Comparison of Processing Standards

The tables are populated with data from the standards from FACT-JACIE, Netcord-FACT, and AABB. Consult the recent versions. WMDA and EFI activities do not cover these activities. The crosswalks are intended to point out the similarities or general principles of the standards and do not necessarily list specific requirements.

Definitions	Abbreviation
FACT-JACIE International Standards for Cellular Therapy Product Collection, Processing and Administration 6th Edition	**F-J**
Netcord-FACT International Standards for Cord Blood Collection, Banking and Release for Administration 6th Edition	**NC-F**
AABB Standards for Cellular Therapy Services 6th Edition	**AA**
Cord Blood Bank	**CBB**
Requirement is addressed	**X**
Requirement is not addressed	**-**
Not Applicable	**NA**

REQUIREMENTS	F-J	NC-F	AA
General Requirements			
Processing standards apply to cells from:			
• Living donors only	X	X	-
• Living donors and cadaveric donors	-	-	X
Facilities must abide by all applicable laws and regulations	X	X	X
Eligibility for accreditation requires a minimum time in: • operation or • minimum level of activity	12 months -	- 500 units banked	6 months -
Facility Requirements			
Registration or accreditation from relevant governmental authority for activities performed	X	X	X
Adequate space, design and location according to workload	X	X	X

REQUIREMENTS	F-J	NC-F	AA
Secure against unauthorized entry	X	X	X
Environmental conditions sufficient to prevent introduction, transmission or spread of communicable disease	X	X	X
Critical facility parameters that might affect operations are controlled, monitored and recorded	X	X	X
Where appropriate controls include temperature, humidity, ventilation, air quality and surface contaminates	X	X	X
Where appropriate environmental monitoring for microorganisms is performed	X	X	X
Documentation of cleaning and sanitation is performed	X	X	X
Period of cleaning record retention is minimally:	3 years	Retention not specified	10 years
Environmental control systems are inspected to ensure adequate operations	X	X	X
Equipment and materials must be adequate in number and type for the workload?	X	-	X
Personnel?	X Adequate Personnel	X Adequate Personnel	X
Storage areas must be controlled to prevent cross-contamination, contamination, or mix-up of products during quarantine or prior to release or distribution	X	X	X
Safety			
Facility operations must minimize risks to health and safety of all within personnel	X	X	X
Safety manual is required and must include instructions for action to exposure to:	X	X	X (requires policies, processes, and procedures)
Communicable Disease	X	X	X
Chemical, Biologic, or Radiological hazards	X	X	X
Medical Waste disposed in a manner that minimizes danger to personnel	X	X	X

REQUIREMENTS	F-J	NC-F	AA
and environment			
Waste disposal shall be in accord with applicable laws and regulations	X	X	X
Facility shall be maintained in clean, sanitary, and orderly manner	X	X	X
Protective attire shall be available and shall be used when handling biological specimens.	X	X	X
Protective attire shall not be worn outside of work area	X	X	-
Personnel			
Laboratory Director required	X	X	X
Minimal requirements include: medical degree or	X	X	X
Doctoral degree in a relevant science	X	X	X
Training or experience for scope of lab activities	X	X	X
Laboratory Medical Director required	X	X	X
Minimal requirements include: Medical degree	X	X	X
Medical license	X	X	X
One year experience in preparation and clinical use of cellular therapy products	X	Experience but no minimum time specified	X Qualified by training and relevant experience
Laboratory Director and Laboratory Medical Director may be same individual	X	X	X
Processing Facility Policies and Procedures			
Policies or procedures addressing the following topics are required:			
Donor and recipient confidentiality	X	X	X
Product receipt	X	X	X
Processing and process controls	X	X	X
Prevention of mix-ups and cross-contamination	X	X	X
RBC compatibility testing and processing of ABO-incompatible products. Must address methods for RBC or plasma depletion	X	-	X
Cryopreservation and thawing	X	X	X

