
HEMATOPOIETIC CELLULAR THERAPY PRODUCT COLLECTION,
PROCESSING, AND ADMINISTRATION
DOCUMENT SUBMISSION REQUIREMENTS



**FACT-JACIE International Standards for Hematopoietic Cellular Therapy
Product Collection, Processing, and Administration**

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HEMATOPOIETIC CELLULAR THERAPY DOCUMENT SUBMISSION REQUIREMENTS

Copies of the following items are required prior to the on-site inspection, and must be uploaded via the online Compliance Application within the FACT Accreditation Portal. For additional information, see the referenced standard and the accompanying information in the Accreditation Manual.

Do not use patient information on the documents submitted. All submitted documents, policies, and Standard Operating Procedures (SOPs) must be in English unless otherwise specified. If your facility utilizes electronic records, hard copies of the primary source data must be assembled and flagged before the inspection, and must be ready for inspector review on-site.

The documents listed in the following pages are only a subset of what inspectors will need to review. Documentation of compliance with each standard must be readily available to the inspectors during the on-site inspection. Items not provided for inspector review by the end of the on-site inspection will be marked as a deficiency. Refer to the [FACT Accreditation Process Requirements](http://www.factwebsite.org/CTLibrary/) on the FACT website at <http://www.factwebsite.org/CTLibrary/> for tips on how to prepare on-site documentation.

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CLINICAL PROGRAM DOCUMENTATION

Clinical Program Director(s)

- Copy of current license to practice medicine in the jurisdiction in which the program is located for each Program Director. If the license is in a language other than English, include a general description in English. [B3.1.1]
 - Copy(ies) of specialty certification(s) for each Clinical Program Director. Documentation of specialty certification in the U.S. can be accessed from [ABIM](#), [ABMS](#), [ABP](#), and [AOA](#). If the documentation is in a language other than English, include a general description in English. [B3.1.1]
- or**
- Physicians who received all or part of their medical and specialty training outside of the United States or Canada must submit documentation of training and experience and a copy of any registration or certification in a relevant specialty. Documentation should describe the specifics of the training received, and may be submitted in the form of curriculum vitae, letters from the directors of the referenced training programs or current department chair, or other similar information. If the documentation is in a language other than English, include a general description in English. [B3.1.1]
- Curriculum vitae for each Clinical Program Director. If one individual serves as a director for multiple facilities, submit this individual's curriculum vitae whenever applicable. If the documentation is in a language other than English, include a summary in English. [B3.1.2]
 - Documentation of at least ten (10) hours of participation per year for each Clinical Program Director in educational activities related to cellular therapy, including hematopoietic progenitor cell (HPC) transplantation, since the previous date of accreditation. Complete and upload the [Educational Activities Form](#) or submit other documentation that includes the equivalent information for each activity: [B3.1.6]
 - Date of activity
 - Title of activity
 - Type of activity (e.g., webinar, meeting, grand round)
 - Topic of activity (e.g., hematology, cell transplantation)
 - Approximate number of hours of activity
 - Complete and upload the [HCT Training and Competency Form](#), [FACT-JACIE Standards 7.0](#) or submit the following for each Clinical Program Director: [B3.3]
 - Documentation of specific training and competency in the skills listed in Standard B3.3.4.
 - For programs requesting accreditation for allogeneic transplantation, documentation of specific training and competency in each of the skills listed in Standard B3.3.5.
 - Documentation of knowledge in the skills listed in Standard B3.3.6.

Attending Physicians (specify adult and pediatric programs if applicable):

- Copy of current license to practice medicine in the jurisdiction in which the program is located for each attending physician. If the license is in a language other than English, include a general description in English. [B3.2.1]
- Copy(ies) of specialty certification(s) for each attending physician, if appropriate. Documentation of specialty certification in the U.S. can be accessed from [ABIM](#), [ABMS](#), [ABP](#), and [AOA](#). If the documentation is in a language other than English, include a general description in English. [B3.2.1]

or

- Physicians who received all or part of their medical and specialty training outside of the United States or Canada must submit documentation of training and experience and a copy of any registration or certification in a relevant specialty. Documentation should describe the specifics of the training received, and may be submitted in the form of curriculum vitae, letters from the directors of the referenced training programs or current department chair, or other similar information. If the documentation is in a language other than English, include a general description in English. [B3.2.1]
- Documentation of at least ten (10) hours of participation per year for each attending physician in educational activities related to cellular therapy, including HPC transplantation, since the previous accreditation date. Complete and upload the [Educational Activities Form](#) or submit other documentation that includes the equivalent information for each activity: [B3.2.2]
 - Date of activity
 - Title of activity
 - Type of activity (e.g., webinar, meeting, grand round)
 - Topic of activity (e.g., hematology, cell transplantation)
 - Approximate number of hours of activity
 - Complete and upload the [HCT Training and Competency Form, FACT-JACIE Standards 7.0](#) or submit the following for each attending physician: [B3.3]
 - Documentation of specific training and competency in the skills listed in Standard B3.3.4.
 - For programs requesting accreditation for allogeneic transplantation, documentation of specific training and competency in each of the skills listed in Standard B3.3.5.
 - Documentation of knowledge in the skills listed in Standard B3.3.6.

Physicians-in-Training

- If physicians-in-training are receiving their training within a program accredited by the Accreditation Council for Graduate Medical Education (ACGME) or equivalent, documentation that physicians-in-training are residents or fellows in an accredited graduate medical education program. [B3.4.2]
- For physicians-in-training not in an accredited graduate medical education program, copy of current license to practice medicine in the jurisdiction in which the program is located for each physician-in-training. If the license is in a language other than English, include a general description in English. [B3.4.1]

- For physicians-in-training not in an accredited graduate medical education program, complete and upload the [HCT Training and Competency Form, FACT-JACIE Standards 7.0](#) or submit the following for each physician-in-training: [B3.4.2]
 - Documentation of specific training and competency development in the skills listed in Standard B3.3.4.
 - For programs requesting accreditation for allogeneic transplantation, documentation of specific training and competency development in each of the skills listed in Standard B3.3.5.

