Response to Comments Received to the 31st edition of Standards for Blood Banks and Transfusion Services

Please note that public comments that were submitted address the proposed 31st 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. This document does not represent a full summary of significant changes to the 31st edition of BBTS Standards. Guidance that appears with the 31st 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	Comment	Change made?	Outcome
1.1.1	We believe that this standard applies specifically to CLIA regulations and patient testing, not to procedures and equipment used for routine blood center component preparation such as an irradiator. Please clarify if this standard and 42CFR 493.1251(d) applies to activities which are outside the scope of CLIA. When our facility responded to a similar nonconformance that the Medical Director did not review and sign Amicus Separator qualifications, the response dated August 12, 2016 was accepted. This response stated that "The Fenwal Amicus Separator does not involve patient testing and would not require Medical Director review under CLIA Guidelines." We believe the irradiator should be evaluated in the same way, under CLIA Guidelines.	No	The committee notes that as stated under standard 1.1.1, all activities that occur in the blood bank or transfusion service would be the responsibility of the medical director, not just the policies, processes and procedures under CLIA. The intent of this standard is to ensure that the medical director is aware of all policies, processes and procedures, and therefore a change to this standard is not needed.
1.1.1	Do National Testing Laboratories (NTLs) really need a medical director? Any abnormal results would be reported back to the facility that submitted the sample and that facility would need a medical director. They do not have any direct donor/patient contact.	No	All facilities accredited under the BBTS Standards require a medical director on staff. The role played by that individual could differ based on the size and responsibilities of the facility, but to ensure compliance with these Standards, an individual with the qualifications expected of a medical director must be on staff.
1.2.2	This sounds like management has to perform the assessments rather than delegating them to someone else to perform. Suggest change to 'review of assessments and other scheduled management reviews'.	No	The committee reviewed this comment but did not think a change was needed at this time. The standard, as written, ensures that internal assessments are performed and that management reviews them.
1.4, 1.4.1	As seen during assessments, facilities tend to think they only need to test the emergency communication systems and nothing else. We suggest either saying 'at a minimum the emergency communication systems' or 'including the emergency communication systems and other aspects …'. May need to break this out into its own standard.	No	The committee reviewed this comment but did not feel a change was needed. Standard 1.4.1 requires a complete and total plan, including communication systems, ensuring that those are included. Guidance will be updated to ensure that this is understood.

Chapter 2	We suggest adding a requirement for continuing education to parallel CT and other standards. Suggest the following verbiage – "The BBTS shall define continuing education requirements for all personnel and ensure that these requirements are met."	No	The committee noted this comment and thinks that the addition of a similar standard would be appropriate to discuss as work on the 32nd edition begins.
3.0	Does calibration, monitoring and maintenance include the operation of the equipment? Shouldn't the operation also conform to requirements?	No	The committee reviewed this comment and did not feel that a change was needed at this time. The committee feels that this concern is adequately covered in standard 3.2 and the substandards the cascade beneath 3.2.
3.5.2, #1	The discussion we had involved what the expectation would be for instruments that have semi-annual and/or annual QC performed. Would this mean that all the products for the last 6-12 months would: A. Need to be retested B. Be considered non-conforming products. The example: A controlled rate freezer that has the temperature calibration checked every 6 months. if we discover the temperature is out of calibration, do we need to consider all of the products in the last six months would need to have a nonconformance generated and/or testing performed?	Yes	When the proposed 31st edition was released for public comment, subnumber 1 was edited to read, "1) Assessment of blood, blood components, tissue, derivatives, and services provided ~~when~~ since the equipment was last qualified ~~is found to be out of calibration~~." Based on the comment (and other comments received) the standard was rewritten as such: "1) Assessment of blood, blood components, tissue, derivatives, and services provided since the equipment was last known to be functioning per manufacturer's written instructions, or facility defined specifications." The committee felt that this change would maintain the initial intent of the change, to ensure that equipment that has been repaired, retooled or recalibrated work as indicated and that there are records to ensure appropriate lookback.
3.5.2, #1	Can you please clarify the meaning of "last qualified?" Does this refer to periodic maintenance, calibration, or validation?	Yes	The committee agreed with the query and adjusted the standard as written above.
3.5.2, #1	Please delete the words *"the equipment was."* Services are not equipment. Should read "since last qualified…"	Yes	The committee agreed with this comment and the change was made.
3.5.2, #1	What would constitute "qualified"? Can a QC or the most recent preventive maintenance be considered an acceptable check of the equipment?	Yes	The committee reviewed this comment, and noted that yes, the examples cited would meet the intent of the standard.

3.5.2, #1	Would this include the last performance qualification or the most recent periodic QC procedure?	Yes	The committee reviewed this comment and in response to the query feels that the most recent procedure would be appropriate.
3.6	Does this include tissues that might be stored at ambient temperatures?	No	The committee reviewed this comment and noted that standard 3.6.1 covers all storage devices of tissues (as well as reagents and derivatives) and as such would require that devices that maintain ambient storage temperatures would be required to meet this standard.
3.7, 3.7.1	Smaller blood banks and facilities may have difficulty instituting alarm systems for reagent-only storage devices.	No	The committee noted this comment but feels that not having an alarm system could lead to reagents falling out of range and then subsequently being used or being discarded due to their status not being determined in an adequate amount of time.
3.7, 3.7.1	Requiring all storage devices for "reagents" to have alarm systems that are set to activate when temp is outside established limits (similar to storage devices for Blood products, tissues, and derivatives) is too much of a burden on the routine Transfusion Service. The additional requirement of a temperature alarm system for reagents is not required in any other area of the clinical laboratory (Chemistry, Hematology, Coagulation, etc.). The absence of reagent alarms has not resulted in additional risk to patient safety, nor has it resulted in documented improvement in the quality of patient testing. Additionally, the acceptable temperature range for most reagents (2-8C) is not the same as most refrigerated blood components (1-6C). This forces the TS to either use 2 different storage devices (one for reagents, one for blood products), or to have 2 separate alarm systems in one storage device, or to use one alarm system set to activate at temps below 2C or above 6C. (This is a very narrow window to maintain.). Recording the temperature of reagent storage devices once per day, once per shift, or even continuously (with external temperature monitoring devices) without requiring a temperature alarm system has been sufficient and effective for the past 50+ years, and I see no "added value" with the requirement of a temperature alarm system. The requirement for an alarm system for storage of reagents should be removed from both the proposed TS/BB standards and the	No	The committee noted this comment but did not feel a change back to the original language was appropriate. The standard does not require the purchase of new refrigerators, nor does it require the segregation of reagents to a separate storage device. The committee notes that at this time, most facilities have moved to an electronic monitoring system and as such the ability to meet this new requirement should not be at issue.

