

Request for Public Review and Comment
Draft 5th Edition
FACT-JACIE International Standards for
Cellular Therapy Product Collection, Processing, and Administration

The Foundation for the Accreditation of Cellular Therapy (FACT) and the Joint Accreditation Committee of ISCT-EBMT (JACIE) have published the draft 5th Edition of the *FACT-JACIE International Standards for Cellular Therapy Product Collection, Processing, and Administration* for inspection and public comment for a 90-day period. Comments will be accepted from April 15, 2011 through July 14, 2011.

These Standards apply to all phases of collection, processing, storage, and administration of cellular therapy products (including hematopoietic progenitor cells and therapeutic cells) that have been derived from marrow or peripheral blood. These Standards do apply to the administration of umbilical cord and/or placental blood, but do not apply to the collection, processing, or banking of these units.

The final Standards will be published on March 1, 2012 and will become effective on May 30, 2012.

The purpose of this document is to request public review and comment on the draft 5th Edition of the *FACT-JACIE International Standards for Cellular Therapy Product Collection, Processing, and Administration*. A description of the documents available for review and a discussion of changes made to the Standards are included.

Note: This document is not an exhaustive list of changes made to the Standards. Refer to the draft Standards to review all changes.

Documents for Review

The cellular therapy community and the public at large are invited to review the following documents, which are available on the FACT and JACIE websites:

1. *FACT-JACIE International Standards for Cellular Therapy Product Collection, Processing, and Administration*, Draft 5th Edition.

This is a redline document intended to highlight the changes made to the Standards. Minor reorganizational changes are not tracked unless it was felt the reorganization was significant. We caution reviewers that not all changes affect the intent of the requirements; rather, some changes are meant to improve the clarity or verbiage of a standard.

2. *FACT-JACIE Cellular Therapy Accreditation Manual*, Draft 5th Edition.

The Accreditation Manual is published for two reasons: 1) to allow review of the new format (see Global Changes to Standards below) and 2) to provide reviewers with an

explanation of the Standards. Comments generally are not expected regarding this guidance information unless reviewers feel it contradicts a standard.

Global Changes to Standards

The following global changes were made to the documents:

1. Separation of Marrow Collection Facility requirements (Part C): Historically, a single section on collection requirements existed for both apheresis collection procedures and bone marrow harvests. Inspection results have shown that not only is marrow collection often closely associated with clinical programs, but that many requirements are outside the control of the marrow collection personnel due to the performance of the procedures in an institutional, hospital-based surgical department. Based on this experience, the Standards Committee separated marrow collection from collection by apheresis into a distinct section (see Specifically Requested Comments below).
2. Division of guidance information: The Cellular Therapy Accreditation Manual provides a significant amount of guidance information intended to explain the Standards and provide helpful tips and examples for complying with the requirements. To clarify the purpose of the information, each section of guidance is divided into the following sections as applicable:
 - Explanation: Discusses the rationale and meaning of a standard.
 - Evidence: Describes what an inspector should review to verify compliance.
 - Example(s): Provides various ways to comply with a standard, though not required.

Specifically Requested Comments

The following is a list of significant changes to the Standards for which the Standards Committee specifically requests comments. This is not an exhaustive list of changes to the Standards, and reviewers are urged to consult the *FACT-JACIE International Standards for Cellular Therapy Product Collection, Processing, and Administration*, Draft 5th Edition, for all the changes and comment as desired.

1. Marrow Collection Facility requirements (Part C): As described above, Marrow Collection Facilities now have a distinct section outlining requirements for marrow collection. Many requirements were removed because they were determined to be either accomplished by the clinical program and/or outside the scope of the marrow collection facilities. Public comments regarding the appropriateness of these changes are requested.
2. Donor requirements (B6, C6, D6): The donor sections of the clinical and collection requirements were reorganized to specify when requirements apply to allogeneic donors only or to both allogeneic and autologous donors. Public comments regarding the clarity of these requirements in terms of allogeneic versus autologous donors are requested.

3. ABO and Rh testing (B6.3.5, C6.3.5, D6.3.6, E6.18): Several changes were made to the requirement for ABO and Rh testing of donors, including: 1) removed requirement for testing on the first day of collection or on the first product collected, 2) added testing of allogeneic recipients in clinical and collection, 3) added red cell antibody screening, and 4) added requirement for testing and screening on two independently collected samples. As with all other FACT-JACIE standards, these are minimum requirements and cellular therapy programs can choose to perform more testing, more frequent testing, and test on the first day of collection. Public comments regarding the appropriateness of these changes are requested.
4. Laboratory testing controls (E6.1.4): The Standards have required processing facilities that contract with outside laboratories for testing to choose laboratories that are certified or accredited by the appropriate regulatory authority. This draft edition requires processing facilities that perform the testing within the facility to meet the same general requirements that would be required to achieve accreditation, such as the use of controls, calibration and standardization of reagents and equipment, staff training, and proficiency testing. These requirements are only applicable to tests that are available from laboratories certified or accredited, such as flow cytometry testing and cell counts using a hematology analyzer. They would not be applicable to testing such as CFU assays. Public comments regarding the addition of these requirements are requested.
5. Extracorporeal photopheresis (ECP) requirements (B7.2): Requirements to ensure the safe administration of ECP were added to the clinical program standards. ECP is becoming more common in the treatment of GVHD and inspectors are encountering ECP processes during inspections. (See the draft Cellular Therapy Accreditation Manual for more details.) In addition to these new requirements, 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. Public comments regarding the appropriateness of ECP in the Standards are requested.
6. Electronic record systems (D11.7, E12.2): As the use of electronic systems to document information and perform functions increases, questions regarding their applicability to the FACT-JACIE Standards arise. The standards in collection and processing were revised to clarify the critical systems that are within the scope of an on-site inspection and the requirements for their use. As the guidance explains, only systems within the control of the facilities requesting accreditation are within the scope of an on-site inspection; it is not the intent of the standards to regulate hospital-wide electronic record systems of which facilities have no control. Public comments regarding the clarity of the scope of electronic record systems in the Standards and the additional requirements are requested.