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1 Introduction

Centres applying for accreditation are required to submit a limited set of documentation in advance of the inspection. This documentation is requested so that the inspectors can understand the centre's activity and organization and to check compliance with some of the standards before the on-site visit.

Inspectors can request additional information prior to the inspection and during the inspection. Those items not provided for inspector review by the end of the inspection will be marked as a deficiency.

2 What documents need to be submitted and how?

Applicants will be requested to upload the documents indicated here to the pre-inspection standards folder structure in SharePoint. The pre-inspection folder structure consists of folders and sub-folders relevant to each part of the standards: Clinical, Immune effector cells, Collection – Bone Marrow and Apheresis, Processing, General, Donors selection-evaluation-management and Labels.

Table 1 - Pre-inspection Documentation List defines which documents need to be uploaded in each folder per scope of accreditation. Each folder's name will include a (#nn) that refers to a document from **Table 1 - Pre-inspection Documentation List**.

When completing the folders please take into account the following:

- All folders need to be populated with a document. If a folder does not apply, the applicant should include a Text file stating the reason.
- Folders should never be deleted.
- Centres shouldn´t use patient names on the documents submitted
- For additional information, Centres should find the Standard referenced and/or the guidance in the Accreditation Manual related to that Standard

The same document might have to be saved into more than one folder. This could be because:

1. The document is relevant to two different sections e.g., labelling for collection and for processing
2. A single document might cover several different areas e.g., donor and patient consent
3. Different inspectors will assess different areas e.g., the clinical inspector will also look at bone marrow while the collection inspector will only look at apheresis

3 When do Centres have to upload these documents?

Documents should be uploaded to SharePoint within 90 days after formal approval of the application form. Once Centres have uploaded the files into their relevant folders, they should inform the Accreditation Coordinator.

Failure to provide the documents in a timely manner will result in the rejection of the application.

4 What language do documents need to be in?

Documents should be in the language of the Centre since JACIE would expect to assign inspectors that speak and understand the language.

However, there may be exceptions to this, in which case JACIE will request a subsection of the documentation to be translated to English (**Table 2 – Required documents for translation**). The

Accreditation Coordinators will notify Centres that translation is required if:

- Centre is in a country where no inspectors are available
- JACIE does not have inspectors anywhere that speak the Centre's language
- The transplant community in a given country has requested that only external inspectors be assigned to avoid conflicts of interest

5 What if Centres upload a document and then it is updated in their system?

Any revised documents should be uploaded to SharePoint at least 4 weeks before the inspection date. Centres should let the JACIE Accreditation Coordinator know if any uploaded documents have been updated.

6 What does JACIE do with these documents?

Firstly, the JACIE Office checks the folders' contents. The staff does not assess the quality of the documentation only if a file or document is present. The inspectors assess the contents of the documents. If documents appear to be missing, the JACIE Office will contact the Centre to ask for the documents.

After this check, JACIE removes the access of the applicant to the pre-audit documentation folder in SharePoint and grants access to the Inspection Team members to prepare for the inspection. On occasion, these files may also be consulted by JACIE staff and/or JACIE Accreditation Committee members. In all cases, anyone given access to the files is reminded of their obligation to keep confidential any information contained therein.

These files are maintained for 10 years.

7 How does JACIE store and distribute these documents?

JACIE uses the Microsoft 365 cloud-based service for document storage and distribution. This system is secured using industry-standard encryption combined with other measures to protect data. See https://www.microsoft.com/en-us/trust-center for their full security specifications.

The Centre should note that it is their responsibility to ensure that the documentation provided to JACIE has appropriate security measures in place before the upload / transfer and to make certain that the respective national laws are followed.

Centres can contact their Accreditation Coordinator or the JACIE Office if they have any questions (jacie@ebmt.org)

TABLE 1 - Pre-inspection Documentation List - Clinical, IEC, Collection – Bone Marrow and Apheresis, Processing.

