Significant Changes and Response to Comments Received to the 10th edition of Standards for Cellular Therapy Product Services

The following table summarizes many of the significant changes made to the 10th edition of Standards for Cellular Therapy Services; it is not, however, exhaustive. Not all changes contained in the CT Standards have been incorporated in detail. Many of the changes that result in the reorganization of a section cannot be fully appreciated without consulting the 10th edition of CT Standards in conjunction with this table; therefore, the numbering follows that of the 10th edition and, where appropriate, the corresponding standard number in the 9th edition is included in parentheses. In cases where a standard has been renumbered, but the substance of the standard has not changed, there is often no entry listed in the table. Like the crosswalk published with the CT Standards, this table is offered to assist individuals in updating their facility's policies, processes, and procedures to conform to the 10th edition. Use of this table should not take the place of a thorough, line-by-line analysis of each standard. Please note that this summary includes examples of comments submitted by users of the document, along with the committee's rationale in making or not making a revision to the document.

Standard	SC/RtC	Comment	Change made?	Outcome
1.1.2 (New)	SC	NA Word in red font add to the guidance document explanation?	NA	The committee created new standard 1.1.2 in conjunction with the creation of new standard 1.5 was added to ensure that accredited facilities remain in compliance with FDA regulations (or regulations pertaining to non-US facilities) as it relates to contamination (suspected or actual) or loss of cell function. This standard was put in place due to many facilities receiving Warning Letters concerning risk points that can directly impact the cellular therapy product and will allow assessors to cite facilities who are not in conformance accordingly.
1.1.2 (New)	RtC	We request the AABB Standards Committee evaluate the efficacy of implementing Standard 1.1.2. While we recognize the necessity for the registering and licensing of cellular therapy products; ultimately decisions regarding registration and licensing are proprietary in nature and should not be subject to accreditation standards.	NO	The committee noted this comment but did not feel a change was needed at this time. This standard is an effort to assist AABB's assessors while on site. The review by an assessor would not be for information considered proprietary, merely that product(s) are listed as required by the Standards and FDA. It should be noted that unlicensed products do not need to be shared as they would be filed under IND.
1.1.3.1 (1.1.2.1.1)	SC	NA	NA	The committee edited standard 1.1.3.1 for clarity. The first sentence of the standard has been split into two standards to ensure that it was understood that having relevant experience and relevant continuing education were both

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				concepts that were required of all procurement medical directors.
1.1.3.1.1 (1.1.2.1.1)	SC	NA	NA	The committee replaced the term "overseen" with "managed or reviewed" for clarity; the change provides more specificity. The requirement of reviewing 5 procedures was shifted to 10, to require 5 per annum, while matching the normal accreditation cycle. Finally, the clause "throughout the preceding two year accreditation cycle" was added to the standard to ensure that it was understood that this requirement applies for each edition and not just one time.
1.1.4.1 (1.1.3.1.1)	SC	NA	NA	The committee edited standard 1.1.4.1 for clarity. The first sentence of the standard has been split into two standards to ensure that it was understood that having relevant experience and relevant continuing education were both concepts that were required of all laboratory medical directors.
1.1.4.1 (1.1.3.1), 1.1.4.1.1 (1.1.3.1.1), 1.1.4.2 (1.1.3.2), 1.1.4.2.1 (1.1.3.2.1)	RtC	These standard need a definition or guidance on what is expected of the terms 'managed or reviewed'. Would a review of the paperwork be sufficient? Does watching the procedure carried out by a tech meet this standard? Needs definition or guidance on what is considered 'relevant experience'. Would being laboratory director for the previous 10 years meet the standard? Does it require previous experience prior to the position, regardless of actual time in the position?	NO	The committee reviewed this comment and felt that in the case of the query of what review could consist of, a review of a facility's policies, processes and procedures would be appropriate so long as those documents expanded on how the requirement was met. It should be noted that relevant in this case is focused on what an individual's area of work is, for instance if you collect product, that would be where your relevant experience and continuing education would have to lie.
1.1.4.2.1 (1.1.3.2.1)	SC	NA	NA	The committee edited standard 1.1.4.2.1 for clarity. The first sentence of the standard has been split into two standards to ensure that it was understood that having relevant experience

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				and relevant continuing education were both concepts that were required of all laboratory directors.
1.1.5.2.1 (1.1.4.2.1)	SC	NA	NA	The committee edited standard 1.1.5.2.1 for clarity. The addition of a new second sentence was done in conjunction with changes made to the other standards focused on requirements for directors. This standard now requires that clinical program directors participate in relevant continuing education during each accreditation cycle.
1.2.3	SC	NA	NA	The committee added a cross-reference to standard 6.1.5 which requires that all policies, processes and procedures be reviewed every two years.
1.2.3.6	SC	NA	NA	The committee edited standard 1.2.3.6 by moving the term "warranted" from the beginning of the standard to following "…procedures…" The intent of the standard has not changed.
1.2.5	SC	NA	NA	The committee edited standard 1.2.5 by adding the clause "on an annual basis" to ensure that the quality system is reviewed by executive management annually. This also ensures that the quality system is reviewed at least twice per accreditation cycle.
1.2.5	RtC	We recommend the AABB Standards Committee clarify the requirements for Standard 1.2.5. Does this standard require an additional review if continuous monitoring is occurring? What defines Executive Management?	NO	The committee reviewed this comment and notes that the review in this case would be defined by the facility and validated. If continuous monitoring is occurring that would meet the standard if the executive management in question is involved. Executive management is defined in the glossary as such: *The highest level of personnel within an organization, including employees and independent contractors, who have*

				responsibility and authority for the facility's operation and the authority to establish or change the facility's quality policy and quality system. Executive management may be an individual or a group of individuals (eg, medical director, laboratory director, chief executive officer, quality assurance committee).
1.5 (New), 1.5.1 (New)	SC	NA	NA	Standards 1.5 and 1.5.1 are new to the edition and were added in conjunction with the creation of new standard 1.1.1.1. These requirements were added to ensure that accredited facilities remain in compliance with FDA regulations as it relates to contamination or causing a loss of cell function. Placing risk assessment, in Chapter 1 Organization, ensures it will be considered "a key quality function" as stated in Standard 1.0 These new standards address the need for a facility to perform a comprehensive review of their processing processes and identify areas that might be at risk of introducing contamination or causing loss of cell function, etc.. Then, as with a process validation (Standard 5.0, 5.2.3), corrective action must be devised and implemented to ensure the risk is minimized or eliminated, and addressed in policies, processes, and procedures in order to ensure product integrity. Finally, an assessment to ensure the corrective action has been effective should be performed. All these activities must be documented and approved by the medical and/or laboratory director, and quality director as applicable and ultimately executive management. These standards added together (1.1.1.1, 1.5 and 1.5.1) give facilities a more solid framework for direction in performing a robust consideration of the risk points throughout the activities which

