This document is for guidance only and is not exhaustive. The level of changes indicated are orientative.

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
B01	**GENERAL**	**B1**	**GENERAL**	No change
B01.01	The Clinical Program shall consist of an integrated medical team that includes a Clinical Program Director(s) housed in a defined location(s).	B1.1	The Clinical Program shall consist of an integrated medical team that includes a Clinical Program Director(s) housed in a defined location(s).	No change
B01.01.01	The Clinical Program shall demonstrate common staff training, protocols, procedures, quality management systems, clinical outcome analysis, and regular interaction among all clinical sites.	B1.1.1	The Clinical Program shall demonstrate common staff training, protocols, Standard Operating Procedures, quality management systems, clinical outcome analyses, and regular interaction among all clinical sites.	Minor
B01.02	The Clinical Program shall use cell collection and processing facilities that meet FACT-JACIE Standards with respect to their interactions with the Clinical Program.	B1.2	The Clinical Program shall use cell collection and processing facilities that meet FACT-JACIE Standards with respect to their interactions with the Clinical Program.	No change
B1.2.1	If cellular therapy products are received directly by the Clinical Program from a third-party provider, the following responsibilities at a minimum shall be defined in a written agreement:	B1.2.1	If the Clinical Program or an intermediary facility receives cellular therapy products directly from a third-party provider, the following responsibilities shall be defined, at a minimum, by a written agreement:	Minor
B1.2.1.1	Traceability and chain of custody of cellular therapy products.	B1.2.1.1	Traceability and chain of custody of cellular therapy products.	No change
B1.2.1.2	Cellular therapy product storage and distribution.	B1.2.1.2	Cellular therapy product storage and distribution.	No change
B1.2.1.3	Verification of cellular therapy product identity.	B1.2.1.3	Verification of cellular therapy product identity.	No change
		B1.2.1.4	Review and verification of product specifications provided by the manufacturer, if applicable.	New
		B1.2.1.5	Readily available access to a summary of documents used to determine allogeneic donor eligibility.	New

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
		B1.2.1.6	Documented evidence of allogeneic donor eligibility screening and testing in accordance with applicable laws and regulations.	New
B01.03	The Clinical Program shall abide by all applicable laws and regulations.	B1.3	The Clinical Program shall abide by all applicable laws and regulations.	No change
B01.03.01	The Clinical Program shall be licensed, registered, or accredited as required by the appropriate governmental authorities for the activities performed.	B1.3.1	The Clinical Program shall be licensed, registered, or accredited as required by the appropriate governmental authorities for the activities performed.	No change
B01.04	The Clinical Program shall have a designated transplant team that includes a Clinical Program Director, a Quality Manager, and a minimum of one (1) additional attending transplant physician. The designated transplant team shall have been in place for at least twelve (12) months preceding initial accreditation.	B1.4	The Clinical Program shall have a designated transplant team that includes a Clinical Program Director, a Quality Manager, and a minimum of one (1) additional attending transplant physician. The designated transplant team shall have been in place and performing cellular therapy for at least twelve (12) months and preceding initial accreditation.	Minor
B01.05	The Clinical Program shall comply with the Minimum Number of New Patients for Accreditation table in Appendix _.	B1.5	The Clinical Program shall comply with the Minimum Number of New Patients for Accreditation table in Appendix _.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
B02	**CLINICAL UNIT**	**B2**	**CLINICAL UNIT**	No change
B02.01	There shall be a designated inpatient unit of appropriate location and adequate space and design that minimizes airborne microbial contamination.	B2.1	There shall be a designated inpatient unit of appropriate location and adequate space and design that minimizes airborne microbial contamination.	No change
B02.02	There shall be a designated outpatient care area that protects the patient from transmission of infectious agents and allows, as necessary, for appropriate patient isolation; confidential examination and evaluation; and administration of intravenous fluids, medications, or blood products.	B2.2	There shall be a designated outpatient care area that protects the patient from transmission of infectious agents and allows, as necessary, for appropriate patient isolation; confidential examination and evaluation; and administration of intravenous fluids, medications, or blood products.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
B02.03	When the preparative regimen, cellular therapy product administration, or initial post-transplant care is provided in an ambulatory setting, there shall be a designated area with appropriate location and adequate space and design to minimize the risk of airborne microbial contamination.	B2.3	When the preparative regimen, cellular therapy product administration, or initial post-transplant care is provided in an ambulatory setting, there shall be a designated area with appropriate location and adequate space and design to minimize the risk of airborne microbial contamination.	No change
B02.04	Facilities used by the Clinical Program shall be maintained in a clean, sanitary, and orderly manner.	B2.4	The Clinical Program shall document facility cleaning and sanitation and maintain order sufficient to achieve adequate conditions for operations.	Moderate
		B2.5	There shall be adequate equipment and materials for the procedures performed.	New
B02.05	There shall be provisions for prompt evaluation and treatment by a transplant attending physician available on a 24-hour basis.	B2.6	There shall be provisions for prompt evaluation and treatment by an attending physician available on a 24-hour basis.	Moderate
B02.06	There shall be written guidelines for communication, patient monitoring, and prompt transfer of patients to an intensive care unit, emergency department, or equivalent when appropriate.	B2.8	There shall be written guidelines for communication, patient monitoring, and prompt triage or transfer of patients to an intensive care unit, emergency department, or equivalent when appropriate.	Minor
		B2.9	There shall be written guidelines for communication between the Clinical Program and the Collection Facility or the registry for the management of collection-related complications.	New
B02.07	There shall be attending physician oversight if general medical physicians, physicians in training, or APPs provide care to transplant patients. The scope of responsibility of general medical physicians or APPs shall be defined.	B2.10	There shall be attending physician oversight if general medical physicians, physicians in training, or APPs provide care to transplant patients. The scope of responsibility of general medical physicians or APPs shall be defined.	No change
B02.08	There shall be a pharmacy providing 24-hour availability of medications needed for the care of transplant patients.	B2.11	There shall be a pharmacy providing 24-hour availability of medications needed for the care of cellular therapy patients.	Negligible

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
B2.8.1	Pharmacies shall have access to medications adequate to treat expected complications of immune effector cell administration, including cytokine release syndrome.	B2.11.1	Pharmacies shall have prompt access to medications adequate to treat expected complications of cellular therapy, including cytokine release syndrome.	Minor
B02.09	There shall be access to renal support under the direction of nephrologists and trained personnel.	B2.12	There shall be access to renal support under the direction of nephrologists and trained personnel.	No change
B02.10	There shall be 24-hour availability of CMV-appropriate and irradiated blood products needed for the care of transplant recipients.	B2.13	There shall be 24-hour availability of CMV-appropriate and irradiated blood products needed for the care of cellular therapy recipients.	Negligible
B02.11	Clinical Programs performing allogeneic transplantation shall use HLA testing laboratories that are capable of carrying out DNA–based intermediate and high resolution HLA-typing and are appropriately accredited by the American Society for Histocompatibility and Immunogenetics (ASHI), European Federation for Immunogenetics (EFI), or other accrediting organizations providing histocompatibility services appropriate for hematopoietic cellular therapy transplant patients.	B2.14	Clinical Programs performing allogeneic transplantation shall use HLA testing laboratories that are capable of carrying out DNA–based intermediate and high resolution HLA typing and are appropriately accredited by the American Society for Histocompatibility and Immunogenetics (ASHI), European Federation for Immunogenetics (EFI), or other accrediting organizations providing histocompatibility services appropriate for hematopoietic cellular therapy transplant patients.	No change
B02.12	Chimerism testing shall be performed in laboratories accredited for the techniques used.	B2.15	Chimerism testing shall be performed in laboratories accredited for the techniques used.	No change
B02.13	There shall be an intensive care unit or equivalent coverage available.	B2.7	There shall be access to an intensive care unit or emergency services.	Minor
B02.14	The Clinical Program shall be operated in a manner designed to minimize risks to the health and safety of employees, patients, donors, visitors, and volunteers.	B2.16	The Clinical Program shall be operated in a manner designed to minimize risks to the health and safety of employees, recipients, donors, visitors, and volunteers.	Minor

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
B02.15	The Clinical Program shall have a written safety manual that includes instructions for action in case of exposure, as applicable, to liquid nitrogen; communicable disease; and to chemical, biological, or radiological hazards.	B2.17	The Clinical Program shall have a written safety manual that includes instructions for action in case of exposure, as applicable, to liquid nitrogen; communicable disease; and to chemical, biological, or radiological hazards.	No change
		B2.18	All waste generated by the Clinical Program activities shall be disposed of in a manner that minimizes any hazard to facility personnel and to the environment in accordance with applicable laws and regulations.	New
		B2.19	Gloves and protective clothing shall be worn while handling biological specimens. Such protective clothing shall not be worn outside the work area.	New
B03	**PERSONNEL**	**B3**	**PERSONNEL**	No change
B03.01	**CLINICAL PROGRAM DIRECTOR**	**B3.1**	**CLINICAL PROGRAM DIRECTOR**	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
B03.01.01	The Clinical Program Director shall be a physician appropriately licensed or certified to practice medicine in the jurisdiction in which the Clinical Program is located and shall have achieved specialist certification in one or more of the following specialties: Hematology, Medical Oncology, Pediatric Immunology, or Pediatric Hematology/Oncology. A physician trained prior to requirements for specialty training may serve as the Clinical Program Director if he/she has documented experience in the field of HPC transplantation extending over ten (10) years.	B3.1.1	The Clinical Program Director shall be a physician appropriately licensed to practice medicine in the jurisdiction in which the Clinical Program is located and shall have achieved specialist certification in one or more of the following specialties: Hematology, Medical Oncology, Immunology, or Pediatric Hematology/Oncology. A physician trained prior to requirements for specialty training may serve as the Clinical Program Director if he/she has documented experience in the field of HPC transplantation extending over ten (10) years.	Moderate
B03.01.02	The Clinical Program Director shall have two (2) years of experience as an attending physician responsible for the direct clinical management of HPC transplant patients in the inpatient and outpatient settings.	B3.1.2	The Clinical Program Director shall have two (2) years of experience as an attending physician responsible for the direct clinical management of HPC transplant patients in the inpatient and outpatient settings.	No change
B03.01.03	The Clinical Program Director shall be responsible for administrative and clinical operations, including compliance with these Standards and applicable laws and regulations.	B3.1.3	The Clinical Program Director shall be responsible for administrative and clinical operations, including compliance with these Standards and applicable laws and regulations.	No change
B03.01.04	The Clinical Program Director shall be responsible for all elements of the design of the Clinical Program including quality management, the selection and care of patients and donors, and cell collection and processing, whether internal or contracted services.	B3.1.4	The Clinical Program Director shall be responsible for all elements of the design of the Clinical Program including quality management, the selection and care of recipients and donors, and cell collection and processing, whether internal or contracted services.	Negligible
B03.01.05	The Clinical Program Director shall have oversight of the medical care provided by all members of the Clinical Program.	B3.1.5	The Clinical Program Director shall have oversight of the medical care provided by all members of the Clinical Program.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
B03.01.05.01	The Clinical Program Director or designee shall be responsible for verifying the knowledge and skills of members of the Clinical Program once per accreditation cycle, at minimum.	B3.1.5.1	The Clinical Program Director or designee shall be responsible for verifying the knowledge and skills of members of the Clinical Program once per accreditation cycle, at a minimum.	No change
B03.01.06	The Clinical Program Director shall participate in ten (10) hours of educational activities related to cellular therapy annually at a minimum.	B3.1.6	The Clinical Program Director shall participate in a minimum of ten (10) hours of educational activities related to cellular therapy annually.	Reordered
B03.01.06.01	Continuing education shall include, but is not limited to, activities related to the field of HPC transplantation.	B3.1.6.1	Continuing education shall include, but is not limited to, activities related to the field of HPC transplantation.	No change
B03.02	**ATTENDING PHYSICIANS**	**B3.2**	**ATTENDING PHYSICIANS**	No change
B03.02.01	Attending physicians shall be appropriately licensed to practice medicine in the jurisdiction of the Clinical Program and should be specialist certified or trained in one of the following specialties: Hematology, Medical Oncology, Immunology, or Pediatric Hematology/Oncology.	B3.2.1	Attending physicians shall be appropriately licensed to practice medicine in the jurisdiction of the Clinical Program and should be specialist certified or trained in one (1) of the following specialties: Hematology, Medical Oncology, Immunology, or Pediatric Hematology/Oncology.	No change
B03.02.01.01	Clinical Programs performing adult transplantation shall have at least one attending physician who has achieved specialist certification in Hematology, Medical Oncology, or Immunology.	B3.2.1.1	Clinical Programs performing adult transplantation shall have at least one (1) attending physician who has achieved specialist certification in Hematology, Medical Oncology, or Immunology.	No change
B03.02.01.02	Clinical Programs performing pediatric transplantation shall have at least one attending physician who has achieved specialist certification in Pediatric Hematology/Oncology or Pediatric Immunology.	B3.2.1.2	Clinical Programs performing pediatric transplantation shall have at least one (1) attending physician who has achieved specialist certification in Pediatric Hematology/Oncology or Pediatric Immunology.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
B03.02.02	Attending physicians shall participate in ten (10) hours of educational activities related to cellular therapy annually at a minimum.	B3.2.2	Attending physicians shall participate in a minimum of ten (10) hours of educational activities related to cellular therapy annually.	Reordered
B03.02.02.01	Continuing education shall include, but is not limited to, activities related to the field of HPC transplantation.	B3.2.2.1	Continuing education shall include, but is not limited to, activities related to the field of HPC transplantation.	No change
B03.03	**TRAINING FOR CLINICAL PROGRAM DIRECTORS AND ATTENDING PHYSICIANS**	**B3.3**	**TRAINING FOR CLINICAL PROGRAM DIRECTORS AND ATTENDING PHYSICIANS**	No change
B03.03.01	Attending physicians shall each have had a minimum total of one year of supervised training in the management of transplant patients in both inpatient and outpatient settings.	B3.3.1	Attending physicians shall each have had a minimum total of one (1) year of supervised training in the management of transplant patients in both inpatient and outpatient settings.	No change
B03.03.02	Clinical training and competency shall include the management of autologous and/or allogeneic transplant recipients, as applicable.	B3.3.2	Clinical training and competency shall include the management of autologous and/or allogeneic transplant recipients, as applicable.	No change
		B3.3.3	Clinical Program Directors and attending physicians shall each be assessed for competency on an annual basis.	New
B03.03.03	Clinical Program Directors and attending physicians shall have received specific training and maintain competency in each of the following areas as applicable to the Clinical Program's services:	B3.3.4	Clinical Program Directors and attending physicians shall have received specific training in each of the following areas as applicable to the Clinical Program’s services:	Negligible
B03.03.03.01	Indications for HPC transplantation.	B3.3.4.1	Indications for allogeneic and autologous HPC transplantation.	Minor
B03.03.03.02	Selection of suitable recipients and appropriate preparative regimens.	B3.3.4.2	Selection of suitable recipients and appropriate preparative regimens.	No change
B03.03.03.03	Allogeneic and autologous donor selection, evaluation, and management.	B3.3.4.3	Donor selection, evaluation, and management.	Minor
B03.03.03.04	Donor and recipient informed consent.	B3.3.4.4	Donor and recipient informed consent.	No change
B03.03.03.05	Administration of ABO incompatible cellular therapy products.			

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
B03.03.03.06	Administration of preparative regimen.	B3.3.4.5	Administration of preparative regimens.	No change
B03.03.03.07	Administration of growth factors for HPC mobilization and for post-transplant hematopoietic cell reconstitution.	B3.3.4.6	Administration of growth factors for HPC mobilization and for post-transplant hematopoietic cell reconstitution.	No change
B03.03.03.08	HPC product infusion and patient management.	B3.3.4.7	Cellular therapy product administration and patient management.	Minor
B03.03.03.09	Management of neutropenic fever.	B3.3.4.8	Management of neutropenic fever.	No change
B03.03.03.10	Diagnosis and management of infectious and non-infectious pulmonary complications of transplantation.	B3.3.4.9	Diagnosis and management of infectious and non-infectious pulmonary complications of transplantation.	No change
B03.03.03.11	Diagnosis and management of fungal disease.	B3.3.4.10	Diagnosis and management of fungal disease.	No change
B03.03.03.12	Diagnosis and management of veno-occlusive disease of the liver and other causes of hepatic dysfunction.	B3.3.4.11	Diagnosis and management of sinusoidal obstruction syndrome and other causes of hepatic dysfunction.	Minor
B03.03.03.13	Management of thrombocytopenia and bleeding, including recognition of disseminated intravascular coagulation.	B3.3.4.12	Management of thrombocytopenia and bleeding, including recognition of disseminated intravascular coagulation.	No change
B03.03.03.14	Management of hemorrhagic cystitis.	B3.3.4.13	Management of hemorrhagic cystitis.	No change
		B3.3.4.14	Blood transfusion management.	new
		B3.3.4.15	Use of irradiated blood products.	new
B03.03.03.15	Management of mucositis, nausea, and vomiting.	B3.3.4.16	Management of mucositis, nausea, and vomiting.	No change
B03.03.03.16	Monitoring and management of pain.	B3.3.4.17	Monitoring and management of pain.	No change
B3.3.3.17	Graft versus host disease.			
B3.3.3.18	Cytokine release syndrome.	B3.3.4.18	Cytokine release syndrome.	No change
B3.3.3.19	Tumour lysis syndrome.	B3.3.4.19	Tumor lysis syndrome and macrophage activation syndrome.	Merged
B3.3.3.20	Macrophage activation syndrome.			
B3.3.3.21	Cardiac dysfunction.	B3.3.4.21	Cardiac dysfunction.	No change
B3.3.3.22	Renal dysfunction.	B3.3.4.22	Renal dysfunction.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
B3.3.3.23	Respiratory distress.	B3.3.4.23	Respiratory distress.	No change
B3.3.3.24	Neurologic toxicity.	B3.3.4.20	Neurologic toxicity.	No change
B3.3.3.25	Anaphylaxis.	B3.3.4.24	Anaphylaxis.	No change
B3.3.3.26	Infectious and non-infectious processes.	B3.3.4.25	Infectious and noninfectious processes.	No change
B03.03.03.17	Diagnosis and management of HPC graft failure.	B3.3.4.26	Diagnosis and management of HPC graft failure.	No change
B03.03.03.18	Evaluation of post-transplant cellular therapy outcomes.	B3.3.4.28	Evaluation of post-transplant cellular therapy outcomes.	No change
B03.03.03.19	Evaluation of late effects of allogeneic and autologous transplants, including cellular, pharmacologic, and radiation therapy.	B3.3.4.29	Evaluation of late effects of cellular therapy.	Minor
B03.03.03.20	Documentation and reporting for patients on investigational protocols.	B3.3.4.30	Documentation and reporting for patients on investigational protocols.	No change
B03.03.03.21	Applicable regulations and reporting responsibilities for adverse events.	B3.3.4.31	Applicable regulations and reporting responsibilities for adverse events.	No change
B03.03.03.22	Palliative and end of life care.	B3.3.4.32	Palliative and end of life care.	No change
		B3.3.4.33	Age-specific donor and recipient care.	new
B03.03.04	Additional specific clinical training and competency required for physicians in Clinical Programs requesting accreditation for allogeneic HPC transplantation shall include:	B3.3.5	Additional specific clinical training and competence required for physicians in Clinical Programs requesting accreditation for allogeneic HPC transplantation shall include:	Negligible
B03.03.04.01	Identification, evaluation, and selection of HPC source, including use of donor registries.	B3.3.5.1	Identification, evaluation, and selection of HPC source, including use of donor registries.	No change
B03.03.04.02	Donor eligibility determination.	B3.3.5.2	Donor eligibility determination.	No change
B03.03.04.03	Methodology and implications of human leukocyte antigen (HLA) typing.	B3.3.5.3	Methodology and implications of HLA typing.	Negligible
B03.03.04.04	Management of patients receiving ABO incompatible HPC products.	B3.3.5.4	Management of patients receiving ABO incompatible HPC products.	No change
B03.03.04.05	Diagnosis and management of immunodeficiencies and opportunistic infections.	B3.3.4.27	Diagnosis and management of immunodeficiencies and opportunistic infections.	No change
B03.03.04.06	Diagnosis and management of acute graft versus host disease.	B3.3.5.5	Diagnosis and management of acute GVHD.	Negligible

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
B03.03.04.07	Diagnosis and management of chronic graft versus host disease.	B3.3.5.6	Diagnosis and management of chronic GVHD.	Negligible
B03.03.05	The attending physicians shall be knowledgeable in the following procedures:	B3.3.6	The attending physicians shall be knowledgeable in the following procedures:	No change
B03.03.05.01	HPC processing.	B3.3.6.3	Cellular therapy product processing.	Minor
B03.03.05.02	HPC cryopreservation.	B3.3.6.4	Cellular therapy product cryopreservation.	Minor
B03.03.05.03	Bone marrow harvest procedures.	B3.3.6.2	Bone marrow harvest procedures.	No change
B03.03.05.04	Apheresis collection procedures.	B3.3.6.1	Apheresis collection procedures.	No change
B03.03.05.05	Extracorporeal photopheresis for GVHD.	B3.3.6.7	Extracorporeal photopheresis for GVHD.	No change
B03.03.05.06	Washing and diluting of cellular therapy products.	B3.3.6.5	Washing and diluting of cellular therapy products.	No change
B3.3.5.7	Cellular therapy product administration.	B3.3.6.6	Cellular therapy product administration procedures.	Negligible
B03.04	PHYSICIANS-IN-TRAINING	**B3.4**	**PHYSICIANS-IN-TRAINING**	No change
B03.04.01	Physicians-in-training shall be licensed to practice in the jurisdiction of the Clinical Program and shall be limited to a scope of practice within the parameters of their training and licensure and shall be appropriately supervised.	B3.4.1	Physicians-in-training shall be licensed to practice in the jurisdiction of the Clinical Program and shall be limited to a scope of practice within the parameters of their training and licensure and shall be appropriately supervised.	No change
B03.04.02	Physicians-in-training shall receive specific training and develop competency in transplant-related skills, including but not limited to those listed in B3.3.3 and B3.3.4.	B3.4.2	Physicians-in-training shall receive specific training and develop competence in transplant-related skills, included within but not limited to those listed in B3.3.4 and B3.3.5.	Negligible
B03.05	**ADVANCED PRACTICE PROVIDERS/PROFESSIONALS**	**B3.5**	**ADVANCED PRACTICE PROVIDERS/PROFESSIONALS (APPs)**	Negligible
B03.05.01	APPs shall be licensed to practice in the jurisdiction of the Clinical Program and shall be limited to a scope of practice within the parameters of their training and licenses.	B3.5.1	APPs shall be licensed to practice in the jurisdiction of the Clinical Program and shall be limited to a scope of practice within the parameters of their training and licenses.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
B03.05.02	APPs shall have received specific training and maintain competency in the transplant-related skills that they routinely practice including but not limited to those listed in B3.3.3 and B3.3.4.	B3.5.2	APPs shall have received specific training and maintain competence in the transplant-related skills that they routinely practice included within but not limited to those listed in B3.3.4 and B3.3.5.	Negligible
B03.05.03	APPs shall participate in ten (10) hours of educational activities related to cellular therapy annually at a minimum.	B3.5.3	APPs shall participate in a minimum of ten (10) hours of educational activities related to cellular therapy annually.	Reordered
B03.05.03.01	Continuing education shall include, but is not limited to, activities related to the field of HPC transplantation.	B3.5.3.1	Continuing education shall include, but is not limited to, activities related to the field of HPC transplantation.	No change
B03.06	**CLINICAL TRANSPLANT TEAM**	**B3.6**	**CLINICAL TRANSPLANT TEAM**	No change
B03.06.01	Clinical Programs performing pediatric transplantation shall have a transplant team trained in the management of pediatric patients.	B3.6.1	Clinical Programs performing pediatric transplantation shall have a transplant team trained in the management of pediatric recipients.	Negligible
B03.06.02	The Clinical Program shall have access to licensed physicians who are trained and competent in marrow collection and utilize a marrow collection facility that meets these Standards.	B3.6.2	The Clinical Program shall have access to licensed physicians who are trained and competent in marrow collection and utilize a marrow collection facility that meets these Standards.	No change
B03.06.03	The Clinical Program shall have access to personnel who are trained and competent in cellular therapy product collection by apheresis and utilize an apheresis collection facility that meets these Standards.	B3.6.3	The Clinical Program shall have access to personnel who are trained and competent in cellular therapy product collection by apheresis and utilize an apheresis collection facility that meets these Standards.	No change
B03.07	**NURSES**	**B3.7**	**NURSES**	No change
B03.07.01	The Clinical Program shall have nurses formally trained and experienced in the management of patients receiving cellular therapy.	B3.7.1	The Clinical Program shall have nurses formally trained and experienced in the management of patients receiving cellular therapy.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
B03.07.02	Clinical Programs treating pediatric patients shall have nurses formally trained and experienced in the management of pediatric patients receiving cellular therapy.	B3.7.2	Clinical Programs treating pediatric recipients shall have nurses formally trained and experienced in the management of pediatric patients receiving cellular therapy.	Negligible
B03.07.03	Training and competency shall include:	B3.7.3	Nurses shall have received specific training and maintain competence in the transplant-related skills that they routinely practice including:	Minor
B03.07.03.01	Hematology/oncology patient care, including an overview of the cellular therapy process.	B3.7.3.1	Hematology/oncology patient care, including an overview of the cellular therapy process.	No change
B03.07.03.02	Administration of preparative regimens.	B3.7.3.2	Administration of preparative regimens.	No change
B03.07.03.03	Administration of blood products, growth factors, cellular therapy products, and other supportive therapies.	B3.7.3.3	Administration of blood products, growth factors, cellular therapy products, and other supportive therapies.	No change
B03.07.03.04	Care interventions to manage cellular therapy complications, including, but not limited to, cytokine release syndrome, tumour lysis syndrome, cardiac dysfunction, respiratory distress, neurologic toxicity, renal and hepatic failure, disseminated intravascular coagulation, anaphylaxis, neutropenic fever, infectious and non-infectious processes, mucositis, nausea and vomiting, and pain management.	B3.7.3.4	Care interventions to manage cellular therapy complications, including, but not limited to, cytokine release syndrome, tumor lysis syndrome, cardiac dysfunction, respiratory distress, neurologic toxicity, macrophage activation syndrome, renal and hepatic failure, disseminated intravascular coagulation, anaphylaxis, neutropenic fever, infectious and noninfectious processes, mucositis, nausea and vomiting, and pain management.	Moderate
B03.07.03.05	Recognition of cellular therapy complications and emergencies requiring rapid notification of the transplant team.	B3.7.3.5	Recognition of cellular therapy complications and emergencies requiring rapid notification of the transplant team.	No change
B03.07.03.06	Palliative and end of life care.	B3.7.3.6	Palliative and end of life care.	No change
B03.07.04	There shall be written policies for all relevant nursing procedures, including, but not limited to:	B3.7.4	There shall be written Standard Operating Procedures or guidelines for nursing procedures, including, but not limited to:	Negligible
B03.07.04.01	Care of immunocompromised patients.	B3.7.4.1	Care of immunocompromised recipients.	Negligible
		B3.7.4.2	Age-specific considerations.	new

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
B03.07.04.02	Administration of preparative regimens.	B3.7.4.3	Administration of preparative regimens.	No change
B03.07.04.03	Administration of cellular therapy products.	B3.7.4.4	Administration of cellular therapy products.	No change
B03.07.04.04	Central venous access device care.	B3.7.4.6	Cental venous access device care.	No change
B03.07.04.05	Administration of blood products.	B3.7.4.5	Administration of blood products.	No change
B3.7.4.6	Detection and management of immune effector cellular therapy complications including, but not limited to, those listed in B3.7.3.4.	B3.7.4.7	Detection and management of immune effector cellular therapy complications including, but not limited to, those listed in B3.7.3.4.	No change
B03.07.05	There shall be an adequate number of nurses experienced in the care of transplant patients.	B3.7.5	There shall be an adequate number of nurses experienced in the care of transplant recipients.	Negligible
B03.07.06	There shall be a nurse/patient ratio satisfactory to manage the severity of the patients' clinical status.	B3.7.6	There shall be a nurse/recipient ratio satisfactory to manage the severity of the recipients' clinical status.	Negligible
B03.08	PHARMACISTS	**B3.8**	**PHARMACISTS**	No change
B03.08.01	Pharmacists shall be licensed to practice in the jurisdiction of the Clinical Program and shall be limited to a scope of practice within the parameters of their training and licensure.	B3.8.1	Pharmacists shall be licensed to practice in the jurisdiction of the Clinical Program and shall be limited to a scope of practice within the parameters of their training and licensure.	No change
B03.08.02	Training shall include:	B3.8.2	Training and knowledge of designated pharmacists shall include:	Minor
B03.08.02.01	An overview of haematology/oncology patient care, including the cellular therapy process, cytokine release syndrome, and neurological toxicities.	B3.8.2.1	Hematology/oncology patient care, including the process of cellular therapy.	Minor
		B3.8.2.2	Adverse events including, but not limited to, cytokine release syndrome and neurological toxicities.	new
B03.08.02.02	Therapeutic drug monitoring, including, but not limited to, anti-infective agents, immunosuppressive therapy, anti-seizure medications, and anticoagulation.	B3.8.2.3	Therapeutic drug monitoring, including, but not limited to, anti-infective agents, immunosuppressive agents, anti-seizure medications, and anticoagulants.	Negligible
B03.08.02.03	Monitoring for and recognition of drug/drug and drug/food interactions and necessary dose modifications.	B3.8.2.4	Monitoring for and recognition of drug/drug and drug/food interactions and necessary dose modifications.	No change
B03.08.02.04	Recognition of medications that require adjustment for organ dysfunction.	B3.8.2.5	Recognition of medications that require adjustment for organ dysfunction.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
B03.08.03	Pharmacists shall be involved in the development and implementation of guidelines or SOPs related to the pharmaceutical management of cellular therapy recipients.	B3.8.3	Designated pharmacists shall be involved in the development and implementation of controlled documents related to the pharmaceutical management of cellular therapy recipients.	Minor
B03.08.04	Designated transplant pharmacists shall participate in ten (10) hours of educational activities related to cellular therapy annually at a minimum.	B3.8.4	Designated pharmacists shall participate in a minimum of ten (10) hours of educational activities related to cellular therapy annually.	Reordered
B03.08.04.01	Continuing education shall include, but is not limited to, activities related to the field of HPC transplantation and cytokine release syndrome and neurological toxicities resulting from cellular therapies.	B3.8.4.1	Continuing education shall include, but is not limited to, activities related to the field of HPC transplantation and cytokine release syndrome and neurological toxicities resulting from cellular therapies.	No change
B03.09	**CONSULTING SPECIALISTS**	**B3.9**	**CONSULTING SPECIALISTS**	No change
B03.09.01	The Clinical Program shall have access to certified or trained consulting specialists and/or specialist groups from key disciplines who are capable of assisting in the management of patients requiring medical care, including, but not limited to:	B3.9.1	The Clinical Program shall have access to certified or trained consulting specialists and/or specialist groups from key disciplines who are capable of assisting in the management of recipients and donors requiring medical care, including, but not limited to:	Minor
B03.09.01.01	Surgery.	B3.9.1.1	Surgery.	No change
B03.09.01.02	Pulmonary medicine.	B3.9.1.2	Pulmonary medicine.	No change
B03.09.01.03	Intensive care.	B3.9.1.3	Intensive care.	No change
B03.09.01.04	Gastroenterology.	B3.9.1.4	Gastroenterology.	No change
B03.09.01.05	Nephrology.	B3.9.1.5	Nephrology.	No change
B03.09.01.06	Infectious diseases.	B3.9.1.6	Infectious disease.	Negligible
B03.09.01.07	Cardiology.	B3.9.1.7	Cardiology.	No change
B03.09.01.08	Pathology.	B3.9.1.8	Pathology.	No change
B03.09.01.09	Psychiatry.	B3.9.1.9	Psychiatry.	No change
B03.09.01.10	Radiology.	B3.9.1.10	Radiology.	No change
B03.09.01.11	Radiation oncology with experience in large-field (e.g., total body or total lymphoid) irradiation treatment protocols, if radiation therapy is administered.	B3.9.1.11	Radiation oncology with experience in large-field (e.g., total body or total lymphoid) irradiation treatment protocols, if radiation therapy is administered.	No change
B03.09.01.12	Transfusion medicine.	B3.9.1.12	Transfusion medicine.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
B03.09.01.13	Neurology.	B3.9.1.13	Neurology.	No change
B03.09.01.14	Ophthalmology.	B3.9.1.14	Ophthalmology.	No change
B03.09.01.15	Obstetrics/Gynecology.	B3.9.1.15	Obstetrics/Gynecology.	No change
B03.09.01.16	Dermatology.	B3.9.1.16	Dermatology.	No change
B03.09.01.17	Palliative and end of life care.	B3.9.1.17	Palliative and end of life care.	No change
B03.09.02	A Clinical Program treating pediatric patients shall have consultants, as defined in B3.X.1, qualified to manage pediatric patients.	B3.9.2	A Clinical Program treating pediatric donors and recipients shall have consultants, as defined in B3.9.1, qualified to manage pediatric patients.	Minor
B03.10	**QUALITY MANAGER**	**B3.10**	**QUALITY MANAGER**	No change
B03.10.01	There shall be a Clinical Program Quality Manager to establish and maintain systems to review, modify, and approve all policies and procedures intended to monitor compliance with these Standards and/or the performance of the Clinical Program.	B3.10.1	There shall be a Clinical Program Quality Manager to establish and maintain systems to review, modify, and approve all policies and Standard Operating Procedures intended to monitor compliance with these Standards or the performance of the Clinical Program.	Negligible
B3.10.2	The Clinical Program Quality Manager should have a reporting structure independent of cellular therapy product manufacturing.	B3.10.2	The Clinical Program Quality Manager should have a reporting structure independent of cellular therapy product manufacturing.	No change
B03.10.03	The Clinical Program Quality Manager shall participate in ten (10) hours of educational activities related to cellular therapy and/or quality management annually at a minimum.	B3.10.3	The Clinical Program Quality Manager shall participate in a minimum of ten (10) hours of educational activities related to cellular therapy and quality management annually.	Reordered
B03.10.03.01	Continuing education shall include, but is not limited to, activities related to the field of HPC transplantation.	B3.10.3.1	Continuing education shall include, but is not limited to, activities related to the field of HPC transplantation.	No change
B03.11	**SUPPORT SERVICES STAFF**	**B3.11**	**SUPPORT SERVICES STAFF**	No change
B03.11.01	The Clinical Program shall have one or more designated staff with appropriate training and education to assist in the provision of pre-transplant patient evaluation, treatment, and post-transplant follow-up and care. Designated staff shall include:	B3.11.1	The Clinical Program shall have one (1) or more designated staff with appropriate training and education to assist in the provision of pre-transplant recipient evaluation, treatment, and post-transplant follow-up and care. Designated staff shall include:	Negligible

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
B03.11.01.01	Dietary staff capable of providing dietary consultation regarding the nutritional needs of the recipient, including enteral and parenteral support, and appropriate dietary advice to avoid food-borne illness.	B3.11.1.1	Dietary staff.	Minor
B03.11.01.02	Social Services staff.	B3.11.1.2	Social Services staff.	No change
B03.11.01.03	Psychology Services staff.	B3.11.1.3	Psychology Services staff.	No change
B03.11.01.04	Physical Therapy staff.	B3.11.1.4	Physical Therapy staff.	No change
B03.11.01.05	Data Management staff sufficient to comply with B9.	B3.11.1.5	Data Management staff sufficient to comply with B9.	No change
B04	**QUALITY MANAGEMENT**	**B4**	**QUALITY MANAGEMENT**	No change
B04.01	There shall be an overall Quality Management Program that incorporates key performance data from clinical, collection, and processing facility quality management.	B4.1	There shall be an overall Quality Management Program that incorporates key performance data from clinical, collection, and processing facility quality management.	No change
B04.01.01	The Clinical Program Director or designee shall have authority over and responsibility for ensuring that the Quality Management Program is effectively established and maintained.	B4.1.1	The Clinical Program Director or designee shall have authority over and responsibility for ensuring that the overall Quality Management Program is effectively established and maintained.	Minor
B04.01.02	The Clinical Program Director shall annually review the effectiveness of the Quality Management Program.	B4.18	The Clinical Program Director or designee shall annually review the effectiveness of the overall Quality Management Program.	Minor
		B4.18.1	The annual report and documentation of the review findings shall be made available to key personnel, the Collection Facility Director, and the Processing Facility Director.	New
B04.02	The Clinical Program shall establish and maintain a written Quality Management Plan.	B4.2	The Clinical Program shall establish and maintain a written Quality Management Plan.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
B04.02.01	The Clinical Program Director or designee shall be responsible for the Quality Management Plan.	B4.2.1	The Clinical Program Director or designee shall be responsible for the Quality Management Plan.	No change
B04.02.02	The Clinical Program Director or designee shall review and report to staff quality management activities, at a minimum, quarterly.	B4.17	The Clinical Program Director or designee shall review the Quality Management activities with representatives in key positions in all elements of the cellular therapy program, at a minimum, quarterly.	Moderate
B04.02.03	The Clinical Program Director or designee shall not have oversight of his/her own work if this person also performs other tasks in the Clinical Program.	B4.17.3	The Clinical Program Director or designee shall not have oversight of his/her own work if this person also performs other tasks in the Clinical Program.	No change
B04.03	The Quality Management Plan shall include, or summarize and reference, an organizational chart of key positions and functions within the cellular therapy program, including clinical, collection, and processing.	B4.3	The Quality Management Plan shall include, or summarize and reference, an organizational chart of key positions and functions within the cellular therapy program, including clinical, collection, and processing.	No change
B04.03.01	The Quality Management Plan shall include a description of how these key positions interact to implement the quality management activities.	B4.3.1	The Quality Management Plan shall include a description of how these key positions interact to implement the Quality Management activities.	No change
B04.04	The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures addressing personnel requirements for each key position in the Clinical Program. Personnel requirements shall include at a minimum:	B4.4	The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures addressing personnel requirements for each key position in the Clinical Program. Personnel requirements shall include at a minimum:	No change
B04.04.01	A current job description for all staff.	B4.4.1	A current job description for all staff.	No change
B04.04.02	A system to document the following for all staff:	B4.4.2	A system to document the following for all staff:	No change
B04.04.02.01	Initial qualifications.	B4.4.2.1	Initial qualifications.	No change
B04.04.02.02	New employee orientation.	B4.4.2.2	New employee orientation.	No change
B04.04.02.03	Initial training and retraining when appropriate for all procedures performed.	B4.4.2.3	Initial training, competency, and retraining when appropriate for all procedures performed.	Minor

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
B04.04.02.04	Competency for each critical function performed.	B4.4.2.4	Continued competency for each critical function performed, assessed annually at a minimum.	Merged
B04.04.02.05	Continued competency at least annually.			
B04.04.02.06	Continuing education.	B4.4.2.5	Continuing education.	No change
B04.05	The Quality Management Plan shall include, or summarize and reference, a comprehensive system for document control and management.	B4.5	The Quality Management Plan shall include, or summarize and reference, a comprehensive system for document control.	Minor
B04.05.01	There shall be policies and procedures for development, approval, implementation, review, revision, and archival of all critical documents.	B4.5.2	There shall be policies or Standard Operating Procedures for the development, approval, implementation, distribution, review, revision, and archival of all critical documents.	Negligible
B04.05.02	There shall be a current listing of all active critical documents that shall comply with the document control system requirements. Controlled documents shall include at a minimum:	B4.5.1	There shall be identification of the types of documents that are considered critical and shall comply with the document control system requirements. Controlled documents shall include at a minimum:	Minor
B04.05.02.01	Policies, protocols, and Standard Operating Procedures.	B4.5.1.1	Policies, protocols, Standard Operating Procedures, and guidelines.	Negligible
B04.05.02.02	Worksheets.	B4.5.1.2	Worksheets.	No change
B04.05.02.03	Forms.	B4.5.1.3	Forms.	No change
B04.05.02.04	Labels.	B4.5.1.4	Labels.	No change
B04.05.03	The document control policy shall include:	B4.5.3	The document control system shall include:	Negligible
B04.05.03.01	A standardized format for policies, procedures, worksheets, and forms.	B4.5.3.1	A standardized format for critical documents.	Negligible
B04.05.03.02	Assignment of numeric or alphanumeric identifier and title to each document and document version regulated within the system.	B4.5.3.2	Assignment of a numeric or alphanumeric identifier and a title to each document and document version regulated within the system.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
B04.05.03.03	A procedure for document approval, including the approval date, signature of approving individual(s), and the effective date.	B4.5.3.3	A system for document approval, including the approval date, signature of approving individual(s), and the effective date.	Negligible
B04.05.03.04	A system to protect controlled documents from accidental or unauthorized modification.	B4.5.3.4	A system to protect controlled documents from accidental or unauthorized modification.	No change
		B4.5.3.5	Review of controlled documents every two (2) years at a minimum.	New
B04.05.03.05	A system for document change control that includes a description of the change, the signature of approving individual(s), approval date(s), effective date, and archival date.	B4.5.3.6	A system for document change control that includes a description of the change, version number, the signature of approving individual(s), approval date(s), communication or training on the change as applicable, effective date, and archival date.	Moderate
B04.05.03.06	Archived policies and procedures, the inclusive dates of use, and their historical sequence shall be maintained for a minimum of ten (10) years from archival or according to governmental or institutional policy, whichever is longer.	B4.5.3.7	Archival of controlled documents, the inclusive dates of use, and their historical sequence for a minimum of ten (10) years from archival or according to governmental or institutional policy, whichever is longer.	Negligible
B04.05.03.07	A system for the retraction of obsolete documents to prevent unintended use.	B4.5.3.8	A system for the retraction of obsolete documents to prevent unintended use.	No change
B04.05.03.08	A system for record creation, assembly, review, storage, archival, and retrieval.			
B04.05.04	There shall be a process for the regular review and assessment of records to identify recurring problems, potential points of failure, or need for process improvement.			
B04.06	The Quality Management Plan shall include, or summarize and reference, policies and procedures for establishment and maintenance of written agreements with third parties whose services impact the clinical care of the recipient and/or donor.	B4.6	The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for the establishment and maintenance of written agreements.	Minor