Advanced Practice Providers/Professionals (APPs)

- Copy of current license to practice as required in the jurisdiction in which the program is located for each APP. If the license is in a language other than English, include a general description in English. [B3.5.1]
- Complete and upload the [HCT Training and Competency Form, FACT-JACIE Standards 7.0](#) or submit the following for each APP in the transplant-related skills that he/she routinely practices: [B3.5.2]
 - Documentation of specific training and competency in the skills listed in Standard B3.3.4 for each APP as applicable.
 - For programs requesting accreditation for allogeneic transplantation, documentation of specific training and competency in each of the skills listed in Standard B3.3.5 for each APP as applicable.
- Documentation of at least ten (10) hours of participation per year for each APP in educational activities related to cellular therapy, including HPC transplantation, since the previous accreditation date. Complete and upload the [Educational Activities Form](#) or submit other documentation that includes the equivalent information for each activity: [B3.5.3]
 - Date of activity
 - Title of activity
 - Type of activity (e.g., webinar, meeting, grand round)
 - Topic of activity (e.g., hematology, cell transplantation)
 - Approximate number of hours of activity

Nurses

- A description of the processes for nursing orientation, training, and competency assessment in the transplant-related skills they routinely practice. [B3.7.3]

Pharmacists

- Copy of current license to practice as required in the jurisdiction in which the program is located for each designated blood and marrow transplant (BMT) pharmacist. If the license is in a language other than English, include a general description in English. [B3.8.1]

- Documentation of at least ten (10) hours of participation per year for each designated pharmacist in educational activities related to the field of HPC transplantation and cytokine release syndrome and neurological toxicities resulting from cellular therapies since the previous accreditation date. Complete and upload the [Educational Activities Form](#) or submit other documentation that includes the equivalent information for each activity: [B3.8.4]
 - Date of activity
 - Title of activity
 - Type of activity (e.g., webinar, meeting, grand round)
 - Topic of activity (e.g., hematology, cell transplantation)
 - Approximate number of hours of activity

Consulting Specialists

A photocopy of board certification or documentation of training and experience for at least one (1) specialist in each specialty field. For programs that treat pediatric recipients and donors, documentation of specialist certification or training for consultants qualified to manage pediatric patients must be submitted. Documentation of specialty certification in the U.S. can be accessed from [ABIM](#), [ABMS](#), [ABP](#), [ABPN](#), [the ABR](#), [the ABA](#), and [AOA](#). If the documentation is in a language other than English, include a general description in English. [B3.9]

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|---|---|
| <p>Peds Adult</p> <ul style="list-style-type: none"> <input type="checkbox"/> <input type="checkbox"/> Surgery [B3.9.1.1] <input type="checkbox"/> <input type="checkbox"/> Intensive Care [B3.9.1.3] <input type="checkbox"/> <input type="checkbox"/> Nephrology [B3.9.1.5] <input type="checkbox"/> <input type="checkbox"/> Cardiology [B3.9.1.7] <input type="checkbox"/> <input type="checkbox"/> Psychiatry [B3.9.1.9] <input type="checkbox"/> <input type="checkbox"/> Radiation Oncology [B3.9.1.11] <input type="checkbox"/> <input type="checkbox"/> Neurology [B3.9.1.13] <input type="checkbox"/> <input type="checkbox"/> Obstetrics/Gynecology [B3.9.1.15] | <p>Peds Adult</p> <ul style="list-style-type: none"> <input type="checkbox"/> <input type="checkbox"/> Pulmonary Medicine [B3.9.1.2] <input type="checkbox"/> <input type="checkbox"/> Gastroenterology [B3.9.1.4] <input type="checkbox"/> <input type="checkbox"/> Infectious Disease [B3.9.1.6] <input type="checkbox"/> <input type="checkbox"/> Pathology [B3.9.1.8] <input type="checkbox"/> <input type="checkbox"/> Radiology [B3.9.1.10] <input type="checkbox"/> <input type="checkbox"/> Transfusion Medicine* [B3.9.1.12] <input type="checkbox"/> <input type="checkbox"/> Ophthalmology [B3.9.1.14] <input type="checkbox"/> <input type="checkbox"/> Dermatology [B3.9.1.16] <input type="checkbox"/> <input type="checkbox"/> Palliative and end of life care [B3.9.1.17] |
|---|---|

**The transfusion medicine requirement is separate from the pathology requirement.*

Clinical Quality Manager

- Documentation of at least ten (10) hours of participation per year for each Clinical Quality Manager in educational activities related to cellular therapy and quality management, including HPC transplantation, since the previous accreditation date. Complete and upload the [Educational Activities Form](#) or submit other documentation that includes the equivalent information for each activity: [B3.10.3]
 - Date of activity
 - Title of activity
 - Type of activity (e.g., webinar, meeting, grand round)
 - Topic of activity (e.g., hematology, cell transplantation, etc.)
 - Approximate number of hours of activity