				directly impact the cellular therapy product; and provides standards for assessors to confirm compliance with applicable regulations for HCTPs, those classified as both 351 and 361 products.
1.5 (New)	RtC	We consider this new standard unnecessary and are concerned that compliance to this standard would cause facilities undue burden. Furthermore, we do not see added value with the implementation of this standard as the intended outcome of ensuring product quality and safety should be achieved through compliance with numerous existing standards. For example: • Standard 8.0 requires facilities to "verify that the quality system and operational activities comply with specified requirements." • Standard 1.2.5 requires "executive management review the quality system on an annual scheduled basis." • Standard 8.5 states there should be a "process to collect and evaluate quality indicator data on a scheduled basis, including adverse events." Through compliance to these standards facilities should be identifying and correcting any issues or risks that affect product quality and safety. Furthermore, through proper change management, facilities should be evaluating the risk of all changes to operations and mitigating identified risks prior to implementation. In the event that this standard is finalized and implemented, we kindly request that AABB provide clarification and/or examples on documentation expectations to demonstrate compliance with the standard.	NO	The committee reviewed this comment but did not feel that removing the standard was necessary. The committee notes that this is an internationally accepted requirement (eg. ISO) and is especially important in cellular therapy facilities. The committee has crafted new guidance to assist in the implementation of this standard which can be found in the Standards Portal or associated guidance publication to this 10th edition.
1.5 (New)	RtC	A frequency of risk assessment should be added to this standard.	NO	The committee noted this comment but felt that the frequency for review and assessment should be defined by the facility.
2.1.6.1 (New)	SC	NA	NA	The committee created this standard for completeness. This ensures that competence is evaluated at least annually for certain activities. This ensures the standards are in line with CLIA.
2.1.6.2 (New)	SC	NA	NA	The committee created this standard for completeness. This ensures individuals who perform moderate and high complexity testing will have semi annual reviews of competence.

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				This ensures the standards are in line with CLIA.
2.1.6.2 (New)	RtC	Please provide a definition or further clarification on what constitutes “moderate and high complexity testing.”	YES	The committee reviewed this comment and noted that these requirements are strictly for facilities located in the United States. The terms are defined in the most up to date code of federal regulations.
2.1.6.3 (New)	SC	NA	NA	The committee created this standard for completeness. This ensures that competence of employees is assessed when new or novel processes or procedures are introduced. This ensures the standards are in line with CLIA.
2.2, #4 (New)	SC	NA	NA	The committee created new subnumber 4 requiring that “Laboratory services” are available to medical and specialty services for patient care. The addition was included for completeness.
3.0	SC	NA	NA	The committee added the term “operate” to standard 3.0 for completeness.
3.1 (New)	SC	NA	NA	The committee added new standard 3.1 to cover equipment specifications, and ensure that they are defined before a facility puRtChases a piece of equipment.
3.1 (former, deleted)	SC	NA	NA	The committee deleted former standard 3.1, Elements of Control, as it was determined that standards 3.2 – 3.2.3 already covered these requirements.
3.3 (New)	SC	NA	NA	The committee added new standard 3.3, Use of Equipment, which is a requirement that all other sets of AABB Standards have included and is included her for completeness.
3.5, #1 (New)	SC	NA	NA	The committee added new subnumber 1 to standard 3.5 which requires that equipment be uniquely identified and traceable.
3.6.2 (New)	SC	NA	NA	The committee added new standard 3.6.2 which requires that facilities have a process in place to

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				ensure that facilities minimize the risk of internal or external data breaches. This is a new standard that will be included in most sets of AABB Standards.
4.3.1	SC	NA	NA	The committee edited the opening sentence of the standard for clarity and parallel construction. The sentence now ensures that "agreements" are replaced with "policies and procedures." This change was made for consistency.
4.3.1	RtC	These orders are not required for cord blood banks where the recipient is not known at the time of collection. For directed donation from sibling, the Medical Orders are necessary before procurement and processing. Propose to change to "These orders are not required for cord blood banks ~~where~~ if the recipient is not known at the time of collection."	YES	The committee noted this comment and adjusted the standard to reinclude the clause "…excluding HPC, Cord Blood products…" which had been removed in the proposed version of the Standards.
4.3.1, #4 (Deleted)	RtC	Bullet 4 should be a separate paragraph, otherwise it implies that cord blood banks (where the recipient is not known) still require agreements that address medical orders for procurement and processing. Suggest deleting "These orders…" and replace with "Agreements that reference these orders"	YES	The committee reviewed this comment and agreed with the concept but felt that reincluding the clause regarding cord blood being reincluded in the stem would serve this.
4.3.3, #3 (New)	SC	NA	NA	The committee created new subnumber 3 for completeness. The requirement ensures that facilities have agreements in place to provide necessary documentation concerning mobilization, procurement, and recipient conditioning.
4.3.3, #3 (New)	RtC	We are requesting the following clarification. For cellular therapy products that may be transferred for long term storage to another facility, is it acceptable for the agreement to specify that administration and pre-transplant regimens are not available at the time the agreement was drafted and signed?	NO	The committee noted this comment but did not make the change. The committee notes that the agreement in this case is based on when something will occur, that this information be shared with the individual that an agreement exists with. As with most standards a timing element is not included and should be defined by the facility.
4.3.3, #3 (New)	RtC	How does this relate to cord blood banks? What specifically would be required?	NO	The committee reviewed this comment and feels that there are instances where this could apply to

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		Cord blood banks normally supply the cryopreserved product but are not involved in any realistic aspect of the treatment nor the timeline of transplant regimes.		cord blood products. However the timeline of the sharing of information should occur when that information becomes available, and should be defined in agreements between the facilities.
4.3.3, #3	RtC	We request that the AABB Standards Committee clarify the requirement for the addition of substandard 3. Specifically, what is the regulatory rationale for a procurement/pre transplant regimen?	YES	The committee noted this comment and due to some confusion as mentioned in the comment, that pre transplant and regimen have both been removed from the standard.
4.3.5, #2	SC	NA	NA	The committee added the clause "labeling" to the standard and a cross reference to standard 5.7. The edits were made for clarity and completeness.
4.5	SC	NA	NA	The committee added a crossreference to FDA regulation, 21 CFR part 11, to ensure users knew what types of signatures for consent were appropriate and required.
4.5.2	SC	NA	NA	The committee added the term "…or gestational materials…" along with cord blood to ensure that the standard (and other standards that have made similar additions) can be interpreted more broadly.
4.5.2	RtC	Informed consent shall be obtained before procurement. The word initiated is too vague. This contradicts Reference Standard 4.5A—Donor Informed Consent or Authorization II A. Recommend removing "or initiated". Reference Standard 5.12A – General Requirements for Cellular Therapy Product Donors. II. Donor Education apply.	NO	The committee noted this comment and wanted to ensure that it was understood that initiation applies to cord blood since the process of "collection" prior to procurement. This can be understood as "staged consent."
4.5.2.1 (New)	SC	NA	NA	This committee created this new standard and was included for completeness. It requires that facilities to identify their vulnerable donor populations and to determine who needs access to a donor advocate.
4.5.2.1 (New)	RtC	Does this also apply to autologous donors for private (Family) cord blood and gestational tissue banking? If not, suggest including "donor advocate not required for cord blood banks where the donor from vulnerable donor population is known at the time of collection."	NO	The committee noted this comment but did not feel that a change was needed at this time. Donor advocates can be helpful regardless of the type of donation that is taking place.

