Significant Changes and Response to Comments Received to the 11th edition of Standards for Cellular Therapy Product Services

Please note that public comments that were submitted address the proposed 11th edition of CT 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.

Standard	SC/RC	Comment	Change made?	Outcome
1.1.2	SC	NA	NA	The committee elected replaced the term "licensure" with "regulatory approval" for clarity. Licensure was deemed too specific and restrictive, and this new terminology ensures that a facility's regional health authority has appropriate oversight.
1.2.3.1.1 (New)	SC	NA	NA	The committee created new standard 1.2.3.1.1 for completeness. The new standard ensures that the signature method in use in the facility is concordant with those in the country where these Standards are being implemented. The new standard reads as such, "Signatures of the individual approving all policies, processes, and procedures shall comply with the requirements of the FDA or relevant Competent Authority."
1.2.3.1.1 (New)	RC	I am not sure this is needed. What are the FDA requirements for "signatures"? what kind of signatures, e.g.., wet or electronic? Seems beyond the scope of AABB standards.	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The inclusion of this standard was made as a result of the COVID-19 pandemic in the cases where a director could not be on site but still had oversight and their signature would be needed.
1.2.4	SC	NA	NA	The committee added the clause, "…is qualified by training with relevant experience in quality management systems. The quality representative …" to standard 1.2.4 for clarity. This ensures parallel construction between this standard and other standards that delineate expectations for individuals who serve in the role of the quality representative.
1.4.1 (New)	SC	NA	NA	The committee created new standard, 1.4.1 for completeness. This standard is based on a similar standard in the Standards for Blood Banks and Transfusion Services. This standard

				ensures that facilities have a policy to address critical supply shortages.
1.5	SC/RtC	A process that results in a report that analyzes the potential for deviations or non-conformances to occur and the corrective and preventive actions to be taken to prevent or minimize risk. ICHQ9 states: "Risk Assessment, (Identify, Analysis, Evaluation). Risk Control, (Reduction, Acceptance). The output of a risk assessment is either a quantitative estimate of risk or a qualitative description of a range of risk." As part of the current editing cycle the following effort is recommended to align terminology and definition between ICHQ9 and AABB 11th Edition Standards by adding quantitative and qualitative score of risk wording to the definition of the assessments for decisions on risk control. It is also suggested to retitle Risk Assessment to Risk Management.	YES	The committee agreed with the comment submitted and elected to replace the title of standard 1.5 with "Risk Management" in place of "Assessment of Risk" to better reflect the actual usage throughout the membership and users of the Standards.
2.1.4	SC	NA	NA	The committee edited standard 2.1.4 for clarity. Subnumber 2 was edited to include the clause, "job specific training" to read, "initial job specific training." Subnumber 4 added the term "training" to "ongoing job-specific" for completeness. The intent of the standard has not changed.
2.1.4.1 (2.1.4)	SC	NA	NA	The content of standard 2.1.4.1 previously appeared as standard 2.1.4. With this creation, the committee added the clause, "…and approve subject matter experts who provide training…" This addition ensures that individuals performing training are qualified to do so.
2.1.4.1 (2.1.4)	RtC	I actually preferred the wording "The facility shall define the qualifications required for trainers." Seems more succinct and clear.	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The committee feels that trainers and subject matter experts are differentiated from one another.
2.1.6.4	SC	NA	NA	The committee added the term "corrective" to the standard for completeness and accuracy. In this case, the action taken would be corrective in the case where a lack of competence is found. The committee also included a cross reference to standard 9.1 to the standard which points to the standard focused on "corrective action."

2.1.6.4	RtC	Would you still consider action such as removing the individual who is not deemed competent “corrective”? My preference is just “Action”. Action could be retraining, re-assessing, or simply removal.	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The committee feels that potentially retaining of an individual to a previous training program may not ensure competence and that the concept of corrective ensures that the individual in this case has achieved competence.
2.1.7.1	SC	NA	NA	The committee edited the content of standard for clarity, however the intent of the standard has not changed. The committee felt that the inclusion of "...and the associated cellular therapy activity..." would ensure that individuals are trained for the work that they perform daily.
2.1.7.1	RtC	The directors and quality representatives share the responsibility of assuring safety and quality of the activities performed by the facility. Though continual education as stated in this standard supports this responsibility, it is equally important to have practical knowledge of facility-specific activities. Therefore, it is recommended these individuals report a minimum number of observations for these activities, as defined by the facility, and within the stated time review period.	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The committee notes that the information requested in the comment is best covered in chapter 1 where each individual’s qualifications and continuing education elements are detailed.
2.2	SC	NA	NA	The committee edited the content of the first sentence of the standard to ensure it can best cover the new activities related to cellular starting materials. The sentence now reads as follows, “The clinical facility shall have an agreement in place to ensure comprehensive care and ~~access to medical specialty services~~ relevant resources required ~~as needed~~ for patient care in cellular therapies, including but not limited to:…”
2.2, #1	SC	NA	NA	The committee has edited subnumber 1to focus only on transfusion medicine, which includes the content that previously was listed in the entry; the information that previously appeared in subnumber 1 will appear in the guidance to this standard. The subnunmber now reads as follows, “**Transfusion medicine** ~~Leukocyte~~

				~~reduced/irradiated blood components for patients receiving hematopoietic stem cell transplants~~.
2.2, #2	SC	NA	NA	The committee edited subnumber 2 to broaden the content while not changing the intent of the standard. The subnumber reads as follows: "Services related to pharmacy."
2.2, #5, 6, 7 (New)	SC	NA	NA	The committee created subnumbers 5, 6, and 7 to propose edits to the scope of the Standards to provide requirements encompassing comprehensive aspects of patient care. The subnumbers read as follows: **5) Acute care or medical facilities.** **6) Social and psychological support.** **7) Long term follow-up based on protocol or treatment plan.**
2.2	RtC	Is it expected that the collection and processing facility has an agreement with the medical facility if all three belong to the same institution and work as one blood and marrow transplant program? Does this apply to the other resources, such as Pharmacy, Laboratory services and Radiology?	NO	The committee reviewed this comment but did not feel that a change was needed at this time, noting that the activities for which a facility is accredited would need agreements within departments and outside vendors to ensure that the standards that apply to their work are adhered to.
3.1	SC	NA	NA	The committee elected to add the concept of "equipment selection" to the standard to mirror the concepts covered in other AABB Standards.
3.1	RtC	What type of evidence could be used to indicate compliance? We do not have a process to document selection of equipment as the selection is not consistent across the lab.	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The committee notes that this information would be included in a purchase agreement or with contract services. While not consistent, the information would be available and it would be suggested that it be standardized.
3.2	SC	NA	NA	The committee added the clause, "…equipment maintenance or repair reports and manufacturer's written instructions." This was added for completeness and to ensure that