REQUIREMENTS	F-J	NC-F	AA
Labeling of products, samples, and associated forms	X	X	X
Product expiration dates and times	X (standard says date but guidance includes time)	Plan to determine expiration is required	X
Product storage and plan if primary device fails	X	X	X
Release and exceptional release	X	X	X
Cellular therapy product recall, to include description of responsibilities and actions to be taken, including regulatory agency notification	X	X	X
Product transport and shipping	X	X	X
Product disposal	X	X	X
Reagent and supply management (or materials management)	X	X	X
Equipment operation, maintenance, and monitoring	X	X	X
Cleaning and sanitation	X	X	X
Environmental control with monitoring plan	X	X	X
Hygiene and use of personal protective attire	X	X	X
Infection control, biosafety, and chemical and radiological safety	X	X	X
Facility management	X	X	X
Decontamination and disposal of medical waste	X	X	X
Emergency and disaster plan describing facility response	X	X	X
Requirement for a Standard Operating Procedures Manual that operates under the document control system. Should also include:	X	X	X
A defined numbering and titling system for SOPs, policies, worksheets and forms	X	X	X
SOP standard form to include: objectives, description of equipment and supplies, acceptable endpoints and range of results	X	X	X
Stepwise description of procedure	X	X	X
References, including to other needed SOPs	X	X	X
Includes copies of current versions of needed work forms, orders, reports, labels, and forms	X	X	X
Review and approval minimally with change and every (specify) years	2	2	Annually

REQUIREMENTS	F-J	NC-F	AA
SOPs relevant to the tasks being performed must be readily available to staff	X	X	X
SOP must be followed	X	X	X
Staff must document review and training on new and revised SOP prior to performing	X	X	X
Archived procedures maintained minimally 10 yrs or according to local regulations whichever is longer	X	X	X
Procedures records must include inclusive dates of use	X	X	X
Product Sampling and Testing			
Processing facility Director is responsible for defining tests and procedures to ensure product safety, viability, and integrity according to defined release criteria.	X	X	X
Product release test results and interpretation must be part of the processing record	X	X	X
Product samples must be representative of the entire product	X	X	X
Sample labels must be sufficient to accurately relate to corresponding product (including stage of processing), donor, or recipient	X	X	X
Must be mechanism to identify individual obtaining sample, date and time (if relevant) sample was taken, and the sample source	X	X	X
Minimal product testing prior to infusion or cryopreservation to include use of a validated assay for:	X	X	X
TNC and viability assessment	X	X	X
Assessment of CD34 content for HPC products	X	X	X
Product sterility	X	X	X
When processing alters the final cell population, the target cell population should be assessed before and after processing	X	X	X
Test procedures performed by the processing facility must be monitored for reliability, accuracy, precision, and performance.	X	X	X
Ongoing proficiency testing required for tests performed by the processing facility	X	X	X

REQUIREMENTS	F-J	NC-F	AA
Communicable disease testing shall be performed using laboratories and testing reagents or kits approved in accordance with applicable laws and regulations	X	X	X
Results for ABO group and Rh type testing shall be available from two independently collected samples. Discrepancies shall be resolved and documented prior to issue of the cellular therapy product.	X	-	X
External laboratories performing testing required by the standards required to be certified for the testing that is performed laboratory.	X	X	X
Products failing to pass tests required for release to be distributed only with appropriate approvals by designated laboratory management and the recipient's transplant physician.	X	X	X
Documentation of the notification of recipient's physician of testing and screening results for ineligible donors is required.	X	X	X
Processing facility must monitor and document results of microbial contamination testing as defined by SOP	X	X	X
Microbial testing results must be reviewed by Processing Facility Director or designee in a timely manner	X	X	X
Recipients physician must be notified in a timely manner of positive results	X	X	X
Minimally one aliquot representative of the cryopreserved product at the time of freezing shall be stored	X	X	X
Aliquots must be stored under conditions that ensure a valid representation of the clinical product.	X	X	X
For cryopreserved products with low volume or low cellular content, a sample representing the final steps of processing shall be stored.	X	X	-
Cryopreserved aliquots shall be stored for a period of time defined by facility SOP	X	X Minimally 1 sample held indefinitely	X
Cryopreserved HPC(CB) products must contain minimally 2 segments integrally attached to bag and containing approximately 200 microliters of	NA	X	X

