

**5th Edition FACT-JACIE International Standards
for Cellular Therapy Product Collection, Processing, and Administration
Summary of Changes**

This document summarizes the changes made to the 5th edition of the *FACT-JACIE International Standards for Cellular Therapy Product Collection, Processing, and Administration*. This summary does not list all changes made to the Standards; refer to the final Cellular Therapy Standards and the accompanying Accreditation Manual for all requirements. These documents will be published on March 1, 2012 and become effective on May 31, 2012.

Changes made to the 5th edition Cellular Therapy Standards and/or its accompanying Accreditation Manual include:

1. New Marrow Collection Facility Standards
 - a. Identified as “Part CM” to avoid re-lettering other sections.
 - b. New section is not identical to either clinical or apheresis.
 - c. Some cross-references to clinical standards exist to accommodate Marrow Collection Facilities seeking independent accreditation.
2. Reorganized Accreditation Manual
 - a. Explanation: Discusses the rationale and meaning of a standard.
 - b. Evidence: Describes what an inspector may review to verify compliance. Inspectors are not restricted to these methods.
 - c. Example(s): Various ways to comply with a standard. Also includes information specific to the United States of America (U.S.) and the European Union (EU).
3. ABO/Rh Testing (B6.3.6, B6.3.7, CM6.3.6, CM6.3.7, C6.3.6, C6.3.7, D6.20)
 - a. Removed requirement for testing on the first day of collection or on the first product collected.
 - b. Removed the requirement for autologous donors.
 - c. Added testing of allogeneic recipients in clinical and collection.
 - d. Added requirement for ABO and Rh testing on two independently collected samples.
 - e. Added red cell antibody screening.
4. Critical Electronic Record Systems (C11.6, D12.2)
 - a. Scope includes systems within the control of the facilities requesting accreditation, not hospital-wide electronic record systems of which facilities have no control.
 - b. Critical systems.
 - i. The system is under the control of the facility. For example, if a pharmaceutical ordering system is managed by a pharmacy department, the collection facility is not expected to validate it.

- ii. The system is used in lieu of paper. If a paper record is generated by a system, and the paper record is verified and then maintained as the official record, this use would not be considered to be used in lieu of paper. If a paper record is generated by the system but the electronic version is the official record, then it would be considered to be used in lieu of paper.
 - iii. The system is used to make decisions. Some programs have systems that serve as data repositories for future reference, but decisions are not made with them. These would not be considered critical.
 - iv. The system performs calculations. If the system performs calculations for personnel rather than the personnel manually performing them, this would be a critical system.
 - v. The system creates and/or stores information used in critical procedures. Any system used as part of critical procedures is considered a critical system. Which procedures are critical are defined in the validation standards. C4.14.1 lists the following critical collection procedures: collection, labeling, storage conditions, and distribution. D14.1 lists the following critical processing procedures: processing, cryopreservation, labeling, storage conditions, and distribution.
5. Cord Blood Administration (B7.1.1, B7.4.1, D6.4, D6.5.2.1, D6.5.2.2)
- a. Rationale.
 - i. Documented adverse reactions.
 - ii. Theoretical risks regarding the processing and use of cord blood units by programs and facilities either unfamiliar with these products or lacking appropriate processes, supplies, reagents, equipment, and/or storage space.
 - iii. New standards apply to any type of cellular therapy product for which the standards are applicable; especially important given the increasing use of third-party products.
 - b. References.
 - i. NMDP BB-IND #7555 Safety Report (August 31, 2009).
 - ii. Health Resources Services Administration Advisory Committee on Blood Stem Cell Transplantation Meeting Summary (May 2011).
 - c. Requirements.
 - i. The clinical service must notify the Processing Facility prior to requesting a cord blood unit.

This outline provides a summary of the 5th edition Cellular Therapy Standards and does not include all changes or requirements. See the FACT-JACIE International Standards for Cellular Therapy Product Collection, Processing, and Administration for all current requirements. The 5th edition will be published on March 1, 2012.

