so. The subnumber reads as follows:

				5.14.8 Pretransfusion Testing for Allogeneic Transfusion of Whole Blood, Red Blood Cell, and Granulocyte Components There shall be two determinations of the recipient's ABO group as specified in Standard 5.14.1. The first determination shall be performed on a current sample, and the second determination by one of the following methods: 3) Retesting the same sample if patient identification was verified at the time of sample collection using an electronic identification system.
5.15.1	SC	NA	NA	The committee elected to edit standard 5.15.1 to ensure that it was understood that the use of group O Whole Blood should only be in trauma or emergent situations. As previously written, the standard could be interpreted to state that the use of this product should be used at all times. The section of standards 5.27 that discusses low titer group O Whole Blood has also been edited and is discussed below. The standard now reads as follows: **5.15.1** Recipients shall receive ABO group-compatible Red Blood Cell components, or ABO group-specific Whole Blood. Standard 5.15.4 applies.
5.15.1	RtC	This standard restricts our capacity to change to ABO group compatible whole blood to maximize use of our blood inventory.	NO	The committee noted this comment but did not feel that a change was needed at this time. The committee notes that there are non-emergent situations where low titer group O whole blood can be used. In the comments to the standards focused on low titer group O whole blood, there are discussions of situations where this product can be used.

5.15.1	RtC	We request the AABB standards committee clarify the intent of this standard specific to utilization of Low Titer Group O Whole Blood (LTOWB). As written the standard implies that LTOWB be utilized only in the event a patient's ABO type is not known, such as in trauma. However, LTOWB is an appropriate resuscitation product to use in some patients whose ABO type Is known, e.g. excessive blood loss.	NO	The committee noted this comment but did not feel that a change was needed at this time. The committee notes that there are non-emergent situations where low titer group O whole blood can be used. In the comments to the standards focused on low titer group O whole blood, there are discussions of situations where this product can be used.
5.19.6	SC	NA	NA	The committee replaced the term "the" with "their" in standard 5.19.6 for clarification. The standard now reads as such: **5.19.6 Massive Transfusion** The BB/TS shall have a policy regarding compatibility testing when, within 24 hours, a patient has received an amount of blood approximating or greater than the patient's total blood volume.
5.19.6	RtC	Please add requirements for Transfusion Services who provides blood for ambulance or helicopter emergency service that transfuse, but patient ends up at a different hospital system.	NO	The committee noted this comment, but did not feel that a change would be appropriate at this time. The committee feels that a change of this magnitude would require input from the membership with a comment period. The committee will consider this inclusion in the 34th edition of Standards for Blood Banks and Transfusion Services.
5.26, #2	RtC	We request that a change be made to subnumber 2 of standard 5.26. The rationale for this change is included below the proposed rewrite of subnumber 2. 2) The appropriate temperature has been maintained. For red blood cell units returned from a clinical area to the blood bank within 60 minutes, the appropriate temperature should not exceed a temperature of more than 14C. • Data from Ramirez-Arcos et al (Vox Sanguinis 2013;105:100-107), de Grandmont et al (Vox Sanguinis 2014 ;107:239-46) and Ramirez-Arcost et al (Transfus Med Hemother 2016;43:396-399) provide evidence that red blood cell (RBC) units that have been outside of controlled temperatures for 60 minutes (on recurrent exposures) have the same quality and are as safe (from a	NO	The committee reviewed this comment but did not feel that a change was appropriate at this time. The committee notes that the standard is written in a way to ensure compliance with the FDA regulations in 21 CFR 640.2, c, 3. The committee will continue to review variances as received and approve as appropriate.

