Significant Changes and Response to Comments Received to the 12th edition of Standards for Cellular Therapy Services

Please note that public comments that were submitted address the proposed 12th edition of *Standards for Cellular Therapy Services* (*CT Standards*), and not the final version. The Cellular Therapies Standards Committee has elected to make the substance of public comments that were submitted a part of this document. Guidance that appears with the 12th edition of *CT Standards* in the Standards Portal provides a more in-depth look at the additions, deletions and changes and the rationales behind those decisions that appear below.

Standard	Significant Change (SC)/Response to Comment (RtC)	Comment	Change made?	Outcome
1.1	RtC	For clarity, the sentence implies that cGMP applies if and when local laws and regulations require it. For example, local laws and regulations require cGMP for cord blood processing. Is this correct?	No	The committee reviewed this comment but did not think that a change was appropriate at this time. To the question, the committee noted that "yes" the assumption of the comment is correct.
1.1, #3 (1.1)	SC	NA	NA	The committee revised standard 1.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **1.1 Executive Management** The organization shall have a defined executive management. Executive management shall have: 3) Authority to establish or make changes to the quality system.
1.1.3	SC	NA	NA	The committee updated standard 1.1.3 for clarity. The committee removed the clauses "shall be a member of executive management" and "(if performed by another facility) and procurement of the product" as they were viewed more in the vein of guidance and less what constitutes a standard. The element of "medical suitability" was included for completeness. The standard now reads as follows: **1.1.3 Procurement Facilities**

				The procurement facility shall have a medical director who is ultimately responsible for ensuring that the determination of donor eligibility and medical suitability was performed, when applicable.
1.1.3	RtC	I am do not feel that the term "ultimately" provides value to the standard. Why not just "who is responsible"? Do we assess "ultimately" differently or is there an expectation that accredited facilities mirror this language?	No	The committee noted this comment but did not feel that a change was appropriate at this time. The term "ultimately" implies a level of oversight and responsibility that ends with the individual in this role.
1.1.3.1	SC	NA	NA	The committee updated standard 1.1.3.1 by including the clause "shall be a part of executive management" as the committee felt it fit better in the standard focused on the actual procurement medical director, and not the facility itself. The committee also added the clause "…the scope of accredited…" and "…under these CT Standards." to ensure that the individual in this role has responsibilities focused around the content of the CT Standards. The standard reads as follows: **1.1.3.1 Procurement Medical Director** The procurement medical director shall be a member of executive management and shall be a licensed physician with relevant experience, and qualified by training. The procurement medical director shall participate in continuing education relevant to the activities performed by the facility as required by these *CT Standards*. The procurement medical director shall have responsibility and authority for the scope of accredited medical activities related to the procurement of cellular therapy products and services under these *CT Standards*. When the medical director delegates these responsibilities to another qualified medical professional

				(designee), the medical director shall retain ultimate responsibility.
1.1.3.1.1	SC	NA	NA	The committee created new standard 1.1.3.1.1, however the content previously appeared as a part of standard 1.1.3.1.2 and the intent has not changed.
1.1.3.1.2 (1.1.3.1.1)	SC	NA	NA	The committee edited this standard for clarity. The committee added the clause "active oversight" to the standard as well as "related to the scope of responsibilities" to ensure that the individual in this role is an active participant in the role. The addition concerning scope was added to ensure that the oversight performed relates to their job functions. The standard reads as follows: **1.1.3.1.2** The procurement medical director shall have had active oversight of a minimum of 10 cell product procurement procedures related to their scope of responsibilities throughout the preceding 2-year accreditation cycle. Standard 2.1.2 applies.
1.1.3.1.2 (1.1.3.1.1)	RtC	Recommend removing the highlighted "or", as it implies one or the other requirement must be met, which is contrary to the committee's intent per the change comments (i.e., The committee edited standard 1.1.3.1.2 to be stricter concerning the expectations of a procurement medical director. This ensures that the procurement medical director is an active participant in this role.)	No	The committee reviewed this comment but did not feel that a change was needed at this time. The committee felt that the term inclusion was important for an understanding of the intent of the standard.
1.1.3.1.2 (1.1.3.1.1)	RtC	The term "actively" appears in these standards. Suggest that the term "actively" be defined for clarity.	No	The committee reviewed this comment but did not feel that a change was needed at this time. The committee feels that the standard as written ensures that the intent is understood.
1.1.4	SC	NA	NA	The committee elected to update standard 1.1.4 for clarity. The committee added the clause "processing facility shall have a laboratory" to ensure that the focus of the standard was clear in terms of the medical director. The standard reads as follows: **1.1.4 Processing Facilities**

				The processing facility shall have a laboratory medical director and a laboratory director who will be responsible for the processing, storage, and/or provision of the product under their responsibilities.
1.1.4	RtC	I am do not feel that the term "ultimately" provides value to the standard. Why not just "who is responsible"? Do we assess "ultimately" differently or is there an expectation that accredited facilities mirror this language?	Yes	Based on the edits made to this standard, the committee removed the term "ultimately" in standard 1.1.4, recognizing that its inclusion would be difficult to assess when two different individuals serve in the role of medical director.
1.1.4.1	SC	NA	NA	The committee updated standard 1.1.4.1 by including the clause "shall be a part of executive management" as the committee felt it fit better in the standard focused on the actual procurement medical director, and not the facility itself. The committee also added the clause "…the scope of accredited…" and "…under these CT Standards." to ensure that the individual in this role has responsibilities focused around the content of the CT Standards. The standard reads as follows: **1.1.4.1 Laboratory Medical Director** The laboratory medical director(s) shall be a member of executive management and shall be a licensed physician with relevant experience, and qualified by training. The processing laboratory medical director shall participate in continuing education in activities performed by the facility as required by these CT Standards. The laboratory medical director(s) shall have responsibility and authority for the scope of accredited medical activities related to the processing and provision of cellular therapy products and services under these CT Standards. When the medical director delegates these responsibilities to another qualified medical professional (designee), the medical director shall retain ultimate responsibility.*

1.1.4.1	RtC	I suggest revising the standard as such: The laboratory medical director(s) shall be a member of executive management and shall be a licensed physician with relevant experience and qualified by training. The processing laboratory medical director shall participate in continuing education in activities performed by the facility as required by these CT Standards. The laboratory medical director(s) shall have responsibility and authority for **donor recruitment, donor eligibility,** medical activities related to the processing, **testing** and provision of cellular therapy products, **clinical outcome** and related services. When the medical director delegates these responsibilities to another qualified medical professional (designee), the medical director shall retain ultimate responsibility.	No	The committee reviewed this comment but did not feel that a change was needed at this time. The inclusion of the clause "scope of accredited" allows facilities to get to a level of detail that is requested by the commenter. The committee felt that the inclusion of terms requested by the commentator would be overly specific.
1.1.4.1.1	SC	NA	NA	The committee created new standard 1.1.4.1.1, however the content previously appeared as a part of standard 1.1.4.1.2 and the intent has not changed.
1.1.4.1.2 (1.1.4.1.1)	SC	NA	NA	The committee edited this standard for clarity. The committee added the clause "active oversight" to the standard as well as "related to the scope of responsibilities" to ensure that the individual in this role is an active participant in the role. The addition concerning scope was added to ensure that the oversight performed relates to their job functions. The standard reads as follows: **1.1.4.1.2** The laboratory medical director shall have had active oversight of a minimum of 10 cell product processing procedures related to their scope of responsibilities throughout the preceding 2-year accreditation cycle. Standard 2.1.2 applies.
1.1.4.1.2 (1.1.4.1.1)	RtC	Please clarify what "actively" means in this standard. As written, the intent and expectations are vague. We suggest listing how establishments can demonstrate adherence to this standard, for example, by specifying that documented review of any of the following, agreements, SOPs, donor eligibility, or training program apply, or similar description.	No	The committee reviewed this comment but did not feel that this change would be appropriate. The term "actively" implies that an action is needed to be taken. The guidance to this standard provides examples of what active oversight would require.

1.1.4.2	SC	NA	NA	The committee updated standard 1.1.4.2 by including the clause "shall be a part of executive management" as the committee felt it fit better in the standard focused on the actual procurement medical director, and not the facility itself. The committee also added the clause "…the scope of accredited…" and "…under these CT Standards." to ensure that the individual in this role has responsibilities focused around the content of the CT Standards. The standard reads as follows: **1.1.4.2 Laboratory Director** The laboratory director shall be a member of executive management and have a relevant doctoral degree, with relevant experience, and who is qualified by training. The laboratory director shall participate in continuing education for the specific cellular therapy products being produced. The laboratory director shall be responsible for all technical aspects of the facility that are related to the processing and provision of cellular therapy products and services under these CT Standards. When the laboratory director delegates these responsibilities to a designee, the laboratory director shall retain ultimate responsibility.†
1.1.4.2.1	SC	NA	NA	The committee created new standard 1.1.4.2.1, however the content previously appeared as a part of standard 1.1.4.2.2. The standard reads as follows: **1.1.4.2.1** The laboratory director shall have at least 1 year of experience in the scope of processing activities performed by the facility.*
1.1.4.2.2 (1.1.4.2.1)	SC	NA	NA	The committee edited this standard for clarity. The committee added the clause "active oversight" to the standard as well as "related to the scope of responsibilities" to ensure that the individual in this role is an active participant in

				the role. The addition concerning scope was added to ensure that the oversight performed relates to their job functions. The standard reads as follows: **1.1.4.2.2** The laboratory director shall have actively managed a minimum of 10 cell product processing procedures throughout the preceding 2-year accreditation cycle**.**
1.1.4.2.2 (1.1.4.2.1)	RtC	Please clarify what "actively" means in this standard. As written, the intent and expectations are vague. We suggest listing how establishments can demonstrate adherence to this standard, for example, by specifying that documented review of any of the following, agreements, SOPs, donor eligibility, or training program apply, or similar description. Additionally, please clarify whether this is meant to be an "or" statement; Standard 1.1.3.1.2 is written as "and" statement.	No	The committee reviewed this comment but did not feel that this change would be appropriate. The term "actively" implies that an action is needed to be taken. The guidance to this standard provides examples of what active oversight would require.
1.1.5.1	SC	NA	NA	The committee edited standard 1.1.5.1 for clarity. The committee added the clause "have a program director" and removed the clause, "shall be a member of executive management." This change mirrors similar edits to this chapter.
1.1.5.2	SC	NA	NA	The committee edited standard 1.1.5.2 for clarity. The committee added the clause "shall be a member of executive management" which previously appeared in standard 1.1.5.1.
1.1.5.2.2 (1.1.5.2.1)	SC	NA	NA	Standard 1.1.5.2.2 is new to this edition, however the content previously appeared as a part of standard 1.1.5.2.1. The intent of the standard has not changed.
1.2	SC	NA	NA	The committee revised standard 1.2 based on updates to the AABB Quality System Essentials. The standard reads as follows: **1.2 Quality System** The organization shall have a quality system. The organization's executive management shall ensure that this quality system is implemented and followed at all levels of the organization.