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4.5.2.1 (New)	RtC	We recommend the AABB Standards Committee consider adding clarifying language as to who would constitute a vulnerable population.	NO	The committee noted this comment and as a result has created guidance to expand on the concept of what is considered a vulnerable population without limiting the concept of the term.
4.8.1.1	SC	NA	NA	The committee expanded the requirements in the standard for completeness. The committee feels that it is important that samples sent to testing laboratories meet the requirements stated in package inserts.
4.8.1.1	RtC	Not all donor screening/testing kits for infectious diseases screening/testing are FDA-cleared, -approved or –licensed used worldwide by testing laboratories. Similarly, not all kits are approved for donor screening by the Competent Authority. In addition, there is ambiguity in terms of "Sample" definition. In general, the "samples" mentioned in packet insert refers to the processed serum/plasma sample. There is no requirement on the whole blood shipped to the testing laboratory. Suggest to also include "Standard 5.12.2.6 applies" in this standard.	YES	The committee agreed with this comment and added in a crossreference to standard 5.12.2.6 as well as standard 5.12.2.10. With reference to the term "sample" this should be covered in the package insert, and not be constrained by a definition in the glossary that could be outdated very quickly.
4.8.1.1	RtC	This may be an issue, as many tests are technically off-label use, such as BACTEC, or certain reagents depending on the interpretation. Clarification on this addition would be ideal, especially for cord blood banks.	NO	The committee reviewed this comment and wanted to clarify that it is focused relevant communicable disease agents or diseases, and not touch on BACTEC as implied in the comment.
4.5A, G (New)	SC	NA	NA	The committee created new letter G as a requirement to ensure facilities have policies in place to discuss potential conflicts of interest during the donor consent process.
4.5A, G (New)	RtC	In a typical family cod blood banking setting, the "vulnerable donors" are often coeRtCed by attending ObGyns who may have financial benefits by collecting (procuring) cord blood on behalf of the banks. On an ethical point, the cord blood collectors (ObGyns, nurses and midwives) shall disclose conflict of interest with the vulnerable donors.	NO	The committee noted this comment, but did not feel a change was needed. All informed consent policies should ensure that donors aren't pushed into donating if they do not wish to.
4.5A, G (New)	RtC	Does this also apply to autologous donors for private (Family) cord blood and gestational tissue banking? If not, suggest the inclusion "with the exception of autologous donors.".	NO	The committee noted this comment but did not feel a change was needed at this time. This requirement applies to all donors, autologous or allogeneic.

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4.5A, G (New)	RtC	We recommend the AABB Standards Committee consider adding clarifying language as to what constitutes a conflict of interest.	YES	The committee noted this comment and has added new guidance to best explain what would constitute a conflict in the case of the informed consent process.
4.7A, F (New)	SC	NA	NA	The committee created new letter F as a requirement to ensure facilities have policies in place to discuss potential conflicts of interest during the patient consent process.
5.1.2.3	SC/RtC	42CFR 493.1236 does say that the results need to be reviewed however doesn't specify who needs to review. 42CFR493.1445 €(3) and (4) define the director responsibilities. 493.1463(a)(4) defines the role of the general supervisor as being responsible for monitoring test analyses. So, under 42CFR493, the director is not required to review results of proficiency testing this may be performed by someone else who meets the general supervisor qualifications.	YES	The committee reviewed this comment and agreed with the intent. The committee as a result added the clause "or designee" to the conclusion of the standard, in conjunction with the addition of the reference to 42 CFR 493.1236.
5.1.2.3.1	SC	NA	NA	The committee elected to add a reference to 42 CFR 493.803 to the standard for completeness. The committee also added the clause "shall be successful" to the standard to ensure the standard was written in a positive frame, noting that the proficiency testing should be the goal.
5.3	SC	NA	NA	The committee added a crossreference to standard 5.30 for completeness.
5.3.1 (5.3.1, 5.3.2, deleted)	SC	NA	NA	The committee elected to remove standard 5.3.2 and take the content that was different from standard 5.3.1 and added it to the edited standard. The standard now reads as such, "For the procurement and processing facilities, this shall include but is not limited to adverse events and complications attributed to procurement, processing, infusion, and/or engraftment."
5.3.2, #5 (New)	SC	NA	NA	The committee added new number requiring clinical facilities maintain engraftment data as a clinical outcome. This ensures the standard is parallel in construction with standard 5.3.1.

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5.3.3 (5.3.4)	SC	NA	NA	The committee removed the term "procure" from this standard for accuracy.
5.3.4 (5.3.5)	SC	NA	NA	The committee removed the list of elements that constituted clinical outcomes as they were deemed too limiting and not uniform for all facilities that process or administer islets. The elements that previously existed in the standard now resides in guidance.
5.8	SC	NA	NA	The committee, based on feedback from the representative from the state of California and with agreement from the CT Standards Committee's representative from the FDA the Committee added a reference to FDA Guidance concerning accuracy in the labeling of CT products, specifically FDA Guidance, July 21, 2020, "Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use." The reference to the CFR, the Guidance and standard 1.1.2 will ensure that facilities need to have complete labels (not just a broad label stating "stem cell product") detailing what the product is and what level of testing it has undergone.
5.8.4	SC	NA	NA	The committee added the clause, "…or terminology consistent with Eurocode labeling terminology" for completeness.
5.9.1	SC	NA	NA	The committee removed the clause "…to the extent necessary…" as it was deemed not assessable.
5.10.1, #3	SC	NA	NA	The committee replaced the term "Product description code and division code" with "Product description code, type of collection, and division code." The change was made to remain in conformance with ISBT nomenclature.

