Summary of Changes

Ninth Edition FACT-JACIE International Standards for Hematopoietic Cellular Therapy

This document summarizes the changes in the Ninth Edition *FACT-JACIE International Standards for Hematopoietic Cellular Therapy*. This summary does not include all changes, such as minor or verbiage changes, or clarifications that do not alter the intent of the Standards. Many of the revisions to the Standards were influenced by advances in the field of cellular therapy as determined by the Standards Committee.

Important content changes addressed in this new edition include:

- A single collection section was created which includes apheresis, marrow, and other tissue sources. This structural reorganization aimed at enhancing clarity, consistency, and applicability across diverse collection methodologies ensures that all Collection Facilities can be assessed against a unified set of requirements.
- Processing Facility Director qualifications were edited to create a pathway for an individual who does not hold a doctoral level degree to serve in this position. Refer to "Advanced Degree," D3.1.1 below.
- Audit Standards were added to provide clarity on what is required in an audit plan and audit report. Additionally, Standards were added which require audits in response to occurrences. Refer to the changes related to audits, B4.8, C4.8, and D4.8 below.
- Labeling recommendations were added to Parts C and D related to collections intended for further manufacturing in accordance with ICCBBA standard ST-018. Refer to C7.1.3 and D7.1.3 below.
- Risk Evaluation and Mitigation Strategy (REMS) requirements were eliminated by the FDA, and various Clinical Program Standards were deleted or edited in response. Refer to B7.9.2.1 below.

This document is organized into five sections that correspond to the sections in the Standards. Part A identifies concepts present throughout the Standards, including a new tenet and new or revised definitions. Part B provides details regarding changes made to the Clinical Standards, Part C details changes made to the Collection Standards, and Part D details changes made to the Processing Standards. Finally, changes to the Appendices are noted in the last table. Each table includes the impacted Standard(s) and an explanation of the change.

PART A: TERMINOLOGY, TENETS, ABBREVIATIONS, AND DEFINITIONS	
A2: Tenets	
Item	**Explanation**
A2.2	New tenet added to address changes in the use of the word "accreditation" within JACIE programs.
A4: Definitions	
Item	**Explanation**
Acuity	New term to define the severity of a patient's illness or condition.
Accreditation cycle	Revised to reflect the new co-publishing relationship with JACIE and international certification.
Advanced Degree	New term defines the education and experience requirements for the Processing Facility Director.
Assent	New term defines the expression of approval or agreement by a minor.
Available for distribution	New term defines when the cellular therapy product may leave the control of the facility.
Cellular therapy	Revised to broaden the scope of the definition.
Clinical Site	New term defines the physical location where a patient or donor receives care.
Collection Facility	Previously "Collection Service," revised for clarification.
Collection Site	New term defines the physical location where cells are collected.
Consent	New term defines the process where a healthcare professional educates a patient about the risks, benefits, and alternatives of a given procedure or intervention.
Deviation	Revised for clarification.
DNV	New term defines an accreditation program which addresses regulatory requirements for hospitals or provides guidance and best practices for clinical specialty organizations.
Fellow	New term defines a physician in a training program in a medical subspecialty.
Fresh	New term defines a product that has not been cryopreserved.
Genetically modified cell	Revised for clarification.
Good Manufacturing Practice (GMP)	Revised to provide clarity on examples of products that are controlled under GMP regulations and state where the current regulations can be located.
Hemodilution	New term defines a decreased concentration of cells and solutes in the blood.
Human cells, tissues, and cellular and tissue-based products (HCT/Ps)	New term defines materials containing or consisting of human cells or tissues.
Immune effector cell	Revised for clarification.

