| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| B1 | General | M1 | General | C1 | General | D1 | General |
| 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). | 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. | 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. | 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. |
| 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. | 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. | 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. | | |
| 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. | | | | | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| 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: | | | | | | |
| B1.2.1.1 | Traceability and chain of custody of cellular therapy products. | | | | | | |
| B1.2.1.2 | Cellular therapy product storage and distribution. | | | | | | |
| B1.2.1.3 | Verification of cellular therapy product identity. | | | | | | |
| B1.2.1.4 | Review and verification of product specifications provided by the manufacturer, if applicable. | | | | | | |
| B1.2.1.5 | Readily available access to a summary of documents used to determine allogeneic donor eligibility. | | | | | | |
| B1.2.1.6 | Documented evidence of allogeneic donor eligibility screening and testing in accordance with applicable laws and regulations. | | | | | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| B1.3 | The Clinical Program shall abide by all applicable laws and regulations. | M1.3 | The Marrow Collection Facility shall abide by all applicable laws and regulations. | C1.3 | The Apheresis Collection Facility shall abide by all applicable laws and regulations. | D1.2 | The Processing Facility shall abide by all applicable laws and regulations. |
| B1.3.1 | The Clinical Program 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. | C1.3.1 | The Apheresis Collection 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. |
| 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. | 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. | 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. | 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. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| B1.5 | The Clinical Program shall comply with the Minimum Number of New Patients for Accreditation table in Appendix _. | 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. | 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. | | |
| **B2** | CLINICAL UNIT | **M2** | MARROW COLLECTION FACILITY | **C2** | APHERESIS COLLECTION FACILITY | **D2** | PROCESSING FACILITY |
| B2.1 | There shall be a designated inpatient unit of appropriate location and adequate space and design that minimizes airborne microbial contamination. | | | | | | |
| | | 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. | 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. | D2.1 | The Processing Facility shall be of adequate space, design, and location for the intended procedures. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| 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. | | | | | | |
| 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. | | | 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. | | |
| | | | | | | D2.1.2 | Oxygen sensors shall be appropriately placed and utilized in areas where liquid nitrogen is present. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| | | | | | | D2.1.3 | The Processing Facility shall be secure to prevent the entrance of unauthorized personnel. |
| | | 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. | 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. | 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. |
| | | 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. | 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. | 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. |
| B2.6 | There shall be provisions for prompt evaluation and treatment by an attending physician available on a 24-hour basis. | | | | | | |
| B2.7 | There shall be access to an intensive care unit or emergency services. | | | | | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| 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. | | | | | | |
| 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. | | | | | | |
| B2.11 | There shall be a pharmacy providing 24-hour availability of medications needed for the care of cellular therapy patients. | | | | | | |
| B2.11.1 | Pharmacies shall have prompt access to medications adequate to treat expected complications of cellular therapy, including cytokine release syndrome. | | | | | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| B2.12 | There shall be access to renal support under the direction of nephrologists and trained personnel. | | | | | | |
| B2.13 | There shall be 24-hour availability of CMV-appropriate and irradiated blood products needed for the care of cellular therapy recipients. | M8.4 | Autologous or CMV-appropriate and irradiated blood components shall be available during the marrow 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. | | |
| | | M2.1.3 | 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. | | |
| | | 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. | 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. | 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. |
| | | M2.3 | Marrow Collection Facility parameters and environmental conditions shall be controlled to protect the safety and comfort of 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. | D2.2 | Processing Facility parameters and environmental conditions shall be controlled to protect the safety and comfort of personnel. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| | | 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. | 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. | D2.3 | There shall be a written assessment of critical facility parameters that may affect processing, storage, or distribution. |
| | | M2.4.1 | The written assessment shall include temperature and humidity at a minimum. | C2.4.1 | The written assessment shall include temperature and humidity at a minimum. | D2.3.1 | The written assessment shall include temperature, humidity, air quality, and surface contaminates at a minimum. |
| | | M2.4.2 | 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. | D2.3.2 | Critical facility parameters identified to be a risk to the cellular therapy product shall be controlled, monitored, and recorded. |
| | | | | 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. | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| | | | | | | 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. |
| B2.4 | The Clinical Program 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. | C2.6 | The Apheresis Collection 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. |
| B2.5 | There shall be adequate equipment and materials for the procedures performed. | M2.6 | There shall be adequate equipment and materials for the procedures performed. | C2.7 | There shall be adequate equipment and materials for the procedures performed. | D2.5 | There shall be adequate equipment and materials for the procedures performed. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| 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. | | | | | | |
| B2.15 | Chimerism testing shall be performed in laboratories accredited for the techniques used. | | | | | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| 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. | M2.7 | There shall be access to an intensive care unit or emergency services. | C2.8 | There shall be access to an intensive care unit or emergency services. | | |
| 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. | 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. | 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. | 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. |
| 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. | 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. | 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. | 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. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| 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. | 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. | 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. | 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. |
| B2.19 | Gloves and protective clothing shall be worn while handling biological specimens. Such protective clothing shall not be worn outside the work area. | M2.11 | Gloves and protective clothing shall be worn while handling biological specimens. Such protective clothing shall not be worn outside the work area. | C2.12 | 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. |
| **B3** | PERSONNEL | **M3** | PERSONNEL | **C3** | PERSONNEL | **D3** | PERSONNEL |
| **B3.1** | CLINICAL PROGRAM DIRECTOR | | | **C3.1** | APHERESIS COLLECTION FACILITY DIRECTOR | **D3.1** | PROCESSING FACILITY DIRECTOR |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| 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. | | | 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. | 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. |
| 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. | | | | | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| 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. | | | 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. | 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. |
| 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. | | | | | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| | | | | 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. | 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. |
| B3.1.5 | The Clinical Program Director shall have oversight of the medical care provided by all members of the Clinical Program. | | | | | | |
| 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. | | | | | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| B3.1.6 | The Clinical Program Director shall participate in a minimum of ten (10) hours of educational activities related to cellular therapy annually. | | | 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. | D3.1.4 | The Processing Facility Director shall participate in a minimum of ten (10) hours of educational activities related to cellular therapy annually. |
| B3.1.6.1 | Continuing education shall include, but is not limited to, activities related to the field of HPC transplantation. | | | C3.1.4.1 | Continuing education shall include, but is not limited to, activities related to the field of HPC transplantation. | D3.1.4.1 | Continuing education shall include, but is not limited to, activities related to the field of HPC transplantation. |
| | | **M3.1** | MARROW COLLECTION FACILITY MEDICAL DIRECTOR | **C3.2** | APHERESIS COLLECTION FACILITY MEDICAL DIRECTOR | **D3.2** | PROCESSING FACILITY MEDICAL DIRECTOR |
| | | 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. | 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. | 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. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| | | M3.1.2 | The Marrow Collection Facility Medical Director or designee shall be responsible for the following elements: | 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. | D3.2.2 | The Processing Facility Medical Director or designee shall be directly responsible for all medical aspects related to the Processing Facility. |
| | | M3.1.2.1 | All technical procedures. | | | | |
| | | M3.1.2.2 | Performance of the marrow collection procedure. | | | | |
| | | M3.1.2.3 | Supervision of staff. | | | | |
| | | M3.1.2.4 | Administrative operations. | | | | |
| | | M3.1.2.5 | The medical care of allogeneic and/or autologous donors undergoing marrow collection. | | | | |
| | | M3.1.2.6 | Pre-collection evaluation of allogeneic and/or autologous donors at the time of donation. | | | | |
| | | M3.1.2.7 | Care of any complications resulting from the collection procedure. | | | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| | | M3.1.2.8 | The Quality Management Program, including compliance with these Standards and other applicable laws and regulations. | | | | |
| | | M3.1.3 | The Marrow Collection Facility Medical Director shall have at least two (2) years experience in 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. | 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. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| | | 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. | 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. | 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. |
| | | 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. | 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. | | |
| | | M3.1.5.1 | Continuing education shall include, but is not limited to, activities related to the field of HPC transplantation. | C3.2.5.1 | Continuing education shall include, but is not limited to, activities related to the field of HPC transplantation. | D3.2.4.1 | Continuing education shall include, but is not limited to, activities related to the field of HPC transplantation. |
| **B3.2** | ATTENDING PHYSICIANS | | | | | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| 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. | | | | | | |
| 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. | | | | | | |
| 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. | | | | | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| B3.2.2 | Attending physicians shall participate in a minimum of ten (10) hours of educational activities related to cellular therapy annually. | | | | | | |
| B3.2.2.1 | Continuing education shall include, but is not limited to, activities related to the field of HPC transplantation. | | | | | | |
| B3.3 | TRAINING FOR CLINICAL PROGRAM DIRECTORS AND ATTENDING PHYSICIANS | | | | | | |
| 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. | | | | | | |
| B3.3.2 | Clinical training and competency shall include the management of autologous and/or allogeneic transplant recipients, as applicable. | | | | | | |
| B3.3.3 | Clinical Program Directors and attending physicians shall each be assessed for competency on an annual basis. | | | | | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| 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: | | | | | | |
| B3.3.4.1 | Indications for allogeneic and autologous HPC transplantation. | | | | | | |
| B3.3.4.2 | Selection of suitable recipients and appropriate preparative regimens. | | | | | | |
| B3.3.4.3 | Donor selection, evaluation, and management. | | | | | | |
| B3.3.4.4 | Donor and recipient informed consent. | | | | | | |
| B3.3.4.5 | Administration of preparative regimens. | | | | | | |
| B3.3.4.6 | Administration of growth factors for HPC mobilization and for post-transplant hematopoietic cell reconstitution. | | | | | | |
| B3.3.4.7 | Cellular therapy product administration and patient management. | | | | | | |
