

Name of Document: G-002-11-Pre-inspection documentation guide Approved by: Eoin McGrath Responsible: Eva Controle Entry: Pre-Inspection documentation list	Creation date: 08/05/2013 Effective date: 22/07/2013 Review date: 24/04/2019 Modification: Change of logo	
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Pre-inspection documentation

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Introduction

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

The requested documentation includes:

- Selection of key SOPs
- Evidence of staff training and qualifications
- Official facility licences and authorisations
- Quality Management Manual or Handbook
- Basic evidence that the QM system is functioning
- Basic data on recent transplant activity
- Consent forms and related information
- Sample labels
- Plans or maps of the centre
- Sample agreements with third-party service providers

See below for full details.

Language

Document 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:

- Centre is located in a country where no inspectors are available
- JACIE may 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

In these cases we must resort to other inspectors to perform the inspection. For these inspectors, one of the key parts of their preparation is reading documents made available in advance. Without this it is very difficult for them to arrive on-site adequately prepared and this would clearly affect the quality of the inspection.

In such cases, JACIE will ask the centre to translate a selection of the documents provided to the inspectors in advance of the inspection and will request the centre to provide local experts to facilitate interviews and understanding of documentation.

Please contact the Accreditations Coordinator at jacie@ebmt.org if you have any doubts about this aspect.

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Pre-formatted folder structure

The documents are submitted in a pre-formatted .ZIP file (📁 Pre-audit documentation folders.zip) that contains folders for the various types of documents. The file and instructions can be downloaded from the Document Centre under the "Pre-Inspection Documentation" section.

The zip file is organised into a series of folders and sub-folders relevant to each part of the standards: Clinical, Collection –Bone Marrow and Apheresis- and Processing.

By following the folder layout, you will be able to group and classify your documents in such a way that the inspectors can easily identify the document and its purpose.

See the graphic below to understand how the folders are organised.

Please note that you might have to save the same document 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

By copying the document to the relevant files, you will make it easier for the inspectors to find the document relevant to their part of the inspection.

Once you have the files gathered together into their relevant folders, you can send them to the JACIE Office.

When do I have to send these documents?

Documents should be sent to the JACIE Office within 30 days after formal approval of the application form. Failure to provide the documents in a timely manner could result in the inspection date being postponed.

What about if I send a document and then it is updated in our system?

Any revised documents should be sent to the JACIE Office before the inspection clearly indicating what changes have been made and what document should be replaced.

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 that 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, the documents are distributed to the Inspection Team members for their preparations. The files are also stored electronically by the JACIE Office in the folders created for each centre after application. On occasion, these files may also be consulted by the Inspection Report Assessors when they review the Inspection Reports and by members of the Accreditation Committee. In the rare event of an appeal to the JACIE Committee, the Committee members may also be given access to these files if necessary.

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 indefinitely.

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How does JACIE store and distribute these documents?

JACIE uses a cloud-based service for document storage and distribution: Dropbox, this system is secured using industry-standard encryption combined with other measures to protect data. See below for their full security specifications.

While our strong preference is to use Dropbox to distribute files, there may be technical or other reasons that do not permit us to do so. In these cases, documents may also be distributed via email as attachments or on CD or USB memory sticks via regular postal or messenger services.

Important notice: JACIE has implemented some changes in order to adapt to the requirements of processing of special categories of personal data listed in the GDPR. Hereinafter JACIE will no longer request applicant centres to provide MEDA forms to the JACIE Office as part of the pre-audit documentation. The MEDA forms will be reviewed by the JACIE inspectors during the on-site visit.

Please note that it is the responsibility of the centre to ensure that the documentation provided to JACIE has appropriate security measures in place before the transfer and to make certain that the respective national laws are followed.

Security specifications



The Dropbox security specification can be read at <https://www.dropbox.com/privacy#security>.

Instructions:

- Download the .zip file to your PC.
- Double-click on the file to open
- Extract the folder to your PC where you can work with the folders and files
- When complete, compress the file again and send to the JACIE Office via one of the channels indicated above.

Contact details

JACIE Accreditation Office
EBMT Secretariat,
Edifici Dr. Frederic Duran i Jordà
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Tel: +34 93 453 8570
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Email: jacie@ebmt.org
www.jacie.org

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Illustrative view of the folder structure. For definitive list, see below.