Other Clinical Documentation

- A completed [Clinical Facility Grid](#), which includes new patient numbers. For initial accreditation, enter data for the previous 12 months. For renewal accreditation, enter data from the start of the current accreditation cycle. [B1.1 and B1.5]
- If the Clinical Program administers immune effector cells (IECs), a completed [IEC List](#). [B1.1]
- General physical floor plan of all program facilities (clinical, marrow collection, apheresis collection, processing). Label all floors of the building(s) that are used for transplant or cellular therapy activities. If the floor plan or diagram is labeled in a language other than English, include a general description of the floor plan or diagram in English. [B1.1]
- A map of the overall organization that includes all facilities (clinical, marrow collection, apheresis collection, processing). If the map is labeled in a language other than English, include a general description of the floor plan or diagram in English. [B1.1]
- If the Clinical Program or intermediary facility receives cellular therapy products directly from a third-party provider, an example or template of a written agreement that defines the following responsibilities at a minimum for each applicable cellular therapy product: [B1.2.1]
 - Traceability and chain of custody of cellular therapy products. [B1.2.1.1]
 - Cellular therapy product storage and distribution. [B1.2.1.2]
 - Verification of cellular therapy product identity. [B1.2.1.3]
 - Review and verification of product specifications provided by the manufacturer, if applicable. [B1.2.1.4]
 - Readily available access to a summary of documents used to determine allogeneic donor eligibility. [B1.2.1.5]
 - Documented evidence of allogeneic donor eligibility screening and testing in accordance with applicable laws and regulations. [B1.2.1.6]
- A copy of the certificate for each licensure, registration, or accreditation required by the appropriate governmental authorities. Include, as appropriate, certificates for accreditation of in-patient facilities, e.g., the Joint Commission, American Osteopathic Association, Det Norske Veritas Healthcare, Australian Council on Healthcare Standards, Canadian Council on Health Services Accreditation, or other certification required by the appropriate governmental authority. If the licensure, registration, or accreditation is in a language other than English, include a general description of the document in English. [B1.3.1]
- A complete recipient list, in Excel or similar format, since the date of your previous accreditation (renewal applicants) or from the twelve months preceding submission of the Compliance Application (initial applicants). Include unique patient identifier, date of transplant, diagnosis, source of cells (marrow, peripheral blood, cord blood), type of transplant (autologous, allogeneic), type of recipient (adult, pediatric), and CIBMTR ID (if applicable). Per United States HIPAA guidelines, do not include protected health information (PHI), e.g., patient names, medical record numbers, birthdate, or others. [B1.5]

- For programs requesting allogeneic transplantation accreditation, submit a copy of the HLA laboratory's current ASHI, EFI, or other appropriate accreditation certificate, including documentation of certification for DNA-based typing. If the certificate is in a language other than English, include a description of the document in English. [B2.14]
 - For ASHI accreditation:
 - Include the accreditation letter in addition to the certificate.
 - If the laboratory is not ASHI-accredited for HSC/BM transplantation, include documentation of HLA expertise available within the Clinical Program for selecting the best matched donor for the recipient.
- For programs requesting allogeneic transplantation accreditation, submit a copy of the certificate of laboratory accreditation for techniques used in chimerism testing. [B2.15]
- Copy of the Clinical Program's Quality Management Plan that includes all requirements listed in B4. [B4.2]
- Copy of the organizational chart of key positions and functions within the cellular therapy program, including clinical, collection, and processing. [B4.3]
- Policies or Standard Operating Procedure(s) for development, approval, implementation, distribution, review, revision, and archival of all critical documents. [B4.5.2]
- Standard Operating Procedure(s) that outlines a standardized format for critical documents and required elements of each procedure. [B4.5.1.1 and B5.3]
- Evidence of a completed outcome analysis, e.g., a report of conclusions, meeting minutes, or completed forms. [B4.7]
- Corrective action plan that meets FACT requirements in response to clinical outcomes below expected ranges, if applicable:
 - 100-day survival that does not meet center-defined benchmarks. [B4.7.3.3]
 - One-year survival that does not meet the expected range when compared to national or international outcome data. Programs in the U.S. must assess one-year survival using the CIBMTR Transplant Center Survival Report. Programs in other regions must define what data it uses for comparison. [B4.7.5.1]
- Schedule of audits that includes dates and subjects of audits already performed and audits planned for the future. At a minimum, the audits listed under B4.8.3 must be included. [B4.8]
- The policy or Standard Operating Procedure for qualification of critical manufacturers, vendors, equipment, supplies, reagents, facilities, and services. [B4.13]
- The policy or Standard Operating Procedure for validation or verification of critical procedures. [B4.14]

- A validation of the marrow collection procedure that includes: [B4.14.2]
 - A summary of the validation plan
 - Number of data points used
 - Acceptance criteria
 - Data collection
 - Evaluation of Data
 - Summary of results and conclusion
 - References, if applicable
 - Review and approval of the plan, results, and conclusion

- Table of Contents from the Clinical Program Standard Operating Procedures Manual that includes the title and identifier for each controlled document. [B5.2]

- Unsigned samples of all allogeneic and autologous donor consent forms. [B6.2]

- Standard Operating Procedure for consenting to be a cellular therapy product donor that contains all required elements. [B6.2]

- Unsigned samples of recipient consent forms and the Standard Operating Procedure for consenting to receive cellular therapy. [B7.1]

- Policies for determining the appropriate volume and the appropriate dose of red blood cells, cryoprotectants, and other additives. [B7.6.1]

- Policy for preparing cord blood units for administration. [B7.6.3]

- Policies or Standard Operating Procedures for addressing appropriate follow-up of recipients after administration of preparative regimens and cellular therapy products. [B7.7]

- Policy or Standard Operating Procedure addressing the administration of immune effector cells and management of complications, if applicable. [B7.11]

- Data management [B9]:
 - Programs audited by CIBMTR:
 - The most recent CIBMTR Audit Results Report, including Appendix D.
 - Corrective Action Plan (CAP) submitted at the last CIBMTR audit, if applicable. CAPs related to systemic errors even if the CER is $\leq 3.0\%$ are required. CAPs related to consent issues or missing documentation are not required.
 - Summary of current progress on implementation of the CAP.
 - An audit report from a recent internal audit (performed within the last 12 months on current data) addressing the effectiveness of the CAP.
 - CIBMTR Continuous Process Improvement Status letters from the past three (3) trimesters.