				accredited facilities activities are specific to the requirement.
3.2.3 3.2.3.1 (deleted)	SC	NA	NA	The committee elected to broaden standard 3.2.3 for clarity. The committee feels, as written, the standard has provided clarity for facility defined performance qualification. The committee also deleted standard 3.2.3.1 as the content was determined to be redundant per the updated language of standard 3.2.3. The standard now reads as follows, **3.2.3** The facility shall demonstrate that equipment performs as expected for its intended use **per facility developed predetermined criteria. Facility developed predetermined criteria shall meet or exceed the specifications established by the manufacturer**."
3.2.3	RtC	I think the intent of this standard is that facilities should demonstrate that equipment is working in their hands per manufacturer's specification and their policies. As an assessor I have seen that facilities accept vendors qualifications without verification that equipment meets their facilities requirements. For example, vendor performs annual maintenance and leaves their document that everything passed. The facility should verify with their own process to quality that the equipment is safe to use on patients/ products and not assume it is okay to use because vendor did preventive maintenance/ repairs per their contracted service agreement. I often suggest at minimum the facility performs their quality monitoring to determine acceptance after reviewing and accepting the vendors documented actions. Does this belong in standard or in guidance? Sometimes only a standard will drive compliance.	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The committee feels that much of what is being requested in the comment is already discussed and covered by standard 3.4.3, which has a crossreference to standard 3.2.
3.2.3	RtC	Not opposed; however, it complicates the standards in my opinion. Also must the facility develop pre-determined criteria if the manufacturer has established specifications and criteria already that the facility agrees with? The wording seems to complicate vs simplify.	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The committee has crafted guidance to ensure that the intent of this standard is clear.
3.4	SC	NA	NA	The committee edited the standard to include the clause, "…and in accordance with the FDA or relevant Competent Authority." for clarity. This ensures that accredited facilities not only mirror the manufacturer's instructions for the equipment, but those of their Competent Authority as well.

3.4.3, #6	SC	NA	NA	The committee elected to replace the term "manufacturer's recommendations" with "manufacturer's written instructions" to ensure parallel structure of style and content throughout the Standards. The addition of a crossreference to standard 3.2, will ensure that facilities qualify all of their equipment.
3.6.1	SC	NA	NA	The committee edited standard 3.6.1 by adding the term "validated" for completeness. This ensures that a facility's alternate system is validated before it is put into use and relied on.
3.6.1	RtC	Is the term "validated" used here consistent with other sets of Standards?	NO	The committee reviewed this comment but did not feel that a change was needed at this time.
3.6.1.1	SC	NA	NA	The committee elected to edit this standard for clarity. The committee replaced the clause, "tested periodically" with "verified at facility-defined intervals." This change ensures parallel construction throughout the edition and mirrors language in other AABB Standards. This change will ensure that assessors have the ability to see when these systems are tested and that they have been verified.
4.1	SC	NA	NA	The committee created new content for standard 4.1, which previously only appeared as a title. The content of this standard ensures that there are agreements containing certain requirements when responsibilities involve more than one facility responsible for activities covered in these Standards from the point of origin of the product until final administration.
4.1	RtC	Is it expected that the collection and processing facility has an agreement with the medical facility if all three belong to the same institution and work as one blood and marrow transplant program? Does this apply to the other resources, such as Pharmacy, Laboratory services and Radiology?	NO	The committee reviewed this comment but did not feel that a change was needed at this time, noting that the **noting that agreements between departments and outside vendors should be in place to ensure adherence to the standards for work on activities for which a facility is accredited.**
4.1.1, #1	SC	NA	NA	The committee edited the content of subnumber 1 for completeness. This edit matches similar

				additions placed throughout this edition of Standards as it relates to compliance with this edition, and Competent Authority regulations as well. The entry now reads as follows, "The customer's requirements are adequately defined in compliance with these *CT Standards* and in accordance with applicable FDA or relevant Competent Authority requirements."
4.1.1, #4, 5 (New)	SC	NA	NA	The committee created new subnumbers 4 and 5 requiring the following: **4) Chain of Identity is maintained,** **5) Chain of Custody is maintained,** These concepts have been included here and throughout the Standards where appropriate.
4.1.1, #6, 7, 8 (New)	SC	NA	NA	The committee created new subnumbers 6, 7, and 8 requiring the following: **6) Quality is maintained from the point of origin to the point of administration or discard.** **7) Conformance with accepted policies and procedures.** **8) Conformance with safety requirements.** **These requirements were added to ensure that a level of quality be maintained through conformance with policies, processes and procedures.**
4.1.2.1 (New)	SC	NA	NA	The committee added new standard 4.1.2.1 to ensure that agreements define the roles and responsibilities of all personnel involved in the cellular therapy process. The standard reads as follows: **4.1.2.1** Roles and responsibilities of key personnel.
4.1.2.1 (New)	RtC	Remove the "all" personnel but add "key personnel" or "job title" of who is responsible for. It is not typical industry practice to add details like this to the Quality Agreement – too specific of details within the agreement are of concern to us from a maintenance/revision perspective when those specific details change (i.e., industry practice is to indicate only which facility is responsible for	YES	When the proposed edition was submitted for public comment, the standard contained the clause, "all personnel" and based on this comment, the committee elected to replace it with "key personnel." This will allow facilities

		certain aspects of the cell therapy process, not which personnel within the facility are responsible).		to identify these individuals, whether that be directors, or senior technicians.
4.1.2.2 (New)	SC	NA	NA	The committee added new standard 4.1.2.2 to ensure that the responsibility of each facility involved in the agreement for all activities covered by these CT Standards to maintain both chain of identity and chain of custody. The standard reads as follows: **4.1.2.2** Roles and responsibilities of each facility involved in the procurement, processing, labeling, storage, distribution, or administration of a cellular therapy product to maintain Chain of Identity and Chain of Custody.
4.1.2.3 (New)	SC	NA	NA	The committee added new standard 4.1.2.3 to ensure that when a deviation, nonconformance or adverse event occur, that information is shared between the facilities that are a party to the agreement. The standard reads as follows: **4.1.2.3** Communication of critical information, including deviations, nonconformances and adverse events. Standard 5.7 applies.
4.1.2.4 (New)	SC	NA	NA	The committee added new standard 4.1.2.4 to ensure that facilities involved in agreement share any nonconformances to the relevant regulatory institutions where appropriate. The standard reads as follows: **4.1.2.4** Reporting of adverse events and nonconformances to regulatory bodies, Competent Authorities, and registries, if applicable.
4.1.2.5 (New)	SC	NA	NA	The committee added new standard 4.1.2.5 to the proposed edition to ensure that agreements reflect requirements for donor and patient care as well as any other facility defined quality requirements. The standard reads as follows:

				4.1.2.5 Specifications and requirements for donor and patient care, quality, safety, and other facility defined critical parameters.
4.2	SC	NA	NA	The committee elected to expand the content of standard 4.2 to ensure that when agreements are proposed and accepted, that this be communicated to affected parties. A record retention requirement has also been added to standard 4.2.
4.3	SC	NA	NA	The committee edited standard 4.3 to mirror the construction of standard 4.1. This ensures that there are agreements containing certain requirements when responsibilities involve more than one facility responsible for activities covered in these standards. The standard now reads as follows, **4.3** When the responsibilities for activities covered by these *CT Standards* involve more than one facility or department, there shall be agreements **that define the following for the cellular therapy product from point of origin to administration** including but not limited to:"
4.3	RtC	The phrase "or department" requires internal agreements within the same facility. What is the definition of "department" and why is there a need for an agreement? Seems duplicative as requirements are described within internal procedures. Also, see language in 4.1 that states agreements are not indicated when activities are within the same institution.	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The definition of "agreement" in the CT Standards reads as follows, "A contract, order, or understanding between two or more parties, such as between a facility and one of its customers. Agreements can be written or verbal, with verbal agreements documented (eg, a written summary of the agreement should be available)."
4.3.1	SC	NA	NA	The committee edited the first sentence of standard 4.3.1 for clarity, while also improving legibility. The intent of the standard has not changed. The standard reads as follows, **4.3.1** The facility shall have medical authorization for procurement and processing of cellular therapy products except where the

