Response to Comments Received to the 30th edition of Standards for Blood Banks and Transfusion Services

Please note that public comments that were submitted address the proposed 30th 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 program unit 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 30th edition of BBTS Standards. Guidance that appears with the 30th 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
3.2.2	The guidance cited with the standard only addresses BECS while this standard addresses all equipment. Maybe the asterisk should be removed or preface the guidance reference by saying "For Blood Establishment Computer Software*"	No	The committee noted this comment, but did not feel a change was needed at this time. When initially added to this standard, the intent was to ensure that operational qualification applies to all pieces of equipment and not merely for computer software.
3.7.3	Where would immediate action that includes moving product to another storage device be covered? This is an immediate action and not really a corrective action, which might include fixing or replacing the storage device.	Yes	The committee agreed with the intent of this comment and added the term "action" after immediate to ensure clarity of what is being requested.
4.1.2.2 (New)	Please add in "Testing performed by facilities outside the US shall be carried out by a qualified lab authorized as a testing center by the relevant competent authority."	Yes	The committee agreed with the intent of this comment and added new standard 4.1.2.2 to eliminate the need for facilities outside the United States to apply for variances that would be granted anyway.
5.1.4	Does standard 4.3.2.1 also apply?	Yes	The committee noted this comment and agreed with it. As such a reference to standard 4.3.2.1 was added.
5.1.5.2 (5.1.5.1)	During the comment period, the BBTS SPU received many comments concerning proposed standard 5.1.5.2; what is included below are examples of the comments received. • The standards use pathogen reduction, but in fact, pathogens are not removed but inactivated by the approved (and non-approved) processes for cellular products. Therefore, Pathogen Inactivation, is a more correct term. However, we realize these techniques reduce the total pathogen burden. • Methods approved outside of the FDA that are CE marked or approved by the country which the laboratory is being accredited should also be allowed. • Is the intent of the change in the Standard to mandate that point of	No	The committee noted these comments and had the following responses: • As it pertains to the language that appear in the standards, the committee notes that the term "pathogen reduction" is consistent with what is used by the FDA and therefore the committee felt that this term was most accurate. • The committee agreed with the comment regarding approval outside of the USA and points users to standard 5.1.5.2.1.

	issue testing or pathogen reduction technology must be used? The wording of the standard is not clear. I think it is meant to apply to the collection of blood components. If the intent of the standard is that we must either use point of issue testing or pathogen inactivated platelets, the standard is premature. We participated in a trial of point of issue testing and we have discontinued the practice. It was an operational nightmare. We plan on using pathogen reduced platelets, but we do not anticipate that they will become widely available before the 30th edition of Standards is in effect. Having said this, eventually AABB should consider when it is appropriate to mandate either point of issue testing or pathogen reduction of platelets.		• The committee reviewed this comment and noted that the standard does not require the use of pathogen reduction technologies, merely that they have the option.
5.1.6.2	Does 3.4 apply?	No	The committee noted this comment but did not feel that an additional cross reference was needed as there is a reference to standard 5.1.6.2 in standard 3.4.
5.1.6.3.1, #1	It is premature to make the proposed changes to the labeling standards. The comment section states that the committee elected to remove the elements because "there are no facilities relabeling units with Codabar labels"; this statement is incorrect. There are facilities that relabel frozen, thawed products with Codabar. In addition, the American Red Cross facilities just recently completed their conversion to ISBT 128 labeling so there are frozen plasma products that would require reassignment of unit ID and complete relabeling for these products when thawed. Leave the standard as is for one more standards cycle and re-assess after that time. Proposed standard: 5.1.6.3.1The following requirements shall apply: 1) Labeling of blood and blood component containers shall be in conformance with the most recent version of the United States Industry Consensus Standard for the Uniform Labeling of Blood and Blood Components using ISBT 128**.* Units conforming to 1985 FDA Uniform Labeling Guidelines are acceptable if collected and labeled before May 1, 2008.†** †Units collected and labeled before ISBT 128 implementation may be relabeled using Codabar.	No	The committee noted this comment, but as there are currently no facilities relabeling units with Codabar labels there was no need to retain the clause in question. Facilities that do relabel are using ISBT 128 approved labels for said relabeling.
5.1.6.5.2	It is premature to make the proposed changes to this labeling standards. The comment section states that the committee elected to remove the elements because "there are no facilities relabeling units with Codabar labels"; this statement is incorrect. There are facilities that relabel frozen, thawed products with Codabar. In addition, the American Red Cross facilities just recently	No	The committee noted this comment but did not feel that retaining the deleted clauses was appropriate. As noted in the change to standard 5.1.6.3.1, #1, facilities that do relabel units do so with ISBT 128 labels and no longer use