		bacterial contamination perspective) as RBC units that have been outside of controlled temperatures at 30 minutes (on recurrent exposures). In the Ramirez-Arcos study, the temperature at 60 minutes was up to 14.2 degrees Celsius +/- 0.2 degrees Celsius. • There are no data that strongly support the use of a 6 degrees Celsius or 10 degrees Celsius maximum for situations of short term exposure (less than 60 minutes) from clinical areas. These short term exposures should NOT be considered the same as storage or transport. As a result, RBC units are being unnecessarily discarded when data show that these units are safe from quality and bacterial contamination indicators. Our facility has applied for and successfully received variance for this standard and has been conducted in our country by the experiments and references noted above and would not be feasible to be independently validated at each of our sites.		
5.27.2, #1 (5.27.1.1)	SC	NA	NA	The committee elected to create a new subnumber 1 for standard 5.27.2 which requires that blood banks and transfusion services define "low titer threshold" for the use of group O whole blood.
5.27.2 (5.27.1.1)	RtC	Please clarify that the intent is for hospital transfusion services to develop policies, processes and procedures for low titer threshold, and not intended for the manufacturing blood establishment to define.	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The situation described in the comment would be defined by both entities as a part of agreements. In that agreement, the receiving facility would define what they are willing to accept in terms of receipt of this product. The committee has expanded upon this in guidance.
5.27.2 (5.27.1.1)	RtC	We request the AABB standards committee clarify the intent of this standard specific to utilization of Low Titer Group O Whole Blood (LTOWB). As written the standard implies that LTOWB be utilized only in the event a patient's ABO type is not known, such as in trauma. However, LTOWB is an appropriate resuscitation product to use in some patients whose ABO type Is known, e.g. excessive blood loss.	YES	The committee agreed with the intent of this comment and as a result moved former standard 5.27.1.1 to appear as 5.27.2 so that it can read alone and not to be read as to be used in emergent situations, but that it should be used in the urgent cases.
5.27.3 (5.27.2)	SC	NA	NA	The committee elected to add a cross reference to standard 5.27.2 for completeness. Standard 5.27.2 focuses on facilities that use low titer

				group O whole blood have policies, processes and procedures for certain situations.
5.27.3 (5.27.2)	RtC	The use of the term "transfusing facility" could be clarified. There are now healthcare systems that have standardized transfusion services that use the same computer system across several facilities and patients are transferred from one facility to a higher acuity level facility for further management of care. If initial testing is performed at a "sister facility", it is acceptable to issue LTOWB or ABO-group compatible Red Blood Cells components at the receiving facility for emergency transfusions before another sample is collected and testing is completed at the receiving facility.	NO	The committee reviewed the comment and did not feel that a change was needed. The committee notes that a facilities policies, processes and procedures should define a transfusion facility. The requirement would be set forth within your network of facilities and would define the term that best meets the reality of your current "situation."
5.27.5 (5.27.4)	SC	NA	NA	The committee edited standard 5.27.5 for clarity. The clause "when possible" was added to the standard and recognizes that in urgent situations, it is sometimes impossible to conduct compatibility testing for the beginning of the transfusion sequence. The standard now reads as follows: **5.27.5** Compatibility testing shall be completed expeditiously using a patient sample collected before the beginning of the transfusion sequence, when possible. Standard 5.19.6 applies.
5.28.2	SC	NA	NA	The committee edited this standard for clarity as there is an expanding scope of providers beyond medical doctors who can prescribe and administer blood products.
5.28.3	SC	NA	NA	The committee added a cross-reference to standard 5.23 for completeness. Standard 5.23 details the final checks that need to occur before issue of blood or blood components.
5.1.6A, #22 (New)	SC	NA	NA	The committee created new entry #22 for completeness. This was included to mirror the requirements in the component section of chapter 5 (5.7.4) and to ensure that if platelets are released for transfusion with a count of < 3.0

<table>
<tr><td></td><td></td><td></td><td></td><td>x 10^{11} that the actual platelet count be displayed.
The entry reads as follows:<table><tr><th>Item No.</th><th>Labeling Item</th><th>Collection or Preparation</th><th>Final Component</th><th>Pooled</th></tr><tr><td>22</td><td>Actual platelet content for apheresis platelets containing < 3.0 x 10^{11}</td><td>NA</td><td>R</td><td>NA</td></tr></table></td></tr>
<tr><td>5.1.6A, footnote 2</td><td>SC</td><td>NA</td><td>NA</td><td>The committee edited footnote 2 to expand the content to include “washed Red Blood Cells” to mirror the changes to standards 5.7.4.16, 5.7.4.17 and 5.7.4.23.</td></tr>
<tr><td>5.1.6A, footnote 5 (New)</td><td>SC</td><td>NA</td><td>NA</td><td>The committee created new footnote 5 which points to 21 CFR c, 4, (i) for completeness. The requirement is attached to entry number 9 focused on expiration date. The requirement reads as follows:
(4)(i) The expiration date, including the day, month, and year, and, if the dating period for the product is 72 hours or less, including any product prepared in a system that might compromise sterility, the hour of expiration.</td></tr>
<tr><td>5.1.6A, footnote 6</td><td>SC</td><td>NA</td><td>NA</td><td>The committee edited footnote 6 to expand the content to include “…cryoprecipitated AHF, PR cryoprecipitated fibrinogen complex…” to mirror the changes to standards 5.7.4.16, 5.7.4.17 and 5.7.4.23.</td></tr>
<tr><td>5.1.6A, footnote 9</td><td>SC</td><td>NA</td><td>NA</td><td>The committee edited footnote 9 to expand the content to include “…cryoprecipitated AHF, PR cryoprecipitated fibrinogen complex…” to</td></tr>
</table>