1.2.1 (1.2.4)	SC	NA	NA	The committee revised standard 1.2.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **1.2.1 Quality Representative** The quality system shall be under the supervision of a designated person who reports to executive management.
1.2.2 (1.2.5)	SC	NA	NA	The committee revised standard 1.2.2 based on updates to the AABB Quality System Essentials. The standard reads as follows: **1.2.2 Management Reviews** Management shall assess the effectiveness of the quality system at defined intervals.
1.2.2.1 (1.2.5)	SC	NA	NA	The committee revised standard 1.2.2.1 by including the clause "shall occur at a minimum" to ensure that management reviews of the quality system occurs on an annual basis.
1.3 (1.2.3, 1.2.3.1)	SC	NA	NA	The committee revised standard 1.3 based on updates to the AABB Quality System Essentials. The standard reads as follows: **1.3 Policies, Processes, and Procedures** Policies, processes, and procedures shall be implemented and maintained to satisfy the applicable requirements of these CT Standards. All such policies, processes, and procedures shall be in writing or captured electronically and shall be followed.
1.3.1 (New)	SC	NA	NA	The committee revised standard 1.3.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **1.3.1** The medical director and/or laboratory director (as applicable) shall approve all medical and technical policies, processes, and procedures.
1.4 (1.5)	SC	NA	NA	The committee revised standard 1.4 based on updates to the AABB Quality System Essentials. The standard reads as follows:

				✎**1.4 Risk Assessment** The facility shall have a process in place to perform risk assessments for activities at defined intervals.
1.4.1 (1.5.1)	SC	NA	NA	The committee revised standard 1.4.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **1.4.1** Mitigation strategies shall identify, assess, and address the level of risk associated with quality and safety.
1.5 (1.4)	SC	NA	NA	The committee added revised standard 1.5 based on updates to the AABB Quality System Essentials. The standard reads as follows: **1.5 Operational Continuity** The organization shall address continuity in the event that operations are at risk.
1.6 (1.3)	SC	NA	NA	The committee revised standard 1.6 based on updates to the AABB Quality System Essentials. The standard reads as follows: **1.6 Emergency Preparedness** The organization shall have an emergency operation plan(s) to respond to the effects of internal and external disasters.
1.6.1.1 (New)	SC	NA	NA	The committee created new standard 1.6.1.1 for consistency and to mirror the requirements of standard 1.2.2.1. The standard reads as follows: **1.6.1.1** This evaluation shall occur, at a minimum, on an annual scheduled basis. Standard 6.1.5 applies.
1.7	RtC	Please ensure that there is corresponding information in AABB Guidance to provide clarification to industry. It is assumed that an organization would not report 'routine' nonconforming events, but rather, only those events that where the result of significant deviation from procedures or negligence (e.g., lack of sterility testing).	Yes	The committee reviewed this comment, agreed that guidance should be written, and subsequently added it to guidance for this standard.
1.7.1 (deleted)	RtC	Reporting nonconforming events falls outside the scope of accreditation and should not be required. Facilities should be required to report to regulatory entities and not accrediting bodies.	Yes	The committee reviewed this comment and agreed with its intent. Based on this feedback and others, we have elected to remove standard

				1.7.1 and narrowed the scope of the intent. This resulted in the creation of standards 1.9.1 and 1.10.
1.7.1 (deleted)	RtC	This seems important, can a timeline be added (e.g. within 30 days) or phrase "as soon as reasonably possible"? Also, when reporting, what should be included in the reporting and do we use the same reporting email accreditation@aabb.org?	Yes	The committee reviewed this comment and agreed with its intent. Based on this feedback and others, we have elected to remove standard 1.7.1 and narrowed the scope of the intent. This resulted in the creation of standards 1.9.1 and 1.10, with 1.10 specifically requiring 30 days of notice. To note, the guidance to this standard provides information on ways to communicate with AABB's Accreditation Department.
1.9 (New)	SC	NA	NA	The committee created new standard 1.9 for completeness. This standard exists in other sets of AABB Standards and mirrors that language. The standard reads as follows: **1.9 Facility Status Changes** The facility shall communicate to AABB within 30 days a change that directly or indirectly impacts a facility's accreditation status.
1.9 (New)	RtC	Can you add which changes will need to be reported? This should be a minimum of a change in procurement, laboratory, or clinical medical director; laboratory director; and Quality Representative. Should it be also required to report changes in ownership or executive management?	No	The committee reviewed this comment but did not feel that a change was needed at this time. The committee feels that this is to be determined by the facility in question based on the scope of their accreditation.
1.9 (New)	RtC	There is a similar standard in the 13th edition of Standards for IRL, Standard 1.1.3, which states, "The laboratory shall communicate initial appointments and staffing changes for the medical director, medical director designee, and immunohematology reference laboratory supervisor within 30 days to AABB's Accreditation and Quality Department." Please specify what changes must be communicated to AABB within 30 days as required by Standard 1.9. It would be helpful to align standard 1.9 to the IRL standard. Please clarify what directly or indirectly affects a facility accreditation status.	No	The committee reviewed this comment but did not feel that a change was needed at this time. The committee feels that this is to be determined by the facility in question based on the scope of their accreditation.
1.9 (New)	RtC	We interpret this standard to be limited to communications to AABB for significant issues, e.g., serious issues with local competent health authority, and not to be inclusive of routine operational changes, e.g., change in	No	The committee reviewed this comment but did not feel that a change was needed at this time. The committee agrees with the comment and notes that accredited facilities should only be

		ownership or relocation, as there is already a mechanism in place to notify AABB of these latter types of changes. Please clarify.		sharing information with the AABB that directly affects the facility's accreditation status. Routine operational changes would not trigger a contact to AABB, but a change in leadership or relocation would definitely fall under this standard.
1.9.1 (New)	SC	NA	NA	The committee created new standard 1.9.1 based on feedback received during the comment period. This standard now requires accredited programs contact AABB if they are under investigation by their relevant Competent Authority. This ensures AABB accreditation's department is aware of all issues that could potentially impact the program or AABB as an accreditation organization. The committee also added a new definition to the Glossary for "Regulatory Enforcement Action" for clarity. The standard reads as follows: **1.9.1** If the organization is the subject of regulatory enforcement action by a relevant Competent Authority, they shall notify AABB within 7 days of receipt of notification. The glossary addition reads as follows: **Regulatory Enforcement Action:** Measures taken by a Competent Authority that include, but are not limited to, progressive measures (eg, suspension or termination of operations, information notices requiring specific documentation or data, fines incurred) or action based on critical triggers (eg, pattern of recurrent, unresolved issues, deficiencies in risk management systems).
1.10 (New)	SC	NA	NA	Standard 1.10 is new to the edition and has been included for completeness. This requirement mirrors requirements set forth by AABB's Accreditation Department.

				The committee also added a new definition to the Glossary for "Unanticipated Event" for clarity. The standard reads as follows: **1.10 Unanticipated Event Notification** Within 30 days, the organization shall notify AABB of the discovery of an event that has caused, is causing, or is likely to cause serious injury or harm, or death, to an individual resulting from deviation(s) related to the scope of these CT Standards. The addition reads as follows: **Unanticipated Event:** Unplanned occurrences that can cause serious injury or harm, or death, to an individual, resulting from a deviation(s).
2.1	SC	NA	NA	The committee revised standard 2.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **2.1 Human Resources** The organization shall employ an adequate number of individuals qualified by education, training, and/or experience.* *21 CFR 1271.170.
2.1.2 (2.1.1)	SC	NA	NA	The committee added the CFRs cited above to ensure that the CT Standards remain consistent with CMS requirements. The standard reads as follows: **2.1.2 Qualification** Personnel performing critical tasks shall be qualified to perform assigned activities on The basis of appropriate education, training, and/or experience.† †42 CFR 493.1403, 42 CFR 493.1409, 42 CFR 493.1415, 42 CFR 493.1421, 42 CFR 493.1441, 42 CFR 493.1447. 42 CFR 493.1453, 42 CFR 493.1459, 42 CFR 493.1461, and 42 CFR493.1487.

				For accredited facilities that are assessed by AABB for CLIA conformance, refer to the Verification of CLIA Compliance Form before onsite assessment.
2.1.2 (2.1.1)	RtC	We agree with the added CFR references for CMS, but question why are CMS references included but FDA references are not? We recommend addition of 21 CFR 1271.170.	Yes	The committee reviewed this comment and agreed with the intent. The committee however felt that the CFR requested would better with standard 2.1.
2.1.3 (New)	SC	NA	NA	The committee added the CFRs cited above to ensure that the CT Standards remain consistent with CMS requirements. The standard reads as follows: **2.1.3 Training** The organization shall provide training for personnel performing critical tasks.‡ ‡21 CFR 211.25.
2.1.3.1, #2, 4 (2.1.4, #2, 4)	SC	NA	NA	The committee edited subnumbers 2 and 4 for completeness. The additions of the clauses, "to perform assigned responsibilities" to #2, and "for employee assigned responsibilities" to #4, ensures that the training given is focused on the work performed by the specific employees. The standard reads as follows: **2.1.3.1** This training shall include: 1) Orientation. 2) Initial job-specific training to perform assigned responsibilities. 3) Quality-systems-related training. 4) Ongoing job-specific training for employee assigned responsibilities. Standards 2.1.4, 2.1.6, and 5.1.1 apply.
2.1.4.1 (2.1.6.4)	SC	NA	NA	The committee revised standard 2.1.4.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **2.1.4.1** Action shall be taken when competence has not been demonstrated. Standard 9.1 applies.

2.1.5.1 (New)	SC	NA	NA	The committee added new standard 2.1.5.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **2.1.5.1** For those authorized to perform or review critical tasks, records of names, signatures, initials or identification codes, and inclusive dates of employment shall be maintained.
2.1.6 (2.1.7)	SC	NA	NA	The committee revised standard 2.1.6 based on updates to the AABB Quality System Essentials. The standard reads as follows: **2.1.6 Continuing Education** The organization shall ensure that continuing education requirements applicable to these CT Standards are met when applicable.
2.1.6.1 (2.1.7.1)	RtC	The language of this standard leaves it to the facility to require or not, CE for all their staff who perform critical activities. The 11th edition version is as follows: "*Requirements of relevant continuing education activities performed by the facility as required by these CT Standards shall be defined for and met by all employees who perform critical tasks*". Unless this is the intent, the current standard will not give our assessor the backing needed to cite facilities for not having CE requirements for staff who perform critical activities.	Yes	The committee reviewed this comment and agreed with its intent. The committee realized that this content was missing from the edition and reincorporated it as standard 2.1.6.2 which reads as follows: **2.1.6.2** Requirements for the relevant continuing education activities performed by the facility as required by these CT Standards shall be defined for employees who perform critical tasks.
3.0	SC	NA	NA	The committee revised standard 3.0 based on updates to the AABB Quality System Essentials. The standard reads as follows: **3.0 Equipment** The organization shall define and control critical equipment.
3.1	SC	NA	NA	The committee revised standard 3.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **3.1 Equipment Specifications** Equipment specifications shall be defined before purchase.