- Programs not audited by CIBMTR [B9]:
 - Programs with no B9 deficiencies for the last three (3) FACT on-site inspections.
 - An audit report from a recent internal audit (performed within the past 12 months on current data).
 - Requirements will be sent to programs for preparation of an on-site data audit to be performed by a FACT clinical inspector.
 - Programs with B9 deficiencies.
 - Dates of the last three (3) on-site FACT inspections and the deficiencies received under B9.1.
 - Corrective Action Plan (CAP) submitted at the most recent inspection that FACT accepted to grant accreditation.
 - Summary of current progress on implementation of the CAP.
 - An audit report from a recent internal audit (performed within the past 12 months on current data) addressing the effectiveness of the CAP.
 - Requirements will be sent to programs for preparation of an on-site data audit to be performed by a FACT clinical inspector.
 - Programs applying for initial accreditation.
 - An audit report from a recent internal audit (performed within the past 12 months on current data) addressing the effectiveness of the CAP.
 - Requirements will be sent to programs for preparation of an on-site data audit to be performed by a FACT clinical inspector.

- Documentation of participation for each defined data management staff in educational activities. Complete and upload the [Educational Activities Form](#) or submit other documentation that contains the equivalent information for each activity: [B9.2.1]
 - Date of activity
 - Title of activity
 - Type of activity (e.g., webinar, meeting, grand round)
 - Topic of activity (e.g., hematology, cell transplantation)
 - Approximate number of hours of activity

Electronic Record Systems:

- Current list of critical electronic record systems under the control of the Clinical Program, including a description of the purpose of each system and how it is used. Complete and upload the [Critical Electronic Record Systems](#) form or submit other documentation that contains the equivalent information for each critical record system. [B10.4.1]

For critical electronic record systems used for record keeping, documentation of validation of the systems must be available on-site as well as a qualified individual to review the documentation with the inspector. Documentation should demonstrate compliance with the following Standards:

- Validated procedures for and documentation of: [B10.4.9]
 - Training and continued competency of personnel in systems use. [B10.4.9.1]
 - Monitoring of data integrity. [B10.4.9.2]
 - Back-up of the electronic records system on a regular schedule. [B10.4.9.3]
 - System assignment of unique identifiers. [B10.4.9.4]

MARROW COLLECTION FACILITY DOCUMENTATION

Marrow Collection Facility Medical Director

- Copy of current license to practice medicine in the jurisdiction in which the program is located for each Marrow Collection Facility Medical Director. If the license is in a language other than English, include a general description in English. [CM3.1.1]
- Curriculum vitae for each Marrow Collection Facility Medical Director. If one individual serves as a director for multiple facilities, submit this individual's curriculum vitae whenever applicable. If the documentation is in a language other than English, include a general description in English. [CM3.1.1 and CM3.1.3]
- Documentation of at least ten (10) hours of participation per year for each Marrow Collection Facility Medical Director in educational activities related to cellular therapy, including HPC transplantation, since the previous accreditation date. Complete and upload the [Educational Activities Form](#) or submit other documentation that includes the equivalent information for each activity: [CM3.1.5]
 - Date of activity
 - Title of activity
 - Type of activity (e.g., webinar, meeting, grand round)
 - Topic of activity (e.g., hematology, apheresis)
 - Approximate number of hours of activity

Marrow Collection Facility Quality Manager

- Documentation of at least ten (10) hours of participation per year for each Marrow Collection Facility Quality Manager in educational activities related to cellular therapy, cell collection, and quality management, including HPC transplantation, since the previous accreditation date. Complete and upload the [Educational Activities Form](#) or submit other documentation that includes the equivalent information for each activity: [CM3.2.3]
 - Date of activity
 - Title of activity
 - Type of activity (e.g., webinar, meeting, grand round)
 - Topic of activity (e.g., hematology, apheresis)
 - Approximate number of hours of activity

Other Marrow Documentation

- A completed [Collection Facility Grid](#). For initial accreditation, enter data for the previous 12 months. For renewal accreditation, enter data from the start of the current accreditation cycle. [CM1.1]
- A map of the overall organization that includes all facilities. If the map is labeled in a language other than English, include a general description of the floor plan or diagram in English. [CM1.1]

- A physical floor plan of all facilities. Label all floors of the building(s) that are used for cellular therapy related activities. If the floor plan or diagram is labeled in a language other than English, include a general description of the floor plan or diagram in English. [CM1.1]
- Certificate of licensure, registration, or accreditation required by the appropriate governmental authority for the activities performed. Include, as appropriate, certificates for accreditation of in-patient facilities, e.g., the Joint Commission, American Osteopathic Association, Det Norske Veritas Healthcare, Australian Council on Healthcare Standards, Canadian Council on Health Services Accreditation, or other certification required by the appropriate governmental authority. If the licensure, registration, or accreditation is in a language other than English, include a general description of the document in English. [CM1.3.1]
- If the Marrow Collection Facility operates independently of the Clinical Program: [CM4.1]
 - Copy of the Quality Management Plan that includes all requirements listed in B4.
 - Copy of the organizational chart of key positions and functions within the organization. [B4.3]
 - Standard Operating Procedure for development, approval, implementation, distribution, review, revision, and archival of all critical documents and a procedure that outlines a standardized format for all critical documents. [B4.5.1 and B4.5.2]
 - Evidence of a completed outcome analysis, e.g., a report of conclusions, meeting minutes, or completed forms.
 - Schedule of audits that includes dates and subjects of audits already performed and audits planned for the future. [B4.8]
 - The policy or Standard Operating Procedure for qualification of critical manufacturers, vendors, equipment, supplies, reagents, facilities, and services. [B4.13]
 - The policy or Standard Operating Procedure for validation or verification of critical procedures. [B4.14]
 - A summary of one completed validation of the ISBT 128 labeling system that includes [CM7.1.2]:
 - A summary of the validation plan
 - Number of data points used
 - Acceptance criteria
 - Data collection
 - Evaluation of Data
 - Summary of results and outcomes
 - References, if applicable
 - Review and approval of the plan, results, and conclusion