PART A: TERMINOLOGY, TENETS, ABBREVIATIONS, AND DEFINITIONS	
A4: Definitions *(Continued)*	
Item	**Explanation**
Investigator's Brochure	New term defines a document used by investigators to facilitate their understanding of the rationale for key features of the protocol.
ISBT 128	Revised to align with the definition published by ICCBBA.
New patient	Revised for clarification.
Nosocomial infection	New term defines an infection that a patient contracts while receiving treatment for another condition in a healthcare setting.
Package insert	New term defines a document prepared by the drug manufacturer which provides drug prescribing information, details, and directions.
Preparative (conditioning) regimen	Revised for clarification.
Procedure	New term defines documents which describe the process required to perform a specific task.
Product code	Revised for clarification.
Product name	Previously "Products," revised to align with the definition published by ICCBBA. The user is referred to the ISBT Standard Terminology website for the list of product name definitions.
Risk assessment	New term defines the process of identifying potential hazards, evaluating the likelihood and severity of harm, and deciding on appropriate measures to control or eliminate the risk.

PART B: CLINICAL PROGRAM STANDARDS		
Standard(s)	**New (N) or Revised (R)**	**Explanation of Change**
B1.4	N	Requires Clinical Programs to comply with collection and processing Standards if they perform any of those functions.
B1.6.4, B1.6.5	R	Expands elements (e.g., recipient identity, certificate of analysis) to be reviewed and/or verified when products are received from a third-party provider.
B1.8–B1.8.1	N	Requires a process to qualify the sites for cellular therapy collections including Chain of Identify and criteria for each site which defines level of donor risk that can be safely managed.
B1.9	N	Requires surgically collected cellular material to be collected at an organization licensed or accredited as defined.
B2.1	R	Expands requirements of inpatient units to include protection against transmission of infectious agents and defines isolation and examination requirements.
B2.3	R	Requires care in an ambulatory setting to be appropriate location and adequate space and design to minimize risk of microbial contamination.
B2.9.1	N	Expands the current personal protective standards to include clothing to be worn upon entering and working within the work area.
B2.13	R	Provides an example of a type of renal support.
B2.16	N	Requires the use of accredited, registered, certified, or licensed laboratories.
B2.18.1	N	Recommends testing for lineage specific chimerism.
B3.1.1	R	Expands to include specialty certifications in the applicable disease area for IEC programs.
B3.2.1.1–B3.2.1.2	R,	Clarifies certification and training requirements for attending physicians.
B3.3.4.2, B3.3.4.3, B3.3.4.10, B3.3.4.22	N, R	Expands training requirements for Clinical Program Directors and attending physicians to include: • Indications for IEC therapies. • Selection of appropriate lymphodepletion regimens. • Immunomodulatory agents. • Management of immune effector cell-associated hemophagocytic lymphohistiocytosis-like syndrome (IEC-HS).
B3.3.6.3, B3.3.6.6	N	Requires attending physician's procedural knowledge to include: • Genetic modification of cells. • Therapeutic apheresis.
B3.6.2.2	R	Adds administration of lymphodepletion regimens to required nurse training.
B3.7.2.2, B3.7.2.3, B3.7.2.5	R	Clarifies pharmacist training and knowledge requirements for adverse events, drug monitoring, and dose adjustments for organ dysfunction, age, weight, and other medical conditions.

PART B: CLINICAL PROGRAM STANDARDS		
Standard(s)	**New (N) or Revised (R)**	**Explanation of Change**
B3.8.1.3, B3.8.1.19	N	Expands required Consulting Specialist to include: • Fertility. • Primary disease specialty, when applicable.
B3.9.2	R	Recommends Clinical Program Quality Manager reporting structure to be independent of clinical program operations.
B3.10.2	R	Requires five hours of continuing education by data management staff.
B3.11–B3.11.1.4	R	Expands supportive roles to require access to a service rather than designated staff.
B4.4.2.5	N	Requires Clinical Programs to document annual GxP training for key positions.
B4.5.1.1	R	Expands controlled documents to include manuals.
B4.6.2	R	Requires agreements include responsibility of the external party to provide clinically relevant information.
B4.7.2	R	Expands cellular therapy product outcomes data to include recipient diagnosis and donor type.
B4.7.3.7	R	Requires outcome analysis and product efficacy review to include monitoring of infections.
B4.8.2–B4.8.2.5	N	Lists required elements of an audit plan, including review and approval.
B4.8.3–B4.8.3.7	N	Lists required elements of an audit report, including review and approval.
B4.8.6	N	Expands Clinical Program audit requirements to include those performed as part of a risk-based approach to the follow-up of occurrences.
B4.9	N	Requires QM Plan to address management of external audits requested by commercial manufacturers or applicable regulatory agency.
B4.10.2	R	Expands notification requirements for products with positive microbial results.
B4.11.3.1	R	Expands documentation requirements for occurrences to include the unique identifier of the involved product if applicable.
B4.11.3.3	R	Expands requirements of the cumulative files of occurrences maintained to include root cause analysis.
B4.17	R	Expands requirements to include review of feedback.
B5.1.12	R	Expands the scope of cellular therapy complications to be managed.
B5.1.20–B5.1.21	N	Expands the requirements of policies or Standard Operating Procedures to include Chain of Identity and Chain of Custody.
B5.3.6	R	Expands the scope of Standard Operating Procedure to include sex, height, and weight in addition to age.
B6.1.2	N	Requires donor selection and evaluation criteria to include the requirement for the donor to be collected at a site with the ability to manage level of acuity and risks from comorbidities.