	proposed IRL standards.		
3.7, 3.7.1	The requirement of storage devices for reagents to have an alarm can pose a burden on transfusion services who do not currently have alarm systems in place on their reagent storage devices. In the event there are reagents stored at room temperature, would these rooms/areas also require an alarm system?	No	The committee reviewed this comment and noted that the Standards require the use of an alarm system and that storage devices are able to maintain appropriate temperatures for all units, and as such, a facility should be meeting this standard as written already.
3.7, 3.7.1	Does everyone store all their BB reagents in a storage device with an alarm system? (In other words, are all your BB reagents kept in a refrigerator (or freezer) which could also be used for blood/blood components?) Since most refrigerated BB reagents must be stored at 2-8 C, and blood is stored at 1-6C, at what temperature(s) are your low and high alarms set to activate? (For example, since we store some BB reagents in refrigerators that can also be used for blood, we have had to change our alarm activation points to 2.5 (low) and 5.5 (high). This is a very narrow "window" to maintain. The requirement to store reagents in a storage device with an alarm system is only being applied to Transfusion Services/Blood Banks, via the AABB Standards. There is no indication that these same requirements will be imposed (by CAP or TJC, for example) for other laboratory reagents, which in my opinion, are just as critical, as reagents used in pretransfusion testing.	No	The committee reviewed this comment but did not think that a change was needed at this time. The committee notes that most manufacturer's sell devices that are set for 1-10^{o}C. Guidance will be crafted surrounding this topic to assist users in its implementation.
3.7.1	Should there be a requirement to test the alarm system to ensure it functions as indicated in this standard?	No	The committee noted this comment, and would point to standards 3.5 and 5.1.3 which requires that equipment be monitored and maintained in accordance with manufacturer's instructions, as well as having a program of quality control.
3.8	Should the temperature of the warming device be checked and recorded before using?	No	The committee reviewed this comment and noted that standard 3.3 which requires that equipment be used in accordance with manufacturer's written instructions.
4.2	If a pen is placed in a parent standard, does it also need to be included in the sub standards? This formatting is not consistent throughout the Standards.	No	The committee reviewed this comment and noted that in some instances the record retention requirement does cascade down into the substandards, and in some cases it does not. The committee suggests reviewing the appropriate record retention chart to determine where

			records are required to be maintained. Unfortunately, a one size fits all approach does not work in this instance.
5.0	Delete “and” before “validated”	No	The committee noted this comment but did not feel that this change was appropriate as it could change the interpretation of the rest of the standard.
5.1.2, 5.1.2.1 (New), 5.1.2.1.1 (New), 5.1.2.1.2 (New)	Suggest expanding to include non-US facilities by adding some of the verbiage from the CT standards: “5.1.2 Proficiency Testing. The facility shall participate in an external proficiency testing program for each analyte measured by the laboratory. 5.1.2.1 In the United States, for each analyte requiring proficiency testing under CLIA, each laboratory shall participate in a CMS-approved proficiency testing program for each analyte requiring proficiency testing under CLIA. 42 CFR 493.1236(b)(1) 5.1.2.1.1 When a CMS-approved program is not available, there shall be a system for determining the accuracy and reliability of test results 5.1.2.2 Facilities not in the US shall participate in an external proficiency testing program, if available, for each analyte. Proficiency testing shall include comparison of test results from an outside laboratory. 5.1.2.2.1 When an external proficiency testing program is not available, there shall be a system for determining the accuracy and reliability of test results. 5.1.2.3 Proficiency testing for each analyte shall be performed twice a year at a minimum. 5.1.2.4 Proficiency testing results shall be reviewed by the medical or laboratory director. 5.1.2.4.1 Proficiency testing failures shall be investigated and corrective action taken, as appropriate.”	Yes	The committee agreed with the intent of this comment and as a result created new standard 5.1.2.1 titled, “Proficiency Testing for Facilities not Subject to US Regulation” which details the proficiency testing requirements surrounding facilities outside the US. New standards 5.1.2.1.1 and 5.1.2.1.2 further detail what facilities can do in the case where an external proficiency testing is not available, and that a comparison to an outside laboratory is a minimum requirement for proficiency testing.
5.1.5.1	Does this standard apply to both blood banks and transfusion services? Is AABB requiring TS to perform the tasks in 5.1.5.1 and 5.1.5.2? Suggest editing the standard by removing “into the collection” and replacing it with “during the collection and manufacturing process.”	Yes	The committee reviewed this comment and noted that the standard does apply to both blood banks and transfusion services. To ensure that this was understood, the committee added the clause, “during collection and processing” in standard 5.1.5.1 to ensure that the scope of the standard was understood.