The image displays three screenshots of a file explorer showing the folder structure of the G-002-11-Pre-inspection documentation guide. Red arrows and circles highlight specific folders and items:

- Left Screenshot:**
 - Red arrow pointing down to **B6 CM6 & C6** and **C7 CM7 & D7**.
 - Red circle around **Checklist**.
 - Red circle around **Part B**.
- Middle Screenshot:**
 - Red circle around **Part C**.
 - Red circle around **BM**.
- Right Screenshot:**
 - Red circle around **PBSC**.
 - Red circle around **Part D**.

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Document checklist

<p>Instructions</p> <ul style="list-style-type: none"> ○ Copies of the following items are required prior to the on-site inspection, and should be submitted in electronic format (Word or PDF) with the Inspection Checklist (Excel file) in advance of the onsite visit. ○ Please do not use patient names on the documents submitted ○ If your facility utilises electronic records, hard copies of the primary source data must be assembled, flagged, and ready for inspector review before the inspection ○ Those items not provided for inspector review by the end of the on-site inspection will be marked as a deficiency ○ For additional information, see the Standard referenced and/or the guidance in the Accreditation Manual related to that Standard ○ Contact the JACIE Office. <p>Documentation available on the day of the inspection</p> <ul style="list-style-type: none"> ○ A selection of Donor Notes must be made available for review during the onsite inspection. ○ Copies of the documents listed below
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DOCUMENTATION		STANDARD	COLLECTION	PROCESSING	CLINICAL
General					
1.	Health authorities licence/certification of facilities, where applicable	B1.3.1, CM1.3.1, C1.3.1, D1.2.1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.	Programme organizational chart that includes key personnel (position and name)		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Quality Manual, Policies and Procedures:					
3.	Quality Management: Complete copy of the facility's Quality Management Plan/Manual	B4, CM4, C4, D4	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.	Four (4) quarterly reports from previous 12 months	B4.2.2, C4.2.2, D4.2.2	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.	Annual report of QM activities	B4.1.2, C4.1.1, D4.1.1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.	List of SOPs including Title, version number and date of last		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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	revision for each applicable facility				
7.	SOP describing the process of writing SOPs		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.	SOP for Training	B4.4, C4.4, D4.4	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9.	Validation: The validation or qualification protocol and an example of one completed validation or qualification study performed by the collection or processing facility staff. An example may be of the validation or qualification of a process, piece of equipment, reagent(s), or supplies used in the Collection or Processing Facility.	C4.14, D4.14	<input type="checkbox"/>	<input type="checkbox"/>	-
10.	Cryopreservation: SOP(s) for each cryopreservation procedure performed in the Processing Facility.	D5.1.7	-	<input type="checkbox"/>	-
	Patients				
11.	Complete patient list for the past twelve (12) month period ending approximately 100 days before submission of pre-inspection documentation and checklist. Do not include any direct identifiers including patient names. For programs that transplant both adult and pediatric patients, indicate on the log which patients are pediatric and which are adult. Include in the table: <ul style="list-style-type: none"> ○ unique patient identifier number (UPN) ○ date of transplant ○ diagnosis ○ source of cells (marrow, peripheral blood, cord blood) ○ type of transplant (autologous; allogeneic). 	B1.5	-	-	<input type="checkbox"/>
12.	Minimum Essential Data (MED-A) forms. PLEASE NOTE: JACIE has implemented some changes in order to adapt to the requirements of processing of special categories of personal data listed in the GDPR . Hereinafter JACIE will no longer request applicant centres to provide MEDA forms to the JACIE Office as part of the pre-audit	B1.5, B9.1	-	-	<input type="checkbox"/>

