

Inspection Process

The tables are populated with data from the standards, manuals and policies from FACT-JACIE, Netcord-FACT, WMDA, AABB and EFI. Consult the current versions.

Definitions	Abbreviation
WMDA International Standards for Unrelated Hematopoietic Stem Cell Donor Registries Version 2017	W
FACT-JACIE International Standards for Cellular Therapy Product Collection, Processing and Administration 5 th Edition	F-J
Netcord-FACT International Standards for Cord Blood Collection, Banking and Release for Administration 5 th Edition	NC-F
AABB Standards for Cellular Therapy Services 6 th Edition	AA
European Federation for Immunogenetics	EFI
Requirement is addressed	X
Requirement is not addressed	-

REQUIREMENTS	W	F-J	NC-F	AA	EFI
Facilities Inspected & Accredited					
Clinical Facility(ies) (Performing infusions)	-	X	-	X	-
Adult	-	X	-	X	-
Pediatric	-	X	-	X	-
Both	-	X	-	X	-
Collection Facility(ies) or Sites- Fixed	-	X (all)	Number Varies based on total sites	X	-
Processing Facilities(ies)	-	X	X	X	-
Cord Blood Bank	X	-	X	X	-
Unrelated donor Registry	X	-	-	-	-
HLA Typing Laboratories	X	X	-	-	-
Transplant Facilities	X	X	-	-	-
Ambulatory Care Facilities	-	X	-	-	-
Categories of Accreditation					
Autologous Cellular Therapy Products	-	X	-	X	-
Alogeneic Cellular Therapy Products	-	X	-	X	-
Both Autologous and Alogeneic Products	-	X	-	X	-
Cord Blood	X	-	X	X	-
Unrelated	X	-	X	X	-
Directed donor	-	-	X	X	-
Autologous	-	-	X	X	-

REQUIREMENTS	W	F-J	NC-F	AA	EFI
Nature of Inspection					
Site Visit	X (at the accreditation phase)	X	X	X	X
Typical Duration (days)	1.5	1-2	2	2	1
Interim Report	X	X	X	-	X
Months post accreditation due	12	12	12	-	12 + 24
Interim audit / visit	-	J: Yes at end of 2nd y accred.	-	-	-
Review of Documents	X	X	X	X	X
Central office verification of submission	X	X	X	X	X
On Site	X(at the accreditation phase)	X	X	X	X
By inspectors in advance	X	X	partial	X	X
Inspection Frequency and Type					
Frequency	4Y	3 y F/4 y J	3	Biannually	3
Announced	X	X	X	-	X
Unannounced	-	-	-	X	-
Post Inspection Review Process					
Inspector(s) reports	X	X	X	X	X
Time limit for completion (days)	14	14	14	Delivered at completion of assessment	14
Central office review and preparation of reports	X	X	X	X	X
Typical time for review (weeks)	4- 6	4	4	Facility has 30 days post-assessment to respond to non-conformances	14
Initial professional review	X	X	X	X	X
Dedicated inspections review committee	X	X	X	X	-
Review by non-dedicated committee (i.e. Board of Directors)	X (Accreditation Committee and in case of not unanimous decision the Board)	-	-	X	-
Typical time for review (weeks)	8-12	8-12	8	2-3	2-4

REQUIREMENTS	W	F-J	NC-F	AA	EFI
Possible outcomes of review					
No response required	X	X	X	X	X
Written response to review ± evidence of correction	X	X	X	X	X
Partial or full reinspection required	-	X	X	X	X
Accreditation not awarded	X	X	X	X	X
Final accreditation decision by:					
Dedicated committee	X	X (J)	-	X	X
Board of Directors	X	X (F)	X	-	-
Publication/Notification of Accreditation					
Publication on accreditation body website	X	X	X	X	X
Letter to facility	X	X	X	X	X
Accreditation certificate	X	X	X	X	X
Circumstances requiring off-cycle review					
Serious adverse event at accredited facility (if become aware)	X	X if involves failure to follow standards	X if involves failure to follow standards	X	-
Complaint to central office judged to be serious	X	X	X	X	-
Evidence that facility is non-compliant with standards/regulations	-	X	X	X	-
Relocation of facility	-	X	X	X	X
Loss of key personnel at facility	-	X	X	X	X
Inspector Qualifications & Training Requirements					
Required years of experience in relevant discipline & degree	Require to be a member of WMDA and for new reviewers to be affiliated with a registry, have at least 3 years of experience in some aspects of registry's operations documented in their CV/ or have Have at least two (2) years of experience in	JACIE: 5 years ¹ FACT	Required combination of education and experience varies based on the facility (Bank, Collection, Laboratory) to be inspected. See FACT website for details. ²	Varies by education level and number of procedures the individual's site performs per year, and by product type. See Appendix 5.1.1.f.a in Accreditation Program Policy Manual.	Combination of education and experience. Must attend a dedicated EFI-run training course (prospective inspectors workshop), and must attend inspection(s) as trainee inspector before considered qualified to inspect.

REQUIREMENTS	W	F-J	NC-F	AA	EFI
	some aspect of registry operations with focused experience or training in quality management or preparation of a registry accreditation application as documented in their curriculum vitae-				
From an accredited facility	-	X (F) / No (J)	X	X	X
Unpaid volunteer	X	X	X	X	X
Employee of accreditation organization	-	-	-	X (required for HCT/P facilities; additional volunteers as needed)	-
Inspector training	X	X	X	X	X
Duration of training (days)	Online training max 6 months for new reviewers, experienced reviewers pass minimum 3 modules per year	2 (J) 1(F)	1	1(classroom) 1 or 2 (training assessments)	1
Post training test?	X	X	X	X	-
Train with experienced inspector	X	X / J: attend 1 inspection as trainee	X	X	X
Complete and pass test every standards cycle	X	X	X	-	-
Repeat one day training every two standards cycle	X	X (F) / J: highly recommended	X	X (annually – not every two standards cycles)	X
View and pass test for periodic online training sessions	X	X	X	-	-
Member of relevant professional society	X	X	X	X	X

REQUIREMENTS	W	F-J	NC-F	AA	EFI
Evidence of continuing education	X	-	-	Must be provided every 2 years	X

¹<http://www.jacie.org/inspectors/how-to-become-an-inspector>

²<http://factwebsite.org/main.aspx?id=143>