				recipient is unknown and the procurement of the product is non invasive:"
4.3.1	RtC	We request that the following sentence be included in standard 4.3.1 prior to the list, "The facility shall ensure that agreements define the following:"	NO	The committee reviewed this comment but did not feel that the standard should be changed. The committee notes that the concept requested is covered in standard 4.3.
4.3.1	RtC	For private banking facilities that process, store, and distribute products that are designated for family use, would the recipient be considered unknown for such products? HPC, cord blood is consider a non-invasive procurement. Would procurement of the umbilical cord and/or placenta consider as non-invasive?	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The committee notes that, yes, that is the case.
4.3.2	SC	NA	NA	The committee edited the title of standard 4.3.2 replacing the term "orders" with "authorization." This change was made for clarity.
4.3.3, #1 (New)	SC	NA	NA	The committee added new subnumber 1 to standard 4.3.3 for parallel construction by including a new requirement for "responsibility for maintaining chain of identity during transfer." This ensures that chain of custody and chain of identity are maintained.
4.3.4	SC	NA	NA	The committee elected to replace the title of standard 4.3.4 with "Instructions" from "Providing Instructions." The title was changed to better reflect the content of the requirements that appear in the standard.
4.3.4 - Title	RtC	Instructions seems to be better fit within procedures shared within an institution and not within an agreement. These types of details are too specific for an agreement.	NO	The committee reviewed this comment but did not feel that a change was appropriate at this time. The committee feels that a need for clear instructions for who is responsible for what in the settings was paramount.
4.3.4, #2,3 (deleted)	SC	NA	NA	The committee elected to combine the requirements of #2 and 3 into one entry. Subnumber 3 reads as follows, "Reporting postinfusion outcomes data and adverse events to the issuing facility and other parties."
4.3.5	SC	NA	NA	The committee elected to remove the clause "departments or…" from the first sentence of the standard for clarity. It was noted that the standard only focuses on facilities, and there are

				instances where a record would not need to be maintained in a transfer situation.
4.3.5, #2	SC	NA	NA	The committee added the clause, "provide records of" to subnumber 2 for clarity. The addition ensures that facilities provide records when necessary and requested.
4.3.5, #2	RtC	During the comment period, the committee received the following comments to an inclusion to the proposed 11th: • How is "in a timely manner" assessed? • Since "in a timely manner" is not defined, then it is not assessable. Please define or clarify the expectations for this phrase.	YES	When the Standards were issued for comment, subnumber 2 included the clause, "timely manner." Based on the comments received, the committee removed the clause and rewrote the entry as a part of subnumber 3 detailed below.
4.3.5, #3 (New)	SC	NA	NA	The committee created subnumber 3 to ensure that facilities define the timeframe as appropriate to meet the intent of the standard, while not including a term such as "timely" which is not assessable. The entry reads as follows: **3) Time frames for making records available for review or transfer upon request.**
4.3.6 (New)	SC	NA	NA	This committee elected to create new standard 4.3.6 to the Standards for clarity. The standard was modeled after similar standards in other sets of AABB Standards and focuses on qualification of suppliers when cellular therapy services involve more than one facility. The standard reads as follows: **4.3.6 Supplier Qualification** When cellular therapy product services involve more than one facility, each facility shall be qualified to perform the scope of activities defined in the agreement in accordance with these *CT Standards*.
4.3.7, #1, 2 (New) (4.3.6)	SC	NA	NA	The committee added new subnumbers 1 and 2 to standard 4.3.7 for parallel construction by including a new requirement for maintaining "chain of identity and custody." The standards read as follows: **4.3.7 Conditions for Product Storage and Disposition**

				When products are transferred between departments or facilities, the following conditions shall be defined: 1) Maintenance of Chain of Identity. 2) Maintenance of Chain of Custody.
4.3.9, #1, 2 (4.3.8)	SC	NA	NA	The committee elected to replace the term "national" with "FDA or relevant Competent Authority" for clarity and to ensure that the Standards would be able to be assessed in facilities outside the United States.
4.5.1	SC	NA	NA	The committee elected to edit standard 4.5.1 for clarity. The additional language ensures that the informed consent documents are updated as needed and that the current medical director is aware of its contents. The phrases, "…at defined intervals…" and "updated as needed" will augment the content of this standard. The standard now reads as follows: Donor informed consent templates shall be reviewed **at defined intervals** and **updated as needed and** approved by the **current** medical director of the facility responsible for obtaining informed consent.
4.5.2.2 (New)	SC	NA	NA	The committee created new standard 4.5.5.2 for completeness. The committee feels that the concept of having a qualified interpreter is of paramount importance that those involved in the donor informed consent process have all the tools necessary to ensure that donors are fully aware of what will occur and what is expected of them. The standard reads as follows: **4.5.2.2** There shall be a process to provide a qualified interpreter when required and/or when applicable.
4.6.1	SC	NA	NA	The committee elected to edit standard 4.6.1 for clarity. The additional language ensures that all authorization templates are reviewed and updated as needed and that the current medical

				director is aware of its contents. The phrases, "…at defined intervals…" and "updated as needed" will augment the content of this standard. The standard now reads as follows: **4.6.1** Any authorization templates shall be reviewed **at defined intervals and updated as needed** and approved by the **current** medical director of the facility responsible for obtaining authorization. This change matches edits made to standard 4.5.1.
4.7.1	SC	NA	NA	The committee elected to edit standard 4.7.1 for clarity. The additional language ensures that all patient informed consent templates are reviewed and updated as needed and that the current medical director is aware of its contents. The phrases, "…at defined intervals…" and "updated as needed" will augment the content of this standard. The standard now reads as follows: **4.7.1** Patient informed consent templates shall be reviewed **at defined intervals and updated as needed** and approved by the **current** medical director of the facility responsible for obtaining informed consent. This change matches edits made to standard 4.5.1 and 4.6.1.
4.5A, I	SC	NA	NA	The committee removed the term "requirements" from the title as it was deemed unnecessary.
4.5A, I, A, 4	SC	NA	NA	The committee edited subnumber 4, by replacing the term "sample" with "specimen" as this was deemed more accurate.
4.5A, I, A, 5	SC	NA	NA	The committee edited subnumber 5, by replacing the term "sample storage" with "intent for use for manufacture or intended manipulation including storage" for clarity. The clause better meets the intent of the standard and informed consent requirements.

4.5A, I, A, 12 (New)	SC	NA	NA	The committee created new number 12 is new to this edition and was included for completeness. There are times when donation of a product can be incentivized and this needs to be included as a part of the donor informed consent process. The entry reads as follows: 4.5A, I 12. Financial or other incentives for donation of cellular therapy products.
4.5A, I, B	SC	NA	NA	The committee added the clause, "and/or translation services" to "B" to match new standard 4.5.5.2. Based on a comment, the clause "when applicable" was included as well.
4.5A, I, B	RtC	Vulnerable donors who may need access to donor advocacy services may not necessarily need a language interpreter or translator (i.e. if the informed consent was written in a language that is native to the donor). Suggest 4.5A (I)(B) to be edited to 'and/or translation' services and to add 'when applicable" to match with the intent of proposed new std 4.5.5.2. Suggested edit: The consenter(s) shall acknowledge in writing that they have received information concerning the risks, benefits, discomforts, and alternatives to human cellular therapy product donation; that they have had an opportunity to have access to donor advocacy and**/or** translation services, **when applicable**; that they have been given the opportunity to ask questions and had those questions answered satisfactorily; and that they have been given a written copy of contact information for future questions related to cellular therapy product donation.	YES	The committee reviewed this comment and felt that the change was appropriate. This ensures that the reference standard is in parallel with standard 4.5.5.2.
4.5A, III, B	SC	NA	NA	The committee elected to clarify the entry by including the qualifier, "either of two ways" for letter B to ensure it is understood that authorization for cadaveric donors can be done by either option.
4.7A, I, B	SC	NA	NA	The committee added the clause, "and translation" to letter B for consistency with new standard 4.5.5.2 and updates to reference standard 4.5A.
5.1.2 (5.1.2.2.1 deleted)	SC	NA	NA	The committee elected to move the sentence that previously appeared as standard 5.1.2.2.1 to appear as a second sentence to standard 5.1.2. The intent of the standard has not changed.

