Collection Section

6th EDITION OF FACT-JACIE STANDARDS

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CM2.3.1 Critical facility parameters identified to be a risk to the cellular therapy product shall be controlled, monitored, and recorded.
PART CM

New in 6th edition

• CM5.1.5 Prevention of mix-ups and cross-contamination.
• CM5.1.12 Hygiene and use of personal protective attire.
• CM5.1.13 Emergency and disaster plan related to the marrow collection procedure.
• CM6.3.5 The Clinical Program shall inform the Collection Facility and Processing Facility of donor test results or if any testing was not performed.

• CM6.3.6 There shall be a written order from a physician specifying, at a minimum, timing and goals of collection.

• CM7.4.6 Cellular therapy products distributed for nonclinical purposes shall be labeled with the statement, “For Nonclinical Use Only.”

• CM8.15.1 Records shall identify the person immediately responsible for each significant step, including dates and times, where appropriate.
PART C

New in 6th edition

- C4.13.1 Qualification plans shall be reviewed and approved by the Apheresis Collection Facility Director or designee.

- C4.14.2 Each validation shall include:
  - C4.14.2.1 An approved validation plan, including conditions to be validated.
  - C4.14.2.2 Acceptance criteria.
  - C4.14.2.3 Data collection.
  - C4.14.2.4 Evaluation of data.
  - C4.14.2.5 Summary of results.
  - C4.14.2.6 Review and approval of the validation plan, results, and conclusion by the Apheresis Collection Facility Director or designee and the Quality Manager or designee.
• C5.1.5 SOP for administration of blood products.

• C8.3.1 All equipment with a critical measuring function shall be calibrated against a traceable standard, if available. Where no traceable standard is available, the basis for calibration shall be described and documented.
PART C

New in 6th edition

- C5.3.10 Reference to a current version of orders, worksheets, reports, labels, and forms.
- C5.4 Copies of Standard Operating Procedures relevant to processes being performed shall be readily available to the facility staff.
• C4.14.3 Changes to a process shall include evaluation of risk to confirm that they do not create an adverse impact anywhere in the operation and shall be validated or verified as appropriate.
PART CM and C

New in 6th edition

BACKUP COVERAGE OF STAFF (CM3.3.2, C3.4.1,)

- Facilities were often found to have minimal staff that was only sufficient should no staff members be absent.

- The number of trained collection personnel shall be adequate for the number of procedures performed and shall include a minimum of one designated trained individual with an identified trained backup to maintain sufficient coverage.
Apheresis Collection
C2: Apheresis Collection Facility

- C2.1 There shall be appropriate designated areas for collection of cellular therapy products, for collected products, and for storage of supplies, reagents, and equipment.

- C2.1.1 The Apheresis Collection Facility shall be divided into defined areas of adequate size to prevent improper labeling, mix-ups, contamination, or cross-contamination of cellular therapy products.

- C2.1.2 There shall be a designated area with appropriate location and adequate space and design to minimize the risk of airborne microbial contamination in outpatient units where collection is performed.
• C2.4 Critical Apheresis Collection Facility parameters that may affect cellular therapy product viability, integrity, contamination, sterility, or cross-contamination during collection, including temperature and humidity at a minimum, shall be assessed for risk to the cellular therapy product.
  • C.2.4.1 Critical facility parameters identified to be a risk to the cellular therapy product shall be controlled, monitored, and recorded.
C2: Apheresis Collection Director

- C3.1 Apheresis Collection Facility Director
  C3.1.1 There shall be an Apheresis Collection Facility Director with a medical degree or degree in a relevant science, qualified by postgraduate training or experience for the scope of activities carried out in the Apheresis Collection Facility. The Apheresis Collection Facility Director may also serve as the Apheresis Collection Facility Medical Director, if appropriately credentialed.

- C3.2 Apheresis Collection Facility Medical Director
  C3.1.1 There shall be an Apheresis Collection Facility Medical Director who is a licensed or certified physician with postgraduate training in cell collection and/or transplantation.
C2: Apheresis Collection Director

- C3.1 Apheresis Collection Facility Director
- C3.2 Apheresis Collection Facility Medical Director

Shall have performed or supervised a minimum of five (5) cellular therapy product apheresis collection procedures in the twelve (12) months preceding accreditation and a minimum average of five (5) cellular therapy product apheresis collection procedures per year within the accreditation cycle.

Shall participate in ten (10) hours of educational activities related to cellular therapy annually at a minimum.

- Continuing education shall include, but is not limited to, activities related to the field of HPC transplantation and apheresis.
C2: Apheresis Quality Manager

C3.3.1 There shall be an Apheresis Collection Facility Quality Manager to establish and maintain systems to review, modify, and approve all policies and procedures intended to monitor compliance with these Standards and/or the performance of the Apheresis Collection Facility.