5.1.5.2	In light of the retraction of the FDA draft guidance document requiring bacterial testing on day 4 and / or day 5 for platelets, can this standard be revised so that it clearly allows for reliance on the blood supplier's initial bacterial detection testing and does not require repeat bacterial testing on day 4/ day 5 by either the transfusion service or blood supplier?	No	The committee noted this comment but did not feel that a change was needed at this time. The committee does not provide links to draft guidances from the FDA as they are in draft form and can change. Once final, the committee would consider a reference, however it should be noted that the standard does not state when testing has to occur.
5.1.5.3	It's not a "true-culture" it's a "true positive;" maybe reword the sentence and include use of the phrases "true positive" and "false positive"?	Yes	The committee agreed with the intent of this comment and replaced the term "true culture" with "true positive culture" for clarity.
5.1.6.5.2	NA	NA	The committee elected to add a cross reference to standard 5.1.6.2 at the end of standard 5.1.6.5.2 which focuses on traceability.
5.1.8.1.2	If 'immediately' difficult to assess, should it still be included here?	No	The term immediate in the case of standard 5.1.8.2 which focuses on the inspection of blood, blood components, tissue or derivatives before shipping should be done immediately.
5.2.1	This contains some but not all of the elements of a donor acknowledgement required in 630.10(g)(2). Specifically, the donors must acknowledge that they have been provided and reviewed information about the risks and hazards of the specific donation procedure. Does the committee want to consider including this element or a reference 630.10(g)(2)? In addition, 630.10(g)(2) states that the donor acknowledgement must be obtained before each donation. I think that is the intent of this standard but it does not specifically state it must be done before each donation. Does the committee want to consider including this?	Yes	The committee agreed with this comment and included a reference to 21 CFR 630.10(g)(2) to standard 5.2.1.
5.2.3	NA	NA	The committee elected to replace the term "of infectious diseases" with "relevant transfusion transmitted infections" to match the current language used.
5.2.3	See comment above about the donor acknowledgement. The informed consent reg are in 630.15(b)(2) (for plasma collected during apheresis) and 640.21(g) (for plateletpheresis). If this section is for the informed consent required in these regs, should these regs be referenced here?	No	The committee reviewed this comment but did not feel that included the cited references added anything to the standard.

5.2.3	Add *relevant* before transfusion transmitted infections as that is what FDA uses.	Yes	The committee agreed with this comment and included the term in the standard for the clause to read, "relevant transfusion transmitted infections."
5.4.2.1	As written, this standard does not appear to restrict what types of information can be obtained after donation. Vital signs, weight, H/H are used to determine donor eligibility – can information about this criteria be obtained after donation? 630.10(c) is very clear that the only type of information that can be obtained 24 hours after collection is that required in 630.10(e) – the donor's medical history which is obtained via the DHQ. Should there be a reference to 630.10(c)?	Yes	The committee agreed with this comment and added a reference to 21 CFR 630.10(c) as suggested.
5.4.4.2	Since this standard requires either hemoglobin or hematocrit to be used, the words "if used" are redundant. Remove the words "if used".	Yes	The committee agreed with the comment and removed the clause "if used" from the standard.
5.5.3.2	640.21(f)(1) states the 8 week deferral is waived if the extracorporeal RBC is less than 100mL AND at least 2 calendar days have passed. Should the standard include this information or point to this reg?	Yes	The committee agreed with this comment and added the clause, "in which case the interval shall be at least two calendar days" to the standard.
5.6.3.2	Can this now be hours later, anywhere like in the lab? I think you need to put "immediately" back or it's a slippery slope.	Yes	In the proposed 31st edition, the committee removed the term "immediate" from standard 5.6.3.2 as it was deemed difficult to assess. However, based on this comment (and others like it) the committee realized that a timeframe that labeling is completed had to be included. As such, the committee replaced the clause "from the donation" with "…and before the tubes and container(s) are separated."
5.6.3.2	I suggest that the terminology should be that the tubes shall be re-identified with the blood container at the time of filling. While identifying after confirms that the blood is in the correct tube, identifying immediately before prevents blood from being put into the wrong tube and therefore ensures that there is not a shortage of blood for testing because an incorrectly labeled tube was used. Also tubes can be re-identified with the blood container at the time of filling if the number on the tube is compared to a label on the blood bag or the sample diversion pouch as the tube is filling. That is neither before or after filling but ensures that the blood tube is appropriately labeled.	Yes	The committee agreed with the intent of the comment and adjusted the standard to ensure that a timeframe to ensure that labeling was completed was included.
5.6.3.2	The word 'immediately' was removed and this word has long been a problem to assess and I am glad to see it removed. Is there a 'when' that this check needs	Yes	The committee reviewed this comment and agreed with its intent and as a result added that