	completed their conversion to ISBT 128 labeling so there are frozen plasma products that would require reassignment of unit ID and complete relabeling for these products when thawed. Leave the standard as is for one more standards cycle and re-assess after that time. Proposed standard: **5.1.6.5.2** If a transfusing facility or other intermediate shipping facility receives a unit labeled with a Codabar Donation Identification Number an IBST 128 donation identification number shall be assigned**, then an ISBT 128 Donation Identification or another Codabar Donation Identification Number may be assigned.** The label shall be affixed to the container and shall identify the facility assigning the identification. **Any other donation identification number, except that of the original collecting facility, shall be removed, obscured, or obliterated. This requirement does not preclude the use of a patient identification number.**		Codabar.
5.1.8.2.1	As a manufacturer without access to the standard, we need to have the conditions that need to be met communicated so we can produce acceptable items for use. What is the standard to be qualified to and what is the validation requirement for the process?	No	The committee noted this comment but no change was needed. For those needing the Standards, they can be accessed here.
5.1.8.2.1	Why is tissue not included in 5.1.8.2.1? Containers used to transport tissue must also be qualified and the process validated when storage temperature for the tissue must be controlled (e.g., refrigerated, frozen or cryopreserved). It looks like this standard was added in the 25th edition. I thought tissue was previously included in this standard (or in a separate but corresponding standard for tissue) but I could be dreaming....either that or I may have previously identified it should be added because it fits....but I don't remember. To "conform to manufacturer's written instructions" like Reference Standard 5.1.8A describes, the transport container would need to maintain the appropriate storage temperature for the duration of transport. Thank you for any assistance you can provide. Here is the parent standard and the standard in question: 5.1.8.2 Transportation Blood, blood components, tissue*, and derivatives shall be inspected immediately before packing for shipment, and shipped for transfusion or transplantation only if specified requirements are met. 5.1.8.2.1 Containers (eg, portable coolers) used to transport blood and blood components issued for transfusion shall be qualified and the process validated for the appropriate transport temperature and time. I looked at the Standards for CT Services and it's covered this way: 5.8.2 Containers shall be qualified at defined intervals to ensure that they	Yes	The committee noted this comment and adjusted the language of the standard to include both tissues and derivatives.

	maintain temperatures within the acceptable range for the expected duration of transport or shipping. 5.8.3 When products are transported or shipped, the extent of temperature monitoring shall be defined and shall be appropriate to the duration of transport or shipping. 5.8.3.1 When cryopreserved products are shipped, the temperature of the shipping container shall be continuously monitored.		
5.2.1, #5 (New)	We agree that donor educational material for this critical safety issue is necessary. To ensure a standardized message is communicated across all accredited donor programs, we recommend that the AABB add a section on the risks of post donation iron deficiency to the "Donor Education Materials – Making Your Donation Safe". http://www.aabb.org/tm/questionnaires/Documents/dhqhpc/v1-4/Donor Educational materials A-M v1.4.doc	No	The committee noted this comment, but did noted that the responsibility for the DHQ falls with the AABB Donor History Questionnaire Task Force and they will review this comment.
5.2.1, #5 (New)	Although we agree with the stated consideration that blood centers should educate donors about the risk of iron deficiency, we feel the standard should further recommend that blood centers advise donors on means to mitigate such risk. While there is no need to be prescriptive about such advice, mitigation strategies include dietary changes, over the counter iron supplements, evaluation by the donor's physician and less intensive donation. Please revise the standard to state: Donors are given educational materials regarding the risks **<u>and mitigation</u>** of post donation iron deficiency.	No	The committee reviewed this comment but did not feel that the addition of "and mitigation" was a step to take at this time. The committee notes that the facility can provide mitigation information as stated in standard 5.3.3.2.
5.3.3.2	Should the two sets of written instruction be separate documents? If it is expected that this be part of the same process or document, maybe it should read: "…written instructions about adverse events that may occur after donation and include actions to take in the event of an adverse event."	Yes	The committee agreed with this comment and edited the standard to remove the second "written instructions" and ended the standard at "donation." The standard now reads as such: The collection facility shall provide the donor with written instructions, including actions to take, about adverse events that may occur after donation."
5.3.3.2	Suggest that the standard be revised as such: The collection facility shall provide the donor with written instructions about adverse events ~~that may occur after donation and written instructions including~~ actions to take in the event of an adverse event following donation.	Yes	The committee agreed with the intent of this comment and as noted above, the change was made.
5.3.3.2	This wording of this standard is confusing. We recommend rewording the standard. To ensure a consistent message, consider combining all donor education standards to one area in the standards (i.e., 5.2.1 Donor Education). Proposed standard:	Yes	The committee agreed with the intent of this comment and the standard was adjusted accordingly.