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
B04.06.01	Agreements shall include the responsibility of the third-party facility performing any step in collection, processing, or testing to comply with applicable laws and regulations and these Standards.	B4.6.1	Agreements shall be established with external parties providing critical services that could affect the quality and safety of the cellular therapy product or health and safety of the donor or recipient.	Minor
		B4.6.2	Agreements shall include the responsibility of the external party performing any step in collection, processing, testing, storage, distribution, or administration to maintain required accreditations and to comply with applicable laws and regulations and these Standards.	New
B04.06.02	Agreements shall be dated and reviewed on a regular basis.	B4.6.3	Agreements shall be dated and reviewed on a regular basis, at a minimum every two (2) years.	Moderate
B04.07	The Quality Management Plan shall include, or summarize and reference, policies and procedures for documentation and review of outcome analysis and cellular therapy product efficacy to verify that the procedures in use consistently provide a safe and effective product.	B4.7	The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for documentation and review of outcome analysis and cellular therapy product efficacy to verify that the procedures in use consistently provide a safe and effective product.	Negligible
B04.07.01	Criteria for cellular therapy product safety, product efficacy, and/or, the clinical outcome shall be determined and shall be reviewed at regular time intervals.	B4.7.1	Criteria for cellular therapy product safety, product efficacy, and the clinical outcome shall be determined and shall be reviewed at regular time intervals.	Negligible
B04.07.02	Both individual cellular therapy product data and aggregate data for each type of cellular therapy product and/or recipient type shall be evaluated.	B4.7.2	Both individual cellular therapy product data and aggregate data for each type of cellular therapy product and recipient type shall be evaluated.	Negligible
B04.07.03	Review of outcome analysis and/or product efficacy shall include at a minimum:	B4.7.3	Review of outcome analysis and/or product efficacy shall include at a minimum:	No change
B04.07.03.01	For HPC products intended for hematopoietic reconstitution, time to engraftment following product administration.	B4.7.3.1	For HPC products intended for hematopoietic reconstitution, time to engraftment following cellular therapy product administration.	Negligible

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
B04.07.03.02	For immune effector cells, an endpoint of clinical function as approved by the Clinical Program Director.	B4.7.3.2	For immune effector cells, an endpoint of clinical function as approved by the Clinical Program Director.	No change
B04.07.03.03	Overall and treatment-related morbidity and mortality at thirty (30) days, one hundred (100) days, and one (1) year after cellular therapy product administration.	B4.7.3.3	Overall and treatment-related morbidity and mortality at thirty (30) days, one hundred (100) days, and one (1) year after cellular therapy product administration.	No change
B04.07.03.04	Acute GVHD grade within one hundred (100) days after allogeneic transplantation.	B4.7.3.4	Acute GVHD grade within one hundred (100) days after allogeneic transplantation.	No change
B04.07.03.05	Chronic GVHD grade within one (1) year after allogeneic transplantation.	B4.7.3.5	Chronic GVHD grade within one (1) year after allogeneic transplantation.	No change
B04.07.03.06	Central venous catheter infection.	B4.7.3.6	Central venous catheter infection.	No change
B04.07.04	Data on outcome analysis and cellular therapy product efficacy, including adverse events related to the recipient, donor, and/or product, shall be provided in a timely manner to entities involved in the collection, processing, and/or distribution of the cellular therapy product.	B4.7.4	Data on outcome analysis and cellular therapy product efficacy, including adverse events related to the recipient, donor, or product, shall be provided in a timely manner to entities involved in the collection, processing, and/or distribution of the cellular therapy product.	Negligible
B04.07.05	The Clinical Program should achieve one-year survival outcome within or above the expected range when compared to national or international outcome data.	B4.7.5	The Clinical Program should achieve one-year survival outcome within or above the expected range when compared to national or international outcome data.	No change
B04.07.05.01	If expected one-year survival outcome is not met, the Clinical Program shall submit a corrective action plan.	B4.7.5.1	If expected one-year survival outcome is not met, the Clinical Program shall implement a corrective action plan that meets FACT or JACIE requirements.	Minor
		B4.7.6	The Clinical Program should set benchmarks for non-relapse mortality at one hundred (100) days after cellular therapy product administration and describe the rationale and process for review in the Quality Management Plan.	New

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
B04.08	The Quality Management Plan shall include, or summarize and reference, policies, procedures, and a schedule for conducting, reviewing, and reporting audits of the Clinical Program's activities to verify compliance with elements of the Quality Management Program and operational policies and procedures.	B4.8	The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for, and a schedule of, audits of the Clinical Program's activities to verify compliance with elements of the Quality Management Program and policies and Standard Operating Procedures, applicable laws or regulations, and these Standards.	Negligible
B04.08.01	Audits shall be conducted on a regular basis by an individual with sufficient expertise to identify problems, but who is not solely responsible for the process being audited.	B4.8.1	Audits shall be conducted by an individual with sufficient expertise to identify problems, but who is not solely responsible for the process being audited.	Negligible
B04.08.02	The results of audits shall be used to recognize problems, detect trends, identify improvement opportunities, implement corrective and preventive actions when necessary, and follow up on the effectiveness of these actions in a timely manner.	B4.8.2	The results of audits shall be used to recognize problems, detect trends, identify improvement opportunities, implement corrective and preventive actions when necessary, and follow-up on the effectiveness of these actions in a timely manner.	No change
B04.08.03	Audits shall include at a minimum:	B4.8.3	Audits shall include at a minimum:	No change
B04.08.03.01	Periodic audit of the accuracy of clinical data.	B4.8.3.1	Periodic audit of the accuracy of clinical data.	No change
B4.8.3.2	Annual audit of safety endpoints and immune effector cellular therapy toxicity management.	B4.8.3.4	Annual audit of safety endpoints and immune effector cellular therapy toxicity management.	No change
B04.08.03.03	Periodic audit of the accuracy of data contained in the Transplant Essential Data Forms of the CIBMTR or the Minimum Essential Data-A Forms of the EBMT.	B4.8.3.8	Periodic audit of the accuracy of the data contained in the Transplant Essential Data Forms of the CIBMTR or the Minimum Essential Data-A Forms of the EBMT.	Negligible
B04.08.03.04	Annual audit of donor screening and testing.	B4.8.3.2	Annual audit of donor screening and testing.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
B04.08.03.05	Annual audit of verification of chemotherapy drug and dose against the prescription ordering system and the protocol.	B4.8.3.6	Annual audit of verification of chemotherapy drug administered against the written order.	Minor
B04.08.03.06	Annual audit of management of cellular therapy products with positive microbial culture results.	B4.8.3.3	Annual audit of management of cellular therapy products with positive microbial culture results.	No change
		B4.8.3.5	Annual audit of documentation that external facilities performing critical contracted services have met the requirements of the written agreements.	New
		B4.8.3.7	Periodic audit of the prescription ordering system against the protocol.	New
B04.09	The Quality Management Plan shall include, or summarize and reference, policies and procedures on the management of cellular therapy products with positive microbial culture results that address at a minimum:	B4.9	The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for the management of cellular therapy products with positive microbial culture results that address at a minimum:	Negligible
		B4.9.1	Criteria for the administration of cellular therapy products with positive microbial culture results.	New
B04.09.01	Notification of the recipient.	B4.9.2	Notification of the recipient.	No change
B04.09.02	Recipient follow-up and outcome analysis.	B4.9.3	Recipient follow-up and outcome analysis.	No change
B04.09.03	Follow-up of the donor, if relevant.	B4.9.4	Follow-up of the donor, if relevant.	No change
		B4.9.5	Investigation of cause.	New
B04.09.04	Reporting to regulatory agencies if appropriate.	B4.9.6	Reporting to regulatory agencies, if appropriate.	No change
B04.09.05	Criteria for the administration of cellular therapy products with positive microbial culture results.			
B04.10	The Quality Management Plan shall include, or summarize and reference, policies and procedures for errors, accidents, biological product deviations, serious adverse events, and complaints, including the following activities at a minimum:	B4.10	The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for occurrences (errors, accidents, deviations, adverse events, adverse reactions, and complaints). The following activities shall be included at a minimum:	Minor

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
B04.10.01	Detection.	B4.10.1	Detection.	No change
B04.10.02	Investigation.	B4.10.2	Investigation.	No change
B04.10.02.01	A thorough investigation shall be conducted by the Clinical Program in collaboration with the Collection Facility, and Processing Facility, and other entities involved in the manufacture of the cellular therapy product, as appropriate.	B4.10.2.1	A thorough investigation shall be conducted by the Clinical Program in collaboration with the Collection Facility, Processing Facility, and other entities involved in the manufacture of the cellular therapy product, as appropriate.	Negligible
B04.10.02.02	Investigations shall identify the root cause and a plan for short- and long-term corrective actions as warranted.	B4.10.2.2	Investigations shall identify the root cause and a plan for short- and long-term corrective and preventive actions as warranted.	Minor
B04.10.03	Documentation.	B4.10.3	Documentation.	No change
B04.10.03.01	Documentation shall include a description of the event, the involved individuals and/or cellular therapy products, when the event occurred, when and to whom the event was reported, and the immediate actions taken.	B4.10.3.1	Documentation shall include a description of the occurrence, date and time of the occurrence, the involved individuals and cellular therapy product(s), when and to whom the occurrence was reported, and the immediate actions taken.	Minor
B04.10.03.02	All investigation reports shall be reviewed in a timely manner by the Clinical Program Director or designee and the Quality Manager.	B4.10.3.2	All investigation reports shall be reviewed in a timely manner by the Clinical Program Director or designee and the Quality Manager.	No change
B04.10.03.03	Cumulative files of errors, accidents, biological product deviations, serious adverse events, and complaints shall be maintained.	B4.10.3.3	Cumulative files of occurrences shall be maintained.	Minor
B04.10.03.04	Cumulative files shall include written investigation reports containing conclusions, follow-up, corrective actions, and a link to the record(s) of the involved cellular therapy products, if applicable.	B4.10.3.4	Cumulative files shall include written investigation reports containing conclusions, follow-up, corrective and preventive actions, and a link to the record(s) of the involved cellular therapy product(s), donor(s), and recipient(s), if applicable.	Minor

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
B04.10.04	Reporting.	B4.10.4	Reporting.	No change
B04.10.04.01	When it is determined that a cellular therapy product was responsible for an adverse reaction, the reaction and results of the investigation shall be reported to the recipient's physician, other facilities participating in the manufacturing of the cellular therapy product, registries, and governmental agencies as required by applicable laws and regulations.	B4.10.4.1	When it is determined that a cellular therapy product has resulted in an adverse event or reaction, the event and results of the investigation shall be reported to the donor's and recipient's physician(s), as applicable, other facilities participating in the manufacturing of the cellular therapy product, registries, and governmental agencies as required by applicable laws and regulations.	Minor
B04.10.04.02	Errors, accidents, biological product deviations, and complaints shall be reported to other facilities performing cellular therapy product functions on the affected cellular therapy product and to the appropriate regulatory and accrediting agencies, registries, grant agencies, and IRBs or Ethics Committees.	B4.10.4.2	Occurrences shall be reported to other facilities performing cellular therapy product functions on the affected cellular therapy product and to the appropriate regulatory and accrediting agencies, registries, grant agencies, sponsors, IRBs, or Ethics Committees.	Minor
B04.10.05	Corrective and preventive action.	B4.10.5	Corrective and preventive action.	No change
B04.10.05.01	Appropriate corrective action shall be implemented if indicated, including both short-term action to address the immediate problem and long-term action to prevent the problem from recurring.	B4.10.5.1	Appropriate action shall be implemented if indicated, including both short-term action to address the immediate problem and long-term action to prevent the problem from recurring.	Minor

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
B04.10.05.02	Follow-up audits of the effectiveness of corrective actions shall be performed in a timeframe as indicated in the investigative report.	B4.10.5.2	Follow-up audits of the effectiveness of corrective and preventive actions shall be performed in a timeframe as indicated in the investigative report.	Minor
B04.10.06	There shall be a defined process to obtain feedback from patients or legally authorized representatives.	B4.16.2	Feedback shall be obtained from donors and recipients or legally authorized representatives.	Negligible
B04.11	The Quality Management Plan shall include, or summarize and reference, policies and procedures for cellular therapy product tracking and tracing that allow tracking from the donor to the recipient or final disposition and tracing from the recipient or final disposition to the donor.	B4.11	The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for cellular therapy product tracking and tracing that allow tracking from the donor to the recipient or final disposition and tracing from the recipient or final disposition to the donor.	Negligible
B04.12	The Quality Management Plan shall include, or summarize and reference, policies and procedures for actions to take in the event the Clinical Program's operations are interrupted.	B4.12	The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for actions to take in the event the Clinical Program's operations are interrupted.	Negligible
B04.13	The Quality Management Plan shall include, or summarize and reference, policies and procedures for qualification of supplies and validation and/or verification of the procedure for marrow collection to achieve the expected end-points, including viability of cells and cellular therapy product characteristics.	B4.13	The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for qualification of critical manufacturers, vendors, equipment, supplies, reagents, facilities, and services.	Minor
B04.13.01	Critical reagents, supplies, equipment, and facilities used for the marrow collection procedure shall be qualified.	B4.13.1	Critical equipment, supplies, reagents, and facilities used for the marrow collection procedure shall be qualified.	Reordered
		B4.13.2	Qualification plans shall include minimum acceptance criteria for performance.	New
B04.13.01.01	Qualification plans shall be reviewed and approved by the Clinical Program Director or designee.	B4.13.3	Qualification plans, results, and reports shall be reviewed and approved by the Quality Manager and Clinical Program Director or designee.	Minor

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
		B4.14	The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for validation or verification of critical procedures.	New
		B4.14.1	Critical procedures to be validated shall include at least the following: marrow collection procedures, labeling, storage, and distribution.	New
B04.13.02	The marrow collection procedure validation shall include:	B4.14.2	Each validation shall include at a minimum:	Significant
B04.13.02.01	An approved validation plan, including conditions to be validated.	B4.14.2.1	An approved validation plan, including conditions to be validated.	No change
B04.13.02.02	Acceptance criteria.	B4.14.2.2	Acceptance criteria.	No change
B04.13.02.03	Data collection.	B4.14.2.3	Data collection.	No change
B04.13.02.04	Evaluation of data.	B4.14.2.4	Evaluation of data.	No change
B04.13.02.05	Summary of results.	B4.14.2.5	Summary of results.	No change
		B4.14.2.6	References, if applicable.	Minor
B04.13.02.06	Review and approval of the validation plan, results, and conclusion by the Marrow Collection Facility Director or designee and the Quality Manager or designee.	B4.14.2.7	Review and approval of the validation plan, validation report, and conclusion by the Quality Manager or designee and the Clinical Program Director or designee.	Moderate
B04.13.03	Changes to a process with the potential to affect the potency, viability, or purity of the cellular therapy product shall include evaluation of risk that the change might create an adverse impact anywhere in the operation and shall be validated or verified as appropriate.	B4.14.3	Significant changes to critical procedures shall be validated and verified as appropriate.	Moderate

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
		B4.15	The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for the evaluation of risk in changes to a process to confirm that the changes do not create an adverse impact or inherent risk elsewhere in the operation.	Separated
		B4.16	The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for obtaining feedback.	New
		B4.16.1	Feedback shall be obtained from associated Collection and Processing Facilities.	New
		B4.17.1	Meetings should have defined attendees, documented minutes, and assigned actions.	New
		B4.17.2	Key performance data and review findings shall be reported to staff.	New
B05	**POLICIES AND PROCEDURES**	**B5**	**POLICIES AND STANDARD OPERATING PROCEDURES**	Negligible
B05.01	The Clinical Program shall establish and maintain policies and/or procedures addressing critical aspects of operations and management in addition to those required in B4. These documents shall include all elements required by these Standards and shall address at a minimum:	B5.1	The Clinical Program shall establish and maintain policies or Standard Operating Procedures addressing critical aspects of operations and management in addition to those required in B4. These documents shall include all elements required by these Standards and shall address at a minimum:	Negligible
B05.01.01	Recipient evaluation, selection, and treatment.	B5.1.1	Recipient evaluation, selection, and treatment.	No change
B05.01.02	Donor and recipient confidentiality.	B5.1.2	Donor and recipient confidentiality.	No change
B05.01.03	Donor and recipient consent.	B5.1.3	Donor and recipient consent.	No change
B05.01.04	Donor screening, testing, eligibility determination, selection, and management.	B5.1.4	Donor screening, testing, eligibility determination, selection, and management.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
B05.01.05	Management of donors who require central venous access.	B5.1.5	Management of donors who require central venous access.	No change
B05.01.06	Administration of the preparative regimen.	B5.1.6	Administration of the preparative regimen.	No change
B05.01.07	Administration of blood products.	B5.1.7	Administration of blood products.	No change
B05.01.08	Administration of HPC and other cellular therapy products, including products under exceptional release.	B5.1.8	Administration of HPC and other cellular therapy products, including products under exceptional release.	No change
B05.01.09	Administration of ABO-incompatible products to include a description of the indication for and processing methods to be used for red cell or plasma reduction.	B5.1.9	Administration of ABO-incompatible products to include a description of the indication for and processing methods to be used for red cell or plasma reduction.	No change
B5.1.10	Management of toxicities of immune effector cellular therapies, including cytokine release syndrome and central nervous system complications.	B5.1.10	Management of cytokine release syndrome and central nervous system toxicities.	Negligible
B05.01.11	Duration and conditions of cellular therapy product storage and indications for disposal.	B5.1.11	Duration and conditions of cellular therapy product storage and indications for disposal.	No change
B05.01.12	Hygiene and use of personal protective equipment.	B5.1.12	Hygiene and use of personal protective equipment and attire.	Minor
B05.01.13	Disposal of medical and biohazard waste.	B5.1.13	Disposal of medical and biohazard waste.	No change
B05.01.14	Emergency and disaster plan, including the Clinical Program response.	B5.1.14	Cellular therapy emergency and disaster plan, including the Clinical Program response.	Minor
B05.02	The Clinical Program shall maintain a detailed Standard Operating Procedures Manual that includes a listing of all current Standard Operating Procedures, including title, identifier, and version.	B5.2	The Clinical Program shall maintain a detailed list of all controlled documents including title and identifier.	Minor

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
B05.03	Standard Operating Procedures shall be sufficiently detailed and unambiguous to allow qualified staff to follow and complete the procedures successfully. Each individual procedure shall include:	B5.3	Standard Operating Procedures shall be sufficiently detailed and unambiguous to allow qualified staff to follow and complete the procedures successfully. Each individual Standard Operating Procedure shall include:	Negligible
B05.03.01	A clearly written description of the objectives.	B5.3.1	A clearly written description of the objectives.	No change
B05.03.02	A description of equipment and supplies used.	B5.3.2	A description of equipment and supplies used.	No change
B05.03.03	Acceptable end-points and the range of expected results.	B5.3.3	Acceptable end-points and the range of expected results.	No change
B05.03.04	A stepwise description of the procedure.	B5.3.4	A stepwise description of the procedure.	No change
B05.03.05	Reference to other Standard Operating Procedures or policies required to perform the procedure.	B5.3.5	Reference to other Standard Operating Procedures or policies required to perform the procedure.	No change
B05.03.06	Age-specific issues where relevant.	B5.3.6	Age-specific issues where relevant.	No change
B05.03.07	A reference section listing appropriate literature.	B5.3.7	A reference section listing appropriate and current literature.	Minor
B05.03.08	Documented approval of each procedure by the Clinical Program Director or designated physician prior to implementation and every two years thereafter.	B5.3.8	Documented approval of each procedure by the Clinical Program Director or designated physician prior to implementation and every two (2) years thereafter.	Negligible
B05.03.09	Documented approval of each procedural modification by the Clinical Program Director or designated physician prior to implementation.	B5.3.9	Documented approval of each procedural modification by the Clinical Program Director or designated physician prior to implementation.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
B05.03.10	Reference to a current version of orders, worksheets, reports, labels, and forms.	B5.3.10	Reference to a current version of orders, worksheets, reports, labels, and forms.	No change
B05.04	Standard Operating Procedures relevant to processes being performed shall be readily available to the facility staff.	B5.4	Controlled documents relevant to processes being performed shall be readily available to the facility staff.	Negligible
B05.05	Staff training and, if appropriate, competency shall be documented before performing a new or revised procedure.	B5.5	Staff training and, if appropriate, competency shall be documented before performing a new or revised Standard Operating Procedure or guideline.	Negligible
B05.06	All personnel shall follow the Standard Operating Procedures related to their positions.	B5.6	All personnel shall follow the policies and Standard Operating Procedures related to their positions.	Negligible
B05.07	Variances shall be pre-approved by the Clinical Program Director and reviewed by the Quality Manager.	B5.7	Planned deviations shall be pre-approved by the Clinical Program Director and reviewed by the Quality Manager.	Minor
B06	**ALLOGENEIC AND AUTOLOGOUS DONOR SELECTION, EVALUATION, AND MANAGEMENT**	**B6**	**ALLOGENEIC AND AUTOLOGOUS DONOR SELECTION, EVALUATION, AND MANAGEMENT**	No change
B06.01	There shall be written criteria for allogeneic and autologous donor selection, evaluation, and management by trained medical personnel.	B6.1	There shall be written criteria for allogeneic and autologous donor selection, evaluation, and management by trained medical personnel.	No change
B06.01.01	Written criteria shall include criteria for the selection of allogeneic donors who are minors or elderly.	B6.1.1	Written criteria shall include criteria for the selection of allogeneic donors who are minors or older donors.	Minor
B06.01.02	Written criteria shall include criteria for the selection of allogeneic donors when more than one donor is available and suitable.	B6.1.2	Written criteria shall include criteria for the selection of allogeneic donors when more than one (1) donor is available and suitable.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
B06.01.03	Information regarding the donation process should be provided to the potential allogeneic donor prior to HLA typing.	B6.1.3	Information regarding the donation process should be provided to the potential allogeneic donor prior to HLA typing.	No change
B06.02	**ALLOGENEIC AND AUTOLOGOUS DONOR INFORMATION AND CONSENT TO DONATE**	**B6.2**	**ALLOGENEIC AND AUTOLOGOUS DONOR INFORMATION AND CONSENT TO DONATE**	No change
B06.02.01	The collection procedure shall be explained in terms the donor can understand, and shall include the following information at a minimum:	B6.2.1	The collection procedure shall be explained in terms the donor can understand, and shall include the following information at a minimum:	No change
B06.02.01.01	The risks and benefits of the procedure.	B6.2.1.1	The risks and benefits of the procedure.	No change
B06.02.01.02	Tests and procedures performed on the donor to protect the health of the donor and the recipient.	B6.2.1.2	Tests and procedures performed on the donor to protect the health of the donor and the recipient.	No change
B06.02.01.03	The rights of the donor or legally authorized representative to review the results of such tests according to applicable laws and regulations.	B6.2.1.3	The rights of the donor or legally authorized representative to review the results of such tests according to applicable laws and regulations.	No change
B06.02.01.04	Alternative collection methods.	B6.2.1.4	Alternative collection methods.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
B06.02.01.05	Protection of medical information and confidentiality.	B6.2.1.5	Protection of medical information and confidentiality.	No change
B06.02.02	Interpretation and translation shall be performed by individuals qualified to provide these services in the clinical setting.	B6.2.2	Interpretation and translation shall be performed by individuals qualified to provide these services in the clinical setting.	No change
B06.02.03	Family members and legally authorized representatives should not serve as interpreters or translators.	B6.2.3	Family members and legally authorized representatives should not serve as interpreters or translators.	No change
B06.02.04	The donor shall have an opportunity to ask questions.	B6.2.4	The donor shall have an opportunity to ask questions.	No change
B06.02.05	The donor shall have the right to refuse to donate.	B6.2.5	The donor shall have the right to refuse to donate or withdraw consent.	Minor
B06.02.05.01	The allogeneic donor shall be informed of the potential consequences to recipient of such refusal.	B6.2.5.1	The allogeneic donor shall be informed of the potential consequences to the recipient of such refusal in the event that consent is withdrawn after the recipient begins the preparative regimen.	Moderate
B06.02.06	Donor informed consent for the cellular therapy product donation shall be obtained and documented by a licensed health care professional familiar with the collection procedure.	B6.2.6	Donor informed consent for the cellular therapy product donation shall be obtained and documented by a licensed health care professional familiar with the collection procedure.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
B06.02.06.01	Informed consent from the allogeneic donor shall be obtained by a licensed health care professional who is not the primary health care professional overseeing care of the recipient.	B6.2.6.1	Informed consent from the allogeneic donor shall be obtained by a licensed health care professional who is not the primary health care professional overseeing care of the recipient.	No change
B06.02.07	In the case of a minor donor, informed consent shall be obtained from the donor's legally authorized representative in accordance with applicable laws and regulations and shall be documented.	B6.2.7	In the case of a donor who is a minor, informed consent shall be obtained from the donor's legally authorized representative in accordance with applicable laws and regulations and shall be documented.	Negligible
B06.02.08	The allogeneic donor shall give informed consent and authorization prior to release of the donor's health or other information to the recipient's physician and/or the recipient.	B6.2.8	The allogeneic donor shall give informed consent and authorization prior to release of the donor's health or other information to the recipient's physician and/or the recipient.	No change
B06.02.09	The donor shall be informed of the policy for cellular therapy product discard or disposal, including actions taken when an intended recipient no longer requires the cellular therapy product.	B6.2.9	The donor shall be informed of the policy for cellular therapy product discard or disposal, including actions taken when an intended recipient no longer requires the cellular therapy product.	No change
B06.02.10	Documentation of consent shall be available to the Collection Facility staff prior to the collection procedure.	B6.2.10	Documentation of consent shall be available to the Collection Facility staff prior to the collection procedure.	No change
B06.03	**ALLOGENEIC AND AUTOLOGOUS DONOR SUITABILITY FOR CELLULAR THERAPY PRODUCT COLLECTION**	**B6.3**	**ALLOGENEIC AND AUTOLOGOUS DONOR SUITABILITY FOR CELLULAR THERAPY PRODUCT COLLECTION**	No change
B06.03.01	There shall be criteria and evaluation policies and procedures in place to protect the safety of donors during the process of cellular therapy product collection.	B6.3.1	There shall be criteria and evaluation policies or Standard Operating Procedures in place to protect the safety of donors during the process of cellular therapy product collection.	Negligible

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
B06.03.01.01	Any abnormal finding shall be reported to the prospective donor with documentation in the donor record of recommendations made for follow-up care.	B6.3.1.1	The Clinical Program shall confirm that clinically significant findings are reported to the prospective donor with documentation in the donor record of recommendations made for follow-up care.	Minor
B06.03.01.02	Allogeneic donor suitability shall be evaluated by a licensed health care professional who is not the primary health care professional overseeing care of the recipient.	B6.3.1.2	Allogeneic donor suitability shall be evaluated by a licensed health care professional who is not the primary health care professional overseeing care of the recipient.	No change
B06.03.01.03	Autologous donors shall be tested as required by applicable laws and regulations.	B6.3.1.3	Autologous donors shall be tested as required by applicable laws and regulations.	No change
B06.03.02	The risks of donation shall be evaluated and documented, including:	B6.3.2	The risks of donation shall be evaluated and documented, including:	No change
B06.03.02.01	Possible need for central venous access.	B6.3.2.1	Possible need for central venous access.	No change
B06.03.02.02	Mobilization therapy for collection of HPC, Apheresis.	B6.3.2.2	Mobilization for collection of HPC, Apheresis.	Negligible
B06.03.02.03	Anesthesia for collection of HPC, Marrow.	B6.3.2.3	Anesthesia for collection of HPC, Marrow.	No change
B06.03.03	The donor should be evaluated for the risk of hemoglobinopathy prior to administration of the mobilization regimen.	B6.3.3	The donor shall be evaluated for the risk of hemoglobinopathy prior to administration of the mobilization regimen.	Significant

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
B06.03.04	A pregnancy test shall be performed for all female donors with childbearing potential within seven (7) days prior to starting the donor mobilization regimen and, as applicable, within seven (7) days prior to the initiation of the recipient's preparative regimen.	B6.3.4	A pregnancy test shall be performed for all female donors with childbearing potential within seven (7) days prior to starting the donor mobilization regimen or undergoing anesthesia, and, as applicable, within seven (7) days prior to the initiation of the recipient's preparative regimen.	Moderate
B06.03.05	Laboratory testing of all donors shall be performed by a laboratory that is accredited, registered, or licensed in accordance with applicable laws and regulations.	B6.3.5	Laboratory testing of all donors shall be performed by a laboratory that is accredited, registered, certified, or licensed in accordance with applicable laws and regulations.	Minor
B06.03.06	The Clinical Program shall inform the Collection Facility and Processing Facility of donor test results or if any testing was not performed.	B6.3.6	The Clinical Program shall inform the Collection Facility and Processing Facility of donor test results or if any testing was not performed.	No change
B06.03.07	There shall be a written order from a physician specifying, at a minimum, timing and goals of collection and processing.	B6.3.7	There shall be a written order from a physician specifying, at a minimum, anticipated date and goals of collection and processing.	Minor
B06.03.08	Issues of donor health that pertain to the safety of the collection procedure shall be communicated in writing to the Collection Facility staff prior to collection.	B6.3.8.1	Issues of donor health that pertain to the safety of the collection procedure shall be communicated in writing to the Collection Facility staff prior to collection.	No change
B06.03.09	Collection from a donor who does not meet Clinical Program collection safety criteria shall require documentation of the rationale for his/her selection by the recipeint's physician.	B6.3.8	Collection from a donor who does not meet collection safety criteria shall require documentation of the rationale for his/her selection by the donor's physician.	Minor
B06.03.10	There shall be a policy for follow-up of donors that includes routine management and the management of collection-associated adverse events.	B6.3.9	There shall be policies or Standard Operating Procedures for follow-up of donors that includes routine management and the management of collection-associated adverse events.	Minor

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
B06.04	**ADDITIONAL REQUIREMENTS FOR ALLOGENEIC DONORS**	B6.4	**ADDITIONAL REQUIREMENTS FOR ALLOGENEIC DONORS**	No change
B06.04.01	A donor advocate shall be available to represent allogeneic donors who are minors or who are mentally incapacitated, as those terms as defined by applicable laws.	B6.4.1	A donor advocate shall be available to represent allogeneic donors who are minors or who are mentally incapacitated, as those terms are defined by applicable laws.	Negligible
B06.04.02	Allogeneic donor infectious disease testing shall be performed using donor screening tests approved or cleared by the governmental authority.	B6.4.2	Allogeneic donor infectious disease testing shall be performed using licensed donor screening tests approved or cleared by the governmental authority.	Negligible
B06.04.03	Allogeneic donors and allogeneic recipients shall be tested for ABO group and Rh type using two independently collected samples. Discrepancies shall be resolved and documented prior to issue of the cellular therapy product.	B6.4.3	Allogeneic donors and allogeneic recipients shall be tested for ABO group and Rh type using two independently collected samples. Discrepancies shall be resolved and documented prior to issue of the cellular therapy product.	No change
B06.04.04	A red cell antibody screen shall be performed on allogeneic recipients.	B6.4.4	A red cell antibody screen shall be performed on allogeneic recipients.	No change
B06.04.05	Allogeneic donors shall be evaluated for risk factors that might result in disease transmission from the cellular therapy product by medical history, physical examination, examination of relevant medical records, and laboratory testing.	B6.4.5	Allogeneic donors shall be evaluated for risk factors that might result in disease transmission from the cellular therapy product by medical history, physical examination, examination of relevant medical records, and laboratory testing.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
B06.04.06	The medical history for allogeneic donors shall include at least the following:	B6.4.6	The medical history for allogeneic donors shall include at least the following:	No change
B06.04.06.01	Vaccination history.	B6.4.6.1	Vaccination history.	No change
B06.04.06.02	Travel history.	B6.4.6.2	Travel history.	No change
B06.04.06.03	Blood transfusion history.	B6.4.6.3	Blood transfusion history.	No change
B06.04.06.04	Questions to identify persons at high risk for transmission of communicable disease as defined by the applicable governmental authority.	B6.4.6.4	Questions to identify persons at high risk for transmission of communicable disease as defined by the applicable governmental authority.	No change
B06.04.06.05	Questions to identify persons at risk of transmitting inherited conditions.	B6.4.6.5	Questions to identify persons at risk of transmitting inherited conditions.	No change
B06.04.06.06	Questions to identify persons at risk of transmitting a hematological or immunological disease.	B6.4.6.6	Questions to identify persons at risk of transmitting a hematological or immunological disease.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
B06.04.06.07	Questions to identify a past history of malignant disease.	B6.4.6.7	Questions to identify a past history of malignant disease.	No change
B06.04.06.08	The allogeneic donor shall confirm that all the information provided is true to the best of his/her knowledge.	B6.4.6.8	The allogeneic donor shall confirm that all the information provided is true to the best of his/her knowledge.	No change
B06.04.07	Allogeneic donors shall be tested for evidence of clinically relevant infection by the following communicable disease agents using tests required by applicable laws and regulations:	B6.4.7	Allogeneic donors shall be tested for evidence of clinically relevant infection by the following communicable disease agents using tests required by applicable laws and regulations:	No change
B06.04.07.01	Human immunodeficiency virus, type 1.	B6.4.7.1	Human immunodeficiency virus, type 1.	No change
B06.04.07.02	Human immunodeficiency virus, type 2.	B6.4.7.2	Human immunodeficiency virus, type 2.	No change
B06.04.07.03	Hepatitis B virus.	B6.4.7.3	Hepatitis B virus.	No change
B06.04.07.04	Hepatitis C virus.	B6.4.7.4	Hepatitis C virus.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
B06.04.07.05	Treponema pallidum (syphilis).	B6.4.7.5	Treponema pallidum (syphilis).	No change
B06.04.08	If required by applicable laws and regulations, allogeneic donors shall also be tested for evidence of clinically relevant infection by the following disease agents:	B6.4.8	If required by applicable laws and regulations, allogeneic donors shall also be tested for evidence of clinically relevant infection by the following disease agents:	No change
B06.04.08.01	Human T cell lymphotrophic virus I.	B6.4.8.1	Human T cell lymphotropic virus I.	No change
B06.04.08.02	Human T cell lymphotrophic virus II.	B6.4.8.2	Human T cell lymphotropic virus II.	No change
B06.04.08.03	West Nile Virus.	B6.4.8.3	West Nile Virus.	No change
B06.04.08.04	Trypanosoma cruzi (Chagas' Disease).	B6.4.8.4	Trypanosoma cruzi (Chagas Disease).	No change
B06.04.09	Blood samples for testing for evidence of clinically relevant infection shall be drawn and tested within timeframes required by applicable laws and regulations.	B6.4.9	Blood samples for testing for evidence of clinically relevant infection shall be drawn and tested within timeframes required by applicable laws and regulations.	No change
B06.04.09.01	Blood samples for communicable disease testing from allogeneic HPC donors shall be obtained within thirty (30) days prior to collection.	B6.4.9.1	Allogeneic HPC, Apheresis or HPC, Marrow blood samples for communicable disease testing from allogeneic HPC donors shall be obtained within thirty (30) days prior to collection.	Minor

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
B06.04.09.02	For viable lymphocyte-rich cells, including mononuclear cells and other cellular therapy products, blood samples from allogeneic donors shall be obtained within seven (7) days prior to or after collection in the U.S. or 30 days prior to collection in European Union member states.	B6.4.9.2	For viable lymphocyte-rich cells, including mononuclear cells and other cellular therapy products, blood samples from allogeneic donors shall be obtained within seven (7) days prior to or after collection in the U.S. or 30 days prior to collection in European Union member states, or in accordance with applicable laws and regulations.	Negligible
B06.04.10	Allogeneic donors shall be tested for CMV (unless previously documented to be positive).	B6.4.10	Allogeneic donors shall be tested for Cytomegalovirus (unless previously documented to be positive).	Negligible
B06.04.11	Additional tests shall be performed as required to assess the possibility of transmission of other infectious and non-infectious diseases.	B6.4.11	Additional tests shall be performed as required to assess the possibility of transmission of other infectious and non-infectious diseases.	No change
B06.04.12	Allogeneic donors and recipients shall be tested for HLA antigens by a laboratory accredited by ASHI, EFI, or other appropriate organization. Typing shall include at a minimum HLA-A, B, and DRB1 type for all allogeneic donors and also HLA-C type for unrelated allogeneic donors and related allogeneic donors other than siblings.	B6.4.12	Allogeneic donors and recipients shall be tested for HLA alleles by a laboratory accredited by ASHI, EFI, or other appropriate organization. Typing shall include at a minimum HLA-A, B, and DRB1 type for all allogeneic donors and also HLA-C type for unrelated allogeneic donors and related allogeneic donors other than siblings.	Minor
B06.04.12.01	DNA high resolution molecular typing shall be used for DRB1 typing.	B6.4.12.1	DNA high resolution molecular typing shall be used for HLA typing.	Minor
B06.04.12.02	Verification typing shall be performed on the selected allogeneic donor using an independently collected sample. Results shall be confirmed prior to administration of the preparative regimen.	B6.4.12.2	Verification typing shall be performed on the selected allogeneic donor using an independently collected sample. Results shall be confirmed prior to administration of the preparative regimen.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
B06.04.12.03	There shall be a procedure to confirm the identity of cord blood units if verification typing cannot be performed on attached segments.	B6.4.12.3	There shall be a policy or Standard Operating Procedure to confirm the identity of cord blood units if verification typing cannot be performed on attached segments.	Minor
B06.04.12.04	There shall be a policy for anti-HLA antibody testing for mismatched donors and recipients.	B6.4.12.4	There shall be a policy or Standard Operating Procedure for anti-HLA antibody testing for mismatched donors and recipients.	Minor
B06.04.13	Allogeneic donor eligibility, as defined by applicable laws and regulations, shall be determined by a physician after history, exam, medical record review, and testing. The donor eligibility determination shall be documented in the recipient's medical record before the recipient's preparative regimen is initiated and before the allogeneic donor begins the mobilization regimen.	B6.4.13	Allogeneic donor eligibility, as defined by applicable laws and regulations, shall be determined by a physician after history, exam, medical record review, and testing. The donor eligibility determination shall be documented in the recipient's medical record before the recipient's preparative regimen is initiated and before the allogeneic donor begins the mobilization regimen.	No change
B06.04.14	Records required for donor eligibility determination shall be in English or translated into English when crossing international borders.	B6.4.14	Records required for donor eligibility determination shall be in English or translated into English when crossing international borders.	No change
B06.04.15	The use of an ineligible allogeneic donor, or an allogeneic donor for whom donor eligibility determination is incomplete, shall require documentation of the rationale for his/her selection by the transplant physician, urgent medical need documentation, and the informed consent of the donor and the recipient.	B6.4.15	The use of an ineligible allogeneic donor, or an allogeneic donor for whom donor eligibility determination is incomplete, shall require documentation of the rationale for his/her selection by the transplant physician, urgent medical need documentation, and the informed consent of the donor and the recipient.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
B06.04.16	Allogeneic donor eligibility shall be communicated in writing to the Collection and Processing Facilities.	B6.4.16	Allogeneic donor eligibility shall be communicated in writing to the Collection and Processing Facilities.	No change
B06.04.17	There shall be a policy covering the creation and retention of allogeneic donor records.	B6.4.17	There shall be a policy for the creation and retention of allogeneic donor records.	Negligible
B06.04.17.01	Allogeneic donor records shall include donor eligibility determination, including the name of the responsible person who made the determination and the date of the determination.	B6.4.17.1	Allogeneic donor records shall include donor eligibility determination, including the name of the responsible person who made the determination and the date of the determination.	No change
B07	**RECIPIENT CARE**	**B7**	**RECIPIENT CARE**	No change
B07.01	Recipient informed consent for the cellular therapy shall be obtained and documented by a licensed health care professional familiar with the proposed therapy.	B7.1	Recipient informed consent for the cellular therapy shall be obtained and documented by a licensed health care professional familiar with the proposed cellular therapy.	Negligible
B07.01.01	The Clinical Program shall provide information regarding the risks and benefits of the proposed cellular therapy.	B7.1.1	The Clinical Program shall provide information regarding the risks and benefits of the proposed cellular therapy.	No change
B07.02	The attending physician shall verify the availability and suitability of a donor or cellular therapy product prior to initiating the recipient's preparative regimen.	B7.2	The attending physician shall confirm the availability and suitability of a donor or cellular therapy product prior to initiating the recipient's preparative regimen.	Negligible
B07.02.01	The Clinical Program shall notify the Processing Facility prior to requesting a cellular therapy product from a cord blood bank, registry, or other facility.	B7.2.1	The Clinical Program shall notify the Processing Facility prior to requesting a cellular therapy product from a cord blood bank, registry, or other facility.	No change
B07.03	Records shall be made concurrently with each step of recipient care in such a way that all steps may be accurately traced.	B7.3	Records shall be made concurrently with each step of recipient care in such a way that all steps may be accurately traced.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
B07.03.01	Records shall identify the person immediately responsible for each significant step, including dates and times (where appropriate) of various steps.	B7.3.1	Records shall identify the person immediately responsible for each significant step, including dates and times (where appropriate) of various steps.	No change
B07.04	There shall be a policy addressing safe administration of the preparative regimen.	B7.4	There shall be policies addressing safe administration of the preparative regimen.	Minor
B07.04.01	The treatment orders shall include the patient height and weight, specific dates of administration, daily doses (if appropriate), and route of administration of each agent.	B7.4.1	The treatment orders shall include the patient's current height and weight, specific dates of administration, daily doses (if appropriate), and route of administration of each agent.	Negligible
B07.04.02	Preprinted orders or electronic equivalent shall be used for protocols and standardized regimens. These orders shall be verified and documented by an attending physician.	B7.4.2	Preprinted orders or electronic equivalent shall be used for protocols and standardized regimens. These orders shall be verified and documented by an attending physician.	No change
B07.04.03	The pharmacist preparing the drug shall verify and document the doses against the protocol or standardized regimen listed on the orders.	B7.4.3	The pharmacist verifying or preparing the drug shall check and document the doses against the protocol or standardized regimen listed on the orders.	Negligible
B07.04.04	Prior to administration of the preparative regimen, one (1) qualified person using a validated process or two (2) qualified people shall verify and document the drug and dose in the bag or pill against the orders and the protocol, and the identity of the patient to receive the therapy.	B7.4.4	Prior to administration of the preparative regimen, one (1) qualified person using a validated process or two (2) qualified persons shall verify and document:	Separated
		B7.4.4.1	The drug and dose in the bag or pill against the orders and the protocol or standardized regimen.	Separated
		B7.4.4.2	The identity of the recipient.	Separated
B07.05	There shall be a policy addressing safe administration of radiation therapy.	B7.5	There shall be policies addressing safe administration of radiation therapy.	Minor

