Inspection Reports

if it wasn't documented

...

it didn't happen

www.jacie.org/document-centre

CHECKLIST

	Part B: Clinical			Inspector: All items compliant? No		Go to Dashboard	
Ref.	Standard	Applicant's assessment	Source of evidence and explanatory text	Inspector's Assessment	Inspector's Comments *(support your answers with additional information)*	Accreditation Committee comments	Applicant's corrections & comments - 1
E.01.C2	The Clinical Program shall use cell collection and processing facilities that meet FACT-JACIE Standards with respect to their interactions with the Clinical Program.		No evidence				
E.01.C3	The Clinical Program shall abide by all applicable laws and regulations.		No evidence				
E.01.C3.01	The Clinical Program shall be licensed, registered, or accredited as required by the appropriate governmental authorities for the activities performed.		No evidence				
E.01.C4	The Clinical Program shall have a designated transplant team that includes a Clinical Program Director, a Quality Manager, and a minimum of one (1) additional attending transplant physician. The designated transplant team shall have been in place for at least twelve (12) months preceding initial accreditation.		No evidence				
E.01.C5	The Clinical Program shall comply with the Minimum Number of New Patients for Accreditation table in Appendix I.		*Indicate total number of transplants of each type performed in last 12 months*		*Indicate total number of transplants of each type performed in last 12 months*		
B.02	CLINICAL UNIT	BLANK CELL	BLANK CELL	BLANK CELL	BLANK CELL	BLANK CELL	BLANK

Snapshot | Dashboard | Part B Clinical | Part B MED-A audit forms | B-CM-C 6 Donors | Part CM Bone Marrow | Part C Apheresis | Part C Processing | Labels-Collection | Labels-Pro

SUMMARY REPORT

Name of Document: R-001-01-Inspection Report Approved by: Eoin McGrath Responsible: Eoin McGrath Entry: Report the findings of an Inspection	Creation date: 17/06/2013 Effective date: 28/06/2013 Review date: 07/04/2014 Modification: "Part" renamed "Section"	JACIE joint accreditation comittee isct-ebmt

Inspection Summary Report

Inspection Report and Recommendations to Applicant

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How inspectors should work on the reports?

1. – Plan
2. – Organize the material
3. – Write
4. – Evaluate
5. – Rewrite

Whatever is the language of the inspection,
the report must be written in **English**

Reports Content

Summary Report

Checklist

SUMMARY REPORT

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SUMMARY REPORT template

Section A. General Information & Overview

Programme/Institution name:	
City:	
Country:	
Type of inspection:	Initial / Reaccreditation / Reinspection [*delete as necessary*]

Inspection date:	*DD-DD/MM/YYYY*	**Date of Inspection Report:**	*DD/MM/YYYY*	**Date of Summary Report:**	[*DD/MM/YYYY for office use only*]

Edition of standards used for inspection:	4th

Accreditation goal *(delete as appropriate)*:

Area	Patient	Allogeneic	Autologous
Clinical	Adult	X	X
	Paediatric	X	X
HPC, Marrow Collection	Adult	X	X
	Paediatric	X	X
HPC, Apheresis Collection	Adult	X	X
	Paediatric	X	X
Processing	-	X	X

Directors *(complete all sections)*

	Clinical (Adults)	Clinical (Paediatrics)	HPC(M) Collection	HPC(A) Collection	Cell Processing
Director					
Medical Director					

Include other information about Directors if necessary:

Information on the Programme

Information on the inspection team

Inspectors:	
Team Leader:	
Clinical Facility(s):	
HPC, Marrow Collection Facility	
HPC, Apheresis Collection Facility:	
Processing Facility:	
Observer(s) and their organisation	-

Services provided to other facilities not inspected during this audit:
[Complete this where the inspector is aware of any other relationships with facilities not part of this application e.g. registries, other hospitals. *If none, mark as 'N/A'.]*

Observations on the interaction between clinical, collection and processing facilities:	
[Reflect on what evidence you saw of interaction and communication between the different facilities]	
Distance between facilities (if possible, please describe the distance, duration and mode e.g. 5km, 10 mins, by car)	
Collection Facility(s) to Clinical Unit(s)	
Collection Facility(s) to Processing Facility	
Processing Facility(s) to Clinical Unit(s)	

Additional remarks:

Other information on the Centre

Section B. Team Leader On-site Inspection Summary

Team Leader On-site Inspection Summary:
[Use this section to describe the inspection. Describe the atmosphere, any incidents that came up, and the overall impression of the programme. This last point is sometimes called the "helicopter view" and means to consider all aspects together and not just as individual elements. The FACT-JACIE standards emphasize the total programme and the interactions in place between the different services. *Each individual inspector should describe the facility(s) he/she has visited in their respective section of this report.* *Again, specific elements or deficiencies should be detailed in the Inspection Checklist]*

Team leader overview

Names & Roles of people you interviewed

Cellular Therapy Product Administration & Clinical Facilities	
Persons interviewed during the Inspection	
Name	**Position/role**
	Programme Director Transplant physician/Consultant/Specialist Physician in training Quality manager Senior Nurse Nurses in training (or newest nurse in the unit) Other BMT unit nurses Pharmacist *[insert or delete positions as necessary]*

Numbers of transplants for 12 months up to inspection date		
	Allogeneic	**Autologous**
Adults	*[This section should be completed]*	*[This section should be completed]*
Paediatrics	*[This section should be completed]*	*[This section should be completed]*

Brief description of facility(s) Inspected:
[Limit the description to the unit e.g. how long it has been established, popula tionships with other organisations, etc. but not specific deficiencies or observations. These shoul the Inspection Checklist]

Main Strengths & Areas for Improvement	
Strengths	○ *[This section should be for general ific deficiencies should be detailed in the Inspection C*
Areas for improvement	○ *[This section should be for general sugg deficiencies should be detailed in the Inspection Chec*

REMEMBER!

CM7, C7 & D7 Labels (Cell Collection & Cell Processing)

Inspector who performed check	Area
	HPC(M)
	HPC(A)
	Processing

CHECKLIST

Ref	Standard	Applicant's Self-assessment	Applicant's Comments *(support your answers with additional information)*	Inspector's Assessment	Inspector's Comments *(support your answers with additional information)*	Accreditation Committee comments	Applicant's corrections & comments
D03	PERSONNEL						
D03.01	PROCESSING FACILITY DIRECTOR						
D03.01.01	There shall be a Processing Facility Director who is an individual with a medical degree or doctoral degree in a relevant science, qualified by training or experience for the scope of activities carried out in the Processing Facility. The Processing Facility Director may also serve as the Processing Facility Medical Director, if appropriately credentialed.	Compliant	LABTMO-SOP-08	Compliant	PROC PRC TRA 06.07.85		
D03.01.02	The Processing Facility Director shall be responsible for all procedures, administrative operations, and the Quality Management Program of the Processing Facility, including compliance with these Standards and other applicable laws and regulations.	Compliant	LABTMO-SOP-08	Compliant	PROC PRC TRA 06.07.85		
D03.01.03	The Processing Facility Director shall participate regularly in educational activities related to the field of cellular processing and/or transplantation	Compliant	LABTMO-SOP-08	Compliant	PROC PRC TRA 06.07.85		

... Part B Clinical | Part B MED-A audit forms | B-CM-C 6 Donors | Part CM Marrow | Part C Apheresis | Part D Processing | All Labels Con

Applicant's Self-assessment	Applicant's Comments *(support your answers with additional information)*	Inspector's Assessment	Inspector's Comments *(support your answers with additional information)*
Compliant		Compliant	
Compliant		Compliant Partially compliant Non-compliant Not applicable	
Compliant			

Applicant's Self-assessment	Applicant's Comments *(support your answers with additional information)*	Inspector's Assessment	Inspector's Comments *(support your answers with additional information)*
Compliant		Partially compliant	
Compliant		Compliant Partially compliant Non-compliant Not applicable	
Compliant			

Applicant's Self-assessment	Applicant's Comments *(support your answers with additional information)*	Inspector's Assessment	Inspector's Comments *(support your answers with additional information)*
Compliant		Non-compliant	
Compliant		Compliant Partially compliant Non-compliant Not applicable	
Compliant			

Applicant's Self-assessment	Applicant's Comments *(support your answers with additional information)*	Inspector's Assessment	Inspector's Comments *(support your answers with additional information)*
Compliant		Not applicable	
Compliant		Compliant Partially compliant Non-compliant Not applicable	
Compliant			

Standard	Applicant's Self-assessment	Applicant's Comments *(support your answers with additional information)*	Inspector's Assessment	Inspector's Comments *(support your answers with additional information)*	Accreditation Committee comments
Initial qualifications.	Compliant		Compliant		
Orientation.	Compliant		Compliant		
Initial training.	Compliant		Compliant		
Competency for each critical function performed.	Compliant		Partially compliant	Thay lack for description of activities regarding initial training because they do not preview actually any new person in the staff	

