

Comparison of Inspection Processes

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

Definitions	Abbreviation
WMDA 208	W
FACT-JACIE 4th Ed	F-J
Netcord-FACT 4th Ed	NC-F
AABB 4 Ed	AA
Y	years

REQUIREMENTS	W	F-J	NC-F	AA
Facilities Inspected & Accredited				
Clinical Facility(ies) (Performing infusions)		X		
Adult		X		
Pediatric		X		
Both		X		
Collection Facility(ies) or Sites		X	X	X
Processing Facilities(ies)		X	X	X
Cord Blood Bank			X	X
Unrelated donor Registry	X			
Categories of Accreditation				
Autologous Cellular Therapy Products		X		X
Allogeneic Cellular Therapy Products		X		X
Both Autologous and Allogeneic Products		X		X
Cord Blood	X		X	X
Unrelated	X		X	X
Directed donor			X	X
Autologous			X	X
Nature of Inspection				

REQUIREMENTS	W	F-J	NC-F	AA
Site Visit	X	X	X	X
Typical Duration (days)	2	1-2	2	2
Interim Report	X	X	X	
Months post accreditation due	12	12	12	
Review of Records	X	X	X	X
Centrally	X	X	X	X
On Site	X	X	X	X
Inspection Frequency and Type				
Frequency	5Y	3Y F/4Y J	3	Biannually
Announced	X	X	X	
Unannounced				X
Post Inspection Review Process				
Inspector(s) reports	X	X	X	X
Time limit for completion (days)	14	14	14	Delivered at completion of assessment
Central office review and preparation of reports	X	X	X	N/A
Typical time for review (weeks)	4	4	4	Facility has 30 days post-assessment to respond to nonconformances
Initial professional review	X	X	X	X
Dedicated inspections review committee	X	X	X	X
Review by non-dedicated committee (i.e. Board of Directors)	X			
Typical time for review (weeks)	8-12	8-12	8	2-3
Possible outcomes of review				
No response required	X	X	X	X
Written response to review ± evidence of correction	X	X	X	X
Partial or full reinspection required		X	X	X

REQUIREMENTS	W	F-J	NC-F	AA
Accreditation not awarded	X	X	X	X
Final accreditation decision by:				
Dedicated inspections approval committee	X			X
Review by non-dedicated approval committee (e.g., Board of Directors)	X	X	X	
Publication/Notification of Accreditation				
Publication on accreditation body website	X	X	X	X
Letter to facility	X	X	X	X
Accreditation certificate	X	X	X	X
Circumstances requiring off cycle review				
Serious adverse event at accredited facility	X			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	
Loss of key personnel at facility		X	X	
Inspector Qualifications & Training Requirements				
Required years of experience in relevant discipline & degree		Required combination of education and experience varies based on the facility (Clinical, Collection, Laboratory) to be inspected. See FACT website for details. ¹	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.
From an accredited facility	X	X	X	
Unpaid volunteer	X	X	X	X
Employee of accreditation organization				X (required for HCT/P facilities; additional

REQUIREMENTS	W	F-J	NC-F	AA
				volunteers as needed)
Completed one day training course with post training test	X	X	X	X
Train with experienced inspector	X	X	X	X
Complete and pass test every standards cycle	X	X	X	
Repeat one day training every two standards cycle	X	X	X	X (annually – not every two standards cycles)
View and pass test for periodic online training sessions	X	X	X	
Member of relevant professional society	X	X	X	X
Evidence of continuing education				Must be provided every 2 years

¹ <http://factwebsite.org/main.aspx?id=142>

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