- A summary of one additional completed validation of the marrow collection procedure that includes [B4.14.2]:
 - A summary of the validation plan
 - Number of data points used
 - Acceptance criteria
 - Data collection
 - Evaluation of Data
 - Summary of results and outcomes
 - References, if applicable
 - Review and approval of the plan, results, and conclusion
- Table of Contents from the Marrow Collection Facility Standard Operating Procedures Manual that includes the title and identifier for each controlled document. [B5.2]
- Current list of critical electronic record systems under the control of the Clinical Program, including a description of the purpose of each system and how it is used. Complete and upload the [Critical Electronic Record Systems](#) form or submit other documentation that contains the equivalent information for each critical record system. [B10.4.1]

For critical electronic record systems used for record keeping, documentation of validation of the systems must be available on-site as well as a qualified individual to review the documentation with the inspector. Documentation should demonstrate compliance with the following Standards:

- Validated procedures for and documentation of: [B10.4.9]
 - Training and continued competency of personnel in systems use. [B10.4.9.1]
 - Monitoring of data integrity. [B10.4.9.2]
 - Back-up of the electronic records system on a regular schedule. [B10.4.9.3]
 - System assignment of unique identifiers. [B10.4.9.4]
- Standard Operating Procedure(s) that outlines required elements of each procedure. [CM5.3]
- Unsigned samples of all allogeneic and autologous donor consent forms and the procedure for consenting for the marrow collection procedure that contains all required elements. [CM6.2]
- Completed examples of each type of in-process collection labels used by the Marrow Collection Facility. Do not include protected health information (PHI), e.g., patient names, medical record numbers, birthdate, or others. Mock identifiers and names must be used. If the labels are in a language other than English, include a general description of the label elements in English. [CM7.4.1]

- Completed examples of each type of label used by the Marrow Collection Facility. Do not include protected health information (PHI), e.g., patient names, medical record numbers, birthdate, or others. Mock identifiers and names must be used. If the labels are in a language other than English, include a general description of the label elements in English. [CM7.4.3]
 - Primary collection container label, applied on completion of collection of products for allogeneic use. [Cellular Therapy Standards Appendix II]
 - Primary collection container label, applied on completion of collection of products for autologous use. [Cellular Therapy Standards Appendix II]
 - Any partial labels applied at distribution for administration by the Marrow Collection Facility. [Cellular Therapy Standards Appendix II]
 - Labels applied to inner and outer shipping containers for products shipped or transported on public roads. [Cellular Therapy Standards Appendix III]

- An SOP for labeling that includes when biohazard and/or warning labels are used, including: [CM7.4.4, Cellular Therapy Standards Appendix II]
 - Biohazard legend
 - Statement "NOT EVALUATED FOR INFECTIOUS SUBSTANCES"
 - Statement "WARNING: Advise Patient of Communicable Disease Risks"
 - Statement "WARNING: Reactive Test Results for [name of disease agent or disease]"
 - Statement "FOR AUTOLOGOUS USE ONLY"

- Examples of documentation that accompanies the cellular therapy product at distribution and a policy or Standard Operating Procedure that discusses the documentation that is distributed with the product. [CM7.4.5, Cellular Therapy Appendix IV]

- Completed examples of documentation of the visual examination of supplies and reagents used to collect cellular therapy products. [CM8.2.2]

- When cellular therapy products are distributed directly from the Marrow Collection Facility to the Clinical Program (If the labels are in a language other than English, include a general description of the label elements in English.) [CM12.1]:
 - Completed examples of autologous and allogeneic labels attached to the product prior to distribution. Do not include PHI. Mock identifiers and names must be used. [Cellular Therapy Standards Appendix II]
 - Completed examples of labels applied to inner and outer containers for products shipped or transported on public roads. Do not include PHI. Mock identifiers and names must be used. [Cellular Therapy Standards Appendix III]
 - Documentation that accompanies the cellular therapy product at distribution and a policy or Standard Operating Procedure that discusses the documentation that is distributed with the product. [D7.4.5, D11.1.4, and Cellular Therapy Standards Appendix IV]

APHERESIS COLLECTION FACILITY DOCUMENTATION

Apheresis Collection Facility Director

- Curriculum vitae for each Apheresis Collection Facility Director. If one individual serves as a director for multiple facilities, submit this individual's curriculum vitae whenever applicable. If the documentation is in a language other than English, include a summary in English. [C3.1.1]
- Documentation of at least ten (10) hours of participation per year for each Apheresis Collection Facility Director in educational activities related to cellular therapy, including HPC transplantation, since the previous accreditation date. Complete and upload the [Educational Activities Form](#) or submit other documentation that includes the equivalent information for each activity: [C3.1.4]
 - Date of activity
 - Title of activity
 - Type of activity (e.g., webinar, meeting, grand round)
 - Topic of activity (e.g., hematology, apheresis)
 - Approximate number of hours of activity

Apheresis Collection Facility Medical Director

- Copy of current license to practice medicine in the jurisdiction in which the program is located for each Apheresis Collection Facility Medical Director. If the license is in a language other than English, include a general description in English. [C3.2.1]
- Curriculum vitae for each Apheresis Collection Facility Medical Director. If one individual serves as a director for multiple facilities, submit this individual's curriculum vitae whenever applicable. If the documentation is in a language other than English, include a summary in English. [C3.2.1 and C3.2.3]
- Documentation of at least ten (10) hours of participation per year for each Apheresis Collection Facility Medical Director in educational activities related to cellular therapy, including HPC transplantation, since the previous accreditation date. Complete and upload the [Educational Activities Form](#) or submit other documentation that includes the equivalent information for each activity: [C3.2.5]
 - Date of activity
 - Title of activity
 - Type of activity (e.g., webinar, meeting, grand round)
 - Topic of activity (e.g., hematology, apheresis)
 - Approximate number of hours of activity