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	documentation. The MEDA forms will be reviewed by the JACIE inspectors during the on-site visit. Please note that it is the responsibility of the centre to ensure that the documentation provided to JACIE has appropriate security measures in place before the transfer and to make certain that the respective national laws are followed.				
Consent					
13.	Unsigned consent forms for consent to be a cellular therapy product donor, including the form and any information give to the donor.	B6.2, CM6.2, C6.2	<input type="checkbox"/> (if not the exclusive responsibility of the clinical unit)	-	<input type="checkbox"/>
14.	Unsigned allogeneic and/or autologous consent forms for the cellular therapy product collection procedure (if not previously submitted with the Clinical Program documentation).	B6.2.1, CM6.2.1, C6.2.1	<input type="checkbox"/> (if not the exclusive responsibility of the clinical unit)	-	-
15.	Agreement between donor and storage facility on the storage duration. (It can be included in a more general consent form to be signed before the product collection)	D12.1.1	<input type="checkbox"/> (if not the exclusive responsibility of the clinical unit)	<input type="checkbox"/> (if not the exclusive responsibility of the clinical unit)	<input type="checkbox"/>
Labelling & Product Information					
	Labelling SOP	C5.1.8, D5.1.6	<input type="checkbox"/>	<input type="checkbox"/>	-
	Completed example of each label used by the processing facility NOTE: Use unique patient identifiers; do not use patient names.	C7, D7			
16.	Primary collection container label, applied at the completion of collection of cells for allogeneic use	Appendix II	<input type="checkbox"/>	-	-
17.	Primary collection container label applied at the completion of collection of cells for autologous use	Appendix II	<input type="checkbox"/>	-	-
18.	Label applied at completion of processing of allogeneic cells.	Appendix II	-	<input type="checkbox"/>	-
19.	Label applied at completion of processing of autologous	Appendix II	-	<input type="checkbox"/>	-

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	cells.				
20.	Labels attached prior to distribution.	Appendix II	-	<input type="checkbox"/>	-
21.	Biohazard and warning labels and method of notifying Clinical staff of biohazard if not written on label.	Appendix III	<input type="checkbox"/>	<input type="checkbox"/>	-
22.	Labels applied prior to transport of cellular therapy products, including inner and outer shipping labels, if applicable.	Appendix II and III	<input type="checkbox"/>	<input type="checkbox"/>	-
23.	Documentation that accompanies product at distribution , if applicable	Appendix IV	<input type="checkbox"/>	<input type="checkbox"/>	-
	Listing of all labels that are applied to each of the following cellular therapy product types:	/	/	/	/
24.	Autologous cellular therapy product from a fully eligible donor at distribution for administration		-	<input type="checkbox"/>	-
25.	Autologous cellular therapy product from a donor with a positive infectious disease marker at distribution for administration		-	<input type="checkbox"/>	-
26.	Allogeneic cellular therapy product from a fully eligible donor at distribution for administration		-	<input type="checkbox"/>	-
27.	Allogeneic cellular therapy product from a donor with a positive infectious disease marker at distribution for administration		-	<input type="checkbox"/>	-
28.	Allogeneic cellular therapy product from a donor with a positive history for infectious disease risk but with negative testing at distribution for administration		-	<input type="checkbox"/>	-
29.	Allogeneic cellular therapy product from a donor not tested within 30 days at the time of distribution for administration		-	<input type="checkbox"/>	-
30.	Copy of current circular of information in use at your facility.	D11.1.4	-	<input type="checkbox"/>	-
	Electronic Records If an electronic record system is used, documentation of validation of the system must be available onsite as well as a	/	/	/	/

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	qualified individual to review the documentation with the inspector. Documentation should demonstrate compliance with the following FACT-JACIE Standards:				
31.	Validated procedures for and documentation of:	D13.2.6			
32.	Systems development	D13.2.6.1	-	<input type="checkbox"/>	-
33.	Numerical designation of system versions if applicable	D13.2.6.2	-	<input type="checkbox"/>	-
34.	Prospective validation of system including hardware, software, and databases	D13.2.6.3	-	<input type="checkbox"/>	-
35.	Installation of the system	D13.2.6.4	-	<input type="checkbox"/>	-
36.	Training and continuing competency of personnel in the use of the system	D13.2.6.5	-	<input type="checkbox"/>	-
37.	Monitoring of data integrity	D13.2.6.6	-	<input type="checkbox"/>	-
38.	Back-up of the electronic records system on a regular schedule	D13.2.6.7	-	<input type="checkbox"/>	-
39.	System maintenance and operations	D13.2.6.8	-	<input type="checkbox"/>	-
40.	System assignment of unique identifiers	D13.2.6.9	-	<input type="checkbox"/>	-
	Audits				
41.	A list of audits performed in the 12 months prior to document submission including scope of the audit and date	B4.8.1, D4.8.1	C4.8.1, <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
42.	A calendar of audits to be performed and their scope	B4.8.1, D4.8.1	C4.8.1, <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Site plans & maps				
43.	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.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
44.	Description of each of the following services including their location relative to the <u>clinical program site(s)</u> :		-	-	-
45.	Radiation Oncology		-	-	<input type="checkbox"/>
46.	Emergency Department		-	-	<input type="checkbox"/>
47.	Blood Bank or transfusion service		-	-	<input type="checkbox"/>

