Summary of Changes

Third Edition FACT-JACIE International Standards for Immune Effector Cells

This document summarizes the changes in the Third Edition *FACT-JACIE International Standards for Immune Effector Cells*. 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 immune effector cell therapy (IEC) as determined by the Standards Committee. In addition, many programs which are accredited under the Hematopoietic Cellular Therapy (HCT) Standards also provide care using IEC therapies. Thus, intentional efforts were made to harmonize both sets of Standards. This edition will be co-published with JACIE.

Important content changes addressed in this new edition include:

- 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 Audit standards below, B4.8, C4.8, and D4.8.
- 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.
- Provisional Accreditation was added as an option for new IEC programs. Details can be found in Appendix I.
- 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 B7.9.1.1 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**
Accreditation cycle	Revised to reflect the new co-publishing relationship with JACIE and international certification.
Acuity	New term defines the severity of a patient's illness or condition.
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.
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.
Corrective action	Revised for clarification.
Deviation	Revised for clarification.
Engraftment	New term defines the reconstitution of recipient hematopoiesis with blood cells and platelets from a donor.
Fresh	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	Revised for clarification.
Immune effector cell	Revised for clarification.
ISBT 128	Revised to align with the definition published by ICCBBA.
New patient	Previously "New recipient," 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	Revised to expand the scope of regulatory authority in response to co-publishing with JACIE.
Procedure	Revised for clarification.
Product code	Revised for clarification.

PART A: TERMINOLOGY, TENETS, ABBREVIATIONS, AND DEFINITIONS	
A4: Definitions *(Continued)*	
Item	**Explanation**
Product name	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.
Suitable	Previously "Suitability," revised for clarification and to specify donor and recipient suitability.
Written	New term defines documentation in human readable form.

PART B: CLINICAL PROGRAM STANDARDS		
Standard(s)	**New (N) or Revised (R)**	**Explanation of Change**
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.
B1.7	R	Refers to Appendix I for number of new patients for accreditation requirements.
B1.8- B1.8.1	N	Requires the process to qualify the sites for cellular therapy collections include written criteria that defines level of donor risk that can be safely managed.
B1.9	R	Expands acceptable surgical collection sites to include those at organizations licensed by a regulatory agency.
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.
B2.12.1	R	Specifies that the pharmacy must have medications to treat potential complications for each recipient.
B2.13	R	Provides an example of a type of renal support.
B2.15	R	Adds requirement of defining the scope of responsibility for physicians-in-training.
B2.16	N	Requires the use of accredited, registered, certified, or licensed laboratories.
B3.2.1.1-B3.2.1.2	R, N	Clarifies and expands certification and training requirements for attending physicians.
B3.3.4.2, B3.3.4.5, B3.3.4.6, B3.3.4.8, B3.3.4.13, B3.3.4.19, B3.3.4.24	R, N	Expands training requirements for Clinical Program Directors and attending physicians to include: • Appropriate preparative regimens, including lymphodepletion regimens. • Selection of preparative regimens. • Administration of cellular therapy products, including hematopoietic progenitor cells (HPC). • Administration and management of Immunomodulatory agents. • Management of blood transfusions. • Management of immune effector cell-associated hemophagocytic lymphohistiocytosis-like syndrome (IEC-HS). • Management of prolonged cytopenia.

PART B: CLINICAL PROGRAM STANDARDS		
Standard(s)	**New (N) or Revised (R)**	**Explanation of Change**
B3.3.6.3	N	Requires Clinical Program attending physician's procedural knowledge to include genetic modification of cells.
B3.6.2.1, B3.6.2.2	N, R	Expands nurse training and experience requirements to include: • Care of patients in the therapeutic disease area. • Administration of lymphodepletion regimens.
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.
B3.8.1.13	N	Expands required Consulting Specialists to include the primary disease area, 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.
B3.11.1–B3.11.1.4	R	Expands supportive roles to require access to a service rather than designated staff.
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.
B4.7.3.3	N	Requires outcome analysis and product efficacy review to include monitoring of prolonged pancytopenia or delayed cell count recovery.
B4.7.3.4	R	Clarifies 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.
B4.8.5.7	N	Expands required Clinical Program audits to include verification of chemotherapy drugs administered against the written order.
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	R	Requires QM Plan to address management of external audits requested by commercial manufacturers or applicable regulatory agency.
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.
B5.1.10	R	Expands the scope of cellular therapy complications to be managed.
B5.1.18–B5.1.19	N	Expands the requirements of policies or Standard Operating Procedures to include Chain of Identity and Chain of Custody.