Apheresis Collection Facility Quality Manager

- Documentation of at least ten (10) hours of participation per year for each Apheresis Collection Facility Quality Manager in educational activities related to cellular therapy, cell collection, and quality management, including HPC transplantation, since the previous accreditation date. Complete and upload the [Educational Activities Form](#) or submit other documentation that includes the equivalent information for each activity: [C3.3.3]
 - Date of activity
 - Title of activity
 - Type of activity (e.g., webinar, meeting, grand round)
 - Topic of activity (e.g., hematology, apheresis)
 - Approximate number of hours of activity

Other Apheresis Documentation

- A completed [Collection Facility Grid](#). For initial accreditation, enter data for the previous 12 months. For renewal accreditation, enter data from the start of the current accreditation cycle. [C1.1]
- A map of the overall organization that includes all facilities. If the map is labeled in a language other than English, include a general description of the floor plan or diagram in English. [C1.1]
- Physical floor plans of all facilities. Label all floors of the building(s) that are used for cellular therapy related activities. If the floor plan(s) or diagram is labeled in a language other than English, include a general description of the floor plan or diagram in English. [C1.1]
- Certificate of licensure, registration, or accreditation required by the appropriate governmental authority for the activities performed. U.S. facilities must submit a copy of the validated FDA registration for Human Cells, Tissues, and Cellular and Tissue Based Products (Form 3356). Facilities in other countries must submit certification required by the appropriate governmental authority. If the licensure, registration, or accreditation is in a language other than English, include a general description of the document in English. [C1.3.1]
- Copy of the Apheresis Collection Facility's Quality Management Plan that includes all requirements listed in C4. [C4.2]
- Copy of the organizational chart of key personnel and functions within the Apheresis Collection Facility [C4.3].
- Policies or Standard Operating Procedure for development, approval, implementation, distribution, review, revision, and archival of all critical documents. [C4.5.2]
- Standard Operating Procedure(s) that outlines a standardized format for critical documents and required elements of each individual procedure. [C4.5. 1 and C5.3]
- Evidence of a completed outcome analysis, e.g., a report of conclusions, meeting minutes, or completed forms. [C4.7]

- Schedule of audits that includes dates and subjects of audits already performed and audits planned for the future. At a minimum, the audits listed in C4.8.3 must be included. [C4.8]
- The policy or Standard Operating Procedure for qualification of critical manufacturers, vendors, equipment, supplies, reagents, facilities, and services. [C4.13]
- The policy or Standard Operating Procedure for validation or verification of critical procedures. [C4.14]
- A summary of one completed validation of the ISBT 128 labeling system that includes: [C4.14.1] [C4.14.2] [C7.1.2]
 - A summary of the validation plan
 - Number of data points used
 - Acceptance criteria
 - Data collection
 - Evaluation of Data
 - Summary of results and outcomes
 - References, if applicable
 - Review and approval of the plan, results, and conclusion
- A summary of one additional completed validation study of a critical procedure of the Apheresis Collection Facility that includes: [C4.14.1, C4.14.2]
 - A summary of the validation and plan
 - Number of data points to be used
 - Acceptance criteria
 - Data collection
 - Evaluation of Data
 - Summary of results and conclusions
 - References, if applicable
 - Review and approval of the plan, results, and conclusion
- Table of Contents from the Apheresis Collection Facility Standard Operating Procedures Manual that includes the title and identifier for each controlled document. [C5.2]
- Unsigned samples of all allogeneic and autologous donor consent forms and the procedure for consenting for the apheresis collection procedure that contains all required elements. [C6.2]
- Completed examples of each type of in-process collection labels used by the Apheresis Collection Facility. Do not include protected health information (PHI), e.g., patient names, medical record numbers, birthdate, or others. Mock identifiers and names must be used. If the labels are in a language other than English, include a general description of the label elements in English. [C7.4.1]
- Completed examples of each type of label used by the Apheresis Collection Facility. Do not include protected health information (PHI), e.g., patient names, medical record numbers, birthdate, or others. Mock identifiers and names must be used. If the labels are in a language other than English, include a general description of the label elements in English. [C7.4.3, Cellular Therapy Standards Appendix II]
 - Primary collection container label, applied on completion of collection of products for

- allogeneic use. [Cellular Therapy Standards Appendix II]
 - Primary collection container label applied on completion of collection of products for autologous use. [Cellular Therapy Standards Appendix II]
 - Any partial labels at distribution applied by the Collection Facility. [Cellular Therapy Standards Appendix II]
 - Labels applied to inner and outer shipping containers for products shipped or transported on public roads. [Cellular Therapy Standards Appendix III]
- An SOP for labeling that includes when biohazard and/or warning labels are used, including: [C7.4.4, Cellular Therapy Standards Appendix II]
 - Biohazard legend
 - Statement "NOT EVALUATED FOR INFECTIOUS SUBSTANCES"
 - Statement "WARNING: Advise Patient of Communicable Disease Risks"
 - Statement "WARNING: Reactive Test Results for [name of disease agent or disease]"
 - Statement "FOR AUTOLOGOUS USE ONLY"
- Documentation that accompanies the cellular therapy product at distribution and a policy or Standard Operating Procedure that discusses the documentation that is distributed with the product. [C7.4.5, Cellular Therapy Standards Appendix IV]
- Current list of critical electronic record systems under the control of the Apheresis Collection Facility, including a description of the purpose of each system and how it is used. Complete and upload the [Critical Electronic Record Systems](#) form or submit other documentation that contains the equivalent information for each critical record system. [C11.7.1]
- Completed examples of documentation of the visual examination of supplies and reagents used to collect cellular therapy products. [C8.2.2]
- A sample log of equipment inspection for cleanliness and compliance with the maintenance schedule prior to each use. [C8.3]
- When cellular therapy products are distributed directly from the Apheresis Collection Facility to the Clinical Program: If the labels are in a language other than English, include a general description of the label elements in English. [C12.1]
 - Completed examples of autologous and allogeneic labels attached to the product prior to distribution. Do not include PHI. Mock identifiers and names must be used. [Cellular Therapy Standards Appendix II]
 - Completed examples of labels applied prior to transport or shipping of cellular therapy products, including inner and outer container labels. Do not include PHI. Mock identifiers and names must be used. [Cellular Therapy Standards Appendix III]
 - Documentation that accompanies the cellular therapy product at distribution and a policy or Standard Operating Procedure that discusses the documentation that is distributed with the product. [D7.4.5, D11.1.4, and Cellular Therapy Standards Appendix IV]