SC = Significant Change, RtC = Response to Comment, NA = Not Applicable

5.1.2.1	SC	NA	NA	The committee elected to remove the clause "In the United States" as it was deemed redundant as the standard is solely focused on CMS, which is only applicable in the United States. For facilities outside the US, standard 5.1.2.2 applies.
5.1.2.1	RtC	Please include the clause, "…as required by applicable national regulations." to the end of the standard.	NO	The committee reviewed this comment but did not feel that a change was needed at this time, as the standard in question is focused only on requirements for facilities in the United States.
5.1.2.1	RtC	Is this standard only applicable to accredited laboratories subjected to CLIA regulations in the US? If yes, suggest to revise this standard to include "...or other acceptable PT program as determined by the relevant local authority". Proficiency testing (PT) for CD34+ enumeration are high complexity tests and are non-waived tests under CLIA thus requiring laboratories to participate in proficiency testing. CD34+ enumeration proficiency testing providers such as College of American Pathologist (CAP) are not part of the CMS approved PT program or approved providers. With the removal of "In United States" in this standard, facilities outside of US are now required to enroll in CMS approved PT program or approved providers. We suggest the following edit: "For each analyte requiring proficiency testing under Clinical Laboratory Improvement Amendments (CLIA)*, each laboratory shall participate in a Centers for Medicare and Medicaid Services (CMS) approved proficiency testing program **or other acceptable PT program as determined by the relevant competent authority ."**	NO	The committee reviewed this comment but did not feel that a change was needed at this time, as the standard in question is focused only on requirements for facilities in the United States. The guidance to the standard will be expanded to reflect what is expected for facilities not in the United States and those that ship units to the United States when a CMS approved proficiency test is not available.
5.1.2.2	SC	NA	NA	The committee added the term "approved" to standard 5.1.2.2 concerning external proficiency testing programs that will ensure that facilities can achieve accreditation.
5.3.1	SC	NA	NA	The committee added the clause "as applicable" to the end of standard 5.3.1 to reflect that there are instances where some outcomes data is not collected.
5.3.2	SC	NA	NA	The committee added the clause, "…the clinical outcomes as specified by the clinical protocols and as applicable…" to the beginning of the standard to indicate that these elements in the list

				that is included with standard 5.3.2 would be determined by clinical protocols.
5.3.2, #6, 7, 8 (New)	SC	NA	NA	The committee added subnumbers 6 – 8 for completeness, understanding that clinical facilities would require that these elements be included as it pertains to outcomes data to be gathered. The subnumbers read as follows: **6) Immune effector cell endpoints.** **7) Hematopoietic reconstitution.** **8) Monitoring of patient safety.**
5.3.2.1 (New)	SC	NA	NA	The committee created new standard 5.3.2.1 for completeness. The intent of the standard is to ensure that the collection of outcomes data be done at facility defined intervals. The standard reads as follows: **5.3.2.1** The clinical facility shall determine the criteria for cellular therapy product safety, product efficacy, and/or clinical outcomes data and collect this data for analysis at defined intervals.
5.3.2.1	RtC	We would like more specific guidance on monitors that would meet the intent of this requirement.	YES	The committee noted this comment and will include new guidance to assist with the implementation of standard 5.3.2.1.
5.3.3, 5.3.4 (Deleted)	SC	NA	NA	Standards 5.3.3 and 5.3.4 that previously appeared in the 10th edition of Standards for Cellular Therapy Services have been deleted. The rationale being that both standards were deemed redundant to standards 5.3.1, 5.3.2 and 5.3.2.1.
5.3.3 (5.3.5)	SC	NA	NA	The committee edited standard 5.3.3 for clarity. The intent of the standard has been updated to read as follows: **5.3.3** For facilities that procure, process or administer **investigational products, there shall be a process for recording and monitoring patient safety and reviewing clinical outcomes as specified by the independent ethics committee-approved protocol(s).**

5.4	SC	NA	NA	The committee edited standard 5.4 for clarity. The committee added the term "supplies" to the standard for completeness. The committee also added the term "function" to appear at the end of the standard for completeness. The committee finally, also added the term "critical" before "materials" to ensure that the standard is accurate. The standard reads as follows: **5.4 Quality Control** The facility shall establish a program of quality control that is sufficiently comprehensive to ensure that critical materials including supplies, reagents and equipment function as specified.
5.4	RtC	What supplies would need functional QC? We have a variety of supplies (mop heads, gowns, gloves, alphawipes, etc) that do not undergo QC but are also low risk. Adding QC to all supplies will be a burden without a commensurate benefit.	YES	The committee reviewed this comment and agreed with the intent of the request. As such, the term "critical" was added to the standard to appear before "materials."
5.5.3	SC	NA	NA	The committee added the term "critical" to the title of the standard for completeness understanding that not all materials used in the facility would be deemed critical. The title now reads, "Qualification of Critical Materials." The clause "whenever possible" was removed from the standard as it served as guidance and not necessary.
5.5.3	RtC	I suggest that "whenever possible" be reincluded back into this standard.	NO	The committee noted this comment but did not feel that reverting the language back into the standard was needed. The committee notes that standard 5.5.3.1 covers this requirement.
5.6.2	SC	NA	NA	The committee replaced the term "patient" with "donor or recipient" in this standard. The committee feels that this is the most accurate term to use in this instance. The committee has done a complete review of the standards to determine where patient and recipient should be used and in this instance the term "recipient" was deemed most appropriate.
5.6.2, #5 (New)	SC	NA	NA	The committee created new Subnumber 5 and was added to ensure that the impact on product

				sterility as a result of personnel movement and instances where workflow is not followed are considered. The subnumber reads as follows: **5) Workflow and movement of personnel through workspaces.**
5.6.2.1	SC	NA	NA	The committee added the clause, "at defined intervals" to the end of the standard to ensure that facilities review the effectiveness of the elements in standard 5.6.2 on a scheduled basis. This matches similar language in other sets of AABB Standards.
5.7	SC	NA	NA	The committee added the elements of "…chain of identity and chain of custody for…" to the standard for completeness and to continue the inclusion of these elements in the Standards where appropriate. The standard reads as follows: **5.7 Product Identification and Traceability** The facility shall establish and maintain policies, processes, and procedures that ensure the **chain of identity and chain of custody for identification** and traceability of each cellular therapy product and all related samples from their initial source, through all processing and testing steps, to their final disposition. Policies, processes, and procedures shall also allow the identification and traceability of each cellular therapy product and all related samples from their final disposition, through all processing and/or testing steps, to their source.
5.7.1	SC	NA	NA	The committee edited standard 5.7.1 by replacing the clause, "This identification" with "Unique identifiers" as the Standards require the use of two unique identifiers. This change was made for parallel construction.