| B3.3.4.8 | Management of neutropenic fever. | | | | | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| B3.3.4.9 | Diagnosis and management of infectious and non-infectious pulmonary complications of transplantation. | | | | | | |
| B3.3.4.10 | Diagnosis and management of fungal disease. | | | | | | |
| B3.3.4.11 | Diagnosis and management of sinusoidal obstruction syndrome and other causes of hepatic dysfunction. | | | | | | |
| B3.3.4.12 | Management of thrombocytopenia and bleeding, including recognition of disseminated intravascular coagulation. | | | | | | |
| B3.3.4.13 | Management of hemorrhagic cystitis. | | | | | | |
| B3.3.4.14 | Blood transfusion management. | | | | | | |
| B3.3.4.15 | Use of irradiated blood products. | | | | | | |
| B3.3.4.16 | Management of mucositis, nausea, and vomiting. | | | | | | |
| B3.3.4.17 | Monitoring and management of pain. | | | | | | |
| B3.3.4.18 | Cytokine release syndrome. | | | | | | |
| B3.3.4.19 | Tumor lysis syndrome and macrophage activation syndrome. | | | | | | |
| B3.3.4.21 | Cardiac dysfunction. | | | | | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| B3.3.4.22 | Renal dysfunction. | | | | | | |
| B3.3.4.23 | Respiratory distress. | | | | | | |
| B3.3.4.20 | Neurologic toxicity. | | | | | | |
| B3.3.4.24 | Anaphylaxis. | | | | | | |
| B3.3.4.25 | Infectious and noninfectious processes. | | | | | | |
| B3.3.4.26 | Diagnosis and management of HPC graft failure. | | | | | | |
| B3.3.4.28 | Evaluation of post-transplant cellular therapy outcomes. | | | | | | |
| B3.3.4.29 | Evaluation of late effects of cellular therapy. | | | | | | |
| B3.3.4.30 | Documentation and reporting for patients on investigational protocols. | | | | | | |
| B3.3.4.31 | Applicable regulations and reporting responsibilities for adverse events. | | | | | | |
| B3.3.4.32 | Palliative and end of life care. | | | | | | |
| B3.3.4.33 | Age-specific donor and recipient care. | | | | | | |
| B3.3.5 | Additional specific clinical training and competence required for physicians in Clinical Programs requesting accreditation for allogeneic HPC transplantation shall include: | | | | | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| B3.3.5.1 | Identification, evaluation, and selection of HPC source, including use of donor registries. | | | | | | |
| B3.3.5.2 | Donor eligibility determination. | | | | | | |
| B3.3.5.3 | Methodology and implications of HLA typing. | | | | | | |
| B3.3.5.4 | Management of patients receiving ABO incompatible HPC products. | | | | | | |
| B3.3.4.27 | Diagnosis and management of immunodeficiencies and opportunistic infections. | | | | | | |
| B3.3.5.5 | Diagnosis and management of acute GVHD. | | | | | | |
| B3.3.5.6 | Diagnosis and management of chronic GVHD. | | | | | | |
| B3.3.6 | The attending physicians shall be knowledgeable in the following procedures: | | | | | | |
| B3.3.6.3 | Cellular therapy product processing. | | | | | | |
| B3.3.6.4 | Cellular therapy product cryopreservation. | | | | | | |
| B3.3.6.2 | Bone marrow harvest procedures. | | | | | | |
| B3.3.6.1 | Apheresis collection procedures. | | | | | | |
| B3.3.6.7 | Extracorporeal photopheresis for GVHD. | | | | | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| B3.3.6.5 | Washing and diluting of cellular therapy products. | | | | | | |
| B3.3.6.6 | Cellular therapy product administration procedures. | | | | | | |
| **B3.4** | PHYSICIANS-IN-TRAINING | | | | | | |
| 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. | | | | | | |
| 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. | | | | | | |
| **B3.5** | ADVANCED PRACTICE PROVIDERS/PROFESSIONALS (APPs) | | | | | | |
| 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. | | | | | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| 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. | | | | | | |
| B3.5.3 | APPs shall participate in a minimum of ten (10) hours of educational activities related to cellular therapy annually. | | | | | | |
| B3.5.3.1 | Continuing education shall include, but is not limited to, activities related to the field of HPC transplantation. | | | | | | |
| **B3.6** | CLINICAL TRANSPLANT TEAM | | | | | | |
| B3.6.1 | Clinical Programs performing pediatric transplantation shall have a transplant team trained in the management of pediatric recipients. | | | | | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| 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. | M3.3.1 | The Marrow Collection Facility shall have access to licensed health care professionals who are trained and competent in marrow collection. | | | | |
| 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. | | | | | | |
| **B3.7** | NURSES | | | | | | |
| B3.7.1 | The Clinical Program shall have nurses formally trained and experienced in the management of 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. | | | | | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| B3.7.3 | Nurses shall have received specific training and maintain competence in the transplant-related skills that they routinely practice including: | | | | | | |
| B3.7.3.1 | Hematology/oncology patient care, including an overview of the cellular therapy process. | | | | | | |
| B3.7.3.2 | Administration of preparative regimens. | | | | | | |
| B3.7.3.3 | Administration of blood products, growth factors, cellular therapy products, and other supportive therapies. | | | | | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| 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. | | | | | | |
| B3.7.3.5 | Recognition of cellular therapy complications and emergencies requiring rapid notification of the transplant team. | | | | | | |
| B3.7.3.6 | Palliative and end of life care. | | | | | | |
| B3.7.4 | There shall be written Standard Operating Procedures or guidelines for nursing procedures, including, but not limited to: | | | | | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| B3.7.4.1 | Care of immunocompromised recipients. | | | | | | |
| B3.7.4.2 | Age-specific considerations. | | | | | | |
| B3.7.4.3 | Administration of preparative regimens. | | | | | | |
| B3.7.4.4 | Administration of cellular therapy products. | | | | | | |
| B3.7.4.5 | Administration of blood products. | | | | | | |
| B3.7.4.6 | Cental venous access device care. | | | | | | |
| 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. | | | | | | |
| B3.7.5 | There shall be an adequate number of nurses experienced in the care of transplant recipients. | | | | | | |
| B3.7.6 | There shall be a nurse/recipient ratio satisfactory to manage the severity of the recipients' clinical status. | | | | | | |
| **B3.8** | PHARMACISTS | | | | | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| 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. | | | | | | |
| B3.8.2 | Training and knowledge of designated pharmacists shall include: | | | | | | |
| B3.8.2.1 | Hematology/oncology patient care, including the process of cellular therapy. | | | | | | |
| B3.8.2.2 | Adverse events including, but not limited to, cytokine release syndrome and neurological toxicities. | | | | | | |
| B3.8.2.3 | Therapeutic drug monitoring, including, but not limited to, anti-infective agents, immunosuppressive agents, anti-seizure medications, and anticoagulants. | | | | | | |
| B3.8.2.4 | Monitoring for and recognition of drug/drug and drug/food interactions and necessary dose modifications. | | | | | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| B3.8.2.5 | Recognition of medications that require adjustment for organ dysfunction. | | | | | | |
| 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. | | | | | | |
| B3.8.4 | Designated pharmacists shall participate in a minimum of ten (10) hours of educational activities related to cellular therapy annually. | | | | | | |
| 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. | | | | | | |
| **B3.9** | CONSULTING SPECIALISTS | | | | | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| 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: | | | | | | |
| B3.9.1.1 | Surgery. | | | | | | |
| B3.9.1.2 | Pulmonary medicine. | | | | | | |
| B3.9.1.3 | Intensive care. | | | | | | |
| B3.9.1.4 | Gastroenterology. | | | | | | |
| B3.9.1.5 | Nephrology. | | | | | | |
| B3.9.1.6 | Infectious disease. | | | | | | |
| B3.9.1.7 | Cardiology. | | | | | | |
| B3.9.1.8 | Pathology. | | | | | | |
| B3.9.1.9 | Psychiatry. | | | | | | |
| B3.9.1.10 | Radiology. | | | | | | |
| 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. | | | | | | |
| B3.9.1.12 | Transfusion medicine. | | | | | | |
| B3.9.1.13 | Neurology. | | | | | | |
| B3.9.1.14 | Ophthalmology. | | | | | | |
| B3.9.1.15 | Obstetrics/Gynecology. | | | | | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| B3.9.1.16 | Dermatology. | | | | | | |
| B3.9.1.17 | Palliative and end of life care. | | | | | | |
| 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. | | | | | | |
| **B3.10** | QUALITY MANAGER | **M3.2** | QUALITY MANAGER | **C3.3** | QUALITY MANAGER | **D3.3** | QUALITY MANAGER |
| 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. | 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. | 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. | 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. |
| B3.10.2 | The Clinical Program Quality Manager should have a reporting structure independent of cellular therapy product manufacturing. | M3.2.2 | The Marrow Collection Facility 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. | D3.3.2 | The Processing Facility Quality Manager should have a reporting structure independent of cellular therapy product manufacturing. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| 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. | 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. | 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. | 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. |
| B3.10.3.1 | 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. | C3.3.3.1 | 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. |
| **B3.11** | SUPPORT SERVICES STAFF | **M3.3** | STAFF | **C3.4** | STAFF | **D3.4** | STAFF |
| | | 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. | 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. | 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. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| | | 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. | 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. | | |
| 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: | | | | | | |
| B3.11.1.1 | Dietary staff. | | | | | | |
| B3.11.1.2 | Social Services staff. | | | | | | |
| B3.11.1.3 | Psychology Services staff. | | | | | | |
| B3.11.1.4 | Physical Therapy staff. | | | | | | |
| B3.11.1.5 | Data Management staff sufficient to comply with B9. | | | | | | |
| **B4** | QUALITY MANAGEMENT | **M4** | QUALITY MANAGEMENT | **C4** | QUALITY MANAGEMENT | **D4** | QUALITY MANAGEMENT |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| B4.1 | There shall be an overall Quality Management Program that incorporates key performance data from clinical, collection, and processing facility quality management. | M4.1 | The Marrow Collection Facility shall comply with B4 if it operates independently of a Clinical Program. | C4.1 | There shall be a Quality Management Program that incorporates key performance data. | D4.1 | There shall be a Quality Management Program that incorporates key performance data. |
| 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. | | | 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. | 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. |
| B4.18 | The Clinical Program Director or designee shall annually review the effectiveness of the overall Quality Management Program. | | | C4.18 | The Apheresis Collection Facility Director or designee shall annually review the effectiveness of the Quality Management Program. | D4.18 | The Processing Facility Director or designee shall annually review the effectiveness of the Quality Management Program. |
| B4.2 | The Clinical Program shall establish and maintain a written Quality Management Plan. | | | C4.2 | The Apheresis Collection Facility shall establish and maintain a written Quality Management Plan. | D4.2 | The Processing Facility shall establish and maintain a written Quality Management Plan. |
| B4.2.1 | The Clinical Program Director or designee shall be responsible for the Quality Management Plan. | | | 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. | D4.2.1 | The Processing Facility Director or designee shall be responsible for the Quality Management Plan as it pertains to the Processing Facility. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| 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. | | | 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. | 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. |
| 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. | | | 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. | D4.3 | The Quality Management Plan shall include, or summarize and reference, an organizational chart of key positions and functions within the Processing Facility. |
| B4.3.1 | 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. | D4.3.1 | The Quality Management Plan shall include a description of how these key positions interact to implement the Quality Management activities. |
| 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: | | | 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: | 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: |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| B4.4.1 | A current job description for all staff. | | | C4.4.1 | A current job description for all staff. | D4.4.1 | A current job description for all staff. |
| B4.4.2 | A system to document the following for all staff: | | | C4.4.2 | A system to document the following for all staff: | D4.4.2 | A system to document the following for all staff: |
| B4.4.2.1 | Initial qualifications. | | | C4.4.2.1 | Initial qualifications. | D4.4.2.1 | Initial qualifications. |
| B4.4.2.2 | New employee orientation. | | | C4.4.2.2 | New employee orientation. | D4.4.2.2 | New employee orientation. |
| B4.4.2.3 | Initial training, competency, and retraining when appropriate for all procedures performed. | | | C4.4.2.3 | Initial training, competency, and retraining when appropriate for all procedures performed. | D4.4.2.3 | Initial training, competency, and retraining when appropriate for all procedures performed. |
| B4.4.2.4 | Continued competency for each critical function performed, assessed annually at a minimum. | | | C4.4.2.4 | Continued competency for each critical function performed, assessed annually at a minimum. | D4.4.2.4 | Continued competency for each critical function performed, assessed annually at a minimum. |
| B4.4.2.5 | Continuing education. | | | C4.4.2.5 | Continuing education. | D4.4.2.5 | Continuing education. |
| B4.5 | The Quality Management Plan shall include, or summarize and reference, a comprehensive system for document control. | | | C4.5 | The Quality Management Plan shall include, or summarize and reference, a comprehensive system for document control. | D4.5 | The Quality Management Plan shall include, or summarize and reference, a comprehensive system for document control. |