PART B: CLINICAL PROGRAM STANDARDS		
Standard(s)	**New (N) or Revised (R)**	**Explanation of Change**
B5.3.6	R	Expands the scope of Standard Operating Procedure to include sex, height, and weight in addition to age.
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	R	Clarifies 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**
B7.6.1	N	Requires safe administration policies to include preparation and administration of cellular therapy products according to manufacturer specifications.
B7.6.4	R	Requires inclusion of the unique identifier(s) for each cellular therapy product and dose(s) administered in the recipient's medical record.
B7.7.5	N	Requires follow-up after preparative regimen administration to include monitoring of prolonged cytopenia.
B7.9.1.1	R	Adds patient follow-up care and instructions to replace specific requirements previously mandated by REMS. 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.
B9.2.3	R	Recommends programs to meet the data requirements of their respective accrediting body and the CIBMTR or EBMT.
B9.2.3.1	N	Requires programs implement a corrective action plan if data accuracy criteria are not met.
B10.3	N	New section title: "RECORDS TO BE MAINTAINED."
B10.4.1.8	N	Requires the use of a defined process for use of electronic signatures with critical electronic records.
B10.4.2	R	Clarifies the scope to include only electronic record systems that are controlled by the Clinical Program.
B10.4.2.4	N	Requires critical electronic record systems under the control of the Clinical Program to authorize and validate system modifications prior to implementation.
B10.4.2.5	R	Expands process and documentation requirements for system development requirements to include verification of calculations and algorithms.

PART C: COLLECTION FACILITY STANDARDS		
Standard(s)	**New (N) or Revised (R)**	**Explanation of Change**
C1.3	R	Defines the requirement for a Collection Facility Director as part of the designated team.
C1.5	R	Refers to Appendix V for requirements for the minimum number of cellular therapy product collections.
C2	R	Section title changed to "Collection Facility."
C2.1.1	N	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.
C2.4.2	R	Defines the scope of environmental parameters to include those which are critical to be managed.
C2.4.3	N	Expands assessment of critical environmental parameters to require conditions be controlled, monitored, and recorded for air quality and surface contaminants if using collection methods that may result in contamination or cross-contamination of cellular therapy products.
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–C3.1.3.3	N	Standards defining education, experience, and continuing education requirements for the Collection Facility Director.
C3.2.1	R	Clarifies Collection Facility Medical Director requirements.
C3.2.1.1-C3.2.1.3	R	Expands Standards defining education, experience, and continuing education requirements for the Collection Facility Director, according to collection type.
C4.5.1.1	R	Expands controlled documents to include manuals.
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.
C4.9	N	Requires QMP to address management of external audits requested by commercial manufacturers or applicable regulatory agency.

PART C: COLLECTION FACILITY STANDARDS		
Standard(s)	**New (N) or Revised (R)**	**Explanation of Change**
C4.10.1	R	Clarifies requirements for whom to notify regarding positive microbial culture results.
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
C4.14.4	R	Clarifies responsibility for review and approval of qualifications.
C4.15.2.7	R	Clarifies responsibility for review and approval of validations.
C4.17	R	Expands requirements to include review of feedback.
C4.18	R	Clarifies responsibility for review of quality management activity.
C4.18.3	R	Clarifies oversight of work responsibilities for the Collection Facility Director.
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 Procedures to include sex, height, and weight in addition to age.
C5.1.7, C5.1.14, C5.1.18, C5.1.22, C5.1.23	N	Expands requirements of policies or Standard Operating Procedures to include: • Administration of blood products. • 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.
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	R	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.
C6.3.4.1	R	Requires appropriate mobilization to be used for the disease being treated and for the donor being collected.
C6.3.5	R	Clarifies pregnancy testing requirements.
C6.3.8	N	Requires the Collection Facility to verify that appropriate donor suitability has been determined.