5.8.1.1 (5.8.4)	SC	NA	NA	The committee has moved former standard 5.8.4 concerning "Label Terminology" to appear as new standard 5.8.1.1 for flow and fit. The content of the standard has not changed.
5.8.2.1	SC	NA	NA	The committee added the clause "FDA and relevant Competent Authority" to the standard for completeness and parallel construction with other standards throughout the edition.
5.8.2.2	SC	NA	NA	The committee added the clause "FDA and relevant Competent Authority" to the standard for completeness and parallel construction with other standards throughout the edition.
5.8.3	SC	NA	NA	The committee edited the title of standard 5.8.3 to appear as "Labeling" and removed the clause "Packaging and" as the standard itself was only focused on labeling. The content of the standard has not changed.
5.8.3	RtC	This section really seems to be about inspection and verification of labeling of CT products. It discusses inspection of labels at various stages, says nothing about "packaging," or the actual performance of "labeling. Does it really belong under 5.8, Labels, labeling and Labeling Controls? Should this be in a section devoted to inspection of products at various stages to include container integrity, product appearance, as well as labeling content and integrity?	YES	The committee noted this comment and felt that the appropriate change would be to title the standard "Labeling" in place of "Packaging."
5.8.4 (New)	SC	NA	NA	The committee created new standard 5.8.4 to ensure that the Standards include a requirement for facilities that use investigational products being approved for use and labeled according to Competent Authority requirements. The standard reads as follows: **5.8.4** Cellular therapy products for investigational use or approved for use by the FDA or relevant Component Authority shall be labeled according to protocol and all elements required shall be included in the accompanying records or readily available. Reference standard 5.8.2A applies.
5.9	SC	NA	NA	The committee added the elements of "…chain of identity and chain of custody for…" to the

				standard for completeness and to continue the inclusion of these elements in the Standards where appropriate. The standard reads as follows: **5.9 Transport and Shipping** The facility shall establish and maintain policies, processes, and procedures that are intended to limit deterioration, prevent damage, ensure timely delivery, and protect the quality of the materials and cellular therapy products during transport and shipping **while maintaining Chain of Custody and Chain of Identity**.
5.9.1	SC	NA	NA	The committee added the clause "FDA and relevant Competent Authority" to the standard for completeness and parallel construction with other standards throughout the edition.
5.9.2	SC	NA	NA	The committee added the clause "shipping or transport" to the standard for completeness. The standard now reads as follows: **5.9.2 Shipping or transport** containers shall be qualified at defined intervals to ensure that they maintain temperatures within the acceptable range for the expected duration of transport or shipping.
5.9.2	RtC	Can AABB expand on the type of shipping or transport containers? Institutions would benefit from knowing if this refers to long-term shipping containers or containers used for short-term transporting products interfacility and/or hand couriered containers versus commercially shipped products.	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The committee feels that providing guidance would be a better solution, understanding that adjusting the standard in the way suggested would box facilities into a situation that does not fit for all members.
5.9.6	SC	NA	NA	The committee edited standard 5.9.6 for completeness, ensuring that the records be maintained to include, "origin, custody, transfer, identity, integrity, and…"
5.10.1, #9 (d)	SC	NA	NA	The committee added the clause "…and tampering." to the standard for completeness. This addition ensures that tampering can be a

				cause of contamination when a facility received a product.
5.10.1.1	SC	NA	NA	The committee edited the standard by replacing the term "identification" with "chain of identity" for parallel construction purposes. This ensures the standard is written in a fashion to mirror other standards throughout the edition.
5.10.1.2	SC	NA	NA	The committee elected to replace the term "person" with "individual" for accuracy. The intent of the standard has not changed.
5.11.1.1	SC	NA	NA	The committee added "humidity" to this standard for completeness. The committee notes that humidity has to be monitored for products maintained at room temperature. The committee also replaced "at least" with "at a minimum" for parallel construction with other standards.
5.12.2	SC	NA	NA	The committee added the clause "when required" to standard 5.12.2 for completeness. The committee noted that there are instances where donor eligibility is not required to be determined.
5.12.2.1.2	SC	NA	NA	The committee added the clause, "…and ensures..." to standard 5.12.2.1.2 for completeness. The standard reads as follows: **5.12.2.1.2** The facility shall have a policy that addresses **and ensures** the privacy and confidentiality of the donor eligibility determination process.
5.12.2.2	SC	NA	NA	The committee added the clause "FDA and relevant Competent Authority" to the standard for completeness and parallel construction with other standards throughout the edition.
5.12.2.2, #1	SC	NA	NA	The committee edited the language of subnumber 1 to mirror the requirement in the CFRs referenced with the standard. The intent of the standard has not changed. The subnumber reads as follows:

				1) HPC, Cord Blood: **<u>Obtain</u>** ~~Collect~~ maternal sample within 7 days before or after **<u>collection</u>** ~~delivery~~.
5.12.2.2, #1	RtC	During the comment period, the committee received the following comments to an edit/error to the proposed 11th: • Include elements in bolded: 1) HPC, Cord Blood: Obtain maternal sample within 7 days before **or after** collection. • The CFR still states at time of collection or 7 days before or after. It is unclear of where the committee sees any indication that you cannot collect after. • We have noted a proposed change related to the timeframe for collecting maternal blood for infectious disease testing, which only allows maternal sample obtained before collection not after delivery. • We would like to push back on the above change of standards - as per the Local Authority requirements -Maternal samples can be collected within 7 days before or after delivery. This will be an issue and will raise un-necessary Non Conforming for our processes. • For maternal samples obtained within 7 days **after** collection, will this impact on donor eligibility determination since it is still within the collection timeframe by the FDA? See Standard 5.12.8. This includes maternal sample collection done on the same day of delivery after cord blood collection. Suggest to reinclude the timeframe for maternal sample collection within 7 days before **or after collection.**	YES	When the CT Standards were issue for public comment, an error was included in the edition that was not intentional. The committee had not meant to remove the clause "or after" in subnumber 1, this was a clerical error.
5.12.2.6	SC	NA	NA	The committee added the clause "FDA and relevant Competent Authority" to the standard for completeness and parallel construction with other standards throughout the edition.
5.12.2.8.1	RtC	We have become aware that international cord blood banks are updating their IDM panels to remove HBcAb when HBV DNA testing is performed. As such, discontinuing the testing may be an option. However, it is important that international banks understand the potential consequences related to US importation of these CBU. Specifically, units from these banks after HBcAb testing is discontinued may be disadvantaged with regard to selection given the incomplete status and DUMN requirement for release for units imported into US for HCT. From a regulatory perspective, we recommend that all CBBs make every effort to align with 21 CFR 1271 subpart C, specifically 21 CFR 1271.85 which includes HBcAb testing. It is true that units not fully tested would still be distributed via Declaration of Urgent Medical Need (DUMN) and as incomplete	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The committee notes the information and when possible share the information with facilities for whom it would be most relevant.

		donor eligibility (DE) determination. However, according to NMDP policy and US regulation 21 CFR 1271.60 indicating the need to make attempts to close out incomplete (DE) determinations, NMDP will still reach out and attempt to close DE determination for products for which DE determination is incomplete.		
5.12.2.9	SC	NA	NA	The committee added the clause "FDA or relevant" to the standard for completeness and parallel construction with other standards throughout the edition.
5.12.3.1.1	SC	NA	NA	The committee added the clause "FDA or relevant" to the standard for completeness and parallel construction with other standards throughout the edition.
5.12.4	SC	NA	NA	The committee added the clause "FDA or relevant" to the standard for completeness and parallel construction with other standards throughout the edition.
5.12.5, #2	SC	NA	NA	The committee added the clause "FDA or relevant" to the standard for completeness and parallel construction with other standards throughout the edition.
5.12.6.2.2	SC	NA	NA	The committee edited the standard for clarity, by including the term "**mandated**" and the term "next of kin **when**…" however the intent of the standard has not changed.
5.12.8	SC	NA	NA	The committee added the clause "FDA or relevant" to the standard for completeness and parallel construction with other standards throughout the edition.
5.12.9	SC	NA	NA	The committee added the clause "FDA or relevant" to the standard for completeness and parallel construction with other standards throughout the edition.
5.12.10	SC	NA	NA	The committee elected to add the clause "or performed" to this standard for completeness. The committee also removed the clause "in accordance with the requirement of the Competent Authority" as it was deemed not necessary.

