

Comparison of Processing Standards

The tables are populated with data from the FACT-JACIE (4th ed.), Netcord-FACT (4th ed.), WMDA and AABB (4th ed.)

Definitions	Abbreviation
WMDA 2008	W
FACT-JACIE 4th Ed	F-J
Netcord-FACT 4th Ed	NC-F
AABB 4 Ed	AA
Cord Blood Bank	CBB
Not Applicable	NA

REQUIREMENTS	W	F-J	NC-F	AA
General Requirements				
Processing standards apply to cells from:				
Living donors only	NA	X	X	X
Living donors and cadaveric donors	NA			X
Facilities must abide by all applicable laws and regulations	NA	X	X	X
Eligibility for accreditation requires a minimum time in operation of minimum level of activity:	NA	12 months		6 months
Facility Requirements				
Registration or accreditation from relevant governmental authority for activities performed	NA	X	X	
Legal entity				
Adequate space, design and location according to workload	NA	X	X	X
Division into defined areas to prevent mix-ups or cross-contamination	NA	X	X	X
Secure against unauthorized entry	NA	X	X	X
Environmental conditions sufficient to prevent introduction, transmission or spread of communicable disease	NA	X	X	X
Critical facility parameters that might affect operations are controlled, monitored and recorded	NA	X	X	X

REQUIREMENTS	W	F-J	NC-F	AA
Where appropriate controls include temperature, humidity, ventilation, air quality and surface contaminates	NA	X	X	X
Where appropriate environmental monitoring for microorganisms is performed	NA	X	X	X
Documentation of cleaning and sanitation is performed	NA	X	X	X
Period of cleaning record retention is minimally:	NA	3 years	X	10 years
Environmental control systems are inspected to ensure adequate operations	NA	X		X
Equipment and materials must be adequate in number and type for the workload? Personnel?	NA	X		X
Storage areas must be controlled to prevent cross-contamination, contamination, or mix-up of products during quarantine or prior to release or distribution	NA	X	X	X
Safety				
Facility operations must minimize risks to health and safety of all within Personnel	NA	X	X	X
Safety manual is required and must include instructions for action to exposure to:	NA	X	X	
Communicable Disease	NA	X	X	
Chemical, Biologic, or Radiological hazards	NA	X	X	X
Medical Waste disposed in a manner that minimizes danger to personnel and environment		X	X	X
Waste disposal shall be in accord with applicable laws and regulations	NA	X	X	X
Facility shall be maintained in clean, sanitary, and orderly manner	NA	X	X	X
Protective attire shall be available and shall be used when handling biological specimens.	NA	X	X	X
Protective attire shall not be worn outside of work area	NA	X	X	
Personnel				
Laboratory Director required	NA	X	X	X
Minimal requirements include: medical degree or	NA	X	X	X
Doctoral degree in a relevant science	NA	X	X	X
Training or experience for scope of lab activities	NA	X	X	X
Laboratory Medical Director required	NA	X	X	X
Minimal requirements include: Medical degree	NA	X	X	X
Medical license	NA	X	X	X
One year experience in preparation and clinical use of cellular therapy products	NA	X	X	

REQUIREMENTS	W	F-J	NC-F	AA
Laboratory Director and Laboratory Medical Director may be same individual	NA	X	X	X
Processing Facility Policies and Procedures				
Policies or procedures addressing the following topics are required:				
Donor and recipient confidentiality	NA	X	X	X
Product receipt	NA	X	X	X
Processing and process controls	NA	X	X	X
Prevention of mix-ups and cross-contamination	NA	X	X	X
RBC compatibility testing and processing of ABO-incompatible products. Must address methods for RBC or plasma depletion	NA	X	X	X
Cryopreservation and thawing	NA	X	X	X
Labeling of products, samples, and associated forms	NA	X	X	X
Product expiration dates and times	NA	X (std says date but guidance includes time)	X	X
Product storage and plan if primary device fails	NA	X	X	X
Release and exceptional release	NA	X	X	X
Cellular therapy product recall, to include description of responsibilities and actions to be taken, including regulatory agency notification	NA	X	X	X
Product transport and shipping	NA	X	X	X
Product disposal	NA	X	X	X
Reagent and supply management (or materials management)	NA	X	X	X
Equipment operation, maintenance, and monitoring	NA	X	X	X
Cleaning and sanitation	NA	X	X	X
Environmental control with monitoring plan	NA	X	X	X
Hygiene and use of personal protective attire	NA	X	X	X
Infection control, biosafety, and chemical and radiological safety	NA	X	X	X
Facility management	NA	X	X	X
Decontamination and disposal of medical waste	NA	X	X	X
Emergency and disaster plan describing facility response	NA	X	X	X
Requirement for a Standard Operating Procedures Manual that operates under the document control system. Should also include:	NA	X	X	X