	5.3.3.2 Donors are given educational materials about actions to take in the event of adverse events following donation.		
5.3.3.2	The vast majority, if not all blood centers already provide written instructions for donors about actions to take in the event of adverse post donation events (usually in the form of advice to seek medical care if the donor has significant concerns). For the rare outlying blood center, this addition to the standard is a good one. It is not clear as the standard is written however, that this would apply to iron deficiency anemia which is uncommonly diagnosed following blood testing triggered by quite common complaints like fatigue or dyspnea after unusual exertion. We believe that adequate pre-donation education about not just the risk, but the mitigation of iron deficiency will achieve the stated goal.	Yes	The committee reviewed this comment and while they did not make the standard stricter than what was proposed, they wish all users to know that they can be stricter in their application of the standard.
5.4.3.1	Please add in the term “adverse” before “reactions” in this standard.	Yes	The committee agreed with the change suggested and the standard was edited to reflect the suggestion.
5.5.2.4 (New)	Please clarify – is the plasma product referenced in this standard, the plasma product removed before PAS is added? If so, the phrase “concurrently” could be confusing. Usually “concurrently” means a separately collected product vs. a product prepared for a collected product (plasma separated from the platelet before PAS is added is not a separately collected product. Recommend restated this as: When a plasma product is made from a platelet product that will be stored in PAS, under the applicable FDA variance, the plasma volume used to make this plasma product will not impact the determination of plasmapheresis frequency classification.	Yes	When initially proposed, standard 5.5.2.4 (then 5.5.2.3) included the clause, “collected concurrently with” which based on this comment was removed and replaced with “is derived from collection of…” to ensure that users understood that this is derived from the plasma removed from a platelet product
5.5.2.4 (New)	Does this mean that the plasma volume in the concurrent plasma collection is not counted, or the plasma in the PAS platelet bag is not counted? If the former, this appears to be a loosening of the Standard allowing a "freebie" plasma collection when collected concurrently with platelets. If the latter it's simply recognition of the fact that there is little plasma in a PAS platelet product. The explanation following the proposed Standard does not answer the question. Clarification may be required.	Yes	As noted above, the committee adjusted the language in the proposed standard to clarify this issue.
5.5.2.4 (New)	When a plasma product is collected concurrently with a platelet product stored in PAS under the applicable FDA variance (aren’t these solutions already approved?), the plasma loss (in the platelets) will not impact the determination of plasmapheresis frequency classification.	Yes	As noted two rows above, the committee adjusted the language in the proposed standard to clarify this issue.
5.5.3.1	The guidance cited with this standard says there should be a week after double and triple platelet collections. How does that fit into this standard? Would 5.5.4 apply?	Yes	The committee noted this comment and agree with what was stated. As a result the committee added elements to the third sentence of the standard to ensure consistency with the guidance cited. The added elements to the standard (in