| 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. | | | 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. | 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. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| 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: | | | 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: | 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: |
| B4.5.1.1 | Policies, protocols, Standard Operating Procedures, and guidelines. | | | C4.5.1.1 | Policies and Standard Operating Procedures. | D4.5.1.1 | Policies and Standard Operating Procedures. |
| B4.5.1.2 | Worksheets. | | | C4.5.1.2 | Worksheets. | D4.5.1.2 | Worksheets. |
| B4.5.1.3 | Forms. | | | C4.5.1.3 | Forms. | D4.5.1.3 | Forms. |
| B4.5.1.4 | Labels. | | | C4.5.1.4 | Labels. | D4.5.1.4 | Labels. |
| B4.5.3 | The document control system shall include: | | | C4.5.3 | The document control system shall include: | D4.5.3 | The document control system shall include: |
| B4.5.3.1 | A standardized format for critical documents. | | | C4.5.3.1 | A standardized format for critical documents. | D4.5.3.1 | A standardized format for critical documents. |
| B4.5.3.2 | Assignment of a numeric or alphanumeric identifier and a 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. | D4.5.3.2 | Assignment of a numeric or alphanumeric identifier and a title to each document and document version regulated within the system. |
| B4.5.3.3 | A system 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. | D4.5.3.3 | A system for document approval, including the approval date, signature of approving individual(s), and the effective date. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| B4.5.3.4 | 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. | D4.5.3.4 | A system to protect controlled documents from accidental or unauthorized modification. |
| B4.5.3.5 | Review of controlled documents every two (2) years at a minimum. | | | C4.5.3.5 | Review of controlled documents every two (2) years at a minimum. | D4.5.3.5 | Review of controlled documents every two (2) years at a minimum. |
| 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. | | | 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. | 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. |
| 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. | | | 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. | 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. |
| B4.5.3.8 | 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. | D4.5.3.8 | A system for the retraction of obsolete documents to prevent unintended use. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| 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. | | | 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. | 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. |
| 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. | | | 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. | 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. |
| 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. | | | 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. | 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. |
| B4.6.3 | Agreements shall be dated and reviewed on a regular basis, at a minimum every two (2) years. | | | C4.6.3 | Agreements shall be dated and reviewed on a regular basis, at a minimum every two (2) years. | D4.6.3 | Agreements shall be dated and reviewed on a regular basis, at a minimum every two (2) years. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| 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. | | | 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. | 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. |
| 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. | | | 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. | 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. |
| 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. | | | C4.7.2 | 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. |
| B4.7.3 | Review of outcome analysis and/or product efficacy shall include at a minimum: | | | | | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| B4.7.3.1 | For HPC products intended for hematopoietic reconstitution, time to engraftment following cellular therapy product administration. | | | 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. | 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. |
| B4.7.3.2 | For immune effector cells, an endpoint of clinical function as approved by the Clinical Program Director. | | | | | | |
| 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. | | | | | | |
| B4.7.3.4 | Acute GVHD grade within one hundred (100) days after allogeneic transplantation. | | | | | | |
| B4.7.3.5 | Chronic GVHD grade within one (1) year after allogeneic transplantation. | | | | | | |
| B4.7.3.6 | Central venous catheter infection. | | | | | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| 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. | | | | | | |
| 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. | | | | | | |
| 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. | | | | | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| 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. | | | | | | |
| 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. | | | 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. | 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. |
| 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. | | | 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. | 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. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| 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. | | | 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. | 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. |
| B4.8.3 | Audits shall include at a minimum: | | | C4.8.3 | Audits shall include at a minimum: | D4.8.3 | Audits shall include at a minimum: |
| | | | | C4.8.3.1 | Annual audit of documentation of interim assessment of donor suitability and eligibility prior to the start of the collection procedure. | | |
| B4.8.3.1 | Periodic audit of the accuracy of clinical data. | | | | | | |
| B4.8.3.4 | Annual audit of safety endpoints and immune effector cellular therapy toxicity management. | | | | | | |
| 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. | | | | | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| B4.8.3.2 | Annual audit of donor screening and testing. | | | C4.8.3.2 | Annual audit of documentation of donor eligibility determination prior to start of the collection procedure. | | |
| B4.8.3.6 | Annual audit of verification of chemotherapy drug administered against the written order. | | | | | | |
| B4.8.3.3 | Annual audit of management of cellular therapy products with positive microbial culture results. | | | C4.8.3.4 | Annual audit of documentation that external facilities performing critical contracted services have met the requirements of the written agreements. | D4.8.3.1 | Annual audits of documentation that external facilities performing critical contracted services have met the requirements of the written agreements. |
| B4.8.3.5 | Annual audit of 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. | D4.8.3.2 | Annual audits of management of cellular therapy products with positive microbial culture results. |
| B4.8.3.7 | Periodic audit of the prescription ordering system against the protocol. | | | | | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| 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: | | | 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: | 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: |
| | | | | | | D4.9.1 | Documentation and product labeling. |
| | | | | | | D4.9.2 | Product quarantine. |
| | | | | | | D4.9.3 | Criteria for cellular therapy product release. |
| | | | | | | D4.9.4 | Identification of individuals authorized to approve release, including the Processing Facility Medical Director at a minimum. |
| B4.9.1 | Criteria for the administration of cellular therapy products with positive microbial culture results. | | | | | | |
| B4.9.2 | Notification of the recipient. | | | C4.9.1 | Notification of the recipient's physician and any other facility in receipt of the cellular therapy product. | | |
| B4.9.3 | Recipient follow-up and outcome analysis. | | | | | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| B4.9.5 | Investigation of cause. | | | C4.9.2 | Investigation of cause. | D4.9.6 | Investigation of cause. |
| B4.9.4 | Follow-up of the donor, if relevant. | | | C4.9.3 | Follow-up of the donor, if relevant. | D4.9.5 | Notification of the recipient's physician, collection facility, and any other facility in receipt of the cellular therapy product. |
| B4.9.6 | Reporting to regulatory agencies, if appropriate. | | | C4.9.4 | Reporting to regulatory agencies, if appropriate. | D4.9.7 | Reporting to regulatory agencies, if appropriate. |
| 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: | | | 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: | 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: |
| B4.10.1 | Detection. | | | C4.10.1 | Detection. | D4.10.1 | Detection. |
| B4.10.2 | Investigation. | | | C4.10.2 | Investigation. | D4.10.2 | Investigation. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| 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. | | | 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. | 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. |
| B4.10.2.2 | Investigations shall identify the root cause and a plan for short- and long-term corrective and preventive 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. | D4.10.2.2 | Investigations shall identify the root cause and a plan for short- and long-term corrective and preventive actions as warranted. |
| B4.10.3 | Documentation. | | | C4.10.3 | Documentation. | D4.10.3 | Documentation. |
| 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. | | | 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. | 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. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| 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. | | | 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. | 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. |
| B4.10.3.3 | Cumulative files of occurrences shall be maintained. | | | C4.10.3.3 | Cumulative files of occurrences shall be maintained. | D4.10.3.3 | Cumulative files of occurrences shall be maintained. |
| 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. | | | 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. | 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. |
| B4.10.4 | Reporting. | | | C4.10.4 | Reporting. | D4.10.4 | Reporting. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| 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. | | | 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. | 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. |
| 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. | | | 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. | 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. |
| B4.10.5 | Corrective and preventive action. | | | C4.10.5 | Corrective and preventive action. | D4.10.5 | Corrective and preventive action. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| 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. | | | 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. | 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. |
| 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. | | | 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. | 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. |
| 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. | | | 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. | 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. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| 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. | | | 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. | 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. |
| 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. | | | 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. | 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. |
| B4.13.1 | Critical equipment, supplies, reagents, and facilities used for the marrow collection procedure shall be qualified. | | | | | | |
| | | | | C4.13.1 | 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. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| B4.13.2 | Qualification plans shall include minimum acceptance criteria for performance. | | | C4.13.2 | Qualification plans shall include minimum acceptance criteria for performance. | D4.13.2 | Qualification plans shall include minimum acceptance criteria for performance. |
| B4.13.3 | Qualification plans, results, and reports shall be reviewed and approved by the Quality Manager and Clinical Program 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. | D4.13.3 | Qualification plans, results, and reports shall be reviewed and approved by the Quality Manager and Processing Facility Director or designee. |
| B4.14 | The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for validation or verification of critical procedures. | | | C4.14 | The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for validation or verification of critical procedures. | D4.14 | The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for validation or verification of critical procedures. |
| B4.14.1 | Critical procedures to be validated shall include at least the following: marrow 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. | D4.14.1 | Critical procedures to be validated shall include at least the following: processing techniques, cryopreservation procedures, testing, labeling, storage, and distribution. |
| B4.14.2 | Each validation shall include at a minimum: | | | C4.14.2 | Each validation shall include at a minimum: | D4.14.2 | Each validation shall include at a minimum: |
| B4.14.2.1 | An approved validation plan, including conditions to be validated. | | | C4.14.2.1 | An approved validation plan, including conditions to be validated. | D4.14.2.1 | An approved validation plan, including conditions to be validated. |
| B4.14.2.2 | Acceptance criteria. | | | C4.14.2.2 | Acceptance criteria. | D4.14.2.2 | Acceptance criteria. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| B4.14.2.3 | Data collection. | | | C4.14.2.3 | Data collection. | D4.14.2.3 | Data collection. |
| B4.14.2.4 | Evaluation of data. | | | C4.14.2.4 | Evaluation of data. | D4.14.2.4 | Evaluation of data. |
| B4.14.2.5 | Summary of results. | | | C4.14.2.5 | Summary of results. | D4.14.2.5 | Summary of results. |
| B4.14.2.6 | References, if applicable. | | | C4.14.2.6 | References, if applicable. | D4.14.2.6 | References, if applicable. |
| 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. | | | 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. | 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. |