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
B07.05.01	There shall be a consultation with a radiation oncologist prior to initiation of therapy if radiation treatment is used in the preparative regimen.	B7.5.1	There shall be a consultation with a radiation oncologist prior to initiation of therapy if radiation treatment is used in the preparative regimen.	No change
B07.05.02	The patient's diagnosis, relevant medical history including pre-existing co-morbid conditions, and proposed preparative regimen shall be made available to the consulting radiation oncologist in writing.	B7.5.2	The recipient's diagnosis, relevant medical history including pre-existing co-morbid conditions, and proposed preparative regimen shall be made available to the consulting radiation oncologist in writing.	Negligible
B07.05.03	A documented consultation by a radiation oncologist shall address any prior radiation treatment the patient may have received, any other factors that may increase the toxicity of the radiation, and include a plan for delivery of radiation therapy.	B7.5.3	A documented consultation by a radiation oncologist shall address any prior radiation treatment the recipient may have received, any other factors that may increase the toxicity of the radiation, and include a plan for delivery of radiation therapy.	Negligible
B07.05.04	Prior to administration of each dose of radiation therapy, the dose shall be verified and documented as per radiation therapy standards.	B7.5.4	Prior to administration of each dose of radiation therapy, the dose shall be verified and documented as per institutional radiation therapy standards.	Minor
B07.05.05	A final report of the details of the radiation therapy administered shall be documented in the patient medical record.	B7.5.5	A final report of the details of the radiation therapy administered shall be documented in the recipient's medical record.	Negligible
B07.06	There shall be a policy addressing safe administration of cellular therapy products.	B7.6	There shall be policies addressing safe administration of cellular therapy products.	Minor
B07.06.01	There shall be a policy for determining the appropriate volume and the appropriate dose of red blood cells, cryoprotectants, and other additives.	B7.6.1	There shall be policies for determining the appropriate volume and the appropriate dose of red blood cells, cryoprotectants, and other additives.	Minor
B07.06.02	There shall be a policy for volume of ABO-incompatible red cells in allogeneic cellular therapy products.	B7.6.2	There shall be policies for the infusion of ABO-incompatible red cells in allogeneic cellular therapy products.	Minor
B07.06.03	There shall be consultation with the Processing Facility regarding cord blood preparation for administration.	B7.6.3	There shall be consultation with the Processing Facility regarding cord blood preparation for administration.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
B07.06.03.01	Cord blood units that have not been red cell reduced prior to cryopreservation shall be washed prior to administration.	B7.6.3.1	Cord blood units that have not been red cell reduced prior to cryopreservation shall be washed prior to administration.	No change
B07.06.03.02	Cord blood units that have been red cell reduced prior to cryopreservation should be diluted or washed prior to administration.	B7.6.3.2	Cord blood units that have been red cell reduced prior to cryopreservation should be diluted or washed prior to administration.	No change
B07.06.04	Two (2) qualified persons shall verify the identity of the recipient and the product and the order for administration prior to the administration of the cellular therapy product.	B7.6.4	Two (2) qualified persons shall verify the identity of the recipient and the product and the order for administration prior to the administration of the cellular therapy product.	No change
B07.06.05	For transplants utilizing cellular therapy products from more than one donor, the first cellular therapy product shall be administered safely prior to administration of the second cellular therapy product.	B7.6.5	For transplants utilizing cellular therapy products from more than one (1) donor, the first cellular therapy product shall be administered safely prior to administration of the second cellular therapy product.	No change
B07.06.06	There shall be documentation in the recipient's medical record of the administered cellular therapy product unique identifier, initiation and completion times of administration, and any adverse events related to administration.	B7.6.6	There shall be documentation in the recipient's medical record of the unique identifier of the administered cellular therapy product, initiation and completion times of administration, and any adverse events related to administration.	Negligible
B07.06.07	A circular of information for cellular therapy products shall be available to staff.	B7.6.7	A circular of information for cellular therapy products shall be available to staff.	No change
B07.06.08	There should be policies and procedures in place for monitoring by appropriate specialists of recipients for post-transplant late effects, including at a minimum endocrine and reproductive function, osteoporosis, cardiovascular risk factors, respiratory function, chronic renal impairment, secondary cancers, and the growth and development of pediatric patients.	B7.7	There shall be policies or Standard Operating Procedures addressing appropriate follow-up of recipients after administration of preparative regimens and cellular therapy products, including, at a minimum, the management of the following elements:	Moderate
		B7.7.1	Management of nausea, vomiting, pain and other discomforts.	new

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
		B7.7.2	Monitoring of blood counts and transfusion of blood products.	new
		B7.7.3	Monitoring of infections and use of antimicrobials.	new
		B7.7.4	Monitoring of organ dysfunction or failure and institution of treatment.	new
		B7.7.5	Monitoring of graft failure and institution of treatment.	new
B07.07	**ADDITIONAL REQUIREMENTS FOR ALLOGENEIC TRANSPLANTATION**			
B07.07.01	Allogeneic recipients should be assessed regularly for evidence of acute GVHD using an established staging and grading system.	B7.7.6	Regular assessment for evidence of acute GVHD using an established staging and grading system.	Minor
B07.07.02	Allogeneic recipients should be assessed regularly for evidence of chronic GVHD using an established staging and grading system.	B7.7.7	Regular assessment for evidence of chronic GVHD using an established staging and grading system.	Minor
B07.07.03	There should be policies and procedures in place for allogeneic recipient post-transplant vaccination schedules and indications.	B7.9	There should be policies or Standard Operating Procedures in place for post-transplant vaccination schedules and indications.	Negligible
		B7.8	There shall be policies or Standard Operating Procedures in place for planned discharges and provision of post-transplant care.	New
B07.08	The Clinical Program shall refer planned discharges and post-transplant care to facilities and health care professionals adequate for post-transplant care.	B7.8.1	When a recipient is discharged prior to engraftment, the Clinical Program shall verify that the following elements are available:	Minor
		B7.8.1.1	A consult between the attending physician and the receiving health care professionals regarding the applicable elements in Standard B7.7.	New
		B7.8.1.2	Facilities that provide appropriate location, adequate space, and protection from airborne microbial contamination.	New
		B7.8.1.3	Appropriate medications, blood products, and additional care required by the recipient.	New

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
B07.08.01	The Clinical Program shall provide or secure oversight of care that meets applicable standards.	B7.8.2	The Clinical Program shall provide appropriate instructions to recipients prior to discharge.	Minor
		B7.8.3	The Clinical Program shall provide appropriate instructions to recipients prior to discharge.	New
B07.09	There shall be a policy addressing indications for and safe administration of ECP if utilized by the Clinical Program.	B7.10	There shall be policies addressing indications for and safe administration of ECP if utilized by the Clinical Program.	Minor
B07.09.01	There shall be a consultation with the facility or physician that performs ECP prior to initiation of therapy.	B7.10.1	There shall be a consultation with the facility or physician that performs ECP prior to initiation of therapy.	No change
B07.09.02	Before ECP is undertaken, there shall be a written therapy plan from an attending physician specifying the patient's diagnosis and GVHD grade, involved organs, timing of the procedure, and any other factors that may affect the safe administration of ECP.	B7.10.2	Before ECP is undertaken, there shall be a written therapy plan from an attending physician specifying the patient's diagnosis and GVHD grade, involved organs, timing of the procedure, and any other factors that may affect the safe administration of ECP.	No change
B07.09.03	A report of the details of ECP administered, including an assessment of the response, shall be documented in the recipient's medical record.	B7.10.3	A report of the details of ECP administered, including an assessment of the response, shall be documented in the recipient's medical record.	No change
B07.09.04	The facility performing ECP shall follow written procedures appropriate for the clinical condition of the patient.	B7.10.4	The facility performing ECP shall follow written Standard Operating Procedures appropriate for the clinical condition of the patient.	Negligible
B7.10	There shall be policies and procedures addressing the administration of immune effector cells and management of complications.	B7.11	There shall be policies or Standard Operating Procedures addressing the administration of immune effector cells and management of complications, if applicable.	Negligible
B7.10.1	There shall be a consultation with the referring physician prior to initiation of immune effector cellular therapy to review the goal and plan of the treatment.	B7.11.1	There shall be a consultation with the referring physician prior to initiation of immune effector cellular therapy to review the goal and plan of the treatment.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
B7.10.2	There shall be regular assessment of the recipient to detect complications, including cytokine release syndrome and neurologic dysfunction.	B7.11.2	There shall be regular assessment of the recipient to detect complications, including cytokine release syndrome and neurologic dysfunction.	No change
B7.10.3	There shall be a written plan for rapid escalation of care, increased intensity of monitoring, and relevant workup to address complications.	B7.11.3	There shall be a written plan for rapid escalation of care, increased intensity of monitoring, and relevant workup to address complications.	No change
B7.10.4	Communication to the clinical staff, intensive care unit, emergency department, and pharmacy shall be timely.	B7.11.4	Communication to the clinical staff, intensive care unit, emergency department, and pharmacy shall be timely.	No change
B7.10.5	The Clinical Program shall have written guidelines for management of complications, including the use of cytokine-blocking agents and corticosteroid administration.	B7.11.5	The Clinical Program shall have written guidelines for management of complications, including the use of cytokine-blocking agents and corticosteroid administration.	No change
		B7.12	There shall be an infrastructure and policies or Standard Operating Procedures in place for provision of appropriate long-term follow-up, treatment, and plans of care.	New
		B7.12.1	There shall be policies or Standard Operating Procedures for monitoring by appropriate specialists of recipients for post-cellular therapy late effects, including at a minimum:	New
		B7.12.1.1	Endocrine and reproductive function and osteoporosis.	New
		B7.12.1.2	Cardiovascular risk factors.	New
		B7.12.1.3	Respiratory function.	New
		B7.12.1.4	Chronic renal impairment.	New
		B7.12.1.5	Secondary malignancies.	New
		B7.12.1.6	Growth and development of pediatric patients.	New
		B7.12.2	There shall be polices or Standard Operating Procedures describing the transition of long-term pediatric recipients to adult care as appropriate.	New

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
		B7.12.2.1	There shall be policies or Standard Operating Procedures describing the acceptance of pediatric recipients into a long-term follow-up clinic for adults.	New
B08	**CLINICAL RESEARCH**	**B8**	**CLINICAL RESEARCH**	No change
B08.01	Clinical Programs shall have formal review of investigational treatment protocols and patient consent forms by a process that is approved under institutional policies and applicable laws and regulations.	B8.1	Clinical Programs shall have formal review of investigational treatment protocols and patient consent forms by a process that is approved under institutional policies and applicable laws and regulations.	No change
B08.01.01	Those Clinical Programs utilizing investigational treatment protocols shall have in place a pharmacy equipped for research activities, including a process for tracking, inventory, and secured storage of investigational drugs.	B8.1.1	Those Clinical Programs utilizing investigational treatment protocols shall have in place a pharmacy equipped for research activities, including a process for tracking, inventory, and secured storage of investigational drugs.	No change
B8.1.2	There shall be a process to manage investigational cellular therapy products.	B8.1.2	There shall be a process to manage investigational cellular therapy products.	No change
B08.02	Documentation for all research protocols performed by the Clinical Program shall be maintained in accordance with institutional policies and applicable laws and regulations, including audits; approvals by the Institutional Review Board, Ethics Committee, or equivalent; correspondence with regulatory agencies; and any adverse events.	B8.2	Documentation for all research protocols performed by the Clinical Program shall be maintained in accordance with institutional policies and applicable laws and regulations, including audits; approvals by the Institutional Review Board, Ethics Committee, or equivalent; correspondence with regulatory agencies; and any adverse events and the resolution.	Minor
B08.03	For clinical research, informed consent shall be obtained from each research subject or legally authorized representative, in language he or she can understand, and under circumstances that minimize the possibility of coercion or undue influence.	B8.3	For clinical research, informed consent shall be obtained from each research subject or legally authorized representative, in language he or she can understand, and under circumstances that minimize the possibility of coercion or undue influence.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
B08.03.01	The research subject or legally authorized representative shall be given the opportunity to ask questions and to have his/her questions answered to his/her satisfaction, and to withdraw from the research without prejudice.	B8.3.1	The research subject or legally authorized representative shall be given the opportunity to ask questions and to have his/her questions answered to his/her satisfaction, and to withdraw from the research without prejudice.	No change
B08.03.02	Informed consent for a research subject shall contain the following elements at a minimum and comply with applicable laws and regulations:	B8.3.2	Informed consent for a research subject shall contain the following elements at a minimum and comply with applicable laws and regulations:	No change
B08.03.02.01	An explanation of the research purposes, a description of the procedures to be followed, and the identification of investigational procedures.	B8.3.2.1	An explanation of the research purposes, a description of the procedures to be followed, and the identification of investigational procedures.	No change
B08.03.02.02	The expected duration of the subject's participation.	B8.3.2.2	The expected duration of the subject's participation.	No change
B08.03.02.03	A description of the reasonably expected risks, discomforts, benefits to the subject and others, and alternative procedures.	B8.3.2.3	A description of the reasonably expected risks, discomforts, benefits to the subject and others, and alternative procedures.	No change
B08.03.02.04	A statement of the extent to which confidentiality will be maintained.	B8.3.2.4	A statement of the extent to which confidentiality will be maintained.	No change
B08.03.02.05	An explanation of the extent of compensation for injury.	B8.3.2.5	An explanation of the extent of compensation for injury.	No change
B08.04	There shall be a process in place to address the disclosure of any issues that may represent a conflict of interest in clinical research.	B8.4	There shall be a process in place to address the disclosure of any issues that may represent a conflict of interest in clinical research.	No change
B09	**DATA MANAGEMENT**	**B9**	**DATA MANAGEMENT**	No change
B09.01	The Clinical Program shall collect all the data necessary to complete the Transplant Essential Data Forms of the CIBMTR or the Minimum Essential Data-A forms of the EBMT.	B9.1	The Clinical Program shall collect all the data necessary to complete the Transplant Essential Data Forms of the CIBMTR or the Minimum Essential Data-A forms of the EBMT.	No change
B09.01.01	Clinical Programs shall submit the data specified in B9.1 to a national or international database if required by applicable laws and regulations.	B9.1.1	Clinical Programs shall submit the data specified in B9.1 to a national or international database if required by applicable laws and regulations.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
B09.01.02	Clinical Programs should submit the data specified in B9.1 for allogeneic and autologous transplants to a national or international database.	B9.1.2	Clinical Programs should submit the data specified in B9.1 for allogeneic and autologous transplants to a national or international database.	No change
B09.01.03	Clinical Programs should collect the data specified in B9.1 for all patients for at least one year following administration of the cellular therapy product.	B9.1.3	Clinical Programs should collect the data specified in B9.1 for all patients for at least one (1) year following administration of the cellular therapy product.	No change
B09.02	The Clinical Program should collect all the data elements included in the applicable CIBMTR Cellular Therapy forms or EBMT forms.	B9.2	The Clinical Program should collect all data elements included in the applicable CIBMTR Cellular Therapy forms or EBMT forms.	Negligible
B09.03	The Clinical Program shall define staff responsible for collecting data and, as appropriate, reporting data to institutional repositories and CIBMTR or EBMT.	B9.3	The Clinical Program shall define staff responsible for collecting data and, as appropriate, reporting data to institutional repositories and CIBMTR or EBMT.	No change
		B9.3.1	Defined data management staff should participate in continuing education annually.	New
B10	**RECORDS**	**B10**	**RECORDS**	No change
B10.01	Clinical Program records related to quality control, personnel training and competency, facility maintenance, facility management, complaints, or other general facility issues shall be retained for a minimum of ten (10) years by the Clinical Program, or longer in accordance with applicable laws and regulations, or by a defined program or institutional policy.	B10.1	Clinical Program records related to quality control, personnel training and competency, facility maintenance, facility management, complaints, or other general facility issues shall be retained for a minimum of ten (10) years by the Clinical Program, or longer in accordance with applicable laws and regulations.	Negligible
B10.01.01	Employee records shall be maintained in a confidential manner and as required by applicable laws and regulations.	B10.1.1	Employee records shall be maintained in a confidential manner and as required by applicable laws and regulations.	No change
		B10.1.2	Cleaning and sanitation records shall be retained for a minimum of three (3) years or longer in accordance with applicable laws or regulations.	New

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
B10.02	Patient and donor records including, but not limited to, consents and records of care, shall be maintained in a confidential manner as required by applicable laws and regulations for a minimum of ten (10) years after the administration of the cellular therapy product, or, if not known, ten (10) years after the date of the distribution, disposition, or expiration, whichever requires the longest maintenance period.	B10.2	Recipient and donor records including, but not limited to, consents and records of care, shall be maintained in a confidential manner as required by applicable laws and regulations for a minimum of ten (10) years after the administration of the cellular therapy product, or, if not known, ten (10) years after the date of the distribution, disposition, or expiration, whichever is latest.	Negligible
B10.03	Research records shall be maintained in a confidential manner as required by applicable laws and regulations for a minimum of ten (10) years after the administration, distribution, disposition, or expiration of the cellular therapy product, whichever is latest.	B10.3	Research records shall be maintained in a confidential manner as required by applicable laws and regulations for a minimum of ten (10) years after the administration, distribution, disposition, or expiration of the cellular therapy product, whichever is latest.	No change
		B10.4	**ELECTRONIC RECORDS**	New
		B10.4.1	The Clinical Program shall maintain a current listing of all critical electronic record systems. Critical electronic record systems shall include at a minimum systems under the control of the Clinical Program that are used as a substitute for paper, to make decisions, to perform calculations, or to create or store information used in critical procedures.	new
		B10.4.2	For all critical electronic record systems, there shall be policies, Standard Operating Procedures, and system elements to maintain the accuracy, integrity, identity, and confidentiality of all records.	New
		B10.4.3	There shall be a means by which access to electronic records is limited to authorized individuals.	New
		B10.4.4	The critical electronic record system shall maintain unique identifiers.	New

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
		B10.4.5	There shall be protection of the records to enable their accurate and ready retrieval throughout the period of record retention.	New
		B10.4.6	For all critical electronic record systems, there shall be an alternative system for all electronic records to allow for continuous operation in the event that critical electronic record systems are not available. The alternative system shall be validated and Clinical Program staff shall be trained in its use.	New
		B10.4.7	For all critical electronic record systems, there shall be written Standard Operating Procedures for record entry, verification, and revision.	New
		B10.4.7.1	A method shall be established or the system shall provide for review of data before final acceptance.	New
		B10.4.7.2	A method shall be established or the system shall provide for the unambiguous identification of the individual responsible for each record entry.	New
		B10.4.8	For all critical electronic record systems, there shall be the ability to generate true copies of the records in both human readable and electronic format suitable for inspection and review.	New
		B10.4.9	For all critical electronic record systems, there shall be validated procedures for and documentation of:	New
		B10.4.9.1	Training and continued competency of personnel in systems use.	New
		B10.4.9.2	Monitoring of data integrity.	New
		B10.4.9.3	Back-up of the electronic records system on a regular schedule.	New
		B10.4.9.4	System assignment of unique identifiers.	New
B10.04	**RECORDS IN CASE OF DIVIDED RESPONSIBILITY**	**B10.5**	**RECORDS IN CASE OF DIVIDED RESPONSIBILITY**	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
B10.04.01	If two (2) or more facilities participate in the collection, processing, or administration of the cellular therapy product, the records of each facility shall show plainly the extent of its responsibility.	B10.5.1	If two (2) or more facilities participate in the collection, processing, or administration of the cellular therapy product, the records of each facility shall show plainly the extent of its responsibility.	No change
B10.04.02	The Clinical Program shall furnish outcome data, in so far as they concern the safety, purity, or potency of the cellular therapy product involved, to other facilities involved in the collection or processing of the cellular therapy product.	B10.5.2	The Clinical Program shall furnish outcome data, related to the safety, purity, or potency of the cellular therapy product involved, to other facilities involved in the collection or processing of the cellular therapy product.	Negligible
C01	**GENERAL**	C1	**GENERAL**	No change
C01.01	These Standards apply to the Apheresis Collection Facility for collection activities of all cellular therapy products collected from living donors.	C1.1	These Standards apply to all collection, storage, and distribution activities performed in the Apheresis Collection Facility for cellular therapy products obtained from living donors.	Minor
C01.02	The Apheresis Collection Facility shall use cell processing facilities that meet FACT-JACIE Standards with respect to their interactions with the Apheresis Collection Facility.	C1.2	The Apheresis Collection Facility shall use cell processing facilities that meet FACT-JACIE Standards with respect to their interactions with the Apheresis Collection Facility.	No change
C01.03	The Apheresis Collection Facility shall abide by all applicable laws and regulations.	C1.3	The Apheresis Collection Facility shall abide by all applicable laws and regulations.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
C01.03.01	The Apheresis Collection Facility shall be licensed, registered, or accredited as required by the appropriate governmental authorities for the activities performed.	C1.3.1	The Apheresis Collection Facility shall be licensed, registered, or accredited as required by the appropriate governmental authorities for the activities performed.	No change
C01.04	The Apheresis Collection Facility shall have an Apheresis Collection Facility Director, an Apheresis Collection Facility Medical Director, a Quality Manager, and at least one (1) additional designated staff member. This team shall have been in place and performing cellular therapy product collections for at least twelve (12) months preceding initial accreditation.	C1.4	The Apheresis Collection Facility shall have an Apheresis Collection Facility Director, an Apheresis Collection Facility Medical Director, a Quality Manager, and a minimum of one (1) additional designated staff member. This team shall have been in place and performing cellular therapy product collections for at least twelve (12) months preceding initial accreditation.	Negligible
C01.05	A minimum of ten (10) cellular therapy products shall have been collected by apheresis in the twelve (12) month period immediately preceding facility accreditation, and a minimum average of ten (10) cellular therapy products shall have been collected by apheresis per year within the accreditation cycle.	C1.5	A minimum of ten (10) cellular therapy products shall have been collected by apheresis in the twelve (12) month period preceding initial accreditation, and a minimum average of ten (10) cellular therapy products shall have been collected by apheresis per year within each accreditation cycle.	Minor
C02	**APHERESIS COLLECTION FACILITY**	**C2**	**APHERESIS COLLECTION FACILITY**	No change
C02.01	There shall be appropriate designated areas for collection of cellular therapy products, for collected products, and for storage of supplies, reagents, and equipment.	C2.1	There shall be appropriate designated areas for collection of cellular therapy products, for collected products, and for storage of equipment, supplies, and reagents.	Minor
C02.01.01	The Apheresis Collection Facility shall be divided into defined areas of adequate size to prevent improper labeling, mix-ups, contamination, or cross-contamination of cellular therapy products.	C2.1.1	The Apheresis Collection Facility shall be divided into defined areas of adequate size to prevent improper labeling, mix-ups, contamination, or cross-contamination of cellular therapy products.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
C02.01.02	There shall be a designated area with appropriate location and adequate space and design to minimize the risk of airborne microbial contamination in outpatient units where collection is performed.	C2.1.2	There shall be a designated area for collection with appropriate location and adequate space and design to minimize the risk of airborne microbial contamination.	Minor
C02.01.03	There shall be a process to control storage areas to prevent mix-ups, contamination, and cross-contamination of all cellular therapy products prior to release or distribution.	C2.1.3	There shall be a process to control storage areas to prevent mix-ups, contamination, and cross-contamination of all cellular therapy products.	Minor
C02.01.04	There shall be suitable space for confidential donor examination and evaluation.	C2.1.4	There shall be suitable space for confidential donor examination and evaluation.	No change
C02.02	The Apheresis Collection Facility shall provide adequate lighting, ventilation, and access to sinks to prevent the introduction, transmission, or spread of communicable disease.	C2.2	The Apheresis Collection Facility shall provide adequate lighting, ventilation, and access to sinks to prevent the introduction, transmission, or spread of communicable disease.	No change
C02.03	Apheresis Collection Facility parameters and environmental conditions shall be controlled to protect the safety and comfort of patients, donors, and personnel.	C2.3	Apheresis Collection Facility parameters and environmental conditions shall be controlled to protect the safety and comfort of donors and personnel.	Minor
C02.04	Critical Apheresis Collection Facility parameters that may affect cellular therapy product viability, integrity, contamination, sterility, or cross-contamination during collection, including temperature and humidity at a minimum, shall be assessed for risk to the cellular therapy product.	C2.4	There shall be a written assessment of critical Apheresis Collection Facility parameters that may affect cellular therapy product viability, integrity, contamination, or cross-contamination during collection.	Moderate
		C2.4.1	The written assessment shall include temperature and humidity at a minimum.	Separated

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
C02.04.01	Critical facility parameters identified to be a risk to the cellular therapy product shall be controlled, monitored, and recorded.	C2.4.2	Critical facility parameters identified to be a risk to the cellular therapy product shall be controlled, monitored, and recorded.	No change
C02.05	When using collection methods that may result in contamination or cross-contamination of cellular therapy products, critical environmental conditions shall be controlled, monitored, and recorded, where appropriate, for air quality and surface contaminates.	C2.5	When using collection methods that may result in contamination or cross-contamination of cellular therapy products, critical environmental conditions shall be controlled, monitored, and recorded, where appropriate, for air quality and surface contaminants.	Negligible
C02.06	The Apheresis Collection Facility shall document facility cleaning and sanitation and maintain order sufficient to achieve adequate conditions for operations.	C2.6	The Apheresis Collection Facility shall document facility cleaning and sanitation and maintain order sufficient to achieve adequate conditions for operations.	No change
C02.07	There shall be adequate equipment and materials for the procedures performed.	C2.7	There shall be adequate equipment and materials for the procedures performed.	No change
C02.08	There shall be access to an intensive care unit and/or emergency services.	C2.8	There shall be access to an intensive care unit or emergency services.	Negligible
	See 2.6			
C02.09	The Apheresis Collection Facility shall be operated in a manner designed to minimize risks to the health and safety of employees, patients, donors, visitors, and volunteers.	C2.9	The Apheresis Collection Facility shall be operated in a manner designed to minimize risks to the health and safety of employees, donors, visitors, and volunteers.	Minor

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
C02.10	The Apheresis Collection Facility shall have a written safety manual that includes instructions for action in case of exposure to communicable disease and to chemical, biological, or radiological hazards.	C2.10	The Apheresis Collection Facility shall have a written safety manual that includes instructions for action in case of exposure, as applicable, to communicable disease and to chemical, biological, or radiological hazards.	Negligible
		C2.11	All waste generated by the Apheresis Collection Facility activities shall be disposed of in a manner that minimizes any hazard to facility personnel and to the environment in accordance with applicable laws and regulations.	New
		C2.12	Gloves and protective clothing shall be worn while handling biological specimens. Such protective clothing shall not be worn outside the work area.	New
C03	**PERSONNEL**	**C3**	**PERSONNEL**	No change
C03.01	**APHERESIS COLLECTION FACILITY DIRECTOR**	**C3.1**	**APHERESIS COLLECTION FACILITY DIRECTOR**	No change
C03.01.01	There shall be an Apheresis Collection Facility Director with a medical degree or degree in a relevant science, qualified by postgraduate training or experience for the scope of activities carried out in the Apheresis Collection Facility. The Apheresis Collection Facility Director may also serve as the Apheresis Collection Facility Medical Director, if appropriately credentialed.	C3.1.1	There shall be an Apheresis Collection Facility Director with a medical degree or degree in a relevant science, with two (2) years of postgraduate training and experience in cellular therapy product collection procedures at a minimum. The Apheresis Collection Facility Director may also serve as the Apheresis Collection Facility Medical Director, if appropriately credentialed.	Significant
C03.01.02	The Apheresis Collection Facility Director shall be responsible for all technical procedures, performance of the collection procedure, supervision of staff, administrative operations, and the Quality Management Program, including compliance with these Standards and other applicable laws and regulations.	C3.1.2	The Apheresis Collection Facility Director shall be responsible for all Standard Operating Procedures, technical procedures, performance of the collection procedure, supervision of staff, administrative operations, and the Quality Management Program, including compliance with these Standards and applicable laws and regulations.	Negligible

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
C03.01.03	The Apheresis Collection Facility Director shall have at least one year experience in cellular therapy product collection procedures.			
C03.01.04	The Apheresis Collection Facility Director shall have performed or supervised a minimum of five (5) cellular therapy product apheresis collection procedures in the twelve (12) months preceding accreditation and a minimum average of five (5) cellular therapy product apheresis collection procedures per year within the accreditation cycle.	C3.1.3	The Apheresis Collection Facility Director shall have performed or supervised a minimum of five (5) cellular therapy product apheresis collection procedures in the twelve (12) months preceding initial accreditation and a minimum average of five (5) cellular therapy product apheresis collection procedures per year within each accreditation cycle.	Negligible
C03.01.05	The Apheresis Collection Facility Director shall participate in ten (10) hours of educational activities related to cellular therapy annually at a minimum.	C3.1.4	The Apheresis Collection Facility Director shall participate in a minimum of ten (10) hours of educational activities related to cellular therapy annually.	Reordered
C03.01.05.01	Continuing education shall include, but is not limited to, activities related to the field of HPC transplantation and apheresis.	C3.1.4.1	Continuing education shall include, but is not limited to, activities related to the field of HPC transplantation.	Minor
C03.02	**APHERESIS COLLECTION FACILITY MEDICAL DIRECTOR**	**C3.2**	**APHERESIS COLLECTION FACILITY MEDICAL DIRECTOR**	No change
C03.02.01	There shall be an Apheresis Collection Facility Medical Director who is a licensed or certified physician with postgraduate training in cell collection and/or transplantation.	C3.2.1	There shall be an Apheresis Collection Facility Medical Director who is a licensed physician with postgraduate certification, and training in cellular therapy product collection and transplantation.	Negligible

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
C03.02.02	The Apheresis Collection Facility Medical Director or designee shall be responsible for the medical care of donors undergoing apheresis, including the pre-collection evaluation of the donor at the time of donation and care of any complications resulting from the collection procedure.	C3.2.2	The Apheresis Collection Facility Medical Director or designee shall be responsible for the medical care of donors undergoing apheresis, including the pre-collection evaluation of the donor at the time of donation and care of any complications resulting from the collection procedure.	No change
C03.02.03	The Apheresis Collection Facility Medical Director shall have at least one year experience in performing and/or supervising cellular therapy product collection procedures.	C3.2.3	The Apheresis Collection Facility Medical Director shall have at least two (2) years experience in performing or supervising cellular therapy product collection procedures.	Significant
C03.02.04	The Apheresis Collection Facility Medical Director shall have performed or supervised a minimum of five (5) cellular therapy product apheresis collection procedures in the twelve (12) months preceding accreditation and a minimum average of five (5) cellular therapy product apheresis collection procedures per year within the accreditation cycle.	C3.2.4	The Apheresis Collection Facility Medical Director shall have performed or supervised a minimum of five (5) cellular therapy product apheresis collection procedures in the twelve (12) months preceding initial accreditation and a minimum average of five (5) cellular therapy product apheresis collection procedures per year within each accreditation cycle.	Negligible
C03.02.05	The Apheresis Collection Facility Medical Director shall participate in ten (10) hours of educational activities related to cellular therapy annually at a minimum.	C3.2.5	The Apheresis Collection Facility Medical Director shall participate in a minimum of ten (10) hours of educational activities related to cellular therapy annually.	Reordered
C03.02.05.01	Continuing education shall include, but is not limited to, activities related to the field of HPC transplantation and apheresis.	C3.2.5.1	Continuing education shall include, but is not limited to, activities related to the field of HPC transplantation.	Minor
C03.03	**QUALITY MANAGER**	**C3.3**	**QUALITY MANAGER**	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
C03.03.01	There shall be an Apheresis Collection Facility Quality Manager to establish and maintain systems to review, modify, and approve all policies and procedures intended to monitor compliance with these Standards and/or the performance of the Apheresis Collection Facility.	C3.3.1	There shall be an Apheresis Collection Facility Quality Manager to establish and maintain systems to review, modify, and approve all policies and Standard Operating Procedures intended to monitor compliance with these Standards or the performance of the Apheresis Collection Facility.	Negligible
C03.03.02	The Quality Manager should have a reporting structure independent of cellular therapy product manufacturing.	C3.3.2	The Apheresis Collection Facility Quality Manager should have a reporting structure independent of cellular therapy product manufacturing.	Negligible
C03.03.03	The Apheresis Collection Facility Quality Manager shall participate in ten (10) hours of educational activities related to cellular therapy, cell collection, and/or quality management annually at a minimum.	C3.3.3	The Apheresis Collection Facility Quality Manager shall participate in a minimum of ten (10) hours of educational activities related to cellular therapy, cell collection, and quality management annually.	Reordered
C03.03.03.01	Continuing education shall include, but is not limited to, activities related to the field of HPC transplantation.	C3.3.3.1	Continuing education shall include, but is not limited to, activities related to the field of HPC transplantation.	No change
C03.04	**STAFF**	**C3.4**	**STAFF**	No change
C03.04.01	The number of trained collection personnel shall be adequate for the number of procedures performed and shall include a minimum of one designated trained individual with an identified trained backup to maintain sufficient coverage.	C3.4.1	The number of trained collection personnel shall be adequate for the number of procedures performed and shall include a minimum of one (1) designated trained individual with an identified trained backup to maintain sufficient coverage.	No change
C03.04.02	For Apheresis Collection Facilities collecting cellular therapy products from pediatric donors, physicians and collection staff shall have documented training and experience in performing these procedures.	C3.4.2	For Apheresis Collection Facilities collecting cellular therapy products from pediatric donors, physicians and collection staff shall have documented training and experience with pediatric donors.	Negligible
C04	**QUALITY MANAGEMENT**	**C4**	**QUALITY MANAGEMENT**	No change
		C4.1	There shall be a Quality Management Program that incorporates key performance data.	New

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
C04.01	The Apheresis Collection Facility Director or designee shall have authority over and responsibility for ensuring that the Quality Management Program is effectively established and maintained.	C4.1.1	The Apheresis Collection Facility Director or designee shall have authority over and responsibility for ensuring that the Quality Management Program is effectively established and maintained.	No change
C04.01.01	The Apheresis Collection Facility Director or designee shall annually review the effectiveness of the Quality Management Program. Documentation of the review findings shall be provided to the Clinical Program Director.	C4.18	The Apheresis Collection Facility Director or designee shall annually review the effectiveness of the Quality Management Program.	Minor
C04.02	The Apheresis Collection Facility shall establish and maintain a written Quality Management Plan.	C4.2	The Apheresis Collection Facility shall establish and maintain a written Quality Management Plan.	No change
C04.02.01	The Apheresis Collection Facility Director or designee shall be responsible for the Quality Management Plan as it pertains to the Apheresis Collection Facility.	C4.2.1	The Apheresis Collection Facility Director or designee shall be responsible for the Quality Management Plan as it pertains to the Apheresis Collection Facility.	No change
C04.02.02	The Apheresis Collection Facility Director or designee shall review and report to staff quality management activities, at a minimum, quarterly.	C4.17	The Apheresis Collection Facility Director or designee shall review the Quality Management activities with representatives in key positions in all elements of the cellular therapy program, at a minimum, quarterly.	Moderate
C04.02.03	The Apheresis Collection Facility Director or designee shall not have oversight of his/her own work if this person also performs other tasks in the Apheresis Collection Facility.	C4.17.3	The Apheresis Collection Facility Director or designee shall not have oversight of his/her own work if this person also performs other tasks in the Apheresis Collection Facility.	No change
C04.03	The Quality Management Plan shall include, or summarize and reference, an organizational chart of key positions and functions within the Apheresis Collection Facility.	C4.3	The Quality Management Plan shall include, or summarize and reference, an organizational chart of key positions and functions within the Apheresis Collection Facility.	No change
C04.03.01	The Quality Management Plan shall include a description of how these key positions interact to implement the quality management activities.	C4.3.1	The Quality Management Plan shall include a description of how these key positions interact to implement the Quality Management activities.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
C04.04	The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures addressing personnel requirements for each key position in the Apheresis Collection Facility. Personnel requirements shall include at a minimum:	C4.4	The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures addressing personnel requirements for each key position in the Apheresis Collection Facility. Personnel requirements shall include at a minimum:	No change
C04.04.01	A current job description for all staff.	C4.4.1	A current job description for all staff.	No change
C04.04.02	A system to document the following for all staff:	C4.4.2	A system to document the following for all staff:	No change
C04.04.02.01	Initial qualifications.	C4.4.2.1	Initial qualifications.	No change
C04.04.02.02	New employee orientation.	C4.4.2.2	New employee orientation.	No change
C04.04.02.03	Initial training and retraining when appropriate for all procedures performed.	C4.4.2.3	Initial training, competency, and retraining when appropriate for all procedures performed.	Minor
C04.04.02.04	Competency for each critical function performed.	C4.4.2.4	Continued competency for each critical function performed, assessed annually at a minimum.	Merged
C04.04.02.05	Continued competency at least annually.			
C04.04.02.06	Continuing education.	C4.4.2.5	Continuing education.	No change
C04.05	The Quality Management Plan shall include, or summarize and reference, a comprehensive system for document control and management.	C4.5	The Quality Management Plan shall include, or summarize and reference, a comprehensive system for document control.	Negligible

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
C04.05.01	There shall be policies and procedures for development, approval, implementation, review, revision, and archival of all critical documents.	C4.5.2	There shall be policies or Standard Operating Procedures for the development, approval, implementation, distribution, review, revision, and archival of all critical documents.	Negligible
C04.05.02	There shall be a current listing of all active critical documents that shall comply with the document control system requirements. Controlled documents shall include at a minimum:	C4.5.1	There shall be identification of the types of documents that are considered critical and shall comply with the document control system requirements. Controlled documents shall include at a minimum:	Negligible
	See C4.5.2.1			
C04.05.02.01	Policies and Standard Operating Procedures.	C4.5.1.1	Policies and Standard Operating Procedures.	No change
C04.05.02.02	Worksheets.	C4.5.1.2	Worksheets.	No change
C04.05.02.03	Forms.	C4.5.1.3	Forms.	No change
C04.05.02.04	Labels.	C4.5.1.4	Labels.	No change
C04.05.03	The document control policy shall include:	C4.5.3	The document control system shall include:	Negligible
C04.05.03.01	A standardized format for policies, procedures, worksheets, forms, and labels.	C4.5.3.1	A standardized format for critical documents.	Minor
C04.05.03.02	Assignment of numeric or alphanumeric identifier and title to each document and document version regulated within the system.	C4.5.3.2	Assignment of a numeric or alphanumeric identifier and a title to each document and document version regulated within the system.	No change
C04.05.03.03	A procedure for document approval, including the approval date, signature of approving individual(s), and the effective date.	C4.5.3.3	A system for document approval, including the approval date, signature of approving individual(s), and the effective date.	Negligible
C04.05.03.04	A system to protect controlled documents from accidental or unauthorized modification.	C4.5.3.4	A system to protect controlled documents from accidental or unauthorized modification.	No change
		C4.5.3.5	Review of controlled documents every two (2) years at a minimum.	New
C04.05.03.05	A system for document change control that includes a description of the change, the signature of the approving individual(s), approval date, effective date, and archival date.	C4.5.3.6	A system for document change control that includes a description of the change, version number, the signature of approving individual(s), approval date(s), communication or training on the change as applicable, effective date, and archival date.	Moderate