PART C: COLLECTION FACILITY STANDARDS		
Standard(s)	**New (N) or Revised (R)**	**Explanation of Change**
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	R	Recommends infectious disease testing protocol to include hemodilution assessment of 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–C7.3.2.1	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.
C7.4.1.1	N	Clarifies label content requirements for Apheresis collections.
C7.4.2–C7.4.2.1	R, N	Expands labeling requirements at the end of the collection.
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.
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.
C9.9.1	N	Clarifies cellular therapy product container requirements.
C9.12	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–C9.14.2	N	New section outlines additional requirements specific to apheresis collection.
C9.15-C9.15.2	R, N	New section clarifies and expands additional requirements specific to bone marrow collection.
C9.16-C9.16.3.4	R	New section clarifies additional requirements specific to tissue collection.
C10.2	N	New section title: "STORAGE DURATION."

PART C: COLLECTION FACILITY STANDARDS		
Standard(s)	**New (N) or Revised (R)**	**Explanation of Change**
C10.2.1-C10.2.2	R	Clarifies requirements related to Storage Duration, including temperature.
C10.3–C10.3.2	N	New section defining requirements for storage temperature.
C10.4–C10.4.1	N	New section defining requirements 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.
C11.5.3	N	Defines requirement when shipping cellular therapy products on public roads to use an outer container that is secured to prevent unauthorized access.
C11.6	R	Clarifies temperature range requirements when transporting or shipping cellular therapy products over an extended period of time.
C11.6.1	R	Recommends using additives when shipping or transporting over a prolonged period of time.
C11.8	N	Requires transport when the recipient received high-dose therapy.
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.
C12.6.2	R	Clarifies scope to include only critical electronic record systems under the control of the Collection Facility.
C12.6.2.4-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.
D2.4.2	R	Defines the scope of environmental parameters to include those which are critical to be managed.
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.
D2.12.1	R	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.
D3.1.3	N	Defines the Processing Facility Director experience requirements.
D3.1.4	R	Clarifies annual training requirements for the Processing Facility Director to include HPC transplantation and quality management.
D3.2.3	N	Defines the Processing Facility Medical Director experience requirements.
D4.5.1.1	R	Expands critical controlled documents to include manuals.
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	Expands 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.
D4.17	R	Expands requirements to include review of feedback.

PART D: PROCESSING FACILITY STANDARDS		
Standard(s)	**New (N) or Revised (R)**	**Explanation of Change**
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.
D8.1.4, D8.1.4.2	N	Defines required assay and testing procedures for cellular therapy products that must be performed, including for HPC products intended for restoration of hematopoiesis, an assay measuring viable CD34.
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.
D9.2.3.1	N	Defines recommendation for samples to represent all processing methods and maximum storage conditions as part of a stability program.
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 shipping or transporting cellular therapy products over an extended period of time.
D10.6.1	R	Clarifies that additives are recommended 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.
D10.8	N	Requires transport when the intended recipient has received high-dose therapy.

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.
D13.1.3	R	Expands communication to include electronic formats that the Processing Facilities may use to communicate the tracking system and requirement for tracking the product at or before the time of product distribution.
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–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 patients a program must treat with Immune Effector Cell Therapy prior to initial accreditation and annually thereafter.	New table including provisional accreditation requirements.
Appendix II: CELLULAR THERAPY PRODUCT LABELING	1. Approximate volume 2. Anticoagulant 3. Recommended storage temperature 4. Donor identifier 5. Biohazard Warning Labels 6. Expiration date and time	1. Partial label changed to AC 2. Partial label changed to AC 3. Partial label changed to AC 4. Label at distribution changed to AF 5. Label at distribution changed to AT 6. 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.