#	DOCUMENTATION	STANDARD	COLLECTION	PROCESSING	CLINICAL	IEC
	General documentation folder					
1	Health authority's license/certification/s of facilities (all applicable to the scope of Accreditation B, CM, C, D)	B1.3.1, CM1.3.1 C1.3.1 D1.2.1	✓	✓	✓	
2	Programme Organigramme/s that include/s key personnel (position and name) (All applicable Organigrammes to the scope of Accreditation: B, C, D)	B4.3 C4.3 D4.3	✓	✓	✓	
3	General physical floor plan of all Programme facilities. If facilities are not located in the same building, include a map showing locations of all sites. Identification/ description of each of the following services including their location relative to the clinical program site(s): Radiation Oncology Emergency Department Blood Bank or transfusion service Intensive Care Unit(s) Pharmacy Investigational Drug Pharmacy		✓	✓	✓	
	B6, CM6 & C6 Donors selection, evaluation and management					
4	Unsigned consent forms for consent to be a cellular therapy product donor, including the form and any information given to the donor **AND** unsigned allogeneic and/or autologous consent forms for the cellular therapy product collection procedure (if not previously submitted with the Clinical Program documentation).	B6.2 CM6.2 C6.2	✓ (if not the exclusive responsibility of the clinical unit)		✓	
5	SOP (or documents) used to determine donor eligibility and suitability	B5.1.4 CM5.1.3 C5.1.3	✓		✓	

#	DOCUMENTATION	STANDARD	COLLECTION	PROCESSING	CLINICAL	IEC
	C7, CM7 & D7 Labels					
6	Labelling SOP	C5.1.9 D5.1.6	✓	✓		
	Listing of all labels that are applied to each step of collection, processing and distribution: *NOTE: Use unique patient identifiers; do not use patient names.*	C7 D7				
7	Primary collection container label, applied at the completion of collection of cells for allogeneic **and** autologous use	Appendix II	✓	✓		
8	Label applied at completion of processing of allogeneic **and** autologous cells.	Appendix II		✓		
9	Labels attached prior to distribution/ Labels applied prior to transport of cellular therapy products, including inner and outer shipping labels, if applicable	Appendix II and III		✓		
10	Documentation that accompanies product at distribution, if applicable	Appendix IV		✓		
11	Biohazard and warning labels and method of notifying Clinical staff of biohazard if not written on label. Labels with incomplete eligibility and positive infections markers	Appendix II	✓	✓		
	PART B, PART C, PART D					
	B2 – HLA Lab Accreditation					
12	For allogeneic transplant programmes, a copy of the HLA laboratory's current ASHI or EFI accreditation certificate	B2.12			✓	
	B3, CM3, C3, D3 - Personnel					
	Clinical Program Director, Facility Directors, Medical Directors (Clinical/Collection/Processing)					
13	Copy of current Medical License for Medical Directors	B3.1.1 C3.2.1 CM3.1.1 D3.2.1	✓	✓	✓	✓

#	DOCUMENTATION	STANDARD	COLLECTION	PROCESSING	CLINICAL	IEC
14	Copy(s) of current certificate(s) of higher specialist training	B3.1.1 CM3.1.1 C3.1.1 C3.2.1 D3.1.1 D3.2.1	✓	✓	✓	✓
15	Curriculum vitae of all directors.		✓	✓	✓	✓
16	Written documentation of regular participation in educational activities related to the field of hematopoietic progenitor cell transplantation, including the minimum information for each activity: ○ Title of activity ○ Type of activity (for example, webinar, meeting, grand round, etc.) ○ Topic of activity (for example, hematology, cell transplantation, etc.) ○ Date of activity ○ Approximate number of hours of activity	B3.1.6 CM3.1.4 C3.1.4 C3.2.4 D3.1.4 D3.2.4	✓	✓	✓	✓
	All other Attending Physicians (specify adult and paediatric programmes, if applicable):	**B3.2**				
17	Copy(s) of current certificate(s) of higher specialist training	B3.2.1			✓	✓
18	Curriculum vitae				✓	✓
19	Copy of current Medical License	B3.2.1			✓	✓
20	Written documentation of regular participation in educational activities related to the field of hematopoietic progenitor cell transplantation, including the minimum information for each activity: ○ Title of activity ○ Type of activity (for example, webinar, meeting, grand round, etc.) ○ Topic of activity (for example, hematology, cell transplantation, etc.) ○ Date of activity ○ Approximate number of hours of activity	B3.2.3			✓	✓