3.2	SC	NA	NA	The committee revised standard 3.2 based on updates to the AABB Quality System Essentials. The standard reads as follows: **3.2 Qualification of Equipment** All critical equipment shall be qualified for its intended use. Equipment shall be requalified, as needed, after repairs and upgrades.
3.2.2	SC	NA	NA	The committee revised standard 3.2.2 to mirror all other AABB Standards and to match the AABB Quality System Essentials. The standard reads as follows: **3.2.2 Operational Qualification** Each piece of equipment and component of an information system shall be verified before actual use.
3.2.3	SC	NA	NA	The committee revised standard 3.2.3 to mirror all other AABB Standards and to match the AABB Quality System Essentials. The standard reads as follows: **3.2.3 Performance Qualification** Equipment shall perform as expected for its intended use.
3.2.3.1 (3.2.3)	SC	NA	NA	The committee edited standard 3.2.3.1 through the inclusion of the clause, "…or be qualified for its intended use." recognizing that there are parameters set forth by facilities for use. This ensures that accredited institutions are meeting those expectations and requirements. The committee also deleted the clause "or exceed" that appeared in the 11th edition as all standards can be exceeded in practice. The standard reads as follows: **3.2.3.1** Facility-developed predetermined criteria shall meet the specifications established by the manufacturer or be qualified for its intended use.
3.4 (New)	SC	NA	NA	The committee revised standard 3.4 to mirror all other AABB Standards and to match the AABB

				Quality System Essentials. The standard reads as follows: **3.4 Unique Identification of Equipment** Equipment shall have unique identification.
3.5 (3.4)	SC	NA	NA	The committee revised standard 3.5 to mirror all other AABB Standards and to match the AABB Quality System Essentials. The standard reads as follows: **3.5 Equipment Monitoring and Maintenance** Equipment shall be monitored and maintained in accordance with the manufacturer's written instructions.
3.5.1 (3.4.1)	SC	NA	NA	The committee revised standard 3.5.1 to mirror all other AABB Standards and to match the AABB Quality System Essentials. The standard reads as follows: **3.5.1 Calibration and Accuracy of Equipment** Calibrations and/or adjustments shall be performed using equipment and materials that have adequate accuracy and precision. At a minimum, calibrations and/or adjustments shall be confirmed as described below unless otherwise indicated by the manufacturer: 1) Before use. 2) After activities that may affect the calibration. 3) At prescribed intervals.
3.5.1.1 (3.4.1, #3)	SC	NA	NA	The committee revised standard 3.5.1.1 to mirror all other AABB Standards and to match the AABB Quality System Essentials. The standard reads as follows: **3.5.1.1** Calibration of equipment shall include details of equipment type, unique identification, location, frequency of checks, check method, acceptance criteria, and specified limitations.
3.5.1.2 (3.4.1, #4)	SC	NA	NA	The committee revised standard 3.5.1.2 to mirror all other AABB Standards and to match the AABB Quality System Essentials. The standard reads as follows:

				3.5.1.2 Equipment used for calibration, inspection, measuring, and testing shall be certified to meet nationally recognized measurement standards. Certification shall occur before initial use, after repair, and at prescribed intervals. Where no such measurement standards exist, the basis for calibration shall be described and recorded.
3.5.2	SC	NA	NA	The committee revised standard 3.5.2 to mirror all other AABB Standards and to match the AABB Quality System Essentials. The standard reads as follows: **3.5.2** When equipment is found to be out of calibration or specification, the validity of previous inspection and test results and the conformance of potentially affected products or services (including those that have already been released or delivered) shall be verified.
3.5.3, #2, 3,6 (3.4.3, #2, 3, 6)	SC	NA	NA	The committee revised standard 3.5.3 to mirror all other AABB Standards and to match the AABB Quality System Essentials. The standard reads as follows: **3.5.3** The organization shall: 1) Define cleaning and sanitization methods and intervals for equipment. 2) Ensure that environmental conditions are suitable for the operations, calibrations, inspections, measurements, and tests carried out. 3) Remove equipment from service that is malfunctioning/out of service and communicate to appropriate personnel. 4) Monitor equipment to ensure that defined parameters are maintained. 5) Ensure that the handling, maintenance, and storage of equipment are such that the equipment remains fit for use. 6) Ensure that all equipment maintenance and repairs are performed by qualified individuals

				and in accordance with the manufacturer's recommendations. Standard 3.2 applies.
3.5.4 (New)	SC	NA	NA	The committee added standard 3.5.4 to mirror all other AABB Standards and to match the AABB Quality System Essentials. The standard reads as follows: **3.5.4 Investigation and Follow-Up** Investigation and follow-up of equipment malfunctions, failures, or adverse events shall include: 1) Assessment of products or services provided since the equipment was last known to be functioning per the manufacturer's written instructions or organization-defined specifications. 2) Assessment of the effect on the safety of individuals affected. 3) Removal of equipment from service, if indicated. 4) Investigation of the malfunction, failure, or adverse event, and a determination if other equipment is similarly affected, as applicable. 5) Requalification of the equipment. 6) Reporting the nature of the malfunction, failure, or adverse event to the manufacturer, when indicated.
3.7, #1, 2 (3.6, #1, 2)	SC	NA	NA	The committee revised standard 3.7 to mirror all other AABB Standards and to match the AABB Quality System Essentials. The standard reads as follows: **3.7 Information Systems** The organization shall have controls in place for the implementation, use, ongoing support, and modifications of information system software, hardware, and databases. Elements of planning and ongoing control shall include:

				1) Numeric designation of system versions with inclusive dates of use. 2) Validation/verification/qualification of system software, hardware, databases, and user defined tables before implementation. 3) Fulfillment of life-cycle requirements for internally developed software. 4) Defined processes for system operation and maintenance. 5) Defined process for authorizing and documenting modifications to the system. 6) System security to prevent unauthorized access. 7) Policies, processes, and procedures and other instructional documents developed using terminology that is understandable to the user. 8) Functionality that allows for display and verification of data before final acceptance of the additions or alterations. 9) Defined process for monitoring of data integrity for critical data elements. 10) System design that establishes and maintains unique identity of the donor, the product, or the service, and the recipient (as applicable). 11) Training and competency of personnel who use information systems. 12) Procedures to ensure confidentiality of protected information.
3.7.1 (3.6.1, 3.6.1.1)	SC	NA	NA	The committee revised standard 3.7.1 to mirror all other AABB Standards and to match the AABB Quality System Essentials. The standard reads as follows: **3.7.1 Alternative Systems** An alternative system shall be maintained to ensure continuous operation in the event that computerized data and computer-assisted functions are unavailable. The alternate

				system shall be tested at defined intervals. Processes and procedures shall address mitigation of the effects of disasters and include recovery plans.
3.7.2 (New)	SC	NA	NA	The committee added standard 3.7.2 to mirror all other AABB Standards and to match the AABB Quality System Essentials. The standard reads as follows: **3.7.2** Personnel responsible for management of information systems shall be responsible for compliance with the regulations that affect the use of the system.
3.7.3 (New)	SC	NA	NA	The committee added standard 3.7.3 to mirror all other AABB Standards and to match the AABB Quality System Essentials. The standard reads as follows: **3.7.3** The organization shall support the management of information systems.
3.7.4 (New)	SC	NA	NA	The committee added standard 3.7.4 to mirror all other AABB Standards and to match the AABB Quality System Essentials. The standard reads as follows: **3.7.4** A system designed to prevent unauthorized access to computers and electronic records shall be in place.
3.8 (New)	SC	NA	NA	The committee created new standard 3.8 to ensure that facilities monitor their critical technology infrastructure and that they function as expected. This standard requires that there are defined checks to monitor that technology is working as intended and expected. The standard reads as follows: **3.8 Technology Infrastructure** The organization shall have an active program to ensure that critical technology infrastructure and communications infrastructure function as intended, including risk-based monitoring or

				testing at facility-defined intervals. Standards 1.4, 1.5, and 1.6 apply.
3.9 (New)	SC	NA	NA	The committee added new standard 3.9 for completeness. This standard does appear in other AABB Standards that require the use of alarm systems. The committee felt that having these elements in chapter 3 was necessary as it relates to equipment. The concept of alarm systems also appears in chapters 5 and 10 but these are not redundant. The standard reads as follows: **3.9 Alarm Systems** Storage devices for cellular therapy products shall have alarms and shall conform to the following standards:
3.9.1 (New)	SC	NA	NA	The committee added new standard 3.9.1 for completeness. This standard does appear in other AABB Standards that require the use of alarm systems. The committee felt that having these elements in chapter 3 was necessary as it relates to equipment. The concept of alarm systems also appears in chapters 5 and 10 but these are not redundant. The standard reads as follows: **3.9.1** The alarm shall be set to activate under conditions that will allow enough time for proper action to be taken before cellular therapy products reach unacceptable conditions.
3.9.2 (New)	SC	NA	NA	The committee added new standard 3.9.2 for completeness. This standard does appear in other AABB Standards that require the use of alarm systems. The committee felt that having these elements in chapter 3 was necessary as it relates to equipment. The concept of alarm systems also appears in chapters 5 and 10 but these are not redundant. The standard reads as follows:

				3.9.2 Activation of an alarm shall initiate a process for immediate action, investigation, and appropriate corrective action.
4.0 (New)	SC	NA	NA	The committee added standard 4.0 to mirror all other AABB Standards and to match the AABB Quality System Essentials. The standard reads as follows: **4.0 Suppliers and Customers** The organization shall ensure that agreements to provide or receive products or services are reviewed, approved, and meet supplier and customer expectations.
4.1 (New)	SC	NA	NA	The committee added standard 4.1 to mirror all other AABB Standards and to match the AABB Quality System Essentials. The standard reads as follows: **4.1 Supplier Qualification** The organization shall evaluate the ability of suppliers of critical materials, equipment, and services to meet specified requirements.
4.1.1 (New)	SC	NA	NA	The committee added standard 4.1,1 to mirror all other AABB Standards and to match the AABB Quality System Essentials. The standard reads as follows: **4.1.1** The organization shall evaluate and participate in the selection of suppliers. If executive management is not included in the selection process, there shall be a mechanism to provide feedback to management with contracting authority.
4.1.2 (New)	SC	NA	NA	The committee added standard 4.1.2 to mirror all other AABB Standards and to match the AABB Quality System Essentials. The standard reads as follows: **4.1.2** When a supplier fails to meet specified requirements, it shall be reported to the management with contracting authority.