- ii. There must be a clinical policy for determining the appropriate volume and appropriate dose of red blood cells, cryoprotectants, and other additives. Cord blood units that have not been red cell reduced must be diluted and/or washed. Double cord blood units must be administered safely prior to administration of the second unit; that is, if adverse reactions begin with the first unit, the second one should not be administered until it is known that the event was not caused by the cord blood unit.
 - iii. The Processing Facility must ensure availability of adequate storage space at the appropriate temperature.
 - iv. If the Processing Facility lacks experience with the type of product requested, personnel must obtain the manufacturer's instructions and follow these to the extent possible.
 - v. The Processing Facility should verify the processing procedures utilizing practice units similar to the cell therapy product. That is, a Processing Facility should not perform processing on a type of product (cord blood) for the first time on a unit intended for administration to a patient.
- 6. Allogeneic Donor Advocacy (B6.3.8, CM6.3.7, C6.3.8)
 - a. Reference: (Walraven et al, 2010) Family Donor Care Management: Principles and recommendations.
 - b. Requirements.
 - i. For donors who are mentally incapacitated or not capable of full consent, including minors, donor advocates should be available.
 - ii. Do not need to be routinely appointed, but should be available if concerns are raised regarding whether the best interest of these individuals are being adequately protected.
 - iii. The donor advocacy role should not be fulfilled by an individual involved in the recipient's care, but a court-appointed advocate is not required.
 - iv. Examples of donor advocates include chaplains, patient advocates, social workers, etc.
 - v. Standards are written with a "should," indicating that these are recommendations and not requirements.
 - vi. The Clinical Program and/or Collection Facility will be required to defend/justify their process(es) if an inspector cites a cellular therapy program for not making donor advocates available to this patient population.

This outline provides a summary of the 5th edition Cellular Therapy Standards and does not include all changes or requirements. See the FACT-JACIE International Standards for Cellular Therapy Product Collection, Processing, and Administration for all current requirements. The 5th edition will be published on March 1, 2012.

7. ISBT 128 Terminology (CM7.1, C7.1, D7.1)
 - a. An implementation plan for *ISBT 128* coding and labeling is now required.
 - b. The *ISBT 128* Cellular Therapy Coding and Labeling Advisory Group has provided many resources and education to help centers implement *ISBT 128* technology.
 - c. See the ICCBBA website: <http://www.iccbba.org/subject-area/cellular-therapy> for resources.
8. Other Labeling Changes (CM/C/D7.2, CM/C/D7.2.5.2, C/D7.2.11, C7.5.1, CM/C7.6.1, D7.8.1)
 - a. The labeling standards were generally reorganized to distinguish between the requirements for pre-ordered labels and print-on-demand labels.
 - b. A controlled labeling procedure that includes a verification step must be used if container label information is transmitted electronically, such as with a bar code.
 - i. This is essentially requiring facilities to have a careful process for electronically transmitting information and to double check the information rather than becoming solely dependent on the technology to work correctly.
 - ii. Additional guidance on this new requirement is expected in the near future.
 - c. Labeling of apheresis products must now occur before the bag is disconnected from the donor, whereas marrow labeling must occur before the bag is removed from the proximity of the donor.
 - d. Appendix III applies to both allogeneic and autologous products as specified.
 - e. Appendix I, Cellular Therapy Product Labeling requires the expiration date to be attached to the product rather than accompanying the product.
9. Transport on Public Roads (CM10, C10, D10, Appendix II)
 - a. Changes recognize the inherent risks of distributing cellular therapy products whether they are transported within buildings, transported on public roads (including airways), and/or shipped.
 - b. The terms “transport” and “shipping” have the same definitions as in the 4th edition.
 - c. The 5th edition includes requirements for all modes of transport, transport on public roads, and shipping.
 - d. The applicable standards and appendix were written to precisely specify when a requirement applies.
10. Appendix IV Removed (Appendix IV)

This outline provides a summary of the 5th edition Cellular Therapy Standards and does not include all changes or requirements. See the FACT-JACIE International Standards for Cellular Therapy Product Collection, Processing, and Administration for all current requirements. The 5th edition will be published on March 1, 2012.