Electronic Record Systems:

- Current list of critical electronic record systems under the control of the Apheresis Collection Facility, including a description of the purpose of each system and how it is used. Complete and upload the [Critical Electronic Record Systems](#) form or submit other documentation that contains the equivalent information for each critical record system. [C11.7.1]

For critical electronic record systems used for record keeping, documentation of validation of the systems must be available on-site as well as a qualified individual to review the documentation with the inspector. Documentation should demonstrate compliance with the following Standards:

- Validated procedures for and documentation of: [C11.7.9]
 - Training and continued competency of personnel in systems use. [C11.7.9.1]
 - Monitoring of data integrity. [C11.7.9.2]
 - Back-up of the electronic records system on a regular schedule. [C11.7.9.3]
 - System assignment of unique identifiers. [C11.7.9.4]

PROCESSING FACILITY DOCUMENTATION

Processing Facility Director

- Curriculum vitae for each Processing Facility Director. If one individual serves as a director for multiple facilities, submit this individual's curriculum vitae whenever applicable. If the documentation is in a language other than English, include a summary in English. [D3.1.1]
- Documentation of at least ten (10) hours of participation per year for each Processing Facility Director in educational activities related to cellular therapy, including HPC transplantation, since the previous date of accreditation. Complete and upload the [Educational Activities Form](#) or submit other documentation that includes the equivalent information for each activity: [D3.1.4]
 - Date of activity
 - Title of activity
 - Type of activity (e.g., webinar, meeting, grand round)
 - Topic of activity (e.g., hematology, cell processing)
 - Approximate number of hours of activity

Processing Facility Medical Director

- Copy of current license to practice medicine in the jurisdiction in which the program is located for each Processing Facility Medical Director. If the license is in a language other than English, include a general description in English. [D3.2.1]
- Curriculum vitae for each Processing Facility Medical Director. If one individual serves as a director for multiple facilities, submit this individual's curriculum vitae whenever applicable. If the documentation is in a language other than English, include a summary in English. [D3.2.1]
- Documentation of at least ten (10) hours of participation per year for each Processing Facility Medical Director in educational activities related to cellular therapy, including HPC transplantation, since the previous accreditation date. Complete and upload the [Educational Activities Form](#) or submit other documentation that includes the equivalent information for each activity: [D3.2.4]
 - Date of activity
 - Title of activity
 - Type of activity (e.g., webinar, meeting, grand round)
 - Topic of activity (e.g., hematology, cell processing)
 - Approximate number of hours of activity

Processing Facility Quality Manager

- Documentation of at least ten (10) hours of participation per year for each Quality Manager in educational activities related to cellular therapy and quality management, including HPC transplantation, since the previous accreditation date. Complete and upload the [Educational Activities Form](#) or submit other documentation that includes the equivalent information for each activity: [D3.3.3]
 - Date of activity
 - Title of activity
 - Type of activity (e.g., webinar, meeting, grand round)
 - Topic of activity (e.g., hematology, cell processing)
 - Approximate number of hours of activity

Other Processing Documentation

- A completed [Processing Facility Grid](#). For initial accreditation, enter data for the previous 12 months. For renewal accreditation, enter data from the start of the current accreditation cycle. [D1.1]
- A map of the overall organization that includes all facilities. If the map is labeled in a language other than English, include a general description of the floor plan or diagram in English. [D1.1]
- Physical floor plans of all facilities. Label all floors of the building(s) that are used for cellular therapy related activities. If the floor plan(s) or diagram is labeled in a language other than English, include a general description of the floor plan or diagram in English. [D1.1]
- Documentation of licensure, registration, and/or accreditation required by the appropriate governmental authority for the activities performed. U.S. facilities must submit a copy of the validated FDA registration for Human Cells, Tissues, and Cellular and Tissue Based Products (Form 3356). Facilities in other countries must submit certification required by the appropriate governmental authority. If the licensure, registration, or accreditation is in a language other than English, include a general description of the document in English. [D1.2.1]
- Copy of the Processing Facility's Quality Management Plan that includes all requirements listed in D4. [D4.2]
- Copy of organizational chart of key positions and functions within the Processing Facility. [D4.3]
- Policies or Standard Operating Procedure for development, approval, implementation, distribution, review, revision, and archival of all critical documents. [D4.5.2]
- Standard Operating Procedure(s) that outlines a standardized format for critical documents and required elements of each procedure. [D4.5. 1 and D5.3]
- Evidence of a completed outcome analysis, e.g., a report of conclusions, meeting minutes, or completed forms. [D4.7]