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
C04.05.03.06	Archived policies and procedures, the inclusive dates of use, and their historical sequence shall be maintained for a minimum of ten (10) years from archival or according to governmental or institutional policy, whichever is longer.	C4.5.3.7	Archival of controlled documents, the inclusive dates of use, and their historical sequence for a minimum of ten (10) years from archival or according to governmental or institutional policy, whichever is longer.	Minor
C04.05.03.07	A system for the retraction of obsolete documents to prevent unintended use.	C4.5.3.8	A system for the retraction of obsolete documents to prevent unintended use.	No change
C04.05.03.08	A system for record creation, assembly, review, storage, archival, and retrieval.			
C04.06	The Quality Management Plan shall include, or summarize and reference, policies and procedures for establishment and maintenance of written agreements with third parties whose services impact the cellular therapy product or clinical care of the donor.	C4.6	The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for the establishment and maintenance of written agreements.	Minor
		C4.6.1	Agreements shall be established with external parties providing critical services that could affect the quality and safety of the cellular therapy product or health and safety of the donor or recipient.	New
C04.06.01	Agreements shall include the responsibility of the facility performing any step in collection, processing, or testing to comply with applicable laws and regulations and these Standards.	C4.6.2	Agreements shall include the responsibility of the external party performing any step in collection, processing, testing, storage, distribution, or administration to maintain required accreditations, and to comply with applicable laws and regulations and these Standards.	Moderate
C04.06.02	Agreements shall be dated and reviewed on a regular basis.	C4.6.3	Agreements shall be dated and reviewed on a regular basis, at a minimum every two (2) years.	Moderate

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
C04.07	The Quality Management Plan shall include, or summarize and reference, policies and procedures for documentation and review of outcome analysis and cellular therapy product efficacy to verify that the procedures in use consistently provide a safe and effective product.	C4.7	The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for documentation and review of outcome analysis and cellular therapy product efficacy to verify that the procedures in use consistently provide a safe and effective product.	Negligible
C04.07.01	Criteria for cellular therapy product safety, product efficacy, and/or the clinical outcome shall be determined and shall be reviewed at regular time intervals.	C4.7.1	Criteria for cellular therapy product safety, product efficacy, or the clinical outcome shall be determined and shall be reviewed at regular time intervals.	Negligible
C04.07.02	Both individual cellular therapy product data and aggregate data for each type of cellular therapy product shall be evaluated.	C4.7.2	Both individual cellular therapy product data and aggregate data for each type of cellular therapy product shall be evaluated.	No change
C04.07.03	For HPC products intended for hematopoietic reconstitution, time to engraftment following product administration measured by ANC and platelet count shall be analyzed.	C4.7.3	For HPC products intended for hematopoietic reconstitution, time to engraftment following cellular therapy product administration measured by ANC and platelet count shall be analyzed.	Negligible
C04.08	The Quality Management Plan shall include, or summarize and reference, policies, procedures, and a schedule for conducting, reviewing, and reporting audits of the Apheresis Collection Facility's activities to verify compliance with elements of the Quality Management Program and operational policies and procedures.	C4.8	The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for, and a schedule of, audits of the Apheresis Collection Facility's activities to verify compliance with elements of the Quality Management Program and policies and Standard Operating Procedures, applicable laws or regulations, and these Standards.	Minor
C04.08.01	Audits shall be conducted on a regular basis by an individual with sufficient expertise to identify problems, but who is not solely responsible for the process being audited.	C4.8.1	Audits shall be conducted by an individual with sufficient expertise to identify problems, but who is not solely responsible for the process being audited.	Minor

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
C04.08.02	The results of audits shall be used to recognize problems, detect trends, identify improvement opportunities, implement corrective and preventive actions when necessary, and follow up on the effectiveness of these actions in a timely manner.	C4.8.2	The results of audits shall be used to recognize problems, detect trends, identify improvement opportunities, implement corrective and preventive actions when necessary, and follow-up on the effectiveness of these actions in a timely manner.	No change
C04.08.03	Audits shall include the following annually at a minimum:	C4.8.3	Audits shall include at a minimum:	Negligible
C04.08.03.01	Documentation of proper donor eligibility determination prior to start of the collection procedure.	C4.8.3.1	Annual audit of documentation of interim assessment of donor suitability and eligibility prior to the start of the collection procedure.	Negligible
		C4.8.3.2	Annual audit of documentation of donor eligibility determination prior to start of the collection procedure.	New
C04.08.03.02	Documentation that external facilities performing critical contracted services have met the requirements of the written agreements.	C4.8.3.3	Annual audit of management of cellular therapy products with positive microbial culture results.	Negligible
		C4.8.3.4	Annual audit of documentation that external facilities performing critical contracted services have met the requirements of the written agreements.	New
C04.09	The Quality Management Plan shall include, or summarize and reference, policies and procedures on the management of cellular therapy products with positive microbial culture results that address at a minimum:	C4.9	The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for the management of cellular therapy products with positive microbial culture results that address at a minimum:	Negligible
C04.09.01	Notification of the recipient's physician.	C4.9.1	Notification of the recipient's physician and any other facility in receipt of the cellular therapy product.	Moderate
C04.09.02	Investigation of cause.	C4.9.2	Investigation of cause.	No change
C04.09.03	Follow-up of the donor, if relevant.	C4.9.3	Follow-up of the donor, if relevant.	No change
		C4.9.4	Reporting to regulatory agencies, if appropriate.	Separated

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
C04.10	The Quality Management Plan shall include, or summarize and reference, policies and procedures for errors, accidents, biological product deviations, serious adverse events, and complaints, including the following activities at a minimum:	C4.10	The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for occurrences (errors, accidents, deviations, adverse events, adverse reactions, and complaints). The following activities shall be included at a minimum:	Minor
	See C4.10			
C04.10.01	Detection.	C4.10.1	Detection.	No change
C04.10.02	Investigation.	C4.10.2	Investigation.	No change
C04.10.02.01	A thorough investigation shall be conducted by the Apheresis Collection Facility in collaboration with the Processing Facility and Clinical Program, as appropriate.	C4.10.2.1	A thorough investigation shall be conducted by the Apheresis Collection Facility in collaboration with the Processing Facility and Clinical Program, as appropriate.	No change
C04.10.02.02	Investigations shall identify the root cause and a plan for short- and long-term corrective actions as warranted.	C4.10.2.2	Investigations shall identify the root cause and a plan for short- and long-term corrective and preventive actions as warranted.	Minor
C04.10.03	Documentation.	C4.10.3	Documentation.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
C04.10.03.01	Documentation shall include a description of the event, the involved individuals and/or cellular therapy products, when the event occurred, when and to whom the event was reported, and the immediate actions taken.	C4.10.3.1	Documentation shall include a description of the occurrence, date and time of the occurrence, the involved individuals and cellular therapy product(s), when and to whom the occurrence was reported, and the immediate actions taken.	Negligible
C04.10.03.02	All investigation reports shall be reviewed in a timely manner by the Apheresis Collection Facility Director, Medical Director, or designee and the Quality Manager.	C4.10.3.2	All investigation reports shall be reviewed in a timely manner by the Apheresis Collection Facility Director, Medical Director or designee, and the Quality Manager.	No change
C04.10.03.03	Cumulative files of errors, accidents, biological product deviations, serious adverse events, and complaints shall be maintained.	C4.10.3.3	Cumulative files of occurrences shall be maintained.	Negligible
C04.10.03.04	Cumulative files shall include written investigation reports containing conclusions, follow-up, corrective actions, and a link to the record(s) of the involved cellular therapy products	C4.10.3.4	Cumulative files shall include written investigation reports containing conclusions, follow-up, corrective and preventive actions, and a link to the record(s) of the involved cellular therapy product(s), donor(s), and recipient(s), if applicable.	Minor
C04.10.04	Reporting.	C4.10.4	Reporting.	No change
C04.10.04.01	When it is determined that a cellular therapy product was responsible for an adverse reaction, the reaction and results of the investigation shall be reported to the recipient's physician, other facilities participating in the manufacturing of the cellular therapy product, registries, and governmental agencies as required by applicable laws.	C4.10.4.1	When it is determined that a cellular therapy product has resulted in an adverse reaction, the event and results of the investigation shall be reported to the donor's and recipient's physician(s), as applicable, other facilities participating in the manufacturing of the cellular therapy product, registries, and governmental agencies as required by applicable laws and regulations.	Moderate

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
C04.10.04.02	Errors, accidents, biological product deviations, and complaints shall be reported to other facilities performing cellular therapy product functions on the affected cellular therapy product and to the appropriate regulatory and accrediting agencies, registries, grant agencies, and IRBs or Ethics Committees.	C4.10.4.2	Occurrences shall be reported to other facilities performing cellular therapy product functions on the affected cellular therapy product and to the appropriate regulatory and accrediting agencies, registries, grant agencies, sponsors, IRBs, or Ethics Committees.	Minor
C04.10.05	Corrective and preventive action.	C4.10.5	Corrective and preventive action.	No change
C04.10.05.01	Appropriate corrective action shall be implemented if indicated, including both short-term action to address the immediate problem and long-term action to prevent the problem from recurring.	C4.10.5.1	Appropriate action shall be implemented if indicated, including both short-term action to address the immediate problem and long-term action to prevent the problem from recurring.	Negligible
C04.10.05.02	Follow-up audits of the effectiveness of corrective actions shall be performed in a timeframe as indicated in the investigative report.	C4.10.5.2	Follow-up audits of the effectiveness of corrective and preventive actions shall be performed in a timeframe as indicated in the investigative report.	Minor
C04.11	The Quality Management Plan shall include, or summarize and reference, policies and procedures for cellular therapy product tracking and tracing that allow tracking from the donor to the recipient or final disposition and tracing from the recipient or final disposition to the donor.	C4.11	The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for cellular therapy product tracking and tracing that allow tracking from the donor to the recipient or final disposition and tracing from the recipient or final disposition to the donor.	Negligible
C04.12	The Quality Management Plan shall include, or summarize and reference, policies and procedures for actions to take in the event the Apheresis Collection Facility's operations are interrupted.	C4.12	The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for actions to take in the event the Apheresis Collection Facility's operations are interrupted.	Negligible

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
C04.13	The Quality Management Plan shall include, or summarize and reference, policies and procedures for qualification of critical reagents, supplies, equipment, and facilities.	C4.13	The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for qualification of critical manufacturers, vendors, equipment, supplies, reagents , facilities, and services.	Moderate
		C4.13.1	Reagents that are not the appropriate grade shall undergo qualification for the intended use.	New
		C4.13.2	Qualification plans shall include minimum acceptance criteria for performance.	New
C04.13.01	Qualification plans shall be reviewed and approved by the Apheresis Collection Facility Director or designee.	C4.13.3	Qualification plans, results, and reports shall be reviewed and approved by the Quality Manager and Apheresis Collection Facility Director or designee.	Minor
C04.14	The Quality Management Plan shall include, or summarize and reference, policies and procedures for validation and/or verification of critical procedures to achieve the expected end-points, including viability of cells and cellular therapy product characteristics.	C4.14	The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for validation or verification of critical procedures.	Minor
C04.14.01	Critical procedures shall include at least the following: collection procedures, labeling, storage, and distribution.	C4.14.1	Critical procedures to be validated shall include at least the following: collection procedures, testing, labeling, storage, and distribution.	Minor
C04.14.02	Each validation shall include:	C4.14.2	Each validation shall include at a minimum:	Negligible
C04.14.02.01	An approved validation plan, including conditions to be validated.	C4.14.2.1	An approved validation plan, including conditions to be validated.	No change
C04.14.02.02	Acceptance criteria.	C4.14.2.2	Acceptance criteria.	No change
C04.14.02.03	Data collection.	C4.14.2.3	Data collection.	No change
C04.14.02.04	Evaluation of data.	C4.14.2.4	Evaluation of data.	No change
C04.14.02.05	Summary of results.	C4.14.2.5	Summary of results.	No change
		C4.14.2.6	References, if applicable.	New

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
C04.14.02.06	Review and approval of the validation plan, results, and conclusion by the Apheresis Collection Facility Director or designee and the Quality Manager or designee.	C4.14.2.7	Review and approval of the validation plan, validation report, and conclusion by the Quality Manager or designee and the Apheresis Collection Facility Director or designee.	Negligible
C04.14.03	Changes to a process shall include evaluation of risk to confirm that they do not create an adverse impact anywhere in the operation and shall be validated or verified as appropriate.	C4.14.3	Significant changes to critical procedures shall be validated and verified as appropriate.	Moderate
		C4.15	The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for the evaluation of risk in changes to a process to confirm that the changes do not create an adverse impact or inherent risk elsewhere in the operation.	New
		C4.16	The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for obtaining feedback.	New
		C4.16.1	Feedback shall be obtained from associated Clinical Programs and Processing Facilities.	New
		C4.16.2	Feedback shall be obtained from donors or legally authorized representatives.	New
		C4.17.1	Meetings should have defined attendees, documented minutes, and assigned actions.	New
		C4.17.2	Key performance data and review findings shall be reported to staff.	New
		C4.18.1	The annual report and documentation of the review findings shall be made available to key personnel, the Clinical Program Director, and the Processing Facility Director.	New
C05	**POLICIES AND PROCEDURES**	**C5**	**POLICIES AND STANDARD OPERATING PROCEDURES**	Negligible

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
C05.01	The Apheresis Collection Facility shall establish and maintain policies and/or procedures addressing critical aspects of operations and management in addition to those required in C4. These documents shall include all elements required by these Standards and shall address at a minimum:	C5.1	The Apheresis Collection Facility shall establish and maintain policies or Standard Operating Procedures addressing critical aspects of operations and management in addition to those required in C4. These documents shall include all elements required by these Standards and shall address at a minimum:	negligible
C05.01.01	Donor and recipient confidentiality.	C5.1.1	Donor and recipient confidentiality.	No change
C05.01.02	Donor consent.	C5.1.2	Donor consent.	No change
	See C5.1.3			
C05.01.03	Donor screening, testing, eligibility determination, and management.	C5.1.3	Donor screening, testing, eligibility determination, and management.	No change
C05.01.04	Management of donors who require central venous access.	C5.1.4	Management of donors who require central venous access.	No change
	See C5.1.3			
C05.01.05	Cellular therapy product collection.	C5.1.5	Cellular therapy product collection.	No change
C05.01.06	Administration of blood products.	C5.1.6	Administration of blood products.	No change
C05.01.07	Prevention of mix-ups and cross-contamination.	C5.1.7	Prevention of mix-ups and cross-contamination.	No change
C05.01.08	Labeling (including associated forms and samples).	C5.1.8	Labeling (including associated forms and samples).	No change
C05.01.09	Cellular therapy product expiration dates.	C5.1.9	Cellular therapy product expiration dates.	No change
C05.01.10	Cellular therapy product storage.	C5.1.10	Cellular therapy product storage.	No change
C05.01.11	Release and exceptional release.	C5.1.11	Release and exceptional release.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
C05.01.12	Transportation and shipping, including methods and conditions to be used for distribution to external facilities.	C5.1.12	Transportation and shipping, including methods and conditions to be used for distribution to external facilities.	No change
C05.01.13	Critical reagent and supply management.	C5.1.13	Critical reagent and supply management.	No change
C05.01.14	Equipment operation, maintenance, and monitoring including corrective actions in the event of failure.	C5.1.14	Equipment operation, maintenance, and monitoring including corrective actions in the event of failure.	No change
C05.01.15	Recalls of equipment, supplies, and reagents.	C5.1.15	Recalls of equipment, supplies, and reagents.	No change
C05.01.16	Cleaning and sanitation procedures including identification of the individuals responsible for the activities.	C5.1.16	Cleaning and sanitation procedures including identification of the individuals responsible for the activities.	No change
C05.01.17	Hygiene and use of personal protective attire.	C5.1.17	Hygiene and use of personal protective equipment and attire.	Minor
C05.01.18	Disposal of medical and biohazard waste.	C5.1.18	Disposal of medical and biohazard waste.	No change
C05.01.19	Emergency and disaster plan, including the Apheresis Collection Facility response.	C5.1.19	Cellular therapy emergency and disaster plan, including the Apheresis Collection Facility response.	Negligible
C05.02	The Apheresis Collection Facility shall maintain a detailed Standard Operating Procedures Manual that includes a listing of all current Standard Operating Procedures, including title, identifier, and version.	C5.2	The Apheresis Collection Facility shall maintain a detailed list of all controlled documents, including title and identifier.	Minor
	See C5.2			

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
C05.03	Standard Operating Procedures shall be sufficiently detailed and unambiguous to allow qualified staff to follow and complete the procedures successfully. Each individual procedure shall include:	C5.3	Standard Operating Procedures shall be sufficiently detailed and unambiguous to allow qualified staff to follow and complete the procedures successfully. Each individual Standard Operating Procedure shall include:	Negligible
C05.03.01	A clearly written description of the objectives.	C5.3.1	A clearly written description of the objectives.	No change
C05.03.02	A description of equipment and supplies used.	C5.3.2	A description of equipment and supplies used.	No change
C05.03.03	Acceptable end-points and the range of expected results.	C5.3.3	Acceptable end-points and the range of expected results.	No change
C05.03.04	A stepwise description of the procedure.	C5.3.4	A stepwise description of the procedure.	No change
C05.03.05	Age-specific issues where relevant.	C5.3.5	Age-specific issues where relevant.	No change
C05.03.06	Reference to other Standard Operating Procedures or policies required to perform the procedure.	C5.3.6	Reference to other Standard Operating Procedures or policies required to perform the procedure.	No change
C05.03.07	A reference section listing appropriate literature.	C5.3.7	A reference section listing appropriate and current literature.	Minor
C05.03.08	Documented approval of each procedure by the Apheresis Collection Facility Director or Medical Director, as appropriate, prior to implementation and every two years thereafter.	C5.3.8	Documented approval of each procedure by the Apheresis Collection Facility Director or Medical Director, as appropriate, prior to implementation and every two (2) years thereafter.	Negligible
C05.03.09	Documented approval of each procedural modification by the Apheresis Collection Facility Director or Medical Director, as appropriate, prior to implementation.	C5.3.9	Documented approval of each procedural modification by the Apheresis Collection Facility Director or Medical Director, as appropriate, prior to implementation.	No change
C05.03.10	Reference to a current version of orders, worksheets, reports, labels, and forms.	C5.3.10	Reference to a current version of orders, worksheets, reports, labels, and forms.	No change
C05.04	Standard Operating Procedures relevant to processes being performed shall be readily available to the facility staff.	C5.4	Controlled documents relevant to processes being performed shall be readily available to the facility staff.	Negligible

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
C05.05	Staff training and, if appropriate, competency shall be documented before performing a new or revised procedure.	C5.5	Staff training and, if appropriate, competency shall be documented before performing a new or revised Standard Operating Procedure.	Negligible
C05.06	All personnel shall follow the Standard Operating Procedures related to their positions.	C5.6	All personnel shall follow the policies and Standard Operating Procedures related to their positions.	Minor
C05.07	Variances shall be pre-approved by the Apheresis Collection Facility Director and/or Medical Director, and reviewed by the Quality Manager.	C5.7	Planned deviations shall be pre-approved by the Apheresis Collection Facility Director and/or Medical Director, and reviewed by the Quality Manager.	Minor
C06	**ALLOGENEIC AND AUTOLOGOUS DONOR EVALUATION AND MANAGEMENT**	**C6**	**ALLOGENEIC AND AUTOLOGOUS DONOR EVALUATION AND MANAGEMENT**	No change
C06.01	There shall be written criteria for allogeneic and autologous donor evaluation and management by trained medical personnel.	C6.1	There shall be written criteria for allogeneic and autologous donor evaluation and management by trained medical personnel.	No change
C06.02	**ALLOGENEIC AND AUTOLOGOUS DONOR INFORMATION AND CONSENT FOR COLLECTION**	**C6.2**	**ALLOGENEIC AND AUTOLOGOUS DONOR INFORMATION AND CONSENT FOR COLLECTION**	No change
C06.02.01	The collection procedure shall be explained in terms the donor can understand, and shall include the following information at a minimum:	C6.2.1	The collection procedure shall be explained in terms the donor can understand, and shall include the following information at a minimum:	No change
C06.02.01.01	The risks and benefits of the procedure.	C6.2.1.1	The risks and benefits of the procedure.	No change
C06.02.01.02	Tests and procedures performed on the donor to protect the health of the donor and the recipient.	C6.2.1.2	Tests and procedures performed on the donor to protect the health of the donor and the recipient.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
C06.02.01.03	The rights of the donor or legally authorized representative to review the results of such tests according to applicable laws and regulations.	C6.2.1.3	The rights of the donor or legally authorized representative to review the results of such tests according to applicable laws and regulations.	No change
C06.02.01.04	Protection of medical information and confidentiality.	C6.2.1.4	Protection of medical information and confidentiality.	No change
C06.02.02	Interpretation and translation shall be performed by individuals qualified to provide these services in the clinical setting.	C6.2.2	Interpretation and translation shall be performed by individuals qualified to provide these services in the clinical setting.	No change
C06.02.03	Family members and legally authorized representatives should not serve as interpreters or translators.	C6.2.3	Family members and legally authorized representatives should not serve as interpreters or translators.	No change
C06.02.04	The donor shall have an opportunity to ask questions.	C6.2.4	The donor shall have an opportunity to ask questions.	No change
C06.02.05	The donor shall have the right to refuse to donate.	C6.2.5	The donor shall have the right to refuse to donate or withdraw consent.	Moderate
C06.02.05.01	The allogeneic donor shall be informed of the potential consequences to the recipient of such refusal.	C6.2.5.1	The allogeneic donor shall be informed of the potential consequences to the recipient of such refusal in the event that consent is withdrawn after the recipient has begun the preparative regimen.	Moderate
C06.02.06	Donor informed consent for the cellular therapy product collection shall be obtained and documented by a licensed health care professional familiar with the collection procedure.	C6.2.6	Donor informed consent for the cellular therapy product collection shall be obtained and documented by a licensed health care professional familiar with the collection procedure.	No change
C06.02.06.01	Informed consent from the allogeneic donor shall be obtained by a licensed health care professional who is not the primary health care professional overseeing care of the recipient.	C6.2.6.1	Informed consent from the allogeneic donor shall be obtained by a licensed health care professional who is not the primary health care professional overseeing care of the recipient.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
C06.02.07	In the case of a donor who is a minor, informed consent shall be obtained from the donor's legally authorized representative in accordance with applicable laws and regulations and shall be documented.	C6.2.7	In the case of a donor who is a minor, informed consent shall be obtained from the donor's legally authorized representative in accordance with applicable laws and regulations and shall be documented.	No change
C06.02.08	The allogeneic donor shall give informed consent and authorization prior to release of the donor's health or other information to the recipient's physician and/or the recipient.	C6.2.8	The allogeneic donor shall give informed consent and authorization prior to release of the donor's health or other information to the recipient's physician and/or the recipient.	No change
C06.02.09	Documentation of consent shall be available to the Apheresis Collection Facility staff prior to the collection procedure.	C6.2.9	Documentation of consent shall be verified by the Apheresis Collection Facility staff prior to the collection procedure.	Minor
C06.03	**ALLOGENEIC AND AUTOLOGOUS DONOR SUITABILITY FOR CELLULAR THERAPY PRODUCT COLLECTION**	**C6.3**	**ALLOGENEIC AND AUTOLOGOUS DONOR SUITABILITY FOR CELLULAR THERAPY PRODUCT COLLECTION**	No change
C06.03.01	There shall be criteria and evaluation policies and procedures in place to protect the safety of donors during the process of cellular therapy product collection.	C6.3.1	There shall be criteria and evaluation policies or Standard Operating Procedures in place to protect the safety of donors during the process of cellular therapy product collection.	Negligible
C06.03.01.01	The Apheresis Collection Facility shall confirm that any abnormal findings are reported to the prospective donor with documentation in the donor record of recommendations made for follow-up care.	C6.3.1.1	The Apheresis Collection Facility shall confirm that clinically significant findings are reported to the prospective donor with documentation in the donor record of recommendations made for follow-up care.	Minor

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
C06.03.01.02	Allogeneic donor suitability shall be evaluated by a licensed health care professional who is not the primary health care professional overseeing care of the recipient.	C6.3.1.2	Allogeneic donor suitability shall be evaluated by a licensed health care professional who is not the primary health care professional overseeing care of the recipient.	No change
C06.03.01.03	Autologous donors shall be tested as required by applicable laws and regulations.	C6.3.1.3	Autologous donors shall be tested as required by applicable laws and regulations.	No change
C06.03.02	The risks of donation shall be evaluated and documented, including:	C6.3.2	The risks of donation shall be evaluated and documented, including:	No change
C06.03.02.01	Possible need for central venous access.	C6.3.2.1	Possible need for central venous access.	No change
C06.03.02.02	Mobilization therapy for collection of HPC, Apheresis.	C6.3.2.2	Mobilization for collection of HPC, Apheresis.	Negligible
C06.03.03	The donor should be evaluated for the risk of hemoglobinopathy prior to administration of the mobilization regimen.	C6.3.3	The donor shall be evaluated for the risk of hemoglobinopathy prior to administration of the mobilization regimen.	Significant
C06.03.04	A pregnancy test shall be performed for all female donors with childbearing potential within seven (7) days prior to starting the donor mobilization regimen and, as applicable, within seven (7) days prior to the initiation of the recipient's preparative regimen.	C6.3.4	A pregnancy test shall be performed for all female donors with childbearing potential within seven (7) days prior to starting the donor mobilization regimen and, as applicable, within seven (7) days prior to the initiation of the recipient's preparative regimen.	No change
C06.03.05	Laboratory testing of all donors shall be performed by a laboratory that is accredited, registered, or licensed in accordance with applicable laws and regulations.	C6.3.5	Laboratory testing of all donors shall be performed by a laboratory that is accredited, registered, certified, or licensed in accordance with applicable laws and regulations.	Minor

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
C06.03.06	The Clinical Program shall inform the Collection Facility and Processing Facility of donor test results or if any testing was not performed.	C6.3.6	The Clinical Program shall inform the Collection Facility and Processing Facility of donor test results or if any testing was not performed.	No change
C06.03.07	Collection from a donor who does not meet Clinical Program collection safety criteria shall require documentation of the rationale for his/her selection by the transplant physician. Collection staff shall document review of these donor safety issues.	C6.3.7	Collection from a donor who does not meet collection safety criteria shall require documentation of the rationale for his/her selection by the donor's physician. Collection staff shall document review of these donor safety issues.	Moderate
C06.03.08	There shall be written documentation of issues of donor health that pertain to the safety of the collection procedure available to the Apheresis Collection Facility staff. Collection staff shall document review of these issues prior to collection.	C6.3.7.1	There shall be written documentation of issues of donor health that pertain to the safety of the collection procedure available to the Apheresis Collection Facility staff. Collection staff shall document review of these issues prior to collection.	No change
C06.03.09	There shall be a policy for follow-up of donors that includes routine management and the management of collection-associated adverse events.	C6.3.8	There shall be policies or Standard Operating Procedures for follow-up of donors that includes routine management and the management of collection-associated adverse events.	Moderate
C06.04	**ADDITIONAL REQUIREMENTS FOR ALLOGENEIC DONORS**	**C6.4**	**ADDITIONAL REQUIREMENTS FOR ALLOGENEIC DONORS**	No change
C06.04.01	A donor advocate shall be available to represent allogeneic donors who are minors or who are mentally incapacitated.	C6.4.1	A donor advocate shall be available to represent allogeneic donors who are minors or who are mentally incapacitated, as those terms are defined by applicable laws.	Minor
C06.04.02	Allogeneic donor infectious disease testing shall be performed using donor screening tests approved or cleared by the governmental authority.	C6.4.2	Allogeneic donor infectious disease testing shall be performed using licensed donor screening tests approved or cleared by the governmental authority.	Minor

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
C06.04.03	The Apheresis Collection Facility shall comply with B6.4.6 through B6.4.6.8 when primarily responsible for donor screening for transmissible disease.	C6.4.3	The Apheresis Collection Facility shall comply with B6.4.6 through B6.4.6.8 when primarily responsible for donor screening for transmissible disease.	No change
C06.04.04	The Apheresis Collection Facility shall comply with B6.4.7 through B6.4.11 when primarily responsible for infectious and non-infectious disease testing of HPC donors.	C6.4.4	The Apheresis Collection Facility shall comply with B6.4.7 through B6.4.11 when primarily responsible for infectious and non-infectious disease testing of donors.	Negligible
C06.04.05	The Apheresis Collection Facility shall comply with B6.4.3, B6.4.4, and B6.4.12 through B6.4.12.4 when primarily responsible for testing for the selection of allogeneic donors.	C6.4.5	The Apheresis Collection Facility shall comply with B6.4.3, B6.4.4, and B6.4.12 through B6.4.12.4 when primarily responsible for testing for the selection of allogeneic donors.	No change
C06.04.06	The Apheresis Collection Facility shall confirm that allogeneic donor eligibility, as defined by applicable laws and regulations, is determined by a physician after history, exam, medical record review, and testing before the donor begins the mobilization regimen.	C6.4.6	The Apheresis Collection Facility shall confirm that allogeneic donor eligibility, as defined by applicable laws and regulations, is determined by a physician after history, exam, medical record review, and testing before the donor begins the mobilization regimen.	No change
C06.04.07	Records required for donor eligibility determination shall be in English or translated into English when crossing international borders.	C6.4.7	Records required for donor eligibility determination shall be in English or translated into English when crossing international borders.	No change
C06.04.08	Collection of a cellular therapy product from an ineligible allogeneic donor, or from an allogeneic donor for whom donor eligibility determination is incomplete, shall require documentation of urgent medical need that includes the rationale for the selection and documentation of the informed consent of the donor and the recipient.	C6.4.8	Collection of a cellular therapy product from an ineligible allogeneic donor, or from an allogeneic donor for whom donor eligibility determination is incomplete, shall require documentation of urgent medical need that includes the rationale for the selection and documentation of the informed consent of the donor and the recipient.	No change
C06.04.09	Allogeneic donor eligibility shall be communicated in writing to the Processing Facility.	C6.4.9	Allogeneic donor eligibility shall be communicated in writing to the Processing Facility.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
C06.05	There shall be a policy covering the creation and retention of donor records including at a minimum:	C6.5	There shall be policies covering the creation and retention of donor records including at a minimum:	Negligible
	See C6.5			
C06.05.01	Donor identification including at least name and date of birth.	C6.5.1	Donor identification including at least name and date of birth.	No change
C06.05.02	Age, gender, and medical history, and, for allogeneic donors, behavioral history.	C6.5.2	Age, gender, and medical history, and, for allogeneic donors, behavioral history.	No change
C06.05.03	Consent to donate.	C6.5.3	Consent to donate.	No change
C06.05.04	Results of laboratory testing.	C6.5.4	Results of laboratory testing.	No change
C06.05.05	Allogeneic donor eligibility determination, including the name of the responsible person who made the determination and the date of the determination.	C6.5.5	Allogeneic donor eligibility determination, including the name of the responsible person who made the determination and the date of the determination.	No change
C07	**CODING AND LABELING OF CELLULAR THERAPY PRODUCTS**	**C7**	**CODING AND LABELING OF CELLULAR THERAPY PRODUCTS**	No change
C07.01	**ISBT 128 CODING AND LABELING**	**C7.1**	**ISBT 128 AND EUROCODE CODING AND LABELING**	Significant

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
C07.01.01	Cellular therapy products shall be identified according to the proper name of the product, including appropriate attributes, as defined in ISBT 128 Standard Terminology for Blood, Cellular Therapy, and Tissue Product Descriptions.	C7.1.1	Cellular therapy products shall be identified by name according to ISBT 128 standard terminology or Eurocode.	Significant
C07.01.02	If coding and labeling technologies have not yet been implemented, the Apheresis Collection Facility shall be actively implementing ISBT 128.	C7.1.2	Coding and labeling technologies shall be implemented using ISBT 128 or Eurocode.	Significant
C07.02	**LABELING OPERATIONS**	**C7.2**	**LABELING OPERATIONS**	No change
C07.02.01	Labeling operations shall be conducted in a manner adequate to prevent mislabeling or misidentification of cellular therapy products, product samples, and associated records.	C7.2.1	Labeling operations shall be conducted in a manner adequate to prevent mislabeling or misidentification of cellular therapy products, product samples, and associated records.	No change
C07.02.01.01	Stocks of unused labels representing different products shall be stored in a controlled manner to prevent errors.	C7.2.1.1	Stocks of unused labels representing different products shall be stored in a controlled manner to prevent errors.	No change
C07.02.01.02	Obsolete labels shall be restricted from use.	C7.2.1.2	Obsolete labels shall be restricted from use.	No change
C07.02.02	Pre-printed labels shall be held upon receipt from the manufacturer pending review and proofing against a copy or template approved by the Apheresis Collection Facility Director or designee to confirm accuracy regarding identity, content, and conformity.	C7.2.2	Pre-printed labels shall be held upon receipt from the manufacturer pending review and proofing against a copy or template approved by the Apheresis Collection Facility Director or designee to confirm accuracy regarding identity, content, and conformity.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
C07.02.03	Print-on-demand label systems shall be validated to confirm accuracy regarding identity, content, and conformity of labels to templates approved by the Apheresis Collection Facility Director or designee.	C7.2.3	Print-on-demand label systems shall be validated to confirm accuracy regarding identity, content, and conformity of labels to templates approved by the Apheresis Collection Facility Director or designee.	No change
C07.02.04	A system for label version control shall be employed.	C7.2.4	A system for label version control shall be employed.	No change
C07.02.04.01	Representative obsolete labels shall be archived minimally for ten (10) years after the last cellular therapy product was distributed with inclusive dates of use or as defined by applicable laws and regulations, whichever is longer.	C7.2.4.1	Representative obsolete labels shall be archived minimally for ten (10) years after the last cellular therapy product was distributed with inclusive dates of use or as defined by applicable laws and regulations, whichever is longer.	No change
C07.02.05	A system of checks in labeling procedures shall be used to prevent errors in transferring information to labels.	C7.2.5	A system of checks in labeling procedures shall be used to prevent errors in transferring information to labels.	No change
C07.02.05.01	Cellular therapy products that are subsequently re-packaged into new containers shall be labeled with new labels before they are detached from the original container.	C7.2.5.1	Cellular therapy products that are subsequently re-packaged into new containers shall be labeled with new labels before they are detached from the original container.	No change
C07.02.05.02	A controlled labeling procedure consistent with applicable law shall be defined and followed if container label information is transmitted electronically during a labeling process. This procedure shall include a verification step.	C7.2.5.2	A controlled labeling procedure consistent with applicable law shall be defined and followed if container label information is transmitted electronically during a labeling process. This procedure shall include a verification step.	No change
C07.02.06	When the label has been affixed to the container, a sufficient area of the container shall remain uncovered to permit inspection of the contents.	C7.2.6	When the label has been affixed to the container, a sufficient area of the container shall remain uncovered to permit inspection of the contents.	No change
C07.02.07	The information entered on a container label shall be verified by one (1) qualified staff member using a validated process to verify the information or two (2) qualified staff members.	C7.2.7	The information entered on a container label shall be verified by one (1) qualified staff member using a validated process or two (2) qualified staff members.	Negligible
C07.02.08	Labeling elements required by applicable laws and regulations shall be present.	C7.2.8	Labeling elements required by applicable laws and regulations shall be present.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
C07.02.09	All data fields on labels shall be completed.	C7.2.9	All data fields on labels shall be completed.	No change
C07.02.10	All labeling shall be clear, legible, and completed using ink that is indelible to all relevant agents.	C7.2.10	All labeling shall be clear, legible, and completed using ink that is indelible to all relevant agents.	No change
C07.02.11	Labels affixed directly to a cellular therapy product bag shall be applied using appropriate materials as defined by the applicable regulatory authority.	C7.2.11	Labels affixed directly to a cellular therapy product bag shall be applied using appropriate materials as defined by the applicable regulatory authority.	No change
C07.02.12	The label shall be validated as reliable for storage under the conditions in use.	C7.2.12	The label shall be validated as reliable for storage under the conditions in use.	No change
C07.03	**PRODUCT IDENTIFICATION**	**C7.3**	**PRODUCT IDENTIFICATION**	No change
C07.03.01	Each cellular therapy product collection shall be assigned a unique numeric or alphanumeric identifier by which it will be possible to trace any cellular therapy product to its donor, its recipient or final disposition, and all records.	C7.3.1	Each cellular therapy product collection shall be assigned a unique numeric or alphanumeric identifier by which it will be possible to trace any cellular therapy product to its donor, its recipient or final disposition, and all records.	No change
C07.03.01.01	The cellular therapy product, product samples, concurrent plasma, and concurrently collected samples shall be labeled with the same identifier.	C7.3.1.1	The cellular therapy product, product samples, concurrent plasma, and concurrently collected samples shall be labeled with the same identifier.	No change
C07.03.01.02	If a single cellular therapy product is stored in more than one container, there shall be a system to identify each container.	C7.3.1.2	If a single cellular therapy product is stored in more than one (1) container, there shall be a system to identify each container.	No change
C07.03.01.03	If cellular therapy products from the same donor are pooled, the pool identifier shall allow tracing to the original products.	C7.3.1.3	If cellular therapy products from the same donor are pooled, the pool identifier shall allow tracing to the original products.	No change
C07.03.01.04	Supplementary identifiers shall not obscure the original identifier.	C7.3.1.4	Supplementary identifiers shall not obscure the original identifier.	No change
C07.03.01.05	The facility associated with each identifier shall be noted on the label.	C7.3.1.5	The facility associated with each identifier shall be named in the documents to accompany the cellular therapy product.	Minor

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
C07.04	**LABEL CONTENT**	**C7.4**	**LABEL CONTENT**	No change
		C7.4.1	At all stages of collection, the cellular therapy product shall be labeled with the proper name of the product and the unique numeric or alphanumeric identifier, at a minimum.	New
C07.04.01	At the end of the cellular therapy product collection, the cellular therapy product label on the primary product container and concurrent plasma container shall bear the information in the Cellular Therapy Product Labeling table in Appendix _.	C7.4.3	At the end of the cellular therapy product collection, the cellular therapy product label on the primary product container and concurrent plasma container shall bear the information in the Cellular Therapy Product Labeling table in Appendix II.	No change
C07.04.02	Each label shall bear the appropriate biohazard and warning labels as found in the Circular of Information (COI) for the Use of Cellular Therapy Products, “Table 2. Biohazard and Warning Labels on Cellular Therapy Products Collected, Processed, and/or Administered in the United States.”	C7.4.4	Each label shall bear the appropriate biohazard and warning labels as found in the Circular of Information for the Use of Cellular Therapy Products, “Table 2. Biohazard and Warning Labels on Cellular Therapy Products Collected, Processed, and/or Administered in the United States.”	No change
		C7.4.6	Any container bearing a partial label at the time of distribution shall be accompanied by the information required by the Cellular Therapy Product Labeling table in Appendix II. Such information shall be attached securely to the cellular therapy product on a tie tag or enclosed in a sealed package to accompany the product.	New
C07.04.03	Labeling at the end of collection shall occur before the cellular therapy product bag is disconnected from the donor.	C7.4.2	Labeling at the end of collection shall occur before the cellular therapy product bag is disconnected from the donor.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
C07.04.04	Cellular therapy products collected in or designated for use in the U.S. shall be accompanied by the elements listed in the Accompanying Documents at Distribution table in Appendix _ at the time of distribution.	C7.4.5	A cellular therapy product collected in or designated for use in the U.S. shall be accompanied by the elements listed in the Accompanying Documentation table in Appendix IV at the time it leaves the control of the Apheresis Collection Facility.	Negligible
C07.04.05	For cellular therapy products distributed before completion of donor eligibility determination, there shall be documentation that donor eligibility determination was completed during or after the use of the product.	C7.4.7	For cellular therapy products distributed before completion of donor eligibility determination, there shall be documentation that donor eligibility determination was completed during or after the use of the product.	No change
C07.04.06	Cellular therapy products distributed for nonclinical purposes shall be labeled with the statement, “For Nonclinical Use Only.”	C7.4.8	Cellular therapy products distributed for nonclinical purposes shall be labeled with the statement, “For Nonclinical Use Only.”	No change
C08	**PROCESS CONTROLS**	**C8**	**PROCESS CONTROLS**	No change
C08.01	Collection of cellular therapy products shall be performed according to written procedures in the Apheresis Collection Facility’s Standard Operating Procedures Manual.	C8.1	Collection of cellular therapy products shall be performed according to written Standard Operating Procedures.	Negligible
C08.02	There shall be a process for inventory control that encompasses equipment, reagents, supplies, and labels.	C8.2	There shall be a process for inventory control that encompasses equipment, supplies, reagents, and labels.	Negligible
C08.02.01	There shall be a system to uniquely identify and track and trace all critical equipment, reagents, supplies, and labels used in the collection of cellular therapy products.	C8.2.1	There shall be a system to uniquely identify and track and trace all critical equipment, supplies, reagents, and labels used in the collection of cellular therapy products.	Negligible