				mirror the changes to standards 5.7.4.16, 5.7.4.17 and 5.7.4.23.
5.1.6A, footnote 12	SC	NA	NA	The committee edited footnote 12 to expand the content to include "…cryoprecipitated AHF, PR cryoprecipitated fibrinogen complex…" to mirror the changes to standards 5.7.4.16, 5.7.4.17 and 5.7.4.23.
5.1.8A, #5	SC	NA	NA	The committee removed the clause from the Expiration column, "…or FDA as approved" following "Closed System: 14 days". The removal was done as the committee deemed it was no longer necessary.
5.1.8A, #10	SC	NA	NA	The committee replaced the expiration time in #10 which read, "24 hours or as approved by FDA" with "Open system: 24 hours Closed system: 14 days" as expiration times have become defined.
5.1.8A, #13, 19, 21	SC	NA	NA	The committee edited entries, 13, 19 and 21 to reflect that platelets can now be maintained for 7 days before expiry dependent upon which system in use. The clause removed "24 hours or" and replaced it with "Up to 7…"
5.1.8A, #19	RtC	Please be consistent with language in the expiration date column: 5 days or up to 7 days depending on the collection system and bacterial testing strategy used [10]	YES	The committee noted this comment and made the change. This was noted in the row above, to remove the clause, "24 hours or" with "Up to 7…"
5.1.8A, #19	RtC	In the "Testing" column: "...collection system and bacterial strategy used" – the term "testing" is missing between bacterial and strategy.	YES	The committee agreed with this comment and the term "testing" was reincluded in the column.
5.1.8A, #19	SC	NA	NA	The committee updated the language in entry #19 to match the language that appears in other entries in similar products in the "Expiration" column.
5.1.8A, #24	SC	NA	NA	The committee added the clause "without agitation" to the storage and transport columns for clarity.

<table>
<tr><td>5.1.8A, #25</td><td>SC</td><td>NA</td><td>NA</td><td>The committee added the clause “without agitation” to the storage and transport columns for clarity.</td></tr>
<tr><td>5.1.8A, #30 (New)</td><td>SC</td><td>NA</td><td>NA</td><td>Based on the edits to standards 5.7.4.16, 5.7.4.17 and 5.7.4.23, new entry #30 was created for Pathogen Reduced Cryoprecipitated Fibrinogen Complex. The entry reads as follows:
<table>
<tr><td>30</td><td>Pathogen Reduced Cryoprecipitated Fibrinogen Complex</td><td>–18 C or colder</td><td>Maintain frozen state</td><td>Up to12 months from date of collection of the first donation in the input plasma pool</td><td>Thaw according to institutional procedures.</td></tr>
</table></td></tr>
<tr><td>5.1.8A, #31 (New)</td><td>SC</td><td>NA</td><td>NA</td><td>Based on the edits to standards 5.7.4.16, 5.7.4.17 and 5.7.4.23, new entry #30 was created for Pathogen Reduced Cryoprecipitated Fibrinogen Complex (after thawing). The entry reads as follows:
<table>
<tr><td>31</td><td>Pathogen Reduced Cryoprecipitated Fibrinogen Complex (after thawing)</td><td>20-24 C</td><td>As close as possible to 20-24 C</td><td>5 days post thaw</td><td></td></tr>
</table></td></tr>
</table>

5.1.8A, #42	SC	NA	NA	The committee edited entry #42 concerning "Liquid Plasma" removing the previous entry in the "Expiration" column, "5 days after expiration of Whole Blood" and replacing it with " CPD or CP2D, the expiration for Liquid Plasma is 26 days. If WB is stored in CPDA-1, the Liquid Plasma expiration date is 40 days." The change was made for clarification.
5.1.8A, #42	RtC	It should be noted that CPD or CP2D, the expiration for Liquid Plasma is 26 days from date of collection.	YES	The committee based on the comment received, removed the clause "following collection" for consistency with entries in the reference standard.
5.1.8A, footnote 6	SC	NA	NA	The committee edited footnote 6 (which applies to platelet components) to reflect the changes made to the entries regarding the expiration times for certain components recognizing the updated expiration times for each entry that has footnote 6 as a reference.
5.1.8A, footnote 10 (deleted)	SC	NA	NA	The committee deleted footnote 10 based on the inclusion of 7 day expirations times now included as a part of the table where appropriate. ~~[10]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."~~
5.4.1A, #7	SC	NA	NA	In line with the removal of the same clause from standard 5.4.4.2, " blood obtained by earlobe puncture shall not be used for this determination", the committee removed the same clause as it appeared in entry #7 for parallel construction.
5.4.1A, #10	SC	NA	NA	The committee edited entry #10 by adding the clause, "For donors previously deferred for…"