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5.10.1, #3	RtC	We disagree with the proposed merging of "Product description code and division code" into a single element "product code" throughout the standards. The ISBT 128 product code data structure contains three discrete data elements; the product description code, the type of collection, and the division code. Although contained in one data structure, each of these elements is a discrete piece of information that we believe should be treated separately. The reasons for this are: 1. It is probable that most information systems extract the data elements from the data structure and store them as distinct data items. 2. It is possible for products to be ISBT 128 labeled with different data structures (e.g. if a future CT product were to be regulated as a medical device in the US it would need to meet FDA UDI labeling requirements and would be labeled with data structures 034 and 032. The product description code and division code would still be present, but not represented in a product code data structure.) 3. In the future information may be transferred in electronic messages and will be sent as individual data elements.	NO	The committee noted this comment and adjusted the content of number 3 to ensure accuracy to ISBT nomenclature.
5.10.1, #3	RtC	We disagree with the proposed merging of "Product description code and division code" into a single element "product code" throughout the standards. The ISBT 128 product code data structure contains three discrete data elements; the product description code, the type of collection, and the division code. Although contained in one data structure, each of these elements is a discrete piece of information that we believe should be treated separately. The reasons for this are: 1) It is probable that most information systems extract the data elements from the data structure and store them as distinct data items. 2) It is possible for products to be ISBT 128 labelled with different data structures (e.g. if a future CT product were to be regulated as a medical device in the US it would need to meet FDA UDI labelled requirements and would be labelled with data structures 034 and 032. The product description code and division code would still be present, but not represented in a product code data structure.) 3) In the future information may be transferred in electronic messages and will be sent as individual data elements.	NO	The committee noted this comment and adjusted the content of number 3 to ensure accuracy to ISBT nomenclature.

5.10.2, #2	SC	NA	NA	The committee added the term "processing" to the subnumber for completeness.
5.12.1	SC	NA	NA	The committee replaced the term "donor" with "medical" in terms of suitability. The term "medical suitability" is more accurate and removes any potential stigma associated with a donor being deemed unsuitable. This does not change the requirement contained in this standard and throughout the document and does not allow for individuals who are not medically suitable to donate products that would be given to another human being. The committee also moved the clause in strike through to be a part of the new requirements concerning the medical record that is used as a part of a donor evaluation.
5.12.1	RtC	Suggest revising for clarification, as the subsections that follow are elements of the evaluation that are based on examination, clinical history and medical records. Re-include the clause "based on"	YES	In the proposed edition, the clause "based on" was removed from the standard. Following the review of this comment, the committee re-included it.
5.12.1.6	SC	NA	NA	In line with the change to standard 5.12.1, the committee replaced the term "donor" with "medical" as it relates to suitability.
5.12.2.8	SC	NA	NA	The committee added the requirement that "West Nile Virus" be included as a test that is required to be performed to determine donor eligibility.
5.12.2.10	SC	NA	NA	The committee added the clause "and emerging infectious diseases" to this standard to ensure that facilities have policies, processes and procedures in place to ensure that they take action when a new diseases emerge.
5.12.2.10	RtC	We recommend that more specific guidance is needed in the identification and screening of infectious and emerging diseases (for example, the classification of infectious diseases should be screened in each geographic area, minimum	NO	The committee noted this comment, but did not feel that a change was needed. The committee has expanded the guidance to the standard for clarity.

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		requirements for screening for emerging diseases especially for current pandemic as COVID ...)		
5.12.6.2.1	SC	NA	NA	The committee added the term "…or gestational materials…" along with cord blood to ensure that the standard (and other standards that have made similar additions) can be interpreted more broadly.
5.12.6.4.1	SC	NA	NA	The committee added the term "…or gestational materials…" along with cord blood to ensure that the standard (and other standards that have made similar additions) can be interpreted more broadly.
5.13.5.1	SC	NA	NA	The committee added the term "…or gestational materials…" along with cord blood to ensure that the standard (and other standards that have made similar additions) can be interpreted more broadly.
5.14.1	SC	NA	NA	The committee added the term "…or gestational materials…" along with cord blood to ensure that the standard (and other standards that have made similar additions) can be interpreted more broadly.
5.14.2, 5.14.2.1	SC	NA	NA	In line with the change to standard 5.12.1, the committee replaced the term "donor" with "medical" as it relates to suitability.
5.14.2.1	RtC	Mothers of cord Blood (5.12D) are tested only after the procurement and not before unlike other sources of CT products.	NO	The committee noted this comment but did not make a change to this standard. The committee made a change to reference standard 5.17B to address this query.
5.14.3	SC	NA	NA	The committee replaced the term "the" with "each" recognizing that there are instances where procurement can take place on more than one day.
5.14.3	RtC	Would changes to 5.14.3 affect family cord blood banks? As indirect collection is the method of procurement (i.e. remote sites), would the health questionnaire forms and baby health assessments meet these changes?	NO	The committee noted this comment, but did not feel that a change was needed at this time. The committee feels that the clause, "…other than

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				for cord blood or gestational materials…" would cover this.
5.14.4.1	SC	NA	NA	The committee added the term "…or gestational materials…" along with cord blood to ensure that the standard (and other standards that have made similar additions) can be interpreted more broadly.
5.14.5	SC	NA	NA	The committee elected to merge standards 5.14.5 and 5.14.5.1 as standard 5.14.5 did not fit appropriately for what was being required. A new standard, 5.14.7, will articulate the change.
5.14.5, #2	SC	NA	NA	The committee replaced the term "Product description code and division code" with "Product description code, type of collection, and division code." The change was made to remain in conformance with ISBT nomenclature.
5.14.5, #7	SC	NA	NA	The committee added the clause, "…procured product…" to the standard for completeness.
5.14.6	SC	NA	NA	The committee edited this standard for clarity. The committee felt that the clause "after completion of procurement" (which has been deleted) implied an action had to be taken immediately which is not the case. The committee replaced the phrase, "shall be reviewed" with "is accurate and complete" for clarity.
5.14.7 (New)	SC	NA	NA	The committee created new standard 5.14.7 to create parallel language with standard 5.14.5. This standard, however, focuses on what minimum requirements are needed to be shared from a procurement facility for a product that is in process.
5.14.7 (New)	RtC	We request the AABB Standards Committee clarify its procurement record requirements. Specifically, if the information required of Standard 5.14.7 is included in the product label, is a separate record required.	NO	The committee notes that product labels and records are different. The procurement record

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				does have to have labeling information, as a label is not a record.
5.14.7.1 (New)	SC	NA	NA	The committee created new standard 5.14.7.1 to create parallel language with standard 5.14.5. This standard, however, focuses on what minimum requirements are needed to be shared from a procurement facility for a product that is in process.
5.15, 5.15.1, 5.15.1.1	SC	NA	NA	The committee replaced the term "endpoints" with "goals" as this is realistically what is articulated in procurement facilities. The term "relevant" replaced "appropriate" as this better fit the sentiment and appropriate has been deemed difficult to assess.
5.15.1.1	SC	NA	NA	The committee also removed the phrase, "…for cells, tissues, or organs procured for autologous use or cells designated for a specific patient…" as it was deemed unnecessary and too limiting. The content will be included in the guidance to the standard.
5.16.1.1	SC	NA	NA	The committee added the term "…or gestational materials…" along with cord blood to ensure that the standard (and other standards that have made similar additions) can be interpreted more broadly.
5.16.1.2	SC	NA	NA	The committee added the term "…or gestational materials…" along with cord blood to ensure that the standard (and other standards that have made similar additions) can be interpreted more broadly.
5.17.1	SC	NA	NA	The committee added the term "…or gestational materials…" along with cord blood to ensure that the standard (and other standards that have made similar additions) can be interpreted more broadly.