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
C08.02.02	Each supply and reagent used to collect cellular therapy products shall be visually examined at receipt and prior to use for damage or evidence of contamination.	C8.2.2	Each supply and reagent used to collect cellular therapy products shall be visually examined at receipt and prior to use for damage or evidence of contamination.	No change
C08.02.03	Supplies and reagents coming into contact with cellular therapy products during collection shall be sterile and of the appropriate grade for the intended use.	C8.2.3	Supplies and reagents coming into contact with cellular therapy products during collection shall be sterile and of the appropriate grade for the intended use.	No change
C08.03	Equipment shall be inspected for cleanliness prior to each use and verified to be in compliance with the maintenance schedule daily prior to use. Equipment shall also be standardized and calibrated on a regularly scheduled basis and after a critical repair or move as described in Standard Operating Procedures and in accordance with the manufacturer's recommendations.	C8.3	Equipment shall be inspected for cleanliness and verified to be in compliance with the maintenance schedule prior to use. Equipment shall also be standardized and calibrated on a regularly scheduled basis and after a critical repair or move as described in Standard Operating Procedures and in accordance with the manufacturer's recommendations.	Reordered
C08.03.01	All equipment with a critical measuring function shall be calibrated against a traceable standard, if available. Where no traceable standard is available, the basis for calibration shall be described and documented.	C8.3.1	All equipment with a critical measuring function shall be calibrated against a traceable standard, if available. Where no traceable standard is available, the basis for calibration shall be described and documented.	No change
C08.03.02	When equipment is found to be out of calibration or specification, there shall be a defined process for action required for cellular therapy products collected since the last calibration.	C8.3.2	When equipment is found to be out of calibration or specification, there shall be a defined process for action required for cellular therapy products collected since the last calibration.	No change
	See C8.3			
C08.04	Equipment shall conform to applicable laws and regulations.	C8.4	Equipment shall conform to applicable laws and regulations.	No change
C08.05	Autologous and/or CMV-appropriate and irradiated blood components shall be available during the apheresis collection procedure for all donors.	C8.5	Autologous or CMV-appropriate and irradiated blood components shall be available during the apheresis collection procedure for all donors.	Negligible

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
		C8.5.1	Allogeneic blood components administered to the donor during apheresis collection should be irradiated prior to transfusion.	New
C08.06	Before cell collection is undertaken, there shall be a written order from a physician specifying, at a minimum, timing and goals of collection.	C8.6	There shall be a written order from a physician specifying, at a minimum, anticipated date and goals of collection.	Minor
C08.07	A complete blood count, including platelet count, shall be performed within 24 hours prior to each subsequent cellular therapy product collection by apheresis.	C8.7	A complete blood count, including platelet count, shall be performed within 24 hours prior to each subsequent cellular therapy product collection by apheresis.	No change
C08.08	There shall be peripheral blood count criteria to proceed with collection.	C8.8	There shall be peripheral blood count criteria to proceed with collection.	No change
C08.09	There shall be written documentation of an assessment of donor suitability for the collection procedure performed by a qualified person immediately prior to each collection procedure.	C8.9	There shall be written documentation of a daily assessment of donor suitability for the collection procedure performed by a qualified person immediately prior to each collection procedure.	Moderate
C08.10	If required, central venous catheters shall be placed by a licensed health care professional qualified to perform the procedure.	C8.10	If required, central venous catheters shall be placed by a licensed health care professional qualified to perform the procedure.	No change
C08.10.01	Adequacy of central line placement shall be verified by the Apheresis Collection Facility prior to initiating the collection procedure.	C8.10.1	Adequacy of central line placement shall be verified by the Apheresis Collection Facility prior to initiating the collection procedure.	No change
C08.11	Administration of mobilization agents shall be under the supervision of a licensed health care professional experienced in their administration and management of complications in persons receiving these agents.	C8.11	Administration of mobilization agents shall be under the supervision of a licensed health care professional experienced in their administration and management of complications in persons receiving these agents.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
C08.12	The Apheresis Collection Facility shall utilize a process for assessing the quality of cellular therapy products to confirm product safety, viability, and integrity and to document that products meet predetermined release specifications. Results of all such assessments shall become part of the permanent record of the product collected.	C8.12	The Apheresis Collection Facility shall utilize a process for assessing the quality of cellular therapy products to confirm product safety, viability, and integrity and to document that products meet predetermined release specifications. Results of all such assessments shall become part of the permanent record of the product collected.	No change
C08.12.01	Methods for collection shall include a process for controlling and monitoring the collection of cellular therapy products to confirm products meet predetermined release specifications.	C8.12.1	Methods for collection shall include a process for controlling and monitoring the collection of cellular therapy products to confirm products meet predetermined release specifications.	No change
C08.12.02	Methods for collection shall employ procedures validated to result in acceptable cell viability and recovery.	C8.12.2	Methods for collection shall employ procedures validated to result in acceptable cell viability, sterility, and recovery.	Moderate
C08.13	Collection methods shall employ aseptic technique so that cellular therapy products do not become contaminated during collection.	C8.13	Collection methods shall employ aseptic technique so that cellular therapy products do not become contaminated during collection.	No change
C08.14	Collection methods for pediatric donors shall employ appropriate age and size adjustments to the procedures.	C8.14	Collection methods for pediatric donors shall employ appropriate age and size adjustments to the procedures.	No change
C08.15	Cellular therapy products shall be packaged in a closed sterile transfer pack appropriate for blood products.	C8.15	Cellular therapy products shall be packaged in a closed sterile transfer pack appropriate for blood products.	No change
C08.16	Records shall be made concurrently with each step of collection of each cellular therapy product in such a way that all steps may be accurately traced.	C8.16	Records shall be made concurrently with each step of collection of each cellular therapy product in such a way that all steps may be accurately traced.	No change
C08.16.01	Records shall identify the person immediately responsible for each significant step, including dates and times, where appropriate.	C8.16.1	Records shall identify the person immediately responsible for each significant step, including dates and times, where appropriate.	No change
C08.17	There shall be a policy addressing safe administration of ECP.	C8.17	There shall be policies addressing safe treatment with ECP.	Minor

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
C08.17.01	Before ECP is undertaken, there shall be a written therapy plan from a physician specifying the patient's diagnosis and GVHD grade, involved organs, indication, timing of the procedure, proposed regimen, and any other factors that may affect the safe administration of ECP.	C8.17.1	Before ECP is undertaken, there shall be a written therapy plan from a physician specifying the patient's diagnosis and GVHD grade, involved organs, indication, timing of the procedure, proposed regimen, and any other factors that may affect the safe treatment with ECP.	Negligible
C08.17.02	The ECP procedure shall be performed according to written standard operating procedures of the facility performing the procedure appropriate for the clinical condition of the patient.	C8.17.2	The ECP shall be performed according to written standard operating procedures of the facility performing the procedure appropriate for the clinical condition of the patient.	Negligible
C08.17.03	A final report of the details of ECP administered shall be documented in the patient's medical record.	C8.17.3	A final report of the details of the ECP treatment shall be documented in the patient's medical record.	Negligible
C09	**CELLULAR THERAPY PRODUCT STORAGE**	**C9**	**CELLULAR THERAPY PRODUCT STORAGE**	No change
C09.01	Apheresis Collection Facilities shall control storage areas to prevent mix-ups, deterioration, contamination, cross-contamination, and improper release or distribution of products.	C9.1	Apheresis Collection Facilities shall control storage areas to prevent mix-ups, deterioration, contamination, cross-contamination, and improper release or distribution of cellular therapy products.	Negligible
C09.02	Apheresis Collection Facilities shall establish policies for the duration and conditions of short-term storage prior to distribution to a Processing Facility or Clinical Program.	C9.2	Apheresis Collection Facilities shall establish policies for the duration and conditions of short-term storage prior to distribution to a Processing Facility or Clinical Program.	No change
C10	**CELLULAR THERAPY PRODUCT TRANSPORTATION AND SHIPPING**	**C10**	**CELLULAR THERAPY PRODUCT TRANSPORTATION AND SHIPPING**	No change
C10.01	Procedures for transportation and shipping of the cellular therapy product shall be designed to protect the integrity of the product and the health and safety of individuals in the immediate area.	C10.1	Standard Operating Procedures for transportation and shipping of the cellular therapy product shall be designed to protect the integrity of the product and the health and safety of individuals in the immediate area.	Negligible

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
C10.02	The primary cellular therapy product container shall be placed in a secondary container that is sealed to prevent leakage.	C10.2	The primary cellular therapy product container shall be placed in a secondary container that is sealed to prevent leakage.	No change
C10.03	The cellular therapy product shall be transported and/or shipped to the Processing Facility in a validated container at a temperature defined in a Standard Operating Procedure.	C10.3	The cellular therapy product shall be transported or shipped to the Processing Facility in a validated container at a temperature defined in a Standard Operating Procedure.	Negligible
C10.03.01	Cellular therapy products that are transported and/or shipped from the collection site to the Processing Facility shall be transported and/or shipped in an outer container made of material adequate to withstand leakage of contents, impact shocks, pressure changes, temperature changes, puncture, and other conditions incident to ordinary handling.	C10.3.1	Cellular therapy products that are transported or shipped from the collection site to the Processing Facility shall be in an outer container made of material adequate to withstand leakage of contents, impact shocks, pressure changes, temperature changes, puncture, and other conditions incident to ordinary handling.	Negligible
C10.03.02	If the intended recipient has received high-dose therapy, the cellular therapy product shall be transported.	C10.3.2	If the intended recipient has received high-dose therapy, the cellular therapy product shall be transported.	No change
C10.04	The cellular therapy product shall be transported and/or shipped with required accompanying records as defined in the transportation and shipping procedure and in compliance with C7.4.4 and C7.4.5.	C10.4	The cellular therapy product shall be transported or shipped with required accompanying records as defined in the transportation and shipping Standard Operating Procedures and in compliance with C7.4.5 and C7.4.7.	Negligible
C10.05	There shall be a record of the date and time of cellular therapy product distribution.	C10.5	There shall be a record of the date and time of cellular therapy product distribution.	No change
C11	**RECORDS**	**C11**	**RECORDS**	No change
C11.01	**GENERAL REQUIREMENTS**	**C11.1**	**GENERAL REQUIREMENTS**	No change
C11.01.01	A records management system shall be established and maintained to facilitate the review of records.	C11.1.1	A records management system shall be established and maintained to facilitate the review of records.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
C11.01.01.01	The records management system shall facilitate tracking of the cellular therapy product from the donor to the recipient or final disposition and tracing from the recipient or final disposition to the donor.	C11.1.1.1	The records management system shall facilitate tracking of the cellular therapy product from the donor to the recipient or final disposition and tracing from the recipient or final disposition to the donor.	No change
C11.01.01.02	For cellular therapy products that are to be distributed for use at another institution, the Apheresis Collection Facility shall inform the receiving institution of the tracking system and requirement for tracking the product in writing or electronic format at or before the time of product distribution.	C11.1.1.2	For cellular therapy products that are to be distributed for use at another institution, the Apheresis Collection Facility shall inform the receiving institution of the tracking system and requirement for tracking the product in writing or electronic format at or before the time of product distribution.	No change
C11.01.02	Records shall be maintained in such a way as to preserve their integrity, preservation, and retrieval.	C11.1.2	Records shall be maintained in such a way as to preserve their integrity, preservation, and retrieval.	No change
	See C11.1.2			
C11.01.04	Safeguards to secure the confidentiality of all records and communications between the collection, processing, and clinical facilities, and their recipients and donors, shall be established and followed in compliance with applicable laws and regulations.	C11.1.4	Safeguards to secure the confidentiality of all records and communications between the collection, processing, and clinical facilities, and their recipients and donors, shall be established and followed in compliance with applicable laws and regulations.	No change
C11.01.03	Records shall be accurate, legible, and indelible.	C11.1.3	Records shall be accurate, legible, and indelible.	No change
	See C11.1.2			
		C11.2	The Apheresis Collection Facility shall define and follow good documentation practices.	New

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
C11.02	Apheresis Collection Facility records related to quality control, personnel training and competency, facility maintenance, facility management, complaints, or other general facility issues shall be retained for a minimum of ten (10) years by the Collection Facility, or longer in accordance with applicable laws and regulations, or a defined program or institution policy.	C11.3	Apheresis Collection Facility records related to quality control, personnel training and competency, facility maintenance, facility management, complaints, or other general facility issues shall be retained for a minimum of ten (10) years by the Collection Facility, or longer in accordance with applicable laws and regulations.	Minor
C11.02.01	Employee records shall be maintained in a confidential manner, as required by applicable laws and regulations.	C11.3.1	Employee records shall be maintained in a confidential manner, as required by applicable laws and regulations.	No change
		C11.3.2	Cleaning and sanitation records shall be retained for a minimum of three (3) years or longer in accordance with applicable laws or regulations.	New
C11.03	Records to allow tracking and tracing of cellular therapy products shall be maintained for a minimum of ten (10) years after final distribution of the product, or as required by applicable laws and regulations. These records shall include product identity, unique numeric or alphanumeric identifier, and collection date and time; and donor and recipient identification as far as known.	C11.4	Records to allow tracking and tracing of cellular therapy products shall be maintained for a minimum of ten (10) years after the administration, distribution, disposition, or expiration of the cellular therapy product, whichever is latest. These records shall include product identity, unique numeric or alphanumeric identifier, and collection date and time; and donor and recipient identification as far as known.	Moderate
C11.04	Patient and donor records including, but not limited to, consents and records of care shall be maintained in a confidential manner as required by applicable laws and regulations for a minimum of ten (10) years after the administration of the cellular therapy product, or, if not known, ten (10) years after the date of the distribution, disposition, or expiration of the product, whichever requires the longest maintenance period.	C11.5	Recipient and donor records including, but not limited to, consents and records of care shall be maintained in a confidential manner as required by applicable laws and regulations for a minimum of ten (10) years after the administration of the cellular therapy product, or, if not known, ten (10) years after the date of the distribution, disposition, or expiration of the product, whichever is latest.	Negligible

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
C11.05	Research records shall be maintained in a confidential manner as required by applicable laws and regulations for a minimum of ten (10) years after the administration, distribution, disposition, or expiration of the cellular therapy product, whichever is latest.	C11.6	Research records shall be maintained in a confidential manner as required by applicable laws and regulations or for a minimum of ten (10) years after the administration, distribution, disposition, or expiration of the cellular therapy product, whichever is latest.	Negligible
C11.06	**ELECTRONIC RECORDS**	**C11.7**	**ELECTRONIC RECORDS**	No change
C11.06.01	The Apheresis Collection Facility shall maintain a current listing of all critical electronic record systems. Critical electronic record systems shall include at a minimum systems under the control of the Apheresis Collection Facility that are used as a substitute for paper, to make decisions, to perform calculations, or to create or store information used in critical procedures.	C11.7.1	The Apheresis Collection Facility shall maintain a current listing of all critical electronic record systems. Critical electronic record systems shall include at a minimum systems under the control of the Apheresis Collection Facility that are used as a substitute for paper, to make decisions, to perform calculations, or to create or store information used in critical procedures.	No change
	See C11.6.1			
	See C11.6.1			
	See C11.6.1			
	See C11.6.1			
C11.06.02	For all critical electronic record systems, there shall be policies, procedures, and system elements to maintain the accuracy, integrity, identity, and confidentiality of all records.	C11.7.2	For all critical electronic record systems, there shall be policies, Standard Operating Procedures, and system elements to maintain the accuracy, integrity, identity, and confidentiality of all records.	Negligible
C11.06.03	There shall be a means by which access to electronic records is limited to authorized individuals.	C11.7.3	There shall be a means by which access to electronic records is limited to authorized individuals.	No change
C11.06.04	The critical electronic record system shall maintain unique identifiers.	C11.7.4	The critical electronic record system shall maintain unique identifiers.	No change
C11.06.05	There shall be protection of the records to enable their accurate and ready retrieval throughout the period of record retention.	C11.7.5	There shall be protection of the records to enable their accurate and ready retrieval throughout the period of record retention.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
C11.06.06	For all critical electronic record systems, there shall be an alternative system for all electronic records to allow for continuous operation in the event that critical electronic record systems are not available. The alternative system shall be validated and Apheresis Collection Facility staff shall be trained in its use.	C11.7.6	For all critical electronic record systems, there shall be an alternative system for all electronic records to allow for continuous operation in the event that critical electronic record systems are not available. The alternative system shall be validated and Apheresis Collection Facility staff shall be trained in its use.	No change
C11.06.07	For all critical electronic record systems, there shall be written procedures for record entry, verification, and revision.	C11.7.7	For all critical electronic record systems, there shall be written Standard Operating Procedures for record entry, verification, and revision.	Negligible
C11.06.07.01	A method shall be established or the system shall provide for review of data before final acceptance.	C11.7.7.1	A method shall be established or the system shall provide for review of data before final acceptance.	No change
C11.06.07.02	A method shall be established or the system shall provide for the unambiguous identification of the individual responsible for each record entry.	C11.7.7.2	A method shall be established or the system shall provide for the unambiguous identification of the individual responsible for each record entry.	No change
C11.06.08	For all critical electronic record systems, there shall be the ability to generate true copies of the records in both human readable and electronic format suitable for inspection and review.	C11.7.8	For all critical electronic record systems, there shall be the ability to generate true copies of the records in both human readable and electronic format suitable for inspection and review.	No change
C11.06.09	For all critical electronic record systems, there shall be validated procedures for and documentation of:	C11.7.9	For all critical electronic record systems, there shall be validated procedures for and documentation of:	No change
		C11.7.9.1	Systems development.	New
		C11.7.9.2	Numerical designation of system versions, if applicable.	New
		C11.7.9.3	Prospective validation of systems, including hardware, software, and databases.	New
C11.06.09.01	Training and continued competency of personnel in systems use.	C11.7.9.4	Training and continued competency of personnel in systems use.	No change
C11.06.09.02	Monitoring of data integrity.	C11.7.9.5	Monitoring of data integrity.	No change
C11.06.09.03	Back-up of the electronic records system on a regular schedule.	C11.7.9.6	Back-up of the electronic records system on a regular schedule.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
C11.06.09.04	System assignment of unique identifiers.	C11.7.9.7	System assignment of unique identifiers.	No change
C11.07	**RECORDS IN CASE OF DIVIDED RESPONSIBILITY**	**C11.8**	**RECORDS IN CASE OF DIVIDED RESPONSIBILITY**	No change
C11.07.01	The Apheresis Collection Facility shall furnish to the facility of final disposition a copy of all records relating to the collection procedures performed in so far as they concern the safety, purity, or potency of the cellular therapy product involved.	C11.8.1	The Apheresis Collection Facility shall furnish to the facility of final disposition a copy of all records relating to the collection procedures performed related to the safety, purity, or potency of the cellular therapy product involved.	Negligible
C11.07.02	If two (2) or more facilities participate in the collection, processing, or administration of the cellular therapy product, the records of each facility shall show plainly the extent of its responsibility.	C11.8.2	If two (2) or more facilities participate in the collection, processing, or administration of the cellular therapy product, the records of each facility shall show plainly the extent of its responsibility.	No change
C12	**DIRECT DISTRIBUTION TO CLINICAL PROGRAM**	**C12**	**DIRECT DISTRIBUTION TO CLINICAL PROGRAM**	No change
C12.01	Where cellular therapy products are distributed directly from the Apheresis Collection Facility to the Clinical Program for administration or for subsequent processing, the Standards related to labeling, documentation, distribution, transportation, and recordkeeping in Sections D7, D10, D11, D13, and the Appendices apply.	C12.1	Where cellular therapy products are distributed directly from the Apheresis Collection Facility to the Clinical Program for administration or for subsequent processing, the Standards related to labeling, documentation, distribution, transportation, and recordkeeping in Sections D7, D10, D11, D13, and the Appendices apply.	No change
CM01	**GENERAL**	**M1**	**General**	No change
CM01.01	These Standards apply to the Marrow Collection Facility for collection activities of all cellular therapy products collected from living donors.	M1.1	These Standards apply to all collection, storage, and distribution activities performed in the Marrow Collection Facility for cellular therapy products obtained from living donors.	Minor
CM01.02	The Marrow Collection Facility shall use cell processing facilities that meet FACT-JACIE Standards with respect to their interactions with the Marrow Collection Facility.	M1.2	The Marrow Collection Facility shall use cell processing facilities that meet FACT-JACIE Standards with respect to their interactions with the Marrow Collection Facility.	No change
CM01.03	The Marrow Collection Facility shall abide by all applicable laws and regulations.	M1.3	The Marrow Collection Facility shall abide by all applicable laws and regulations.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
CM01.03.01	The Marrow Collection Facility shall be licensed, registered, or accredited as required by the appropriate governmental authorities for the activities performed.	M1.3.1	The Marrow Collection Facility shall be licensed, registered, or accredited as required by the appropriate governmental authorities for the activities performed.	No change
CM01.04	The Marrow Collection Facility shall have a Marrow Collection Facility Medical Director, a Quality Manager, and at least one (1) additional designated staff member. This team shall have been in place and performing cellular therapy product collections for at least twelve (12) months preceding initial accreditation.	M1.4	The Marrow Collection Facility shall have a Marrow Collection Facility Medical Director, a Quality Manager, and a minimum of one (1) additional designated staff member. This team shall have been in place and performing cellular therapy product collections for at least twelve (12) months preceding initial accreditation.	Reordered
CM01.05	A minimum of one (1) marrow collection procedure shall have been performed in the twelve (12) month period immediately preceding facility accreditation, and a minimum average of one (1) marrow collection procedure per year shall be performed within the accreditation cycle.	M1.5	A minimum of one (1) marrow collection procedure shall have been performed in the twelve (12) month period preceding initial accreditation, and a minimum average of one (1) marrow collection procedure per year shall be performed within each accreditation cycle.	Minor
CM02	**MARROW COLLECTION FACILITY**	**M2**	**MARROW COLLECTION FACILITY**	No change
CM02.01	There shall be appropriate designated areas for collection of cellular therapy products, for collected products, and for storage of supplies, reagents, and equipment.	M2.1	There shall be appropriate designated areas for collection of cellular therapy products, for collected products, and for storage of equipment, supplies, and reagents.	Minor
CM02.01.01	The Marrow Collection Facility shall be divided into defined areas of adequate size to prevent improper labeling, mix-ups, contamination, or cross-contamination of cellular therapy products.	M2.1.1	The Marrow Collection Facility shall be divided into defined areas of adequate size to prevent improper labeling, mix-ups, contamination, or cross-contamination of cellular therapy products.	No change
CM02.01.02	There shall be a process to control storage areas to prevent mix-ups, contamination, and cross-contamination of all cellular therapy products prior to release or distribution.	M2.1.2	There shall be a process to control storage areas to prevent mix-ups, contamination, and cross-contamination of all cellular therapy products.	Minor

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
CM02.01.03	There shall be a process for confidential donor examination and evaluation.	M2.1.3	There shall be suitable space for confidential donor examination and evaluation.	Minor
CM02.02	The Marrow Collection Facility shall provide adequate lighting, ventilation, and access to sinks to prevent the introduction, transmission, or spread of communicable disease.	M2.2	The Marrow Collection Facility shall provide adequate lighting, ventilation, and access to sinks to prevent the introduction, transmission, or spread of communicable disease.	No change
CM02.03	Critical Marrow Collection Facility parameters that may affect cellular therapy product viability, integrity, contamination, sterility, or cross-contamination during collection, including temperature and humidity at a minimum, shall be assessed for risk to the cellular therapy product.	M2.4	There shall be a written assessment of critical Marrow Collection Facility parameters that may affect cellular therapy product viability, integrity, contamination, or cross-contamination during collection.	Minor
		M2.4.1	The written assessment shall include temperature and humidity at a minimum.	Separated
CM02.03.01	Critical facility parameters identified to be a risk to the cellular therapy product shall be controlled, monitored, and recorded.	M2.4.2	Critical facility parameters identified to be a risk to the cellular therapy product shall be controlled, monitored, and recorded.	No change
CM02.04	Marrow Collection Facility parameters and environmental conditions shall be controlled to protect the safety and comfort of patients, donors, and personnel.	M2.3	Marrow Collection Facility parameters and environmental conditions shall be controlled to protect the safety and comfort of donors and personnel.	Negligible
CM02.05	The Marrow Collection Facility shall document facility cleaning and sanitation and maintain order sufficient to achieve adequate conditions for operations.	M2.5	The Marrow Collection Facility shall document facility cleaning and sanitation and maintain order sufficient to achieve adequate conditions for operations.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
CM02.06	There shall be adequate equipment and materials for the procedures performed.	M2.6	There shall be adequate equipment and materials for the procedures performed.	No change
CM02.07	There shall be access to an intensive care unit and/or emergency services.	M2.7	There shall be access to an intensive care unit or emergency services.	Negligible
CM02.08	The Marrow Collection Facility shall be operated in a manner designed to minimize risks to the health and safety of employees, patients, donors, visitors, and volunteers.	M2.8	The Marrow Collection Facility shall be operated in a manner designed to minimize risks to the health and safety of employees, donors, visitors, and volunteers.	Negligible
CM02.09	The Marrow Collection Facility shall have a written safety manual that includes instructions for action in case of exposure, as applicable, to communicable disease and to chemical, biological, or radiological hazards.	M2.9	The Marrow Collection Facility shall have a written safety manual that includes instructions for action in case of exposure, as applicable, to communicable disease and to chemical, biological, or radiological hazards.	No change
		M2.10	All waste generated by the Marrow Collection Facility activities shall be disposed of in a manner that minimizes any hazard to facility personnel and to the environment in accordance with applicable laws and regulations.	New
		M2.11	Gloves and protective clothing shall be worn while handling biological specimens. Such protective clothing shall not be worn outside the work area.	New
CM03	**PERSONNEL**	**M3**	**PERSONNEL**	No change
CM03.01	**MARROW COLLECTION FACILITY MEDICAL DIRECTOR**	**M3.1**	**MARROW COLLECTION FACILITY MEDICAL DIRECTOR**	No change
CM03.01.01	There shall be a Marrow Collection Facility Medical Director who is a licensed physician with postgraduate training in cell collection and/or transplantation.	M3.1.1	There shall be a Marrow Collection Facility Medical Director who is a licensed physician with postgraduate certification and training in cellular therapy product collection and transplantation.	Negligible
CM03.01.02	The Marrow Collection Facility Medical Director or designee shall be responsible for the following elements:	M3.1.2	The Marrow Collection Facility Medical Director or designee shall be responsible for the following elements:	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
CM03.01.02.01	All technical procedures.	M3.1.2.1	All technical procedures.	No change
CM03.01.02.02	Performance of the marrow collection procedure.	M3.1.2.2	Performance of the marrow collection procedure.	No change
CM03.01.02.03	Supervision of staff.	M3.1.2.3	Supervision of staff.	No change
CM03.01.02.04	Administrative operations.	M3.1.2.4	Administrative operations.	No change
CM03.01.02.05	The medical care of allogeneic and/or autologous donors undergoing marrow collection.	M3.1.2.5	The medical care of allogeneic and/or autologous donors undergoing marrow collection.	No change
CM03.01.02.06	Pre-collection evaluation of allogeneic and/or autologous donors at the time of donation.	M3.1.2.6	Pre-collection evaluation of allogeneic and/or autologous donors at the time of donation.	No change
CM03.01.02.07	Care of any complications resulting from the collection procedure.	M3.1.2.7	Care of any complications resulting from the collection procedure.	No change
CM03.01.02.08	The Quality Management Program, including compliance with these Standards and other applicable laws and regulations.	M3.1.2.8	The Quality Management Program, including compliance with these Standards and other applicable laws and regulations.	No change
CM03.01.03	The Marrow Collection Facility Medical Director shall have at least one year experience in cellular therapy product collection procedures.	M3.1.3	The Marrow Collection Facility Medical Director shall have at least two (2) years experience in cellular therapy product collection procedures.	Significant
CM03.01.04	The Marrow Collection Facility Medical Director shall have performed or supervised at least ten (10) marrow collection procedures within his/her career.	M3.1.4	The Marrow Collection Facility Medical Director shall have performed or supervised ten (10) marrow collection procedures within his/her career at a minimum.	Minor
CM03.01.05	The Marrow Collection Facility Medical Director shall participate in ten (10) hours of educational activities related to cellular therapy annually at a minimum.	M3.1.5	The Marrow Collection Facility Medical Director shall participate in a minimum of ten (10) hours of educational activities related to cellular therapy annually.	Reordered
CM03.01.05.01	Continuing education shall include, but is not limited to, activities related to the field of HPC transplantation and marrow collection.	M3.1.5.1	Continuing education shall include, but is not limited to, activities related to the field of HPC transplantation.	Minor

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
CM03.02	**QUALITY MANAGER**	**M3.2**	**QUALITY MANAGER**	No change
CM03.02.01	There shall be a Marrow Collection Facility Quality Manager to establish and maintain systems to review, modify, and approve all policies and procedures intended to monitor compliance with these Standards and/or the performance of the Marrow Collection Facility.	M3.2.1	There shall be a Marrow Collection Facility Quality Manager to establish and maintain systems to review, modify, and approve all policies and Standard Operating Procedures intended to monitor compliance with these Standards or the performance of the Marrow Collection Facility.	Negligible
		M3.2.2	The Marrow Collection Facility Quality Manager should have a reporting structure independent of cellular therapy product manufacturing.	new
CM03.02.02	The Marrow Collection Facility Quality Manager shall participate in ten (10) hours of educational activities related to cellular therapy, cell collection, and/or quality management annually at a minimum.	M3.2.3	The Marrow Collection Facility Quality Manager shall participate in a minimum of ten (10) hours of educational activities related to cellular therapy, cell collection, and quality management annually.	Reordered
CM03.02.02.01	Continuing education shall include, but is not limited to, activities related to the field of HPC transplantation.	M3.2.3.1	Continuing education shall include, but is not limited to, activities related to the field of HPC transplantation.	No change
CM03.03	**STAFF**	**M3.3**	**STAFF**	No change
CM03.03.01	The Marrow Collection Facility shall have access to licensed health care professionals who are trained and competent in marrow collection.	M3.3.1	The Marrow Collection Facility shall have access to licensed health care professionals who are trained and competent in marrow collection.	No change
CM03.03.02	The number of trained collection personnel shall be adequate for the number of procedures performed and shall include a minimum of one designated trained individual with an identified trained backup to maintain sufficient coverage.	M3.3.2	The number of trained collection personnel shall be adequate for the number of procedures performed and shall include a minimum of one (1) designated trained individual with an identified trained backup to maintain sufficient coverage.	No change
CM03.03.03	For Marrow Collection Facilities collecting cellular therapy products from pediatric donors, physicians and collection staff shall have documented training and experience in performing these procedures.	M3.3.3	For Marrow Collection Facilities collecting cellular therapy products from pediatric donors, physicians and collection staff shall have documented training and experience with pediatric donors.	Negligible
CM04	**QUALITY MANAGEMENT**	**M4**	**QUALITY MANAGEMENT**	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
CM04.01	The Marrow Collection Facility shall comply with B4 if it operates independently of a Clinical Program.	M4.1	The Marrow Collection Facility shall comply with B4 if it operates independently of a Clinical Program.	No change
CM05	**POLICIES AND PROCEDURES**	**M5**	**POLICIES AND STANDARD OPERATING PROCEDURES**	Negligible
CM05.01	The Marrow Collection Facility shall establish and maintain policies and/or procedures addressing critical aspects of operations and management in addition to those required in CM4. These documents shall include all elements required by these Standards and shall address at a minimum:	M5.1	The Marrow Collection Facility shall establish and maintain policies or Standard Operating Procedures addressing critical aspects of operations and management in addition to those required in CM4. These documents shall include all elements required by these Standards and shall address at a minimum:	Negligible
CM05.01.01	Donor and recipient confidentiality.	M5.1.1	Donor and recipient confidentiality.	No change
CM05.01.02	Donor consent.	M5.1.2	Donor consent.	No change
CM05.01.03	Donor screening, testing, eligibility determination, and management.	M5.1.3	Donor screening, testing, eligibility determination, and management.	No change
CM05.01.04	Cellular therapy product collection.	M5.1.4	Cellular therapy product collection.	No change
		M5.1.5	Administration of blood products.	new
CM05.01.05	Prevention of mix-ups and cross-contamination.	M5.1.6	Prevention of mix-ups and cross-contamination.	No change
CM05.01.06	Labeling (including associated forms and samples).	M5.1.7	Labeling (including associated forms and samples).	No change
CM05.01.07	Cellular therapy product expiration dates.	M5.1.8	Cellular therapy product expiration dates.	No change
CM05.01.08	Cellular therapy product storage.	M5.1.9	Cellular therapy product storage.	No change
CM05.01.09	Release and exceptional release.	M5.1.10	Release and exceptional release.	No change
CM05.01.10	Transportation and shipping, including methods and conditions to be used for distribution to external facilities.	M5.1.11	Transportation and shipping, including methods and conditions to be used for distribution to external facilities.	No change
CM05.01.11	Critical equipment, reagent, and supply management including recalls and corrective actions in the event of failure.	M5.1.12	Critical equipment, reagent, and supply management including recalls and corrective actions in the event of failure.	No change
CM05.01.12	Hygiene and use of personal protective attire.	M5.1.13	Hygiene and use of personal protective equipment and attire.	Minor

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
CM05.01.13	Emergency and disaster plan related to the marrow collection procedure.	M5.1.14	Cellular therapy emergency and disaster plan related to the marrow collection procedure.	Negligible
CM05.02	The Marrow Collection Facility shall comply with B5.2 if it operates independently of a Clinical Program.	M5.2	The Marrow Collection Facility shall comply with B5.2 if it operates independently of a Clinical Program.	No change
CM05.03	Standard Operating Procedures required in CM5.1 shall be sufficiently detailed and unambiguous to allow qualified staff to follow and complete the procedures successfully. Each individual procedure shall include:	M5.3	Standard Operating Procedures required in CM5.1 shall be sufficiently detailed and unambiguous to allow qualified staff to follow and complete the procedures successfully. Each individual Standard Operating Procedure shall include:	Negligible
CM05.03.01	A clearly written description of the objectives.	M5.3.1	A clearly written description of the objectives.	No change
CM05.03.02	A description of equipment and supplies used.	M5.3.2	A description of equipment and supplies used.	No change
CM05.03.03	Acceptable end-points and the range of expected results.	M5.3.3	Acceptable end-points and the range of expected results.	No change
CM05.03.04	A stepwise description of the procedure.	M5.3.4	A stepwise description of the procedure.	No change
CM05.03.05	Age-specific issues where relevant.	M5.3.5	Age-specific issues where relevant.	No change
CM05.03.06	Reference to other Standard Operating Procedures or policies required to perform the procedure.	M5.3.6	Reference to other Standard Operating Procedures or policies required to perform the procedure.	No change
CM05.03.07	A reference section listing appropriate literature.	M5.3.7	A reference section listing appropriate and current literature.	Minor
CM05.03.08	Documented approval of each procedure by the Marrow Collection Facility Medical Director prior to implementation and every two years thereafter.	M5.3.8	Documented approval of each procedure by the Marrow Collection Facility Medical Director prior to implementation and every two (2) years thereafter.	Negligible
CM05.03.09	Documented approval of each procedural modification by the Marrow Collection Facility Medical Director or designated physician prior to implementation.	M5.3.9	Documented approval of each procedural modification by the Marrow Collection Facility Medical Director or designated physician prior to implementation.	No change
CM05.03.10	Reference to a current version of orders, worksheets, reports, labels, and forms.	M5.3.10	Reference to a current version of orders, worksheets, reports, labels, and forms.	No change
CM05.04	Standard Operating Procedures relevant to processes being performed shall be readily available to the facility staff.	M5.4	Controlled documents relevant to processes being performed shall be readily available to the facility staff.	Negligible

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
CM05.05	Staff training and, if appropriate, competency shall be documented before performing a new or revised procedure.	M5.5	Staff training and, if appropriate, competency shall be documented before performing a new or revised Standard Operating Procedure.	Negligible
CM05.06	All personnel shall follow the Standard Operating Procedures related to their positions.	M5.6	All personnel shall follow the policies and Standard Operating Procedures related to their positions.	Minor
CM05.07	Variances shall be pre-approved by the Marrow Collection Facility Medical Director, and reviewed by the Quality Manager.	M5.7	Planned deviations shall be pre-approved by the Marrow Collection Facility Medical Director and reviewed by the Quality Manager.	Minor
CM06	**ALLOGENEIC AND AUTOLOGOUS DONOR EVALUATION AND MANAGEMENT**	**M6**	**ALLOGENEIC AND AUTOLOGOUS DONOR EVALUATION AND MANAGEMENT**	No change
CM06.01	There shall be written criteria for allogeneic and autologous donor evaluation and management by trained medical personnel.	M6.1	There shall be written criteria for allogeneic and autologous donor evaluation and management by trained medical personnel.	No change
CM06.02	**ALLOGENEIC AND AUTOLOGOUS DONOR INFORMATION AND CONSENT FOR COLLECTION**	**M6.2**	**ALLOGENEIC AND AUTOLOGOUS DONOR INFORMATION AND CONSENT FOR COLLECTION**	No change
CM06.02.01	The collection procedure shall be explained in terms the donor can understand, and shall include the following information at a minimum:	M6.2.1	The collection procedure shall be explained in terms the donor can understand, and shall include the following information at a minimum:	No change
CM06.02.01.01	The risks and benefits of the procedure.	M6.2.1.1	The risks and benefits of the procedure.	No change
CM06.02.01.02	Tests and procedures performed on the donor to protect the health of the donor and the recipient.	M6.2.1.2	Tests and procedures performed on the donor to protect the health of the donor and the recipient.	No change
CM06.02.01.03	The rights of the donor or legally authorized representative to review the results of such tests according to applicable laws and regulations.	M6.2.1.3	The rights of the donor or legally authorized representative to review the results of such tests according to applicable laws and regulations.	No change
CM06.02.01.04	Protection of medical information and confidentiality.	M6.2.1.4	Protection of medical information and confidentiality.	No change
CM06.02.02	Interpretation and translation shall be performed by individuals qualified to provide these services in the clinical setting.	M6.2.2	Interpretation and translation shall be performed by individuals qualified to provide these services in the clinical setting.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
CM06.02.03	Family members and legally authorized representatives should not serve as interpreters or translators.	M6.2.3	Family members and legally authorized representatives should not serve as interpreters or translators.	No change
CM06.02.04	The donor shall have an opportunity to ask questions.	M6.2.4	The donor shall have an opportunity to ask questions.	No change
CM06.02.05	The donor shall have the right to refuse to donate.	M6.2.5	The donor shall have the right to refuse to donate or withdraw consent.	Moderate
CM06.02.05.01	The allogeneic donor shall be informed of the potential consequences to recipient of such refusal.	M6.2.5.1	The allogeneic donor shall be informed of the potential consequences to the recipient of such refusal in the event that consent is withdrawn after the recipient has begun the preparative regimen.	Moderate
CM06.02.06	Donor informed consent for the cellular therapy product collection shall be obtained and documented by a licensed health care professional familiar with the collection procedure.	M6.2.6	Donor informed consent for the cellular therapy product collection shall be obtained and documented by a licensed health care professional familiar with the collection procedure.	No change
CM06.02.06.01	Informed consent from the allogeneic donor shall be obtained by a licensed health care professional who is not the primary health care professional overseeing care of the recipient.	M6.2.6.1	Informed consent from the allogeneic donor shall be obtained by a licensed health care professional who is not the primary health care professional overseeing care of the recipient.	No change
CM06.02.07	In the case of a minor donor, informed consent shall be obtained from the donor's legally authorized representative in accordance with applicable laws and regulations and shall be documented.	M6.2.7	In the case of a donor who is a minor, informed consent shall be obtained from the donor's legally authorized representative in accordance with applicable laws and regulations and shall be documented.	Negligible
CM06.02.08	The allogeneic donor shall give informed consent and authorization prior to release of the donor's health or other information to the recipient's physician and/or the recipient.	M6.2.8	The allogeneic donor shall give informed consent and authorization prior to release of the donor's health or other information to the recipient's physician or the recipient.	Negligible
CM06.02.09	Documentation of consent shall be available to the Marrow Collection Facility staff prior to the collection procedure.	M6.2.9	Documentation of consent shall be verified by the Marrow Collection Facility staff prior to the collection procedure.	Minor