4.2 (4.0)	SC	NA	NA	The committee revised standard 4.2 to mirror all other AABB Standards and to match the AABB Quality System Essentials. The standard reads as follows: **4.2 Agreements** Agreements and any incorporated changes shall be reviewed and communicated.
4.2.1.1 (New)	SC	NA	NA	The committee new standard 4.2.1.1 to ensure that all agreements are reviewed at least once during every accreditation cycle at a minimum. The standard reads as follows: **4.2.1.1** This review shall occur at a minimum of every 2 years.
4.2.1.1 (New)	RtC	The proposed biennial review requirement does not necessarily add quality assurance or guarantee that agreements align with their original intent between AABB inspection cycles. Rather, it introduces an unnecessary administrative burden without improving product quality. Agreements are already subject to regular quality checks per standards 4.2.2–4.2.5.2, which cover updates, documented communications, and quality control (QC) in collection, processing, storage, and distribution. The standard operating procedures (SOPs) guiding each stage of cell therapy collections are rigorously maintained and continually reviewed, ensuring quality. Any updates to agreements are promptly communicated and documented in alignment with standard 4.2.4, making a mandatory two-year review redundant. Suggest the deletion of: This review shall occur at a minimum of every two years.	No	The committee reviewed this comment but did not feel that a change was needed at this time. The committee feels that the addition adds value to the standard.
4.2.2 (4.2)	SC	NA	NA	The committee revised standard 4.2.2 to mirror all other AABB Standards and to match the AABB Quality System Essentials. The standard reads as follows: **4.2.2** Changes to agreements shall be communicated to affected parties.
4.2.3 (4.3)	SC	NA	NA	The committee revised standard 4.2.3 to mirror all other AABB Standards and to match the AABB Quality System Essentials. The standard reads as follows:

				4.2.3 The responsibilities for activities covered by these CT Standards when more than one organization is involved shall be specified by agreement.
4.2.3.1, #6 (4.1.1, #6)	SC	NA	NA	The committee edited the opening clause of standard 4.2.3.1 replacing the clause, "…the facility or department" with "..all involved parties…" recognizing that this standard applies to more than just a facility or department. In subnumber 6 the committee expanded the content to recognize that there is space in agreements that are beyond origin to administration or discard. The standard reads as follows: **4.2.3.1** Before acceptance of a documented verbal or written agreement, the agreement shall be reviewed by all involved parties to ensure that: 6) Cellular starting material or product quality is maintained under the scope of activities covered by the parties' agreement per specified requirements.
4.2.3.2.3 (4.1.2.3)	SC	NA	NA	The committee elected to edit standard 4.2.3.2.3 by including the clause, "…and changes in facility status" for parallel construction with the creation of new standard 1.9. The standard reads as follows: **4.2.3.2.3** Communication of critical information, including deviations, nonconformances, and adverse events, and changes in facility status. Standards 1.9 and 5.5 apply.
4.2.3.2.6 (New)	SC	NA	NA	The committee created new standard 4.2.3.2.6 to ensure that all parties covered by the agreement(s) incorporate the core elements of the QSEs that are included in this edition. The standards now reads as follows: **4.2.3.2.6** Incorporation of quality system essentials required by these CT Standards.

4.3 (New)	SC	NA	NA	The committee added standard 4.3 based on updates to the AABB Quality System Essentials. The standard reads as follows: **4.3 Incoming Receipt, Inspection, and Testing** Incoming products or services, equipment, and materials shall be received, inspected, and tested, as necessary, before approval for use.
4.3 (New)	RtC	Consider removing services from the serial list, it may not be possible inspect and test services before using them.	No	The committee reviewed this comment but did not feel that a change was needed at this time. The committee feels that this provides value to the edition.
4.8.1, #2	SC	NA	NA	The committee updated subnumber 2 to mirror similar language found in other AABB Standards surrounding the requirement to be accredited by AABB or a similar accrediting body. The entry reads as follows: **4.8.1 Evaluation and Qualification of Suppliers of Materials and Services** The facility shall ensure that suppliers of critical materials or services are qualified and selected based on the supplier's ability to meet specified requirements, including ensuring the following: 2) Facilities providing tests or manufacturing services required by these CT Standards are accredited by AABB or other relevant standard-setting organizations.
4.8.1, #3 (New)	SC	NA	NA	The committee created new Subnumber to the edition for completeness and was included to ensure that accredited facilities are working with suppliers who have been approved to provide those services by the appropriate Competent Authority. The entry reads as follows: **4.8.1 Evaluation and Qualification of Suppliers of Materials and Services** The facility shall ensure that suppliers of critical materials or services are qualified and selected

				based on the supplier's ability to meet specified requirements, including ensuring the following: 3) The supplier is appropriately qualified or authorized to provide such service as required by the relevant Competent Authority.
4.5A, I. A	RtC	Please clarify the expectation of specificity in the donor consent or authorization. It is unclear whether the expectation is to list the exact commercial application as written in the standard in the donor consent.	No	The committee reviewed this comment but did not feel that a change was needed at this time. The committee notes that this change would not be applicable to all users. The committee noted that consent should be tailored to the product/application and to get specific in this place would be contrary to the intent of the standard.
4.5A, I, A, 5)	SC	NA	NA	The committee expanded the intent of subnumber 5 to provide examples of what elements can be included as a part of intended use. The entry reads as follows: **Reference Standard 4.5A—Donor Informed Consent or Authorization** I. General Informed Consent A. Description of participation, including: 5) Intended use, which may include research, process development, quality control and training, or commercial applications, including manufacture or manipulation, storage, disposition including discard, in-vitro manipulation, and analysis.
4.7A, I., A, 2	SC	NA	NA	The committee elected to remove the term "preparative" recognizing that "preparative" could limit the scope and understanding of the requirement.
5.0	SC	NA	NA	The committee revised standard 5.0 based on updates to the AABB Quality System Essentials. The standard reads as follows: **5.0 Process Control** The organization shall ensure the quality of products or services.

5.1.1 (5.2.1)	SC	NA	NA	The committee revised standard 5.1.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **5.1.1 Change Control** When the organization develops new processes or procedures or changes existing ones, they shall be validated before implementation.
5.1.1.1 (5.2.1)	RtC	We are questioning why this standard is singled out for reference to 2.1.2, when 2.1.2 applies to performance of any critical tasks, not just approval of change controls?	No	The committee reviewed this comment but did not feel that this change was appropriate at this time. The committee feels that the inclusion of this crossreference to the standard focused on training of employees is of paramount importance.
5.1.2 (5.4)	SC	NA	NA	The committee revised standard 5.1.2 based on updates to the AABB Quality System Essentials. The standard reads as follows: **5.1.2 Quality Control** A program of quality control shall be established that is sufficiently comprehensive to ensure that products, equipment, materials, and analytical functions perform as intended. Standard 1.2.2 applies.
5.1.3, #3 (5.2.2, #3)	SC	NA	NA	The committee added a crossreference to standard 1.4 to standard 5.1.3 subnumber 3 focused on risk assessment for completeness. The committee also added reference to the CFRs focused on general good tissue practices. The standard reads as follows: **5.1.3 Process Planning** Quality requirements shall be incorporated into new or changed processes, products, services, and novel methods. Planning and implementation activities shall include the following: 3) Evaluation of risk.* Standard 1.4 applies.
5.1.4 (5.2.3)	SC	NA	NA	The committee revised standard 5.1.4 based on updates to the AABB Quality System Essentials. The standard reads as follows:

				5.1.4 Process Validation Before implementation, the new or changed processes and procedures shall be validated.
5.1.4.1, #1 (5.2.3.1, #1)	SC	NA	NA	The committee revised standard 5.1.4.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **5.1.4.1** Validation activities shall include the following: 1) Identification of objectives, individual(s) responsible, expected outcomes, and/or performance measures.
5.1.6 (New)	SC	NA	NA	The committee added new standard 5.1.8 based on updates to the AABB Quality System Essentials. The standard reads as follows: **5.1.6 Use of Materials** All materials shall be stored and used in accordance with the manufacturer's written instructions and shall meet specified requirements.
5.1.7 (New)	SC	NA	NA	The committee added new standard 5.1.7 based on updates to the AABB Quality System Essentials. The standard reads as follows: **5.1.7 Inspection** The organization shall ensure that products or services are inspected at organization-defined stages.
5.1.8 (New)	SC	NA	NA	The committee added new standard 5.1.8 based on updates to the AABB Quality System Essentials. The standard reads as follows: **5.1.8 Identification and Traceability** The organization shall ensure that all products or services are identified and traceable.
5.1.9 (New)	SC	NA	NA	The committee added new standard 5.1.8 based on updates to the AABB Quality System Essentials.

				The standard reads as follows: **5.1.9 Handling, Storage, and Transportation** The organization shall ensure that products or services are handled, stored, and transported in a manner that prevents damage, limits deterioration, and provides traceability.*
5.1.9.1 (New)	SC	NA	NA	The committee created new standard 5.1.9.1 to ensure that suppliers provide evidence of traceability of product to the facility they have agreements with. The standard reads as follows: **5.1.9.1** The facility shall ensure that suppliers and/or consignees of cellular therapy products provide evidence of processes for traceability, tracking, and recall of products. Standard 7.2.5 applies.
5.1.9.1 (New)	RtC	Consignee receipt of product without complete chain of custody falls under complaint and should not be a required standard.	No	The committee reviewed this comment but did not feel that a change was needed at this time. The committee feels that this standard is important and its inclusion is of paramount importance to the community.
5.1.9.1	RtC	We do not have concerns with the standard as written but would like clarification in the portal guidance as to what type of "evidence" we would be expected to provide to show compliance.	No	The committee noted this comment but did not feel that a change was needed at this time. The committee has created guidance to provide assistance in the standard's implementation.
5.1.9.1.1 (New)	SC	NA	NA	The committee created new standard 5.1.9.1.1 for completeness. This standard recognizes that there are instances where a provider of a product may not have complete chain of custody and that their use is approved knowing this information. The standard reads as follows: **5.1.9.1.1** The facility shall have a policy for the use/issue of a cellular therapy product provided by a supplier and/or received by a consignee that lacks a complete chain of custody. Standards 7.2.4 and 7.2.6.2 apply.
5.1.10.1.1 (New)	SC	NA	NA	The committee created new standard 5.1.10.1.1 for completeness. The standard ensures that the

				IRL Standards mirror the requirements set forth by CMS in July 2022 with an effective date of 2024. This mostly focuses on wave testing, which is not performed by our laboratories, however the requirement does focus on proficiency testing referrals and what is and is not allowed until the results of proficiency testing is complete and submitted. The standard reads as follows: **5.1.10.1.1** Laboratories shall ensure that no interlaboratory communications pertaining to proficiency test events occur until after the submission deadline.* *42 CFR 493.801(b)(3).
5.1.10.1.2 (New)	SC	NA	NA	The committee created new standard 5.1.10.1.2 for completeness. This addition was made in conjunction with the addition of the CFR cited, which requires that laboratories that perform proficiency testing show that they can successfully perform the act. Laboratories that attempt to have their samples outsourced would not meet the requirements in the CFR. The standard reads as follows: **5.1.10.1.2** The laboratory shall ensure that no portion of a proficiency testing sample is sent to another laboratory for analysis.† †42 CFR 493.801(b)(4).
5.1.10.1.3 (New)	SC	NA	NA	The committee added new standard 5.1.10.1.3 to the edition for completeness. This addition was made in conjunction with the addition of the CFR cited, which requires that if a laboratory receives samples for proficiency testing from an outside source that they immediately contact CMS who will instruct them on how to move forward. The standard reads as follows: **5.1.10.1.3** Any laboratory that receives a proficiency testing sample from another

				laboratory for testing shall notify CMS of the receipt of the sample.‡ ‡42 CFR 493.801(b)(4).
5.1.10.3.1 (5.1.2.3.1)	SC	NA	NA	The committee added the clause, "…including notification to potentially impacted parties and appropriate regulatory bodies, as applicable." for clarity. The expansion ensures that all individuals that need to be contacted in the case of a failure are notified. The standard reads as follows: **5.1.10.3.1** Proficiency testing shall be successful. Failures shall be investigated and corrective actions taken, including notification to potentially impacted parties and appropriate regulatory bodies, as applicable.‡ Standard 1.4 applies.
5.3 (5.5)	SC	NA	NA	The committee has added the term "quarantine" to standard 5.3 for completeness. This addition represents the current practice in the field. The standard reads as follows: **5.3 Materials Management** There shall be policies, processes, and procedures for the qualification, receipt, handling, quarantine, storage, and utilization of all materials used in the procurement, processing, and administration of cellular therapy products. Critical materials shall be identified and traceable.
5.3.2.1 (New)	SC	NA	NA	The committee created new standard 5.3.2.1 focused on quarantine for completeness. The standard reads as follows: **5.3.2.1 Quarantine of Critical Materials** The facility shall establish a process for quarantine and disposition of critical supplies and materials.
5.3.2.1 (New)	RtC	The clause "quarantine and release" presumes all supplies and materials are released or made available for use after quarantine (some are rejected). Can	Yes	The committee reviewed the comment and agreed with the intent. The standard was updated.