	to be done or not? For instance, does the check between the blood container and the tubes need to be done while the patient is still present at the donation site? Or can it be done by component processing back at the donor center? If this latter time is acceptable, then no change is suggested. If a timeframe is needed, suggest spelling it out in a separate sentence.		clause, "…and before the tubes and container(s) are separated" as a timeframe that users of the standard would be held to.
5.6.5	We recommend that the language in the standard be consistent with the title change and state the following: If blood is to be transported from the collection site, it shall be placed in a qualified container having sufficient refrigeration capacity to cool the blood continuously toward a temperature range of 1 to 10 C until it arrives at the processing site.	Yes	The committee agreed with the comment and edited the standard to remove the clause "to the component processing laboratory" ensuring that the content of the standard matched the new title.
5.6.6.1	Does it mean the product was not retained by the donor or not retained by the blood center? Does it mean the process shall ensure safe reinfusion of the collected product/	Yes	The committee agreed with the comment and removed the term "autologous" and added "to the donor" at the conclusion of the standard.
5.6.7.1 #2	As written, the standard makes it seem the only criteria for allowing the units from HH or other TP donors to be used for allogeneic transfusion is that the donor's condition will not affect the product. The regulation does state this in 630.15(a)(2)(ii)(B), but there are other conditions that must be met. Specifically, the donor must meet donor eligibility criteria (630.15(a)(2)(i)) and the donation will not adversely affect the donor's health (630.15(a)(2)(ii)(B)). At a minimum, should these conditions also be included in the standard? I note there are other conditions in the regulations (e.g., TP done under a prescription and no fee is charged) but I did not know how much needed to be included in the standards if a link to the regulation was provided.	Yes	The committee had issued the proposed 31st edition with a change to subnumber 2 to attempt to mirror the language in the current code of federal regulations. Based on this comment, the committee edited subnumber 2 to read, "The phlebotomy is for hereditary hemochromatosis and there is no charge for the procedure."
5.7.3	Should pathogen reduction be included here?	No	The committee reviewed this comment, but did not feel that the addition of pathogen reduction to this standard would be appropriate at this time due to the lack of input from the membership. The committee will consider this for the 32nd edition however.
5.7.3.1	The LR guidance says: ... statistically valid plan based on 95% confidence that more than 95% of the components will meet the recommended results. We recommend this standard be revised to "greater than 95% of units sampled meet this criterion."	NA	The committee agreed with this comment and elected to remove the clause "at least" from this standard, and include the "greater than or equal to" sign which would assist with clarity.
5.7.3.1	Consider adding sampling size rather than the FDA sample size of 4/month	No	The committee reviewed this comment but did

	regardless of how many units are collected in a one month period.		not feel that this change should be made. Such a change would require created a sample size that would not fit for all users. The committee points to the guidance which explains this further.
5.7.4.5	We checked the TM and does not specifically state there should be at least 80% recovery of the RBCs after washing, but it does say that the hemoglobin of washed RBCs must be at least 40g (Hct 65-75%), hemolysis <0.8% and protein in final supernatant <0.5 g/unit. Did the committee want to include any product standards here, similar to what is included for other RBC products?	No	The committee reviewed the comment but did not feel that a change was needed at this time. The committee feels that what is included in the Technical Manual would best serve as guidance and will look at the content to determine if there is a need to supplement the current guidance.
5.7.4.9, 5.7.4.10	I see that the less than or equal to symbols are being used instead of the specific words. We actually had to discuss this too because we realized there was some confusion when the symbols were used. We made an internal policy that we would use specific words rather than the symbols. For example, 5.7.4.10 includes the term $\leq$ -18 C. We found that some centers and individuals think less than -18 is really -17 or -16, etc. So now we use the term "-18 C or colder." I note that the term "-18 C or colder" is on the ISBT label and in our revised 610.53 reg.	NA	The committee elected to replace the "less than or equal to" symbols in standards 5.7.4.9 and 5.7.4.10 with "or colder." This matches the current ISBT 128 nomenclature, and alleviates any confusion of what the symbol meant. Changes have been made in reference standard 5.1.8A where appropriate.
5.7.4.11	FDA has approved at least one collection system (SOLX) to make PF24RT24 from Whole Blood.	No	The committee noted this comment and has passed it along to the Circular of Information Task Force for their information.
5.8.5	T. cruzi is only required to be tested once on a donor. We are a very mobile society. Should we consider adding travel like we have for malaria, and if a donor has been in an area/situation where they might have been exposed, that they be retested?	No	The committee did not feel that a change was needed at this time and felt that facilities that currently have a variance for not performing this test are meeting the standard through preventive donor screening and subsequent deferral if necessary.
5.8.5, 5.8.6	Is it time to add that for international facilities, test kits need to be FDA-approved or approved by the Competent Authority?	No	The committee reviewed this comment but did not think a change was needed as this requirement is already covered in standard 4.3.2.1.
5.14.5 (5.16.2.2)	So since 5.16.2.2 is now under 5.14.5, does that mean that two types are always required? Not only for electronic crossmatches?	No	The committee noted this comment and pointed to the title of the standard which provides clarity to the query. This testing does not have to occur on every sample as noted in the standard.