- a. The Standards require compliance with the most recent regulatory requirements and the most current resources from some industry initiatives.
 - b. This appendix was removed from the 5th edition.
 - i. The actual links may change.
 - ii. It is more helpful to reference the sources within the applicable standards themselves.
 - 1. The specific references are now in the Standards.
 - 2. Current links can be found on the FACT website.
 - 3. Links are still present throughout the guidance document and those will be updated as much as possible.
11. Extracorporeal Photopheresis (B7.3)
- a. Extracorporeal photopheresis/photochemotherapy (ECP) is a leukapheresis-based immunomodulatory therapy used in the treatment of acute and chronic graft versus host disease (GVHD), along with other non-transplant indications involving the separation of leukocytes by apheresis followed by addition of a psoralen, usually 8-methoxypsoralen (8-MOP) and exposure to UVA light.
 - b. ECP is becoming more common in the treatment of GVHD and inspectors are encountering ECP processes during inspections.
 - c. Inspectors and facilities are reminded that ECP therapy results in the collection (and sometimes processing) of a cellular therapy product and facilities are expected to comply with collection and processing requirements as they apply.
 - d. There are different methodologies for ECP that include both closed and open circuits.
 - i. In closed systems, which are more common, collected leukocytes remain integral to the circuit of the cell separator.
 - ii. In a minority of ECP procedures, the leukapheresis product is detached at some point (e.g., for addition of psoralen and/or UV irradiation).
 - e. If ECP is a part of therapy for GVHD or other indications for BMT patients within a Clinical Program or Collection Facility applying for FACT or JACIE accreditation, the activities must meet the Standards as they apply.
 - i. It is common for patients requiring ECP to attend a hospital or unit (such as dermatology) that may have no other relationship with the Clinical Program aside from the provision of ECP.
 - ii. If ECP is performed at a site not applying for accreditation, then the Clinical Program must be able to demonstrate a robust written agreement that meets the requirements in B7.3.

This outline provides a summary of the 5th edition Cellular Therapy Standards and does not include all changes or requirements. See the FACT-JACIE International Standards for Cellular Therapy Product Collection, Processing, and Administration for all current requirements. The 5th edition will be published on March 1, 2012.

12. Quality Management (B/C/D4.2.2.4, B/C/D4.5, B/C/D4.6.2, B/C/D4.10, B/C/D4.12)
 - a. Annual report: The annual report must always be performed to take a longitudinal look at how the QM program is performing. Many programs like to incorporate this into their quarterly reports, which is acceptable so long as the report also includes at least an annual view of the QM functions. The difference is that an annual report contains data from a period of time longer than one quarter; quarterly reports can be based around minutes from the regular quality management meetings and should summarize activities such as training performed, documents reviewed, audits performed and procedures introduced or amended. They are intended to demonstrate that a quality management system is functioning and being monitored.
 - b. Document control: Anything related to document review, revision, maintenance, and archival was moved to this section. This includes some requirements from the Policies and Procedures section in the 4th edition.
 - c. Written agreements: Agreements must be dated, reviewed, and renewed regularly. This is to prevent outdated agreements and to encourage programs to review their agreements to ensure they are still in compliance with the Standards and with applicable laws and regulations.
 - d. Deviations: Programs were often cited for not performing each of the steps required for errors, accidents, deviations, and complaints. The 5th edition simply divided the standard for clarity. Many redundancies were removed.
 - e. Interruption of Operations: This requirement no longer pertains to just computer systems, but to other types of interruptions such as drug shortages, power outages, equipment failures, etc. – basically interruptions that do not rise to the level of a disaster (which is covered under the SOP requirement for disaster plans).
 - i. It is appreciated that it is difficult to anticipate every possible situation that may occur.
 - ii. The Standards do not require the program to outline actions for specific events; rather, the program is required to describe actions to take when an interruption presents, including who needs to be contacted, how to prioritize cases, and key personnel to be involved in identifying alternative steps to continue functions.
13. Policies and Procedures (B/C/CM/D5)
 - a. Clarification that policies *and* procedures are not required for every item listed in 5.1; a policy *and/or* procedure is acceptable.