5.12.10	RtC	This is preceded with a section on "Transport and Shipping (Standard 5.9) and 5.10 "Inspection and Testing." Seems like it could at least have a reference under Std. 5.8. All these sections are very complex, especially labeling which is so well defined in the Reference Tables.	YES	The committee agreed with this comment and added a crossreference to standard 5.8 in this standard along with the crossreference to reference standard 5.9.5A.
5.14.2.3	SC	NA	NA	The committee elected to edit standard 5.14.2.3 to ensure that the timeframes and determinations of when to perform a complete blood count is provided at several steps and is not conducted in a fashion that is harmful to the potential donor. This change also expands the standard to allow for all cells collected by apheresis to be procured, including CAR-T cells which do not require mobilization. The standard reads as follows: **5.14.2.3** For marrow donors or donors of cells collected by apheresis, facilities shall: 1) Define criteria to evaluate the results of a complete blood count before each procurement. 2) Define timeframes for obtaining a complete blood count prior to the initial procurement. 3) Obtain a complete blood count within 24 hours prior to each subsequent procurement after the initial procurement.
5.14.5, #4	SC	NA	NA	The committee added the clause "and/or patient" to subnumber 4 of standard 5.14.5.for completeness. This addition has been made to all standards that focus on records throughout chapter 5 where appropriate.
5.14.7	SC	NA	NA	The committee added the elements of "…while maintaining chain of custody." to the standard for completeness and to continue the inclusion of these elements in the Standards where appropriate. The standard reads as follows: **5.14.7 Procurement Record Availability** Each facility performing procurement shall provide a product procurement record to the facility receiving the product while maintaining chain of custody. Chapter 4, Agreements, applies.

5.14.7.1	SC	NA	NA	The committee added the clause "and/or patient" to subnumber 4 of standard 5.14.7.1 for completeness. This addition has been made to all standards that focus on records throughout chapter 5 where appropriate.
5.14.7.1	RtC	Change "patient" to "recipient".	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The committee noted that in this case the standard does relate to the patient.
5.17	RtC/SC	Is this standard really about "Testing during Processing"?	YES	The committee noted this comment and changed the title of standard 5.17 from "Processing" to "Testing." This change does reflect that this is what the standard is primarily focused on.
5.17.2	SC	NA	NA	The committee added the clause "and/or patient" to subnumber 4 of standard 5.17.2 for completeness. This addition has been made to all standards that focus on records throughout chapter 5 where appropriate.
5.17.2	RtC	Change "patient" to "recipient".	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The committee noted that in this case the standard does relate to the patient.
5.17.5	SC	NA	NA	The committee added the elements of "…while maintaining chain of custody." to the standard for completeness and to continue the inclusion of these elements in the Standards where appropriate. The standard reads as follows: **5.17.5 Processing Records** Each facility(ies) performing processing, preservation, or storage shall provide a copy of the product processing record insofar as the processing records concern the safety, purity, and potency of the product involved or a summary of the product processing record to the facility(ies) receiving the product while maintaining chain of custody. Chapter 4, Agreements, applies.
5.18	SC	NA	NA	The committee edited standard 5.18 to include the clause "…and length of storage…" to ensure

				that facilities determine the time that will ensure that products maintain their viability.
5.19.3, #4	SC	NA	NA	The committee added the clause "and/or patient" to subnumber 4 of standard 5.19.3 for completeness. This addition has been made to all standards that focus on records throughout chapter 5 where appropriate.
5.20.2.1	SC	NA	NA	The committee added the clause, "and an assessment of potency" to standard 5.20.2.1. This addition was done to ensure that facilities be able to measure the levels of potency once products are recovered post thaw. The standards reads as follows: **5.20.2.1** The stability program shall include product container integrity, viable cell recovery, and an assessment of potency of the relevant cell population(s).
5.20.2.1	RtC	Change "a measure of potency" to read "and/or evidence of potency" so that engraftment outcomes would meet this requirement.	NO	The committee noted this comment but felt that the change made to replace "measure" with "assessment" was more appropriate but did meet the needs of this comment.
5.22.2.2, #2	SC	NA	NA	The committee edited subnumber 2 of standard 5.22.2.2for clarity. By including the clause, "facility defined" the need to include the elements that were deleted, "as defined in applicable policies, processes and procedures" as they were deemed redundant. The edit does not change the intent of the standard.
5.24.2	SC	NA	NA	The committee added the elements of "…while maintaining chain of custody." to the standard for completeness and to continue the inclusion of these elements in the Standards where appropriate. The standard reads as follows: **5.24.2** At distribution and issue of allogeneic products, the following information shall accompany the product or be readily available wherever the product is located to maintain chain of custody:

5.24.2, #2	SC	NA	NA	The committee added the clause "FDA or relevant" to the standard for completeness and parallel construction with other standards throughout the edition.
5.25	SC	NA	NA	The committee added the elements of "…while maintaining chain of identity." to the standard for completeness and to continue the inclusion of these elements in the Standards where appropriate. The standard reads as follows: **5.25 Clinical Program** The facility shall have policies, processes, and procedures for patient care, including the administration of specific therapies and medical interventions while maintaining chain of identity.
5.25.1	SC	NA	NA	The committee elected to edit standard 5.25.1 for clarity. The committee added the clause, "…ensure that…" and "…are met and continue to be met before…" to ensure that the patient evaluation is conducted in a manner to ensure that evaluation criteria is determined before treatment.
5.26.1	SC	NA	NA	The committee elected to replace the term "patient" with "recipient" for clarity. As a part of a comprehensive review of all uses of patient and recipient where appropriate the standards have been updated. The standard reads as follows: **5.26.1 Medical Orders** Orders for clinical care of the recipient shall uniquely identify the recipient and medical treatment ordered. Specific instructions shall be provided in the order.
5.26.1.1	SC	NA	NA	The committee edited standard 5.26.1.1 by adding the terms "qualified" and "an authorized" for completeness and parallel construction with similar requirements throughout the edition. The standard reads as follows:

				5.26.1.1 Medical therapy(ies) shall be ordered by a qualified physician or an authorized health-care professional.
5.27	SC	NA	NA	The committee elected to replace the term "patient" with "recipient" for clarity. As a part of a comprehensive review of all uses of patient and recipient where appropriate the standards have been updated. The standard reads as follows: **5.27 Preparation of the Recipient for Administration of Cellular Therapy Products** The facility shall have policies, processes, and procedures for the preparation of the recipient for administration of cellular therapy product(s) which shall address, at a minimum, the following:
5.28.1	SC	NA	NA	The committee added the elements of "…while maintaining chain of custody and chain of identity." to the standard for completeness and to continue the inclusion of these elements in the Standards where appropriate. The standard reads as follows: **5.28.1 Receipt of Cellular Therapy Products** The clinical facility shall have procedures for the receipt, and preparation, of products while maintaining chain of identity and chain of custody. Standards 5.7, 5.8, 5.10, and 5.22 apply.
5.29.3	SC	NA	NA	The committee added the elements of "…while maintaining chain of identity." to the standard for completeness and to continue the inclusion of these elements in the Standards where appropriate. The standard reads as follows: **5.29.3** There shall be procedures for recording adverse events and processes for the communication of such events from the clinical facility to the issuing facility and/or registry while maintaining chain of identity. Chapter 7, Deviations, Nonconforming Products or

				Services, and Adverse Events, applies. Standards 4.3.4 and 4.3.5 apply.
5.29.4, #1	SC	NA	NA	The committee elected to replace the term "patient" with "recipient" for clarity. As a part of a comprehensive review of all uses of patient and recipient where appropriate the standards have been updated. The standard reads as follows: **5.29.4 Records of Administration** Records of administration shall include: 1) Patient's name and unique identifier(s).
5.29.4, #1	RtC	Revert back to "Recipient's". I do not thing the change is appropriate.	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The committee noted that in this case the standard does relate to the patient.
5.29.5, 5.29.5, #1	SC	NA	NA	The committee elected to replace the term "patient" with "recipient" for clarity. As a part of a comprehensive review of all uses of patient and recipient where appropriate the standards have been updated. The standard reads as follows: **5.29.5 Patient Records** Patient records shall include the following: 1) Patient's name and unique identifier(s).
5.29.5, #11 (New)	SC	NA	NA	The committee elected to add new subnumber #11 for completeness and parallel construction. The requirement states the following: 11) Other relevant testing records.
5.29.5	RtC	Revert back to "Recipient's". I do not thing the change is appropriate.	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The committee noted that in this case the standard does relate to the patient.
5.8.2A, #11	SC	NA	NA	The committee elected to add in the term "patient" along with "recipient" for clarity. As a part of a comprehensive review of all uses of patient and recipient where appropriate the standards have been updated.

<table>
<tr><td>5.8.2A, #11</td><td>RtC</td><td>Please remove “Patient/” from #11.</td><td>NO</td><td>The committee reviewed this comment but did not feel that a change was needed at this time. The committee noted that in this case the standard does relate to the patient.</td></tr>
<tr><td>5.8.2A. #14 (New)</td><td>SC</td><td>NA</td><td>NA</td><td>The committee added new entry 14 to the Standards to ensure that products from donors who are CMV positive are identified as such and the product indicates as much on the accompanying label. This ensures that facilities test donors for CMV and label accordingly with these Standards.
The standard reads as follows:
<table>
<tr><th>Item No.</th><th>Element</th><th>Completion of Procurement[1]</th><th>In-Process Label[1]</th><th>Completion of Processing</th><th>Distribution and Issue[2]</th></tr>
<tr><td><u>14</u></td><td><u>CMV status of the donor (if applicable)</u></td><td><u>N/A</u></td><td><u>N/A</u></td><td><u>N/A</u></td><td>R</td></tr>
</table></td></tr>
<tr><td>5.8.2A, footnote 9 (New)</td><td>SC</td><td>NA</td><td>NA</td><td>The committee added new footnote #9 for completeness. The committee added the elements of “Ensure maintenance of chain of identity.” to the standard for completeness and to continue the inclusion of these elements in the Standards where appropriate.
The footnote reads as follows:
[9] Ensure maintenance of chain of identity.</td></tr>
<tr><td>5.12A, I</td><td>SC</td><td>NA</td><td>NA</td><td>The committee edited roman number I of reference standard 5.12A to include the concepts of “translation services.” This change was made to remain in concert with new standard 4.5.5.2</td></tr>
</table>

				and reference standards 4.5A and 4.7A. The entry reads as follows: Donor Advocacy and Translation Services All allogeneic donors or their legally authorized representatives shall be provided with the opportunity to access donor advocacy including translation services.
5.12A, III, B, 2	SC	NA	NA	The committee added the term "medical suitability" and "qualified" for completeness and parallel construction with similar requirements throughout the edition. The standard reads as follows: 2) Autologous Donors A medical suitability assessment specific to the donation procedure shall be performed by a qualified health-care professional and approved by a physician before the scheduled procurement.
5.12B, footnote 9	SC	NA	NA	The committee added the requirement to include HLA-C as a part of laboratory testing for all allogeneic donors with regard to HLA type where applicable in the update to footnote 9. This ensures that the standards mirror current practice.
5.12B, HLA - C	RtC	Please update HLA testing requirements to include HLA-C. NMDP notes that both WMDA and FACT include standards for minimum typing requirements of unrelated donors that are inclusive of HLA-C determination, whereas AABB does not include HLA-C as a minimum typing criteria for unrelated donors. It is our perspective that this is an important aspect of clinical HLA testing requirements for HLA C. If the committee declines adding this additional typing, we respectfully request the opportunity for additional discussions before the standards are finalized as we would like to continue to point to AABB and FACT Standards as minimal criteria for network participation.	YES	The committee agreed with this comment and added HLA-C testing to the reference standard 5.12B.
5.12B, footnote	SC	NA	NA	The committee added the clause "FDA or relevant" to the standard for completeness and parallel construction with other standards throughout the edition.
5.12C, footnote	SC	NA	NA	The committee added the clause "FDA or relevant" to the standard for completeness and

				parallel construction with other standards throughout the edition.
5.12D, footnote	SC	NA	NA	The committee added the clause "FDA or relevant" to the standard for completeness and parallel construction with other standards throughout the edition.
5.12E, footnote	SC	NA	NA	The committee added the clause "FDA or relevant" to the standard for completeness and parallel construction with other standards throughout the edition.
5.17A, #1	SC	NA	NA	The committee edited number 1 of 5.17A to mirror the way content is presented in reference standard 5.17B. The additional requirements have been included as a part of cell characterization to mirror what is required in the field currently as well as by other standards setting bodies. The entry reads as follows: The following processing tests shall be performed on each cellular therapy product at defined steps during processing: 1) Cell characterization specific to the cellular therapy product. This includes: b) Total nucleated cells and/or CD45 viability. c) CD34 cell count. d) CD34 cell viability. e) Nucleated red cell count or corrected total nucleated cell count.
5.17B, #2	SC	NA	NA	The committee added "HLA- C" to number 2 to the list of minimum loci that are determined using DNA based technologies. This mirrors the footnote in reference standard 5.12B concerning HLA-C testing.
5.17B, #2	RtC	Please update HLA testing requirements to include HLA-C. NMDP notes that both WMDA and FACT include standards for minimum typing requirements of unrelated donors that are inclusive of HLA-C determination, whereas AABB does not include HLA-C as a minimum typing criteria for unrelated donors.	YES	The committee agreed with this comment and added HLA-C testing to the reference standard 5.17B.