| B4.14.3 | Significant changes to critical procedures shall be validated and verified as appropriate. | | | C4.14.3 | Significant changes to critical procedures shall be validated and verified as appropriate. | D4.14.3 | Significant changes to critical procedures shall be validated and verified as appropriate. |
| 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. | | | 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. | 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. |
| B4.16 | The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for obtaining feedback. | | | C4.16 | The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for obtaining feedback. | D4.16 | The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for obtaining feedback. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| B4.16.1 | Feedback shall be obtained from associated Collection and Processing Facilities. | | | C4.16.1 | Feedback shall be obtained from associated Clinical Programs and Processing Facilities. | D4.16.1 | Feedback shall be obtained from associated Clinical Programs and Collection Facilities. |
| B4.16.2 | Feedback shall be obtained from donors and recipients or legally authorized representatives. | | | C4.16.2 | Feedback shall be obtained from donors or legally authorized representatives. | | |
| 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. | | | 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. | 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. |
| B4.17.1 | Meetings should have defined attendees, documented minutes, and assigned actions. | | | C4.17.1 | Meetings should have defined attendees, documented minutes, and assigned actions. | D4.17.1 | Meetings should have defined attendees, documented minutes, and assigned actions. |
| B4.17.2 | Key performance data and review findings shall be reported to staff. | | | C4.17.2 | Key performance data and review findings shall be reported to staff. | D4.17.2 | Key performance data and review findings shall be reported to staff. |
| 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. | | | 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. | 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. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| **B5** | POLICIES AND STANDARD OPERATING PROCEDURES | **M5** | POLICIES AND STANDARD OPERATING PROCEDURES | **C5** | POLICIES AND STANDARD OPERATING PROCEDURES | **D5** | POLICIES AND STANDARD OPERATING PROCEDURES |
| 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: | 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: | 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: | 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: |
| B5.1.1 | Recipient evaluation, selection, and treatment. | | | | | | |
| B5.1.2 | Donor and recipient confidentiality. | M5.1.1 | Donor and recipient confidentiality. | C5.1.1 | Donor and recipient confidentiality. | D5.1.1 | Donor and recipient confidentiality. |
| B5.1.3 | Donor and recipient consent. | M5.1.2 | Donor consent. | C5.1.2 | Donor consent. | | |
| B5.1.4 | Donor screening, testing, eligibility determination, selection, and management. | M5.1.3 | Donor screening, testing, eligibility determination, and management. | C5.1.3 | Donor screening, testing, eligibility determination, and management. | | |
| | | | | | | D5.1.2 | Cellular therapy product receipt. |
| | | | | | | D5.1.3 | Processing and process control. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| B5.1.5 | Management of donors who require central venous access. | | | C5.1.4 | Management of donors who require central venous access. | | |
| B5.1.6 | Administration of the preparative regimen. | | | | | | |
| | | M5.1.4 | Cellular therapy product collection. | C5.1.5 | Cellular therapy product collection. | | |
| B5.1.7 | Administration of blood products. | M5.1.5 | Administration of blood products. | C5.1.6 | Administration of blood products. | | |
| B5.1.8 | Administration of HPC and other cellular therapy products, including products under exceptional release. | | | | | | |
| 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. | | | | | 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. |
| B5.1.10 | Management of cytokine release syndrome and central nervous system toxicities. | | | | | | |
| | | M5.1.6 | Prevention of mix-ups and cross-contamination. | C5.1.7 | Prevention of mix-ups and cross-contamination. | D5.1.5 | Prevention of mix-ups and cross-contamination. |
| | | M5.1.7 | Labeling (including associated forms and samples). | C5.1.8 | Labeling (including associated forms and samples). | D5.1.6 | Labeling (including associated forms and samples). |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| B5.1.11 | Duration and conditions of cellular therapy product storage and indications for disposal. | | | | | D5.1.7 | Cryopreservation and thawing. |
| | | M5.1.8 | Cellular therapy product expiration dates. | C5.1.9 | Cellular therapy product expiration dates. | D5.1.8 | Cellular therapy product expiration dates. |
| | | M5.1.9 | Cellular therapy product storage. | C5.1.10 | Cellular therapy product storage. | D5.1.9 | Cellular therapy product storage to include alternative storage if the primary storage device fails. |
| | | M5.1.10 | Release and exceptional release. | C5.1.11 | Release and exceptional release. | D5.1.10 | Release and exceptional release. |
| | | M5.1.11 | 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. | D5.1.11 | Transportation and shipping, including methods and conditions within the Processing Facility and to and from external facilities. |
| | | | | | | D5.1.12 | Cellular therapy product recall, to include a description of responsibilities and actions to be taken, and notification of appropriate regulatory agencies. |
| | | | | | | D5.1.13 | Cellular therapy product disposal. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| | | M5.1.12 | Critical equipment, reagent, and supply management including recalls and corrective actions in the event of failure. | C5.1.13 | Critical reagent and supply management. | D5.1.14 | Critical reagent and supply management. |
| | | | | C5.1.14 | 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. |
| | | | | C5.1.15 | Recalls of equipment, supplies, and reagents. | D5.1.16 | Recalls of equipment, supplies, and reagents. |
| | | | | C5.1.16 | 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. |
| | | | | | | D5.1.18 | Environmental control to include a description of the environmental monitoring plan. |
| B5.1.12 | Hygiene and use of personal protective equipment and attire. | M5.1.13 | Hygiene and use of personal protective equipment and attire. | C5.1.17 | Hygiene and use of personal protective equipment and attire. | D5.1.19 | Hygiene and use of personal protective equipment and attire. |
| B5.1.13 | Disposal of medical and biohazard waste. | | | C5.1.18 | Disposal of medical and biohazard waste. | D5.1.20 | Disposal of medical and biohazard waste. |
| B5.1.14 | Cellular therapy emergency and disaster plan, including the Clinical Program response. | M5.1.14 | Cellular therapy emergency and disaster plan related to the marrow collection procedure. | C5.1.19 | Cellular therapy emergency and disaster plan, including the Apheresis Collection Facility response. | D5.1.21 | Cellular therapy emergency and disaster plan, including the Processing Facility response. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| B5.2 | The Clinical Program shall maintain a detailed list of all controlled documents including title and identifier. | M5.2 | The Marrow Collection Facility shall comply with B5.2 if it operates independently of a Clinical Program. | C5.2 | The Apheresis Collection Facility shall maintain a detailed list of all controlled documents, including title and identifier. | D5.2 | The Processing Facility shall maintain a detailed list of all controlled documents, including title and identifier. |
| 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: | 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: | 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: | 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: |
| B5.3.1 | A clearly written description of the objectives. | M5.3.1 | A clearly written description of the objectives. | C5.3.1 | A clearly written description of the objectives. | D5.3.1 | A clearly written description of the objectives. |
| B5.3.2 | A description of equipment and supplies used. | M5.3.2 | A description of equipment and supplies used. | C5.3.2 | A description of equipment and supplies used. | D5.3.2 | A description of equipment and supplies used. |
| B5.3.3 | Acceptable end-points and the range of expected results. | M5.3.3 | Acceptable end-points and the range of expected results. | C5.3.3 | Acceptable end-points and the range of expected results. | D5.3.3 | Acceptable end-points and the range of expected results. |
| B5.3.4 | A stepwise description of the procedure. | M5.3.4 | A stepwise description of the procedure. | C5.3.4 | A stepwise description of the procedure. | D5.3.4 | A stepwise description of the procedure. |
| B5.3.6 | Age-specific issues where relevant. | M5.3.5 | Age-specific issues where relevant. | C5.3.5 | Age-specific issues where relevant. | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| B5.3.5 | 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. | C5.3.6 | 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. |
| B5.3.7 | A reference section listing appropriate and current literature. | M5.3.7 | A reference section listing appropriate and current literature. | C5.3.7 | A reference section listing appropriate and current literature. | D5.3.6 | A reference section listing appropriate and current literature. |
| 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. | M5.3.8 | Documented approval of each procedure by the Marrow Collection Facility Medical Director prior to implementation and every two (2) 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. | 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. |
| B5.3.9 | Documented approval of each procedural modification by the Clinical Program 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. | C5.3.9 | Documented approval of each procedural modification by the Apheresis Collection 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. |
| B5.3.10 | 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. | C5.3.10 | 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. |
| B5.4 | Controlled documents 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. | C5.4 | Controlled documents 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. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| B5.5 | Staff training and, if appropriate, competency shall be documented before performing a new or revised Standard Operating Procedure or guideline. | M5.5 | Staff training and, if appropriate, competency shall be documented before performing a new or revised Standard Operating Procedure. | C5.5 | Staff training and, if appropriate, competency shall be documented before performing a new or revised Standard Operating Procedure. | D5.5 | Staff training and, if appropriate, competency shall be documented before performing a new or revised Standard Operating Procedure. |
| B5.6 | All personnel shall follow the policies and Standard Operating Procedures related to their positions. | M5.6 | All personnel shall follow the policies and Standard Operating Procedures related to their positions. | C5.6 | All personnel shall follow the policies and Standard Operating Procedures related to their positions. | D5.6 | All personnel shall follow the policies and Standard Operating Procedures related to their positions. |
| B5.7 | Planned deviations shall be pre-approved by the Clinical Program 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. | C5.7 | Planned deviations shall be pre-approved by the Apheresis Collection 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. |
| B6 | ALLOGENEIC AND AUTOLOGOUS DONOR SELECTION, EVALUATION, AND MANAGEMENT | M6 | ALLOGENEIC AND AUTOLOGOUS DONOR EVALUATION AND MANAGEMENT | C6 | ALLOGENEIC AND AUTOLOGOUS DONOR EVALUATION AND MANAGEMENT | | |
| B6.1 | There shall be written criteria for allogeneic and autologous donor selection, 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. | C6.1 | There shall be written criteria for allogeneic and autologous donor evaluation and management by trained medical personnel. | | |
| B6.1.1 | Written criteria shall include criteria for the selection of allogeneic donors who are minors or older donors. | | | | | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| B6.1.2 | Written criteria shall include criteria for the selection of allogeneic donors when more than one (1) donor is available and suitable. | | | | | | |
| B6.1.3 | Information regarding the donation process should be provided to the potential allogeneic donor prior to HLA typing. | | | | | | |
| B6.2 | ALLOGENEIC AND AUTOLOGOUS DONOR INFORMATION AND CONSENT TO DONATE | M6.2 | ALLOGENEIC AND AUTOLOGOUS DONOR INFORMATION AND CONSENT FOR COLLECTION | C6.2 | ALLOGENEIC AND AUTOLOGOUS DONOR INFORMATION AND CONSENT FOR COLLECTION | | |
| B6.2.1 | 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: | C6.2.1 | The collection procedure shall be explained in terms the donor can understand, and shall include the following information at a minimum: | | |
| B6.2.1.1 | The risks and benefits of the procedure. | M6.2.1.1 | The risks and benefits of the procedure. | C6.2.1.1 | The risks and benefits of the procedure. | | |
| B6.2.1.2 | 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. | C6.2.1.2 | Tests and procedures performed on the donor to protect the health of the donor and the recipient. | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| 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. | 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. | 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. | | |
| B6.2.1.4 | Alternative collection methods. | | | | | | |
| B6.2.1.5 | Protection of medical information and confidentiality. | M6.2.1.4 | Protection of medical information and confidentiality. | C6.2.1.4 | Protection of medical information and confidentiality. | | |
| B6.2.2 | 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. | C6.2.2 | Interpretation and translation shall be performed by individuals qualified to provide these services in the clinical setting. | | |
| B6.2.3 | 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. | C6.2.3 | Family members and legally authorized representatives should not serve as interpreters or translators. | | |
| B6.2.4 | The donor shall have an opportunity to ask questions. | M6.2.4 | The donor shall have an opportunity to ask questions. | C6.2.4 | The donor shall have an opportunity to ask questions. | | |
| B6.2.5 | The donor shall have the right to refuse to donate or withdraw consent. | M6.2.5 | The donor shall have the right to refuse to donate or withdraw consent. | C6.2.5 | The donor shall have the right to refuse to donate or withdraw consent. | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| 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. | 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. | 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. | | |