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
CM06.03	**ALLOGENEIC AND AUTOLOGOUS DONOR SUITABILITY FOR CELLULAR THERAPY PRODUCT COLLECTION**	**M6.3**	**ALLOGENEIC AND AUTOLOGOUS DONOR SUITABILITY FOR CELLULAR THERAPY PRODUCT COLLECTION**	No change
CM06.03.01	There shall be criteria and evaluation policies and procedures in place to protect the safety of donors during the process of cellular therapy product collection.	M6.3.1	There shall be criteria and evaluation policies or Standard Operating Procedures in place to protect the safety of donors during the process of cellular therapy product collection.	Negligible
CM06.03.01.01	The Marrow Collection Facility shall confirm that any abnormal findings are reported to the prospective donor with documentation in the donor record of recommendations made for follow-up care.	M6.3.1.1	The Marrow Collection Facility shall confirm that clinically significant findings are reported to the prospective donor with documentation in the donor record of recommendations made for follow-up care.	Minor
CM06.03.01.02	Allogeneic donor suitability shall be evaluated by a licensed health care professional who is not the primary health care professional overseeing care of the recipient.	M6.3.1.2	Allogeneic donor suitability shall be evaluated by a licensed health care professional who is not the primary health care professional overseeing care of the recipient.	No change
CM06.03.01.03	Autologous donors shall be tested as required by applicable laws and regulations.	M6.3.1.3	Autologous donors shall be tested as required by applicable laws and regulations.	No change
CM06.03.02	The risks of donation shall be evaluated and documented, including anesthesia for marrow collection.	M6.3.2	The risks of donation shall be evaluated and documented, including anesthesia for marrow collection.	No change
		M6.3.3	The donor shall be evaluated for the risk of hemoglobinopathy prior to administration of the mobilization regimen, if utilized.	new
CM06.03.03	A pregnancy test shall be performed for all female donors with childbearing potential within seven (7) days prior to starting the donor mobilization regimen and, as applicable, within seven (7) days prior to the initiation of the recipient's preparative regimen.	M6.3.4	A pregnancy test shall be performed for all female donors with childbearing potential within seven (7) days prior to starting the donor mobilization regimen (if mobilized donor is used) or undergoing anesthesia, and, as applicable, within seven (7) days prior to the initiation of the recipient's preparative regimen.	Minor

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
CM06.03.04	Laboratory testing of all donors shall be performed by a laboratory that is accredited, registered, or licensed in accordance with applicable laws and regulations.	M6.3.5	Laboratory testing of all donors shall be performed by a laboratory that is accredited, registered, certified, or licensed in accordance with applicable laws and regulations.	Minor
CM06.03.05	The Clinical Program shall inform the Collection Facility and Processing Facility of donor test results or if any testing was not performed.	M6.3.6	The Clinical Program shall inform the Collection Facility and Processing Facility of donor test results or if any testing was not performed.	No change
CM06.03.06	There shall be a written order from a physician specifying, at a minimum, timing and goals of collection.			
CM06.03.07	Collection from a donor who does not meet Clinical Program collection safety criteria shall require documentation of the rationale for his/her selection by the transplant physician. Collection staff shall document review of these donor safety issues.	M6.3.7	Collection from a donor who does not meet collection safety criteria shall require documentation of the rationale for his/her selection by the donor's physician. Collection staff shall document review of these donor safety issues.	Negligible
CM06.03.08	There shall be written documentation of issues of donor health that pertain to the safety of the collection procedure available to the Marrow Collection Facility staff. Collection staff shall document review of these issues prior to collection.	M6.3.7.1	There shall be written documentation of issues of donor health that pertain to the safety of the collection procedure available to the Marrow Collection Facility staff. Collection staff shall document review of these issues prior to collection.	No change
CM06.03.09	There shall be a policy for follow-up of donors that includes routine management and the management of collection-associated adverse events.	M6.3.8	There shall be policies or Standard Operating Procedures for follow-up of donors that includes routine management and the management of collection-associated adverse events.	Negligible

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
CM06.04	**ADDITIONAL REQUIREMENTS FOR ALLOGENEIC DONORS**	**M6.4**	**ADDITIONAL REQUIREMENTS FOR ALLOGENEIC DONORS**	No change
CM06.04.01	A donor advocate shall be available to represent allogeneic donors who are minors or who are mentally incapacitated.	M6.4.1	A donor advocate shall be available to represent allogeneic donors who are minors or who are mentally incapacitated, as those terms are defined by applicable laws.	Minor
CM06.04.02	Allogeneic donor infectious disease testing shall be performed using donor screening tests approved or cleared by the governmental authority.	M6.4.2	Allogeneic donor infectious disease testing shall be performed using licensed donor screening tests approved or cleared by the governmental authority.	Negligible
		M6.4.3	The Marrow Collection Facility shall comply with B6.4.6 through B6.4.6.8 when primarily responsible for donor screening for transmissible disease.	New
		M6.4.4	The Marrow Collection Facility shall comply with B6.4.7 through B6.4.11 when primarily responsible for infectious and non-infectious disease testing of HPC donors.	New
		M6.4.5	The Marrow Collection Facility shall comply with B6.4.3, B6.4.4, and B6.4.12 through B6.4.12.4 when primarily responsible for testing for the selection of allogeneic donors.	New
CM07	**CODING AND LABELING OF CELLULAR THERAPY PRODUCTS**	**M7**	**CODING AND LABELING OF CELLULAR THERAPY PRODUCTS**	No change
CM07.01	**ISBT 128 CODING AND LABELING**	**M7.1**	**ISBT 128 AND EUROCODE CODING AND LABELING**	Significant
CM07.01.01	Cellular therapy products shall be identified according to the proper name of the product, including appropriate attributes, as defined in ISBT 128 Standard Terminology for Blood, Cellular Therapy, and Tissue Product Descriptions.	M7.1.1	Cellular therapy products shall be identified by name according to ISBT 128 standard terminology or Eurocode.	Significant
CM07.01.02	If coding and labeling technologies have not yet been implemented, the Marrow Collection Facility shall be actively implementing ISBT 128.	M7.1.2	Coding and labeling technologies shall be implemented using ISBT 128 or Eurocode.	Significant

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
CM07.02	**LABELING OPERATIONS**	**M7.2**	**LABELING OPERATIONS**	No change
CM07.02.01	Labeling operations shall be conducted in a manner adequate to prevent mislabeling or misidentification of cellular therapy products, product samples, and associated records.	M7.2.1	Labeling operations shall be conducted in a manner adequate to prevent mislabeling or misidentification of cellular therapy products, product samples, and associated records.	No change
CM07.02.01.01	Stocks of unused labels representing different products shall be stored in a controlled manner to prevent errors.	M7.2.1.1	Stocks of unused labels representing different products shall be stored in a controlled manner to prevent errors.	No change
CM07.02.01.02	Obsolete labels shall be restricted from use.	M7.2.1.2	Obsolete labels shall be restricted from use.	No change
CM07.02.02	Pre-printed labels shall be held upon receipt from the manufacturer pending review and proofing against a copy or template approved by the Marrow Collection Facility Medical Director or designee to confirm accuracy regarding identity, content, and conformity.	M7.2.2	Pre-printed labels shall be held upon receipt from the manufacturer pending review and proofing against a copy or template approved by the Marrow Collection Facility Medical Director or designee to confirm accuracy regarding identity, content, and conformity.	No change
CM07.02.03	Print-on-demand label systems shall be validated to confirm accuracy regarding identity, content, and conformity of labels to templates approved by the Marrow Collection Facility Medical Director or designee.	M7.2.3	Print-on-demand label systems shall be validated to confirm accuracy regarding identity, content, and conformity of labels to templates approved by the Marrow Collection Facility Medical Director or designee.	No change
CM07.02.04	A system for label version control shall be employed.	M7.2.4	A system for label version control shall be employed.	No change
CM07.02.04.01	Representative obsolete labels shall be archived minimally for ten (10) years after the last cellular therapy product was distributed with inclusive dates of use or as defined by applicable laws and regulations, whichever is longer.	M7.2.4.1	Representative obsolete labels shall be archived minimally for ten (10) years after the last cellular therapy product was distributed with inclusive dates of use or as defined by applicable laws and regulations, whichever is longer.	No change
CM07.02.05	A system of checks in labeling procedures shall be used to prevent errors in transferring information to labels.	M7.2.5	A system of checks in labeling procedures shall be used to prevent errors in transferring information to labels.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
CM07.02.05.01	Cellular therapy products that are subsequently re-packaged into new containers shall be labeled with new labels before they are detached from the original container.	M7.2.5.1	Cellular therapy products that are subsequently re-packaged into new containers shall be labeled with new labels before they are detached from the original container.	No change
CM07.02.05.02	A controlled labeling procedure consistent with applicable law shall be defined and followed if container label information is transmitted electronically during a labeling process. This procedure shall include a verification step.	M7.2.5.2	A controlled labeling procedure consistent with applicable law shall be defined and followed if container label information is transmitted electronically during a labeling process. This procedure shall include a verification step.	No change
CM07.02.06	When the label has been affixed to the container, a sufficient area of the container shall remain uncovered to permit inspection of the contents.	M7.2.6	When the label has been affixed to the container, a sufficient area of the container shall remain uncovered to permit inspection of the contents.	No change
CM07.02.07	The information entered on a container label shall be verified by one (1) qualified staff member using a validated process to verify the information or two (2) qualified staff members.	M7.2.7	The information entered on a container label shall be verified by one (1) qualified staff member using a validated process or two (2) qualified staff members.	Minor
CM07.02.08	Labeling elements required by applicable laws and regulations shall be present.	M7.2.8	Labeling elements required by applicable laws and regulations shall be present.	No change
CM07.02.09	All data fields on labels shall be completed.	M7.2.9	All data fields on labels shall be completed.	No change
CM07.02.10	All labeling shall be clear, legible, and completed using ink that is indelible to all relevant agents.	M7.2.10	All labeling shall be clear, legible, and completed using ink that is indelible to all relevant agents.	No change
CM07.02.11	Labels affixed directly to a cellular therapy product bag shall be applied using appropriate materials as defined by the applicable regulatory authority.	M7.2.11	Labels affixed directly to a cellular therapy product bag shall be applied using appropriate materials as defined by the applicable regulatory authority.	No change
CM07.02.12	The label shall be validated as reliable for storage under the conditions in use.	M7.2.12	The label shall be validated as reliable for storage under the conditions in use.	No change
CM07.03	**PRODUCT IDENTIFICATION**	**M7.3**	**PRODUCT IDENTIFICATION**	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
CM07.03.01	Each cellular therapy product collection shall be assigned a unique numeric or alphanumeric identifier by which it will be possible to trace any cellular therapy product to its donor, its recipient or final disposition, and all records.	M7.3.1	Each cellular therapy product collection shall be assigned a unique numeric or alphanumeric identifier by which it will be possible to trace any cellular therapy product to its donor, its recipient or final disposition, and all records.	No change
CM07.03.01.01	The cellular therapy product, product samples, and concurrently collected samples shall be labeled with the same identifier.	M7.3.1.1	The cellular therapy product, product samples, and concurrently collected samples shall be labeled with the same identifier.	No change
CM07.03.01.02	If a single cellular therapy product is stored in more than one container, there shall be a system to identify each container.	M7.3.1.2	If a single cellular therapy product is stored in more than one (1) container, there shall be a system to identify each container.	No change
CM07.03.01.03	Supplementary identifiers shall not obscure the original identifier.	M7.3.1.3	Supplementary identifiers shall not obscure the original identifier.	No change
CM07.03.01.04	The facility associated with each identifier shall be noted on the label.	M7.3.1.4	The facility associated with each identifier shall be named in the documents to accompany the cellular therapy product.	Minor
CM07.04	**LABEL CONTENT**	**M7.4**	**LABEL CONTENT**	No change
CM07.04.01	At the end of the cellular therapy product collection, the cellular therapy product label on the primary product container shall bear the information in the Cellular Therapy Product Labeling table in Appendix _.	M7.4.1	At all stages of collection, the cellular therapy product shall be labeled with the proper name of the product and the unique numeric or alphanumeric identifier, at a minimum.	Moderate
CM07.04.02	Each label shall bear the appropriate biohazard and warning labels as found in the Circular of Information (COI) for the Use of Cellular Therapy Products, “Table 2. Biohazard and Warning Labels on Cellular Therapy Products Collected, Processed, and/or Administered in the United States.”	M7.4.4	Each label shall bear the appropriate biohazard and warning labels as found in the Circular of Information for the Use of Cellular Therapy Products, “Table 2. Biohazard and Warning Labels on Cellular Therapy Products Collected, Processed, and/or Administered in the United States.”	Negligible
		M7.4.3	At the end of the cellular therapy product collection, the cellular therapy product label on the primary product container shall bear the information in the Cellular Therapy Product Labeling table in Appendix II.	New

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
CM07.04.03	Labeling at the end of collection shall occur before the cellular therapy product bag is removed from the proximity of the donor.	M7.4.2	Labeling at the end of collection shall occur before the cellular therapy product bag is removed from the proximity of the donor.	No change
CM07.04.04	Cellular therapy products collected in or designated for use in the U.S. shall be accompanied by the elements listed in the Accompanying Documents at Distribution table in Appendix _ at the time of distribution.	M7.4.5	A cellular therapy product collected in or designated for use in the U.S. shall be accompanied by the elements listed in the Accompanying Documentation table in Appendix IV at the time it leaves the control of the Marrow Collection Facility.	Minor
		M7.4.6	Any container bearing a partial label at the time of distribution shall be accompanied by the information required by the Cellular Therapy Product Labeling table in Appendix II. Such information shall be attached securely to the cellular therapy product on a tie tag or enclosed in a sealed package to accompany the product.	New
CM07.04.05	For cellular therapy products distributed before completion of donor eligibility determination, there shall be documentation that donor eligibility determination was completed during or after the use of the product.	M7.4.7	For cellular therapy products distributed before completion of donor eligibility determination, there shall be documentation that donor eligibility determination was completed during or after the use of the product.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
CM07.04.06	Cellular therapy products distributed for nonclinical purposes shall be labeled with the statement, “For Nonclinical Use Only.”	M7.4.8	Cellular therapy products distributed for nonclinical purposes shall be labeled with the statement, “For Nonclinical Use Only.”	No change
CM08	**PROCESS CONTROLS**	**M8**	**PROCESS CONTROLS**	No change
CM08.01	Collection of cellular therapy products shall be performed according to written collection procedures.	M8.1	Collection of cellular therapy products shall be performed according to written Standard Operating Procedures.	Negligible
CM08.02	There shall be a process for inventory control that encompasses equipment, reagents, supplies, and labels.	M8.2	There shall be a process for inventory control that encompasses equipment, supplies, reagents, and labels.	Reordered
CM08.02.01	There shall be a system to uniquely identify and track and trace all critical equipment, reagents, supplies, and labels used in the collection of cellular therapy products.	M8.2.1	There shall be a system to uniquely identify and track and trace all critical equipment, supplies, reagents, and labels used in the collection of cellular therapy products.	Reordered
CM08.02.02	Each supply and reagent used to collect cellular therapy products shall be visually examined at receipt and prior to use for damage or evidence of contamination.	M8.2.2	Each supply and reagent used to collect cellular therapy products shall be visually examined at receipt and prior to use for damage or evidence of contamination.	No change
CM08.02.03	Supplies and reagents coming into contact with cellular therapy products during collection shall be sterile and of the appropriate grade for the intended use.	M8.2.3	Supplies and reagents coming into contact with cellular therapy products during collection shall be sterile and of the appropriate grade for the intended use.	No change
CM08.03	Equipment for the marrow collection procedure shall conform to applicable laws and regulations.	M8.3	Equipment for the marrow collection procedure shall conform to applicable laws and regulations.	No change
CM08.04	Autologous and/or CMV-appropriate and irradiated blood components shall be available during the marrow collection procedure for all donors.	M8.4	Autologous or CMV-appropriate and irradiated blood components shall be available during the marrow collection procedure for all donors.	Negligible
		M8.4.1	Allogeneic blood components administered to the donor during marrow collection should be irradiated prior to transfusion.	New

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
CM08.05	Before cell collection is undertaken, there shall be a written order from a physician specifying, at a minimum, timing and goals of collection.	M8.5	There shall be a written order from a physician specifying, at a minimum, anticipated date and goals of collection.	Minor
CM08.06	There shall be peripheral blood count criteria to proceed with collection.	M8.6	There shall be peripheral blood count criteria to proceed with collection.	No change
CM08.07	There shall be written documentation of an assessment of donor suitability for the collection procedure performed by a qualified person immediately prior to each collection procedure.	M8.7	There shall be written documentation of an assessment of donor suitability for the collection procedure performed by a qualified person immediately prior to each collection procedure.	No change
CM08.08	General or regional anesthesia, if required, shall be performed or supervised by a licensed, specialist-certified anesthesiologist.	M8.8	General or regional anesthesia, if required, shall be performed or supervised by a licensed, specialist-certified anesthesiologist.	No change
CM08.09	Administration of mobilization agents shall be under the supervision of a licensed health care professional experienced in their administration and management of complications in persons receiving these agents.	M8.9	Administration of mobilization agents shall be under the supervision of a licensed health care professional experienced in their administration and management of complications in persons receiving these agents.	No change
CM08.10	The Marrow Collection Facility shall utilize a process for assessing the quality of cellular therapy products to confirm product safety, viability, and integrity and to document that products meet predetermined release specifications. Results of all such assessments shall become part of the permanent record of the product collected.	M8.10	The Marrow Collection Facility shall utilize a process for assessing the quality of cellular therapy products to confirm product safety, viability, and integrity and to document that products meet predetermined release specifications. Results of all such assessments shall become part of the permanent record of the product collected.	No change
CM08.10.01	Methods for collection shall include a process for controlling and monitoring the collection of cellular therapy products to confirm products meet predetermined release specifications.	M8.10.1	Methods for collection shall include a process for controlling and monitoring the collection of cellular therapy products to confirm products meet predetermined release specifications.	No change
CM08.10.02	Methods for collection shall employ procedures validated to result in acceptable cell viability and recovery.	M8.10.2	Methods for collection shall employ procedures validated to result in acceptable cell viability, sterility, and recovery.	Moderate

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
CM08.11	Collection methods shall employ aseptic technique so that cellular therapy products do not become contaminated during collection.	M8.11	Collection methods shall employ aseptic technique so that cellular therapy products do not become contaminated during collection.	No change
CM08.12	Collection methods for pediatric donors shall employ appropriate age and size adjustments to the procedures.	M8.12	Collection methods for pediatric donors shall employ appropriate age and size adjustments to the procedures.	No change
CM08.13	Cellular therapy products shall be packaged in a closed sterile transfer pack appropriate for blood or marrow products.	M8.13	Cellular therapy products shall be packaged in a closed sterile transfer pack appropriate for blood or marrow products.	No change
CM08.14	HPC, Marrow products shall be filtered to remove particulate material prior to final packaging, distribution, or administration using filters that are non-reactive with blood.	M8.14	HPC, Marrow products shall be filtered to remove particulate material prior to final packaging, distribution, or administration using filters that are non-reactive with blood.	No change
CM08.15	Records shall be made concurrently with each step of collection of each cellular therapy product in such a way that all steps may be accurately traced.	M8.15	Records shall be made concurrently with each step of collection of each cellular therapy product in such a way that all steps may be accurately traced.	No change
CM08.15.01	Records shall identify the person immediately responsible for each significant step, including dates and times, where appropriate.	M8.15.1	Records shall identify the person immediately responsible for each significant step, including dates and times, where appropriate.	No change
CM09	**CELLULAR THERAPY PRODUCT STORAGE**	**M9**	**CELLULAR THERAPY PRODUCT STORAGE**	No change
CM09.01	Marrow Collection Facilities shall control storage areas to prevent mix-ups, deterioration, contamination, cross-contamination, and improper release or distribution of products.	M9.1	Marrow Collection Facilities shall control storage areas to prevent mix-ups, deterioration, contamination, cross-contamination, and improper release or distribution of cellular therapy products.	Negligible
CM09.02	Marrow Collection Facilities shall establish policies for the duration and conditions of short-term storage prior to distribution to a Processing Facility or Clinical Program.	M9.2	Marrow Collection Facilities shall establish policies for the duration and conditions of short-term storage prior to distribution to a Processing Facility or Clinical Program.	No change
CM10	**CELLULAR THERAPY PRODUCT TRANSPORTATION AND SHIPPING**	**M10**	**CELLULAR THERAPY PRODUCT TRANSPORTATION AND SHIPPING**	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
CM10.01	Procedures for transportation and shipping of the cellular therapy product shall be designed to protect the integrity of the product and the health and safety of individuals in the immediate area.	M10.1	Standard Operating Procedures for transportation and shipping of the cellular therapy product shall be designed to protect the integrity of the product and the health and safety of individuals in the immediate area.	Negligible
CM10.02	The primary cellular therapy product container shall be placed in a secondary container that is sealed to prevent leakage.	M10.2	The primary cellular therapy product container shall be placed in a secondary container that is sealed to prevent leakage.	No change
CM10.03	The cellular therapy product shall be transported and/or shipped to the Processing Facility in a validated container at a temperature defined in a Standard Operating Procedure.	M10.3	The cellular therapy product shall be transported or shipped to the Processing Facility in a validated container at a temperature defined in a Standard Operating Procedure.	Negligible
CM10.03.01	Cellular therapy products that are transported and/or shipped from the collection site to the Processing Facility shall be transported and/or shipped in an outer container made of material adequate to withstand leakage of contents, impact shocks, pressure changes, temperature changes, puncture, and other conditions incident to ordinary handling.	M10.3.1	Cellular therapy products that are transported or shipped from the collection site to the Processing Facility shall be in an outer container made of material adequate to withstand leakage of contents, impact shocks, pressure changes, temperature changes, puncture, and other conditions incident to ordinary handling.	Negligible
CM10.03.02	If the intended recipient has received high-dose therapy, the cellular therapy product shall be transported.	M10.3.2	If the intended recipient has received high-dose therapy, the cellular therapy product shall be transported.	No change
CM10.04	The cellular therapy product shall be transported and/or shipped with required accompanying records as defined in the transportation and shipping procedure and in compliance with CM7.4.4 and CM7.4.5.	M10.4	The cellular therapy product shall be transported or shipped with required accompanying records as defined in the transportation and shipping Standard Operating Procedure and in compliance with CM7.4.5 and CM7.4.7.	Negligible
CM10.05	There shall be a record of the date and time of cellular therapy product distribution.	M10.5	There shall be a record of the date and time of cellular therapy product distribution.	No change
CM11	**RECORDS**	**M11**	**RECORDS**	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
CM11.01	The Marrow Collection Facility shall comply with B10 if it operates independently of a Clinical Program.	M11.1	The Marrow Collection Facility shall comply with B10 if it operates independently of a Clinical Program.	No change
CM12	**DIRECT DISTRIBUTION TO CLINICAL PROGRAM**	**M12**	**DIRECT DISTRIBUTION TO CLINICAL PROGRAM**	No change
CM12.01	Where cellular therapy products are distributed directly from the Marrow Collection Facility to the Clinical Program for administration or subsequent processing, the Standards related to labeling, documentation, distribution, transportation, and recordkeeping in Sections D7, D10, D11, D13, and the Appendices apply.	M12.1	Where cellular therapy products are distributed directly from the Marrow Collection Facility to the Clinical Program for administration or subsequent processing, the Standards related to labeling, documentation, distribution, transportation, and recordkeeping in Sections D7, D10, D11, D13, and the Appendices apply.	No change
D01	**GENERAL**	**D1**	**GENERAL**	No change
D01.01	These Standards apply to all processing, storage, and distribution activities performed in the Processing Facility on cellular therapy products obtained from living donors.	D1.1	These Standards apply to all processing, storage, and distribution activities performed in the Processing Facility on cellular therapy products obtained from living donors.	No change
D01.02	The Processing Facility shall abide by all applicable laws and regulations.	D1.2	The Processing Facility shall abide by all applicable laws and regulations.	No change
D01.02.01	The Processing Facility shall be licensed, registered, or accredited as required by the appropriate governmental authorities for the activities performed.	D1.2.1	The Processing Facility shall be licensed, registered, or accredited as required by the appropriate governmental authorities for the activities performed.	No change
D01.03	The Processing Facility shall have a Processing Facility Director, a Processing Facility Medical Director and Quality Manager, at least one designated staff member actively performing cellular therapy product processing. This team shall have been in place for at least twelve (12) months preceding initial accreditation.	D1.3	The Processing Facility shall have a Processing Facility Director, a Processing Facility Medical Director, a Quality Manager, and a minimum of one (1) additional designated staff member. This team shall have been in place and actively performing cellular therapy product processing for at least twelve (12) months preceding initial accreditation.	Minor
D02	**PROCESSING FACILITY**	**D2**	**PROCESSING FACILITY**	No change
D02.01	The Processing Facility shall be of adequate space, design, and location for the intended procedures.	D2.1	The Processing Facility shall be of adequate space, design, and location for the intended procedures.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
D02.01.01	The Processing Facility shall provide adequate lighting, ventilation, and access to sinks to prevent the introduction, transmission, or spread of communicable disease.	D2.1.1	The Processing Facility shall provide adequate lighting, ventilation, and access to sinks to prevent the introduction, transmission, or spread of communicable disease.	No change
D02.01.02	Oxygen sensors shall be appropriately placed and utilized in areas where liquid nitrogen is present.	D2.1.2	Oxygen sensors shall be appropriately placed and utilized in areas where liquid nitrogen is present.	No change
D02.01.03	The Processing Facility shall be secure to prevent the entrance of unauthorized personnel.	D2.1.3	The Processing Facility shall be secure to prevent the entrance of unauthorized personnel.	No change
D02.01.04	The Processing Facility shall be divided into defined areas of adequate size to prevent improper labeling, mix-ups, contamination, or cross-contamination of cellular therapy products.	D2.1.4	The Processing Facility shall be divided into defined areas of adequate size to prevent improper labeling, mix-ups, contamination, or cross-contamination of cellular therapy products.	No change
D02.01.05	There shall be a process to control storage areas to prevent mix-ups, contamination, and cross-contamination of all cellular therapy products prior to release or distribution.	D2.1.5	There shall be a process to control storage areas to prevent mix-ups, contamination, and cross-contamination of all cellular therapy products.	Negligible
D02.02	Processing Facility parameters and environmental conditions shall be controlled to protect the safety and comfort of personnel.	D2.2	Processing Facility parameters and environmental conditions shall be controlled to protect the safety and comfort of personnel.	No change
D02.03	Critical facility parameters that may affect processing, storage, or distribution, including temperature and humidity at a minimum, shall be assessed for risk to the cellular therapy product.	D2.3	There shall be a written assessment of critical facility parameters that may affect processing, storage, or distribution.	Moderate
		D2.3.1	The written assessment shall include temperature, humidity, air quality, and surface contaminates at a minimum.	Separated
D02.03.01	Critical facility parameters identified to be a risk to the cellular therapy product shall be controlled, monitored, and recorded.	D2.3.2	Critical facility parameters identified to be a risk to the cellular therapy product shall be controlled, monitored, and recorded.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
D02.04	When using procedures that may result in contamination or cross-contamination of cellular therapy products or when performing more than minimal manipulation, critical environmental conditions shall be controlled, monitored, and recorded where appropriate for air quality and surface contaminates.			
	See D2.4			
D02.04.01	The Processing Facility shall qualify environmental control systems and validate cleaning and sanitation procedures appropriate for the environmental classification and degree of manipulation performed.	D2.3.3	The Processing Facility shall qualify environmental control systems and validate cleaning and sanitation procedures appropriate for the environmental classification and degree of manipulation performed.	No change
D02.05	The Processing Facility shall document facility cleaning and sanitation and maintain order sufficient to achieve adequate conditions for operations.	D2.4	The Processing Facility shall document facility cleaning and sanitation and maintain order sufficient to achieve adequate conditions for operations.	No change
D02.06	There shall be adequate equipment and materials for the procedures performed.	D2.5	There shall be adequate equipment and materials for the procedures performed.	No change
D02.07	The Processing Facility shall be operated in a manner designed to minimize risks to the health and safety of employees, patients, donors, visitors, and volunteers.	D2.6	The Processing Facility shall be operated in a manner designed to minimize risks to the health and safety of employees, visitors, and volunteers.	Minor
D02.08	The Processing Facility shall have a written safety manual that includes instructions for action in case of exposure, as applicable, to liquid nitrogen; communicable disease; and to chemical, biological, or radiological hazards.	D2.7	The Processing Facility shall have a written safety manual that includes instructions for action in case of exposure, as applicable, to liquid nitrogen; communicable disease; and to chemical, biological, or radiological hazards.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
D02.09	All waste generated by the Processing Facility activities shall be disposed of in a manner that minimizes any hazard to facility personnel and to the environment in accordance with applicable laws and regulations.	D2.8	All waste generated by the Processing Facility activities shall be disposed of in a manner that minimizes any hazard to facility personnel and to the environment in accordance with applicable laws and regulations.	No change
	See D2.5			
D02.10	Gloves and protective clothing shall be worn while handling biological specimens. Such protective clothing shall not be worn outside the work area.	D2.9	Gloves and protective clothing shall be worn while handling biological specimens. Such protective clothing shall not be worn outside the work area.	No change
D03	**PERSONNEL**	**D3**	**PERSONNEL**	No change
D03.01	**PROCESSING FACILITY DIRECTOR**	**D3.1**	**PROCESSING FACILITY DIRECTOR**	No change
D03.01.01	There shall be a Processing Facility Director with a medical degree, doctoral degree, or equivalent degree in a relevant science, qualified by a minimum of two (2) years training and experience for the scope of activities carried out in the Processing Facility.	D3.1.1	There shall be a Processing Facility Director with a medical degree, doctoral degree, or equivalent degree in a relevant science, qualified by a minimum of two (2) years training and experience for the scope of activities carried out in the Processing Facility.	No change
D03.01.02	The Processing Facility Director shall be responsible for all procedures, administrative operations, and the Quality Management Program of the Processing Facility, including compliance with these Standards and other applicable laws and regulations.	D3.1.2	The Processing Facility Director shall be responsible for all Standard Operating Procedures, administrative operations, and the Quality Management Program of the Processing Facility, including compliance with these Standards and applicable laws and regulations.	Negligible
		D3.1.3	The Processing Facility Director shall have performed or supervised a minimum of five (5) cellular therapy product processing procedures in the twelve (12) months preceding initial accreditation and a minimum average of five (5) cellular therapy product processing procedures per year within each accreditation cycle.	new
D03.01.03	The Processing Facility Director shall participate in ten (10) hours of educational activities related to cellular therapy annually at a minimum.	D3.1.4	The Processing Facility Director shall participate in a minimum of ten (10) hours of educational activities related to cellular therapy annually.	Reordered

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
D03.01.03.01	Continuing education shall include, but is not limited to, activities related to the field of HPC transplantation and processing.	D3.1.4.1	Continuing education shall include, but is not limited to, activities related to the field of HPC transplantation.	Minor
D03.02	**PROCESSING FACILITY MEDICAL DIRECTOR**	**D3.2**	**PROCESSING FACILITY MEDICAL DIRECTOR**	No change
D03.02.01	There shall be a Processing Facility Medical Director who is a licensed or certified physician with a minimum of two (2) years postgraduate training and practical and relevant experience for the scope of activities carried out in the preparation and clinical use of cellular therapy products.	D3.2.1	There shall be a Processing Facility Medical Director who is a licensed physician with a minimum of two (2) years postgraduate certification, with training and practical and relevant experience for the scope of activities carried out in the preparation and clinical use of cellular therapy products.	Minor
D03.02.02	The Processing Facility Medical Director or designee shall be directly responsible for all medical aspects related to the Processing Facility.	D3.2.2	The Processing Facility Medical Director or designee shall be directly responsible for all medical aspects related to the Processing Facility.	No change
		D3.2.3	The Processing Facility Medical Director shall have performed or supervised a minimum of five (5) cellular therapy product processing procedures in the twelve (12) month period preceding initial accreditation and a minimum average of five (5) cellular therapy product processing procedures per year within each accreditation cycle.	new
D03.02.03	The Processing Facility Medical Director shall participate in ten (10) hours of educational activities related to cellular therapy annually at a minimum.	D3.2.4	The Processing Facility Medical Director shall participate in a minimum of ten (10) hours of educational activities related to cellular therapy annually.	Reordered
D03.02.03.01	Continuing education shall include, but is not limited to, activities related to the field of HPC transplantation and processing.	D3.2.4.1	Continuing education shall include, but is not limited to, activities related to the field of HPC transplantation.	No change
D03.03	**QUALITY MANAGER**	**D3.3**	**QUALITY MANAGER**	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
D03.03.01	There shall be a Processing Facility Quality Manager to establish and maintain systems to review, modify, and approve all policies and procedures intended to monitor compliance with these Standards and/or the performance of the Processing Facility.	D3.3.1	There shall be a Processing Facility Quality Manager to establish and maintain systems to review, modify, and approve all policies and Standard Operating Procedures intended to monitor compliance with these Standards or the performance of the Processing Facility.	Negligible
D03.03.02	The Processing Facility Quality Manager should have a reporting structure independent of cellular therapy product manufacturing.	D3.3.2	The Processing Facility Quality Manager should have a reporting structure independent of cellular therapy product manufacturing.	No change
D03.03.03	The Processing Facility Quality Manager shall participate in ten (10) hours of educational activities related to cellular therapy processing and/or quality management annually at a minimum.	D3.3.3	The Processing Facility Quality Manager shall participate in a minimum of ten (10) hours of educational activities related to cellular therapy and Quality Management annually.	Reordered
D03.03.03.01	Continuing education shall include, but is not limited to, activities related to the field of HPC transplantation.	D3.3.3.1	Continuing education shall include, but is not limited to, activities related to the field of HPC transplantation.	No change
D03.04	**STAFF**	**D3.4**	**STAFF**	No change
D03.04.01	The number of trained processing personnel shall be adequate for the number of procedures performed and shall include a minimum of one designated trained individual with an identified trained backup to maintain sufficient coverage.	D3.4.1	The number of trained processing personnel shall be adequate for the number of procedures performed and shall include a minimum of one (1) designated trained individual with an identified trained backup to maintain sufficient coverage.	No change
D04	**QUALITY MANAGEMENT**	**D4**	**QUALITY MANAGEMENT**	No change
		D4.1	There shall be a Quality Management Program that incorporates key performance data.	New
D04.01	The Processing Facility Director or designee shall have authority over and responsibility for ensuring that the Quality Management Program is effectively established and maintained.	D4.1.1	The Processing Facility Director or designee shall have authority over and responsibility for ensuring that the Quality Management Program is effectively established and maintained.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
D04.01.01	The Processing Facility Director or designee shall annually review the effectiveness of the Quality Management Program. Documentation of the review findings shall be provided to the Clinical Program Director.	D4.18	The Processing Facility Director or designee shall annually review the effectiveness of the Quality Management Program.	Minor
D04.02	The Processing Facility shall establish and maintain a written Quality Management Plan.	D4.2	The Processing Facility shall establish and maintain a written Quality Management Plan.	No change
D04.02.01	The Processing Facility Director or designee shall be responsible for the Quality Management Plan as it pertains to the Processing Facility.	D4.2.1	The Processing Facility Director or designee shall be responsible for the Quality Management Plan as it pertains to the Processing Facility.	No change
D04.02.02	The Processing Facility Director or designee shall review and report to staff quality management activities, at a minimum, quarterly.			
D04.02.03	The Processing Facility Director or designee shall not have oversight of his/her own work if this person also performs other tasks in the Processing Facility.	D4.17.3	The Processing Facility Director or designee shall not have oversight of his/her own work if this person also performs other tasks in the Processing Facility.	No change
D04.03	The Quality Management Plan shall include, or summarize and reference, an organizational chart of key positions and functions within the Processing Facility.	D4.3	The Quality Management Plan shall include, or summarize and reference, an organizational chart of key positions and functions within the Processing Facility.	No change
D04.03.01	The Quality Management Plan shall include a description of how these key positions interact to implement the quality management activities.	D4.3.1	The Quality Management Plan shall include a description of how these key positions interact to implement the Quality Management activities.	No change
D04.04	The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures addressing personnel requirements for each key position in the Processing Facility. Personnel requirements shall include at a minimum:	D4.4	The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures addressing personnel requirements for each key position in the Processing Facility. Personnel requirements shall include at a minimum:	No change
D04.04.01	A current job description for all staff.	D4.4.1	A current job description for all staff.	No change
D04.04.02	A system to document the following for all staff:	D4.4.2	A system to document the following for all staff:	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
D04.04.02.01	Initial qualifications.	D4.4.2.1	Initial qualifications.	No change
D04.04.02.02	New employee orientation.	D4.4.2.2	New employee orientation.	No change
D04.04.02.03	Initial training and retraining when appropriate for all procedures performed.	D4.4.2.3	Initial training, competency, and retraining when appropriate for all procedures performed.	Minor
D04.04.02.04	Competency for each critical function performed.	D4.4.2.4	Continued competency for each critical function performed, assessed annually at a minimum.	Merged
D04.04.02.05	Continued competency at least annually.			
D04.04.02.06	Continuing education.	D4.4.2.5	Continuing education.	No change
	See D4.4.2.3			
D04.05	The Quality Management Plan shall include, or summarize and reference, a comprehensive system for document control and management.	D4.5	The Quality Management Plan shall include, or summarize and reference, a comprehensive system for document control.	Minor
D04.05.01	There shall be policies and procedures for development, approval, implementation, review, revision, and archival of all critical documents.	D4.5.2	There shall be policies or Standard Operating Procedures for the development, approval, implementation, distribution, review, revision, and archival of all critical documents.	Minor
D04.05.02	There shall be a current listing of all active critical documents that shall comply with the document control system requirements. Controlled documents shall include at a minimum:	D4.5.1	There shall be identification of the types of documents that are considered critical and shall comply with the document control system requirements. Controlled documents shall include at a minimum:	Negligible
	See D4.5.2.1			
D04.05.02.01	Policies and Standard Operating Procedures.	D4.5.1.1	Policies and Standard Operating Procedures.	No change
D04.05.02.02	Worksheets.	D4.5.1.2	Worksheets.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
D04.05.02.03	Forms.	D4.5.1.3	Forms.	No change
D04.05.02.04	Labels.	D4.5.1.4	Labels.	No change
D04.05.03	The document control policy shall include:	D4.5.3	The document control system shall include:	Negligible
D04.05.03.01	A standardized format for policies, procedures, worksheets, forms, and labels.	D4.5.3.1	A standardized format for critical documents.	Negligible
D04.05.03.02	Assignment of a numeric or alphanumeric identifier and title to each document and document version regulated within the system.	D4.5.3.2	Assignment of a numeric or alphanumeric identifier and a title to each document and document version regulated within the system.	Negligible
D04.05.03.03	A procedure for document approval, including the approval date, signature of approving individual(s), and the effective date.	D4.5.3.3	A system for document approval, including the approval date, signature of approving individual(s), and the effective date.	Negligible
D04.05.03.04	A system to protect controlled documents from accidental or unauthorized modification.	D4.5.3.4	A system to protect controlled documents from accidental or unauthorized modification.	No change
		D4.5.3.5	Review of controlled documents every two (2) years at a minimum.	New
D04.05.03.05	A system for document change control that includes a description of the change, the signature of approving individual(s), approval date(s), effective date, and archival date.	D4.5.3.6	A system for document change control that includes a description of the change, version number, the signature of approving individual(s), approval date(s), communication or training on the change as applicable, effective date, and archival date.	Moderate
D04.05.03.06	Archived policies and procedures, the inclusive dates of use, and their historical sequence shall be maintained for a minimum of ten (10) years from archival or according to governmental or institutional policy, whichever is longer.	D4.5.3.7	Archival of controlled documents, the inclusive dates of use, and their historical sequence for a minimum of ten (10) years from archival or according to governmental or institutional policy, whichever is longer.	Negligible
D04.05.03.07	A system for the retraction of obsolete documents to prevent unintended use.	D4.5.3.8	A system for the retraction of obsolete documents to prevent unintended use.	No change
D04.05.03.08	A system for record creation, assembly, review, storage, archival, and retrieval.			