		It is our perspective that this is an important aspect of clinical HLA testing requirements for HLA C. If the committee declines adding this additional typing, we respectfully request the opportunity for additional discussions before the standards are finalized as we would like to continue to point to AABB and FACT Standards as minimal criteria for network participation.		
5.17B, 5, c	RtC	Post thaw viability, total nucleated cell (TNC) count, confirmatory HLA typing, and growth of colony forming units (CFU) or viable CD34 are not performed upon banking but upon confirmatory testing being ordered. Clarification is requested on whether the requirement for post thaw viable CD34 testing on an integral segment is required on units banked starting in 2013 or units on which confirmatory testing has been requested since 2013. Unfortunately, integrally attached segments are finite and multiple segments on each unit are already designated for specific use. These specific uses regularly mean that no segment is available to perform the CD34 testing. We recommend #5c be edited to also allow the testing to be performed on a reference sample stored under the same conditions as the unit to cover required testing when an attached segment is not available.	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The committee expects all users to perform CD34 assay testing on all cord blood units before issue. The committee expects that facilities have, at a minimum, two integrally attached segments to sample, and understand many have more than two segments.
5.17B, 6	SC	NA	NA	The committee added the clause "FDA or relevant" to the standard for completeness and parallel construction with other standards throughout the edition.
5.17C, 4	SC	NA	NA	The committee edited number 4 by replacing the clause, "Antigen expression" with "Characterization of cell identity" to ensure accuracy and to mirror other changes in the edition.
5.17C, 5	SC	NA	NA	The committee edited number 5 by replacing the term "Potency" with "Functional" to ensure that the entry in the reference standard mirrors the edit made to standard 5.20.2.1.
5.17C, 7	SC	NA	NA	The committee updated number 7 to include the clause "Sterility" and "and other relevant assays" for completeness. These updates were included to mirror other edits made in the edition.
5.17C, 7	SC	NA	NA	The committee added the clause "FDA or relevant" to the standard for completeness and parallel construction with other standards throughout the edition.

5.17C, 8 (New)	SC	NA	NA	The committee added new entry 8, to the reference standard to ensure that the standards are complete, recognizing the need to include the characterization of cell product purity and potency. The number reads as follows: Characterization of cell product purity as required by an IND or license application or as approved by the FDA or relevant Competent Authority.
6.2.1.1	SC	NA	NA	The committee added the elements of "…by maintaining chain of identity and chain of custody..." to the standard for completeness and to continue the inclusion of these elements in the Standards where appropriate. The standard reads as follows: **6.2.1.1 Record Traceability** The records system shall ensure the traceability by maintaining chain of identity and chain of custody of all of the following:
6.2.4.1 (New)	SC	NA	NA	The committee created new standard 6.2.4.1 for completeness. The new standard ensures that any changes to records that could affect the safety of the recipient be reviewed by an appropriate individual. The standard reads as follows: **6.2.4.1** Modifications or changes that can affect the safety of the recipient or quality of the cellular therapy product shall be approved by the authorized individual. Chain of identity shall be maintained.
6.2.8	SC	NA	NA	The committee added the clause requiring "privacy" be maintained as a part of the confidentiality perspective for donor, employee and patient records.
6.2.9	SC	NA	NA	The committee added the clause "FDA or relevant" to the standard for completeness and parallel construction with other standards throughout the edition.

6.2.9.1	SC	NA	NA	The committee added the clause "FDA or relevant" to the standard for completeness and parallel construction with other standards throughout the edition.
6.3.1.1	SC	NA	NA	The committee edited standard 6.3.1.1 to better mirror what occurs in accredited laboratories and what would be expected in terms of confidentiality of records, and what individuals can have access to those records. The standard now reads as follows: **6.3.1.1** Individuals shall be identified and defined by job description that are authorized to create, modify, maintain or transmit records in a controlled and approved manner in conformance with the FDA or relevant Competent Authority requirements. ~~authorization to access and release data and information shall be defined, and individuals authorized to enter, change, and release results shall be identified.~~
6.3.1.1	RtC	Access and functionality within an electronic record system are controlled by defined user access (roles). Staff are assigned their roles based on their responsibility and trained accordingly. It is a concern that the statement "defined by job description" can be narrowly interpreted. It is unclear as to what evidence is expected to meet this regulation.	NO	The committee noted this comment but did not feel that a change was needed at this time. The committee expects users of the Standards to include in their employees job descriptions who has access to records that would be deemed secure. This ensures consistency across all AABB accredited facilities.
6.3.4.3	SC	NA	NA	The committee elected to edit standard 6.3.4.3 for clarity. The committee replaced the term "periodically" with "defined intervals" understanding that this provides parallel construction with other sets of AABB Standards and standards within this edition.
7.2.1 (New)	SC	NA	NA	The committee created new standard 7.2.1 to mirror the language contained in the Standards for Blood Banks and Transfusion Services, understanding the need for facilities to perform lookback procedures in the case of a nonconformance. The standard reads as follows:

				7.2.1 Product Review, Investigation and Lookback The facility shall have policies, processes, and procedures to identify nonconforming products and the initiation of an investigation, including lookback as applicable, as soon as possible.
7.2.1 (New)	RtC	Should if applicable be added? Does every non-conforming product require a lookback?	YES	When proposed this standard did not include "as applicable" as per the comment not every nonconforming product would require lookback. As such the committee added the clause, "lookback as applicable" based on this request.
7.2.1.2 (New)	SC	NA	NA	The committee elected to create new standard 7.2.1.2 based on the creation of new standard 7.2.1 which requires when applicable to perform lookback on nonconforming products. The standard reads as follows: **7.2.1.2** Products identified as nonconforming following distribution shall be reported to the FDA or relevant Competent Authority in accordance with written policies, processes, and procedures.
7.2.1.3 (New)	SC	NA	NA	The committee elected to create new standard 7.2.1.3 based on the creation of new standard 7.2.1 which requires when applicable to perform lookback on nonconforming products. The standard reads as follows: **7.2.1.3** Customers shall be notified when the nonconforming products can impact the purity, potency, safety or efficacy of the product.
7.2.1.3 (New)	RtC	Product review, investigation, and lookback is not needed for cellular therapies. This would present an undue burden on labs and a negligible chance of identifying an additional risk to a patient. Non-conforming products are already required to be reported to NMDP and the processing laboratory. The processing laboratory or principal investigator, as appropriate, is then required to notify the FDA. An added complication for HPC, Cord Blood banks is the identification of the donor. Infectious disease testing is performed on the donor mother, but the baby is the donor. A baby can only donate at the time of birth while a donor mother can donate with each delivery. Would cord blood banks be required to perform	No	The committee noted this comment but did not feel that a change was needed at this time. The committee feels that the update to standard 7.2.1 by including "lookback as applicable" would address the needs expressed in the comment.

		lookback similar to blood bank? There is not a clear benefit to performing these reviews.		
7.3.2	SC	NA	NA	The committee elected to add a crossreference to standard 5.30 for completeness. Standard 5.30 focuses on postadministration monitoring on the collection of outcome data following the administration of products.
8.4	SC	NA	NA	The committee added the term "evaluates" to the standard for completeness. The committee felt that this inclusion mirrors the work being done in facilities accredited by AABB.
8.5	SC	NA	NA	The committee elected to add a crossreference to standard 1.2.4 for completeness. Standard 1.2.4 requires that the quality representative is a part of executive management and as a result aware of all quality monitoring.
10.0	SC	NA	NA	The committee added the clause "FDA or relevant" to the standard for completeness and parallel construction with other standards throughout the edition.
Glossary – Bioassay	SC	NA	NA	The committee added the term "bioassay" to the glossary for completeness.