5.14.5 (5.16.2.2)	Standard 5.16.2.2 in 30th edition discusses 2 determinations of the recipient's ABO/Rh group as specified in Standard 5.14.1. By referring to standard 5.14.1, is the intent of the standard that the ABO/Rh for BOTH determinations include forward red cell typing AND reverse typing (especially for a Computer Crossmatch)? I do not see these specifics for the second determination in the FDA's guidance for Computer crossmatch. They call the second determination a confirmation. Very curious; don't believe CAP defines that it must be forward and reverse also! Please clarify for current AND future Standards.	No	The committee reviewed this comment and noted that the first determination has to be done on a current sample, while the second provides option on how to meet the standard.
5.14.5 (5.16.2.2)	The renumbering of standard 5.16.2.2 to standard 5.14.5 will require a second blood type for all patients, not just for those who qualify for the Use of Computer to Detect ABO Incompatibility (electronic/computer crossmatch). Is this the intent of the renumbering? My interpretation of this currently is that these are not required for all patients, only those where electronic/computer crossmatches are being used.	No	The committee reviewed the comment and noted that the movement of the standard does not add an extra burden upon the individual implementing the standard any further than what is currently required in the standard.
5.14.5 (5.16.2.2)	Is the intent of the standard only to apply to electronic crossmatch or to electronic and manual crossmatch?	No	The committee noted this comment and points out that an electronic crossmatch is not required, there are other processes if validated to meet the intent.
5.14.5 (5.16.2.2)	Consider rewording Standard 5.14.6-3) to align with FDA guidance (computer crossmatch): In certain situations when only one specimen may be available for testing, such as in emergencies or when only one sample is received for home transfusion, repeat testing may be performed on the same specimen, but the repeat test should be performed either by a different technologist or by the same technologist using different reagents. Or clarify in AABB Standards Guidance whether following repeat testing on the same sample per the FDA computer crossmatch guidance will satisfy #3 of Standard 5.14.6.	No	The committee reviewed the comment but did not think that a change was needed at this time. Guidance will be provided to ensure that the intent of the standard is understood and how the standard is to be implemented.
5.15.1	The BB/TS SC received many comments suggesting a change to standard 5.15.1, examples of the request and tone are included below: • Our group is recommending that the AABB Standards Committee modify standard 5.15.1 to permit the use of low titer, group O whole blood (WB) in all massively bleeding patients regardless of their ABO group. The WP recommends deleting the requirement for administering WB in an ABO-identical manner from 5.15.1, and creating a new standard and substandard as follows: New standard 1: Low titer, group O whole blood can be administered in an uncrossmatched manner to recipients with a life-threatening	Yes	The committee reviewed these comments and others of a similar vein and elected to edit standard 5.15.1 (and subsequently standards 5.27.1, 5.27.1.1 and 5.27.2) to include the allowance to use low titer group O Whole Blood (for non group O or for recipients whose ABO group is unknown. The use of this product however, can only be in situations defined by each facility's policies, processes and

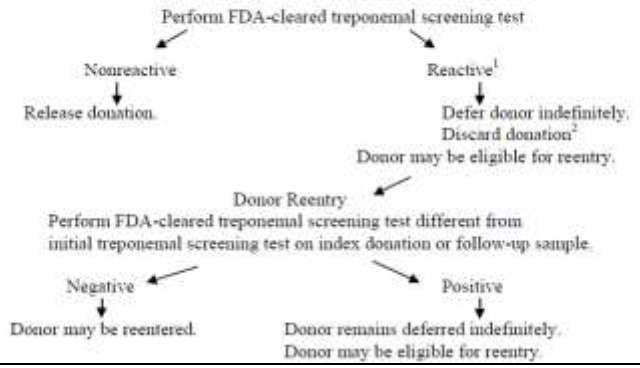
	hemorrhage regardless of the recipient's ABO group. New standard 1.1: Low titer WB shall be defined as <200 for both anti-A and –B. • We suggest modifying *Standard* 5.15.1 to permit the use of low titer, group O whole blood (WB) in massively bleeding patients prior to the availability of type-specific blood. The rationale provided in their proposal is sound, and we agree that there is a need for this product for both prehospital use and in-hospital use for patients with life-threatening hemorrhage. From the literature cited, the potential benefits of using low titer group O whole blood appear to outweigh the risks of trans-fusing low titer, potentially incompatible plasma in this population. Several committee members commented that our support for this change does not obviate the need for appropriately designed and executed studies that (1.) standardize the measurement of anti-A and B titers and (2.) address the outcomes attendant on transfusing low titer type O whole blood. Others suggested considering the *Standards* to ask individual collection facilities for clear definitions of what they consider "low titer". • We agree that there is an urgent need for this product for both prehospital use and in-hospital use for patients with life-threatening hemorrhage. The potential benefit of using low titer group O whole blood far outweighs the minor risks of transfusing low titer potentially incompatible plasma in this population. • We strongly support and endorse modifying standard 5.15.1 to permit the use of low titer, group O whole blood (WB) in massively bleeding patients regardless of the recipient's ABO group. We agree that there is an urgent need for this product for both prehospital use and in-hospital use for patients with life-threatening hemorrhage. The potential benefit of using low titer group O whole blood far outweighs the minor risks of transfusing low titer potentially incompatible plasma in this population.		procedures. Standard 5.27.1.1 (detailed further in this chart) requires defined policies, processes and procedures for the use of low titer group O Whole Blood, the maximum amount of volume/units allowed per event and patient monitor for adverse effects. The committee edited standard 5.15.1 (and subsequently, 5.27.1, 5.27.1.1, and 5.27.2) based on the comments, but also on the fact that many variance requests had been received for the use of this product that showed the use of this product in a controlled manner was effective.
5.17.1.1, 5.17.1.2 and 5.17.1.2.1	Per these requirements, a repeat ABO/Rh and antibody screen would be required if a neonate was discharged, but was readmitted within their first 4 months of life. This does not seem like it would be scientifically necessary, as the neonate would not be creating antibodies until after they are 4 months of	No	The committee reviewed this comment but did not feel that a change was needed at this time. The committee notes that if a neonate is readmitted to the hospital, then they should be