| 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. | 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. | 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. | | |
| 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. | 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. | 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. | | |
| 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. | 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. | 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. | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| 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. | 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. | 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. | | |
| 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. | | | | | | |
| B6.2.10 | Documentation of consent shall be available to the 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. | C6.2.9 | Documentation of consent shall be verified by the Apheresis Collection Facility staff prior to the collection procedure. | | |
| B6.3 | ALLOGENEIC AND AUTOLOGOUS DONOR SUITABILITY FOR CELLULAR THERAPY PRODUCT COLLECTION | M6.3 | ALLOGENEIC AND AUTOLOGOUS DONOR SUITABILITY FOR CELLULAR THERAPY PRODUCT COLLECTION | C6.3 | ALLOGENEIC AND AUTOLOGOUS DONOR SUITABILITY FOR CELLULAR THERAPY PRODUCT COLLECTION | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| 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. | 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. | 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. | | |
| 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. | 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. | 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. | | |
| 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. | 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. | 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. | | |
| B6.3.1.3 | 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. | C6.3.1.3 | Autologous donors shall be tested as required by applicable laws and regulations. | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| B6.3.2 | The risks of donation shall be evaluated and documented, including: | M6.3.2 | The risks of donation shall be evaluated and documented, including anesthesia for marrow collection. | C6.3.2 | The risks of donation shall be evaluated and documented, including: | | |
| B6.3.2.1 | Possible need for central venous access. | | | C6.3.2.1 | Possible need for central venous access. | | |
| B6.3.2.2 | Mobilization for collection of HPC, Apheresis. | | | C6.3.2.2 | Mobilization for collection of HPC, Apheresis. | | |
| B6.3.2.3 | Anesthesia for collection of HPC, Marrow. | | | | | | |
| B6.3.3 | The donor shall be evaluated for the risk of hemoglobinopathy prior to administration of the mobilization regimen. | M6.3.3 | The donor shall be evaluated for the risk of hemoglobinopathy prior to administration of the mobilization regimen, if utilized. | C6.3.3 | The donor shall be evaluated for the risk of hemoglobinopathy prior to administration of the mobilization 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. | 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. | 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. | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| 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. | 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. | 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. | | |
| 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. | 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. | 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. | | |
| 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. | 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. | 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. | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| 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. | 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. | 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. | | |
| 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. | 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. | 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. | | |
| B6.4 | ADDITIONAL REQUIREMENTS FOR ALLOGENEIC DONORS | M6.4 | ADDITIONAL REQUIREMENTS FOR ALLOGENEIC DONORS | C6.4 | ADDITIONAL REQUIREMENTS FOR ALLOGENEIC DONORS | | |
| 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. | 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. | 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. | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| B6.4.2 | Allogeneic donor infectious disease testing shall be performed using licensed 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. | C6.4.2 | Allogeneic donor infectious disease testing shall be performed using licensed donor screening tests approved or cleared by the governmental authority. | | |
| 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. | | | | | | |
| B6.4.4 | A red cell antibody screen shall be performed on allogeneic recipients. | | | | | | |
| 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. | | | | | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| B6.4.6 | The medical history for allogeneic donors shall include at least the following: | 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. | 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. | | |
| B6.4.6.1 | Vaccination history. | | | | | | |
| B6.4.6.2 | Travel history. | | | | | | |
| B6.4.6.3 | Blood transfusion history. | | | | | | |
| B6.4.6.4 | Questions to identify persons at high risk for transmission of communicable disease as defined by the applicable governmental authority. | | | | | | |
| B6.4.6.5 | Questions to identify persons at risk of transmitting inherited conditions. | | | | | | |
| B6.4.6.6 | Questions to identify persons at risk of transmitting a hematological or immunological disease. | | | | | | |
| B6.4.6.7 | Questions to identify a past history of malignant disease. | | | | | | |
| B6.4.6.8 | The allogeneic donor shall confirm that all the information provided is true to the best of his/her knowledge. | | | | | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| | | 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. | 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. | | |
| 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: | | | | | | |
| B6.4.7.1 | Human immunodeficiency virus, type 1. | | | | | | |
| B6.4.7.2 | Human immunodeficiency virus, type 2. | | | | | | |
| B6.4.7.3 | Hepatitis B virus. | | | | | | |
| B6.4.7.4 | Hepatitis C virus. | | | | | | |
| B6.4.7.5 | Treponema pallidum (syphilis). | | | | | | |
| 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: | | | | | | |
| B6.4.8.1 | Human T cell lymphotropic virus I. | | | | | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| B6.4.8.2 | Human T cell lymphotropic virus II. | | | | | | |
| B6.4.8.3 | West Nile Virus. | | | | | | |
| B6.4.8.4 | Trypanosoma cruzi (Chagas Disease). | | | | | | |
| 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. | | | | | | |
| 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. | | | | | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| 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. | | | | | | |
| B6.4.10 | Allogeneic donors shall be tested for Cytomegalovirus (unless previously documented to be positive). | | | | | | |
| B6.4.11 | Additional tests shall be performed as required to assess the possibility of transmission of other infectious and non-infectious diseases. | | | | | | |
| | | 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. | 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. | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| 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. | | | | | | |
| B6.4.12.1 | DNA high resolution molecular typing shall be used for HLA typing. | | | | | | |
| 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. | | | | | | |
| 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. | | | | | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| B6.4.12.4 | There shall be a policy or Standard Operating Procedure for anti-HLA antibody testing for mismatched donors and recipients. | | | | | | |
| 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. | | | 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. | | |
| B6.4.14 | 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. | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| 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. | | | 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. | D8.3.3 | For ineligible donors or donors for whom eligibility determination is incomplete, documentation of urgent medical need and physician approval for use. |
| B6.4.16 | Allogeneic donor eligibility shall be communicated in writing to the Collection and Processing Facilities. | | | C6.4.9 | Allogeneic donor eligibility shall be communicated in writing to the Processing Facility. | | |
| B6.4.17 | There shall be a policy for the creation and retention of allogeneic donor records. | | | C6.5 | There shall be policies covering the creation and retention of donor records including at a minimum: | | |
| | | | | C6.5.1 | Donor identification including at least name and date of birth. | | |
| | | | | C6.5.2 | Age, gender, and medical history, and, for allogeneic donors, behavioral history. | | |
| | | | | C6.5.3 | Consent to donate. | | |
| | | | | C6.5.4 | Results of laboratory testing. | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| 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. | | | C6.5.5 | Allogeneic donor eligibility determination, including the name of the responsible person who made the determination and the date of the determination. | | |
| | | | | | | D6 | EQUIPMENT, SUPPLIES, AND REAGENTS |
| | | | | | | 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. |
| | | | | | | 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: |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| | | 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. | 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. | 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. |
| | | | | | | 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. |
| | | | | | | 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. |
| | | 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. | 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. | 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. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| | | | | | | D6.2.4.1 | Reagents shall undergo initial qualification for the intended use. |
| | | | | | | D6.2.4.2 | Where there are no suitable clinical or pharmaceutical grade reagents available, reagents shall undergo lot-to-lot functional verification. |
| | | | | | | 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. |
| | | | | | | D6.2.5 | Cleaning and sterilizing of non-disposable supplies or instruments using a procedure verified to remove infectious agents and other contaminants. |
| | | | | | | D6.2.6 | Use of supplies and reagents in a manner consistent with manufacturer instructions. |
| | | | | | | D6.2.7 | Process to prevent the use of expired reagents and supplies. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| | | | | | | 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. |
| | | | | | | 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. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| | | | | 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. | D6.5 | The equipment shall be inspected for cleanliness and verified to be in compliance with the maintenance schedule prior to use. |
| | | | | | | 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. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| | | | | 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. | 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. |
| | | | | 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. | 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. |
| | | | | | | D6.7 | There shall be a Standard Operating Procedure that addresses the actions to take in the event of equipment malfunction or failure. |
| | | M8.3 | Equipment for the marrow collection procedure shall conform to applicable laws and regulations. | C8.4 | Equipment shall conform to applicable laws and regulations. | D6.8 | Equipment shall conform to applicable laws and regulations. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| | | | | | | D6.9 | Lot numbers, expiration dates, manufacturers of critical reagents and supplies, and key equipment used in each procedure shall be documented. |
| | | M8.2 | There shall be a process for inventory control that encompasses equipment, supplies, reagents, and labels. | C8.2 | There shall be a process for inventory control that encompasses equipment, supplies, reagents, and labels. | 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: |
| | | 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. | 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. | D6.10.1 | A system to uniquely identify and track all critical reagents and supplies used to manufacture cellular therapy products. |
| | | | | | | D6.10.2 | A system to identify each cellular therapy product for which each critical reagent or supply was used. |
| | | | | | | D6.10.3 | A system to maintain adequate stocks of reagents and supplies for the procedures to be performed. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| | | **M7** | CODING AND LABELING OF CELLULAR THERAPY PRODUCTS | **C7** | CODING AND LABELING OF CELLULAR THERAPY PRODUCTS | **D7** | CODING AND LABELING OF CELLULAR THERAPY PRODUCTS |
| | | **M7.1** | ISBT 128 AND EUROCODE CODING AND LABELING | **C7.1** | ISBT 128 AND EUROCODE CODING AND LABELING | **D7.1** | ISBT 128 AND EUROCODE CODING AND LABELING |
| | | M7.1.1 | Cellular therapy products shall be identified by name according to ISBT 128 standard terminology or Eurocode. | C7.1.1 | Cellular therapy products shall be identified by name according to ISBT 128 standard terminology or Eurocode. | D7.1.1 | Cellular therapy products shall be identified by name according to ISBT 128 standard terminology or Eurocode. |
| | | M7.1.2 | Coding and labeling technologies shall be implemented using ISBT 128 or Eurocode. | C7.1.2 | Coding and labeling technologies shall be implemented using ISBT 128 or Eurocode. | D7.1.2 | Coding and labeling technologies shall be implemented using ISBT 128 or Eurocode. |
| | | **M7.2** | LABELING OPERATIONS | **C7.2** | LABELING OPERATIONS | **D7.2** | LABELING OPERATIONS |
| | | 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. | 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. | 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. |