#	DOCUMENTATION	STANDARD	COLLECTION	PROCESSING	CLINICAL	IEC
	Nurses	**B3.6**				
21	Document describing the following: ○ Number of nurses per patient ○ Number of permanent staff / rotational staff ○ Employment of relief nurses ○ Number of nurses with specialist qualifications in oncology and/or hematology	B3.6			✓	✓
22	Nursing Guidelines for care interventions to manage cellular therapy complications, including, but not limited to, cytokine release syndrome, tumor lysis syndrome, cardiac dysfunction, respiratory distress, neurologic toxicity, renal and hepatic failure, disseminated intravascular coagulation, anaphylaxis, neutropenic fever, infectious and non-infectious processes, mucositis, nausea and vomiting, and pain management	B3.6.2.5				✓
	Pharmacists	**B3.7**				
23	Copy of current license	B3.7.1			✓	✓
24	Written documentation of regular participation in educational activities related to the field of hematopoietic progenitor cell transplantation, including the minimum information for each activity B3.8.4.1 ○ Title of activity ○ Type of activity (for example, webinar, meeting, grand round, etc.) ○ Topic of activity (for example, hematology, cell transplantation, etc.) ○ Date of activity ○ Approximate number of hours of activity	B.3.7.4			✓	✓
	Consulting Specialists	**B3.8**				
	Documentation of appropriate credentialing of the consulting specialists and/or specialist groups:					
25	Cardiology	B3.8.1.1			✓	
26	Dermatology	B3.8.1.2			✓	
27	Gastroenterology	B3.8.1.3			✓	
28	Infectious Diseases	B3.8.1.4			✓	
29	Intensive Care	B3.8.1.5			✓	✓
30	Nephrology	B3.8.1.6			✓	

#	DOCUMENTATION	STANDARD	COLLECTION	PROCESSING	CLINICAL	IEC
31	Neurology	B3.8.1.7			✓	✓
32	Obstetrics/Gynecology	B3.8.1.8			✓	
33	Ophthalmology	B3.8.1.9			✓	
34	Palliative and end of life care	B3.8.1.10			✓	
35	Pathology	B3.8.1.11			✓	
36	Psychiatry	B3.8.1.12			✓	
37	Pulmonary Medicine	B3.8.1.13			✓	
38	Radiation oncology with experience in large-field (e.g., total body or total lymphoid) irradiation treatment protocols, if radiation therapy is administered.	B3.8.1.14			✓	
39	Radiology	B3.8.1.15			✓	
40	Surgery	B3.8.1.16			✓	
41	Transfusion medicine	B3.8.1.17			✓	
	Quality Manager	**B3.9**				
42	Written documentation of regular participation in educational activities related to the field of hematopoietic progenitor cell transplantation, including the minimum information for each activity: ○ Title of activity ○ Type of activity (for example webinar, meeting, grand round, etc.) ○ Topic of activity (for example, hematology, cell transplantation, etc.) ○ Date of activity ○ Approximate number of hours of activity	B.3.9.3 CM3.2.3 C3.3.3 D3.3.3	✓	✓	✓	
	Data Manager	**B3.10**				
43	Curriculum vitae				✓	
	Support Services Staff	**B3.11**				
	Documentation of appropriate credentialing of the support services staff:					
44	Dietary staff	B3.11.1.1			✓	
45	Social Services staff.	B3.11.1.2			✓	
46	Psychology Services staff.	B3.11.1.3			✓	
47	Physical Therapy staff.	B3.11.1.4			✓	

#	DOCUMENTATION	STANDARD	COLLECTION	PROCESSING	CLINICAL	IEC
	B4, CM4, C4, D4, Quality Management					
48	**QM Plan:** Complete copy of the facility's Quality Management Plan/Manual	B4.2 C4.2 D4.2	✓	✓	✓	✓
49	**SOP for Training:** SOP for Training (including Initial training, competency, and retraining of all employees)	B4.4.2.3 C4.4.2.3 D4.4.2.3	✓	✓	✓	
50	**Third Parties:** Description of any service(s) (i.e., collection or processing) that is performed for the Clinical Program by another facility under a contract.	B4.6 C4.6 D4.6			✓	✓
51	**Third Parties:** Description of any service(s) (i.e., collection or processing) that the applicant program provides for other facilities by contract.		✓	✓		
52	**Third Parties:** Sample Service Level Agreement (SLA) or contract with an external service provider e.g. microbiology testing laboratory, manufacturing company		✓	✓	✓	✓
53	**Outcome review:** Written criteria used for reviewing cellular therapy product safety, product efficacy, and/or the clinical outcome and including frequency of review.	B4.7.1				✓
54	**Outcome review:** For immune effector cells, the endpoint(s) of clinical function as approved by the Clinical Program Director	B4.7.3.2				✓
55	**Audits:** A list of audits performed in the 12 months prior to document submission including scope of the audit, date and follow up done.	B4.8 C4.8 D4.8	✓	✓	✓	✓
56	**Audits:** A calendar of audits to be performed in the future and their scope. See Standard B4.8.3 for minimum required audits to be reflected.	B4.8 C4.8 D4.8	✓	✓	✓	✓
57	**Traceability, chain of custody:** SOP/Policies for traceability, chain of custody, chain of identity	B4.11 C4.11 D4.11	✓	✓	✓	
58	**Validation:** Validation protocol or SOP	C4.14 D4.14	✓	✓		
59	**Validation:** Example of one completed validation study performed by the collection and processing facility staff. An example may be of the validation of a process or procedure	C4.14 D4.14	✓	✓		