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
D04.06	The Quality Management Plan shall include, or summarize and reference, policies and procedures for establishment and maintenance of written agreements with third parties whose services impact the cellular therapy product.	D4.6	The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for the establishment and maintenance of written agreements.	Negligible
		D4.6.1	Agreements shall be established with external parties providing critical services that could affect the quality and safety of the cellular therapy product or health and safety of the donor or recipient.	New
D04.06.01	Agreements shall include the responsibility of the facility performing any step in processing, testing, or storage to comply with applicable laws and regulations and these Standards.	D4.6.2	Agreements shall include the responsibility of the external party performing any step in collection, processing, testing, storage, distribution, or administration to maintain required accreditations and to comply with applicable laws and regulations and these Standards.	Moderate
D04.06.02	Agreements shall be dated and reviewed on a regular basis.	D4.6.3	Agreements shall be dated and reviewed on a regular basis, at a minimum every two (2) years.	Moderate
D04.07	The Quality Management Plan shall include, or summarize and reference, policies and procedures for review of outcome analysis and cellular therapy product efficacy to verify that the procedures in use consistently provide a safe and effective product.	D4.7	The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for review of outcome analysis and cellular therapy product efficacy to verify that the procedures in use consistently provide a safe and effectiv product.	Negligible
D04.07.01	Criteria for cellular therapy product safety, product efficacy, and/or the clinical outcome, shall be determined and shall be reviewed at regular time intervals.	D4.7.1	Criteria for cellular therapy product safety, product efficacy, or the clinical outcome shall be determined and shall be reviewed at regular time intervals.	Negligible
D04.07.02	Both individual cellular therapy product data and aggregate data for each type of cellular therapy product shall be evaluated.	D4.7.2	Both individual cellular therapy product data and aggregate data for each type of cellular therapy product shall be evaluated.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
D04.07.03	For HPC products intended for hematopoietic reconstitution, time to engraftment following cellular therapy product administration measured by ANC and platelet count shall be analyzed.	D4.7.3	For HPC products intended for hematopoietic reconstitution, time to engraftment following cellular therapy product administration measured by ANC and platelet count shall be analyzed.	No change
D04.08	The Quality Management Plan shall include, or summarize and reference, policies, procedures, and a schedule for conducting, reviewing, and reporting audits of the Processing Facility's activities to verify compliance with elements of the Quality Management Program and operational policies and procedures.	D4.8	The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for, and a schedule of, audits of the Processing Facility's activities to verify compliance with elements of the Quality Management Program and policies and Standard Operating Procedures, applicable laws or regulations, and these Standards.	Minor
D04.08.01	Audits shall be conducted on a regular basis by an individual with sufficient expertise to identify problems, but who is not solely responsible for the process being audited.	D4.8.1	Audits shall be conducted by an individual with sufficient expertise to identify problems, but who is not solely responsible for the process being audited.	Minor
D04.08.02	The results of audits shall be used to recognize problems, detect trends, identify improvement opportunities, implement corrective and preventive actions when necessary, and follow-up on the effectiveness of these actions in a timely manner.	D4.8.2	The results of audits shall be used to recognize problems, detect trends, identify improvement opportunities, implement corrective and preventive actions when necessary, and follow-up on the effectiveness of these actions in a timely manner.	No change
		D4.8.3	Audits shall include at a minimum:	New
		D4.8.3.1	Annual audits of documentation that external facilities performing critical contracted services have met the requirements of the written agreements.	New
D04.08.03	Documentation that external facilities performing critical contracted services have met the requirements of the written agreements shall be audited annually.	D4.8.3.2	Annual audits of management of cellular therapy products with positive microbial culture results.	Reordered

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
D04.09	The Quality Management Plan shall include, or summarize and reference, policies and procedures on the management of cellular therapy products with positive microbial culture results that address at a minimum:	D4.9	The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for the management of cellular therapy products with positive microbial culture results that address at a minimum:	Negligible
D04.09.01	Documentation and product labeling.	D4.9.1	Documentation and product labeling.	No change
D04.09.02	Product quarantine.	D4.9.2	Product quarantine.	No change
D04.09.03	Criteria for product release.	D4.9.3	Criteria for cellular therapy product release.	Negligible
D04.09.04	Identification of individuals authorized to approve release, including the Processing Facility Medical Director at a minimum.	D4.9.4	Identification of individuals authorized to approve release, including the Processing Facility Medical Director at a minimum.	No change
D04.09.05	Investigation of cause.	D4.9.6	Investigation of cause.	No change
D04.09.06	Notification of the recipient's physician, collection facility, and/or any other facility in receipt of the cellular therapy product.	D4.9.5	Notification of the recipient's physician, collection facility, and any other facility in receipt of the cellular therapy product.	Negligible
D04.09.07	Reporting to regulatory agencies, if appropriate.	D4.9.7	Reporting to regulatory agencies, if appropriate.	No change
D04.10	The Quality Management Plan shall include, or summarize and reference, policies and procedures for errors, accidents, biological product deviations, serious adverse events, and complaints, including the following activities at a minimum:	D4.10	The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for occurrences (errors, accidents, deviations, adverse events, adverse reactions, and complaints). The following activities shall be included at a minimum:	Minor
	See D4.10			
D04.10.01	Detection.	D4.10.1	Detection.	No change
D04.10.02	Investigation.	D4.10.2	Investigation.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
D04.10.02.01	A thorough investigation shall be conducted by the Processing Facility in collaboration with the Collection Facility and Clinical Program, as appropriate.	D4.10.2.1	A thorough investigation shall be conducted by the Processing Facility in collaboration with the Collection Facility and Clinical Program, as appropriate.	No change
D04.10.02.02	Investigations shall identify the root cause and a plan for short- and long-term corrective actions as warranted.	D4.10.2.2	Investigations shall identify the root cause and a plan for short- and long-term corrective and preventive actions as warranted.	Minor
D04.10.03	Documentation.	D4.10.3	Documentation.	No change
D04.10.03.01	Documentation shall include a description of the event, the involved individuals and/or cellular therapy products, when the event occurred, when and to whom the event was reported, and the immediate actions taken.	D4.10.3.1	Documentation shall include a description of the occurrence, date and time of the occurrence, the involved individuals and cellular therapy product(s), when and to whom the occurrence was reported, and the immediate actions taken.	Minor
D04.10.03.02	All investigation reports shall be reviewed in a timely manner by the Processing Facility Director, Medical Director or designee, and the Quality Manager.	D4.10.3.2	All investigation reports shall be reviewed in a timely manner by the Processing Facility Director, Medical Director or designee, and the Quality Manager.	No change
D04.10.03.03	Cumulative files of errors, accidents, biological product deviations, serious adverse events, and complaints shall be maintained.	D4.10.3.3	Cumulative files of occurrences shall be maintained.	Minor
D04.10.03.04	Cumulative files shall include written investigation reports containing conclusions, follow-up, corrective actions, and a link to the record(s) of the involved cellular therapy products.	D4.10.3.4	Cumulative files shall include written investigation reports containing conclusions, follow-up, corrective and preventive actions, and a link to the record(s) of the involved cellular therapy product(s), donor(s), and recipient(s), if applicable.	Minor
D04.10.04	Reporting.	D4.10.4	Reporting.	No change
	See D4.10.5			

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
D04.10.04.01	When it is determined that a cellular therapy product was responsible for a serious adverse reaction, the reaction report and results of the investigation shall be made available to the recipient's physician, other facilities participating in the manufacturing of the cellular therapy product, registries, and governmental agencies as required by applicable laws.	D4.10.4.1	When it is determined that a cellular therapy product has resulted in an adverse event or reaction, the event and results of the investigation shall be made available to the donor's and recipient's physician(s), as applicable, other facilities participating in the manufacturing of the cellular therapy product, registries, and governmental agencies as required by applicable laws and regulations.	Minor
D04.10.04.02	Errors, accidents, biological product deviations, and complaints shall be reported to other facilities performing cellular therapy product functions on the affected cellular therapy product and to the appropriate regulatory and accrediting agencies, registries, grant agencies, and IRBs or Ethics Committees.	D4.10.4.2	Occurrences shall be reported to other facilities performing cellular therapy product functions on the affected cellular therapy product and to the appropriate regulatory and accrediting agencies, registries, grant agencies, sponsors, IRBs, or Ethics Committees.	Negligible
D04.10.05	Corrective and preventive action.	D4.10.5	Corrective and preventive action.	No change
D04.10.05.01	Appropriate corrective action shall be implemented if indicated, including both short-term action to address the immediate problem and long-term action to prevent the problem from recurring.	D4.10.5.1	Appropriate action shall be implemented if indicated, including both short-term action to address the immediate problem and long-term action to prevent the problem from recurring.	Minor

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
D04.10.05.02	Follow-up audits of the effectiveness of corrective actions shall be performed in a timeframe as indicated in the investigative report.	D4.10.5.2	Follow-up audits of the effectiveness of corrective and preventive actions shall be performed in a timeframe as indicated in the investigative report.	Minor
D04.11	The Quality Management Plan shall include, or summarize and reference, policies and procedures for cellular therapy product tracking and tracing that allow tracking from the donor to the recipient or final disposition and tracing from the recipient or final disposition to the donor.	D4.11	The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for cellular therapy product tracking and tracing that allow tracking from the donor to the recipient or final disposition and tracing from the recipient or final disposition to the donor.	Negligible
D04.12	The Quality Management Plan shall include, or summarize and reference, policies and procedures for actions to take in the event the Processing Facility's operations are interrupted.	D4.12	The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for actions to take in the event the Processing Facility's operations are interrupted.	Negligible
D04.13	The Quality Management Plan shall include, or summarize and reference, policies and procedures for qualification of critical supplies, manufacturers, vendors, reagents, equipment, and facilities.	D4.13	The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for qualification of critical manufacturers, vendors, equipment, supplies, reagents, facilities, and services.	Reordered
D04.13.01	Qualification plans shall be reviewed and approved by the Processing Facility Director or designee.	D4.13.3	Qualification plans, results, and reports shall be reviewed and approved by the Quality Manager and Processing Facility Director or designee.	Minor

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
		D4.13.2	Qualification plans shall include minimum acceptance criteria for performance.	New
D04.13.02	Reagents that are not the appropriate grade shall undergo qualification for the intended use.	D4.13.1	Reagents that are not the appropriate grade shall undergo qualification for the intended use.	No change
D04.14	The Quality Management Plan shall include, or summarize and reference, policies and procedures for validation and/or verification of critical procedures to achieve the expected end-points, including viability of cells and cellular therapy product characteristics.	D4.14	The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for validation or verification of critical procedures.	Negligible
D04.14.01	Critical procedures to be validated or verified shall include at least the following: processing techniques, cryopreservation procedures, labeling, storage, and distribution.	D4.14.1	Critical procedures to be validated shall include at least the following: processing techniques, cryopreservation procedures, testing, labeling, storage, and distribution.	Minor
D04.14.02	Each validation shall include:	D4.14.2	Each validation shall include at a minimum:	Negligible
D04.14.02.01	An approved validation plan, including conditions to be validated.	D4.14.2.1	An approved validation plan, including conditions to be validated.	No change
D04.14.02.02	Acceptance criteria.	D4.14.2.2	Acceptance criteria.	No change
D04.14.02.03	Data collection.	D4.14.2.3	Data collection.	No change
D04.14.02.04	Evaluation of data.	D4.14.2.4	Evaluation of data.	No change
D04.14.02.05	Summary of results.	D4.14.2.5	Summary of results.	No change
		D4.14.2.6	References, if applicable.	New
D04.14.02.06	Review and approval of the validation plan, results, and conclusion by the Processing Facility Director or designee and the Quality Manager or designee.	D4.14.2.7	Review and approval of the validation plan, validation report, and conclusion by the Quality Manager or designee and the Processing Facility Director or designee.	Minor
D04.14.03	Changes to a process shall include evaluation of risk to confirm that they do not create an adverse impact anywhere in the operation and shall be validated or verified as appropriate.	D4.14.3	Significant changes to critical procedures shall be validated and verified as appropriate.	Minor

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
		D4.15	The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for the evaluation of risk in changes to a process to confirm that the changes do not create an adverse impact or inherent risk elsewhere in the operation.	New
		D4.16	The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for obtaining feedback.	New
		D4.16.1	Feedback shall be obtained from associated Clinical Programs and Collection Facilities.	New
		D4.17	The Processing Facility Director or designee shall review the Quality Management activities with representatives in key positions in all elements of the cellular therapy program, at a minimum, quarterly.	New
		D4.17.1	Meetings should have defined attendees, documented minutes, and assigned actions.	New
		D4.17.2	Key performance data and review findings shall be reported to staff.	New
		D4.18.1	The annual report and documentation of the review findings shall be made available to key personnel, the Clinical Program Director, and the Collection Facility Director.	New
D05	**POLICIES AND PROCEDURES**	**D5**	**POLICIES AND STANDARD OPERATING PROCEDURES**	Negligible
D05.01	The Processing Facility shall establish and maintain policies and/or procedures addressing critical aspects of operations and management in addition to those required in D4. These documents shall include all elements required by these Standards and shall address at a minimum:	D5.1	The Processing Facility shall establish and maintain policies or Standard Operating Procedures addressing critical aspects of operations and management in addition to those required in D4. These documents shall include all elements required by these Standards and shall address at a minimum:	Negligible

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
D05.01.01	Donor and recipient confidentiality.	D5.1.1	Donor and recipient confidentiality.	No change
D05.01.02	Cellular therapy product receipt.	D5.1.2	Cellular therapy product receipt.	No change
D05.01.03	Processing and process control.	D5.1.3	Processing and process control.	No change
D05.01.04	Processing of ABO-incompatible cellular therapy products to include a description of the indication for and processing methods to be used for red cell and plasma depletion.	D5.1.4	Processing of ABO-incompatible cellular therapy products to include a description of the indication for and processing methods to be used for red cell and plasma depletion.	No change
D05.01.05	Prevention of mix-ups and cross-contamination.	D5.1.5	Prevention of mix-ups and cross-contamination.	No change
D05.01.06	Labeling (including associated forms and samples).	D5.1.6	Labeling (including associated forms and samples).	No change
D05.01.07	Cryopreservation and thawing.	D5.1.7	Cryopreservation and thawing.	No change
D05.01.08	Cellular therapy product expiration dates.	D5.1.8	Cellular therapy product expiration dates.	No change
D05.01.09	Cellular therapy product storage to include alternative storage if the primary storage device fails.	D5.1.9	Cellular therapy product storage to include alternative storage if the primary storage device fails.	No change
D05.01.10	Release and exceptional release.	D5.1.10	Release and exceptional release.	No change
D05.01.11	Transportation and shipping, including methods and conditions within the Processing Facility and to and from external facilities.	D5.1.11	Transportation and shipping, including methods and conditions within the Processing Facility and to and from external facilities.	No change
D05.01.12	Cellular therapy product recall, to include a description of responsibilities and actions to be taken, and notification of appropriate regulatory agencies.	D5.1.12	Cellular therapy product recall, to include a description of responsibilities and actions to be taken, and notification of appropriate regulatory agencies.	No change
D05.01.13	Cellular therapy product disposal.	D5.1.13	Cellular therapy product disposal.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
D05.01.14	Critical reagent and supply management.	D5.1.14	Critical reagent and supply management.	No change
D05.01.15	Equipment operation, maintenance, and monitoring including corrective actions in the event of failure.	D5.1.15	Equipment operation, maintenance, and monitoring including corrective actions in the event of failure.	No change
D05.01.16	Recalls of equipment, supplies, and reagents.	D5.1.16	Recalls of equipment, supplies, and reagents.	No change
D05.01.17	Cleaning and sanitation procedures including identification of the individuals responsible for the activities.	D5.1.17	Cleaning and sanitation procedures including identification of the individuals responsible for the activities.	No change
D05.01.18	Environmental control to include a description of the environmental monitoring plan.	D5.1.18	Environmental control to include a description of the environmental monitoring plan.	No change
D05.01.19	Hygiene and use of personal protective equipment.	D5.1.19	Hygiene and use of personal protective equipment and attire.	Minor
D05.01.20	Disposal of medical and biohazard waste.	D5.1.20	Disposal of medical and biohazard waste.	No change
D05.01.21	Emergency and disaster plan, including the Processing Facility response.	D5.1.21	Cellular therapy emergency and disaster plan, including the Processing Facility response.	Negligible
D05.02	The Processing Facility shall maintain a detailed Standard Operating Procedures Manual that includes a listing of all current Standard Operating Procedures, including title, identifier, and version.	D5.2	The Processing Facility shall maintain a detailed list of all controlled documents, including title and identifier.	Minor
	See D5.2			

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
D05.03	Standard Operating Procedures shall be sufficiently detailed and unambiguous to allow qualified staff to follow and complete the procedures successfully. Each individual procedure shall include:	D5.3	Standard Operating Procedures shall be sufficiently detailed and unambiguous to allow qualified staff to follow and complete the procedures successfully. Each individual Standard Operating Procedure shall include:	No change
D05.03.01	A clearly written description of the objectives.	D5.3.1	A clearly written description of the objectives.	No change
D05.03.02	A description of equipment and supplies used.	D5.3.2	A description of equipment and supplies used.	No change
D05.03.03	Acceptable end-points and the range of expected results.	D5.3.3	Acceptable end-points and the range of expected results.	No change
D05.03.04	A stepwise description of the procedure.	D5.3.4	A stepwise description of the procedure.	No change
D05.03.05	Reference to other Standard Operating Procedures or policies required to perform the procedure.	D5.3.5	Reference to other Standard Operating Procedures or policies required to perform the procedure.	No change
D05.03.06	A reference section listing appropriate literature.	D5.3.6	A reference section listing appropriate and current literature.	Minor
D05.03.07	Documented approval of each procedure by the Processing Facility Director or Medical Director, as appropriate, prior to implementation and every two years thereafter.	D5.3.7	Documented approval of each procedure by the Processing Facility Director or Medical Director, as appropriate, prior to implementation and every two (2) years thereafter.	No change
D05.03.08	Documented approval of each procedural modification by the Processing Facility Director or Medical Director, as appropriate, prior to implementation.	D5.3.8	Documented approval of each procedural modification by the Processing Facility Director or Medical Director, as appropriate, prior to implementation.	No change
D05.03.09	Reference to a current version of orders, worksheets, reports, labels, and forms.	D5.3.9	Reference to a current version of orders, worksheets, reports, labels, and forms.	No change
D05.04	Standard Operating Procedures relevant to processes being performed shall be readily available to the facility staff.	D5.4	Controlled documents relevant to processes being performed shall be readily available to the facility staff.	Negligible
D05.05	Staff training and, if appropriate, competency shall be documented before performing a new or revised procedure.	D5.5	Staff training and, if appropriate, competency shall be documented before performing a new or revised Standard Operating Procedure.	Negligible

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
D05.06	All personnel shall follow the Standard Operating Procedures related to their positions.	D5.6	All personnel shall follow the policies and Standard Operating Procedures related to their positions.	Negligible
D05.07	Variances shall be pre-approved by the Processing Facility Director and/or Medical Director, and reviewed by the Quality Manager.	D5.7	Planned deviations shall be pre-approved by the Processing Facility Director and/or Medical Director, and reviewed by the Quality Manager.	Minor
D06	**EQUIPMENT, SUPPLIES, AND REAGENTS**	**D6**	**EQUIPMENT, SUPPLIES, AND REAGENTS**	No change
D06.01	Equipment, supplies, and reagents used to process cellular therapy products shall be used in a manner that maintains product function and integrity and prevents product mix-ups, contamination, and cross-contamination.	D6.1	Equipment, supplies, and reagents used to process cellular therapy products shall be qualified and used in a manner that maintains product function and integrity and minimizes risks of product mix-ups, contamination, and cross-contamination.	Minor
D06.02	Supplies and reagents used in processing, testing, cryopreservation, and storage shall be controlled by a materials management system that includes requirements for the following at a minimum:	D6.2	Supplies and reagents used in processing, testing, cryopreservation, and storage shall be controlled by a materials management system that includes requirements for the following at a minimum:	No change
D06.02.01	Visual examination of each supply and reagent used to manufacture cellular therapy products for damage or evidence of contamination upon receipt and acceptance into inventory.	D6.2.1	Visual examination of each supply and reagent used to manufacture cellular therapy products for damage or evidence of contamination upon receipt and acceptance into inventory.	No change
D06.02.02	Records of receipt that shall include the supply or reagent type, quantity, manufacturer, lot number, date of receipt, acceptability, and expiration date.	D6.2.2	Records of receipt that shall include the supply or reagent type, quantity, manufacturer, lot number, date of receipt, acceptability, and expiration date.	No change
D06.02.03	Storage of materials under the appropriate environmental conditions in a secure, sanitary, and orderly manner to prevent mix up or unintended use.	D6.2.3	Storage of materials under the appropriate environmental conditions in a secure, sanitary, and orderly manner to prevent mix up or unintended use.	No change
D06.02.04	Use of supplies and reagents coming into contact with cellular therapy products during processing, storage, and/or administration that are sterile and of the appropriate grade for the intended use.	D6.2.4	Use of supplies and reagents coming into contact with cellular therapy products during processing, storage, and/or administration that are sterile and of the appropriate grade for the intended use.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
		D6.2.4.1	Reagents shall undergo initial qualification for the intended use.	New
		D6.2.4.2	Where there are no suitable clinical or pharmaceutical grade reagents available, reagents shall undergo lot-to-lot functional verification.	New
		D6.2.4.3	Lot-to-lot functional verification shall include acceptance criteria to confirm that new lots perform as expected compared to the previous lots.	New
D06.02.05	Cleaning and sterilizing of non-disposable supplies or instruments using a procedure verified to remove infectious agents and other contaminants.	D6.2.5	Cleaning and sterilizing of non-disposable supplies or instruments using a procedure verified to remove infectious agents and other contaminants.	No change
D06.02.06	Use of supplies and reagents in a manner consistent with manufacturer instructions.	D6.2.6	Use of supplies and reagents in a manner consistent with manufacturer instructions.	No change
D06.02.07	Process to prevent the use of expired reagents and supplies.	D6.2.7	Process to prevent the use of expired reagents and supplies.	No change
D06.03	There shall be a system to uniquely identify and track all critical equipment used in the processing of cellular therapy products. The system shall identify each cellular therapy product for which the equipment was used.	D6.3	There shall be a system to uniquely identify and track all critical equipment used in the processing of cellular therapy products. The system shall identify each cellular therapy product for which the equipment was used.	No change
	See D6.3			
D06.04	Equipment used in cellular therapy product processing, testing, cryopreservation, storage, and distribution shall be maintained in a clean and orderly manner and located to facilitate cleaning, sanitation, calibration, and maintenance according to established schedules.	D6.4	Equipment used in cellular therapy product processing, testing, cryopreservation, storage, and distribution shall be maintained in a clean and orderly manner and located to facilitate cleaning, sanitation, calibration, and maintenance according to established schedules.	No change
D06.05	The equipment shall be inspected for cleanliness prior to each use and verified to be in compliance with the maintenance schedule daily prior to use.	D6.5	The equipment shall be inspected for cleanliness and verified to be in compliance with the maintenance schedule prior to use.	Reordered

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
D06.06	The equipment shall be standardized and calibrated on a regularly scheduled basis and after a critical repair or move as described in Standard Operating Procedures and in accordance with the manufacturer's recommendations.	D6.6	The equipment shall be standardized and calibrated on a regularly scheduled basis and after a critical repair or move as described in Standard Operating Procedures and in accordance with the manufacturer's recommendations.	No change
D06.06.01	All equipment with a critical measuring function shall be calibrated against a traceable standard, if available. Where no traceable standard is available, the basis for calibration shall be described and documented.	D6.6.1	All equipment with a critical measuring function shall be calibrated against a traceable standard, if available. Where no traceable standard is available, the basis for calibration shall be described and documented.	No change
D06.06.02	When equipment is found to be out of calibration or specification, there shall be a defined process for action required for cellular therapy products manufactured since the last calibration.	D6.6.2	When equipment is found to be out of calibration or specification, there shall be a defined process for action required for cellular therapy products manufactured since the last calibration.	No change
D06.07	There shall be a procedure that addresses the actions to take in the event of equipment malfunction or failure.	D6.7	There shall be a Standard Operating Procedure that addresses the actions to take in the event of equipment malfunction or failure.	Negligible
D06.08	Equipment shall conform to applicable laws and regulations.	D6.8	Equipment shall conform to applicable laws and regulations.	No change
D06.09	Lot numbers, expiration dates, and manufacturers of critical reagents and supplies and identification of key equipment used in each procedure shall be documented.	D6.9	Lot numbers, expiration dates, manufacturers of critical reagents and supplies, and key equipment used in each procedure shall be documented.	No change
	See D8.10			

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
	See D8.12.1			
D06.10	The Processing Facility shall use an inventory control system to document the availability and identity of critical reagents and supplies. This shall include at a minimum:	D6.10	The Processing Facility shall use an inventory control system to document the availability and identity of critical reagents and supplies. This shall include at a minimum:	No change
D06.10.01	A system to uniquely identify and track all critical reagents and supplies used to manufacture cellular therapy products.	D6.10.1	A system to uniquely identify and track all critical reagents and supplies used to manufacture cellular therapy products.	No change
D06.10.02	A system to identify each cellular therapy product for which each critical reagent or supply was used.	D6.10.2	A system to identify each cellular therapy product for which each critical reagent or supply was used.	No change
D06.10.03	A system to maintain adequate stocks of reagents and supplies for the procedures to be performed.	D6.10.3	A system to maintain adequate stocks of reagents and supplies for the procedures to be performed.	No change
D07	**CODING AND LABELING OF CELLULAR THERAPY PRODUCTS**	**D7**	**CODING AND LABELING OF CELLULAR THERAPY PRODUCTS**	No change
D07.01	**ISBT 128 CODING AND LABELING**	**D7.1**	**ISBT 128 AND EUROCODE CODING AND LABELING**	Significant
D07.01.01	Cellular therapy products shall be identified according to the proper name of the product, including appropriate attributes, as defined in ISBT 128 Standard Terminology for Blood, Cellular Therapy, and Tissue Product Descriptions.	D7.1.1	Cellular therapy products shall be identified by name according to ISBT 128 standard terminology or Eurocode.	Significant

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
D07.01.02	If coding and labeling technologies have not yet been implemented, the Processing Facility shall be actively implementing ISBT 128.	D7.1.2	Coding and labeling technologies shall be implemented using ISBT 128 or Eurocode.	Significant
D07.02	**LABELING OPERATIONS**	**D7.2**	**LABELING OPERATIONS**	No change
D07.02.01	Labeling operations shall be conducted in a manner adequate to prevent mislabeling or misidentification of cellular therapy products, product samples, and associated records.	D7.2.1	Labeling operations shall be conducted in a manner adequate to prevent mislabeling or misidentification of cellular therapy products, product samples, and associated records.	No change
D07.02.01.01	Stocks of unused labels representing different cellular therapy products shall be stored in a controlled manner to prevent errors.	D7.2.1.1	Stocks of unused labels representing different cellular therapy products shall be stored in a controlled manner to prevent errors.	No change
D07.02.01.02	Obsolete labels shall be restricted from use.	D7.2.1.2	Obsolete labels shall be restricted from use.	No change
D07.02.02	Pre-printed labels shall be held upon receipt from the manufacturer pending review and proofing against a copy or template approved by the Processing Facility Director or designee to confirm accuracy regarding identity, content, and conformity.	D7.2.2	Pre-printed labels shall be held upon receipt from the manufacturer pending review and proofing against a copy or template approved by the Processing Facility Director or designee to confirm accuracy regarding identity, content, and conformity.	No change
D07.02.03	Print-on-demand label systems shall be validated to confirm accuracy regarding identity, content, and conformity of labels to templates approved by the Processing Facility Director or designee.	D7.2.3	Print-on-demand label systems shall be validated to confirm accuracy regarding identity, content, and conformity of labels to templates approved by the Processing Facility Director or designee.	No change
D07.02.04	A system for label version control shall be employed.	D7.2.4	A system for label version control shall be employed.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
D07.02.04.01	Representative obsolete labels shall be archived minimally for ten (10) years after the last cellular therapy product was distributed with inclusive dates of use or as defined by applicable laws and regulations, whichever is longer.	D7.2.4.1	Representative obsolete labels shall be archived minimally for ten (10) years after the last cellular therapy product was distributed with inclusive dates of use or as defined by applicable laws and regulations, whichever is longer.	No change
D07.02.05	A system of checks in labeling procedures shall be used to prevent errors in transferring information to labels.	D7.2.5	A system of checks in labeling procedures shall be used to prevent errors in transferring information to labels.	No change
D07.02.05.01	Cellular therapy products that are subsequently re-packaged into new containers shall be labeled with new labels before they are detached from the original container.	D7.2.5.1	Cellular therapy products that are subsequently re-packaged into new containers shall be labeled with new labels before they are detached from the original container.	No change
D07.02.05.02	A controlled labeling procedure consistent with applicable law shall be defined and followed if container label information is transmitted electronically during a labeling process. This procedure shall include a verification step.	D7.2.5.2	A controlled labeling procedure consistent with applicable law shall be defined and followed if container label information is transmitted electronically during a labeling process. This procedure shall include a verification step.	No change
D07.02.06	When the label has been affixed to the container, a sufficient area of the container shall remain uncovered to permit inspection of the contents.	D7.2.6	When the label has been affixed to the container, a sufficient area of the container shall remain uncovered to permit inspection of the contents.	No change
D07.02.07	The information entered on a container label shall be verified by one (1) qualified staff member using a validated process to verify the information or two (2) qualified staff members prior to distribution of the cellular therapy product.	D7.2.7	The information entered on a container label shall be verified by one (1) qualified staff member using a validated process or two (2) qualified staff members.	Negligible
D07.02.08	Labeling elements required by applicable laws and regulations shall be present.	D7.2.8	Labeling elements required by applicable laws and regulations shall be present.	No change
D07.02.09	All data fields on labels shall be completed.	D7.2.9	All data fields on labels shall be completed.	No change
D07.02.10	All labeling shall be clear, legible, and completed using ink that is indelible to all relevant agents.	D7.2.10	All labeling shall be clear, legible, and completed using ink that is indelible to all relevant agents.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
D07.02.11	Labels affixed directly to a cellular therapy product bag shall be applied using appropriate materials as defined by the applicable regulatory authority.	D7.2.11	Labels affixed directly to a cellular therapy product bag shall be applied using appropriate materials as defined by the applicable regulatory authority.	No change
D07.02.12	The label shall be validated as reliable for storage under the conditions in use.	D7.2.12	The label shall be validated as reliable for storage under the conditions in use.	No change
D07.03	**PRODUCT IDENTIFICATION**	**D7.3**	**PRODUCT IDENTIFICATION**	No change
D07.03.01	Each cellular therapy product shall be assigned a unique numeric or alphanumeric identifier by which it will be possible to trace any cellular therapy product to its donor, its recipient or final disposition, and all records.	D7.3.1	Each cellular therapy product shall be assigned a unique numeric or alphanumeric identifier by which it will be possible to trace any cellular therapy product to its donor, its recipient or final disposition, and all records.	No change
D07.03.01.01	The cellular therapy product, product samples, concurrent plasma, and concurrently collected samples shall be labeled with the same identifier.	D7.3.1.1	The cellular therapy product, product samples, concurrent plasma, and concurrently collected samples shall be labeled with the same identifier.	No change
D07.03.01.02	If a single cellular therapy product is stored in more than one container, there shall be a system to identify each container.	D7.3.1.2	If a single cellular therapy product is stored in more than one (1) container, there shall be a system to identify each container.	No change
D07.03.01.03	If cellular therapy products from the same donor are pooled, the pool identifier shall allow tracing to the original products.	D7.3.1.3	If cellular therapy products from the same donor are pooled, the pool identifier shall allow tracing to the original products.	No change
D07.03.01.04	Supplementary identifiers shall not obscure the original identifier.	D7.3.1.4	Supplementary identifiers shall not obscure the original identifier.	No change
D07.03.01.05	The facility associated with each identifier shall be noted on the label.	D7.3.1.5	The facility associated with each identifier shall be named in the documents to accompany the cellular therapy product.	Minor

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
D07.03.01.06	If the original identifier is replaced, documentation shall link the new identifier to the original.	D7.3.1.6	If the original identifier is replaced, documentation shall link the new identifier to the original.	No change
D07.04	**LABEL CONTENT**	**D7.4**	**LABEL CONTENT**	No change
D07.04.01	At the completion of processing and at distribution for administration, the cellular therapy product label on the primary product container and concurrent plasma container shall bear the information in the Cellular Therapy Product Labeling table in Appendix _.	D7.4.1	At all stages of processing, the cellular therapy product shall be labeled with the proper name of the product and the unique numeric or alphanumeric identifier, at a minimum.	Moderate
D07.04.02	Each label shall bear the appropriate biohazard and warning labels as found in the Circular of Information for the Use of Cellular Therapy Products, “Table 2. Biohazard and Warning Labels on Cellular Therapy Products Collected, Processed, and/or Administered in the United States.”	D7.4.4	Each label shall bear the appropriate biohazard and warning labels as found in the Circular of Information for the Use of Cellular Therapy Products, “Table 2. Biohazard and Warning Labels on Cellular Therapy Products Collected, Processed, and/or Administered in the United States.”	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
		D7.4.3	At the completion of processing and at distribution for administration, the cellular therapy product label on the primary product container and concurrent plasma container shall bear the information in the Cellular Therapy Product Labeling table in Appendix II.	New
D07.04.03	Any container bearing a partial label shall be accompanied by the information required by the Cellular Therapy Product Labeling table in Appendix _. Such information shall be attached securely to the cellular therapy product on a tie tag or enclosed in a sealed package to accompany the product.	D7.4.6	Any container bearing a partial label at the time of distribution shall be accompanied by the information required by the Cellular Therapy Product Labeling table in Appendix II. Such information shall be attached securely to the cellular therapy product on a tie tag or enclosed in a sealed package to accompany the product.	Minor

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
D07.04.04	The name and address of the facility that determines that the cellular therapy product meets release criteria and the name and address of the facility that makes the product available for distribution shall either appear on the product label or accompany the product at distribution.	D7.4.2	The name and address of the facility that determines that the cellular therapy product meets release criteria and the name and address of the facility that makes the product available for distribution shall either appear on the product label or accompany the product at distribution.	No change
D07.04.05	Cellular therapy products collected in or designated for use in the U.S. shall have the elements in the Accompanying Documents at Distribution table in Appendix _ accompany the cellular therapy product when it leaves the Processing Facility.	D7.4.5	A cellular therapy product collected in or designated for use in the U.S. shall have the elements in the Accompanying Documentation table in Appendix IV accompany the cellular therapy product at the time it leaves the control of the Processing Facility.	Negligible
D07.04.06	For cellular therapy products distributed before completion of donor eligibility determination, there shall be documentation that donor eligibility determination was completed during or after distribution of the cellular therapy product and that the physician using the product was informed of the results of that determination.	D7.4.7	For cellular therapy products distributed before completion of donor eligibility determination, there shall be documentation that donor eligibility determination was completed during or after distribution of the cellular therapy product and that the physician using the product was informed of the results of that determination.	No change
D07.04.07	Cellular therapy products distributed for nonclinical purposes shall be labeled with the statement, “For Nonclinical Use Only.”	D7.4.8	Cellular therapy products distributed for nonclinical purposes shall be labeled with the statement, “For Nonclinical Use Only.”	No change
D08	**PROCESS CONTROLS**	**D8**	**PROCESS CONTROLS**	No change
D08.01	There shall be a process for controlling and monitoring the manufacturing of cellular therapy products so that products meet predetermined release specifications.	D8.1	There shall be a process for controlling and monitoring the manufacturing of cellular therapy products so that products meet predetermined release specifications.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
D08.01.01	The Processing Facility Director shall define tests and procedures for measuring and assaying cellular therapy products to assure their safety, viability, and integrity and to document that products meet predetermined release specifications. Results of all such tests and procedures shall become part of the permanent record of the product processed.	D8.1.1	The Processing Facility Director shall define tests and procedures for measuring and assaying cellular therapy products to assure their safety, viability, and integrity and to document that products meet predetermined release specifications. Results of all such tests and procedures shall become part of the permanent record of the product processed.	No change
D08.01.02	There shall be a documented system for the identification and handling of test samples so that they are accurately related to the corresponding cellular therapy product, donor, or recipient.	D8.1.2	There shall be a documented system for the identification and handling of test samples so that they are accurately related to the corresponding cellular therapy product, donor, or recipient.	No change
D08.01.02.01	There shall be a mechanism to identify the individual obtaining the sample, the sample source, the date, and the time, if appropriate.	D8.1.2.1	There shall be a mechanism to identify the individual obtaining the sample, the sample source, the date, and the time, if appropriate.	No change
D08.01.02.02	Samples obtained for testing shall be representative of the cellular therapy product to be evaluated.	D8.1.2.2	Samples obtained for testing shall be representative of the cellular therapy product to be evaluated.	No change
D08.01.03	There shall be the establishment of appropriate and validated assays and test procedures for the evaluation of cellular therapy products.	D8.1.3	There shall be the establishment of appropriate and validated assays and test procedures for the evaluation of cellular therapy products.	No change
D08.01.03.01	For all cellular therapy products, a total nucleated cell count and viability measurement shall be performed.	D8.1.3.1	For all cellular therapy products, a total nucleated cell count and viability measurement shall be performed.	No change
D08.01.03.02	For HPC products intended for restoration of hematopoiesis, an assay measuring viable CD34 shall be performed.	D8.1.3.2	For HPC products intended for restoration of hematopoiesis, an assay measuring viable CD34 shall be performed.	No change
D08.01.03.03	For cellular therapy products undergoing manipulation that alters the final cell population, a relevant and validated assay, where available, shall be employed for evaluation of the viable target cell population before and after the processing procedures.	D8.1.3.3	For cellular therapy products undergoing manipulation that alters the final cell population, a relevant and validated assay, where available, shall be employed for evaluation of the viable target cell population before and after the processing procedures.	No change
		D8.1.4	For tests required by these Standards performed within the Processing Facility:	New

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
D08.01.04.01	There shall be a process for monitoring the reliability, accuracy, precision, and performance of laboratory test procedures and instruments.	D8.1.4.1	There shall be a process for monitoring the reliability, accuracy, precision, and performance of laboratory test procedures and instruments.	No change
D08.01.04.02	New reagent lots shall be verified to provide comparable results to current lots or to give results in agreement with suitable reference material before or concurrently with being placed into service.	D8.1.4.2	New reagent lots shall be verified to provide comparable results to current lots or to give results in agreement with suitable reference material before or concurrently with being placed into service.	No change
D08.01.04.03	Where available, controls shall be used each day of testing and shown to give results within the defined range established for that material.	D8.1.4.3	Where available, controls shall be used each day of testing and shown to give results within the defined range established for that material.	No change
D08.01.04.04	Function checks shall be performed for testing instruments prior to testing donor, recipient, or cellular therapy product samples.	D8.1.4.4	Function checks shall be performed for testing instruments prior to testing donor, recipient, or cellular therapy product samples.	No change
D08.01.04.05	For tests performed within the Processing Facility, there shall be documentation of ongoing proficiency testing as designated by the Processing Facility Director. The results shall be reviewed by the Processing Facility Director or designee and outcomes reviewed with the staff.	D8.1.4.5	For tests performed within the Processing Facility, there shall be documentation of ongoing proficiency testing as designated by the Processing Facility Director. The results shall be reviewed by the Processing Facility Director or designee and outcomes reviewed with the staff.	No change
D08.01.05	Tests required by these Standards, not performed by the Processing Facility, shall be performed by a laboratory that is certified, licensed, or accredited by the appropriate laboratory regulatory agency.	D8.1.5	Tests required by these Standards, not performed by the Processing Facility, shall be performed by a laboratory that is certified, licensed, or accredited by the appropriate laboratory regulatory agency.	No change
D08.01.06	Infectious disease testing required by these Standards shall be performed using screening tests approved or cleared by the governmental authority for cellular therapy product donors.	D8.1.6	Infectious disease testing required by these Standards shall be performed using licensed screening tests approved or cleared by the governmental authority for cellular therapy product donors.	Minor