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5.17.2, #2	SC	NA	NA	The committee replaced the term "Product description code and division code" with "Product description code, type of collection, and division code." The change was made to remain in conformance with ISBT nomenclature.
5.17.5	SC	NA	NA	The committee elected to break the standard up from one paragraph to an opening sentence followed by two subnumbers; one focused on the product processing record and a summary of the product processing record.
5.19	SC	NA	NA	The committee elected to replace the term "known" with "validated" to ensure that the standard is in conformance with FDA requirements.
5.19	RtC	We suggest adding "and potency" to the end of the standard. The standard would read as such, "Cellular therapy products shall be cryopreserved using a controlled-rate freezing procedure or equivalent procedure known validated to maintain acceptable viability **and potency**."	NO	The committee noted this comment but did not feel that including potency in this standard as it was not an accurate representation of what is maintained for products maintained in cryopreservation.
5.19	RtC	Will facilities be required to perform a validation on the CRF if one was not previously on file, but still meet the standards prior to 10th edition? Would historical data be sufficient?	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The committee expects to see documented product validation to show that viability is maintained. It should be noted that a retrospective review would be sufficient to meet the standard.
5.19.3, #2	SC	NA	NA	The committee replaced the term "Product description code and division code" with "Product description code, type of collection, and division code." The change was made to remain in conformance with ISBT nomenclature.
5.24.1, #3	SC	NA	NA	The committee replaced the term "Product description code and division code" with "Product description code, type of collection,

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				and division code." The change was made to remain in conformance with ISBT nomenclature.
5.25.1	SC	NA	NA	The committee added the clause "…and approved by a physician" to the end of the standard as in the clinical setting, a health-care professional can perform the evaluation, however it has to be approved by a physician.
5.25.1	RtC	Does the medical director of a cord blood bank fulfill this requirement?	NO	The committee noted this comment, however did not feel a change would be needed as this standard is focused on clinical programs and would not apply to cord blood banks.
5.26.1.2	SC	NA	NA	The committee added the clause "…the dose." to the standard for completeness.
5.26.1.2	RtC	We request that the AABB Standards Committee provide clarification as to dose specificity. Does the standard require an exact dosage value, e.g. *50 ml* or is it acceptable to provide a dose range, e.g. *up to 8 Mg per kg*?	NO	The committee noted this comment but did not feel that a change was needed as this requirement would be defined by the facility.
5.28.1	SC	NA	NA	The committee edited this standard to remove the clause, "…patient care service administering the final cellular therapy product…: and replaced it with "clinical facility" for clarity. The committee notes that the administration of products does not appear until standard 5.29.
5.28.2	SC	NA	NA	The committee edited standard 5.28.2 to parallel standard 5.28.1, similar to changes previously noted. The term "clinical facility" replaced "administering service" understanding that this standard appears in the clinical section and they would be the facility performing the administration.
5.29	SC	NA	NA	The committee replaced the term "clinical facility" with "patient care service" for completeness and parallel construction throughout the Standards.
5.29.1	SC	NA	NA	The committee edited standard 5.29.1 to reformat the standard for consistency with

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				AABB Standards setting norms. The intent of the standard has not changed.
5.29.2 (5.29.2, 5.29.3 merged)	SC	NA	NA	The committee elected to merge standards 5.29.2 and 5.29.3 as the inclusion of both was redundant.
5.29.2, #1 (5.29.3, #1)	SC	NA	NA	Entry number 1 has been edited for clarity replacing the terms “due to” with “resulting from” and replacing “infusion” with “administration.”
5.29.2 #9 (New)	SC	NA	NA	The committee created new subnumber 9 is new to the edition and was added to ensure that the complications of immune effector cellular therapy were covered by the standard. This new entry supplements the requirements in line with subnumbers 2 and 3.
5.29.3 (5.29.4)	SC	NA	NA	The committee replaced the term “patient care service” with “clinical facility” to ensure consistency of language throughout the edition.
5.29.4, #3 (5.29.5, #3)	SC	NA	NA	The committee replaced the term “Product description code and division code” with “Product description code, type of collection, and division code.” The change was made to remain in conformance with ISBT nomenclature.
5.29.4, #11 (5.29.5, #11)	SC	NA	NA	The committee edited this entry to the standard by removing the term “appropriate” from the standard as that term is not assessable.
5.29.5, #3 (5.29.6, #3)	SC	NA	NA	The committee replaced the term “Product description code and division code” with “Product description code, type of collection, and division code.” The change was made to remain in conformance with ISBT nomenclature.

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5.30.1 (New)	SC	NA	NA	The committee created this standard to ensure that clinical facility's that are required to provide data to a registry (e.g. CIBMTR) do so in a manner that is consistent and appropriate.
5.8.2A, #4	SC	NA	NA	The committee replaced the term "Product description code" as it appeared in the previous edition with "Product description code, collection type, and division code." The change was made to remain in conformance with ISBT nomenclature.
5.8.2A, #25	SC	NA	NA	The committee created new entry #25 for consistency with current requirements set forth by the Food and Drug Administration. This language is consistent with what currently exists in the Standards for Blood Banks and Transfusion Services.
5.8.2A, footnote 6 (New)	SC	NA	NA	The committee created a new footnote that ensures that in times where the size of the label being permanently attached at the time of distribution and issue cannot accommodate all the information required, the accompanying label will and be referred to.
5.9.5A, #4	SC	NA	NA	The committee edited entry number four to include, "…certificate of analysis, manufacturer's insert, investigator's brochure, or equivalent." for clarity and accuracy.
5.12A, II, A	SC	NA	NA	The committee elected to remove the clause "…he or she has…" in this section as well as through the reference standards to replace the clause with "they have" to ensure the standard remained gender neutral.
5.12A, II, A	RtC	Suggest deleting addition of "or viewed" as content can be read online.	YES	The committee reviewed this comment and agreed with the suggestion to remove "…or viewed…" that had been included in the proposed edition.

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5.12A, II, B, 3	SC	NA	NA	The committee elected to edit the entry on educational materials for marrow donors to mirror the language and structure that appears for apheresis donors in number 4. The entry now reads as follows: a) Information about the marrow donation procedure. b) Risks and discomforts of marrow donation. c) General risks and discomforts of anesthesia.
5.12A, II, B, 4	SC	NA	NA	The committee elected to re-write the content of subletters a and d of the section on educational materials for apheresis donors to mirror the language and structure of the entries in number 3. The entries now read as follows: a) Information about the apheresis procedure. d) Risks and discomforts of growth factor and/or other pharmacologic agent(s), where applicable.
5.12A, III, A, 1	SC	NA	NA	The committee edited the title of this section and the content of entry #1 to remain consistent with the change to standard 5.12.1. As such, the committee replaced the term “donor” with “medical” as it relates to suitability.
5.12A, III, A, 2	SC	NA	NA	The committee edited this entry to ensure that allogeneic donors do not have their ability to donate performed by a physician who is involved with the care of the recipient. For autologous donors, this would not apply. The entry now reads as such: Medical suitability shall be determined by a physician who, in the case of allogeneic donors, cannot be directly involved with the care of the recipient. The entry was also edited to remain consistent with the change to standard 5.12.1. As such, the committee replaced the term “donor” with “medical” as it relates to suitability.