Clarify any answers
using the Comments column

There shall be a defined process improvement plan that includes policies or procedures for the recognition and investigation of the cause of all issues that require corrective action.	Compliant	LABTMO-PES-10	Compliant				Compliant
The implementation of corrective actions shall include both short-term action to address the immediate problem and long-term action to prevent the problem's recurrence.	Compliant		Compliant				Compliant
Follow-up activities shall be conducted to determine if the corrective actions were effective.	Compliant		Compliant				Compliant
The Quality Management Plan shall include, or summarize and reference, policies and procedures for cellular therapy product tracking and tracing that allows tracking from the donor to the recipient or final disposition and tracing from the recipient or final disposition to the donor.	Compliant	LABTMO-PES-10	Compliant				Compliant

Part B MED-A audit forms | B-CM-C 6 Donors | Part CM Marrow | Part C Apheresis | Part D Processing | All Labels Content | Shipping Labels

Processing & Collection inspector:
Don't forget to check togheter and complete labels checklist

Checklist – 6th EDITION

Part B: Clinical

Inspector: All Items compliant? No

Yes
✓ No

Complete all as compliant. Please note that by selecting "Yes" you are confirming that all items on this checklist were found by you to be compliant with the Standards.

Ref.	Standard	Applicant's assessment	Source of evidence and explanatory text	Inspector: All Items compliant?	Inspector's comments
B.01	GENERAL	BLANK CELL	BLANK CELL	BLANK	
B.01.01	The Clinical Program shall consist of an integrated medical team that includes a Clinical Program Director(s) housed in a defined location(s).		No evidence		
B.01.01.01	The Clinical Program shall demonstrate common staff training, protocols, procedures, quality management systems, clinical outcome analysis, and regular interaction among all clinical sites.		No evidence		
B.01.02	The Clinical Program shall use cell collection and processing facilities that meet FACT-JACIE Standards with respect to their interactions with the Clinical Program.		No evidence		
B.01.03	The Clinical Program shall abide by all applicable laws and regulations.		No evidence		
B.01.03.01	The Clinical Program shall be		No evidence		

JACIE joint accreditation committee isct ebmt

EBMT European Society for Blood and Marrow Transplantation

ISCT International Society for Cellular Therapy

Checklist – 6th EDITION

Ref.	Standard	Applicant's assessment	Source of evidence and explanatory text	Inspector's Assessment
				Items compliant? Yes
B.01	GENERAL	BLANK CELL	BLANK CELL	BLANK CELL
B.01.01	The Clinical Program shall consist of an integrated medical team that includes a Clinical Program Director(s) housed in a defined location(s).		No evidence	Compliant
B.01.01.01	The Clinical Program shall demonstrate common staff training, protocols, procedures, quality management systems, clinical outcome analysis, and regular interaction among all clinical sites.		No evidence	Compliant
B.01.02	The Clinical Program shall use cell collection and processing facilities that meet FACT-JACIE Standards with respect to their interactions with the Clinical Program.		No evidence	Compliant
B.01.03	The Clinical Program shall abide by		No evidence	

JACIE joint accreditation committee isct ebmt

EBMT European Society for Blood and Marrow Transplantation

International Society for Cellular Therapy ISCT

Checklist – 6th EDITION

- Instructions
- Basic application details
- Definitions
- Snapshot
- Dashboard
- Part B Clinical
- Part B MED-A audit forms
- B-CM-C 6 Donors
- Part CM Bone Marrow
- Part C Apheresis
- Part D Processing

Informative tabs
Tabs to be filled center/inspectors

- Labels-Collection
- Labels-Processing
- Shipping & Transport
- Appendix I-Min transplants
- Appendix II-CT Labeling
- Appendix III-Labels for shipping
- Appendix IV-Docs at distribution
- Changes