This outline provides a summary of the 5th edition Cellular Therapy Standards and does not include all changes or requirements. See the FACT-JACIE International Standards for Cellular Therapy Product Collection, Processing, and Administration for all current requirements. The 5th edition will be published on March 1, 2012.

- b. The list of items that must be covered in a policy and/or procedure was updated – some items were added and some were removed.
 - c. Document control standards, such as the SOP for SOPs, standardized formats, and numbering and titling conventions, were moved to the document control substandards for quality management.
 - d. The manual must include a listing of all current SOPs so that it is clear which SOPs are in effect.
 - e. Only SOPs relevant to processes being performed must be readily available to the facility staff. That is, the entire SOP manual does not need to be present in its entirety to each staff member regardless if they perform only a few of the procedures. The procedures they do perform must be readily available.
 - f. The standard was revised to clarify that an SOP can be implemented even if all staff members have not been trained – the new requirement is that no staff member can perform the SOP until he or she has been trained.
14. Communicable Disease Testing (B6.3.1.3, B6.4.3, CM6.3.1.3, C6.3.1.3, Appendix III)
- a. Communicable disease testing of autologous donors in connection with product collection is no longer required by these Standards unless such testing is required by other applicable laws and regulations.
 - b. Testing for these disease agents is recommended as part of the autologous donor suitability assessment.
 - i. Positive findings from such assessments must still be reported to the appropriate Collection and Processing Facility to ensure that proper labeling and storage is performed.
 - ii. If not tested, the product label must include the appropriate statement and the appropriate storage conditions must be applied.
15. Other Donor Evaluation and Testing (B/C6.3.3, B/C6.3.4, B6.3.5.1, B6.4.8.2, CM6.3.3)
- a. Evaluation of risks of hemoglobinopathy (note that a test is not required).
 - b. The timing of pregnancy assessment (note that a test is not required):
Assessment must be performed within seven days preceding donor mobilization, product collection, or initiation of the preparative regimen, whichever occurs earliest.
 - c. Clinical Programs must inform the Collection and Processing Facilities of donor test results or if any testing was not performed.
 - d. Verification HLA typing must be performed using an independent sample prior to allogeneic donor selection. Per the definition of verification typing, the same level

This outline provides a summary of the 5th edition Cellular Therapy Standards and does not include all changes or requirements. See the FACT-JACIE International Standards for Cellular Therapy Product Collection, Processing, and Administration for all current requirements. The 5th edition will be published on March 1, 2012.

of resolution is not required, but the two results must be in concordance with each other before selecting the donor.

16. Donor Suitability and Conflict of Interest (B/CM/C6.2.4.1, B/CM/C6.3.1.2)

- a. Rationale.
 - i. Medical literature supports the idea that having the allogeneic donor evaluated by a physician or health care professional who is not the primary transplant provider of the recipient decreases the potential conflict of interest with regard to the welfare of the recipient and the welfare of the donor.
 - ii. See “Family Donor Care Management: Principles and recommendations,” (Walraven et al, 2010).
 - iii. The American Academy of Pediatrics (AAP) and the American Society of Blood and Marrow Transplantation (ASBMT) recommend this practice for related donations.
- b. The Standards recommend that donor informed consent and donor suitability evaluation be performed by licensed physicians or other licensed health care professionals who are not the primary transplant physician or healthcare professional overseeing the recipient.
- c. Examples of who could evaluate the donor include:
 - i. Another member of the BMT program.
 - ii. A clinician or qualified nurse who is not a member of the team.
 - iii. The donor’s primary care physician if he/she possesses knowledge of the donation procedure.
 - iv. A general internal medicine clinic or a clinic not directly associated with the Clinical Program.