		this be changed to "...quarantine and disposition of critical supplies and materials"?		
5.3.3.1, 5.3.3.1.1, 5.3.3.1.2 (5.5.3.1, 5.5.3.1.1)	RtC	These standards would need to apply to agreements as well. Perhaps the concept could be included in the standards, or a crossreference to chapter 4?	Yes	The committee reviewed this comment and agreed with its intent. The committee elected to add a crossreference to standard 4.2 as a part of standard 5.3.3.
5.3.3.1.2 (New)	SC	NA	NA	The committee created new standard 5.3.3.1.2 for completeness. This concept is in place in current medical practice. The standard reads as follows: **5.3.3.1.2** The facility shall qualify, verify, and validate critical materials for their intended use.
5.3.5 (5.5.5)	SC	NA	NA	The committee added the clause, "according to specified requirements…" to ensure that the methods used are in accordance with defined requirements specific to the product in use. The standard reads as follows: **5.3.5 Utilization** Non-single-use materials that come into contact with the patient or cellular therapy products during procurement, processing, or administration shall be cleaned and sterilized. Sterilization methods shall be validated and monitored, according to specified requirements.
5.4.1, #10 (New)	SC	NA	NA	The committee added "Labeling" as new #10 to standard 5.4.1, #10 for completeness. The standard reads as follows: **5.4.1 Cellular Therapy Product Manipulation** Cellular therapy product manipulation shall address the following: 10) Labeling.
5.4.2, #6 (New)	SC	NA	NA	The committee added "Sterilization of equipment, as applicable" as new subnumber 6

				to standard 5.4.2 ensuring that sterilization is a part of aseptic methods. The standard reads as follows: **5.4.2 Aseptic Methods** Procurement, processing, and clinical facilities shall establish and maintain policies, processes, and procedures designed to minimize contamination of the product and infection of the donor or recipient. The following shall be addressed: 6) Sterilization of equipment, as applicable.
5.4.3, #4 (New)	SC	NA	NA	The committee added "Physical and/or temporal segregation of cellular therapy products determined to be nonconforming or where donor eligibility has not been determined or the donor is ineligible" as new subnumber 4 to standard 5.4.3, to ensure that the standards remain in conformance with FDA regulations. The requirement should be in place with accredited institutions currently. The standard reads as follows: **5.4.3 Operational Controls** Operational controls shall prevent mix-ups and contamination. The following shall be defined: 4) Physical and/or temporal segregation of cellular therapy products determined to be nonconforming or where donor eligibility has not been determined or the donor is ineligible.
5.5.1.2	RtC	The committee's comments state, "The committee added a crossreference to standard 1.4 focused on risk assessment for completeness. The committee also added reference to the CFRs focused on general good tissue practices.", however, no reference to 1.4 appears in the "revised" standard.	Yes	The committee agreed with this comment and added the crossreference to standard 1.4 to standard 5.5.1.2 for completeness.
5.6.1.4 (New)	SC	NA	NA	The committee created new standard 5.6.1.4 to ensure that accredited facilities have plans in place to recognize and address new labeling requirements as appropriate. The standard reads as follows:

				5.6.1.4 The facility shall have policies to address emerging labeling standards and ensure action is taken, as applicable.
5.8.1 (5.10.1)	RtC	Suggest adding "quantity/volume/dose as applicable" to this standard. HCTPs that are tissue products would have the same lot number and therefore the quantity is important to keep record of at receipt.	No	The committee reviewed this comment but did not feel that a change was needed at this time. The committee feels that subnumber 4 covers the intent of the comment, especially as it pertains to "attributes."
5.8.1, #6 (New)	SC	NA	NA	The committee added subnumber 6 to this edition for completeness, ensuring that the chain of identity identifier was a part of the receipt process. This concept is new to the edition and expands on "chain of identity", which was introduced in the previous edition. The entry reads as follows: **5.8.1 Receipt of Incoming Cells, Tissues, and Organs** At the time of receipt, incoming cells, tissues, and organs shall be inspected, sampled, and/or tested, as appropriate, to determine their acceptability. Standards 5.6.1, 5.6.3, and 5.7.6 apply. Records of the following shall be maintained: 6) Unique, traceable, chain-of-identity identifier, if applicable.
5.8.1, #10, e (5.10.1, #9)	SC	NA	NA	The committee edited subnumber 10 for language and grammar purposes, the intent of the requirement has not changed. The entry reads as follows; **5.8.1 Receipt of Incoming Cells, Tissues, and Organs** At the time of receipt, incoming cells, tissues, and organs shall be inspected, sampled, and/or tested, as appropriate, to determine their acceptability. Standards 5.6.1, 5.6.3, and 5.7.6 apply. Records of the following shall be maintained:

				10) Results of inspection upon receipt, if applicable, including: e) Acceptable temperature range.
5.8.1, #10, e (5.10.1, #9)	RtC	Please consider re-wording to "Within Acceptable temperature range throughout shipment"	No	The committee reviewed this comment but did not feel that a change was needed at this time. The committee feels that the wording provided is clearer.
5.8.1.2, #4 (New)	SC	NA	NA	The committee added new subnumber 4 to the edition which reads, “The cells, tissues, or organs are determined to be nonconforming, or donor eligibility has not been determined, or the donor is ineligible” recognizing that a donor with an incomplete eligibility or an ineligible donor’s cells should be quarantined and segregated appropriately. The standard reads as follows: **5.8.1.2** Cells, tissues, and organs shall be quarantined upon receipt and their disposition determined by a qualified individual when any of the following occur: 4) The cells, tissues, or organs are determined to be nonconforming, or donor eligibility has not been determined, or the donor is ineligible.
5.9.3 (5.11.3)	RtC	Consider adding another standard to require facilities to ensure the continuous monitoring system is working and recording temperature/humidity or other environmental factors that are being monitored on a daily basis in the light of some recent failures noted by some facilities where the system was not working, and they did not know it for quite some time and as a results products were compromised. Also note that FDA does not consider remote monitoring systems as a medical device subject to review or approval, at least when used for blood products.	Yes	The committee noted this comment and agreed with the intent. The committee however did not feel that the placement in chapter 5 would be appropriate. The committee did add new standard 3.8 for completeness which covers the intent of the comment submitted.
5.10.2.10 (5.12.2.10)	SC	NA	NA	The committee added references to the two new FDA guidances concerning Mycobacterium tuberculosis and Sepsis for completeness. This ensures that individuals implementing the standards are aware of the guidances. Recognizing that these guidances were reissued by the FDA for public comment, the references

				may be edited by the committee following the publication of the edition.
5.10.7 (5.12.7)	RtC/SC	Please note that use of an HCT/P from an ineligible donor or from a donor for whom the donor eligibility has not been completed is not generally permitted for licensed or investigational products. Recommend adding "Or allowed only according to local and/or FDA and relevant Competent Authority regulations" or similar wording.	Yes	The committee agreed with the intent of this comment and the change was implemented. The committee, based on this feedback, added the phrase, "and according to local and/or FDA and relevant Competent Authority regulations" to the standard for completeness. The standard now reads as follows: **5.10.7 Products from Ineligible Donors** The biohazard label shall be attached to any allogeneic product for which there are abnormal donor screening or testing results. All allogeneic products from ineligible donors shall be provided only under urgent medical need and according to local and/or FDA or relevant Competent Authority regulations. The product shall be labeled with the phrase "WARNING: Advise patient of communicable disease risks." Reference Standard 5.6.2A, Requirements for Labeling of Cellular Therapy Products, applies.
5.10.10.1 (5.12.10.1)	SC	NA	NA	The committee has added a clause for completeness stating, "…or reactive infectious disease marker…" mirroring the current labeling requirements for autologous products. The standard reads as follows: **5.10.10.1** The biohazard label shall be attached to autologous products for which there is abnormal or reactive infectious disease marker testing or donor screening results. Any product with abnormal testing results shall also be labeled with the statement "WARNING: Reactive test results for [name of disease agent or disease]."
5.11.4 (5.13.4)	SC	NA	NA	The committee replaced the term "anesthesiologist" with "provider" recognizing that there are individuals who can provide

				anesthesia and are doing so while not being a licensed anesthesiologist. The standard reads as follows: **5.11.4** Administration of local anesthesia to the donor shall be performed under the supervision of a credentialed physician. Sedation (monitored anesthesia care), regional anesthesia, or general anesthesia shall be administered under the supervision of a licensed anesthesia provider. Pain management for postprocedure care shall be available, if necessary.
5.12.1.1 (New)	SC	NA	NA	The committee created new standard 5.12.1.1 recognizing that there are certain products that do not require a medical order for procurement. The standard reads as follows: **5.12.1.1** Cord blood, gestational materials, or tissue or cellular starting materials collected from a noninvasive procedure and before identification of an intended recipient do not require a medical order before procurement. Standard 5.22 applies.
5.12.6 (5.14.6)	SC	NA	NA	The committee added the clause "cellular starting material" to the standard to expand the scope of the Standards. The standard reads as follows: **5.12.6 Review of Procurement Records** The facility shall ensure that the procurement record for each cellular therapy product or cellular starting material is accurate and complete in a specified time frame.
5.12.7 (5.14.7)	SC	NA	NA	The committee edited this standard for clarity, recognizing that "access" is more of an encompassing term than "a" which is what previously appeared in the standard. **5.12.7 Procurement Record Availability** Each facility performing procurement shall provide access to product procurement record(s) to the facility receiving the product while

				maintaining the chain of custody. Chapter 4, Suppliers and Customers, applies.
5.15.1 (5.17.1)	SC	NA	NA	The committee edited standard 5.15.1 by removing the clause "except for cord blood or gestational material manufacturing facilities" and used the basis to create new standard 5.15.1.1. The standard reads as follows: **5.15.1 Medical Order for Processing, Preservation, or Storage** The facility performing processing, preservation, or storage shall obtain an order from a health-care provider, if applicable. The order shall contain information that uniquely identifies the donor and the recipient. Specific instruction for cell processing and preservation shall be provided in the order as appropriate.
5.15.1.1 (New)	SC	NA	NA	The committee added new substandard 5.15.1.1 to allow for information surrounding cord blood, gestational materials, and cell starting materials and what is expected to be included on a medical record for these products. The standard reads as follows: **5.15.1.1** Facilities that process, preserve, or store cord blood, gestational materials, tissue, or cellular starting materials collected from a noninvasive procedure and before identification of an intended recipient are not required to obtain a medical order before processing, preservation, or storage. Standard 4.2.3.1 applies.
5.15.2, #5 (New)	SC	NA	NA	The committee added subnumber 5 to this edition for completeness, ensuring that the chain of identity identifier was a part of the receipt process. This concept is new to the edition, and expands on "chain of identity", which was introduced in the previous edition. The entry reads as follows:

				5.15.2 Processing Record A complete processing record shall include: 5) Unique, traceable, chain-of-identity identifier, if applicable.
5.15.2, #8 (5.17.2, #7, #8, #9, #10, #11, #12)	SC	NA	NA	The committee noted that the elements in subnumber 8 apply to all processing records, not merely cryopreservation records, and edited the standard as such. The subnumber reads as follows: **5.15.2 Processing Record** A complete processing record shall include: 8) All details of critical processing, preservation, and storage steps.* Records shall include: a) Date and time (if applicable) of critical steps. b) Names of persons responsible for each step. c) Names, manufacturers, lot numbers, and expiration dates of all critical materials d) used in processing, preservation, and storage. d) Quantities of reagents used. e) Identifiers of equipment used.
5.15.2, #8 (5.17.2, #7, #8, #9, #10, #11, #12)	RtC	Should not the sub items a-e be applicable to all processing? Why is it limited to cryopreservation only? (these standards are applicable for more than minimally manipulated HCTPs)	Yes	The committee noted this comment and agreed with the intent. The committee elected to remove the clause, "…for cryopreserved products" allowing the standard to be applicable to processing facilities as requested.
5.15.3 (5.17.3)	SC	NA	NA	The committee added the clause "cellular starting material" to the standard to expand the scope of the Standards. The standard reads as follows: **5.15.3 Determination of Acceptable Values or Ranges** The facility shall define test methods and the acceptable values or ranges for defined critical characteristics of each product or cellular starting material [eg, recovery of specific cell populations, cell viability, cell identification and potency assays, function(s), purity, as

				appropriate, and sterility]. Reference Standards 5.15A, Processing Tests for HPC, Apheresis and HPC, Marrow; 5.15B, Processing Tests for HPC, Cord Blood Products or Gestational Materials; and 5.15C, Processing Tests for Cellular Therapy Products Other than HPC, Apheresis; HPC, Marrow; and HPC, Cord Blood or Gestational Materials, apply.
5.15.5 (5.17.5)	SC	NA	NA	The committee added the clause "cellular starting material" to the standard to expand the scope of the Standards. The standard reads as follows: **5.15.5 Processing Records** Each facility or the facilities 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 or cellular starting material involved, or a summary of the product processing record to the facility(ies) receiving the product, while maintaining chain of custody. Chapter 4, Suppliers and Customers, applies.
5.17 (5.19)	SC	NA	NA	The committee added the clause "cellular starting material" to the standard to expand the scope of the Standards. The standard reads as follows: **5.17 Cryopreservation of Cellular Therapy Products or Cellular Starting Materials** Cellular therapy products or cellular starting material shall be cryopreserved using a controlled rate freezing procedure or equivalent procedure validated to maintain viability. The temperature of the product(s) and/or freezing process shall be monitored.
5.17.2 (5.19.2)	RtC	In the note about the proposed change after 5.17.2 it seems to imply that COI-I is optional. If so, why add the phrase, "if applicable".	No	The committee reviewed this comment but did not feel that a change was needed at this time.

				The committee noted that there are products in which the COI is not applicable because not everything is listed that applies to the product.
5.17.3, #5 (New)	SC	NA	NA	The committee created new subnumber 5 in standard 5.17.3 for completeness. In the previous edition, the committee had introduced this concept and felt it would be appropriate to add here. The standard reads as follows: **5.17.3 Records for Cryopreserved Products** Cryopreservation records shall include, as applicable: 5) Unique, traceable, chain-of-identity identifier, if applicable.
5.17.3, #5 (New)	RtC	The use of 'if applicable' in new subnumber five is redundant with the lead in sentence for 5.17.3.	No	The committee noted this comment but did not feel that a change was appropriate at this time. The committee feels that the clause is important, as there are instances where this information is not available.
5.17.3, #11 (5.19.3, #10)	SC	NA	NA	The committee removed the clause, "if applicable" as it was deemed contrary to the focus of the standard, which is specific to cryopreservation records. The standard now reads as follows: **5.17.3 Records for Cryopreserved Products** Cryopreservation records shall include, as applicable: 11) Temperature record during cryopreservation.
5.18.2 (New)	SC	NA	NA	The committee created new standard 5.18.2 to ensure that facilities have stability programs for all expiring products. The standard was created for completeness. The standard reads as follows: **5.18.2** Stability and expiration dating programs shall be based on the storage conditions for the final product.
5.18.2	RtC	The committee created new standard 5.18.2 to ensure that facilities have stability programs for all expiring products. Is the committee's intent to	Yes	The committee agreed with the intent of the comment. The committee elected to remove the

		include stability when holding apheresis products at room temperature? In the past, stability was applied only to cryopreserved product.		term “final” which appeared in the proposed edition as it appeared before “final product” to ensure that it is clear that there is a need for a stability program.
5.18.3.1 (5.20.2.1)	SC	NA	NA	The committee added the term “purity” to standard 5.18.3.1 for completeness. The standard reads as follows: **5.18.3.1** The stability program shall include product container integrity, viable cell recovery, and an assessment of potency and purity of the relevant cell population(s).
5.21, #3 (5.23, #3)	SC	NA	NA	The committee added the clause, “…including container closure and integrity…” for completeness. The standard reads as follows: **5.21 Distribution** Upon request for distribution, the following items shall be reviewed: 3) Product condition by visual inspection, including container closure and integrity.
5.22, #3 (5.24, #3)	SC	NA	NA	The committee added the clause, “…including container closure and integrity…” for completeness. The standard reads as follows: **5.22 Product Issue** Before issue, the following items shall be reviewed: 3) Product condition by visual inspection, including container closure and integrity.
5.22.1, #6 (5.24.1, #6)	SC	NA	NA	The committee added the clause, “…including container closure and integrity…” to subnumber 6 for completeness. The standard reads as follows: **5.22.1** The issuing facility shall review and verify the following items at the time of final cellular therapy product distribution/issue: 6) Product condition by visual inspection, including container closure and integrity.

5.22.1, #10 (5.24.1, #10)	SC	NA	NA	The committee edited subnumber 10 for clarity, replacing “Date and time of issue” with “Date(s) and time(s) of issue.”
5.22.1, #10 (5.24.1, #10)	RtC	Please clarify the value in reviewing and verifying the time of the request. We do not receive the time of the request for all products, particularly cryopreserved products. We see no value in obtaining this information from the issuing facility. Please clarify if the time requirement would only apply in certain cases.	Yes	As presented in the proposed edition, the committee had submitted the standard as, “Date(s) and time(s) of request and issue.” Based on this comment and others, the committee reverted the language to the 11th edition with the edit to pluralize the entry.
5.22.1, #10 (5.24.1, #10)	RtC	Can you please help to clarify? I don't understand why the date/time of request would be important to review and verify before distribution/issue. At the time of final distribution/issue, subnumbers 7-9 are "recorded" rather than "reviewed and verified."	Yes	As presented in the proposed edition, the committee had submitted the standard as, “Date(s) and time(s) of request and issue.” Based on this comment and others, the committee reverted the language to the 11th edition with the edit to pluralize the entry.
5.22.1, #10 (5.24.1, #10)	RtC	Please clarify which “request” date/time you’re referring to, i.e., is it the date/time of order (if yes, then why would the literal date/time bring value to the issue process, rather than just the presence of the request), or do you mean the date/time requested for issue (if yes to this, then it is problematic to request the time, as time is figured out via many different routes/variables and is not on the original clinical provider request, but determined by the cell therapy lab).	Yes	As presented in the proposed edition, the committee had submitted the standard as, “Date(s) and time(s) of request and issue.” Based on this comment and others, the committee reverted the language to the 11th edition with the edit to pluralize the entry.
5.22.2, #6 (New)	SC	NA	NA	The committee added subnumber 6 to the edition for completeness. This closes the circle of what needs to be included for the distribution of allogeneic products. The standard reads as follows: **5.22.2** 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 the chain of custody: 6) A statement that the product was stored under the applicable environmental conditions as outlined in the instructions. Standard 7.2.6.2 applies.

5.22.2, #6 (New)	RtC	This is covered under 5.21 referencing 4.1.3 and 4.2.5. We are already required to include storage excursions in the information accompanying each distributed product. Wouldn't this statement need to be qualified by exception if there are excursions? Is this standard linked to a specific regulatory requirement?	Yes	The committee reviewed this comment and agreed with the intent. As presented in the proposed edition, the term "appropriate" was included, which was replaced with "applicable" and an additional crossreference to standard 7.2.6.2 was included for completeness, focusing on the release of nonconforming products.
5.22.4 (New)	SC	NA	NA	The committee added new standard 5.22.4 to the edition for completeness. The standard was added to ensure that facilities that have products returned identify those products and follow the requirements in subnumbers 1 – 4 prior to any potential reissue. The committee felt that there was a gap by not having a requirement focused on the return of a cellular therapy product. The standard reads as follows: **5.22.4 Return of Cellular Therapy Products** The facility shall have a policy for the return of cellular therapy products that includes: 1) The reason for the return of the cellular therapy product. 2) Inspection of the product for the following elements that can affect product quality, including, but not limited to: a) Maintenance of appropriate storage and transportation conditions. b) Integrity of the product container closure. c) Traceability and chain of custody of the cellular therapy product. d) Product expiration date and time 3) Determination of the acceptability and disposition of the product, such as reissue, storage, further manufacturing, or discard. 4) Notification and consultation with the patient's physician or other relevant parties, as applicable.
5.22.5 (New)	SC	NA	NA	The committee added new standard 5.22.5 to the edition to ensure that facilities that are reissuing

				returned products to inventory have to follow the 4 subnumbers to ensure that the safest possible product is reissued. The standard reads as follows: **5.22.5 Reissue of Cellular Therapy Products** The facility shall have a policy for the reissue of cellular therapy products that includes: 1) Criteria for reissue eligibility. 2) An approval process, including authorization from the laboratory director in consultation with the patient's physician or other relevant parties, as applicable. 3) Maintenance of traceability and chain of custody. 4) Product preparation for reissue, including label verification. Standard 5.22 applies.
5.23 (5.25)	SC	NA	NA	The committee added the clause, "…and chain of custody" for completeness. The standard reads as follows: **5.23 Clinical Program** The facility shall have policies, processes, and procedures for patient care, including the administration of specific therapies and medical interventions while maintaining the chain of identity and chain of custody.
5.23.2 (5.25.2)	SC	NA	NA	The committee added the clause "including" in the standard to expand the scope of the communication requirements beyond just when responsibility changes for patient care. The standard reads as follows: **5.23.2** The facility shall ensure that orders and responsibility for the provision of patient care are defined and communicated, including whenever responsibility changes.
5.26.2, #5 (5.28.2, #5)	SC	NA	NA	The committee added the clause, "…including container closure and integrity…" for completeness. The standard reads as follows:

<table>
<tr><td></td><td></td><td></td><td></td><td>5.26.2 The clinical facility shall review and verify the following items at the time of final cellular therapy product receipt:
5) Product condition by visual inspection, including container closure and integrity.
Standard 4.1 applies.</td></tr>
<tr><td>5.27.5, #2 (New)</td><td>SC</td><td>NA</td><td>NA</td><td>The committee added new subnumber 2 requiring that patient records include the “order for administration” for completeness. The standard reads as follows:
5.27.5 Patient Records
Patient records shall include the following:
2) Order for administration.</td></tr>
<tr><td>5.6.2A, #7 (New)</td><td>SC</td><td>NA</td><td>NA</td><td>The committee added new entry 7 for completeness. The entry adds a row for “unique, traceable, chain of identity identification.” This mirrors the requirements for ISBT labeling that are currently in use by accredited facilities and appear in other sections of the Standards.
The entry reads as follows:
<table>
<tr><td>7</td><td>Unique, traceable, chain of identity identification</td><td>P</td><td>P</td><td>P</td><td>P</td></tr>
</table>
</td></tr>
<tr><td>5.10B, II (5.12B, II)</td><td>SC</td><td>NA</td><td>NA</td><td>The committee added the new entry to the reference standard for completeness, recognizing xenotransplantation is conducted by AABB accredited laboratories.
The entry reads as follows:
<table>
<tr><td>II. Clinical Evaluation to Protect</td><td></td></tr>
</table>
</td></tr>
</table>

<table>
<tr><td></td><td></td><td></td><td></td><td>
<table>
<tr><td>the Safety of the Recipient[3]</td><td></td></tr>
<tr><td>Risk of transmission of infectious agents to others by product collection, processing, storage, or handling, including those associated with xenotransplantation</td><td>Yes</td></tr>
</table>
</td></tr>
<tr><td>5.10B, II
(5.12B, II)</td><td>SC</td><td>NA</td><td>NA</td><td>
Based on additions of the guidances added to standard 5.10.2.10, reference standard 5.10B has added an entry surrounding the need to perform a risk assessment of patients for potential exposure to Mycobacterium tuberculosis.
This includes footnotes to the guidances noted.
The entry reads as follows:
<table>
<tr><td></td><td>Required (Yes/No)[1]</td></tr>
<tr><td>History and behavioral risk for exposure to the following infectious agents or diseases[3]:</td><td></td></tr>
<tr><td>Sepsis[7]</td><td>Yes</td></tr>
<tr><td>Mycobacterium tuberculosis (Mtb)[8]</td><td>Yes</td></tr>
</table>
[7] FDA Guidance for Industry, January 2025, “Recommendations to Reduce the Risk of Transmission of Mycobacterium tuberculosis (Mtb) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)”
[8]FDA Guidance for Industry, January 2025, “Recommendations to Reduce the Risk of Transmission of Disease Agents Associated with Sepsis by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)”
</td></tr>
</table>

<table>
<tr>
<td>5.10D, II
(5.12D, II)</td>
<td>SC</td>
<td>NA</td>
<td>NA</td>
<td>The committee added the new entry to the reference standard for completeness, recognizing xenotransplantation is conducted by AABB accredited laboratories.
The entry reads as follows:
<table>
<tr><td>II. Clinical Evaluation to Protect the Safety of the Recipient[3]</td><td></td></tr>
<tr><td>Risk of transmission of infectious agents to others by product collection, processing, storage, or handling, including those associated with xenotransplantation</td><td>Yes</td></tr>
</table>
</td>
</tr>
<tr>
<td>5.10D, II
(5.12D, II)</td>
<td>SC</td>
<td>NA</td>
<td>NA</td>
<td>Based on additions of the guidances added to standard 5.10.2.10, reference standard 5.10D has added an entry surrounding the need to perform a risk assessment of patients for potential exposure to Mycobacterium tuberculosis.
This includes footnotes to the guidances noted.
The entry reads as follows:
<table>
<tr><td></td><td>Required (Yes/No)[1]</td></tr>
<tr><td>History and behavioral risk for exposure to the following infectious agents or diseases[3]:</td><td></td></tr>
<tr><td>Sepsis[7]</td><td>Yes</td></tr>
<tr><td>Mycobacterium tuberculosis (Mtb)[8]</td><td>Yes</td></tr>
</table>
[7] FDA Guidance for Industry, January 2025, “Recommendations to Reduce the Risk of</td>
</tr>
</table>

<table>
<tr><td></td><td></td><td></td><td></td><td>Transmission of Mycobacterium tuberculosis (Mtb) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)”
[8]FDA Guidance for Industry, January 2025, “Recommendations to Reduce the Risk of Transmission of Disease Agents Associated with Sepsis by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)”</td></tr>
<tr><td>5.10E, II
(5.12E, II)</td><td>SC</td><td>NA</td><td>NA</td><td>The committee added the new entry to the reference standard for completeness, recognizing xenotransplantation is conducted by AABB accredited laboratories.
The entry reads as follows:
<table>
<tr><td>II. Clinical Evaluation to Protect the Safety of the Recipient[3]</td><td></td></tr>
<tr><td>Risk of transmission of infectious agents to others by product collection, processing, storage, or handling, including those associated with xenotransplantation</td><td>Yes</td></tr>
</table></td></tr>
<tr><td>5.10E, II
(5.12E, II)</td><td>SC</td><td>NA</td><td>NA</td><td>Based on additions of the guidances added to standard 5.10.2.10, reference standard 5.10E has added an entry surrounding the need to perform a risk assessment of patients for potential exposure to Mycobacterium tuberculosis.
This includes footnotes to the guidances noted.
The entry reads as follows:
<table>
<tr><td></td><td>Required (Yes/No)[1]</td></tr>
<tr><td>History and behavioral risk for exposure to the</td><td></td></tr>
</table></td></tr>
</table>

				<table><tr><td>following infectious agents or diseases[3]:</td><td></td></tr><tr><td>Sepsis[7]</td><td>Yes</td></tr><tr><td>Mycobacterium tuberculosis (Mtb)[8]</td><td>Yes</td></tr></table> [7] FDA Guidance for Industry, January 2025, "Recommendations to Reduce the Risk of Transmission of Mycobacterium tuberculosis (Mtb) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)" [8]FDA Guidance for Industry, January 2025, "Recommendations to Reduce the Risk of Transmission of Disease Agents Associated with Sepsis by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)"
5.15C , 5, b (5.17C)	SC	NA	NA	The committee added the clause "purity" to entry #5 for completeness which mirrors additional edits made to the edition. The entry reads as follows: The following processing tests shall be performed on each cellular therapy product at defined steps during processing: 5) Other assays: b) Relevant purity and potency assay(s) shall be defined by the facility.
6.1	SC	NA	NA	The committee revised standard 6.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.1 Document Control** The organization shall control all documents that relate to the requirements of these BB/TS Standards. Documents shall be protected from unauthorized access and accidental or unauthorized modification, deletion, or destruction.
6.1.1	SC	NA	NA	The committee revised standard 6.1.1 based on updates to the AABB Quality System Essentials. The standard reads as follows:

				6.1.1 Format Documents shall be in standardized formats. Additional policies, processes, and procedures (such as those in an operator's manual or published in the AABB Technical Manual) may be incorporated by reference.
6.1.3 (6.1.3, 6.3.1.1)	SC	NA	NA	The committee revised standard 6.1.3 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.1.3 Document Changes** Changes to documents shall be reviewed and approved by an authorized individual.
6.1.9 (New)	SC	NA	NA	The committee added standard 6.1.9 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.1.9** The organization shall use only current and valid documents. Applicable documents shall be available at all locations where activities essential to meeting the requirements of these CT Standards are performed.
6.1.9 (New)	RtC	cGMP sterile class (class C above) does not allow documentation activity inside cleanroom for sterile process where essential activities are carried out which is also subjected to inspection by the Competent Authority. Suggest the following edit: The organization shall use only current and valid documents. Applicable documents shall be available at all locations where activities essential to meeting the requirements of these CT Standards are performed, subject to applicable Competent Authority and current good manufacturing practice (cGMP) requirements.	No	The committee reviewed this comment but did not feel that a change was needed at this time. The committee felt that the issues raised would be addressed in guidance. Of note, the feedback is discussed in standard 1.1, #3.
6.2 (6.2, 6.2.1)	SC	NA	NA	The committee revised standard 6.2 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.2 Record Control** The organization shall maintain a system for identification, collection, indexing, accessing, filing, storage, maintenance, and disposition of original records.

6.2.1 (New)	SC	NA	NA	The committee added standard 6.2.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.2.1 Records** Records shall be complete, retrievable in a period appropriate to the circumstances, and protected from accidental or unauthorized destruction or modification.
6.2.5.1 (New)	SC	NA	NA	The committee added standard 6.2.5.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.2.5.1** Changes to records (including electronic records) shall be verified for accuracy and completeness.
6.2.8	SC	NA	NA	The committee revised standard 6.2.8 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.2.8 Confidentiality** The organization shall ensure the confidentiality of records.
6.3	SC	NA	NA	The committee revised standard 6.3 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.3 Electronic Records** The organization shall support the management of information systems.
6.3.1.1 (6.3.1)	SC	NA	NA	The committee revised standard 6.3.1.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.3.1.1** The authorization to access and release data and information shall be defined, and individuals authorized to enter, change, and release results shall be identified.
6.3.2.1	SC	NA	NA	The committee revised standard 6.3.2.1 based on updates to the AABB Quality System Essentials. The standard reads as follows:

				6.3.2.1 Data shall be accurately, reliably, and securely sent from the point of entry to final destination.
6.3.2.2.1	SC	NA	NA	The committee revised standard 6.3.2.2.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.3.2.2.1** The organization shall archive records or data from media and platforms no longer in use.
6.3.3	SC	NA	NA	The committee revised standard 6.3.3 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.3.3 Storage Media** Data storage media shall be protected from damage or unintended access and destruction.
6.3.4	SC	NA	NA	The committee revised standard 6.3.4 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.3.4 Backup Data** The organization shall back up all critical data.
7.0	SC	NA	NA	The committee revised standard 7.0 based on updates to the AABB Quality System Essentials. The standard reads as follows: **7.0 Deviations, Nonconformances, and Adverse Events** The organization shall capture, assess, investigate, and monitor failures to meet specified requirements. The responsibility for review and authority for the disposition of nonconformances shall be defined. These events shall be reported in accordance with specified requirements and to outside agencies as required.*
7.1	SC	NA	NA	The committee revised standard 7.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **7.1 Deviations**