	age, regardless of treatment at other facilities, etc. I feel that a new sample should not be required until the neonate reaches the age of 4 months.		re-typed to ensure that in the time between visits they have not become immunocompromised in any way.
5.26	The standard is arguable as to whether Red Cell products may be warmed above 10 degrees C or not. Some sites argue that the transfusion must be started within 30 minutes of leaving the TS, but the temperature of the bag need not be tested to ensure it has not warmed to an unacceptable temperature if it is returned for storage beyond 10 degrees or 30 minutes. The "30 minute rule" has been taken to a new unacceptable disagreement the decisive factor being the "start of transfusion" vs. "temperature of product.	No	The committee reviewed this comment but did not feel that a change was needed at this time. Substandard number 2 of standard 5.26 requires that the appropriate temperature be maintained for all products that are to be reissued.
5.27	It should not be necessary to specify here (at Standard 5.14.6) that Standard 5.27.1 applies. The standard 5.27.1 to issue group O Red Blood Cells when recipient ABO group is not known is appropriately located in the section regarding Urgent Requirement for Blood and Blood Components. Tying issuance of group O Red Blood Cells to the requirement for 2 determinations of recipient's ABO group may lead to drainage of the group O community supply.	No	The committee reviewed this comment but did not think that a change would be appropriate. The committee feels that the standard ensures a level of safety that is necessary in urgent situations.
5.27.1	Should be recipients who have, not has.	No	The committee noted this comment but did not make the change.
5.27.5.1	Should 'immediately' also be removed here since it is difficult to assess?	No	The committee reviewed this comment and noted that there are instances in which the term "immediate" would be appropriate to use, which is the case here. Further, the CLIA reference cited for standard 5.27.5 uses the term "immediate" as well, highlighting the need for immediacy in this case.
5.28.3	Since 'immediately' difficult to assess, should it still be included here?	No	The committee reviewed this comment and noted that there are instances in which the term "immediate" would be appropriate to use, which is the case here.
5.28.4	Positively identify the recipient and match blood component to the recipient through the use of two independent identifiers. This is the practice when the transfusionist and one other individual check the blood, normally name and MRN are checked. When an electronic identification is used instead of the second individual, the current available system on the market only scan the MRN or the CSN of patient armband, patient information will show then the transfusionist will check both name and MRN. Does that comply with standards	No	The committee reviewed this comment but did not feel that a change to the standard was needed. The committee feels that the process described in this comment would meet the intent of the standard as written, to have an electronic check followed by a human check twice

	since technically only identifier is scanned by the electronic system which replaced the second individual?		thereafter.
5.29.1	I would like to see component blood type included in this standard. The standard should state that the "patient's medical record shall include.... the name of the component, the donation identification number AND BLOOD TYPE, the date and time. The blood type of donor components is very important for certain classes of patients; blood and marrow transplant patients and ABO-incompatible heart transplant patients to name a few. Physicians require this information as part of patient care and should be able to get it via a patient's medical record. As we were building our new LIS system we discovered that it does not send the component blood type to the patient care LIS. The company asked me to give them the standard that required this. I was quite surprised that 5.29.1 did not state that the component blood type was required to be on a patient's medical record. I've asked fellow blood bankers about this and they all thought it was a standard because all of us consider it a standard of care to ensure that the component blood type was "on the chart". They were quite shocked when I told them that there is no standard that states that the component blood type must be on the patient's medical record.	Yes	The committee agreed with this comment and as a result, added the clause, "…the donor ABO/Rh type…" to the standard for completeness.
5.1.6A, footnote 14	There are other labeling requirements for RP in 606.121(c)(10) and (11).	Yes	The committee agreed with the comment and added the additional CFR references.
5.1.8A, #14-22	We disagree with the change made. Putting the "maximum storage time without agitation" from the additional criteria column to the transportation column implies that it only applies during that phase. The title "additional criteria" does not imply that this is optional.	No	The committee noted this comment but did not agree with the intent. The requirement for "constant agitation" currently resides in both the storage and transport columns respectively.
5.1.8A, #14-22	A question on moving this from additional criteria to transport column: Will the maximum time without agitation be 24 hours for storage as well as transportation? It's confusing as to why it would be only under the transport column.	No	The committee noted this comment, and would point out that the transport and expiration times are indicated in each column, for transport, the maximum time without agitation would be 30 hours and for expiration the expiration is 24 hours to 5 days dependent upon the collection system.
5.1.8A, #14-22	Would a reader think that a product that expires in 4 – 24 hours will be able to be used up to 30 hours?	No	The committee reviewed this comment but did not think that there should be any confusion as

			both columns are clearly indicated what each expiration time is for.
5.1.8A, #14-22	There are three studies, as indicated below, documented in the journal Transfusion, that support Apheresis Platelets in plasma is the better medium to support a 30 hour maximum storage time without agitation and Apheresis Platelets Platelet Additive Solution (PAS) should have a maximum storage time without agitation of 24 hours. Wagner et al. (2008). The influence of simulated shipping conditions (24- or 30-hr interruption of agitation) on the in vitro properties of apheresis platelets during 7-day storage, Transfusion, 48:1072-1080. Wagner et al. (2008). Comparison of the in vitro properties of apheresis platelets during 7-day storage after interrupting agitation for one or three periods, Transfusion, 48:2492-2500. Moroff et al. (2012). Comparative in vitro evaluation of apheresis platelets stored with 100% plasma or 65% platelet additive solution III/35% plasma and including periods without agitation under simulated shipping conditions, Transfusion, 52:834-843. Please provide further clarification for the change in maximum storage time without agitation from 24 hours to 30 hours for the Platelet Components listed in Reference Standard 5.1.8A.	No	The committee noted this comment but did not think that a change for apheresis platelets in PAS to 24 hours of storage time would be appropriate at this time.
5.1.8A, #17	Footnote 3 is the regulation for shipping temperatures and not expiration dates. Regulations for expiration dates is 610.53(b).	Yes	The committee agreed with this comment and adjusted the footnote cited in entry #17 to the appropriate column.
5.1.8A, #19	Acknowledging the FDA's acceptance of apheresis platelets stored at 1-6^{o}C without agitation for up to 3 days, when only used in the resuscitation of actively bleeding patients.	Yes	The committee agreed with this comment and in the "Additional Criteria" column added the following, "Other temperatures according to storage bag instructions. * 21 CFR 610.53 Agitation requirements at 1-6 C" This change is in accordance with the FDA regulations.
5.1.8A, #31 and 32	Should this entry and 31 also point to footnote 7?	Yes	The committee agreed with this comment and the change was made.