<table>
<tr><td></td><td></td><td></td><td></td><td>to the “Criteria” column to remain consistent with current FDA requirements.
The committee also replaced the previous deferral of “Permanent” with “Defer in accordance with FDA Guidance” to match current FDA donor deferral requirements.</td></tr>
<tr><td>5.4.1A, #14 – Monkeypox /small pox</td><td>RtC/SC</td><td>This is submitted based on concerns expressed during the recent DHTF meeting regarding small pox vaccines and the need to differentiate the vaccine type and deferrals to ensure accuracy in deferrals. We share those concerns and are proposing a solution to fend off confusion and criticism by proposing this solution.
The highlighted revisions are based on precise language from FDA and the Jynneos vaccine package insert to provide clarity and prevent confusion when assess donors for receipt of a smallpox vaccine. This is also consistent with all information provided by FDA in response to our inquiry at the time of approval/release in 2019.
We propose this clarification – based on the model used for cholera vaccines.

<table><tr><td>14) Immunizations and Vaccinations</td><td>•Receipt of toxoids, or synthetic or killed viral, bacterial, or rickettsial vaccines if donor is symptom-free and afebrile [Anthrax, Cholera (inactivated), Diphtheria, Hepatitis A, Hepatitis B, Influenza, Lyme disease, Paratyphoid, Pertussis, Plague, Pneumococcal polysaccharide, Polio (Salk/injection), Rabies, Rocky Mountain spotted fever, Tetanus, Typhoid (by injection)]
• Receipt of recombinant vaccine [eg, HPV and Zoster Recombinant, Adjuvanted (Shingrix) Vaccine]</td><td>None</td></tr></table></td><td>Yes</td><td>The committee agreed with the comment and created a new entry specifically geared around the inclusion of the monkeypox and smallpox.</td></tr>
</table>

<table>
<tr>
<td></td>
<td></td>
<td>
<table>
<tr><td></td><td>• Receipt of intranasal live attenuated flu vaccine</td><td></td></tr>
<tr><td></td><td>• Smallpox Vaccine</td><td>Refer to FDA Guidance[2]</td></tr>
</table>
[2]FDA Guidance for Industry: Recommendations for Deferral of Donors and Quarantine and Retrieval of Blood and Blood Recent Recipients of Smallpox Vaccine (Vaccinia Virus) and Certain Contacts of Smallpox Vaccine Recipients - (December 30, 2002).
</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.4.1A, #14 – SARS COV2</td>
<td>SC</td>
<td>NA</td>
<td>NA</td>
<td>The committee added a new entry to reference standard 5.4.1A concerning the receipt of SARS COV2 vaccines and any associated deferrals for clarity. The content of the entry matches the requirements set forth by the FDA in September 2020 that was also included as a separate guidance released by the committee in September 2020. The guidance can be found at this link.</td>
</tr>
<tr>
<td>5.4.1A, #14 – Receipt of other Vaccines</td>
<td>SC</td>
<td>NA</td>
<td>NA</td>
<td>The committee edited the deferral period associated with the receipt of other vaccines for consistency by removing the 12 month deferral requirement to remain consistent with the most recent Medication Deferral List. This change allows the medical director more discretion in making deferral decisions in these instances. The deferral period now reads as follows:
<table>
<tr><td>14) Immunizations and Vaccinations</td><td>• Receipt of other vaccines, including unlicensed vaccines</td><td>As determined by the medical director or defer according to the current version of the Medication Deferral List</td></tr>
</table>
</td>
</tr>
</table>