			bold) reads as follows, "**When 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."
5.7.3.1	Please capitalize "Whole Blood" in the standard.	Yes	The committee noted this comment and the change was made.
5.7.3.1	Please consider editing the standard to read as follows: "…<5 x 10^6 for Red Blood Cells and Apheresis or Pooled Platelets **(4-6 units)** and to <8.3 x 10^5…"	No	The committee noted this comment but did not feel that a change was needed at this time. The amount of units is defined by the facility.
5.7.4.2.1	Proposal for Revision: Current Standard 5.7.4.2.1: "Red Blood Cells shall be frozen within 6 days of collection, except when rejuvenated. Rare units may be frozen without rejuvenation up to the date of expiration." 29th Edition Standards, 2014, AABB. Proposed Standard 5.7.4.2.1: "Red Blood Cells, including rare units, shall be frozen within 6 days of collection, except when rejuvenated. ~~Rare units may be frozen without rejuvenation up to the date of expiration.~~ Reason for Request: Pre-1997: RBCs cryopreserved at < 6days or rejuvenated (per Standard D2.220, 17th Edition, 1994, AABB) 1997: rejuvesol Solution FDA Approval (NDA# BN950522) 2008: rejuvesol Solution removed from market (Raw material supply issue) 2008-2014: Standards revised to allow cryopreservation without rejuvenation Oct. 2013: rejuvesol Solution FDA Approval for reintroduction to market (same NDA#) Submission required due to manufacturing process changes (minimal changes to indications compared to original 1997 approval) 2014+: rejuvesol Solution commercially available A review of the history of AABB Standards reveals that from the 1980s until approximately 2008, facilities wishing to cryopreserve units, rare or otherwise, were required to do so either within 6 days of collection or rejuvenate if older than 6 days. In 2007, Citra Labs (then enCyte Systems/Cytosol Laboratories, Inc.), was no longer able to manufacture rejuvesol Solution (the only commercially available rejuvenation solution) due to raw material issues, and ceased its production. Because rejuvenation was no longer an option, the blood banking community revised the requirement to allow cryopreservation of rare units more than 6 days old. The raw materials supply concerns have since been resolved and rejuvesol Solution was reintroduced and is commercially available with the same indications for use as it was originally marketed. We respectfully request that the Standard stated above be revised based on these	No	The committee noted this comment but did not feel that a change was needed at this time. The review of the package insert for this product lacked information concerning reagents. As such the committee did not feel that this change would be appropriate at this time.

	premises: 1. rejuvesol Solution is now commercially available (return Standard to previous state): 2. Rare units, in particular, should be rejuvenated to restore their 2,3-DPG and ATP to assure the most efficient oxygen delivery at time of transfusion. Often times, a single rare unit may be available at time of transfusion and rejuvenation is the best way to ensure the highest quality and efficacy we can offer to our patients. Supporting Literature Please refer to attachments as listed below: 1. 1997 rejuvesol Solution package insert 2. 2013 rejuvesol Solution package insert 3. 12th Ed. AABB Standards (ref Standard: B4.222), 1987 4. 17th Ed. AABB Standards (ref Standard: D2.220 and D2.500), 1994 5. 25th Ed. AABB Standards (ref Standard: 5.7.5.2.1) 2008		
5.7.4.4	Did the committee have any discussion regarding use of total hemoglobin for the final QC as dictated by the FDA? We have many rare units that are able to pass total hemoglobin, but due to age or other donor issues, these units do not pass the 80% recovery required by the AABB. I fear we lose some extremely rare units that don't meet the % recovery.	No	The committee reviewed this comment but did not feel a change was needed at this time. In instances such as those described in the comment, the committee notes that a medical override can be used in the case of a rare unit.
5.7.4.9.1, 5.7.4.10.1, 5.7.4.11.1 (New)	How would a facility assess if a chemical alteration has occurred? The standard should require the facility to protect from chemical exposure, as this process can be identified/monitored during product manufacturing. Proposed standard: 5.7.4.11.1 If a liquid freezing bath is used, the container shall be protected from chemical **exposure** ~~alteration~~.	Yes	The committee agreed with the proposed change to standard 5.7.4.11.1 and expanded it to standards 5.7.4.9.1 and 5.7.4.10.1 as well for consistency.
5.7.4.20, 5.7.4.23	Should this standard also include having a pH of $\geq$ 6.2 like the other platelet products?	Yes	The committee agreed with the comment and has added the clause, "and have a pH □6.2 at the end of allowable storage" to standards 5.7.4.20 and 5.7.4.23 for consistency and clarity.
5.8.3	Please capitalize "blood cell" in the title of the standard.	Yes	The committee agreed with the comment submitted and the change was made.
5.8.4	It would be helpful to add a comment to this Standard that (per our FDA CSO): "This change must be reported in a "Prior Approval Supplement" as described under 21 CFR 60L12(b)"	No	The committee noted this comment but did not feel that this change would be appropriate.
5.8.7	Suggest adding this guidance with this standard: Guidance for Industry: Requalification Method for Reentry of Blood Donors Deferred Because of Reactive Test Results for Antibody to Hepatitis B Core Antigen (Anti-HBc) (May 2010)	Yes	The committee agreed with the suggestion and a reference to the guidance was added.
5.9.5	Please consider editing the standard to read as follows, "After the final label(s) have been affixed/attached to the units there shall be a method to ~~confirm that this label is correct~~ **verify that the correct information is captured on the label**." We feel this may provide an additional level of clarity as to the intention of the	Yes	The committee noted this comment and the change was made. The committee agreed that as previously written there could be confusion as to whether the standard required verification that the label was correctly applied or whether it