| | | M7.2.1.1 | 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. | D7.2.1.1 | Stocks of unused labels representing different cellular therapy products shall be stored in a controlled manner to prevent errors. |
| | | M7.2.1.2 | Obsolete labels shall be restricted from use. | C7.2.1.2 | Obsolete labels shall be restricted from use. | D7.2.1.2 | Obsolete labels shall be restricted from use. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| | | 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. | 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. | 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. |
| | | 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. | 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. | 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. |
| | | M7.2.4 | A system for label version control shall be employed. | C7.2.4 | A system for label version control shall be employed. | D7.2.4 | A system for label version control shall be employed. |
| | | 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. | 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. | 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. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| | | M7.2.5 | 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. | D7.2.5 | A system of checks in labeling procedures shall be used to prevent errors in transferring information to labels. |
| | | 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. | 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. | 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. |
| | | 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. | 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. | 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. |
| | | 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. | 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. | 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. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| | | 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. | 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. | 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. |
| | | M7.2.8 | 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. | D7.2.8 | Labeling elements required by applicable laws and regulations shall be present. |
| | | M7.2.9 | All data fields on labels shall be completed. | C7.2.9 | All data fields on labels shall be completed. | D7.2.9 | All data fields on labels shall be completed. |
| | | M7.2.10 | 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. | D7.2.10 | All labeling shall be clear, legible, and completed using ink that is indelible to all relevant agents. |
| | | 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. | 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. | 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. |
| | | M7.2.12 | 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. | D7.2.12 | The label shall be validated as reliable for storage under the conditions in use. |
| | | **M7.3** | PRODUCT IDENTIFICATION | **C7.3** | PRODUCT IDENTIFICATION | **D7.3** | PRODUCT IDENTIFICATION |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| | | 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. | 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. | 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. |
| | | M7.3.1.1 | The cellular therapy product, product samples, 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. | D7.3.1.1 | The cellular therapy product, product samples, concurrent plasma, and concurrently collected samples shall be labeled with the same identifier. |
| | | 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. | 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. | 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. |
| | | | | C7.3.1.3 | 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. |
| | | M7.3.1.3 | Supplementary identifiers shall not obscure the original identifier. | C7.3.1.4 | Supplementary identifiers shall not obscure the original identifier. | D7.3.1.4 | Supplementary identifiers shall not obscure the original identifier. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| | | M7.3.1.4 | The facility associated with each identifier shall be named in the documents to accompany the cellular therapy product. | C7.3.1.5 | The facility associated with each identifier shall be named in the documents to accompany the cellular therapy product. | D7.3.1.5 | The facility associated with each identifier shall be named in the documents to accompany the cellular therapy product. |
| | | | | | | D7.3.1.6 | If the original identifier is replaced, documentation shall link the new identifier to the original. |
| | | **M7.4** | LABEL CONTENT | **C7.4** | LABEL CONTENT | **D7.4** | LABEL CONTENT |
| | | 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. | 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. | 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. |
| | | 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. | C7.4.2 | Labeling at the end of collection shall occur before the cellular therapy product bag is disconnected from the donor. | 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. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| | | 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. | 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. | 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. |
| | | 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.” | 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.” | 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.” |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| | | 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. | 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. | | |
| | | | | | | 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. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| | | 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. | 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. | 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. |
| | | 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. | 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. | 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. |
| | | M7.4.8 | 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.” | D7.4.8 | Cellular therapy products distributed for nonclinical purposes shall be labeled with the statement, “For Nonclinical Use Only.” |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| B7 | RECIPIENT CARE | | | | | | |
| 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. | | | | | | |
| B7.1.1 | The Clinical Program shall provide information regarding the risks and benefits of the proposed cellular therapy. | | | | | | |
| 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. | | | | | | |
| 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. | | | | | | |
| B7.3 | Records shall be made concurrently with each step of recipient care in such a way that all steps may be accurately traced. | | | | | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| B7.3.1 | Records shall identify the person immediately responsible for each significant step, including dates and times (where appropriate) of various steps. | | | | | | |
| B7.4 | There shall be policies addressing safe administration of the preparative regimen. | | | | | | |
| 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. | | | | | | |
| 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. | | | | | | |
| 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. | | | | | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| 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: | | | | | | |
| B7.4.4.1 | The drug and dose in the bag or pill against the orders and the protocol or standardized regimen. | | | | | | |
| | | **M8** | PROCESS CONTROLS | **C8** | PROCESS CONTROLS | **D8** | PROCESS CONTROLS |
| | | M8.1 | Collection of cellular therapy products shall be performed according to written Standard Operating Procedures. | C8.1 | Collection of cellular therapy products shall be performed according to written Standard Operating Procedures. | | |
| | | 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. | 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. | D8.1 | There shall be a process for controlling and monitoring the manufacturing of cellular therapy products so that products meet predetermined release specifications. |
| | | M8.4.1 | Allogeneic blood components administered to the donor during marrow collection should be irradiated prior to transfusion. | C8.5.1 | Allogeneic blood components administered to the donor during apheresis collection should be irradiated prior to transfusion. | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| B6.3.7 | There shall be a written order from a physician specifying, at a minimum, anticipated date and goals of collection and processing. | M8.5 | There shall be a written order from a physician specifying, at a minimum, anticipated date 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. | | |
| | | | | 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. | | |
| | | M8.6 | There shall be peripheral blood count criteria to proceed with collection. | C8.8 | There shall be peripheral blood count criteria to proceed with collection. | | |
| | | 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. | 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. | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| | | 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. | 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. | | |
| | | M8.8 | General or regional anesthesia, if required, shall be performed or supervised by a licensed, specialist-certified anesthesiologist. | | | | |
| | | | | C8.10 | If required, central venous catheters shall be placed by a licensed health care professional qualified to perform the procedure. | | |
| | | | | C8.10.1 | Adequacy of central line placement shall be verified by the Apheresis Collection Facility prior to initiating the collection procedure. | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| | | 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. | 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. | | |
| | | M8.12 | 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. | | |
| | | M8.13 | Cellular therapy products shall be packaged in a closed sterile transfer pack appropriate for blood or marrow products. | C8.15 | Cellular therapy products shall be packaged in a closed sterile transfer pack appropriate for blood products. | | |
| | | 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. | | | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| | | | | | | 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. |
| | | | | | | 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. |
| | | | | | | 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. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| | | | | | | D8.1.2.2 | Samples obtained for testing shall be representative of the cellular therapy product to be evaluated. |
| | | | | | | D8.1.3 | There shall be the establishment of appropriate and validated assays and test procedures for the evaluation of cellular therapy products. |
| | | | | | | D8.1.3.1 | For all cellular therapy products, a total nucleated cell count and viability measurement shall be performed. |
| | | | | | | D8.1.3.2 | For HPC products intended for restoration of hematopoiesis, an assay measuring viable CD34 shall be performed. |
| | | | | | | 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. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| | | | | | | D8.1.4 | For tests required by these Standards performed within the Processing Facility: |
| | | | | | | D8.1.4.1 | There shall be a process for monitoring the reliability, accuracy, precision, and performance of laboratory test procedures and instruments. |
| | | | | | | 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. |
| | | | | | | 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. |
| | | | | | | D8.1.4.4 | Function checks shall be performed for testing instruments prior to testing donor, recipient, or cellular therapy product samples. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| | | | | | | 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. |
| | | | | | | 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. |
| | | | | | | 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. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| | | | | | | 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. |
| | | | | | | D8.1.8 | Notification of the recipient's physician of nonconforming cellular therapy products and approval for their release shall be documented. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| | | | | | | 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. |
| | | | | | | D8.3 | For allogeneic cellular therapy products, information required by the Processing Facility prior to distribution of the product shall include: |
| | | | | | | D8.3.1 | A statement of donor eligibility. |
| | | | | | | D8.3.2 | For ineligible donors, the reason for their ineligibility. |
| | | M8.10.2 | Methods for collection shall employ procedures validated to result in acceptable cell viability, sterility, and recovery. | C8.12.2 | Methods for collection shall employ procedures validated to result in acceptable cell viability, sterility, and recovery. | D8.4 | Processing procedures shall be validated in the Processing Facility and documented to result in acceptable target cell viability and recovery. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| | | | | | | D8.4.1 | Published validated processes shall be verified within the Processing Facility prior to implementation. |
| | | | | | | D8.4.2 | The Processing Facility shall use validated methods for preparation of cellular therapy products for administration. |
| B7.6.3.1 | 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. |
| B7.6.3.2 | 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. |
| | | | | | | 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. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| | | | | | | 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. |
| | | | | | | D8.5 | Critical control points and associated assays shall be identified and performed on each cellular therapy product as defined in Standard Operating Procedures. |
| | | M8.11 | 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. | 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. |
| | | | | | | 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. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| | | | | | | D8.6.2 | The effectiveness of measures to avoid contamination and cross-contamination shall be verified and monitored. |
| | | | | | | D8.7 | The Processing Facility shall monitor and document microbial contamination of cellular therapy products after processing as specified in Standard Operating Procedures. |
| | | | | | | D8.7.1 | The results of microbial cultures shall be reviewed by the Processing Facility Director or designee in a timely manner. |