PART B: CLINICAL PROGRAM STANDARDS		
Standard(s)	**New (N) or Revised (R)**	**Explanation of Change**
B6.2.1.2	N	Expands the requirements for the collection consent to include intent of the collection for treatment or research.
B6.2.2	R	Acknowledges that consent for collection may occur in either the Clinical Program or Collection Facility. The Standard details what is required when consent is obtained by the Clinical Program.
B6.2.2.7	R	Clarifies additional parameters when the legally authorized representative needs to provide informed consent.
B6.2.2.8	N	Recommends Clinical Programs include a process to obtain appropriate assent from minor donors.
B6.3	R	Updated section title: "SUITABILITY DETERMINATION FOR ALLOGENEIC AND AUTOLOGOUS DONORS."
B6.3.2.4	N	Expands the risks of donation to be documented and evaluated to include other donor-specific risks.
B6.3.3	N	Expands suitability determination to include the provision of anesthesia requirements.
B6.3.4	N	Expands suitability determination to include requirements for the administration of mobilization agents.
B6.3.4.1	R	Requires appropriate mobilization to be used for the disease being treated and for the donor being collected.
B6.3.5-B6.3.5.2	R, N	Clarifies and expands pregnancy testing requirements.
B6.3.6	R	Clarifies requirements for hemoglobinopathy testing.
B6.3.6.1	N	Expands donor hemoglobinopathy risk assessment to include timing of the evaluation.
B6.3.10	R	Defines Collection Facility Medical Director approval for collections which do not meet donor suitability requirements.
B6.3.12.1	N	Expands management of collection-associated adverse events to include tracking and trending.
B6.4.4.1	N	Recommends hemodilution in the donor be assessed, and acceptance criteria defined prior to collection of blood samples for infectious disease testing.
B6.4.19	R	Expands allogeneic donor records requirements to include donor suitability documentation.
B7.1.2	N	Requires recipient informed consent for the therapy to be obtained prior to collection for directed donations.
B7.2.2	N	Recommends expansion for availability and suitability assessment to include obtaining information regarding the cellular therapy product from the manufacturer.