17. Minimum Transplant Volumes (B1.5, B1.6)

- a. At the time of the initial application, the Clinical Program must meet the minimum number of transplants at the time of *accreditation* and not *application* as in previous editions. The change is order to encourage smaller programs to pursue accreditation and means that programs that are below or do not comfortably exceed this minimum number may apply. However, such programs must be very clear that accreditation will only be awarded when the can demonstrate that they at least meet or exceed the minimum number of transplants in the preceding 12 month period.
- b. In the fifth edition, the minimum volume is based upon the accreditation cycle.

This outline provides a summary of the 5th edition Cellular Therapy Standards and does not include all changes or requirements. See the FACT-JACIE International Standards for Cellular Therapy Product Collection, Processing, and Administration for all current requirements. The 5th edition will be published on March 1, 2012.

- i. Because FACT and JACIE accreditation cycles are different (FACT's are three years and JACIE's are four years), the Standards are written to require an average annual number.
- ii. Programs must transplant an average of ten new patients per year in the accreditation cycle for allogeneic accreditation and an average of five new patients per year in the accreditation cycle for autologous transplantation.
- iii. From FACT's perspective, for renewal accreditation, programs must transplant a minimum of 30 new patients for allogeneic/allogeneic and autologous accreditation or 15 new patients for autologous accreditation.
- iv. From JACIE's perspective, for renewal accreditation, programs must transplant a minimum of 40 new patients for allogeneic/allogeneic and autologous accreditation or 20 new patients for autologous accreditation.
- c. Also applies to programs with multiple sites and combined adult and pediatric programs.
 - i. If a clinical site only performs autologous transplantation as part of a Clinical Program seeking allogeneic and autologous accreditation, it must transplant a minimum average of five new autologous patients per year within the accreditation cycle.

18. Clinical Unit (B2.1.1.1, B2.4.1.1)

- a. The program must have written guidelines for clear communication and prompt transfer during and ongoing monitoring of the transfer of patients to an intensive care unit or equivalent coverage. Who should be transferred and when is the decision of the patient's physician.
- b. A policy for the scope of care and afterhours coverage of general medical physicians is required.
 - i. It is recognized that many hospitals are using general medical physicians, and it's also recognized that transplant physicians are not always *physically* at the hospital on a 24-hour basis (though a transplant physician must be *available* on a 24-hour basis).
 - ii. In these cases, the Clinical Program needs to outline what general medical physicians, i.e., non-transplant physicians, can and cannot do for their patients and when the transplant attending physician needs to be contacted.

19. Clinical Program Director (B3.1.1, B3.1.2, B3.1.5)

- a. Directors are required to have achieved board certification in one of the specialties listed in the Standards; Adult Immunology was removed.

This outline provides a summary of the 5th edition Cellular Therapy Standards and does not include all changes or requirements. See the FACT-JACIE International Standards for Cellular Therapy Product Collection, Processing, and Administration for all current requirements. The 5th edition will be published on March 1, 2012.