- Schedule of audits that includes dates and subjects of audits already performed and audits planned for the future. At a minimum, the audits listed in D4.8.3 must be included. [D4.8]
- The policy or Standard Operating Procedure for qualification of critical manufacturers, vendors, equipment, supplies, reagents, facilities, and services. [D4.13]
- The policy or Standard Operating Procedure for the validation or verification of critical procedures. [D4.14]
- A summary of one completed validation of the ISBT 128 labeling system that includes: [D4.14.1] [D4.14.2] [D7.1.2]
 - A summary of the validation plan
 - Number of data points used
 - Acceptance criteria
 - Data collection
 - Evaluation of Data
 - Summary of results and outcomes
 - References, if applicable
 - Review and approval of the plan, results, and conclusion
- A summary of one additional completed validation study of a critical procedure of the Processing Facility that includes: [D4.14.1, D4.14.2]
 - A summary of the validation plan
 - Number of data points to be used
 - Acceptance criteria
 - Data collection
 - Evaluation of Data
 - Summary of results
 - References, if applicable
 - Review and approval of the plan, results, and conclusion
- Complete cryopreservation and thawing Standard Operating Procedure(s) that includes the directions for cryopreservation and preparation of the cryoprotectant solution. [D5.1.7]
- If the Processing Facility performs processing with more-than-minimal manipulation, a Standard Operating Procedure(s) for release and exceptional release. [D5.1.10]
- Table of Contents from the Processing Facility Standard Operating Procedures Manual that includes the title and identifier for each controlled document. [D5.2]
- Completed examples of documentation of the visual examination of supplies and reagents used to manufacture cellular therapy products. [D6.2.1]
- A sample log of equipment inspection for cleanliness and compliance with the maintenance schedule prior to each use. [D6.5]

- Completed examples of each type of in-process processing labels used by the Processing Facility. Do not include protected health information (PHI), e.g., patient names, medical record numbers, birthdate, or others. Mock identifiers and names must be used. If the labels are in a language other than English, include a general description of the label elements in English. [D7.4.1]

- Completed examples of each type of label used by the Processing Facility. Do not include protected health information (PHI), e.g., patient names, medical record numbers, birthdate, or others. Mock identifiers and names must be used. If the labels are in a language other than English, include a general description of the label elements in English. [D7.4.3]
 - Any partial labels at distribution applied by the Processing Facility. [Cellular Therapy Standards Appendix II]
 - Labels applied at completion of processing of allogeneic products collected from marrow and allogeneic products collected by apheresis, as applicable. [Cellular Therapy Standards Appendix II]
 - Labels applied at completion of processing of autologous products collected from marrow and autologous products collected by apheresis, as applicable. [Cellular Therapy Standards Appendix II]
 - Labels applied prior to distribution for allogeneic products collected from marrow and allogeneic products collected by apheresis, as applicable. [Cellular Therapy Standards Appendix II]
 - Labels applied prior to distribution for autologous products collected from marrow and autologous products collected by apheresis, as applicable. [Cellular Therapy Standards Appendix II]
 - Labels applied to inner and outer shipping containers for products shipped or transported on public roads. [Cellular Therapy Standards Appendix III]

- Standard Operating Procedure for labeling that includes when biohazard and/or warning labels are used, including: [D7.4.4, Appendix II]
 - Biohazard legend
 - Statement "NOT EVALUATED FOR INFECTIOUS SUBSTANCES"
 - Statement "WARNING: Advise Patient of Communicable Disease Risks"
 - Statement "WARNING: Reactive Test Results for [name of disease agent or disease]"
 - Statement "FOR AUTOLOGOUS USE ONLY"

- If processing personnel apply labels to cellular therapy products at completion of collection: Do not include PHI. Mock identifiers and names must be used. If the labels are in a language other than English, include a general description of the label elements in English. [D7.4.5]
 - Completed example of a primary collection container label applied on completion of allogeneic cellular therapy product collection from marrow or by apheresis, as applicable. [Cellular Therapy Standards Appendix II]
 - Completed example of a primary collection container label applied on completion of autologous cellular therapy product collection from marrow or by apheresis, as applicable. [Cellular Therapy Standards Appendix II]
 - Completed examples of labels applied prior to transport or shipping of cellular therapy products, including inner and outer container labels. [Cellular Therapy Standards Appendix III]

- Documentation that accompanies the cellular therapy product at distribution and a policy or Standard Operating Procedure that discusses the documentation that is distributed with the product. [D7.4.5, Cellular Therapy Standards Appendix IV]
- Policy or Standard Operating Procedure for preparing cord blood units for administration. [D8.4.3 and D8.4.4]
- A written stability program that evaluates the viability and potency of cryopreserved cellular therapy products, and the results of the last annual assessment. [D9.2.2]
- If a document other than the current version of the inter-organizational *Circular of Information for the Use of Cellular Therapy Products* is used, submit the document made available to clinical staff containing the following information: (Must be in English) [D11.1.4]
 - Use of the cellular therapy product, indications, contraindications, side effects and hazards, dosage, and administration recommendations. [D11.1.4.1]
 - Handling the cellular therapy product to minimize the risk of contamination or cross-contamination. [D11.1.4.2]
 - Appropriate warnings related to the prevention of the transmission or spread of communicable diseases. [D11.1.4.3]
- A pre-collection written agreement between the storage facility and the designated recipient or the donor that includes the length of storage, circumstances for disposal, and option to transfer the cellular therapy product to another facility. [D12.1.1 and D12.1.2]

Electronic Record Systems:

- Current list of critical electronic record systems under the control of the Processing Facility, including a description of the purpose of each system and how it is used. Complete and upload the [Critical Electronic Record Systems](#) form or submit other documentation that contains the equivalent information for each critical record system. [D13.3.1]

If an electronic record system under the control of the facility is used for record keeping, documentation of validation of the system must be available on-site as well as a qualified individual to review the documentation with the inspector. Documentation should demonstrate compliance with the following Standards:

- Validated procedures for and documentation of: [D13.3.9]
 - Systems development. [D13.3.9.1]
 - Numerical designation of system versions if applicable. [D13.3.9.2]
 - Prospective validation of system including hardware, software, and databases. [D13.3.9.3]
 - Installation of the system. [D13.3.9.4]
 - Training and continued competency of personnel in the use of the system. [D13.3.9.5]
 - Monitoring of data integrity. [D13.3.9.6]
 - Back-up of the electronic records system on a regular schedule. [D13.3.9.7]
 - System maintenance and operations. [D13.3.9.8]
 - System assignment of unique identifiers. [D13.3.9.9]