REQUIREMENTS	F-J	NC-F	AA
representative sample			
One integrally attached segment must be used to verify HLA typing, and should be used to verify viability and potency for banked HPC(CB)	NA	X	-
Serum or plasma samples (not heparinized) of >3.6 mL stored -70 C or colder in at least 2 vials stored.	NA	X	-
Minimally sample sufficient to obtain 50 microgram genomic DNA required from banked HPC(CB)	NA	X	-
Maternal Samples for Banked HPC(CB)			
Serum or plasma samples (not heparinized) of >3.6 mL stored -70°C or colder in at least 2 vials stored	NA	X	-
Minimally sample sufficient to obtain 50 microgram genomic DNA required	NA	X	-
Product Processing			
Written physician order to laboratory required for processing to be performed. Must minimally include:	X	Documentation of Consent needed for HPC(CB)	X
Product type to be processed	X	NA	-
Recipient and donor identifiers	X	NA	X
Processing to be performed	X	NA	X
Anticipated date processing to begin	X	NA	-
Processing facility must have information on donor eligibility prior to post-processing distribution to include:	X	X	X
Statement of donor eligibility	X	X	X
If donor is ineligible, reason for ineligibility	X	X	X
If applicable, documentation of urgent medical need and physician approve for use	X	X	X
Processing procedure must be validated to ensure acceptable target cell viability and recovery	X	X	X

REQUIREMENTS	F-J	NC-F	AA
Published procedures validated by another entity must be verified within the laboratory	X	-	X
Critical control points in processing procedure SOPs must be identified and appropriate checks (tests, etc.) performed to monitor	X	X	X
Processing shall be performed using aseptic techniques	X	X	X
Processing steps requiring exposure to the environment must be performed under conditions of appropriately specified air quality and cleanliness	X	X	X Addressed by environmental controls
Processing procedures, including equipment, supplies, and reagents, must minimize risk of mix-ups and cross-contamination	X	X	X
The effectiveness of measures to avoid contamination and cross-contamination must be verified and monitored	X	X	X
Must have a system to track the use of critical equipment for a given processing procedure and to determine the processing procedures for which a given piece of equipment was used	X	X	X
System to document that equipment is clean and verified to be in compliance with its maintenance schedule prior to use	X	X	X
Products that are more than minimally manipulated must be processed only after IRB or ethics committee approval and recipients signs informed consent	X	X	-
Cellular therapy product must be processed within 48 hours if unrelated and 72 hours if related	-	X	-
Freezing bags must be visually examined for leaking, seal breakage, overfilling or under filling before cryopreservation	-	X	-
Processing Documents			
Records made concurrently with processing that identify individual responsible for the performance of each step	X	X	X
Identification code records (e.g. signatures, initials) maintained to accurately link to full identification of individual and their inclusive dates of employment	X	X	X

REQUIREMENTS	F-J	NC-F	AA
Test results include their interpretation where appropriate	X	X	X
Lot numbers, expiration dates, and identity of manufacturers of critical reagents, supplies, and key equipment maintained for each processing procedure	X	X	X
Processing procedure records to be reviewed by Director or designee prior to release or distribution	X	X	X
Records to include documentation of physician notification when clinically relevant endpoints are not met	X	Policy to manage	X
Record to include remedial actions taken when clinically relevant endpoints are not met	X	Policy to manage	X
Product Storage			
Product storage areas shall be controlled to prevent mix-ups, deterioration, contamination, cross-contamination, and improper distribution of the cellular therapy product	X	X	X
Duration and conditions of product storage and indications for disposal shall be established	X	X Stability program required	X
Recipients, donors and associated clinical programs should be informed of storage policies before product collection	X	X	X
The Processing Facility shall establish expiration dates and times for fresh products and for products post thawing	X	X	X
Product storage temperatures shall be defined within an SOP	X	X	X
Temperature ranges shall be appropriate to maintain product viability and function and to inhibit infectious agents over the designated storage period	X	X	X
Cryopreserved cellular therapy products must be stored at -150^{o}C or colder	-	X	X
The duration of warming events during storage of cryopreserved products must be documented and potential effect on product assessed	-	X	X