- i. Pediatric Immunology is still accepted as one of the specialties given the use of HPCs for immunological indications in pediatric patients.
 - ii. Note that attending physicians with board certification in Adult Immunology still meet the Standards, as this change is only for the Clinical Program Director.
 - b. Published contributions are no longer required for Program Directors who were trained prior to board certification being available.
 - c. Clinical Program Directors are required to have two years of experience as an attending physician responsible for the *direct* clinical management of HPC transplant patients in the inpatient and outpatient settings.
 - d. Directors must have oversight of all members of the Clinical Program and must verify the knowledge and skills of mid-level practitioners on the transplant team in addition to the physicians.
- 20. Physician Competency (B3.4.3. (2, 4, 5, 6, 14, 15, 16, 17, 19, 20, 22))
 - a. Physicians must *receive* specific training.
 - b. Physicians must *maintain* competency.
 - c. There were *many* changes to B3.4.3; programs are advised to audit their existing processes against the 5th edition.
- 21. Other Personnel (B3.5, B3.6, B3.7, B3.8, B3.9)
 - a. Mid-level practitioners.
 - i. Required to receive specific training and maintain competency in skills they routinely practice.
 - ii. The skills listed in the Standard were reduced because the other skills typically are only performed by physicians.
 - b. Nurses.
 - i. Nursing representatives on the Standards Committee made recommendations based upon the care transplant nurses actually deliver.
 - ii. There is a more comprehensive list of training requirements. Notable additions include:
 - 1. Recognizing complications and emergencies requiring rapid notification of the clinical team.
 - 2. Palliative and end of life care.
 - iii. There is also a clearer list of required nursing SOPs; one notable change is the required procedure for administration of cellular therapy products.
 - c. Consultants.

This outline provides a summary of the 5th edition Cellular Therapy Standards and does not include all changes or requirements. See the FACT-JACIE International Standards for Cellular Therapy Product Collection, Processing, and Administration for all current requirements. The 5th edition will be published on March 1, 2012.

- i. The Standards Committee believes it is acceptable to provide documentation of the program's arrangements and agreements with specialist groups of the required specialty, rather than requesting programs to submit qualifications of individual consultants.
 - ii. This documentation should be available with your hospital credentialing department if you are based in a larger institution.
 - d. QM Supervisor.
 - i. Clinical Programs should now have someone designated to serve as the QM Supervisor to establish and maintain the QM Program. If there is no QM Supervisor, the inspector will cite this as a variance and the program will need to submit an explanation to FACT.
 - ii. This does not need to be a dedicated full-time QM staff member.
 - iii. The individual can be someone who performs other duties in the program, be shared with the larger institution's QM department, or be a part-time employee.
 - e. Support Services Staff.
 - i. Support services staff must have appropriate training and education.
 - ii. Psychology was added.
22. Clinical Quality Management (B4.1, B4.2, B4.3, B4.9.5, B4.10.7, B4.13, B4.14)
- a. Clarification: The Clinical QM Program encompasses clinical, collection, and processing.
 - i. It is acceptable to have separate QM Plans for each; however, the clinical QM Plan must outline how QM data from collection and processing are incorporated into the clinical QM activities.
 - ii. Verbiage throughout B4.1 and B4.2 was changed to clarify this concept.
 - b. Competency for each critical function performed and continued competency is required to be documented for medical and nursing staff.
 - c. There must be criteria for administration of products with positive microbial culture results. It is not sufficient to say that a Clinical Program would never use these products. While this may be the case, a contingency plan is expected to be in place in case of urgent medical need.
 - d. There must be a process for obtaining feedback from patients and their representatives.
 - i. The first draft of the 5th edition required patient satisfaction surveys, which was greatly dissented upon by public comments.

This outline provides a summary of the 5th edition Cellular Therapy Standards and does not include all changes or requirements. See the FACT-JACIE International Standards for Cellular Therapy Product Collection, Processing, and Administration for all current requirements. The 5th edition will be published on March 1, 2012.

- ii. The standard was revised to require a defined process for obtaining feedback.
 - 1. It is acceptable to use a hospital-wide system if there is one.
 - 2. Surveys specific to the Clinical Program are not required as long as the program is incorporated into the larger feedback process.
 - e. Qualification and validation.
 - i. With the separation of the marrow collection standards from apheresis, the Clinical QM Standards apply to marrow collection when the marrow facility operates in conjunction with the clinical program.
 - ii. This necessitated the addition of qualification and validation to the clinical standards.
 - 1. These pertain only to the marrow collection procedure.
 - 2. For renewal accreditation, this is not a new requirement for marrow collection, and the documentation should already be present.
23. Outcome Analysis (B4.7)
- a. Overall and treatment-related morbidity and mortality must be analyzed.
 - i. 100 days post transplant.
 - ii. 1 year post transplant.
 - b. Clinical Programs must provide outcome data and adverse events to entities involved in collection, processing, and distribution of the product
24. Audits (B4.8)
- a. Clarification that the data collected based upon the TED forms must be audited for accuracy – not outcomes.
 - i. There is no standard for outcomes.
 - ii. Inspectors are only to determine if the data recorded by the program matches the primary source data.
 - iii. Audits are necessary for FACT to perform because inaccurate data are often cited. It is the hope that changing the standard to clarify the “accuracy” of the data must be audited will improve data collection.
 - b. Other audits.
 - i. Audits to determine that verification of the chemo drug and dose against the orders and protocol is performed.
 - ii. Audits verifying whether cellular therapy products with positive microbial culture results are managed appropriately.