REQUIREMENTS	W	F-J	NC-F	AA
A defined numbering and titling system for SOPs, policies, worksheets and forms	NA	X	X	X
SOP standard form to include: objectives, description of equipment and supplies, acceptable endpoints and range of results	NA	X	X	X
Stepwise description of procedure	NA	X	X	X
References, including to other needed SOPs	NA	X	X	X
Includes copies of current versions of needed work forms, orders, reports, labels, and forms	NA	X	X	X
Review and approval minimally with change and every (specify) years	NA	2	X	Annually
SOPs relevant to the tasks being performed must be readily available to staff	NA	X	X	X
SOP must be followed	NA		X	X
Staff must document review and training on new and revised SOP prior to performing	NA	X	X	X
Archived procedures maintained minimally 10 yrs or according to local regulations whichever is longer	NA	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.	NA	X	X	X
Product release test results and interpretation must be part of the processing record			X	X
Product samples must be representative of the entire product	NA	X	X	X
Sample labels must be sufficient to accurately relate to corresponding product (including stage of processing), donor, or recipient	NA	X	X	X
Must be mechanism to identify individual obtaining sample, date and time (if relevant) sample was taken, and the sample source	NA	X	X	X
Minimal product testing prior to infusion or cryopreservation to include use of a validated assay for:	NA	X	X	X
TNC and viability assessment	NA	X	X	X
Assessment of CD34 content for HPC products	NA	X	X	X
Product sterility	NA	X	X	X
When processing alters the final cell population, the target cell population should be assessed before and after processing.	NA	X	X	
Test procedures performed by the processing facility must be monitored for reliability, accuracy, precision, and performance.	NA	X	X	X

REQUIREMENTS	W	F-J	NC-F	AA
Ongoing proficiency testing required for tests performed by the processing facility	NA	X	X	X
Communicable disease testing shall be performed using laboratories and testing reagents or kits approved in accordance with applicable laws and regulations	NA	X	X	X
Allogeneic products containing red blood cells at the time of administration shall be tested for ABO and Rh on at least two occasions from independent samples and the results must agree before distribution.	NA	X (at time of 1 st product collection for 4 th Ed, as written for 5 th Ed draft)		X
External laboratories performing testing required by the standards required to be certified for the testing that is performed laboratory.	NA	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.	NA	X	X	X
Documentation of the notification of recipient's physician of testing and screening results for ineligible donors is required.	NA	X	X	X
Processing facility must monitor and document results of microbial contamination testing as defined by SOP	NA	X	X	X
Microbial testing results must be reviewed by Processing Facility Director or designee in a timely manner	NA	X	X	X
Recipients physician must be notified in a timely manner of positive results	NA	X	X	X
Minimally one aliquot representative of the cryopreserved product at the time of freezing shall be stored	NA	X	X	X
Aliquots must be store under conditions that ensure a valid representation of the clinical product.	NA	X	X	X
For cryopreserved products with low volume or low cellular content, a sample representing the final steps of processing shall be stored.	NA	X	X	
Cryopreserved aliquots shall be stored for a period of time defined by facility SOP	NA	X	X	
Product Processing				
Written physician order to laboratory required for processing to be performed. Must minimally include:	NA	X	X	X
Product type to be processed	NA	X	X	
Recipient and donor identifiers	NA	X	X	X
Processing to be performed	NA	X	X	
Anticipated date processing to begin	NA	X	X	