5.1.8A, #33 and 34	Should this and the ones above be footnote 6, not 5?	Yes	The committee agreed with this comment and the change was made.
5.1.8A, #35	The evidence justifying restricting the shelf life of Thawed Plasma to 5 days rather than 7 or 10 days.	No	The committee reviewed this comment but they determined that there was not enough evidence at this time to make the change.
5.1.8A, #39	The evidence justifying allowing Liquid Plasma to have a shelf life 5 days beyond the whole blood shelf life (26 – 42 days depending on the preparation method) rather than restricting the shelf life to 15 days or less when used for transfusion.	No	The committee reviewed this comment but did not feel that a change was needed at this time. The current wording of the standard remains in line with the current FDA regulations and therefore a change was not deemed necessary.
5.1.8A, #40	Shouldn't there be a reference to footnote 5 here?	Yes	The committee agreed with this comment and the change was made.
5.4.1A, #1	The draft proposes removing the minimum age of 16 years for blood donors since the competent authority decides. With new studies on the risks of iron deficiency, it is clear that blood donation by adolescents is dangerous to them. Hence, it seems prudent for AABB Standards to maintain at least a minimum donation age of 16. While this wouldn't currently impact donor centers in the USA, it might impact blood donations in other countries.	Yes	The committee reviewed the comment and agreed that leaving the minimum age requirement for donations of 16 years in the reference standard was appropriate.
5.4.1A, #1	We noted that the specific minimum age requirement (...or $\geq$ 16 years) was removed. There are 3 states that have no state law about minimum donation age. Some donor centers have interpreted the existing standard to mean that they can collect from 16 year olds with parental permission, even if their state law is silent on 16 year olds but allows donation by 17 or 18 year olds. Under the new Standard, would these centers change their practices and stop collecting from 16 year olds? In addition, California allows donation by 15 year olds. Is the intent of the Standard to allow further lowering of the donation age by individual states? In light of the heightened concern about collecting from teenage donors, how does AABB anticipate blood centers will handle this issue?	Yes	The committee reviewed the comment and agreed with its intent and felt that reincluded the 16 year old minimum requirement was appropriate at this time.
5.4.1A, #9	We've identified another "hedgehog pathway inhibitor" indicated for the treatment of adult patients with locally advanced basal cell carcinoma. This drug, Odomzo, is similar to the drug, Erivedge which was added earlier in the year. Odomzo has a "Warnings and Precautions" labeling statement to advise patients not to donate blood for 20 months after the last dose. The DHTF Medication Deferral Group has decided to add it as	Yes	The committee noted this comment and added in "Sonidegib (eg Odomzo) into the Drug Therapy column with a 24 month deferral.

	a 24 month deferral to keep things simple. We have not yet issued an updated MDL because they have been debating whether to add the HIV PreP drug Truvada also. The addition of Odomzo is definitely a confirmed addition. Just wanted to give BBTS the information for consideration in the 31st addition.		
5.4.1A, #13	Added for clarification; FDA often gets questions about whether the term "live" also applies to tissues and organs.	Yes	The committee noted that "live" in this case applies to cells, tissues and organs and as a result updated the entry for clarity.
5.4.1A, #15	There is no deferral period listed for this item. Is this because based on the screening and confirmatory tests, the donors may be reentered at some time? Maybe you want to consider placing the following statement in the deferral box: In accordance with FDA Guidance	Yes	The committee agreed with this comment and shifted the footnote from the "Category" column to the "Deferral Period" column.
5.4.1A, #15	Should we have an option for "none" as deferral period for Syphilis reactive first treponemal screening test with negative different treponemal screening test? As FDA has this path available? FDA Guidance reentry option allows immediate reentry without confirmatory test, no 12 month deferral as shown in the diagram below: **Figure 2: Donor Testing and Management When Using a Treponemal Screening Test as the Test of Record for the Detection of Syphilis**  	Yes	The committee noted this comment and based on its content, adjusted entry letter be to read, "Donor who has a reactive screening test for syphilis." In addition, the committee added a deferral time for subletter b which reads, "Indefinite – Donor re-entry in accordance with FDA Guidance."
Chapter 6	Suggest adding some/all of the verbiage from CT Standard 6.2.10: "Records shall be reviewed for accuracy, completeness, and compliance with applicable standards, laws, and regulations."	No	The committee reviewed the comment, but did not feel that the change was needed at this time. The committee will consider this for the 32nd edition.

6.1.3	Add a reference to the CFR indicating that the CLIA Lab Director is the only one who can approve new/revised documents.	Yes	The committee reviewed this comment, but noted that standard 1.3.1 already references this regulation. Therefore, the committee added a cross reference to standard 1.3.1 in this standard.
6.2	We note that each table has a different title and all are not called "Retention of Records."	No	The committee noted this comment but did not feel that a change was needed at this time.
6.2.3	Does this refer to samples as well? If not, are there elements that should be captured in relationship to samples? Or expand 5.1.6.2?	No	The committee reviewed this comment but did not feel that a change was needed at this time. The committee notes the standard requires tracking from source to final disposition, which is not always the case with samples, therefore a change would not be needed. The committee feels that the language in standard 5.1.6.2 is sufficient at this time.
6.2.5.1	Since 'immediately' is difficult to assess, would it be better to say 'concurrently' here?	No	The committee reviewed this comment and noted that there are instances in which the term "immediate" would be appropriate to use, which is the case here.
6.2B, #12	If we maintain the final interpretation of our antibody identification work ups in our LIS (indefinitely) – must we also keep the paper antibody identification work ups with the original reaction results rule outs and any extended test records?	No	The committee noted this comment but did not feel that a change was needed at this time.
6.2B, #22	6.2B Retention of Patient Records, Item #22 Standard 5.23 lists seven (7) points under Verification at issue and a retention of 10 years. Standard 5.23 Issue of Blood and Blood Components only lists six (6) aspects under "Verification shall include:" Same for Item #5 standard 5.24 for Reference standard 6.2D Retention of Tissue Records. Listed are seven (7) criteria to store once Tissue is issued. However, standard 5.24 Issue of Tissue and Derivatives only lists six (6) types of information that shall be verified. My suggestion is to add "7. Personnel issuing and accepting blood components" to the standard 5.23 and add "4. Personnel dispensing tissue and 5. Personnel accepting tissue for use" to standard 5.24 This would clarify the record retention requirement with the standard.	Yes	The committee agreed with the suggestion and added the complete list from the standard for consistency.