This outline provides a summary of the 5th edition Cellular Therapy Standards and does not include all changes or requirements. See the FACT-JACIE International Standards for Cellular Therapy Product Collection, Processing, and Administration for all current requirements. The 5th edition will be published on March 1, 2012.

- iii. Recipient Day 100 treatment related mortality is no longer in the audit section because it is really an analysis of outcome.
- 25. Written Criteria for Donors (B6.1)
 - a. Clinical Programs must have written criteria for:
 - i. The selection of allogeneic donors who are minors.
 - ii. The selection of allogeneic donors when more than one is available and suitable.
 - b. Programs must give information regarding the donation process to potential allogeneic donors prior to HLA typing.
 - i. Sufficient information for allogeneic donors should be provided before the potential donor undergoes HLA typing so as to protect the potential donor from undue pressure should he/she be the only suitable donor.
 - ii. Many comments voiced concern that this could become a costly and inefficient practice if all potential donors had to undergo a consent process. This was never the intent, and for clarification, the standard was moved out of the informed consent section and was changed to a “should” standard.
 - iii. A full informational session regarding the donation process is not required to meet this standard.
 - 1. Other acceptable methods include a brochure, pamphlet, or telephone conversation.
 - 2. Information provided by unrelated donor registries may be useful sources of information.
- 26. Collection Personnel (CM3.1, CM3.2, C3.1.3.1, C3.2.3.1, C3.3)
 - a. No longer a requirement for a Marrow Collection Facility Director.
 - i. The Marrow Collection Facility Medical Director is responsible for everything he/she was responsible for under the 4th edition and is now also responsible for all technical procedures, performance of the collection procedure, supervision of staff, administrative operations, the QM Program, and compliance with the FACT Standards.
 - ii. These tasks can still be delegated, but the Marrow Collection Facility Medical Director is ultimately responsible.
 - b. The Apheresis Collection Facility Director and the Apheresis Collection Facility Medical Director must have performed or supervised a minimum of four collection procedures within the 12 months preceding accreditation and a minimum average of 4 procedures per year within the accreditation cycle.

This outline provides a summary of the 5th edition Cellular Therapy Standards and does not include all changes or requirements. See the FACT-JACIE International Standards for Cellular Therapy Product Collection, Processing, and Administration for all current requirements. The 5th edition will be published on March 1, 2012.