				The organization shall capture, assess, investigate, and report events that deviate from accepted policies, processes, or procedures. The assessment shall ensure timely and appropriate clinical management of the recipient, if applicable.
7.2	SC	NA	NA	The committee revised standard 7.2 based on updates to the AABB Quality System Essentials. The standard reads as follows: **7.2 Nonconformances** Upon discovery, nonconforming products or services shall be evaluated and their disposition determined.
7.2.1 (New)	SC	NA	NA	The committee added standard 7.2.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **7.2.1** Nonconforming products shall be quarantined and/or destroyed.
7.2.2	SC	NA	NA	The committee revised standard 7.2.2 based on updates to the AABB Quality System Essentials. The standard reads as follows: **7.2.2** The unintended distribution or use of products or services that do not conform to specified requirements shall be prevented.
7.2.3 (New)	SC	NA	NA	The committee added standard 7.2.3 to the edition mirroring a standard in the 34th edition of Standards for Blood Banks and Transfusion Services. The standard reads as follows: **7.2.3** The organization shall: 1) Identify, quarantine, retrieve, recall, and determine the disposition of nonconforming products. 2) Identify and manage nonconforming products or services.
7.2.4 (New)	SC	NA	NA	The committee added standard 7.2.4 to the edition mirroring a standard in the 34th edition of Standards for Blood Banks and Transfusion Services. The standard reads as follows:

				7.2.4 Released Nonconforming Products or Services Products or services that are determined after release not to conform to specified requirements shall be evaluated to determine the effect of the nonconformance on the quality and/or safety of the product or service.
7.2.4.1 (New)	SC	NA	NA	The committee added standard 7.2.4.1 to the edition mirroring a standard in the 34th edition of Standards for Blood Banks and Transfusion Services. The standard reads as follows: **7.2.4.1** Records shall include the disposition of the nonconforming product or service, the rationale, and the name(s) of the individual(s) responsible for the decision.
7.2.4.1.1 (7.2)	SC	NA	NA	The committee has added new standard 7.2.4.1.1 for completeness, though concepts appeared in 7.2. This mirrors requirements set forth by national requirements and accreditation requirements. The standards reads as follows: **7.2.4.1.1** The records shall include a description of nonconformances and any subsequent actions taken.
7.2.6.1, #1 (7.2.2.1, #1)	SC	NA	NA	The committee edited the language in the introduction sentence and subnumber 1 for clarity but the intent of the standard has not changed. The standard reads as follows: **7.2.6.1** A nonconforming material or product shall be managed in one of the following ways: 1) Modified to meet the specified requirements.
7.2.6.2 (7.2.2.2)	SC	NA	NA	The committee added the clause, "…and other relevant facility defined personnel, including quality representative" to the standard for completeness. The committee noted that there are more individuals that can release a nonconforming product, however the medical

				director would retain ultimate responsibility for all actions and decisions. The standard reads as follows: **7.2.6.2 Authorized Release of Nonconforming Products** A nonconforming product shall be released by exception only when there is a documented clinical need for the product and when approved by the relevant medical director and other relevant facility-defined personnel, including a quality representative. Standard 5.20.1 applies.
7.2.6.2 (7.2.2.2)	RtC	If the intent is that the Medical Director can delegate authority to other facility defined personnel to release nonconforming product (as indicated in the committee comments), that is not what is said here (i.e., the term "and" implies the MD approval itself is required in addition to the delegated individuals and quality). We recommend updating the highlighted "and" to "and/or" with reference to 5.20.1. Please also clarify if this is intended to apply to licensed biologicals and IND manufactured and released for storage/administration to our site?	No	The committee reviewed the comment but did not feel that a change was needed at this time. The committee noted that the designee requirements are covered in chapter 1. Regarding the query surrounding IND, if it is nonconforming, it is no longer licensed. We also have a requirement for the urgent medical need for the release of nonconforming product in the standards.
7.3.6 – 7.3.6.1.2 (New)	SC	NA	NA	The committee added new standards 7.3.6 – 7.3.6.1.2 for completeness. These standards were based on existing standards in the Standards for Blood Banks and Transfusion Services, 34th edition. The standards read as follows: **7.3.6 Communicable Diseases** **7.3.6.1 Reporting of Communicable Diseases** The administering facility shall have a defined process to evaluate and report communicable disease transmission by cellular therapy products. The process shall include the following (Standard 5.10.2.8 applies): **7.3.6.1.1** Prompt investigation of each event by the appropriate medical director or

				designee. **7.3.6.1.2** If transmission is confirmed or not ruled out, the identity of the implicated cellular therapy product(s) shall be reported to the collecting facility, supplier, or manufacturer.
7.4.1 (New)	SC	NA	NA	The committee added new standard 7.4.1 to the edition to ensure that facilities that share reporting responsibilities of deviations, nonconformances and adverse events define responsibility through agreement. This would include the roles of both parties in reporting. The standard reads as follows: **7.4.1** When more than one facility is responsible for the reporting of deviations, nonconforming products, and adverse events, the responsibility to share results of any subsequent investigation(s) shall be defined by agreement.
8.0	SC	NA	NA	The committee revised standard 8.0 based on updates to the AABB Quality System Essentials. The standard reads as follows: **8.0 Internal and External Assessments** The organization shall conduct assessments of operations and quality systems.
8.1	SC	NA	NA	The committee revised standard 8.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **8.1 Internal Assessments** The organization shall conduct internal assessments. Internal assessments shall be performed by personnel independent of those having direct responsibility for the activity being assessed.
8.4 (8.5)	RtC	In the light of some of the issues that have come up recently with some of our facilities, would it be possible to consider inventory audits and audits of the providers of services and product to ensure requirements are met?	No	The committee reviewed this comment but did not feel that a change was needed at this time. The committee noted that standard 5.9 already covers what is requested in the comment.

8.4.1 (New)	SC	NA	NA	The committee added standard 8.4.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **8.4.1** The organization shall provide data generated to the personnel who have responsibility for the quality indicator data collected.
9.0	SC	NA	NA	The committee revised standard 9.0 based on updates to the AABB Quality System Essentials. The standard reads as follows: **9.0 Process Improvement** The organization shall collect data, perform analysis, and follow up on issues requiring corrective and preventive action, including near-miss events.
9.1, #1 (New)	SC	NA	NA	The committee added subnumber 1 to standard 9.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **9.1 Corrective Action** The organization shall have a process for corrective action that includes: 1) Description of the event.
9.1.1 (9.1, #2)	SC	NA	NA	The committee revised standard 9.1.1 based on updates to the AABB Quality System Essentials, which includes some verbiage from standard 9.1 in the previous edition. The standard reads as follows: **9.1.1** Investigation and corrective action shall include consideration of deviations, nonconformances, and complaints.
9.2, #1	SC	NA	NA	The committee revised standard 9.2, #1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **9.2 Preventive Action** The organization shall have a process for preventive action that includes:

				1) Analysis of appropriate sources of information to detect, analyze, and eliminate potential causes of nonconformances.
9.2, #4 (New)	SC	NA	NA	The committee added new subnumber 4 to standard 9.2 for completeness. The entry reads as follows: **9.2 Preventive Action** The organization shall have a process for preventive action that includes: 4) Risk assessment and mitigation strategies at defined intervals.
10.0	SC	NA	NA	The committee revised standard 10.0 based on updates to the AABB Quality System Essentials. The standard reads as follows: **10.0 Facilities and Safety** The organization shall ensure safe environmental conditions. The work area shall be suitable for the activities performed. Safety programs shall meet local, state, and national regulations.
10.1	SC	NA	NA	The committee revised standard 10.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **10.1 Safe Environment** The organization shall minimize and respond to environmentally related risks to the health and safety of all individuals and products or services. Suitable quarters, environment, and equipment shall be available to maintain safe operations.
10.1.4 #3 (10.2.1, #3)	SC	NA	NA	The committee edited standard 10.1.4 for completeness and clarity through the inclusion of the clause, “Monitors cleaning or sanitation processes to…” The standard reads as follows: **10.1.4 Environmental Controls** The facility shall design, approve, and implement an environmental control system that:

				3) Monitors cleaning or sanitation processes to minimize and mitigate contamination or accidental exposure to infectious disease agents.
10.1.4	RtC	Add a record requirement for this item...specifically for #3 to be in compliance with 21 CFR 1271.190(d)(2). Additionally, add a record retention requirement as required by this same CFR. GMP, GTP, GLP -- Can we add verbiage, definitions, guidance, etc. that instructs our members that if they adhere to the standards, then they are adhering to these? Many of our facilities are trying to adhere to EU directives because they are doing business in the EU. I did a crosswalk from the directives to the 11th edition of the standards. Can we add standards to address the gaps so that if our facilities adhere to the standards, then they also meet the EU directives? I will send the crosswalk and the directives to the standards email.	Yes	The committee reviewed this comment and agreed, adding a record retention requirement to subnumber 3 to address this request.
10.2 (New)	SC	NA	NA	The committee added standard 10.2 based on updates to the AABB Quality System Essentials. The standard reads as follows: **10.2 Biological, Chemical, and Radiation Safety** The organization shall monitor adherence to biological, chemical, and radiation safety standards and regulations.
10.3 (New)	SC	NA	NA	The committee added standard 10.3 based on updates to the AABB Quality System Essentials. The standard reads as follows: **10.3 Handling and Discarding of Biological Materials** Biological materials shall be handled and discarded in a manner that minimizes the potential for human exposure to infectious agents.
Glossary – Cellular Starting Materials (CSM)	SC	NA	NA	The committee edited the glossary entry for Cellular Starting Materials for accuracy and to reflect the updates since the release of the previous edition. The glossary entry reads as follows:

				Cellular Starting Material (CSM): Initial or raw biological material from cells, tissue, or organs that may be further manipulated through various techniques such as processing, selection, expansion, gene-editing, and other combinations of engineering for therapeutic benefit.
Glossary - Handling	SC	NA	NA	The committee created this definition for completeness reflecting the content of standard 5.1.9. The glossary entry reads as follows: **Handling:** The various operations involved in the preparation, processing, and movement of materials and products. This includes actions such as receiving, transporting, unpacking, sorting, and preparing items for manufacturing or further distribution.
Glossary – Human Subject Research	SC	NA	NA	The committee created this definition for completeness reflecting the content of standard 1.10. The glossary entry reads as follows: **Human Subject Research:** Refers to any study, investigation, or experiment that involves the collection, use, analysis, or dissemination of data obtained from living individuals.
Glossary - Procuremen t	SC	NA	NA	The committee edited the definition of procurement to include "cellular starting material" for completeness. The glossary entry reads as follows: **Procurement:** The act of obtaining a cellular therapy product(s) or cellular starting material from a donor by facility-approved methods, including, but not limited to, apheresis, marrow harvest, cord blood or gestational material collection, or organ or tissue harvesting from a donor.
Glossary - Stakeholder	SC	NA	NA	The committee created this definition for completeness reflecting the content of standard 1.8.

				The glossary entry reads as follows: **Stakeholder:** An individual, group, or organization that has an interest or concern in activities performed by a facility accredited by AABB, or as defined through an agreement of two or more parties.