	standard.		required verification that the information on the label is correct.
5.11.2.2	There are instances when multiple samples are collected on the same day. Should the time also be noted?	Yes	The committee agreed with this comment and added the clause, “and time” to cover situations where multiple samples are collected on the same day.
5.11.2.4 (New)	Is the Blood Bank Identification Barcode Band (BBID) system acceptable in complying with the standard? a. If the lab staff identified the patient electronically with an electronic device and printed out a label for the BBID band and specimen using the same electronic device is this acceptable to comply with the standard? b. If the nurses identified the patient and drew and labeled the BBID band and specimen, but did not use an electronic system in identifying the patient, is this acceptable in complying with this standard?	No	The committee noted this comment but did not feel a change was needed. The committee notes that the decision to use an electronic method or a manual one is at the discretion of the facility and as long as you can verify the label and validate the process your facility will meet the intent of the standard as written.
5.11.2.4 (New)	The CAP standard TRM.30575 Misidentification Risk states – The facility has a plan to implement a system to reduce the risk of mistransfusion for non-emergent red cell transfusions. We recommend modifying the terminology of the AABB standard to include non-emergent red cell transfusions so that unnecessary and possibly harmful delays can be avoided in acute care settings. In an emergency situation it may not be possible to obtain two separately collected samples from the patient. Continual transfusion with O negative blood if a second sample cannot be obtained will rapidly deplete the blood bank inventory of O negative red cells and make determination of the patient’s actual blood type difficult if and when a second sample is collected. While in a non-urgent setting collecting a second sample is not as problematic, waiting to provide type specific blood in a trauma setting until a second sample is obtained can lead to less than optimal patient care	No	The committee reviewed this comment but did not feel a change was needed at this time. It should be noted that facilities need only a policy to reduce risk and that how that is addressed is defined in each facility.
5.14.2	A facility may inadvertently stop performing weak D testing on all patients based on standard 5.14.3 which states "The test for weak D is unnecessary when testing the patient." Infants and adults might be placed into the same "patient" category because this standard does not distinguish between infants and adult patients. Standard 5.30.2 #3 states that weak D testing is required for the fetus/infant. Standard 5.14.2 should refer to this standard. I recommend the following change (in red font): Standard 5.14.2: Rh type shall be determined with anti-D reagent. The test for weak D is unnecessary when testing the patient. Standard 5.30.2 #3 applies.	No	The committee reviewed this comment but did not think a change was needed at this time. The committee also points out that adding a crossreference to standard 5.30 implies that what falls below it in the standards (5.30.1 – 5.30.5) would apply.
5.14.2	Please retain the word “unnecessary”. Most blood banks don’t have sophistication to determine which weak D’s need RhIg and which do not. This will add cost and time and not result in improved patient care. What is important is to identify partial Ds at risk for anti-D, and provide them with	No	The committee noted this comment but did not feel it would be appropriate to retain the term “unnecessary” with the inclusion of the term “optional.”

	Rh(D) negative blood.		
5.14.3	Please capitalize “Blood Cell” in the title.	Yes	The committee agreed with this comment and the change was made.
5.14.3.2	We recommend reformatting the standard as such: A sample shall be obtained from the patient within 3 days of the scheduled transfusion in the following situations. Day 0 is the day of draw. 1. If the patient has been transfused in the preceding 3 months with blood or a blood component containing allogeneic red blood cells 2. If the patient has been pregnant within the preceding 3 months 3.If the history is uncertain or unavailable.	Yes	The committee agreed with this comment and the change was made.
5.17.1.2.1	This standard has the addition of "Readmission testing during the neonatal period shall be done using neonate serum or plasma." What "testing" does this include/expect/require? Is another antibody screen test required? Please clarify what "testing" is required upon readmission during the neonate period (< 4 months).	Yes	The committee agreed with the comment submitted and adjusted the language for clarity. A crossreference to standard 5.14 was added as well.
5.19.7	How will the BB/TS develop this policy? Is this really the responsibility of the BB/TS alone? Sometimes there are no alternative products in the BB/TS for patients at risk for TACO. There may be interventions that should be considered when the need for transfusing such patients arises. This would parallel existing 5.19.3.1.1. Also, a BB or TS, or even a clinician, can’t know everyone at risk. Suggest adding the clause, “identified as being at risk for TACO.”	Yes	The committee included in the final wording of the standard, “at increased risk” per the request. The standard now reads as follows, “The BB/TS shall have a policy for responding to requests for products for patients identified by the ordering physician or other authorized health professional as being at increased risk for TACO.”
5.19.7	Given all transfusion recipients are at risk for TACO the policy is really every transfusion service should have appropriate transfusion guidelines.	No	The committee noted this comment and directs all individuals with questions to the guidance contained in the version of the 30th edition that is online in the Standards Portal.
5.19.7	This standard should be accompanied by suggestions or recommendations to fulfill the requirement. How does the Transfusion Service identify patients at risk for TACO and what are appropriate measures for transfusion of those patients?	No	As noted above, guidance is provided in the online version of the 30th edition.
5.19.7	I am a little concerned about having a policy about TACO... not sure we will always know which patients are at risk when we receive an order in the blood bank.	No	The committee reviewed this comment and noted that the best way to ensure that the individuals in your facility has all the information needed that the laboratory should provide these educational materials to their clinicians.
5.19.7	Who identifies and what criteria should be used to determine what patients are at risk for TACO? We believe any patient receiving a transfusion to be "at risk" for TACO and would treat/ advise each accordingly. Please clarify this statement.	No	The committee reviewed this comment and noted that the donor center staff would be the identifying individual in this case.