PART B: CLINICAL PROGRAM STANDARDS		
Standard(s)	**New (N) or Revised (R)**	**Explanation of Change**
B7.6.3	N	Requires safe administration policies to include preparation and administration of cellular therapy products according to manufacturer specifications.
B7.6.8	R	Requires an Investigator's Brochure and other product information be available for the safe administration of products.
B7.7.5	R	Requires monitoring of prolonged cytopenia following administration of preparative regimens and cellular products.
B7.9.2.1	R	Patient follow-up care and instructions to replace specific requirements which were previously required by REMS. Requirements such as wallet cards and other communication instructions are no longer required.
B7.11.1	R	Requires policies or Standard Operating Procedures for post-therapy vaccination schedules and indications.
B7.11.2	N	Recommends long-term follow-up to include psychosocial care.
B7.11.3.7, B7.11.3.8	N	Requires monitoring of late effects to include assessment for psychosocial needs and neurological and neurocognitive complications.
B8.3.2.6-B8.3.2.8	N	Requires informed consent for research to include whether the participant will receive compensation, study sponsor identification, and if there is a potential conflict of interest.
B9.2	R	Reflects changes to the form names required by CIBMTR and EBMT.
B9.2.2	R	Expands the requirement to collect and submit data for a minimum of one (1) year following administration.
B9.2.3.1	N	Requires programs implement a corrective action plan if data accuracy criteria are not met.
B9.3	R	Reflects changes to the form names required by CIBMTR and EBMT.
B10.1–B10.1.6	N	Defines the required elements of a record management systems.
B10.2	N	Requires defining and following good documentation practices.
B10.3	N	New section title: "RECORDS TO BE MAINTAINED."
B10.3.5-B10.3.5.1	N	Requires records allow tracking and tracing of products to include the product code and unique numeric or alphanumeric identifier(s) and be maintained for a minimum of ten (10) years.
B10.4.1.8	N	Requires the use of a defined process for use of electronic signatures with critical electronic records.
B10.4.1.12	N	Adds requirement for critical electronic record systems to include authorization, documentation, and validation.
B10.4.2	R	Clarifies scope to include only electronic record systems that are controlled by the Clinical Program.
B10.4.2.1–B10.4.2.6	N	Defines process and documentation requirements for critical electronic record systems under the control of the Clinical Program.

PART C: COLLECTION FACILITY STANDARDS		
Standard(s)	**New (N) or Revised (R)**	**Explanation of Change**
C1.5	R	Refers to Appendix V for the minimum number of cellular therapy product collections requirements.
C1.6, C1.7	N	Requires a process to qualify the sites for cellular therapy collections including Chain of Identify and criteria for each site which defines level of donor risk that can be safely managed.
C2.1.1	R	Requires the designated area for collection to include an appropriate location of adequate space and design to minimize the risk of microbial contamination.
C2.4	R	Expands the requirement to include storage areas in the written assessment of critical Collection Facility environmental parameters.
C2.9.1	N	Expands the current personal protective standards to include clothing to be worn upon entering and working within the work area.
C3.1.1	R	Clarifies the Collection Facility Director credentials.
C3.1.3.1–C3.1.3.3	R	Expands Standards defining education, experience, and continuing education requirements for the Collection Facility Director, according to collection type.
C3.2.1	R	Clarifies Collection Facility Medical Director requirements.
C3.2.1.2	R	Defines requirements for the Marrow Collection Facility Medical Director.
C3.2.1.3	N	Defines performance of procedure requirements for the Collection Medical Director for Other Tissue.
C3.2.2	R	Expands the Collection Facility Medical Director's responsibilities.
C3.3.2	R	Recommends the Collection Facility Quality Manager reporting structure to be independent of collection operations.
C3.4.3.1	R	Expands attending physician oversight responsibility to include physicians-in-training.
C4.5.1.1	R	Expands controlled documents to include protocols, manuals, and guidelines.
C4.7.2	R	Expands cellular therapy product outcomes data to include recipient diagnosis and donor type.
C4.8.2–C4.8.2.5	N	Lists required elements of an audit plan, including review and approval.
C4.8.3–C4.8.3.7	N	Lists required elements of an audit report, including review and approval.
C4.8.5.1–C4.8.5.2	R	Clarifies Collection Facility annual audit requirements for donor eligibility and suitability.
C4.8.5.5	N	Expands required Collection Facility audits to include environmental monitoring.
C4.8.6	N	Expands Collection Facility audit requirements to include those performed as part of a risk-based approach to the follow-up of occurrences.