REQUIREMENTS	F-J	NC-F	AA
Products shall not be stored in proximity to materials that may adversely affect the cellular therapy product	X	X	X
Products immersed in liquid nitrogen shall be stored by methods that minimize the risk of cross-contamination	X	X	X
The Processing Facility shall define in an SOP a process for the quarantine of products from donors for whom eligibility determination is incomplete	X	X	X
Quarantined cellular therapy products shall be easily distinguishable and stored in a manner to minimize cross-contamination and inappropriate distribution	X	X	X
Temperature controlled product storage devices shall have a system to monitor the temperature continuously and to record the temperature minimally every 4 hours	X	X	X at defined intervals rather than 4 hours
Devices containing products immersed in liquid nitrogen shall include a mechanism to ensure that levels of liquid nitrogen are sufficient to maintain the product within the specified temperature range	X	X	X
Cellular therapy product storage devices shall have alarm systems that are continuously active and that have audible signals or other effective notification methods.	X	X	X
Periodic tests of alarm system function are required	X	X	X
The alarm system shall be capable of alerting a responsible individual on a 24-hour basis	X	X	X
Alarms shall activate at a temperature or level of LN2 sufficient to allow time for product salvage	X	X	X
Written instructions shall be posted in the immediate area of storage devices and remote alarm locations with instructions to be followed if the device fails and instructions for notifying responsible personnel	X	X	-
Instructions shall outline procedures to maintain products at a safe temperature and should outline corrective actions to be taken	X	X	X
Additional storage devices of the appropriate temperature shall be identified and available in the event of primary storage device failure	X	X	X

REQUIREMENTS	F-J	NC-F	AA
Storage devices shall be located in a secure area and accessible only to authorized personnel	X	X	X
The Processing Facility shall maintain an inventory control system to identify the location of products and their associated samples. Records shall include:	X	X	X
• Product or specimen name	X	X	X
• Product unique identifier	X	X	X
• Recipient name or unique identifier	X	X (Maternal identifier required for CB)	X
Storage device and location within the storage device	X	X	X
Product Transport and Shipping			
The Processing Facility shall establish procedures for transportation, shipping and receipt of cellular therapy products	X	X	X
Transportation and shipping procedures shall protect the integrity of the product and the health and safety of individuals involved in accordance with applicable laws and regulations	X	X	X
Primary fresh product containers shall be placed in a sealed secondary container	X	X	-
A outer shipping container validated to maintain the storage temperature specified by the Processing Facility shall be used when:	X	X	X
Transport is for an extended period of time	X	X	-
Transport or shipping requires the use of public roads	X	X	-
The outer shipping container shall be made of materials sufficient to preserve the safety and integrity of the product during shipping	X	X	X
The shipping contains shall conform to applicable regulations for the mode of transportation used	X	X	X
The temperature of cryopreserved products shall be continuously monitored during shipping.	X	X	X
The shipping facility shall maintain a record of the temperature over the	X	X	X

REQUIREMENTS	F-J	NC-F	AA
period of travel and this information shall be provided to the receiving institution	Receiving facility required to obtain Temp record from shipper	Record required but no requirement to provide to receiving institution	
Transportation and Shipping methods shall be defined and shall include:	X	X	X
Minimizing transit time	X	X	X
Use of a qualified courier for recipients who have begun transplant conditioning therapy	X	-	X
Alternative transport plan in case of emergency	X	X	X
Prohibition against product exposure to X-Ray irradiation devices design to detect metal objects; Only manual inspection allowed	X	-	X
Product receipt methods shall be defined and shall include:	X	X	X
Establishment of criteria for acceptance, rejection and quarantine	X	X	X
Inspection for integrity of primary container, product appearance, product labeling, and evidence of microbial contamination	X	X	X
Verification of appropriate shipping or transport method	X	X	-
Documentation of the temperature of shipping containers upon arrival	X	X	X
For cryopreserved products a record of container temperature during shipping	X	X	X
Verification of receipt of a summary of records used to determine donor eligibility for allogeneic products	X	X	X
A procedure to maintain products in quarantine until all release criteria are met	X	X	X
Transportation and shipping records shall be maintained and shall include:	X	X	X
• Records sufficient to permit tracing of the product from one site to the other	X	X	X
• Date and time product was distributed	X	X	X
• Date and time product was received	X	X	X