#	DOCUMENTATION	STANDARD	COLLECTION	PROCESSING	CLINICAL	IEC
60	**Quarterly QM:** Quarterly QM Activity Reports	B4.17 C4.17 D4.17	✓	✓	✓	
61	**Annual Report:** Report from last annual review of the effectiveness of the overall Quality Management Program.	B4.18 C4.18 D4.18	✓	✓	✓	
	B5, C5, D5 Policies and SOPs					
62	**Administration of HPC & IEC:** SOP(s) for administration of HPC and other cellular therapy products, including products under exceptional release	B5.1.8			✓	✓
63	**Receipt of IEC by pharmacy:** Detailed description of the pharmacy procedure for receipt of IEC products at the hospital, storage policy and pharmacy oversight if storage is outside the pharmacy	-				✓
64	**Management of IEC toxicities:** SOP for Management of toxicities of immune effector cellular therapies, including cytokine release syndrome and central nervous system complications.	B5.1.12				✓
65	**Collection:** SOP(s) for adult/paediatric cellular therapy product collection	CM5.1.5 C5.1.6	✓			
66	**Cryopreservation and thawing:** SOP(s) for cryopreservation and thawing	D5.1.3.1		✓		
67	**Storage:** SOP(s) for cellular therapy product storage	CM5.1.10 C5.1.11 D5.1.8		✓		
68	**Transport and Shipping:** SOP(s) for packaging, transportation and shipping	CM5.1.12 C5.1.14 D5.1.10		✓		
69	**Waste disposal:** SOP(s) for disposal of medical and biohazard waste (include IEC if applicable)	D5.1.18 D5.1.18.1		✓		
70	**List of SOPs** including Title, version number and date of last revision for each applicable facility	B5.2 C5.2 D5.2	✓	✓	✓	✓
71	**SOP about SOPs:** SOP describing the process of writing SOPs	B5.3 C5.3 D5.3	✓	✓	✓	

Table 2 – Required documentation for translation per inspector:

	Inspectors			
Document	**Clin**	**Coll**	**Pro**	**QM**
Floor plan of facility(ies). All areas of the plan shall be labelled in English in order to identify the different activities (data entering, processing, storage etc.)	✓	✓	✓	
Summary of the relationship and interaction among all participating facilities and services including testing labs and registries.	✓	✓	✓	
Concise curriculum vitae of directors and Quality managers.	✓	✓	✓	
A copy of the Quality Management Plan(s), including the organizational chart of key personnel and functions within the program, including clinical, collection and processing.	✓	✓	✓	✓
List of SOPs including Title, version number and date of last Revision for each applicable facility [B5.2, CM5.2, C5.2, D5.2]	✓	✓	✓	✓
A sample of Quality meetings minutes.	✓	✓	✓	✓
SOP describing the process of writing SOPs [B4.5.2, CM4.1, C4.5.2, D4.5.2].				✓
A list of audits performed in the 12 months prior to document submission including scope of the audit and date [B4.8, CM4.8, C4.8, D4.8].				✓
A list of all incidents and changes for the previous calendar year				✓
Collection and analysis of transplant outcome data (for example Annual Report or Audit Report)	✓			
Unsigned allogeneic and/or autologous consent forms for the cellular therapy product collection procedure [B6.2.1], [CM6.2.1], [C6.2.1].	✓	✓		
SOPs related to Donor recruitment, eligibility criteria and acceptance criteria for test results (communicable disease testing, HLA typing)	✓	✓		
SOP for Bone Marrow Harvest including release criteria.	✓			
SOP for Collection Apheresis including release criteria.		✓		
Examples of all labels (partial label, label at completion of collection, label at completion of processing and prior cryopreservation, label at time of release, labels used on outer containers for transport and shipping, Biohazard and Warning labels and documentation of when they are used)		✓	✓	
Documentation that accompanies a product at distribution or an SOP that outlines accompanying documentation			✓	
A validation or qualification protocol and a summary of one completed validation or qualification study performed by the Collection or Processing Facility. An example may be the validation or qualification of a process, piece of equipment, reagent(s), or supplies used in the Apheresis/ Processing Facility [C4.13, C4.14, D4.13, D4.14]		✓	✓	
SOP for Processing including criteria for product acceptance and Criteria for product release.			✓	
Complete cryopreservation SOP(s) that includes the directions for cryopreservation including preparation of the cryoprotectant solution [D5.1.6]			✓	