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5.12A, III, A, 2, a)	RtC	For Cord Blood donors the medical suitability shall be determined by the Medical Director of the cord blood bank who shall be experienced in such activities. Recommend replacing the above to "shall be determined by Laboratory Medical Director"	NO	The committee noted this comment however they did not feel that a change would be appropriate. Concerning cord blood, a healthcare professional a more accurate representation of who performs the donor suitability of a donor.
5.12A, III, A, 3	SC	NA	NA	The entry was also edited to remain consistent with the change to standard 5.12.1. As such, the committee replaced the term "donor" with "medical" as it relates to suitability.
5.12A, III, A, 4	SC	NA	NA	The entry was also edited to remain consistent with the change to standard 5.12.1. As such, the committee replaced the term "donor" with "medical" as it relates to suitability.
5.12A, III, A, 5	SC	NA	NA	The entry was also edited to remain consistent with the change to standard 5.12.1. As such, the committee replaced the term "donor" with "medical" as it relates to suitability. The clause, "…and the beginning of mobilization" was added to the standard for completeness.
5.12A, III, A, 8	SC	NA	NA	The committee elected to edit entry #8 for clarity. The committee added the term "applicable" to the stem sentence to ensure that the appropriate facility was being assessed in this case. Also, in subletter "b" the committee added the clause "of clinically significant findings" to "donor notification." Finally, the committee edited subletter c for clarity as it was deemed, too wordy. The entry now reads as such: c) Identification and disposition of collected products.
5.12A, III, B, 2	SC	NA	NA	The committee edited number 2 to mirror a change made to standard 5.25.1, allowing for a health assessment to be performed by a health-care professional but approved by a physician.

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5.12B, III	SC	NA	NA	The committee edited the title of section III to read, "Laboratory testing for Allogeneic Donors" removing the clause "required for." The header we edited for clarity.
5.12B, III, West Nile Virus	SC	NA	NA	The committee edited the entry for West Nile Virus moving it from not required as a test for allogeneic donors to a required one based on the current FDA Guidance.
5.12B, III, West Nile Virus	RtC	We acknowledge that WNV is endemic in United States and testing is required as it is considered a relevant communicable disease by the FDA 21 CRF 1271.80(d)(1). However, WNV is not endemic to certain regions in the world e.g. South East Asia, South Asia and North Asia. We suggest to include a separate standard stating: "For facilities not subjected to United States laws and regulations, testing of WNV RNA shall meet testing requirements for allogeneic donors of cellular therapy products in that country as required by a Competent Authority."	NO	The committee noted this comment but did not feel that a change was needed. The committee requests that individuals who operate in a facility where west nile virus is not prevalent, then facilities can apply for a variance. As a part of the variance, the committee would request that facilities perform donor screening to ensure no potential donors have been exposed to west nile virus in their travels.
5.12D, III, West Nile Virus	SC	NA	NA	The committee edited the entry for West Nile Virus moving it from not required as a test for allogeneic donors to a required one based on the current FDA Guidance.
5.12D, III, West Nile Virus	RtC	We acknowledge that WNV is endemic in United States and testing is required as it is considered a relevant communicable disease by the FDA 21 CRF 1271.80(d)(1). However, WNV is not endemic to certain regions in the world e.g. South East Asia, South Asia and North Asia. We suggest to include a separate standard stating: "For facilities not subjected to United States laws and regulations, testing of WNV RNA shall meet testing requirements of Mothers of Cord Blood or Gestational Material Donors in that country as required by a Competent Authority."	NO	The committee noted this comment but did not feel that a change was needed. The committee requests that individuals who operate in a facility where west nile virus is not prevalent, then facilities can apply for a variance. As a part of the variance, the committee would request that facilities perform donor screening to ensure no potential donors have been exposed to west nile virus in their travels.
5.12D, III, West Nile Virus	RtC	We suggest a review of the mandatory WNV test for mother of cord blood, because of: - In some countries including Vietnam, this disease has not been detected despite the warning of the Ministry of Health as dangerous.	NO	The committee noted this comment but did not feel that a change was needed. The committee requests that individuals who operate in a facility where west nile virus is not prevalent, then facilities can apply for a variance. As a part of the variance, the committee would

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		- The test KIT seems to be not specific and gives positive false results in area of Dengue pandemic.		request that facilities perform donor screening to ensure no potential donors have been exposed to west nile virus in their travels.
5.12E, History of Behavioral Risk	SC	NA	NA	The committee elected to remove the requirement to screen for a history of rabies for Cadaveric Donors as it is not required by the FDA for HCT/Ps, nor is it exactly relevant to the products and practices covered by this set of Standards.
5.17A	SC	NA	NA	The committee elected to separate the reference standards into three distinct tables, focused on HPC, Apheresis and HPC, Marrow (in 5.17A) traditional HPCs, Cord Blood (in 5.17B) and then all other products in (5.17C). Many of the elements that have been removed from 5.17A now exist in newly created 5.17C.
5.17A, 1	SC	NA	NA	The committee removed the elements in strikethrough have been moved to new reference standard 5.17C. See below: 1) Cell count and viability specific to the cellular therapy product. This includes: a) ~~For HPC, Marrow, the t~~otal nucleated cell count. b) ~~For HPC, Apheresis,~~ CD34+ cell count. ~~c) For T Cell, CD3+ cell count.~~ ~~d) For islets, islet equivalents (IEQ).~~ ~~e) For other cellular therapy products, the relevant cell count shall be defined by the facility.~~