| | | | | | | D8.7.2 | The recipient's physician shall be notified in a timely manner of any positive microbial cultures. |
| | | 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. | 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. | D8.8 | Records shall be made concurrently with each step of the processing, testing, cryopreservation, storage, and administration or disposal/disposition/distributio n of each cellular therapy product in such a way that all steps may be accurately traced. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| | | M8.15.1 | 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. | D8.8.1 | Records shall identify the person immediately responsible for each significant step, including dates and times, where appropriate. |
| | | | | | | D8.8.2 | Records shall show the test results and the interpretation of each result, where appropriate. |
| | | | | | | D8.9 | The Processing Facility Director or designee shall review the processing record for each cellular therapy product prior to release or distribution. |
| | | | | | | 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. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| | | | | | | 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. |
| | | | | | | D8.11.1 | The Processing Facility shall adhere to GMP appropriate for the degree of cellular therapy product manipulation. |
| | | | | | | D8.12 | For allogeneic cellular therapy products containing red blood cells at the time of administration: |
| | | | | | | 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. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| | | | | | | D8.12.2 | Results for a red cell antibody screen on the recipient shall be available. |
| | | | | | | 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. |
| | | | | | | D8.14 | One or more samples representing the cryopreserved cellular therapy product shall be stored. |
| | | | | | | D8.14.1 | Sample(s) from cryopreserved cellular therapy products shall be stored under conditions that achieve a valid representation of the clinical product. |
| | | | | | | D8.14.2 | Cryopreserved samples shall be retained according to institutional Standard Operating Procedures. |
| B7.4.4.2 | The identity of the recipient. | | | | | | |
| B7.5 | There shall be policies addressing safe administration of radiation therapy. | | | | | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| 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. | | | | | | |
| 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. | | | | | | |
| 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. | | | | | | |
| 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. | | | | | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| B7.5.5 | A final report of the details of the radiation therapy administered shall be documented in the recipient's medical record. | | | | | | |
| B7.6 | There shall be policies addressing safe administration of cellular therapy products. | | | | | | |
| B7.6.1 | There shall be policies for determining the appropriate volume and the appropriate dose of red blood cells, cryoprotectants, and other additives. | | | | | | |
| B7.6.2 | There shall be policies for the infusion of ABO-incompatible red cells in allogeneic cellular therapy products. | | | | | | |
| B7.6.3 | There shall be consultation with the Processing Facility regarding cord blood preparation for administration. | | | | | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| 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. | | | | | | |
| 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. | | | | | | |
| 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. | | | | | | |
| B7.6.7 | A circular of information for cellular therapy products shall be available to staff. | | | | | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| 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: | | | | | | |
| B7.7.1 | Management of nausea, vomiting, pain and other discomforts. | | | | | | |
| B7.7.2 | Monitoring of blood counts and transfusion of blood products. | | | | | | |
| B7.7.3 | Monitoring of infections and use of antimicrobials. | | | | | | |
| B7.7.4 | Monitoring of organ dysfunction or failure and institution of treatment. | | | | | | |
| B7.7.5 | Monitoring of graft failure and institution of treatment. | | | | | | |
| B7.7.6 | Regular assessment for evidence of acute GVHD using an established staging and grading system. | | | | | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| B7.7.7 | Regular assessment for evidence of chronic GVHD using an established staging and grading system. | | | | | | |
| B7.9 | There should be policies or Standard Operating Procedures in place for post-transplant vaccination schedules and indications. | | | | | | |
| B7.8 | There shall be policies or Standard Operating Procedures in place for planned discharges and provision of 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: | | | | | | |
| B7.8.1.1 | A consult between the attending physician and the receiving health care professionals regarding the applicable elements in Standard B7.7. | | | | | | |
| B7.8.2 | The Clinical Program shall provide appropriate instructions to recipients prior to discharge. | | | | | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| B7.8.3 | The Clinical Program shall provide appropriate instructions to recipients prior to discharge. | | | | | | |
| B7.10 | There shall be policies addressing indications for and safe administration of ECP if utilized by the Clinical Program. | | | C8.17 | There shall be policies addressing safe treatment with ECP. | | |
| B7.10.1 | There shall be a consultation with the facility or physician that performs ECP prior to initiation of therapy. | | | | | | |
| 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. | | | 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. | | |
| 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. | | | C8.17.3 | A final report of the details of the ECP treatment shall be documented in the patient's medical record. | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| B7.10.4 | The facility performing ECP shall follow written Standard Operating Procedures 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. | | |
| B7.11 | There shall be policies or Standard Operating Procedures addressing the administration of immune effector cells and management of complications, if applicable. | | | | | | |
| 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. | | | | | | |
| B7.11.2 | There shall be regular assessment of the recipient to detect complications, including cytokine release syndrome and neurologic dysfunction. | | | | | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| B7.11.3 | There shall be a written plan for rapid escalation of care, increased intensity of monitoring, and relevant workup to address complications. | | | | | | |
| B7.11.4 | Communication to the clinical staff, intensive care unit, emergency department, and pharmacy shall be timely. | | | | | | |
| B7.11.5 | The Clinical Program shall have written guidelines for management of complications, including the use of cytokine-blocking agents and corticosteroid administration. | | | | | | |
| 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. | | | | | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| 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: | | | | | | |
| B7.12.1.1 | Endocrine and reproductive function and osteoporosis. | | | | | | |
| B7.12.1.2 | Cardiovascular risk factors. | | | | | | |
| B7.12.1.3 | Respiratory function. | | | | | | |
| B7.12.1.4 | Chronic renal impairment. | | | | | | |
| B7.12.1.5 | Secondary malignancies. | | | | | | |
| B7.12.1.6 | Growth and development of pediatric patients. | | | | | | |
| B7.12.2 | There shall be polices or Standard Operating Procedures describing the transition of long-term pediatric recipients to adult care as appropriate. | | | | | | |
| 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. | | | | | | |
| **B8** | CLINICAL RESEARCH | | | | | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| 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. | | | | | | |
| 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. | | | | | | |
| B8.1.2 | There shall be a process to manage investigational cellular therapy products. | | | | | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| 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. | | | | | | |
| 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. | | | | | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| 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. | | | | | | |
| B8.3.2 | Informed consent for a research subject shall contain the following elements at a minimum and comply with applicable laws and regulations: | | | | | | |
| B8.3.2.1 | An explanation of the research purposes, a description of the procedures to be followed, and the identification of investigational procedures. | | | | | | |
| B8.3.2.2 | The expected duration of the subject's participation. | | | | | | |
| B8.3.2.3 | A description of the reasonably expected risks, discomforts, benefits to the subject and others, and alternative procedures. | | | | | | |
| B8.3.2.4 | A statement of the extent to which confidentiality will be maintained. | | | | | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| B8.3.2.5 | An explanation of the extent of compensation for injury. | | | | | | |
| 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. | | | | | | |
| **B9** | DATA MANAGEMENT | | | | | | |
| 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. | | | | | | |
| 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. | | | | | | |
| B9.1.2 | Clinical Programs should submit the data specified in B9.1 for allogeneic and autologous transplants to a national or international database. | | | | | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| 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. | | | | | | |
| B9.2 | The Clinical Program should collect all data elements included in the applicable CIBMTR Cellular Therapy forms or EBMT forms. | | | | | | |
| B9.3 | The Clinical Program shall define staff responsible for collecting data and, as appropriate, reporting data to institutional repositories and CIBMTR or EBMT. | | | | | | |
| B9.3.1 | Defined data management staff should participate in continuing education annually. | | | | | | |
| | | **M9** | CELLULAR THERAPY PRODUCT STORAGE | **C9** | CELLULAR THERAPY PRODUCT STORAGE | **D9** | CELLULAR THERAPY PRODUCT STORAGE |
| | | 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. | 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. | D9.1 | Processing Facilities shall control storage areas to prevent mix-ups, deterioration, contamination, cross-contamination, and improper distribution of cellular therapy products. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| | | 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. | 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. | | |
| | | | | | | **D9.2** | STORAGE DURATION |
| | | | | | | 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. |
| | | | | | | 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. |
| | | | | | | **D9.3** | TEMPERATURE |
| | | | | | | D9.3.1 | Storage temperatures shall be defined in Standard Operating Procedures. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
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| | | | | | | 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. |
| | | | | | | 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. |
| | | | | | | 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. |
| | | | | | | **D9.4** | PRODUCT SAFETY |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| | | | | | | 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. |
| | | | | | | D9.4.2 | For cellular therapy products immersed in liquid nitrogen, procedures to minimize the risk of cross-contamination of products shall be employed. |
| | | | | | | D9.4.3 | Processes for storing cellular therapy products in quarantine shall be defined in Standard Operating Procedures. |
| | | | | | | 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. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| | | | | | | 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. |
| | | | | | | 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. |
| | | | | | | **D9.5** | STORAGE MONITORING |
| | | | | | | 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. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| | | | | | | 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. |
| | | | | | | **D9.6** | ALARM SYSTEMS |
| | | | | | | D9.6.1 | Storage devices for cellular therapy products or reagents for cellular therapy product processing shall have alarm systems that are continuously active. |
| | | | | | | D9.6.2 | Alarm systems shall have audible and visible signals or other effective notification methods. |
| | | | | | | D9.6.3 | Alarm systems shall be checked periodically for function. |
| | | | | | | 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. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| | | | | | | D9.6.5 | Alarms shall be set to activate at a temperature or level of liquid nitrogen that will allow time to salvage products. |
| | | | | | | 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. |
| | | | | | | D9.6.6.1 | Instructions shall include a procedure for notifying processing personnel. |
| | | | | | | D9.6.7 | Storage devices of appropriate temperature shall be available for cellular therapy product storage if the primary storage device fails. |
| | | | | | | 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. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| | | | | | | 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: |
| | | | | | | D9.8.1 | Cellular therapy product unique identifier. |
| | | | | | | D9.8.2 | Recipient name or unique identifier. |
| | | | | | | D9.8.3 | Storage device identifier. |
| | | | | | | D9.8.4 | Location within the storage device. |
| | | **M10** | CELLULAR THERAPY PRODUCT TRANSPORTATION AND SHIPPING | **C10** | CELLULAR THERAPY PRODUCT TRANSPORTATION AND SHIPPING | **D10** | CELLULAR THERAPY PRODUCT TRANSPORTATION AND SHIPPING |
| | | 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. | 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. | 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. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| | | M10.2 | 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. | D10.2 | The primary product container for non-frozen cellular therapy products shall be placed in a secondary container and sealed to prevent leakage. |
| | | 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. | 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. | 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. |
| | | | | | | D10.4 | Conditions shall be established and maintained to preserve the integrity and safety of cellular therapy products during transport or shipping. |