5.19.7	We agree that a policy for this critical safety issue is necessary. Consider changing the standard to state "patients at *increased* risk" to ensure the focus is on high risk patients. Proposed standard: **5.19.7 Transfusion Associated Circulatory Overload (TACO)** The BB/TS shall have a policy for responding to requests for products for patients at <u>increased</u> risk for TACO.	Yes	The committee reviewed this comment and agreed with its intent and as noted above the term "increased" concerning risk was included.
5.19.7	The proposed standard requires facilities to have a policy for responding to requests for products for patients at risk for TACO. Can the SPU provide clarification and a rationale as to why this was included in this edition?	Yes	The committee reviewed this comment and has crafted guidance that is available in the online version of the 30th edition in the Standards Portal.
5.20, #6, 5.21, #6	What is the purpose of having these articles "(6) Identity of the source facility" in the Blood Standards?	Yes	In the proposed edition, a new subnumber 6 had been included in standards 5.20 and 5.21 requiring that facilities identify the "Identity of the source facility." The committee elected to delete the new subnumbers and added "manufacturer's written instructions" into the header which would encompass this and allow the standards to be more consistent with current tissue and derivative regulations.
5.22	The definition of Final Inspection in the glossary seems to fit the activities in 5.23. Can 5.22 be merged with 5.23?	No	The committee reviewed this comment and did not feel that a change would be appropriate. Standards for tissues and derivatives in this case could not be merged as there are different requirements for their preparation.
5.30	The sentence umbrellas the whole of 5.30 and "3" in 5.30.2 "requires weak D when testing for D is negative" (as it should in this circumstance), whereas the introductory sentence has the conditional "if". Suggest adding in the clause, "…patients <u>(as determined by serologic and/or molecular methods)</u>." And adding a reference to standard 5.30.2.	No	The committee noted this comment but did not feel that a change was appropriate at this time. The committee adjusted standard 5.30.2 to address the fact that testing for weak D is optional.
5.30	We feel the addition is unnecessary because the requirement for performing is Weak D testing and/or *RHD* Genotyping is optional. If a facility does not perform Weak D testing and/or *RHD* Genotyping, will an assessor expect to see a policy stating that the testing is not performed? Proposed standard:	No	The committee reviewed this comment but did not this a change was needed at this time. In this case an assessor will only be reviewing validated processes to meet the intent of this standard. It is at the discretion of the facility to choose which form of testing to perform.