5.4.1A. #16	RtC	Is it possible to review the decision to refuse blood from donors who were in the UK and was resident during the outbreak of CJD in the late 80's and early 90's?	No	The committee reviewed this comment but did not feel that a change was appropriate at this time. The deferral period for this donor risk is determined by the FDA. Should the FDA adjust its deferral periods, the Standards Committee will follow suit.
6.2.6	SC	NA	NA	The committee edited the way standard 6.2.6 was written mirror a similar change made in the Standards for Immunohematology Reference Laboratories. The standard now reads as a sentence as opposed to as a phrase; the intent of the standard has not changed. The standard now reads as follows: **6.2.6 Changes to Records** There shall be processes and procedures for changes to records.
6.2B, #12	RtC	We request a change of retention time from Indefinite to 50 years. Our reason is that we see records increasing in age it will be increasingly difficult to maintain records indefinitely. Therefore, requesting to consider changing the retention period from indefinite to 50 years Maximum retention is 50 years as per Canadian Standards Association and Health Canada Regulations.	NO	The committee reviewed this comment but did not feel that a change was appropriate at this time. The records in question pertain specifically to clinically significant antibodies, and with these units, there is a possibility that the patient in question could still be living after the 50 years which would cause a potential gap that could lead to potential deviations.
7.5.1.2, #3, c	RtC	According to BBTS Std 7.5.1.2, *when a transfusion is discontinued, the following shall be performed: 3) Except in the cases of signs and symptoms suggestive of mild allergic reactions (urticaria):* ***c) A post transfusion sample shall be obtained from the patient and sent to the BBTS***. The standard then goes on to list actions that shall be taken. (*7.5.2.1) For suspected hemolytic transfusion reactions, the evaluation shall include the following: 1) post transfusion reaction serum or plasma shall be inspected…2) A repeat ABO group; 3) A direct antiglobulin test*, etc. Further evaluation for suspected non-hemolytic transfusion reactions, including but not limited to, febrile reactions, possible bacterial contamination, and pulmonary reactions (TRALI AND TACO) do not include the need for the specimen that is collected when the transfusion is discontinued.	NO	The committee reviewed this comment but does not feel that a change is needed at this time. The committee feels that it is safer to have a sample for evaluation at a later time, than to not. This ensures that facilities are able to perform an evaluation on a sample in the case of stopping future adverse reactions and potentially harming patients.

		We would like to propose that the requirement for a post-transfusion specimen be moved to the section related to hemolytic transfusion reactions (7.5.2.1) and allow transfusion service medical directors to determine the need for post-transfusion specimens in regards to all other types of reactions to blood products including platelets and plasma. Our current policy is to require a specimen for all reactions (other than urticarial) so that we can be compliant with the standards, however in most cases, this specimen is not needed and therefore is not processed, especially in the case of reactions to platelets. This practice does not support patient blood management initiatives. Collection of a specimen that is not needed for the transfusion workup subjects the patient to un-necessary phlebotomies as well as accumulated blood loss which could subsequently cause hospital-acquired anemia.		
7.5.2.2	SC	NA	NA	The committee has expanded standard 7.5.2.2 by including the clause “pulmonary reactions” to the content. These reactions, specifically TRALI and TACO are becoming far more frequent and the committee wishes to recognize this.
7.5.2.2.1 (New)	SC	NA	NA	The committee created new standard 7.5.5.2.1 and was included for completeness. This standard ensures the Standards are consistent with the most recent FDA guidance on microbial testing for bacterial contamination. The standard reads as follows: **7.5.2.2.1** The BB/TS shall have policies, processes and procedures for referral for microbial testing for bacterial contamination.
7.5.2.2.1 (New)	RtC	Regarding the new standard 7.5.2.2.1: The BB/TS shall have policies, processes and procedures for referral for culture testing for bacterial contamination. Std 7.5.2.2 states "...shall have a process to evaluate...possible bacterial contamination...". Adding the new Std 7.5.2.2.1 for referral culture testing seems too prescriptive given the preceding standard. What if a lab performs molecular testing for bacterial identification?	YES	The committee reviewed this comment and updated the proposed language from the edition circulated for comment to replace the term “culture” with “microbial” as the term “microbial” truly covers everything discussed in the standard.
7.5.2.3	SC	NA	NA	The committee has expanded standard 7.5.2.3 by including the clause “pulmonary reactions” to the content. These reactions, specifically TRALI

				and TACO are becoming far more frequent and the committee wishes to recognize this.
7.5.2.3	RtC	Please clarify that TACO does not need to be reported to the collecting blood establishment and the colleting facility does not need to investigate TACO since it is not considered to be related to an attribute of the donor or blood components as per 7.5.2.4.	NO	The committee reviewed this comment but did not feel that a change was needed at this time. This does agree in principle with the comment, however it should be noted that the standards do not mandate that you have to report this information to the collecting facility in either standard.
10.3	SC	NA	NA	The committee edited the title of this standard by replacing the term “discard” with “handling”. The committee feels that this term better reflects the content of the standard. The committee felt that the term “discard” did not accurately represent the content of the standard.