| | | | | | | D10.5 | Cellular therapy products that are shipped to another facility or transported on public roads shall be packaged in an outer container. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| | | | | | | D10.5.1 | The outer container shall conform to the applicable regulations regarding the mode of transportation or shipping. |
| | | 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. | 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. | 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. |
| | | 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. | 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. | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| | | | | | | D10.5.2.1 | The temperature of the shipping container shall be continuously monitored during shipment of cellular therapy products. |
| | | | | | | D10.5.2.2 | The shipping facility shall maintain a record of the temperature over the period of travel. |
| | | | | | | D10.5.3 | The outer container shall be secured. |
| | | | | | | 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. |
| | | | | | | 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. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| | | | | | | 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. |
| | | | | | | 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. |
| | | M10.3.2 | 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. | D10.7 | If the intended recipient has received high-dose therapy, the cellular therapy product shall be transported. |
| | | | | | | D10.8 | There shall be plans for alternative means of transport or shipping in an emergency. |
| | | | | | | 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. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| | | | | | | **D11** | DISTRIBUTION AND RECEIPT |
| | | | | | | **D11.1** | DISTRIBUTION CRITERIA |
| | | | | | | 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. |
| | | | | | | D11.1.1.1 | Records shall demonstrate traceability from the donor to the recipient and from the recipient to the donor. |
| | | | | | | 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. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| | | | | | | 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. |
| | | | | | | 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. |
| | | | | | | 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. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| | | | | | | 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. |
| | | | | | | 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. |
| | | | | | | 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: |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| | | | | | | D11.1.4.1 | The use of the cellular therapy product, indications, contraindications, side effects and hazards, dosage, and administration recommendations. |
| | | | | | | D11.1.4.2 | Instructions for handling the cellular therapy product to minimize the risk of contamination or cross-contamination. |
| | | | | | | D11.1.4.3 | Appropriate warnings related to the prevention of the transmission or spread of communicable diseases. |
| | | | | | | **D11.2** | DISTRIBUTION RECORDS |
| | | | | | | 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: |
| | | | | | | D11.2.1.2 | Unique identifier of the intended recipient. |
| | | | | | | D11.2.1.1 | The proper product name and identifier. |
| | | | | | | D11.2.1.3 | Documentation of donor eligibility determination, as appropriate. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| | | | | | | D11.2.1.4 | Identification of the facilities that requested and distributed the product. |
| | | M10.5 | 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. | D11.2.1.6 | Date and time cellular therapy product was distributed. |
| | | | | | | D11.2.1.7 | Date and time cellular therapy product was received. |
| | | | | | | D11.2.1.8 | Identity of the transporting or shipping facility. |
| | | | | | | D11.2.1.5 | Identity of the receiving facility. |
| | | | | | | D11.2.1.9 | Identity of personnel responsible for cellular therapy product transportation or shipping and of personnel responsible for receiving the product. |
| | | | | | | D11.2.1.10 | Identity of the courier. |
| | | | | | | D11.2.1.11 | Documentation of any delay or problems incurred during transportation or shipping. |
| | | | | | | **D11.3** | RECEIPT OF CELLULAR THERAPY PRODUCTS |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| | | | | | | D11.3.1 | Standard Operating Procedures shall be established and maintained for acceptance, rejection, and quarantine of cellular therapy products. |
| | | | | | | D11.3.2 | The receipt of each cellular therapy product shall include inspection to verify: |
| | | | | | | D11.3.2.1 | The integrity of the cellular therapy product container. |
| | | | | | | D11.3.2.2 | The appearance of the cellular therapy product for evidence of mishandling or microbial contamination. |
| | | | | | | D11.3.2.3 | Appropriate labeling. |
| | | | | | | 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. |
| | | | | | | D11.3.3 | There shall be Standard Operating Procedures to verify that the cellular therapy product was appropriately transported or shipped. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| | | | | | | D11.3.3.1 | The receiving facility shall document the temperature inside the container upon arrival if shipped or transported on public roads. |
| | | | | | | D11.3.3.2 | For cryopreserved cellular therapy products, receiving facility records shall include documentation of the container temperature during shipping. |
| | | | | | | D11.3.4 | The receiving facility shall review and verify cellular therapy product specifications provided by the manufacturer, if applicable. |
| | | | | | | 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. |
| | | | | | | D11.3.7 | The receiving facility shall have readily available access to a summary of documents used to determine allogeneic donor eligibility. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| | | | | | | 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. |
| | | | | | | 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. |
| | | | | | | 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. |
| | | | | | | **D12** | DISPOSAL |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| | | | | | | D12.1 | Disposal of cellular therapy products shall include the following requirements: |
| | | | | | | 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. |
| | | | | | | 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. |
| | | | | | | D12.1.3 | Documentation of no further need for the cellular therapy product before any product is discarded. |
| | | | | | | D12.1.3.1 | For HPC products, this shall include documentation of the designated recipient’s death, if applicable. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| | | | | | | 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. |
| | | | | | | D12.1.5 | A method of disposal and decontamination that meets applicable laws and regulations for disposal of biohazardous materials and/or medical waste. |
| | | | | | | D12.2 | Processing Facilities, in consultation with the Clinical Program, shall establish policies for the duration and conditions of storage and indications for disposal. |
| | | | | | | 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. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| | | | | | | 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. |
| | | | | | | 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. |
| **B10** | RECORDS | **M11** | RECORDS | **C11** | RECORDS | **D13** | RECORDS |
| | | M11.1 | The Marrow Collection Facility shall comply with B10 if it operates independently of a Clinical Program. | | | | |
| | | | | **C11.1** | GENERAL REQUIREMENTS | | |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| | | | | C11.1.1 | A records management system shall be established and maintained to facilitate the review of records. | D13.1 | There shall be a records management system for quality and cellular therapy product record creation, assembly, review, storage, archival, and retrieval. |
| | | | | | | 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. |
| | | | | 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. | 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. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| | | | | 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. | 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. |
| | | | | C11.1.2 | Records shall be maintained in such a way as to preserve their integrity, preservation, and retrieval. | D13.1.4 | Records shall be maintained in such a way as to secure their integrity, preservation, and retrieval. |
| | | | | C11.1.3 | Records shall be accurate, legible, and indelible. | D13.1.5 | Records shall be accurate, legible, and indelible. |
| | | | | 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. | 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. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| | | | | C11.2 | The Apheresis Collection Facility shall define and follow good documentation practices. | D13.2 | The Processing Facility shall define and follow good documentation practices. |
| | | | | | | **D13.4** | RECORDS TO BE MAINTAINED |
| 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. | | | 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. | 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. |
| B10.1.1 | Employee records shall be maintained in a confidential manner and 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. | D13.4.1.1 | Employee records shall be maintained in a confidential manner, as required by applicable laws and regulations. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| 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. | | | 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. | 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. |
| | | | | 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. | 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. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| 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. | | | 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. | 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. |
| 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. | | | 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. | 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. |
| **B10.4** | ELECTRONIC RECORDS | | | **C11.7** | ELECTRONIC RECORDS | **D13.3** | ELECTRONIC RECORDS |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| 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. | | | 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. | 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. |
| 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. | | | 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. | 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. |
| B10.4.3 | 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. | D13.3.3 | There shall be a means by which access to electronic records is limited to authorized individuals. |
| B10.4.4 | The critical electronic record system shall maintain unique identifiers. | | | C11.7.4 | The critical electronic record system shall maintain unique identifiers. | D13.3.4 | The critical electronic record system shall maintain unique identifiers. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| B10.4.5 | 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. | D13.3.5 | There shall be protection of the records to enable their accurate and ready retrieval throughout the period of record retention. |
| 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. | | | 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. | 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. |
| B10.4.7 | For all critical electronic record systems, there shall be written Standard Operating 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. | D13.3.7 | For all critical electronic record systems, there shall be written Standard Operating Procedures for record entry, verification, and revision. |
| B10.4.7.1 | 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. | D13.3.7.1 | A method shall be established or the system shall provide for review of data before final acceptance. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| 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. | | | 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. | 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. |
| 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. | | | 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. | 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. |
| B10.4.9 | 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: | D13.3.9 | For all critical electronic record systems, there shall be validated procedures for and documentation of: |
| | | | | C11.7.9.1 | Systems development. | D13.3.9.1 | Systems development. |
| | | | | C11.7.9.2 | Numerical designation of system versions, if applicable. | D13.3.9.2 | Numerical designation of system versions, if applicable. |
| | | | | C11.7.9.3 | Prospective validation of systems, including hardware, software, and databases. | D13.3.9.3 | Prospective validation of systems, including hardware, software, and databases. |
| | | | | | | D13.3.9.4 | Installation of the system. |
| B10.4.9.1 | Training and continued competency of personnel in systems use. | | | C11.7.9.4 | Training and continued competency of personnel in systems use. | D13.3.9.5 | Training and continued competency of personnel in systems use. |
| B10.4.9.2 | Monitoring of data integrity. | | | C11.7.9.5 | Monitoring of data integrity. | D13.3.9.6 | Monitoring of data integrity. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| B10.4.9.3 | 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. | D13.3.9.7 | Back-up of the electronic records system on a regular schedule. |
| | | | | | | D13.3.9.8 | System maintenance and operations. |
| B10.4.9.4 | System assignment of unique identifiers. | | | C11.7.9.7 | System assignment of unique identifiers. | D13.3.9.9 | System assignment of unique identifiers. |
| | | | | | | D13.3.10 | All system modifications shall be authorized, documented, and validated prior to implementation. |
| **B10.5** | RECORDS IN CASE OF DIVIDED RESPONSIBILITY | | | **C11.8** | RECORDS IN CASE OF DIVIDED RESPONSIBILITY | **D13.5** | RECORDS IN CASE OF DIVIDED 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. | | | 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. | 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. |
| | | | | | | 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. |

| Ref | Standard | Ref2 | Standard2 | Ref3 | Standard3 | Ref4 | Standard4 |
|---|---|---|---|---|---|---|---|
| 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. | | | 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. | 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. |
| | | **M12** | DIRECT DISTRIBUTION TO CLINICAL PROGRAM | **C12** | DIRECT DISTRIBUTION TO CLINICAL PROGRAM | | |
| | | 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. | 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. | | |