REQUIREMENTS	W	F-J	NC-F	AA
Processing facility must have information on donor eligibility prior to post-processing distribution to include:	NA	X	X	X
Statement of donor eligibility	NA	X	X	X
If donor is ineligible, reason for ineligibility	NA	X	X	X
If applicable, documentation of urgent medical need and physician approve for use	NA	X	X	X
Processing procedure must be validated to ensure acceptable target cell viability and recovery	NA	X	X	X
Published procedures validated by another entity must be verified within the laboratory	NA	X	X	X
Critical control points in processing procedure SOPs must be identified and appropriate checks (tests, etc.) performed to monitor	NA	X	X	X
Processing shall be performed using aseptic techniques.	NA	X	X	X
Processing steps requiring exposure to the environment must be performed under conditions of appropriately specified air quality and cleanliness.	NA	X	X	
Processing procedures, including equipment, supplies, and reagents, must minimize risk of mix-ups and cross-contamination	NA	X	X	X
The effectiveness of measures to avoid contamination and cross-contamination must be verified and monitored	NA	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	NA	X	X	X
System to document that equipment is clean and verified to be in compliance with it's maintenance schedule prior to use	NA	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	NA	X	X	
Processing Documents				
Records made concurrently with processing that identify individual responsible for the performance of each step	NA	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	NA	X	X	X
Test results include their interpretation where appropriate	NA	X	X	X
Lot numbers, expiration dates, and identity of manufacturers of critical reagents, supplies, and key equipment maintained for each processing procedure	NA	X	X	X
Processing procedure records to be reviewed by Director or designee prior to release or distribution	NA	X	X	X
Records to include documentation of physician notification when clinically relevant	NA	X	X	X

REQUIREMENTS	W	F-J	NC-F	AA
endpoints are not met				
Record to include remedial actions taken when clinically relevant endpoints are not met	NA	X	X	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	NA	X	X	X
Duration and conditions of product storage and indications for disposal shall be established	NA	X	X	X
Recipients, donors and associated clinical programs should be informed of storage policies before product collection	NA	X	X	X
The Processing Facility shall establish expiration dates and times for fresh products and for products post thawing	NA	X	X	X
Product storage temperatures shall be defined within an SOP	NA	X	X	X
Temperature ranges shall be appropriate to maintain product viability and function and to inhibit infectious agents over the designated storage period	NA	X	X	X
Products shall not be stored in proximity to materials that may adversely affect the cellular therapy product.	NA	X		X
Products immersed in liquid nitrogen shall be stored by methods that minimize the risk of cross-contamination	NA	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	NA	X	X	X
Quarantined cellular therapy products shall be easily distinguishable and stored in a manner to minimize cross-contamination and inappropriate distribution	NA	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.	NA	X	X	X [not every 4 hours necessarily – at defined intervals]
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	NA	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.	NA	X	X	X
Periodic tests of alarm system function are required	NA	X	X	X
The alarm system shall be capable of alerting a responsible individual on a 24-hour basis.	NA	X	X	X
Alarms shall activate at a temperature or level of LN2 sufficient to allow time for product salvage	NA	X	X	X

REQUIREMENTS	W	F-J	NC-F	AA
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.	NA	X	X	
Instructions shall outline procedures to maintain products at a safe temperature and should outline corrective actions to be taken	NA	X	X	
Additional storage devices of the appropriate temperature shall be identified and available in the event of primary storage device failure	NA	X	X	X
Storage devices shall be located in a secure area and accessible only to authorized personnel	NA	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:	NA	X	X	X
Product or specimen name	NA	X	X	X
Product unique identifier	NA	X	X	X
Recipient name or unique identifier	NA	In error says donor, but to be corrected in 5 th Edition to recipient	X	X
Storage device and location within the storage device	NA		X	
Product Transport and Shipping			X	
The Processing Facility shall establish procedures for transportation, shipping and receipt of cellular therapy products	NA	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	NA	X	X	X
Primary fresh product containers shall be placed in a sealed secondary container	NA	X	X	
A outer shipping container validated to maintain the storage temperature specified by the Processing Facility shall be used when:	NA	X	X	X
Transport is for an extended period of time	NA	X	X	
Transport or shipping requires the use of public roads	NA	X	X	
The outer shipping container shall be made of materials sufficient to preserve the safety and integrity of the product during shipping	NA	X	X	X
The shipping contains shall conform to applicable regulations for the mode of transportation used	X	X	X	X
The temperature of cryopreserved products shall be continuously monitored during shipping.	NA	X	X	X
The shipping facility shall maintain a record of the temperature over the period of travel and this information shall be provided to the receiving institution	NA	X	X	X
Transportation and Shipping methods shall be defined and shall include:		X	X	X