- i. This translates into a minimum of 12 procedures within a cycle for FACT accreditation and 16 procedures for JACIE accreditation.
 - ii. This is more than the required number under the fourth edition.
 - c. Both marrow and apheresis facilities must have a QM supervisor to establish and maintain the QM Program.
 - i. This does not need to be a dedicated full-time QM staff member.
 - ii. The individual can be someone who performs other duties in the program, be shared with the larger institution's QM department, or be a part-time employee.
27. Collection Quality Management (CM4.1, C4.7.2, C4.8.3.2)
- a. The marrow section refers the reader back to the clinical QM standards.
 - i. In most cases, the clinical QM program covers marrow collection.
 - ii. There may be cases in which a marrow facility is FACT or JACIE accredited independently of a clinical program, which necessitated the need for a standard that cross-references part B.
 - b. For products collected by apheresis not intended for hematopoietic reconstitution, criteria for efficacy or outcome must be determined and reviewed.
 - i. Product efficacy based on outcome may be more difficult to document for other TC products.
 - ii. The assessment will differ for each product type.
 - c. Apheresis Collection Facilities must now audit documentation that external facilities performing critical contracted services met the requirements of the written agreements. Critical services include those that could potentially change the identity, purity, potency, or safety of the cellular therapy product if altered or omitted. Documentation could include evidence of valid and up-to-date certification or licensing of the external facility, e.g., ISO, regulatory authorization, etc.
28. Collection Process Controls (CM/C8.2, CM/C8.2.3, C8.7, CM8.7, C8.8, CM/C8.13)
- a. The process for inventory control must encompass equipment in addition to reagents, supplies, and labels.
 - b. Supplies and reagents coming into contact with cellular therapy products during collection must be sterile and of the appropriate grade for the intended use.
 - c. Central venous catheters (CVC) can be placed by a licensed health care provider other than a physician if qualified. The same is true for the administration of mobilization agents as long as they are experienced in their administration and management of complications in persons receiving the agents.

This outline provides a summary of the 5th edition Cellular Therapy Standards and does not include all changes or requirements. See the FACT-JACIE International Standards for Cellular Therapy Product Collection, Processing, and Administration for all current requirements. The 5th edition will be published on March 1, 2012.

- d. Records must be made concurrently with each step of collection of each product in a way that all steps may be accurately traced.
29. Other Collection Changes (CM/C10.1.4, CM/C11.1)
- a. If a patient has undergone high-dose marrow ablative treatment in preparation for transplant, the facility must use a qualified courier to transport and/or ship these products.
 - b. For marrow, B10 applies and is typically covered by the Clinical Program. Marrow Collection Facilities operating independently of a Clinical Program must submit evidence of compliance with B10.
 - c. Several requirements were added to the apheresis records requirement that outline minimum guidelines for a record management system.
30. Laboratory Testing Controls (D6.1.4)
- a. Facilities that perform the testing within the facility are required to meet the same general requirements that would be required to achieve accreditation by the appropriate regulatory authority.
 - i. Use of controls.
 - ii. Calibration and standardization of reagents and equipment.
 - iii. Staff training and proficiency testing.
 - b. These requirements are only applicable to tests that are available from laboratories certified or accredited.
 - i. Includes tests such as flow cytometry testing and cell counts using a hematology analyzer.
 - ii. Requirements would not be applicable to testing such as CFU assays.
31. Expansion (D6.1.7.1, D8.1.2, D9.4.3.1)
- a. In the fourth edition, processing facilities were required to notify the recipient's physician of testing and screening results for ineligible products. Now facilities must notify the transplant physician of all nonconforming products and the physician's approval for release must be documented.
 - b. Products that were issued for administration were required to meet pre-determined release criteria prior to issue in the fourth edition, and, with the fifth edition, all products distributed from the Processing Facility, whether or not they are distributed for administration, must meet release criteria. An example of this is release to a Clinical Program for subsequent processing.
 - c. Products with incomplete donor eligibility determination were required to be quarantined in the 4th edition, and now facilities must also quarantine products that have positive infectious disease results and/or positive microbial cultures.

This outline provides a summary of the 5th edition Cellular Therapy Standards and does not include all changes or requirements. See the FACT-JACIE International Standards for Cellular Therapy Product Collection, Processing, and Administration for all current requirements. The 5th edition will be published on March 1, 2012.

- i. This does not require separate storage, and it is understood that microbial culture results are not immediately available.
- ii. The standard requires the facility to designate in some way, physically, electronically, or temporally, that the product is not to be released without the appropriate documentation.

This outline provides a summary of the 5th edition Cellular Therapy Standards and does not include all changes or requirements. See the FACT-JACIE International Standards for Cellular Therapy Product Collection, Processing, and Administration for all current requirements. The 5th edition will be published on March 1, 2012.