REQUIREMENTS	F-J	NC-F	AA
• Identity of the transporting or shipping facility	X	X	X
• Identity of the receiving facility	X	X	X
• Identify of the personnel responsible for transport or shipping and person responsible for product receipt	X	X	X
• Identity of the courier, if appropriate	X	X	-
• Documentation of any delays or problems during transport or shipping	X	Required to verify transport method did not affect viability	-
Cellular Therapy Product Disposal or Transfer			
Processing Facility shall have policies and procedures for product disposal or transfer to include:	X	X	X
Pre-collection written agreement regarding the duration of storage and the circumstances for disposal	X	X	X
Option for transfer of the product to another facility if the designated recipient is alive after the agreed upon storage interval	X	X	X
Policies, SOP, and agreements in place if all or part of a CB bank inventory is transferred to another facility	NA	X	X
CB bank to supply facility in receipt of all or part of a CB bank inventory with all records related to the collection, processing, testing, and storage of the units and attached or associated samples so as to allow receiving facility to meet relevant standards	NA	X	-
Facility in receipt of all or part of a CB bank inventory required to verify through observation or testing: integrity and viability results of the units, completeness of records, need to store units in quarantine based on criteria designed to prevent transmission of communicable disease	NA	X	X
Documentation of the intended recipients death or no further need for the product prior to discard	X	NA	X
Policy in place for discard or disposition of HPC(CB) to include release	NA	X	X

REQUIREMENTS	F-J	NC-F	AA
for : clinical use, research, QA activities, discard			
Policies for management of nonconforming HPC(CB) units not accepted into inventory, that fail to meet endpoints or specifications, and that have positive or indeterminate test results	NA	X	X
Approval by the recipients transplant physician or the Processing Facility Medical Director or by individuals authorized to approve product discard for product discard or other disposition	X	X	X
Approval by the Processing Facility Medical Director of the method of disposal	X	-	X
Disposal by a method in compliance with applicable laws and regulations for the disposal of biohazardous materials and/or medical waste	X	X	X
Storage and disposal of product obtained through donor registries that is in agreement with the policies of the registry	X	NA	-
In the event there is no pre-existing agreement for product storage or discard and the patient is lost to follow-up the storage facility shall have a policy or procedure requiring the following:	X	Not directly addressed. Need overall policy for disposition	X
Communication with the designated recipients physician regarding the need for continued storage	X	NA	X
A documented effort to notify the donor or designated recipient regarding product disposition, disposal or transfer	X	If related	X
Discard or transfer records shall minimally include the identity of the product transferred, the date of discard or transfer, the disposition of the product, and the method of disposal or transfer	X	X	X
Records to be maintained			
Records to be maintained minimally 10 years or longer in accord with applicable laws and regulations or for a period of time defined by institution policy include those related to:	X	X	X
• Quality control	X	X	X

REQUIREMENTS	F-J	NC-F	AA
• Personnel training and competency	X	X	X
• Facility management and maintenance	X	X	X
• Other facility issues	X	X	X
• Facility cleaning records shall be maintained minimally 3 years	X	No time limit specified	X
Records to be maintained minimally 10 years after the date of administration or distribution or in accord with laws and regulations include:	X	Only equipment limited to 10 y others not specified	X
• Processing records	X	X	X
• Compatibility test records	X	X	X
• Cryopreservation records	X	X	X
• Distribution records	X	X	X
• Records of errors, accidents, adverse reactions, and complaints	X	X	X
• Quality management records	X	X	X
When responsibilities for the collection, processing or distribution of the cellular therapy product involve two or more facilities, each facility must clearly show the extent of its responsibility	X	X	X
The Processing Facility must maintain a listing of the names, addressed, and the responsibility of other facilities that perform manufacturing steps on a cellular therapy product	X	X	X
There shall be a system to track all manufacturing steps performed by other facilities	X	X	X
The Processing Facility shall furnish to the facility of final disposition a copy of all records related to the collection, processing, and storage of the product as they related to the safety, purity, or potency of the product	X	X	X