C3.3.2 The Apheresis Collection Facility Quality Manager shall participate in ten (10) hours of educational activities related to cellular therapy, cell collection, and/or quality management annually at a minimum.

C3.3.2.1 Continuing education shall include, but is not limited to, activities related to the field of HPC transplantation.
C2: Apheresis Collection

Before collection

C6.2.9 Documentation of consent shall be available to the Apheresis Collection Facility staff prior to the collection procedure.

6.3.6 The Clinical Program shall inform the Collection Facility and Processing Facility of donor test results or if any testing was not performed.
C2: Apheresis Collection

Before collection

C6.3.7 Collection from a donor who does not meet Clinical Program collection safety criteria shall require documentation of the rationale for his/her selection by the transplant physician. Collection staff shall document review of these donor safety issues.

C6.3.8 There shall be written documentation of issues of donor health that pertain to the safety of the collection procedure available to the Apheresis Collection Facility staff. Collection staff shall document review of these issues prior to collection.
C8.10 If required, central venous catheters shall be placed by a licensed health care professional qualified to perform the procedure.

C8.10.1 Adequacy of central line placement shall be verified by the Apheresis Collection Facility prior to initiating the collection procedure.
C8.9 There shall be written documentation of an assessment of donor suitability for the collection procedure performed by a qualified person immediately prior to each collection procedure.
C2: Apheresis Collection

At the time of collection

C8.7 Equipment shall be inspected for cleanliness prior to each use and verified to be in compliance with the maintenance schedule daily prior to use. Equipment shall also be standardized and calibrated on a regularly scheduled basis and after a critical repair or move as described in Standard Operating Procedures and in accordance with the manufacturer’s recommendations.
C2: Apheresis Collection

At the time of collection

C8.7 A complete blood count, including platelet count, shall be performed within 24 hours prior to each subsequent cellular therapy product collection by apheresis.

C8.8 There shall be peripheral blood count criteria to proceed with collection.
C2: Apheresis Collection

At the time of collection

C8.5 Autologous and/or CMV-appropriate and irradiated blood components shall be available during the apheresis collection procedure for all donors.

C8.6 Before cell collection is undertaken, there shall be a written order from a physician specifying, at a minimum, timing and goals of collection.
C2: Apheresis Collection

During collection

C7.4 LABEL CONTENT

C7.4.1 At the end of the cellular therapy product collection, the cellular therapy product label on the primary product container and concurrent plasma container shall bear the information in the Cellular Therapy Product Labeling table in Appendix

C7.4.3 Labeling at the end of collection shall occur before the cellular therapy product bag is disconnected from the donor.
C2: Apheresis Collection

At the time of collection

C7.1 ISBT 128 CODING AND LABELING

C7.1.1 Cellular therapy products shall be identified according to the proper name of the product, including appropriate attributes, as defined in ISBT 128 Standard Terminology for Blood, Cellular Therapy, and Tissue Product Descriptions.

C7.1.2 If coding and labeling technologies have not yet been implemented, the Apheresis Collection Facility shall be actively implementing ISBT 128.
C2: Apheresis Collection During collection

C8.13 Collection methods shall employ aseptic technique so that cellular therapy products do not become contaminated during collection.

C8.16 Records shall be made concurrently with each step of collection of each cellular therapy product in such a way that all steps may be accurately traced.

C8.16.1 Records shall identify the person immediately responsible for each significant step, including dates and times, where appropriate.
C2: Apheresis Collection

After collection

C8.15 Cellular therapy products shall be packaged in a closed sterile transfer pack appropriate for blood products.

C9.2 Apheresis Collection Facilities shall establish policies for the duration and conditions of short-term storage prior to distribution to a Processing Facility or Clinical Program.

C10.2 The primary cellular therapy product container shall be placed in a secondary container that is sealed to prevent leakage.

C10.3 The cellular therapy product shall be transported and/or shipped to the Processing Facility in a validated container at a temperature defined in a Standard Operating Procedure.
C2: Apheresis Collection

After collection

C10.3.2 If the intended recipient has received high-dose therapy, the cellular therapy product shall be transported.

Shipping: The physical act of transferring a cellular therapy product within or between facilities. During shipping the product leaves the control of trained personnel at the distributing or receiving facility.

Transport: The physical act of transferring a cellular therapy product within or between facilities. During transportation the product does not leave the control of trained personnel at the transporting or receiving facility.
C8.17 There shall be a policy addressing safe administration of ECP.

C8.17.1 Before ECP is undertaken, there shall be a written therapy plan from a physician specifying the patient’s diagnosis and GVHD grade, involved organs, indication, timing of the procedure, proposed regimen, and any other factors that may affect the safe administration of ECP.
C8.17.2  The ECP procedure shall be performed according to written standard operating procedures of the facility performing the procedure appropriate for the clinical condition of the patient.

C8.17.3  A final report of the details of ECP administered shall be documented in the patient’s medical record.
Thank you very much for your attention!