	5.30 Rh Immune Globulin The transfusion service shall have a policy for Rh Immune Globulin prophylaxis for Rh-negative patients who have been exposed to Rh-positive red blood cells. ~~This policy shall include if Weak D testing and/or *RHD* Genotyping are performed.~~		
5.30	As written this could be misinterpreted that weak D testing and *RHD* genotyping may be standards of care. Some re-wording could accommodate the performance of such testing in appropriate patient subgroups without unintended sanction or endorsement. Please revise the standard as such: The transfusion service shall have a policy for Rh Immune Globulin prophylaxis for Rh-negative patients who have been exposed to Rh-positive red blood cells. This policy shall consider the results of ~~include~~ Weak D and/or *RHD* genotyping, if ~~are~~ performed.	Yes	The committee reviewed this comment and agreed that as originally written in the proposed edition, there could be some confusion as to whether RHD genotyping was required. As such the committee edited the standard to read as follows, "The transfusion service shall have a policy for Rh Immune Globulin prophylaxis for Rh-negative patients who have been exposed to Rh-positive red blood cells. The results of Weak D testing and/or *RHD* Genotyping, if performed, shall be evaluated when determining Rh Immune Globulin prophylaxis."
5.1.6A, General	The ISBT labeling guide has changed. There are critical changes in the revision. The current standards and 5.1.6A do not reference the updated version and the text in the charts is not compliant with the revised ISBT document and the US 3.0 consensus document. The issue lies with how the text is supposed to appear on the label. I had a licensure packet before the FDA and they noted this and I only received a provisional licensure until I can make the changes to my labels. Call me if you need me to explain further (301-402-1704). I was on an assessment team and their labels did not comply either. I could not site it as they did comply with the current version of standards. I told the facility of the discrepancy. The committee should pull the FDA issued Guidance and the US Consensus for Labeling and compare it to the current version of standards.	Yes	The committee noted this comment and agreed that an update was needed with certain entries, those changes were made and are detailed below.
5.1.6A, #12 (New)	This should be updated to be compliant with external requirements.	Yes	The committee agreed with this comment and created a new #12 to be consistent with the FDA Final Rule. The new footnote (#8) will lead users to the Final Rule itself.
5.1.6A, #25 Pooled column	Shouldn't recipient name be on pooled product?	No	The committee reviewed this comment and noted that dedicated products are not pooled as there is only one donor to one individual.

5.1.6A, #26 Pooled column	If these are dedicated donors, wouldn't this labeling apply?	No	The committee reviewed this comment and noted that dedicated products are not pooled as there is only one donor to one individual.
5.1.6A, footnote #14	Regarding 21 CFR 610.40(h)(2)(ii), this applies to all products not just RP. Why is this included here?	No	The committee noted this comment but did not feel that it would be appropriate to remove the footnote. The cited references apply in the case where a facility is issuing positive recovered plasma. If that is not something that a facility is doing, it would not apply.
5.1.8A, #12 and #13 Expiration Column	None of the apheresis instruments cleared in the US use CPDA-1. But 610.53 requires 35 days for CPDA RBC and doesn't specify WB vs apheresis.	Yes	The committee noted this comment and agreed with the intent. The committee removed the requirement for CPDA 1: 35 days as a result.
5.4.1A, #10 (5.4.1A, #9)	According to 2010 CJD/vCJD guidance, this is be a permanent deferral, not indefinite as indicated in the chart. DHQ will also need to be changed.	Yes	The committee noted this comment and agreed that a change was needed. As such, the committee adjusted the language in the first bullet to read, "Receipt of allogeneic dura mater or pituitary growth hormone of human origin" including allogeneic. The deferral period was changed as a result from "indefinite" to "permanent." In the second bullet the committee edited the entry to read, "Receipt of blood, components, or human tissue" deleting, "or plasma derived from clotting factor concentrates."
5.4.1A, #13 (11)	Suggest adding a new footnote to the entry on incarceration to read: Guidance for Industry: Recommendations for Screening, Testing, and Management of Blood Donors and Blood and Blood Components Based on Screening Tests for Syphilis (September 2014)		The committee agreed with this comment and the footnote was added.
6.2.7	Would you like to include a reference to 21 CFR Part 11?	Yes	The committee agreed with this comment and a reference to 21 CFR Part 11 was included.
7.0	I recommend deleting (b) so that it's just 21 CFR 606.171 (to include (a) since "who must report" is as significant as "what should I report").	Yes	The committee agreed with this request and letter "b" was removed from 21 CFR 606.171.
7.1.4	Is determining the effect of the nonconformance on the recipient included here or would this only happen if there was an adverse event in the recipient?	Yes	The committee noted this comment and agreed with its intent. As a result, the committee added the clause, "and recipient safety" to the standard. This inclusion should cover all products,