5.17A, 2	SC	NA	NA	The committee removed the elements in strikethrough have been moved to new reference standard 5.17C. The element removed is below: ~~2. Antigen expression analysis specific to the cellular therapy product, if applicable.~~
5.17A, 2 (5.17A, 3)	SC	NA	NA	The committee added the clause "as determined by the appropriate medical director" to subletter "b" understanding that the standards contain different directors for each discipline and that they alone determine when a notification is released. Subletter c is new to the edition and was added to parallel "b" which focused only on the donor. The entries read as such: b) If results affect the donor's health, as determined by the appropriate medical director, notify the donor's physician. c) If the results affect the therapeutic value of the product or the recipient's health, as determined by the appropriate medical director, notify the recipient's physician of positive culture results.
5.17A, #3 (5.17A, #5)	SC	NA	NA	The committee edited number 3 for clarity as the clause in strikethrough would not apply to the newly revised products covered in reference standard 5.17A; the clause would apply only to products now in reference standard 5.17C. The entry now reads as such: 3) ~~If the final product contains red cells, after receipt or before administration,~~ ABO group and Rh typing shall be performed on a cellular therapy product or donor sample obtained at the

				time of procurement and compared to previous records.
5.17A, 4 (moved)	SC	NA	NA	The committee removed the elements in strikethrough have been moved to new reference standard 5.17C. The element removed is below: ~~4. Potency assay specific to the cellular therapy product. This includes:~~ ~~a) A test for viability.~~ ~~b) For HPCs, CD34 analysis or comparable assay (except for marrow).~~ ~~c) For other cellular therapy products, the relevant potency assay shall be defined by the facility.~~
5.17A, #6 (Moved)	SC	NA	NA	The committee removed the elements in strikethrough have been moved to new reference standard 5.17C. The element removed is below: ~~6) Testing of cultured cells shall include endotoxin and mycoplasma testing, unless not required under an investigational new drug or license application or as approved by the Competent Authority.~~
5.17B, 1	SC	NA	NA	The committee elected to remove the requirement that "results be reported withing 7 days of…" as it was deemed redundant to the content of standard 5.12.2.2.
5.17B, 3, b	SC	NA	NA	The committee edited subletter "b" to read, "Total nucleated cell and/or CD45 viability" adding "total nucleated cell and/or CD 45" for completeness and accuracy.
5.17B, 3, b	RtC	Suggest revising to 'total nucleated cell' for clarity.	YES	The committee agreed with this comment and added the clause to the requirement that when submitted as proposed did not include this clause.
5.17B, 3, c	SC	NA	NA	The committee replaced the term "assay" with "enumeration." This change was made for clarity.

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5.17B, 4	SC	NA	NA	The committee added the sentence, "For products cryopreserved for possible future use, speciation and antibiotic drug sensitivities shall be performed." for completeness. It should be noted that AABB accredited institutions are performing this activity.
5.17B, 4	RtC	We are requesting clarification regarding the intent of the language added to the proposed standards. Specifically, for products that are going to be cryopreserved, must speciation and sensitivities be performed on a sample prior to cryopreservation or would a post-thaw sample be an acceptable specimen?	NO	The committee noted this comment but did not feel that a change was needed at this time. The committee will delve further in guidance for potential requirements with regard to private vs public cord blood banks.
5.17B, 4	RtC	We recommend that the standard clearly describes which samples are subject to this test. For example: Currently our bank does not have a policy of storing cord blood stem cell samples contaminated with microorganisms, is antibiotic sensitivity testing required?	NO	The committee noted this comment but did not feel that a change was needed at this time. The committee notes that if a facility does not store any product and there is no cryopreservation taking place, the requirement would not apply.
5.17B, 4	SC	NA	NA	The committee edited the elements in the first sentence of this requirement to ensure parallel construction of the sentence that appears below it. The first sentence is focused on the donor, while the second sentence is focused on the recipient of the product. This change, to reference both donors has been made throughout the Standards where appropriate. Both sentences were separated from the paragraph structure and made to appear as bullets for clarity. The standard reads as follows: a) The mother's physician or; if a physician is not identified, notify the mother. b) The recipient's physician. If the results affect the therapeutic value of the product or the recipient's health, as determined by the appropriate medical director, notify the recipient's physician of the positive culture results.

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5.17B, 4	RtC	We are requesting clarification regarding this proposed standard. The product is sampled after processing, but the final sterility assessment of a cellular therapy product can take more than four weeks given the nature of specimen culture and requirements for speciation and sensitivity. The temporal displacement in the time between specimen procurement and result reporting is distant enough, such that the likelihood of detrimental donor health effects due to a positive culture will likely already have been realized by the donor's healthcare provider. Therefore, as a cellular therapy bank, should the result notification be focused on donor suitability?	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The focus of the requirement is donor health, and any information that can affect the donor's health should be shared regardless of timeframe following donation.
5.17B, 4	RtC	Need clarification, as all HPC is being frozen for potential future use in public and family banks. Which antibiotic sensitivities are required?	NO	The committee reviewed this comment, but did not feel that this change was appropriate at this time. This standard would apply to all banks, both public and private and would be facility defined.
5.17B, 5, b	SC	NA	NA	The committee added the clause, "If used for hematopoietic reconstitution…" as there are instances where hemoglobinopathy testing is not performed in the case where a donor is deemed healthy and not immune-compromised.
5.17B, 5, b	RtC	We request a review of the required testing of the CB products. In particular the requirement to test all CB (or donor) intended for allogeneic use for abnormal hemoglobinopathies. In the case of an infusion of an otherwise healthy patient, not immuno-compromised, not intended to engraft, a hemoglobinopathy in the donor CB would not have a significant impact on the recipient. Please consider specifying that the requirement for testing for hemoglobinopathies be only for allogeneic CB used for hematopoietic reconstitution.	YES	The committee agreed with this comment and added the clause, "If used for hematopoietic reconstitution…"
5.17B, 5, c	SC	NA	NA	The committee elected to edit the standard for clarity by removing the clause "Colony forming unit and/or" for clarity. The committee noted that Viable CD34 assay is the most common test performed and most accurate, and therefore the committee felt that it would be appropriate to focus the standard thusly.
5.17B, 5, c	RtC	Viability of CD34+ may be deceiving from an attached segment as the in most cases the post thaw apoptotic markers are not used to eliminate the dying cells. On the other hand, there are many papers published to use CFU Assay as a gold	NO	The committee reviewed the comment and did not feel that a change was needed at this time. The change made to the standard by removing

		standard to predict the engraftment potential of the cord blood products used for hematopoietic reconstitution. Not sure why AABB has taken this unjustified step to downgrade they quality of their standards. References Page K.M. Zhang L. Mendizabal A. Wease S. Carter S. Gentry T. et al. Total colony-forming units are a strong, independent predictor of neutrophil and platelet engraftment after unrelated umbilical cord blood transplantation: a single-center analysis of 435 cord blood transplants. Biol Blood Marrow Transplant. 2011; 17: 1362-1374 Radke TF, Barbosa D, Duggleby RtC, Saccardi R, Querol S, Kögler G. The Assessment of Parameters Affecting the Quality of Cord Blood by the Appliance of the Annexin V Staining Method and Correlation with CFU Assays. Stem Cells Int. 2013;2013:823912. Sergio Querol (2012) Cord blood banking: current status, Hematology, 17:sup1, s185-s188,		the clause "colony forming unit and/or" should address this comment.
5.17B, 5, c	SC	NA	NA	The committee added the term "assay" and "post cryopreservation" for accuracy and completeness. This will ensure the standards are in line with current practice.
5.17B, 5, d (New)	SC	NA	NA	The committee added new subletter 5 which reads, "other tests as required by the applicable registry" in conjunction with new standard 5.30.1. This should ensure that facilities participating in a registry will remain parallel.
5.17B, 5, d (New)	RtC	This requirement should include as required by "the Transplant centers" or registry.	NO	The committee noted this comment but did not feel that a change was needed at this time but would consider the addition in a future edition.
5.17C (New)	SC	NA	NA	The committee added this reference standard to the edition and was added to focus on "other products" outside of the traditional HPCs the Standards cover. This format was used previously in the 6th edition and as the CT Standards continue to expand their scope the return of this reference standard made sense. Note, that many of the elements included in 5.17C previously appeared as a part of 5.17A.

