

**Request for Public Review and Comment**  
**Draft Second Edition**  
***FACT Standards for Immune Effector Cells***

The Foundation for the Accreditation of Cellular Therapy (FACT) published the draft Second Edition [FACT Standards for Immune Effector Cells](#) for inspection and public comment. These Standards apply to immune effector cells used to modulate an immune response for therapeutic intent, such as dendritic cells, natural killer cells, T cells, and B cells. This includes, but is not limited to, genetically engineered chimeric antigen receptor T cells (CAR-T cells) and therapeutic vaccines. Comments will be accepted through August 30, 2020. Following review and consideration of all submitted comments, the final Second Edition of these Standards will be published in May 2021.

This draft is a redline document intended to highlight new and revised Standards. Minor reorganization and changes intended to clarify the intent rather than to change the requirements are not tracked. To assist in your review, use the [Summary of Changes](#) document that highlights changes made in the draft. **The Summary of Changes is not an exhaustive list of all 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 first edition. The following is a list of proposed changes for which the Standards Committee specifically requests comment.

1. In the second edition, the concept of designee was moved from individual standards to the beginning of the document as a **tenet** in Section A2.2. This reflects a change in the opinion of the Standards Committee to assert that any activity, rather than only specified activities, can be delegated to an appropriate designee as the term designee is defined in Section A4. The person appointing the designee retains the ultimate responsibility. The phrase “or designee” was removed from individual standards throughout. Do you have any comment on the removal of the phrase “or designee” from individual standards and the inclusion of A2.2 as a tenet applicable throughout the Standards?
2. Significant specific standards were added to address mandated risk management plan requirements for Clinical Programs utilizing licensed (or equivalent regulatory approval) cellular therapy products. Complementary standards were added to the Collection and Laboratory sections. As noted in the language of the Standard, these requirements are intended to be applicable as appropriate to processes performed and in accordance with Applicable Law, acknowledging that there may be variability across national boundaries. The Accreditation Manual will include additional information and examples of the expectations. These new standards are outlined in the Summary of Changes document. Do you have any comment on the added risk management standards? (See B7.9-B7.10; C8.12-C8.13; D8.15-D8.16; D3.4.2)

3. The FACT Gene-Modified Cell Task Force proposed additional standards specifically related to gene-modified cellular therapy products and applicable as appropriate to the processes performed. These new requirements are highlighted for review and specific comment in the Summary of Changes document. Do you have any comment on the proposed requirements related to gene-modified cells? (See B3.1.6; B3.2.2; B3.5.3; B3.7.2.2; B3.8.4.1; B3.10.3.1; B4.7.3.2; B5.1.15.1; C5.1.15.1; D2.8; D5.1.19.1; D12.1.1.1)
4. For Programs administering licensed (or equivalent regulatory approval) cellular therapy products, particularly immune effector cells, the collection of a cellular therapy product used as starting material for further manufacturing may be considered to be part of the manufacturing process, thereby making some GMP requirements relevant to collection and laboratory processing in particular regions. For these Programs in these jurisdictions, minimal annual training of personnel in applicable cGMP is required and has been added to sections C and D of the draft second edition Standards. For Programs that are not involved in collection of cellular therapy products for further manufacturing or in jurisdictions where it is not required, this training requirement would be not applicable. When published, the accompanying Accreditation Manual will further explain regional requirements and provide examples of compliance. Do you have any comment related to this training requirement? (See C4.4.2.5; D4.4.2.5)
5. In the draft second edition of Standards, cellular therapy products transported internally within a facility must be packaged in a closed and rigid outer container. The outer container for internal transport must be labeled as defined in the new section of Appendix II, Table B. Do you have any comment on the inclusion of these required specifications? (See D10.6-D10.6.1; Appendix II, Table B)

#### Instructions for Submitting Public Comments

To submit comments regarding the draft second edition FACT Standards for Immune Effector Cells, follow the steps below. Comments will be accepted through August 30, 2020.

1. Access the Comment Form at <https://forms.gle/VNdCRC5PUTsZ8CvK8>.
2. Type in your contact information and comments on the form. Complete all fields so that the Standards Committee fully understands your opinion. If appropriate, suggest alternative language.
3. Submit the form when you are finished. After the form has been submitted, it cannot be changed. Additional comments may be submitted by completing another form. There is no limit to the number of forms that can be submitted.