The table below includes responses that are required (FACT requested comments)

Public Comment Required Questions	ASHI Official Response
Part B standards for minimum new patients for accreditation have been converted to a table in Appendix I. Are the Standards and table clear and useful?	The Table in Appendix I is clear and useful
B2 standards propose use of HLA typing laboratories accredited by ASHI, EFI, or other organizations providing “appropriate” services related to the care of transplant patients. Is this change appropriate and is there supporting information available?	As we commented in relation to the FACT Cord Blood Standards, proposed standard B2.4.6 is not specific enough since it does not indicate how “appropriate” services will be determined for US or European labs or for labs in other countries and is not specific enough in relation to DNA-based typing. We would suggest that FACT change the phrase back to other “equivalent” organizations and strictly define “equivalent” as other organizations with equivalent requirements for Laboratory Director documented expertise in Histocompatibility Testing for HPC transplant, equivalent inspector training requirements, equivalent relevant standards for laboratory histocompatibility testing important for HPC transplant and the requirement for timely updates in standards in relation to new technologies and changes in nomenclature. The standard should also specify that laboratories must have the capability of performing deoxyribonucleic acid (DNA)-based HLA typing at lower and high resolution as required for transplantation.
B2 requires that chimerism testing be performed in laboratories accredited for that service. Is it feasible to require accredited laboratories for chimerism testing?	Re: proposed standard B2.4.7, since both ASHI and EFI accredit laboratories for chimerism testing, it is VERY feasible to require that accredited laboratories be used. Programs using Laboratories without that accreditation could send the samples to an accredited laboratory.
B3.4 Physicians-in-training and B3.8 Pharmacists are new sections added to the Clinical Personnel section. Do you have comments regarding these additions	ASHI has no comment on these proposed new sections
B4.6.3 standards include additional metrics for outcome analysis, including acute Graft versus Host Disease (GVHD), assessed according to established staging and grading systems, and central venous catheter infection. Do you have comments on these, or other, metrics to facilitate quality improvement, and potential methods for tracking data?	ASHI has no comment on these proposed new sections
B6.3, CM6.3, and C6.3 require pregnancy testing. Is this new requirement appropriate?	ASHI has no comment on these proposed new requirements
B7.5 includes new requirements for the care of allogeneic recipients. Are these standards appropriate?	ASHI has no comment on these proposed new requirements

B7.7.2 and C8.17 include extracorporeal photochemotherapy (ECP) requirements, including a written therapy plan from an attending physician specifying the patient's diagnosis and GVHD grade, organs involved, and proposed regimen. Do these changes increase clarity?	ASHI has no comment on these proposed new requirements
B3, CM3, C3, and D3 propose a specified minimum number of continuing education hours for key personnel. Do the prescribed numbers reduce ambiguity and improve clarity?	ASHI supports the new requirements for relevant continuing education for key personnel
CM1.4 increases the number of marrow collection procedures throughout the accreditation cycle from a minimum average of one to two marrow collection procedures per year. Will organizations be able to meet this standard?	ASHI has no comment on these proposed new requirements
CM7.1.2, C7.1.2, and D7.1.2 require that organizations be actively implementing ISBT 128 coding and labeling technologies. Will organizations be able to comply with this standard?	ASHI has no comment on these proposed new requirements
Standard C8.10.1 has been interpreted to require imaging techniques. Is this interpretation appropriate, and how do different catheter sites dictate necessary verification techniques?	ASHI has no comment on these proposed new requirements
Several new standards in Part D relate to cellular therapy product processing in facilities with classified air (e.g., clean rooms), manipulation that may require compliance with U.S. 351 or EU ATMP regulations, or distribution to or receipt from third-party manufacturers. Are these requirements feasible?	ASHI has no comment on these proposed new requirements

This table includes additional responses to the same and other standards.

Additional Proposed Standards with ASHI Comments	ASHI Official Response
B6.4.10 Allogeneic donors and recipients shall be tested at a minimum for HLA-A, B, and DRB1 type by a laboratory accredited by ASHI, EFI, or other appropriate organization. HLA-C testing shall be performed for unrelated allogeneic donors and related allogeneic donors other than siblings.	To ensure adequate collection of relevant information for future data analyses and since multiple publications attest to the importance of other loci, it would important to also add them now. ASHI therefore suggests that the last part of this standard be modified as follows: *HLA-C. HLA-DQB1, HLA-DQA1 and HLA-DPB1testing shall be performed for unrelated allogeneic donors and related allogeneic donors other than siblings demonstrated by family studies or other methods to be genetically identical for all loci.* ASHI also recommends that the word "appropriate" organization be changed back to "equivalent" and that "equivalent" be defined as: *"other organizations with equivalent requirements for Laboratory Director documented expertise in Histocompatibility Testing for HPC transplant, equivalent inspector training requirements, equivalent relevant standards for laboratory histocompatibility testing important for HPC transplant and the requirement for timely updates in standards in relation to new technologies and changes in nomenclature"*
B6.4.10.1 DNA high resolution molecular typing shall be used for DRB1 typing.	This requirement could be excessive for cases of sibling donors who can be certain to be genotypically identical because all four parental haplotypes have been identified by sufficient testing of family members and all four haplotypes are heterozygous for at least HLA-A and HLA-DRB1. We would suggest that this standard be changed as follows: *Perform high resolution DRB1 typing or other testing to definitively establish the HLA identity of phenotypically HLA- identical siblings. This assessment may be achieved by such additional testing as: 1. Testing enough relatives to determine genotypes for the patient and donor; 2. Performing functional assays to assess HLA identity/differences; 3. Other means as deemed appropriate to assess HLA identity.* *For unrelated donors and related donors other than genetically identical siblings perform at least A, B, DRB1 and C typing using high resolution DNA typing methods prior to transplant.*

B6.4.10.2 Verification typing shall be performed on the selected allogeneic donor using an independently collected sample. Results shall be confirmed prior to collection.	ASHI suggests that the last sentence of this standard be modified as follows: *Results shall be confirmed before the conditioning of the patient commences.*
B6.4.10.3 There shall be a procedure to confirm the identity of cord blood units if verification typing cannot be performed on attached segments.	There should be some specification for how centers should perform verification of units without an attached segment. We recommend adding: *Typing of a small aliquot of the thawed unit using a rapid HLA typing method for HLA-A and –B or HLA-A, -B, and –DRB1 before the transplant commences is required.*
B6.4.10.4 - There shall be a policy for anti-HLA antibody testing for mismatched donors and recipients.	This standard does not seem to us to be strong enough, especially since many centers perform transplants for highly sensitized candidates. In contrast, for example, for rbc antibody testing, the testing is actually "required" as in: CM6.3.10 A red cell antibody screen <u>shall</u> be performed on allogeneic recipients. We would suggest that B6.4.10.4 be changed to: *HLA antibody screening recipients for donor-specific antibodies and/or crossmatch tests shall be performed for all candidates with an HLA-A, B, or DRB1 mismatched potential allogeneic donor using a recipient sample collected within 30 days of transplant. If anti HLA antibodies are evaluated and reactivity is detected against alleles of loci not typed for in the donor, then typing of untested donor loci should be performed to rule out possible donor-specific antibodies. Antibody identification or crossmatch testing must be performed in a laboratory accredited for that testing.*
D8.12.2 Results for a red cell antibody screen on the recipient shall be available.	An additional standard is needed since, obviously, the results for the testing for donor-specific HLA antibodies also need to be available. We recommend: *Results for testing for donor-specific HLA antibodies shall be available*.