PART C: COLLECTION FACILITY STANDARDS		
Standard(s)	**New (N) or Revised (R)**	**Explanation of Change**
C4.9	N	Requires QMP to address management of external audits requested by commercial manufacturers or applicable regulatory agency.
C4.11.3.1	R	Expands documentation for occurrences to include the unique identifier of the involved product, if applicable.
C4.11.3.3	R	Expanded requirements of the cumulative files of occurrences maintained to include root cause analysis.
C4.14.1	N	Requires equipment, software, supplies, reagents, and facilities used for cellular therapy product collection procedures to be qualified.
C4.14.4	R	Expands qualification requirements to include review and approval of conclusions.
C4.17	R	Expands requirements to include review of feedback.
C4.19	R	Clarifies responsibility for review of the effectiveness of the QM Program annually.
C5.1.4	R	Expands the scope of Standard Operating Procedure to include sex, height, and weight in addition to age.
C5.1.14, C5.1.18, C5.1.22, C5.1.23	N	Expands requirements of policies or Standard Operating Procedures to include: • Cellular therapy product disposal. • Environmental control. • Chain of Identity. • Chain of Custody.
C5.1.17	R	Expands cleaning and sanitation procedures to include operating rooms as applicable.
C5.3.2	R	Adds reagents as a required element to be included in each Standard Operating Procedure.
C6.1.1	N	Requires donor evaluation and management include the requirement for the donor to be collected at a site with the ability to manage level of acuity and risks from comorbidities.
C6.2.1.6	N	Requires donor consent to include alternative collection methods.
C6.2.5	R	Details elements needed in the consent for collection.
C6.2.6	R	Clarifies additional parameters when the legally authorized representative needs to provide informed consent.
C6.2.6.1	N	Recommends Collection Facilities include a process to obtain appropriate assent from minor donors.
C6.3.2.4	N	Expands risks of donation to be documented and evaluated to include other donor-specific risks.
C6.3.3	R	Clarifies provider requirements when anesthesia is performed.
C6.3.4.1	R	Requires appropriate mobilization to be used for the disease being treated and for the donor being collected.

PART C: COLLECTION FACILITY STANDARDS		
Standard(s)	**New (N) or Revised (R)**	**Explanation of Change**
C6.3.8	N	Requires the Collection Facility to verify that appropriate donor suitability has been determined.
C6.3.9	R	Defines the Collection Facility Medical Director's approval for collections which do not meet donor suitability requirements.
C6.3.12.1	N	Requires a process to track and trend collection-associated adverse events.
C6.4.1	R	Clarifies circumstances in which a donor advocate is required.
C6.4.2.1	N	Recommends infectious disease testing protocol to include hemodilution assessment in the donor prior to collection of blood samples.
C6.5.1	R	Expands allogeneic donor records required elements to include suitability determination.
C7.1.3	N	Recommends standardized labeling for collections for further manufacturing.
C7.3.2–7.3.2.1	N	Recommends assignment of an ISBT 128 Chain of Identity Identifier for each product or donation intended for further manufacturing and linking of all donations.
C7.3.5	N	Requires that the product donation identifier be linked when the original is replaced.
C7.4.1.1	N	Clarifies label content requirements for Apheresis collections.
C7.4.2–C7.4.2.1	R	Expands labeling requirements at the end of collection.
C7.4.7	R	Expands cellular therapy product documentation requirements for products distributed before donor eligibility determination has been completed.
C8	N	New section for Equipment, Supplies, and Reagents.
C8.1	N	Defines requirements for qualification and use of equipment, supplies, and reagents.
C8.3.3–C8.3.8	N, R	Expands requirements for inventory control.
C8.4.2	N	Defines equipment management requirements including standardizing and calibrating.
C8.5	N	Defines documentation requirements for equipment, supplies, and reagents used in procedures.
C9.4	R	Expands peripheral blood count criteria requirements prior to proceeding with collection.
C9.4.1	N	Defines requirement to meet and document peripheral blood count criteria prior to each collection.
C9.7	N	Defines requirement to verify donor identity and intended collection procedure prior to initiating the collection procedure.
C9.8	R	Expands the scope of collection methods to include sex, height, and weight in addition to age.