			including blood, blood components, tissues and derivatives.
7.2	Suggest adding a reference to this Guidance: Guidance for Industry: Notifying FDA of Fatalities Related to Blood Collection or Transfusion (September 22, 2003)	Yes	The committee agreed with this comment and included the Guidance for reference.
7.5.1.2 (7.4.1.2)	The term "immediately" is used in several places in the standards. Does AABB want to consider defining this timeframe or is this being left to the individual blood establishments?	No	The committee reviewed this comment and determined that no change was needed. In these cases, the onus is on the facility to define "immediately" and then share this with the assessor once on site to show that they are meeting the standard.
7.5.2 (7.4.2)	The terms "prompt" and "promptly" are used in several places in the standards. Does AABB want to consider defining this timeframe or is this being left to the individual establishments?	No	The committee reviewed this comment and determined that no change was needed. In these cases, the onus is on the facility to define "promptly" and then share this with the assessor once on site to show that they are meeting the standard.
7.5.2.3 (7.4.2.3)	Please note that the hemovigilance definitions are intended for surveillance not for diagnosis. We suggest changing back to previous wording.	Yes	In the proposed edition of the 30th edition standard 7.5.2.3 was re-written to include the concept of classifying adverse events with standardized definitions. Based on the comments received, the committee removed the standardization elements and adjusted the language to match new standard 7.3.
7.5.2.3 (7.4.2.3)	The Centers for Disease Control and Prevention operates the National Healthcare Safety Network (NHSN) Hemovigilance Module, which is a national surveillance system that captures data on transfusion-related adverse events, including transfusion reactions and process errors (e.g., incidents) resulting in transfusion reactions. NHSN has case definitions which have been previously developed in collaboration with AABB and subject matter experts. These definitions are consistent with international case definitions, including ISBT, used by hemovigilance systems globally. NHSN Hemovigilance Module case definitions would be appropriate for use in this proposed standard. Suggested revision: Interpretation and classification of the reaction according to national standardized definitions, such as those used in the National Healthcare Safety Network's Hemovigilance Module, shall be recorded in the	Yes	In the proposed edition of the 30th edition standard 7.5.2.3 was re-written to include the concept of classifying adverse events with standardized definitions. Based on the comments received, the committee removed the standardization elements and adjusted the language to match new standard 7.3.

	patient's medical record and, if suggestive of hemolysis, bacterial contamination, TRALI, or other serious adverse event related to transfusion, the interpretation shall be reported to the patient's physician immediately. Standard 7.4.2.4 applies.		
7.5.2.3 (7.4.2.3)	What set of standardized terminology is the Standards Committee recommending a facility use? The explanation states that the standard was edited based on a recommendation from the AABB Hemovigilance committee "to ensure that facilities use standardized terminology for classifying and reporting transfusion reactions". Currently the CDC *NHSN Biovigilance Component Hemovigilance Module Surveillance Protocol v2.1.3* states that "Surveillance definitions are distinctly different from clinical definitions…The surveillance definitions are not intended as clinical diagnostic criteria or to provide treatment guidance". We recommend more specific directions on "standard terminology" are provided or the statement should be removed from the standard. Proposed standard: 7.4.2.3 Interpretation and classification of the <u>evaluation of a</u> ~~according to standardized definitions~~ reaction shall be recorded in the patient's medical record and, if suggestive of hemolysis, bacterial contamination, TRALI, or other serious adverse event related to transfusion, the interpretation shall be reported to the patient's physician immediately. Standard 7.4.2.4 applies.	Yes	In the proposed edition of the 30th edition standard 7.5.2.3 was re-written to include the concept of classifying adverse events with standardized definitions. Based on the comments received, the committee removed the standardization elements and adjusted the language to match new standard 7.3.
7.5.2.3 (7.4.2.3)	Please provide clarity as to why the interpretation and classification of the evaluation reaction are to be include in the patient's medical records. Also what is meant by "according to standardized definitions?" Is this speaking to standardized definitions which are facility specific, or more global such as what is required of AABB Hemovigilance? 7.4.2.3 Interpretation and classification of the <u>evaluation of a</u> ~~according to standardized definitions~~ reaction shall be recorded in the patient's medical record and, if suggestive of hemolysis, bacterial contamination, TRALI, or other serious adverse event related to transfusion, the interpretation shall be reported to the patient's physician immediately. Standard 7.4.2.4 applies.	Yes	In the proposed edition of the 30th edition standard 7.5.2.3 was re-written to include the concept of classifying adverse events with standardized definitions. Based on the comments received, the committee removed the standardization elements and adjusted the language to match new standard 7.3.
7.5.5.1 (7.4.6.1)	Please check regulation 21 CFR 482.27(b) contains the lookback requirements.	Yes	The committee noted this comment and adjusted the reference cited with this standard to ensure accuracy.

Glossary – Final Inspection	This sounds like the final check before issue in 5.23 and not the Final Inspection in 5.22	No	The committee noted this comment but did not think a change was needed and that the existing definition was sufficient.