New tabs
Updated tabs

Checklist – Pilot Test Inspections

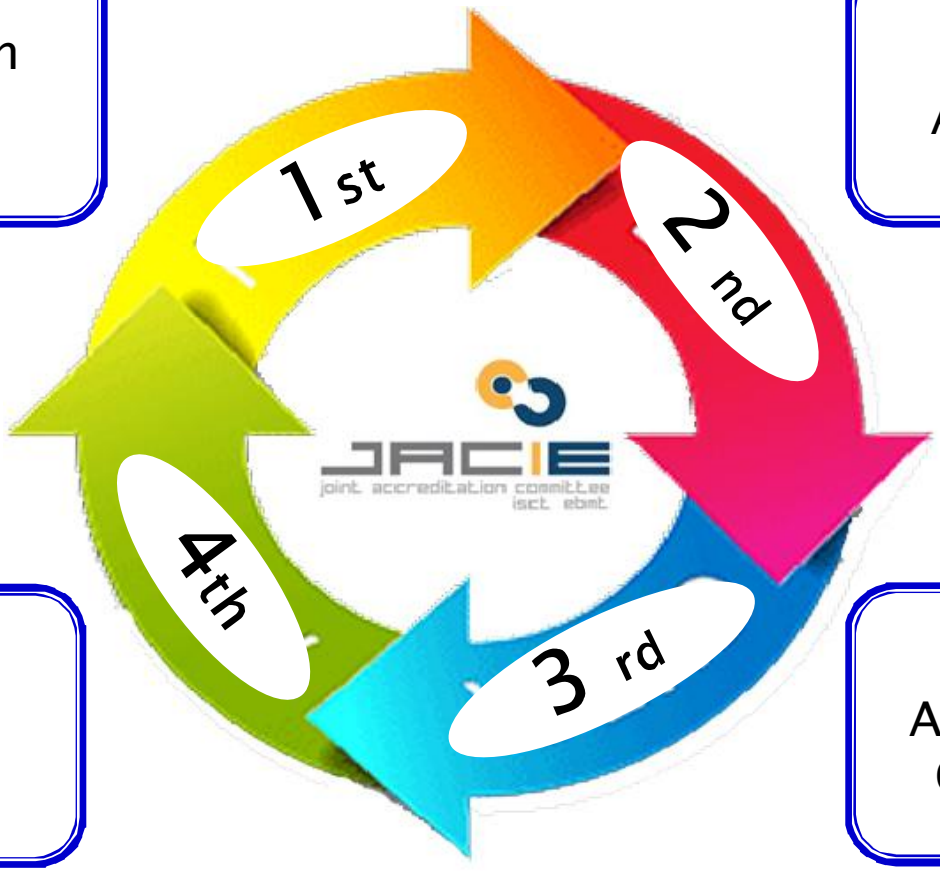
Inspector	Ref	Standard	Applicant's Self-assessment	Applicant's Comments *(support your answers with additional information)*	Inspector's Assessment	Inspector's Comments *(support your answers with additional information)*
QM	D05.03.09	A current version of orders, worksheets, reports, labels, and forms, where applicable.	Compliant		Compliant	
QM	D05.04	Copies of Standard Operating Procedures relevant to processes being performed shall be readily available to the facility staff.	Compliant		Compliant	
QM	D05.05	All personnel in the Processing Facility shall follow the Standard Operating Procedures related to their positions.	Compliant		Compliant	
QM	D05.06	Review and/or training by a staff member shall be documented before the staff member is allowed to perform new and revised policies and procedures.	Non-compliant	SOP-020-33	Non-compliant	Lack of evidence
LAB	**D06**	**PROCESS CONTROLS**				
LAB	D06.01	There shall be a process for controlling and monitoring the manufacturing of cellular therapy products to ensure products meet predetermined release specifications.	Compliant		Compliant	
LAB	D06.01.01	The Processing Facility Director shall define tests and procedures for measuring and assaying cellular therapy products to ensure their safety, viability, and integrity and to document that products meet predetermined release specifications. Results of all such tests and procedures shall become part of the permanent record of the product processed.	Compliant	SOP-001-14	Compliant	
LAB	D06.01.02	There shall be a documented system for the identification and handling of test samples so that they are accurately related to the corresponding cellular therapy product, donor, or recipient, as applicable.	Compliant		Compliant	

Part B Clinical | Part B MED-A audit forms | B-CM-C 6 Donors | Part C Apheresis | **Part D Processing** | All Labels Content | Shipping Labels | Changes | Feuil1