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
D08.01.07	Cellular therapy products that do not meet allogeneic donor eligibility requirements, or for which allogeneic donor eligibility determination is not yet complete, shall be distributed only if there is documented urgent medical need for the product. Documentation shall include, at a minimum, the approval of the recipient's physician and the Processing Facility Medical Director or other designated physician.	D8.1.7	Cellular therapy products that do not meet allogeneic donor eligibility requirements, or for which allogeneic donor eligibility determination is not yet complete, shall be distributed only if there is documented urgent medical need for the product. Documentation shall include, at a minimum, the approval of the recipient's physician and the Processing Facility Medical Director or other designated physician.	No change
D08.01.08	Notification of the recipient's physician of nonconforming cellular therapy products and approval for their release shall be documented.	D8.1.8	Notification of the recipient's physician of nonconforming cellular therapy products and approval for their release shall be documented.	No change
D08.02	Before a cellular therapy product is processed, shipped, or otherwise prepared for administration, there shall be a written request from the recipient's physician specifying the cellular therapy product type, recipient and donor identifiers, the type of processing that is to be performed, and the anticipated date of processing.	D8.2	Before a cellular therapy product is processed, shipped, or otherwise prepared for administration, there shall be a written request from the recipient's physician specifying the cellular therapy product type, recipient and donor identifiers, the type of processing that is to be performed, and the anticipated date of processing.	No change
D08.03	For allogeneic cellular therapy products, information required by the Processing Facility prior to distribution of the product shall include:	D8.3	For allogeneic cellular therapy products, information required by the Processing Facility prior to distribution of the product shall include:	No change
D08.03.01	A statement of donor eligibility.	D8.3.1	A statement of donor eligibility.	No change
D08.03.02	For ineligible donors, the reason for their ineligibility.	D8.3.2	For ineligible donors, the reason for their ineligibility.	No change
D08.03.03	For ineligible donors or donors for whom eligibility determination is incomplete, documentation of urgent medical need and physician approval for use.	D8.3.3	For ineligible donors or donors for whom eligibility determination is incomplete, documentation of urgent medical need and physician approval for use.	No change
D08.04	Processing procedures shall be validated in the Processing Facility and documented to result in acceptable target cell viability and recovery.	D8.4	Processing procedures shall be validated in the Processing Facility and documented to result in acceptable target cell viability and recovery.	No change
D08.04.01	Published validated processes shall be verified within the Processing Facility prior to implementation.	D8.4.1	Published validated processes shall be verified within the Processing Facility prior to implementation.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
D08.04.02	The Processing Facility shall use validated methods for preparation of cellular therapy products for administration.	D8.4.2	The Processing Facility shall use validated methods for preparation of cellular therapy products for administration.	No change
D08.04.03	Cord blood units that have not been red cell reduced prior to cryopreservation shall be washed prior to administration.	D8.4.3	Cord blood units that have not been red cell reduced prior to cryopreservation shall be washed prior to administration.	No change
D08.04.04	Cord blood units that have been red cell reduced prior to cryopreservation should be diluted or washed prior to administration.	D8.4.4	Cord blood units that have been red cell reduced prior to cryopreservation should be diluted or washed prior to administration.	No change
D08.04.05	If the Processing Facility lacks experience with the type of cellular therapy product requested for a recipient, personnel shall obtain the manufacturer’s instructions and follow these instructions to the extent possible.	D8.4.5	If the Processing Facility lacks experience with the type of cellular therapy product requested for a recipient, personnel shall obtain the manufacturer’s instructions and follow these instructions to the extent possible.	No change
D08.04.05.01	The Processing Facility should verify the processing procedures utilizing practice units similar to the cellular therapy product intended for administration when feasible.	D8.4.5.1	The Processing Facility should verify the processing procedures utilizing practice units similar to the cellular therapy product intended for administration when feasible.	No change
D08.05	Critical control points and associated assays shall be identified and performed on each cellular therapy product as defined in Standard Operating Procedures.	D8.5	Critical control points and associated assays shall be identified and performed on each cellular therapy product as defined in Standard Operating Procedures.	No change
D08.06	Methods for processing shall employ aseptic technique and cellular therapy products shall be processed in a manner that minimizes the risk of cross-contamination.	D8.6	Methods for processing shall employ aseptic technique and cellular therapy products shall be processed in a manner that minimizes the risk of cross-contamination.	No change
D08.06.01	Where processing of tissues and cells involves exposure to the environment, processing shall take place in an environment with specified air quality and cleanliness.	D8.6.1	Where processing of tissues and cells involves exposure to the environment, processing shall take place in an environment with specified air quality and cleanliness.	No change
D08.06.02	The effectiveness of measures to avoid contamination and cross-contamination shall be verified and monitored.	D8.6.2	The effectiveness of measures to avoid contamination and cross-contamination shall be verified and monitored.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
D08.07	The Processing Facility shall monitor and document microbial contamination of cellular therapy products after processing as specified in Standard Operating Procedures.	D8.7	The Processing Facility shall monitor and document microbial contamination of cellular therapy products after processing as specified in Standard Operating Procedures.	No change
D08.07.01	The results of microbial cultures shall be reviewed by the Processing Facility Director or designee in a timely manner.	D8.7.1	The results of microbial cultures shall be reviewed by the Processing Facility Director or designee in a timely manner.	No change
D08.07.02	The recipient's physician shall be notified in a timely manner of any positive microbial cultures.	D8.7.2	The recipient's physician shall be notified in a timely manner of any positive microbial cultures.	No change
D08.08	Records shall be made concurrently with each step of the processing, testing, cryopreservation, storage, and administration or disposal/disposition/distribution of each cellular therapy product in such a way that all steps may be accurately traced.	D8.8	Records shall be made concurrently with each step of the processing, testing, cryopreservation, storage, and administration or disposal/disposition/distribution of each cellular therapy product in such a way that all steps may be accurately traced.	No change
D08.08.01	Records shall identify the person immediately responsible for each significant step, including dates and times, where appropriate.	D8.8.1	Records shall identify the person immediately responsible for each significant step, including dates and times, where appropriate.	No change
D08.08.02	Records shall show the test results and the interpretation of each result, where appropriate.	D8.8.2	Records shall show the test results and the interpretation of each result, where appropriate.	No change
D08.09	The Processing Facility Director or designee shall review the processing record for each cellular therapy product prior to release or distribution.	D8.9	The Processing Facility Director or designee shall review the processing record for each cellular therapy product prior to release or distribution.	No change
D08.10	There shall be documented notification to the recipient's physician and the Processing Facility Medical Director of clinically relevant processing end-points not met and remedial actions taken.	D8.10	There shall be documented notification to the recipient's physician and the Processing Facility Medical Director of clinically relevant processing end-points not met and remedial actions taken.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
D08.11	Processing using more-than-minimal manipulation shall only be performed with Institutional Review Board or Ethics Committee approval, with the written informed consent of the donor, if applicable, and the recipient of the cellular therapy product, and in compliance with applicable laws and regulations.	D8.11	Processing using more-than-minimal manipulation shall only be performed with Institutional Review Board or Ethics Committee approval, with the written informed consent of the donor, if applicable, and the recipient of the cellular therapy product, and in compliance with applicable laws and regulations.	No change
D08.11.01	The Processing Facility shall adhere to good manufacturing practices (GMP) appropriate for the degree of cellular therapy product manipulation.	D8.11.1	The Processing Facility shall adhere to GMP appropriate for the degree of cellular therapy product manipulation.	Negligible
D08.12	For allogeneic cellular therapy products containing red blood cells at the time of administration:	D8.12	For allogeneic cellular therapy products containing red blood cells at the time of administration:	No change
D08.12.01	Results for ABO group and Rh type testing shall be available from two independently collected samples. Discrepancies shall be resolved and documented prior to issue of the cellular therapy product.	D8.12.1	Results for ABO group and Rh type testing shall be available from two (2) independently collected samples. Discrepancies shall be resolved and documented prior to issue of the cellular therapy product.	Negligible
D08.12.02	Results for a red cell antibody screen on the recipient shall be available.	D8.12.2	Results for a red cell antibody screen on the recipient shall be available.	No change
D08.13	There shall be a procedure to confirm the identity of cord blood units if confirmatory typing cannot be performed on attached segments.	D8.13	There shall be a Standard Operating Procedure to confirm the identity of cord blood units if verification typing cannot be performed on attached segments.	Negligible
D08.14	One or more samples representing the cryopreserved cellular therapy product shall be stored.	D8.14	One or more samples representing the cryopreserved cellular therapy product shall be stored.	No change
D08.14.01	Sample(s) from cryopreserved cellular therapy products shall be stored under conditions that achieve a valid representation of the clinical product.	D8.14.1	Sample(s) from cryopreserved cellular therapy products shall be stored under conditions that achieve a valid representation of the clinical product.	No change
D08.14.02	Cryopreserved samples shall be retained according to institutional Standard Operating Procedures.	D8.14.2	Cryopreserved samples shall be retained according to institutional Standard Operating Procedures.	No change
D09	**CELLULAR THERAPY PRODUCT STORAGE**	**D9**	**CELLULAR THERAPY PRODUCT STORAGE**	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
D09.01	Processing Facilities shall control storage areas to prevent mix-ups, deterioration, contamination, cross-contamination, and improper distribution of cellular therapy products.	D9.1	Processing Facilities shall control storage areas to prevent mix-ups, deterioration, contamination, cross-contamination, and improper distribution of cellular therapy products.	No change
D09.02	**STORAGE DURATION**	**D9.2**	**STORAGE DURATION**	No change
D09.02.01	Processing Facilities processing, storing, and/or releasing cellular therapy products for administration shall assign an expiration date and time for non-cryopreserved products and for products thawed after cryopreservation.	D9.2.1	Processing Facilities processing, storing, and/or releasing cellular therapy products for administration shall assign an expiration date and time for non-cryopreserved products and for products thawed after cryopreservation.	No change
D09.02.02	There shall be a written stability program that evaluates the viability and potency of cryopreserved cellular therapy products, minimally annually.	D9.2.2	There shall be a written stability program that evaluates the viability and potency of cryopreserved cellular therapy products, annually at a minimum.	Negligible
D09.03	**TEMPERATURE**	**D9.3**	**TEMPERATURE**	No change
D09.03.01	Storage temperatures shall be defined in Standard Operating Procedures.	D9.3.1	Storage temperatures shall be defined in Standard Operating Procedures.	No change
D09.03.02	Noncryopreserved cellular therapy products shall be maintained within a specific temperature range to maintain viability and function, to inhibit infectious agents, and for a period of time not to exceed that specified in Standard Operating Procedures.	D9.3.2	Noncryopreserved cellular therapy products shall be maintained within a specific temperature range to maintain viability and function, to inhibit infectious agents, and for a period of time not to exceed that specified in Standard Operating Procedures.	No change
D09.03.03	Cryopreserved cellular therapy products shall be stored within a temperature range, as defined in Standard Operating Procedures, that is appropriate for the product and cryoprotectant solution used.	D9.3.3	Cryopreserved cellular therapy products shall be stored within a temperature range, as defined in Standard Operating Procedures, that is appropriate for the product and cryoprotectant solution used.	No change
D09.03.04	Prior to receipt of a cellular therapy product from an external facility, there shall be confirmation that the product can be appropriately stored.	D9.3.4	Prior to receipt of a cellular therapy product from an external facility, there shall be confirmation that the product can be appropriately stored.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
D09.04	**PRODUCT SAFETY**	**D9.4**	**PRODUCT SAFETY**	No change
D09.04.01	Materials that may adversely affect cellular therapy products shall not be stored in the same refrigerators or freezers as the cellular therapy products.	D9.4.1	Materials that may adversely affect cellular therapy products shall not be stored in the same refrigerators or freezers as the cellular therapy products.	No change
D09.04.02	For cellular therapy products immersed in liquid nitrogen, procedures to minimize the risk of cross-contamination of products shall be employed.	D9.4.2	For cellular therapy products immersed in liquid nitrogen, procedures to minimize the risk of cross-contamination of products shall be employed.	No change
D09.04.03	Processes for storing cellular therapy products in quarantine shall be defined in Standard Operating Procedures.	D9.4.3	Processes for storing cellular therapy products in quarantine shall be defined in Standard Operating Procedures.	No change
D09.04.03.01	Quarantined cellular therapy products shall be easily distinguishable and stored in a manner that minimizes the risks of cross-contamination and inappropriate distribution.	D9.4.3.1	Quarantined cellular therapy products shall be easily distinguishable and stored in a manner that minimizes the risks of cross-contamination and inappropriate distribution.	No change
D09.04.03.02	All cellular therapy products with positive infectious disease test results for relevant communicable disease agents and/or positive microbial cultures shall be quarantined.	D9.4.3.2	All cellular therapy products with positive infectious disease test results for relevant communicable disease agents and/or positive microbial cultures shall be quarantined.	No change
D09.04.03.03	Processing Facilities storing cellular therapy products shall quarantine each product until completion of the donor eligibility determination as required by applicable laws and regulations.	D9.4.3.3	Processing Facilities storing cellular therapy products shall quarantine each product until completion of the donor eligibility determination as required by applicable laws and regulations.	No change
D09.05	**STORAGE MONITORING**	**D9.5**	**STORAGE MONITORING**	No change
D09.05.01	Refrigerators and freezers used for storage where cellular therapy products are not fully immersed in liquid nitrogen shall have a system to monitor the temperature continuously and to record the temperature at least every four (4) hours.	D9.5.1	Refrigerators and freezers used for storage where cellular therapy products are not fully immersed in liquid nitrogen shall have a system to monitor the temperature continuously and to record the temperature at least every four (4) hours.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
D09.05.02	There shall be a mechanism to confirm that levels of liquid nitrogen in liquid nitrogen freezers are consistently maintained to assure that cellular therapy products remain within the specified temperature range.	D9.5.2	There shall be a mechanism to confirm that levels of liquid nitrogen in liquid nitrogen freezers are consistently maintained to assure that cellular therapy products remain within the specified temperature range.	No change
D09.06	**ALARM SYSTEMS**	**D9.6**	**ALARM SYSTEMS**	No change
D09.06.01	Storage devices for cellular therapy products or reagents for cellular therapy product processing shall have alarm systems that are continuously active.	D9.6.1	Storage devices for cellular therapy products or reagents for cellular therapy product processing shall have alarm systems that are continuously active.	No change
D09.06.02	Alarm systems shall have audible and visible signals or other effective notification methods.	D9.6.2	Alarm systems shall have audible and visible signals or other effective notification methods.	No change
D09.06.03	Alarm systems shall be checked periodically for function.	D9.6.3	Alarm systems shall be checked periodically for function.	No change
D09.06.04	If trained personnel are not always present in the immediate area of the storage device, a system shall be in place that alerts responsible personnel of alarm conditions on a 24-hour basis.	D9.6.4	If trained personnel are not always present in the immediate area of the storage device, a system shall be in place that alerts responsible personnel of alarm conditions on a 24-hour basis.	No change
D09.06.05	Alarms shall be set to activate at a temperature or level of liquid nitrogen that will allow time to salvage products.	D9.6.5	Alarms shall be set to activate at a temperature or level of liquid nitrogen that will allow time to salvage products.	No change
D09.06.06	Written instructions to be followed if the storage device fails shall be displayed in the immediate area of the storage device and at each remote alarm location.	D9.6.6	Written instructions to be followed if the storage device fails shall be displayed in the immediate area of the storage device and at each remote alarm location.	No change
D09.06.06.01	Instructions shall include a procedure for notifying processing personnel.	D9.6.6.1	Instructions shall include a procedure for notifying processing personnel.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
D09.06.07	Storage devices of appropriate temperature shall be available for cellular therapy product storage if the primary storage device fails.	D9.6.7	Storage devices of appropriate temperature shall be available for cellular therapy product storage if the primary storage device fails.	No change
D09.07	The storage device shall be located in a secure area and accessible only to authorized personnel.	D9.7	The storage device shall be located in a secure area and accessible only to personnel authorized by the Processing Facility Director or designee.	Minor
D09.08	The Processing Facility shall use an inventory control system to identify the location of each cellular therapy product and associated samples. The inventory control system records shall include:	D9.8	The Processing Facility shall use an inventory control system to identify the location of each cellular therapy product and associated samples. The inventory control system records shall include:	No change
D09.08.01	Cellular therapy product unique identifier.	D9.8.1	Cellular therapy product unique identifier.	No change
D09.08.02	Recipient name or unique identifier.	D9.8.2	Recipient name or unique identifier.	No change
D09.08.03	Storage device identifier.	D9.8.3	Storage device identifier.	No change
D09.08.04	Location within the storage device.	D9.8.4	Location within the storage device.	No change
D10	**CELLULAR THERAPY PRODUCT TRANSPORTATION AND SHIPPING**	**D10**	**CELLULAR THERAPY PRODUCT TRANSPORTATION AND SHIPPING**	No change
D10.01	Procedures for transportation and shipping of cellular therapy products shall be designed to protect the integrity of the product and the health and safety of individuals in the immediate area.	D10.1	Standard Operating Procedures for transportation and shipping of cellular therapy products shall be designed to protect the integrity of the product and the health and safety of individuals in the immediate area.	Negligible

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
D10.02	The primary product container for non-frozen cellular therapy products shall be placed in a secondary container and sealed to prevent leakage.	D10.2	The primary product container for non-frozen cellular therapy products shall be placed in a secondary container and sealed to prevent leakage.	No change
D10.03	Cellular therapy products that require a temperature-controlled environment and that are transported or shipped over an extended period of time shall be transported or shipped in a container validated to maintain the appropriate temperature range.	D10.3	Cellular therapy products that require a temperature-controlled environment and that are transported or shipped over an extended period of time shall be transported or shipped in a container validated to maintain the appropriate temperature range.	No change
D10.04	Conditions shall be established and maintained to preserve the integrity and safety of cellular therapy products during transport or shipping.	D10.4	Conditions shall be established and maintained to preserve the integrity and safety of cellular therapy products during transport or shipping.	No change
D10.05	Cellular therapy products that are shipped to another facility or transported on public roads shall be packaged in an outer container.	D10.5	Cellular therapy products that are shipped to another facility or transported on public roads shall be packaged in an outer container.	No change
D10.05.01	The outer container shall conform to the applicable regulations regarding the mode of transportation or shipping.	D10.5.1	The outer container shall conform to the applicable regulations regarding the mode of transportation or shipping.	No change
D10.05.02	The outer container shall be made of material adequate to withstand leakage of contents, shocks, pressure changes, and other conditions incident to ordinary handling during transport or shipping.	D10.5.2	The outer container shall be made of material adequate to withstand leakage of contents, shocks, pressure changes, and other conditions incident to ordinary handling during transport or shipping.	No change
D10.05.02.01	The temperature of the shipping container shall be continuously monitored during shipment of cellular therapy products.	D10.5.2.1	The temperature of the shipping container shall be continuously monitored during shipment of cellular therapy products.	No change
D10.05.02.02	The shipping facility shall maintain a record of the temperature over the period of travel.	D10.5.2.2	The shipping facility shall maintain a record of the temperature over the period of travel.	No change
D10.05.03	The outer container shall be secured.	D10.5.3	The outer container shall be secured.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
D10.05.04	The outer container shall be labeled as defined in the Cellular Therapy Product Labels for Shipping and Transport on Public Roads table in Appendix _.	D10.5.4	The outer container shall be labeled as defined in the Cellular Therapy Product Labels for Shipping and Transport on Public Roads table in Appendix III.	No change
D10.05.05	There shall be a document inside the outer container that includes all the information required on the outer container, in conformity with the Cellular Therapy Product Labels for Shipping and Transport on Public Roads table in Appendix _.	D10.5.5	There shall be a document inside the outer container that includes all the information required on the outer container, in conformity with the Cellular Therapy Product Labels for Shipping and Transport on Public Roads table in Appendix III.	No change
D10.05.06	The outer container shall be labeled in accordance with applicable laws and regulations regarding the cryogenic material used and the transport or shipment of biological materials.	D10.5.6	The outer container shall be labeled in accordance with applicable laws and regulations regarding the cryogenic material used and the transport or shipment of biological materials.	No change
D10.06	The transit time shall be within time limits determined by the distributing facility in consultation with the receiving facility to maintain cellular therapy product safety.	D10.6	The transit time shall be within time limits determined by the distributing facility in consultation with the receiving facility to maintain cellular therapy product safety.	No change
D10.07	If the intended recipient has received high-dose therapy, the cellular therapy product shall be transported.	D10.7	If the intended recipient has received high-dose therapy, the cellular therapy product shall be transported.	No change
D10.08	There shall be plans for alternative means of transport or shipping in an emergency.	D10.8	There shall be plans for alternative means of transport or shipping in an emergency.	No change
D10.09	The cellular therapy products should not be passed through X-Ray irradiation devices designed to detect metal objects. If inspection is necessary, the contents of the container should be inspected manually.	D10.9	Cellular therapy products should not be passed through X-Ray irradiation devices designed to detect metal objects. If inspection is necessary, the contents of the container should be inspected manually.	No change
D11	**DISTRIBUTION AND RECEIPT**	**D11**	**DISTRIBUTION AND RECEIPT**	No change
D11.01	**DISTRIBUTION CRITERIA**	**D11.1**	**DISTRIBUTION CRITERIA**	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
D11.01.01	The processing, collection, and transport or shipping records for each cellular therapy product shall be reviewed by the Processing Facility Director or designee for compliance with Standard Operating Procedures and applicable laws and regulations prior to product release or distribution.	D11.1.1	The processing, collection, and transport or shipping records for each cellular therapy product shall be reviewed by the Processing Facility Director or designee for compliance with Standard Operating Procedures and applicable laws and regulations prior to product release or distribution.	No change
D11.01.01.01	Records shall demonstrate traceability from the donor to the recipient and from the recipient to the donor.	D11.1.1.1	Records shall demonstrate traceability from the donor to the recipient and from the recipient to the donor.	No change
D11.01.02	Each cellular therapy product shall meet pre-determined release criteria prior to distribution from the Processing Facility. The release criteria shall include donor eligibility determination for allogeneic products.	D11.1.2	Each cellular therapy product shall meet pre-determined release criteria prior to distribution from the Processing Facility. The release criteria shall include donor eligibility determination for allogeneic products.	No change
D11.01.02.01	The Processing Facility Director or designee shall give specific authorization for release when the cellular therapy product does not meet technical release criteria.	D11.1.2.1	The Processing Facility Director or designee shall give specific authorization for release when the cellular therapy product does not meet technical release criteria.	No change
D11.01.02.02	The Processing Facility Medical Director or designee shall give specific authorization for release when the cellular therapy product does not meet clinically relevant release criteria.	D11.1.2.2	The Processing Facility Medical Director or designee shall give specific authorization for release when the cellular therapy product does not meet clinically relevant release criteria.	No change
D11.01.02.03	Documentation of agreement of the Processing Facility Medical Director or designee and the recipient's physician consent to use any non-conforming product shall be retained in the processing record if such release is allowed by policies, procedures, or package inserts of licensed products.	D11.1.2.3	Documentation of agreement between the Processing Facility Medical Director or designee and the recipient's physician to use any non-conforming product shall be retained in the processing record if such release is allowed by policies, Standard Operating Procedures, or package inserts of licensed products.	Negligible
D11.01.03	Each cellular therapy product issued for administration shall be visually inspected by two (2) trained personnel immediately before release to verify the integrity of the product container and appropriate labeling.	D11.1.3	Each cellular therapy product issued for administration shall be visually inspected by two (2) trained personnel immediately before release to verify the integrity of the product container and appropriate labeling.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
D11.01.03.01	A cellular therapy product shall not be released when the container is compromised and/or recipient or donor information is not verified unless the Processing Facility Director or designee gives specific authorization for the product's release.	D11.1.3.1	A cellular therapy product shall not be released when the container is compromised and/or recipient or donor information is not verified unless the Processing Facility Director or designee gives specific authorization for the product's release.	No change
D11.01.04	For each type of cellular therapy product, the Processing Facility shall maintain and distribute or make a document available to clinical staff containing the following:	D11.1.4	For each type of cellular therapy product, the Processing Facility shall maintain and distribute or make a document available to clinical staff containing the following:	No change
D11.01.04.01	The use of the cellular therapy product, indications, contraindications, side effects and hazards, dosage, and administration recommendations.	D11.1.4.1	The use of the cellular therapy product, indications, contraindications, side effects and hazards, dosage, and administration recommendations.	No change
D11.01.04.02	Instructions for handling the cellular therapy product to minimize the risk of contamination or cross-contamination.	D11.1.4.2	Instructions for handling the cellular therapy product to minimize the risk of contamination or cross-contamination.	No change
D11.01.04.03	Appropriate warnings related to the prevention of the transmission or spread of communicable diseases.	D11.1.4.3	Appropriate warnings related to the prevention of the transmission or spread of communicable diseases.	No change
		D11.2	**DISTRIBUTION RECORDS**	New
D11.02	The cellular therapy product processing records shall contain a written record of product distribution including, at a minimum:	D11.2.1	The cellular therapy product distribution records shall permit tracking and tracing of the cellular therapy product, and shall contain the following information at a minimum:	Minor
D11.02.01	The distribution date and time.			
D11.02.02	Unique identifier of the intended recipient.	D11.2.1.2	Unique identifier of the intended recipient.	No change
D11.02.03	The proper product name and identifier.	D11.2.1.1	The proper product name and identifier.	No change
D11.02.04	Documentation of donor eligibility determination.	D11.2.1.3	Documentation of donor eligibility determination, as appropriate.	Minor
D11.02.05	Identification of the facilities that requested and distributed the product.	D11.2.1.4	Identification of the facilities that requested and distributed the product.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
	See D11.4.8			
D11.03	Records shall permit tracing of the cellular therapy product from one facility to another, and shall include:			
D11.03.01	Date and time cellular therapy product was distributed.	D11.2.1.6	Date and time cellular therapy product was distributed.	No change
D11.03.02	Date and time cellular therapy product was received.	D11.2.1.7	Date and time cellular therapy product was received.	No change
D11.03.03	Identity of the transporting or shipping facility.	D11.2.1.8	Identity of the transporting or shipping facility.	No change
D11.03.04	Identity of the receiving facility.	D11.2.1.5	Identity of the receiving facility.	No change
D11.03.05	Identity of personnel responsible for cellular therapy product transportation or shipping and of personnel responsible for receiving the product.	D11.2.1.9	Identity of personnel responsible for cellular therapy product transportation or shipping and of personnel responsible for receiving the product.	No change
D11.03.06	Identity of the courier.	D11.2.1.10	Identity of the courier.	No change
D11.03.07	Documentation of any delay or problems incurred during transportation or shipping.	D11.2.1.11	Documentation of any delay or problems incurred during transportation or shipping.	No change
D11.04	**RECEIPT OF CELLULAR THERAPY PRODUCTS**	**D11.3**	**RECEIPT OF CELLULAR THERAPY PRODUCTS**	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
D11.04.01	Procedures shall be established and maintained for acceptance, rejection, and quarantine of cellular therapy products.	D11.3.1	Standard Operating Procedures shall be established and maintained for acceptance, rejection, and quarantine of cellular therapy products.	Negligible
D11.04.02	The receipt of each cellular therapy product shall include inspection to verify:	D11.3.2	The receipt of each cellular therapy product shall include inspection to verify:	No change
D11.04.02.01	The integrity of the cellular therapy product container.	D11.3.2.1	The integrity of the cellular therapy product container.	No change
D11.04.02.02	The appearance of the cellular therapy product for evidence of mishandling or microbial contamination.	D11.3.2.2	The appearance of the cellular therapy product for evidence of mishandling or microbial contamination.	No change
D11.04.02.03	Appropriate labeling.	D11.3.2.3	Appropriate labeling.	No change
D11.04.03	If the primary container or temperature of the cellular therapy product has been compromised, the Processing Facility Director or designee shall give specific authorization to return the product to inventory.	D11.3.6	If the temperature of the cellular therapy product has been compromised, the Processing Facility Director or designee shall give specific authorization to return the product to inventory.	Minor
D11.04.04	There shall be procedures to verify that the cellular therapy product was appropriately transported or shipped.	D11.3.3	There shall be Standard Operating Procedures to verify that the cellular therapy product was appropriately transported or shipped.	Negligible
D11.04.04.01	The receiving facility shall document the temperature of the outer container upon arrival.	D11.3.3.1	The receiving facility shall document the temperature inside the container upon arrival if shipped or transported on public roads.	Significant
D11.04.04.02	For cryopreserved cellular therapy products, receiving facility records shall include documentation of the outer container temperature during shipping.	D11.3.3.2	For cryopreserved cellular therapy products, receiving facility records shall include documentation of the container temperature during shipping.	Negligible
D11.04.05	The receiving facility shall review and verify product specifications provided by the manufacturer, if applicable.	D11.3.4	The receiving facility shall review and verify cellular therapy product specifications provided by the manufacturer, if applicable.	Negligible

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
D11.04.06	There shall be procedures to maintain cellular therapy products in quarantine until they have been determined to meet criteria for release from quarantine.	D11.3.5	There shall be Standard Operating Procedures to maintain cellular therapy products in quarantine until they have been determined to meet criteria for release from quarantine.	Negligible
D11.04.07	The receiving facility shall have readily available access to a summary of documents used to determine allogeneic donor eligibility.	D11.3.7	The receiving facility shall have readily available access to a summary of documents used to determine allogeneic donor eligibility.	No change
D11.04.07.01	For cellular therapy products received from an external facility, there shall be documented evidence of donor eligibility screening and testing in accordance with applicable laws and regulations.	D11.3.7.1	For cellular therapy products received from an external facility, there shall be documented evidence of donor eligibility screening and testing in accordance with applicable laws and regulations.	No change
D11.04.08	When cellular therapy products are returned to the Processing Facility after distribution for administration, there shall be documentation in the Processing Facility records of the events requiring return, the temporary storage temperature when at the clinical facility, the results of inspection upon return, and subsequent action taken to protect product safety and viability.	D11.3.8	When cellular therapy products are returned to the Processing Facility after distribution for administration, there shall be documentation in the Processing Facility records of the events requiring return, the temporary storage temperature when at the clinical facility, the results of inspection upon return, and subsequent action taken to protect product safety and viability.	No change
D11.04.08.01	The Processing Facility Director or designee shall consult with the recipient's physician regarding reissue or disposal of the returned product.	D11.3.8.1	The Processing Facility Director or designee shall consult with the recipient's physician regarding reissue or disposal of the returned cellular therapy product.	Negligible
D12	**DISPOSAL**	**D12**	**DISPOSAL**	No change
D12.01	Disposal of cellular therapy products shall include the following requirements:	D12.1	Disposal of cellular therapy products shall include the following requirements:	No change
D12.01.01	A pre-collection written agreement between the storage facility and the designated recipient or the donor defining the length of storage and the circumstances for disposal of cellular therapy products.	D12.1.1	A pre-collection written agreement between the storage facility and the designated recipient or the donor defining the length of storage and the circumstances for disposal of cellular therapy products.	No change
D12.01.02	The option to transfer the cellular therapy product to another facility if the designated recipient is still alive after the agreed upon storage interval.	D12.1.2	The option to transfer the cellular therapy product to another facility if the designated recipient is still alive after the agreed upon storage interval.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
D12.01.03	Documentation of no further need for the cellular therapy product before any product is discarded.	D12.1.3	Documentation of no further need for the cellular therapy product before any product is discarded.	No change
D12.01.03.01	For HPC products, this shall include documentation of the designated recipient's death, if applicable.	D12.1.3.1	For HPC products, this shall include documentation of the designated recipient's death, if applicable.	No change
D12.01.04	Approval by the Processing Facility Medical Director or the recipient's physician for cellular therapy product discard or other disposition, and method of disposal.	D12.1.4	Approval by the Processing Facility Medical Director in consultation with the recipient's physician for cellular therapy product discard or other disposition, and method of disposal.	moderate
D12.01.05	A method of disposal and decontamination that meets applicable laws and regulations for disposal of biohazardous materials and/or medical waste.	D12.1.5	A method of disposal and decontamination that meets applicable laws and regulations for disposal of biohazardous materials and/or medical waste.	No change
D12.01.06	Processing Facilities, in consultation with the Clinical Program, shall establish policies for the duration and conditions of storage and indications for disposal.	D12.2	Processing Facilities, in consultation with the Clinical Program, shall establish policies for the duration and conditions of storage and indications for disposal.	No change
D12.01.06.01	Recipients, donors, and associated Clinical Programs should be informed about policies for directed cellular therapy products as part of the informed consent process and before the cellular therapy product collection.	D12.2.1	Recipients, donors, and associated Clinical Programs should be informed about policies for directed cellular therapy products as part of the informed consent process and before the cellular therapy product collection.	No change
D12.01.07	If there is no pre-existing agreement describing conditions for cellular therapy product storage and/or discard or if the intended recipient is lost to follow-up, the storage facility shall make a documented effort to notify the donor, cellular therapy product manufacturer, or designated recipient's physician and facility about product disposition, including disposal or transfer.	D12.2.2	If there is no pre-existing agreement describing conditions for cellular therapy product storage and/or discard or if the intended recipient is lost to follow-up, the storage facility shall make a documented effort to notify the donor, cellular therapy product manufacturer, or designated recipient's physician and facility about product disposition, including disposal or transfer.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
	See D12.1.7			
	See D12.1.7			
D12.02	The records for discarded or transferred cellular therapy products shall indicate the product was discarded or transferred, date of discard or transfer, disposition, and method of disposal or transfer.	D12.3	The records for discarded or transferred cellular therapy products shall indicate the product was discarded or transferred, date of discard or transfer, disposition, and method of disposal or transfer.	No change
D13	**RECORDS**	**D13**	**RECORDS**	No change
D13.01	There shall be a records management system for quality and cellular therapy product record creation, assembly, review, storage, archival, and retrieval.	D13.1	There shall be a records management system for quality and cellular therapy product record creation, assembly, review, storage, archival, and retrieval.	No change
D13.01.01	The records management system shall facilitate the review of records pertaining to a particular cellular therapy product prior to distribution and for follow-up evaluation or investigation.	D13.1.1	The records management system shall facilitate the review of records pertaining to a particular cellular therapy product prior to distribution and for follow-up evaluation or investigation.	No change
D13.01.02	The records management system shall facilitate tracking of the cellular therapy product from the donor to the recipient or final disposition and tracing from the recipient or final disposition to the donor.	D13.1.2	The records management system shall facilitate tracking of the cellular therapy product from the donor to the recipient or final disposition and tracing from the recipient or final disposition to the donor.	No change
D13.01.03	For cellular therapy products that are to be distributed for use at another institution, the Processing Facility shall inform the receiving institution of the tracking system and requirement for tracking the product in writing or electronic format at or before the time of product distribution.	D13.1.3	For cellular therapy products that are to be distributed for use at another institution, the Processing Facility shall inform the receiving institution of the tracking system and requirement for tracking the product in writing or electronic format at or before the time of product distribution.	No change
D13.01.04	Records shall be maintained in such a way as to secure their integrity, preservation, and retrieval.	D13.1.4	Records shall be maintained in such a way as to secure their integrity, preservation, and retrieval.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
D13.01.05	Records shall be accurate, legible, and indelible.	D13.1.5	Records shall be accurate, legible, and indelible.	No change
	See D13.1.6			
D13.01.06	Safeguards to secure the confidentiality of all records and communications between the collection, processing, and clinical facilities, and their recipients and donors shall be established and followed in compliance with applicable laws and regulations.	D13.1.6	Safeguards to secure the confidentiality of all records and communications between the collection, processing, and clinical facilities, and their recipients and donors, shall be established and followed in compliance with applicable laws and regulations.	No change
		D13.2	The Processing Facility shall define and follow good documentation practices.	New
D13.02	**ELECTRONIC RECORDS**	**D13.3**	**ELECTRONIC RECORDS**	No change
D13.02.01	The Processing Facility shall maintain a current listing of all critical electronic record systems. Critical electronic record systems shall include at a minimum systems under the control of the Processing Facility that are used as a substitute for paper, to make decisions, to perform calculations, or to create or store information used in critical procedures.	D13.3.1	The Processing Facility shall maintain a current listing of all critical electronic record systems. Critical electronic record systems shall include at a minimum systems under the control of the Processing Facility that are used as a substitute for paper, to make decisions, to perform calculations, or to create or store information used in critical procedures.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
D13.02.02	For all critical electronic record systems, there shall be policies, procedures, and system elements to maintain the accuracy, integrity, identity, and confidentiality of all records.	D13.3.2	For all critical electronic record systems, there shall be policies, Standard Operating Procedures, and system elements to maintain the accuracy, integrity, identity, and confidentiality of all records.	Negligible
D13.02.02.01	There shall be a means by which access to electronic records is limited to authorized individuals.	D13.3.3	There shall be a means by which access to electronic records is limited to authorized individuals.	No change
D13.02.02.02	The critical electronic record system shall maintain unique identifiers.	D13.3.4	The critical electronic record system shall maintain unique identifiers.	No change
D13.02.02.03	There shall be protection of the records to enable their accurate and ready retrieval throughout the period of record retention.	D13.3.5	There shall be protection of the records to enable their accurate and ready retrieval throughout the period of record retention.	No change
D13.02.03	For all critical electronic record systems, there shall be an alternative system for all electronic records to allow for continuous operation of the Processing Facility in the event that critical electronic record systems are not available. The alternative system shall be validated and Processing Facility staff shall be trained in its use.	D13.3.6	For all critical electronic record systems, there shall be an alternative system for all electronic records to allow for continuous operation of the Processing Facility in the event that critical electronic record systems are not available. The alternative system shall be validated and Processing Facility staff shall be trained in its use.	No change
D13.02.04	For all critical electronic record systems, there shall be written procedures for record entry, verification, and revision.	D13.3.7	For all critical electronic record systems, there shall be written Standard Operating Procedures for record entry, verification, and revision.	Negligible
D13.02.04.01	A method shall be established or the system shall provide for review of data before final acceptance.	D13.3.7.1	A method shall be established or the system shall provide for review of data before final acceptance.	No change
D13.02.04.02	A method shall be established or the system shall provide for the unambiguous identification of the individual responsible for each record entry.	D13.3.7.2	A method shall be established or the system shall provide for the unambiguous identification of the individual responsible for each record entry.	No change

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
D13.02.05	For all critical electronic record systems, there shall be the ability to generate true copies of the records in both human readable and electronic format suitable for inspection and review.	D13.3.8	For all critical electronic record systems, there shall be the ability to generate true copies of the records in both human readable and electronic format suitable for inspection and review.	No change
D13.02.06	For all critical electronic record systems, there shall be validated procedures for and documentation of:	D13.3.9	For all critical electronic record systems, there shall be validated procedures for and documentation of:	No change
D13.02.06.01	Systems development.	D13.3.9.1	Systems development.	No change
D13.02.06.02	Numerical designation of system versions, if applicable.	D13.3.9.2	Numerical designation of system versions, if applicable.	No change
D13.02.06.03	Prospective validation of systems, including hardware, software, and databases.	D13.3.9.3	Prospective validation of systems, including hardware, software, and databases.	No change
D13.02.06.04	Installation of the system.	D13.3.9.4	Installation of the system.	No change
D13.02.06.05	Training and continued competency of personnel in systems use.	D13.3.9.5	Training and continued competency of personnel in systems use.	No change
D13.02.06.06	Monitoring of data integrity.	D13.3.9.6	Monitoring of data integrity.	No change
D13.02.06.07	Back-up of the electronic records system on a regular schedule.	D13.3.9.7	Back-up of the electronic records system on a regular schedule.	No change
D13.02.06.08	System maintenance and operations.	D13.3.9.8	System maintenance and operations.	No change
D13.02.06.09	System assignment of unique identifiers.	D13.3.9.9	System assignment of unique identifiers.	No change
D13.02.07	All system modifications shall be authorized, documented, and validated prior to implementation.	D13.3.10	All system modifications shall be authorized, documented, and validated prior to implementation.	No change
D13.03	**RECORDS TO BE MAINTAINED**	**D13.4**	**RECORDS TO BE MAINTAINED**	No change
D13.03.01	Processing Facility records related to quality control, personnel training and competency, facility maintenance, facility management, complaints, or other general facility issues shall be retained for a minimum of ten (10) years by the Processing Facility, or longer in accordance with applicable laws or regulations, or with a defined program or institution policy.	D13.4.1	Processing Facility records related to quality control, personnel training and competency, facility maintenance, facility management, complaints, or other general facility issues shall be retained for a minimum of ten (10) years by the Processing Facility, or longer in accordance with applicable laws or regulations.	Minor

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
		D13.4.1.1	Employee records shall be maintained in a confidential manner, as required by applicable laws and regulations.	New
D13.03.01.01	Facility maintenance records pertaining to facility cleaning and sanitation shall be retained for at least three (3) years or longer in accordance with applicable laws or regulations, or with defined program or institution policy. All other facility maintenance records shall be retained as in D13.3.1.	D13.4.1.2	Facility maintenance records pertaining to facility cleaning and sanitation shall be retained for a minimum of three (3) years or longer in accordance with applicable laws or regulations.	Negligible
D13.03.02	Records to allow tracing of cellular therapy products shall be maintained for a minimum of ten (10) years after final distribution of the product, or as required by applicable laws and regulations. These records shall include collection and processing facility identity, unique numeric or alphanumeric identifier, collection date and time, product identity, and donor and recipient information as found on the original container.	D13.4.2	Records to allow tracing of cellular therapy products shall be maintained for a minimum of ten (10) years after the date of the cellular therapy product's distribution, disposition, or expiration, or the creation of the cellular therapy product record, whichever is most recent, or according to applicable laws and regulations or institutional policy, whichever is latest. These records shall include collection and processing facility identity, unique numeric or alphanumeric identifier, collection date and time, product identity, and donor and recipient information as found on the original container.	moderate

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
D13.03.03	All records pertaining to the processing, testing, storage, or distribution of cellular therapy products shall be maintained for a minimum of ten (10) years after the date of administration, or if the date of administration is not known, then a minimum of ten (10) years after the date of the cellular therapy product's distribution, disposition, or expiration, or the creation of the cellular therapy product record, whichever is most recent, or according to applicable laws and regulations or institutional policy, whichever requires the longest maintenance period.	D13.4.3	All records pertaining to the processing, testing, storage, or distribution of cellular therapy products shall be maintained for a minimum of ten (10) years after the date of administration, or if the date of administration is not known, then a minimum of ten (10) years after the date of the cellular therapy product's distribution, disposition, or expiration, or the creation of the cellular therapy product record, whichever is most recent, or according to applicable laws and regulations or institutional policy, whichever is latest.	Minor
	See D13.3.3			
	See D13.3.3			
	See D13.3.3			
	See D13.3.3			
		D13.4.4	Research records shall be maintained in a confidential manner as required by applicable laws and regulations or for a minimum of ten (10) years after the administration, distribution, disposition, or expiration of the cellular therapy product, whichever is latest.	New
D13.04	**RECORDS IN CASE OF DIVIDED RESPONSIBILITY**	**D13.5**	**RECORDS IN CASE OF DIVIDED RESPONSIBILITY**	No change
D13.04.03	If two (2) or more facilities participate in the collection, processing, or distribution of the cellular therapy product, the records of the Processing Facility shall show plainly the extent of its responsibility.	D13.5.3	If two (2) or more facilities participate in the collection, processing, or administration of the cellular therapy product, the records of the Processing Facility shall show plainly the extent of its responsibility.	Minor

06.1 ref	6.1 standard	07ref	07 standard	Changes 6.01-7
D13.04.01	The Processing Facility shall maintain a listing of the names, addresses, and responsibilities of other facilities that perform manufacturing steps on a cellular therapy product.	D13.5.1	The Processing Facility shall maintain a listing of the names, addresses, and responsibilities of other facilities that perform manufacturing steps on a cellular therapy product.	No change
D13.04.02	The Processing Facility shall furnish to the facility of final disposition a copy of all records relating to the collection, processing, and storage procedures performed in so far as the records concern the safety, purity, or potency of the cellular therapy product involved.	D13.5.2	The Processing Facility shall furnish to the facility of final disposition a copy of all records relating to the collection, processing, and storage procedures performed related to the safety, purity, or potency of the cellular therapy product involved.	Negligible