PART C: COLLECTION FACILITY STANDARDS		
Standard(s)	**New (N) or Revised (R)**	**Explanation of Change**
C9.9.1	N	Clarifies cellular therapy product container requirements.
C9.13	N	Defines requirement to provide a summary of all cellular therapy product records relating to the collection procedure and storage procedures to the relevant parties.
C9.14 -C14.2	N	New section outlines additional requirements specific to apheresis collection.
C9.15-C9.15.3	N	New section outlines additional requirements specific to bone marrow collection.
C9.16-C9.16.3.4	N	New section outlines additional requirements specific to other tissue collection.
C10.2	N	New section title: "STORAGE DURATION."
C10.3–C10.3.2	N	New section defining requirements for storage temperature.
C10.4–C10.4.1	N	New section defining requirement for storage monitoring.
C11.3	N	Requires establishment and maintenance of conditions for the safe transport or shipping of cellular therapy products.
C11.4–C11.4.1	N	Defines requirements for internal transport of cellular therapy products.
C11.5–C11.5.5	N	Defines requirements for cellular therapy products shipped or transported on public roads.
C11.6	R	Clarifies temperature range requirements when transporting or shipping the cellular therapy product over an extended period of time.
C11.6.1	R	Recommends using additives when shipping or transporting over a prolonged period of time.
C11.9	N	Requires the transit time of cellular therapy products to be within the time limits determined by the distributing facility and in consultation with the receiving facility.
C11.10	N	Requires a plan for alternative means of transport or shipping in an emergency.
C11.13	N	Recommends preventing products from being exposed to X-ray irradiation.
C12.1	N	Defines the elements of a record management system for cellular therapy products.
C12.3	N	New section title: "RECORDS TO BE MAINTAINED."
C12.3.1	R	Clarifies retention requirements of Collection Facility records.
C12.3.2	R	Clarifies retention requirements for validation study records.
C12.6.1.8	N	Requires a defined process for the use of electronic signatures with critical electronic records.
C12.6.1.12	N	Adds requirements for critical electronic record system modifications.
C12.6.2	R	Clarifies scope to include only electronic systems that are controlled by the Collection Facility.

PART C: COLLECTION FACILITY STANDARDS		
Standard(s)	**New (N) or Revised (R)**	**Explanation of Change**
C12.6.2.2– C12.6.2.6	N, R	Clarifies and expands process and documentation requirements for critical electronic record systems under the control of the Collection Facility.

PART D: PROCESSING FACILITY STANDARDS		
Standard(s)	**New (N) or Revised (R)**	**Explanation of Change**
D2.1.1	R	Clarifies the requirement for the processing area to be in an appropriate location of adequate space and design to minimize risk of airborne or surface microbial contamination.
D2.9.1	N	Expands the current personal protective standards to include clothing to be worn upon entering and working within the work area.
D2.11.1–D2.11.3	N	Defines oxygen sensor and alarm requirements in areas where liquid nitrogen is present.
D2.12–D2.12.1	N	Clarifies requirements for transporting and shipping collection kits.
D3.1.1	R	Expands minimum education and experience required for the Processing Facility Director to create a pathway for an individual who does not possess a doctoral level degree.
D3.1.2	R	Clarifies the scope of responsibilities of the Processing Facility Director to include technical procedures, performance of processing procedures, and supervision of staff.
D3.1.4	R	Clarifies annual training requirements for the Processing Facility Director to include quality management.
D3.2.3	R	Requires the Processing Facility Medical Director experience to include the option to perform, supervise or review processing procedures.
D4.5.1.1	R	Expands critical controlled documents to include protocols, manuals, and guidelines.
D4.7.2	R	Expands review of product and aggregate data to include recipient diagnosis and donor type.
D4.8.2–D4.8.2.5	N	Lists required elements of an audit plan, including review and approval.
D4.8.3–D4.8.3.7	N	Lists required elements of an audit report, including review and approval.
D4.8.5.3	N	Expands required Processing Facility audits to include environmental monitoring.
D4.8.6	N	Expands Processing Facility audit requirements to include those performed as part of a risk-based approach to follow-up of occurrences.
D4.9	N	Requires QMP to address management of external audits requested by commercial manufacturers or applicable regulatory agency.
D4.11.3.1	R	Expands documentation for occurrences to include the unique identifier of the involved product, if applicable.
D4.11.3.3	R	Expanded requirements of the cumulative files of occurrences maintained to include root cause analysis.
D4.11.4.1	R	Expands reporting of occurrence report investigation results.
D4.14.1	N	Requires equipment, software, supplies, reagents, and facilities used for cellular therapy product manufacturing procedures to be qualified.
D4.14.4	R	Expands qualification requirements to include review and approval of conclusions.