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5.17C, 1 (New)	SC	NA	NA	The committee created number 1 which was built off of the same requirement in reference standard 5.17B and expanded upon to match the content of the title.
5.17C, 2 (New)	SC	NA	NA	The committee added number 2 which previously appeared as number 1 in reference standard 5.17A, and the content has not changed.
5.17C, 3 (New)	SC	NA	NA	The committee added number 3 which previously appeared as number 2 in reference standard 5.17A, and the content has not changed.
5.17C, 4 (New)	SC	NA	NA	The committee added number 4 which previously appeared as number 2 in reference standard 5.17A, and the content has not changed.
5.17C, 5, a	SC	NA	NA	The committee added number 5, letter a, which previously appeared as number 4c in reference standard 5.17A, and the content has not changed.
5.17C, 6	SC	NA	NA	The committee added number 6, as number 5 in reference standard 5.17A, and the content has not changed.
5.17C, 7	SC	NA	NA	The committee added number 7, as number 4 in reference standard 5.17A, and the content has not changed.
6.2.11, #3 (New)	SC	NA	NA	The committee added new subnumber 3, "permit ready identification" for completeness.
6.2.11, #4 (6.2.11, #3)	SC	NA	NA	The committee expanded new subnumber 4 adding the clause, "…in a defined timeframe." to ensure that facilities had validated retrieval times for records.
6.3.2	SC	NA	NA	The committee added a reference to an FDA Guidance, " FDA Guidance for Industry, December 2018, "Data Integrity and Compliance with Drug cGMP Questions and Answers." For completeness.
6.3.2.1 (New)	SC	NA	NA	The committee created this new standard and was added to ensure there was understanding that some media are no longer supported, but

				that records do still exist in this fashion and that facilities need to have the ability to access and read them.
6.3.4.1	SC	NA	NA	The committee added the term "secured" to the standard for completeness.
7.0	SC	NA	NA	The committee added the term "monitor" to the standard for completeness.
7.1.3, 7.1.3.1	SC	NA	NA	The committee split standard 7.1.3 into two separate standards, creating 7.1.3 and 7.1.3.1. The committee felt that splitting the standard would be more appropriate for clarity.
7.1.3.1	RtC	We recommend this standard include the Quality department's approval as well.	NO	The committee noted this comment and found that it would be more appropriate to have this review conducted by the individuals noted in the standard.
7.3.1	SC	NA	NA	The committee added the term "monitor" to the standard for completeness. The committee also added the term "report", which is contained in the standards but moved so that they would appear in line with proper workflow.
7.3.1	RtC	Probably no changes is required to the proposed standard and it should be fine as written. However, some clarification of intent or guidance would be helpful. It is not clear whether the target of the reporting is to a registry, a transplant center, or an agency (via AE report or via annual IND report). Some guidance may be helpful on whether the facility process should document what/who/how the reporting is to be conducted and/or whether it is sufficient to capture this in an agreement with the collection facility.	NO	The committee noted this comment but did not think a change was needed at this time. The committee points to standard 7.4 which covers this concept more broadly. The guidance to the standard has been updated with this comment in mind.
7.3.2	SC	NA	NA	The committee added the term "monitor" to the standard for completeness. The committee also added the term "report", which is contained in the standards but moved so that they would appear in line with proper workflow.
8.2	SC	NA	NA	The committee added the clause, "applicable to the activities performed in the facility" as well as a cross reference to standard 1.0 for clarity and completeness.

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8.5 (New)	SC	NA	NA	The committee added new standard 8.5 to this edition for completeness. This standard exists in all other sets of Standards that AABB provides accreditation for. The committee also included the definition of "Quality Indicator Data" to the Glossary that reads as follows: **Quality Indicator Data:** Information that may be collected and used to determine whether an organization is meeting its quality objectives as defined by top management in its quality policy. Indicators are measured by data for movement or regression with regard to those quality intentions. The data used for monitoring a quality indicator may consist of single-souRtCe data or multiple-souRtCe data, as long as it is clear how the data will come together to define the indicator.
9.1, #4	SC	NA	NA	The committee edited subnumber 4 to include the clause "…reviewed and found to be" for clarity and completeness.
10.0	SC	NA	NA	The committee added a cross reference to standard 2.1.4 to ensure that all employees are trained on the elements covered in standard 10.0.
Glossary – Active Labor	SC	NA	NA	The committee added this term to the glossary for completeness. The definition is included below: **Active Labor:** A period characterized by regular painful uterine contractions, a substantial degree of cervical effacement and more rapid cervical dilatation from 5 cm until full dilatation for first and subsequent labors**.**

Glossary – Completion of Processing	SC	NA	NA	The committee added this term to the glossary for completeness. The definition is included below: **Completion of Processing:** The point in processing at which no further actions are required to be taken in connection with a cellular therapy product before it is placed into storage.
Glossary - Distribution	SC	NA	NA	The committee edited the definition of Distribution, to replace the term "transferring" with "releasing" as the definition was causing confusion with the term "transfer." The definition now reads as follows: **Distribution:** The act of releasing a cellular therapy product or an authorized nonconforming product meet applicable requirements.
Glossary – Gestational Materials	SC	NA	NA	The committee added this term to the glossary for completeness. The definition is included below: **Gestational Materials:** Any tissue procured at or near the time of birth; eg, umbilical cord tissue, placental tissue, amniotic fluid.
Glossary – Label (Accompanying)	SC	NA	NA	The committee added this term to the glossary for completeness. The definition is included below: **Label (Accompanying):** Product information is available with the product, or is available electronically.
Glossary – Label (Affixed)	SC	NA	NA	The committee added this term to the glossary for completeness. The definition is included below: **Label (Affixed):** A label that is in physical contact with the container.
Glossary – Label (Attached)	SC	NA	NA	The committee added this term to the glossary for completeness. The definition is included below:

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				Label (Attached): A label that is securely fastened to the product container by means of a tie-tag or alternative method.
Glossary – Procurement Endpoint (Deleted)	SC	NA	NA	The committee deleted the term "Procurement Endpoint" from the Glossary as the term was deleted from the Standards previously.