

Request for Public Review and Comment
Draft 7th Edition
FACT-JACIE International Standards for
Hematopoietic 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 7th edition of the [FACT-JACIE International Standards for Hematopoietic Cellular Therapy Product Collection, Processing, and Administration](#) and accompanying [Accreditation Manual](#) for inspection and public comment for a 90-day period. Comments will be accepted from May 1, 2017 through July 30, 2017.

These Standards apply to all phases of collection, processing, storage, and administration of hematopoietic cellular therapy products. This includes hematopoietic progenitor cells (HPCs), mononuclear cells (MNCs), and immune effector cells (IECs) derived from marrow, apheresis, or cord blood, and administered by a FACT-accredited blood and marrow transplant team.

The final Standards will be published on March 1, 2018 and will become effective on May 30, 2018.

The draft is a redline document intended to highlight the changes made to the Standards. Minor reorganization and clarifying changes are not tracked. Some changes are new standards; however, some are intended to clarify the intent rather than change the requirements. **This document is not an exhaustive list of changes made to the Standards. Refer to the draft Standards to review all changes.**

The Standards Committee invites comments and suggestions related to any standard, whether it is new, revised, or unchanged from the 6th edition. The following is a list of proposed changes for which the Standards Committee specifically requests comment.

1. The 6th edition FACT-JACIE Standards required that facilities be actively implementing ISBT 128 at a minimum. The 7th edition draft Standards requires that ISBT 128 or Eurocode be fully implemented. Appendix II, "Cellular Therapy Product Labeling," has been updated to concisely convey requirements specific to both ISBT 128 and Eurocode. (CM/C/D7.1, Appendix II)
2. A new standard in the 7th edition draft Standards recommends Clinical Programs set benchmarks for non-relapsed mortality at 100 days after cellular therapy product administration and describe the rationale and process for review in the Quality Management Plan. These benchmarks should allow the program to assess non-relapsed mortality at 100 days, and identify specific corrective actions to take when a benchmark is not met. See accompanying Accreditation Manual for additional guidance. (B4.7.6)

3. The 7th edition draft Standards includes increased requirements for inclusion of risk assessment as part of document control, change control, occurrence investigations, qualifications, and validations throughout the transplant program (clinical, collection, and processing). In previous editions, the inclusion of risk assessment was limited to validation studies in the collection and processing sections. (B/C/D4.15)
4. The Clinical Program must refer planned discharges and post-transplant care to facilities and health care professionals adequate for post-transplant care. A new substandard requires that recipients who have not achieved hematological stability shall only be discharged to Clinical Programs that meet FACT-JACIE Standards. *Note this Standard is not intended to require discharge only to fully accredited programs. See accompanying Accreditation Manual for additional guidance.* (B7.8.1)
5. Electronic record requirements (similar to those applicable to processing facilities) were added to the clinical section to address systems used to support cellular therapy-specific activities. It is not the intent of these Standards to include hospital-based electronic medical records, but only those electronic systems that are under the control of the Clinical Program. (B10.4)
6. The requirement that autologous and/or CMV-appropriate and irradiated blood components be available during the collection procedure for all donors is currently in the 6th edition Standards. The 7th edition draft Standards includes a substandard that requires allogeneic blood components administered to a donor during the collection procedure be irradiated prior to transfusion to protect the recipient of the product from third-party donor lymphocytes. (CM8.4.1, C8.5.1)
7. Use of supplies and reagents of the appropriate grade is currently required. The Accreditation Manual includes the explanation that if the appropriate grade of reagent is not used, lot-to-lot functional validation is required. The 7th edition draft Standards includes a proposed standard that explicitly states this requirement. Informative guidance is based on review and comparison of labeling and accompanying documentation of various DMSO products in common use. (D6.2.4.1)

Instructions for Submitting Public Comments

To submit comments regarding the draft 7th edition FACT-JACIE Standards, follow the steps below. Comments will be accepted through July 30, 2017.

1. Access the Comment Form at <https://www.surveymonkey.com/r/FACT-JACIE>.
2. Type in your contact information and comments on the form. Fill in all fields so that the Standards Committee fully understands your position.
3. Submit the form when you are finished. Once the form has been submitted, it cannot be changed. However, additional comments may be submitted by completing the form again. There is no limit to the number of forms that can be submitted.