PART D: PROCESSING FACILITY STANDARDS		
Standard(s)	**New (N) or Revised (R)**	**Explanation of Change**
D4.17	R	Expands requirements to include review of feedback.
D5.1.20–D5.1.21	N	Expands the requirements of policies or Standard Operating Procedures to include Chain of Identity and Chain of Custody.
D6.3	R	Clarifies the requirements for inventory control that includes equipment, containers for transport and shipping, and labels.
D6.3.2.1	N	Defines requirements for quarantining supplies and reagents.
D6.3.5.1	R	Requires reagents which come into contact with the cellular therapy product to meet predetermined specifications as part of the initial qualification.
D6.3.5.2	N	Defines requirement for reagents which come into contact with the cellular therapy product to undergo a risk assessment as part of the initial qualification.
D6.4	N	Defines requirement for equipment management.
D6.4.2.2	N	Defines requirement for calibration of equipment.
D7.1.3	N	Recommends standardized labeling for collections for further manufacturing.
D7.3.2–D7.3.2.1	N	Recommends assignment of an ISBT 128 Chain of Identity Identifier for each product or donation intended for further manufacturing and the linking of all donations.
D7.4.9	N	Requires labels from third-party manufacturers to comply with the Standards and Applicable Law.
D8.1.3.1–D8.1.3.5	N	Requires established, appropriate, and validated assays and testing procedures for the evaluation of cellular therapy products, as applicable.
D8.1.4	N	Defines requirements for assay and testing procedures for cellular therapy products that must be performed.
D9.2.1	R	Clarifies the scope of products to be included in the storage conditions validation.
D9.2.1.1	N	Requires validated procedures for conditions and duration of storage for non-cryopreserved, cryopreserved, and thawed products.
D9.2.2	R	Clarifies the types of cellular therapy products which require the assignment of an expiration date.
D9.3	R	Updated section title: "STORAGE TEMPERATURE."
D9.6.3	R	Clarifies the requirements for when alarm systems are checked.
D10.6	R	Clarifies temperature range requirements when transporting or shipping cellular therapy products over an extended period of time.
D10.6.1	N	Recommends using additives when shipping or transporting over a prolonged period of time.
D10.7	N	Requires risk assessment to evaluate the need for continuous temperature monitoring during transportation or shipment of products.

PART D: PROCESSING FACILITY STANDARDS		
Standard(s)	**New (N) or Revised (R)**	**Explanation of Change**
D10.11	N	Defines requirements for accompanying records during transport and shipping of products.
D10.12	N	Requires date and time of distribution to be recorded.
D13.3.2	R	Clarifies retention requirements for validation studies.
D13.4.1.8	N	Requires use of a defined process for the use of electronic signatures with critical electronic records.
D13.4.2	R	Clarifies scope to include only electronic systems that are controlled by the Processing Facility.
D13.4.2.4, D13.4.2.5	N, R	Clarifies and expands process and documentation requirements for critical electronic record systems under the control of the Processing Facility.

APPENDICES		
Number/Name	**Topic**	**Change**
Appendix I: MINIMUM NUMBER OF NEW PATIENTS FOR ACCREDITATION	Details the number of new cellular therapy patients a program must treat prior to initial accreditation and annually thereafter.	1. Added Immune Effector Cell requirements for each location type. 2. Increased the requirements of allogeneic recipients from 5 to 10 in each applicable site for adult or pediatric programs performing both allogeneic and autologous transplants in multiple clinical sites.
Appendix II: CELLULAR THERAPY PRODUCT LABELING	1. Approximate volume 2. Anticoagulant 3. Recommended storage temperature 4. Expiration date and time	1. Partial label changed to AC 2. Partial label changed to AC 3. Partial label changed to AC 4. Expiration date and expiration time combined; Label at completion of collection added AC
Appendix V: MINIMUM NUMBER OF CELLULAR THERAPY PRODUCT COLLECTIONS	Details the minimum number of collections required for initial and continued accreditation.	New table added.