Report pathway

Inspection Team

Report Assessors



Center

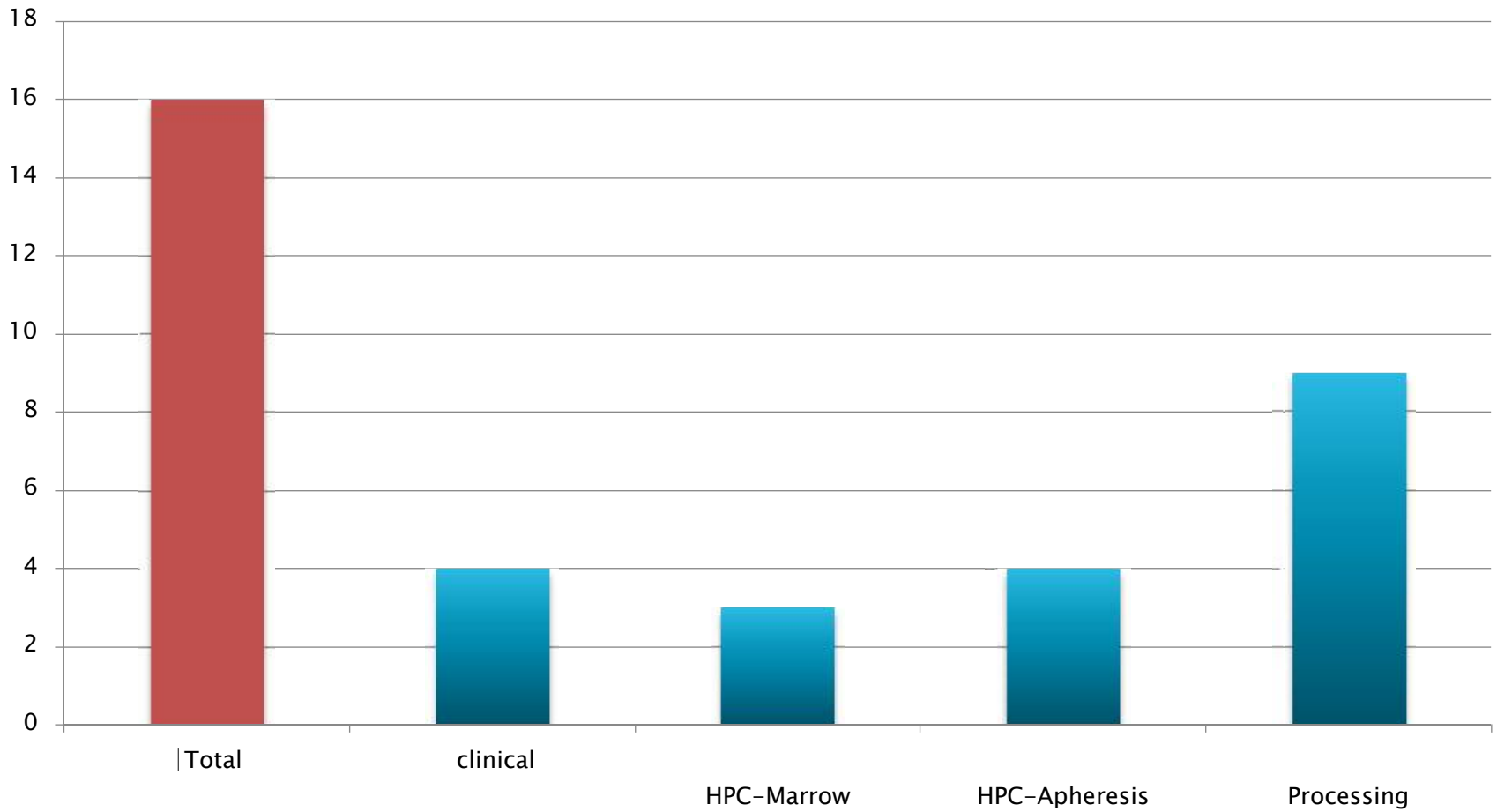
JACIE Accreditation Committee

JACIE joint accreditation committee isct ebmt

EBMT European Society for Blood and Marrow Transplantation

International Society for Cellular Therapy ISCT

In 2014: Accreditation Committee changed compliance in 31% reports reviewed (16/51 reports)



EXERCISE 1

SCOPE:

Do you know what the JACIE Accreditation Committee decided?

INSPECTION REPORTING

Ivana Ferrero
Processing inspector
Report Assesor

Stem Cell Transplantation and Cellular Therapy Unit
Regina Margherita Children's Hospital - Turin

2015 EBMT
European Society for Blood and Marrow Transplantation

JACIE

JACIE Inspector Meeting

Carole Charley
Inspection Report Assessor

"Changes made to compliances:
Post Accreditation Committee review"

41st Annual Meeting of the European Society for Blood and Marrow Transplantation
22 – 25 March 2015 - Istanbul, Turkey

Thank you for your attention
Questions or comments welcomed