REQUIREMENTS	W	F-J	NC-F	AA
Minimizing transit time	X	X	X	
Use of a qualified courier for recipients who have begun transplant conditioning therapy	X	X	X	X
Alternative transport plan in case of emergency	X	X	X	X
Prohibition against product exposure to X-Ray irradiation devices design to detect metal objects, Only manual inspection allowed	X	X	X	X
Product receipt methods shall be defined and shall include:		X	X	X
Establishment of criteria for acceptance, rejection and quarantine	NA	X	X	X
Inspection for integrity of primary container, product appearance, product labeling, and evidence of microbial contamination	NA	X	X	X
Verification of appropriate shipping or transport method	NA	X	X	
Documentation of the temperature of shipping containers upon arrival	NA	X	X	X
For cryopreserved products a record of container temperature during shipping	NA	X	X	X
Verification of receipt of a summary of records used to determine donor eligibility for allogeneic products	NA	X	X	X
A procedure to maintain products in quarantine until all release criteria are met	NA	X	X	X
Transportation and shipping records shall be maintained and shall include:	NA	X	X	X
Records sufficient to permit tracing of the product from one site to the other	X	X	X	X
Date and time product was distributed	X	X	X	X
Date and time product was received	X	X	X	X
Identity of the transporting or shipping facility	X	X	X	X
Identity of the receiving facility	X	X	X	X
Identify of the personnel responsible for transport or shipping and person responsible for product receipt	X	X	X	X
Identity of the courier, if appropriate	X	X	X	
Documentation of any delays or problems during transport or shipping	X	X	X	
Cellular Therapy Product Disposal				
Processing Facility shall have policies and procedures for product disposal to include:		X	X	X
Pre-collection written agreement regarding the duration of storage and the circumstances for disposal	NA	X	X	X
Option for transfer of the product to another facility if the designated recipient is alive after the agreed upon storage interval	NA	X	X	X
Documentation of the intended recipients death or no further need for the product prior to	NA	X	X	X

REQUIREMENTS	W	F-J	NC-F	AA
discard				
Approval by the recipients transplant physician or the Processing Facility Medical Director for product discard or other disposition	NA	X	X	X
Approval by the Processing Facility Medical Director of the method of disposal	NA	X	X	X
Disposal by a method in compliance with applicable laws and regulations for the disposal of biohazardous materials and/or medical waste	NA	X	X	X
Storage and disposal of product obtained through donor registries that is in agreement with the policies of the registry	NA	X	X	
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	X	X
Communication with the designated recipients physician regarding the need for continued storage	NA	X	X	X
A documented effort to notify the donor or designated recipient regarding product disposition, disposal or transfer	NA	X	X	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.	NA	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:	NA	X	X	X
Quality control	NA	X	X	X
Personnel training and competency	NA	X	X	X
Facility management and maintenance	NA	X	X	X
Other facility issues	NA	X	X	X
Facility cleaning records shall be maintained minimally 3 years	NA	X	X	X
Records to be maintained minimally 10 years after the date of administration or distribution or in accord with laws and regulations include:		X	X	X
Processing records	NA	X	X	X
Compatibility test records	NA	X	X	X
Cryopreservation records	NA	X	X	X
Distribution records	NA	X	X	X
Records of errors, accidents, adverse reactions, and complaints	NA	X	X	X
Quality management records	NA	X	X	X
When responsibilities for the collection, processing or distribution of the cellular therapy product	NA	X	X	X

REQUIREMENTS	W	F-J	NC-F	AA
involve two or more facilities, each facility must clearly show the extent of its responsibility.				
The Processing Facility must maintain a listing of the names, addresses, and the responsibility of other facilities that perform manufacturing steps on a cellular therapy product	NA	X	X	X
There shall be a system to track all manufacturing steps performed by other facilities	NA	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	NA	X	X	X