7.1.4	It seems like 606.171 could go here. That regulation applies only if the nonconforming products are released.	Yes	The committee agreed with this comment and added in the reference as requested.
7.3	As few countries has no national definitions or classification for Donor or patient adverse effect, I suggest to add to the statement: if nationally no known classification BB/TS shall follow known international classification (or add similar clarification of what to follow).	No	The committee noted this comment, but did not feel a change was needed for standard 7.3 at this time. The committee however did create new standard 7.3.1 to assist users from outside the United States which reads as follows: **7.3.1** Internationally recognized classifications shall be used when no national classifications exist.
7.3 RC	We do not support Proposed Standard 7.3 without further definition of "nationally recognized classifications." In particular, we need reassurance that "nationally recognized classifications" is met by our policies, processes, and procedures for our hemovigilance program. Our hemovigilance program has been in existence from 2003, and when initially formed, it was the only "national hemovigilance program" in the U.S. Since then, the CDC NHSN Hemovigilance Program has implemented. Our program has contributed many valuable findings to the transfusion medicine/blood banking literature through its data collection and analyses, plus implementation of process improvements in transfusion medicine/blood banking in the U.S. and abroad. If the terminology of "nationally recognized classifications" is left in proposed Standard 7.3, we suggest an asterisk be used to provide examples of such classifications or an addition to the text of Standard 7.3 be made providing examples of "nationally recognized classifications" ("…e.g., UK SHOT, Canadian Blood Services, HemaQuebec, Amercian Red Cross ARCHP, CDC NHSN Hemovigilance, Swissmedic, French AFSSAPS Hemovigilance, etc."). One further concern with the wording of Proposed Standard 7.3 is that it is unclear whether a transfusion service or blood bank in one country could utilize the "nationally recognized classification" of another country and still be in compliance with the Standard. Based on the current wording, that would seem to be permissible, and probably should be, since the current wording does not restrict it. Even in Canada, would it be permissible for a transfusion service or blood bank in Quebec to use the Canadian Blood Services hemovigilance classifications and be in	No	The committee reviewed this comment but did not agree that a change to the proposed language was needed at this time. The intent of this edit to the standard is to move towards a nationally recognized hemovigilance program and the allowance for the use of center based nomenclature would be a step back from the previous wording of the standard. The Portal will contain guidance to assist with the implementation of this change.

	compliance with the Standard?		
7.5.1	Change "Response to Immediate Transfusion Reaction" because when the symptoms are seen, it is not yet a Transfusion Reaction. It is a symptom or sign of a clinical response possibly related to the transfusion. Re-wording this requirement will improve recognition and increase numbers of workups when the patient is experiencing adverse signs and symptoms.	No	The committee reviewed this comment and feels that the standard as written addresses the issues contained therein while also pointing to standard 7.5.1.1 which specifically addresses these issues.
7.5.1.2	If 'immediately' is difficult to assess, should it still be included here?	No	The committee reviewed this comment, and noted that there are instances where the term "immediate" is needed and in this case, for discontinued transfusion, it shall remain in the standard.
7.5.2, 7.5.2.1	It needs to be clear that other than maybe urticarial or TRALI, all transfusion reactions should be checked as potential hemolytic transfusion reactions up front. For instance, hemolytic and non-hemolytic transfusion reactions share some of the same symptoms.	No	The committee noted this comment, but did not feel that a change was needed. The committee points to standard 7.5.2.2 and 7.5.2.3 which focus on TRALI.
7.5.2.3, 7.5.2.4	Since "immediately" was removed from other standards because it was difficult to assess, should it be removed here, too?	No	The committee reviewed this comment, and noted that there are instances where the term "immediate" is needed and in this case, for notification following an adverse reaction, it shall remain in the standard.
Glossary - Regulation	Did the committee want to consider stating that regulations are required, binding like laws?	No	The committee reviewed this comment but did not feel that a change was needed as the term "law" appears in the definition of the term.
Glossary - Supplier	Material is defined as "a good or supply item used in the manufacturing process" and a product is defined as "a tangible result of a process or procedure." Therefore, suppliers provide materials used in the manufacturing process along with the tangible results of manufacturing processes and procedures, i.e. products.	No	The committee reviewed this comment but did not think a change was needed. Allowing the definition to be read in a broader fashion was the intent in this case.
Glossary – Thereapeutic Phlebtomy	Suggested verbiage: "If therapeutic procedures are not part of the blood bank and the blood bank has no involvement in donor selection, screening, phlebotomy/apheresis procedures and any resulting therapeutic product, etc. then the requirements do not apply and the blood bank	No	The committee reviewed the suggested re-write but did not think that a change was needed.

	medical director does not have to be current on what is happening."		
Glossary - Xenotransplantation	Added for clarification; FDA often gets questions about whether the term "live" also applies to tissues and organs.	Yes	The committee reviewed this comment and made the change as they had in reference standard 5.4.1A.