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48.	Intensive Care Unit(s),		-	-	<input type="checkbox"/>
49.	Pharmacy		-	-	<input type="checkbox"/>
50.	Investigational Drug Pharmacy		-	-	<input type="checkbox"/>
Third Party Agreements					
51.	Description of any service(s) (i.e., collection or processing) that is performed for the Clinical Program by another facility under a contract.		-	-	<input type="checkbox"/>
52.	Description of any service(s) (i.e., collection or processing) that the applicant program provides for other facilities by contract.		<input type="checkbox"/>	<input type="checkbox"/>	-
53.	Sample Service Level Agreement (SLA) or contract with an external service provider e.g. microbiology testing laboratory	B4.6, C4.6, D4.6	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
54.	HLA laboratory: For allogeneic transplant programmes, a copy of the HLA laboratory's current ASHI or EFI accreditation certificate	B2.11	-	-	<input type="checkbox"/>
Personnel					
Director or Heads of Service (Clinical/Collection/Processing)		B3.1			
55.	Copy of current Medical License for <u>Medical Directors</u>	B3.1.1, C3.1.1, D3.2.1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
56.	Curriculum vitae, if not previously submitted, of <u>all</u> directors.	B3.3, C3.4, D3.4	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
57.	Documented experience including the size and complexity of the program as well as the approximated number of transplant patients the person has managed and photocopies of five (5) representative publications from the field of hematopoietic progenitor cell transplantation extending over ten (10) years.	B3.1.1, C3.1.1, D3.1.1	-	-	<input type="checkbox"/>
58.	Written documentation of one (1) year of specific clinical training as defined by Standard B3.3 <i>or</i> Written documentation of at least two (2) years experience as an attending physician as defined in Standard B3.1.2.	B3.3, C3.1.4 B3.1.2	-	-	<input type="checkbox"/>
59.	Written documentation of regular participation in	B3.1.6, C3.1.5 ,	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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	educational activities related to the field of hematopoietic progenitor cell transplantation, including the minimum information for each activity: <ul style="list-style-type: none"> ○ 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 	D3.1.3			
/	All Other Attending Physicians (specify adult and paediatric programmes if applicable):	B3.2	/	/	/
60.	Copy(s) of current certificate(s) of higher specialist training	B3.2.1			
61.	Copy of documentation of completion of requisite residency and fellowship	B3.2.1	-	-	<input type="checkbox"/>
62.	Copy of current medical license.	B3.2.1	-	-	<input type="checkbox"/>
63.	Written documentation of one (1) year of specific clinical training as defined by Standard B3.2 <i>or</i> Written documentation of at least two (2) years experience as an attending physician as defined in Standard B3.2.1	B3.4 B3.2.1	-	-	<input type="checkbox"/>
64.	Written documentation of regular participation in educational activities related to the field of hematopoietic progenitor cell transplantation, including the minimum information for each activity: B3.2.2 <ul style="list-style-type: none"> ○ 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 		-	-	<input type="checkbox"/>

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	<ul style="list-style-type: none"> ○ Approximate number of hours of activity 				
	Physician Training for Clinical Programme Directors and Attending Physicians	B3.3			
65.	Written documentation of specific training and competency in each of the cognitive skills listed in Standard B3.3.3 for each attending physician including Programme Director.	B3.3	-	-	<input type="checkbox"/>
66.	For Programmes requesting allogeneic transplantation accreditation, written documentation of specific training and competency in each of the cognitive skills listed in Standard B3.3.4.	B3.3.4, B3.2.2	-	-	<input type="checkbox"/>
67.	Written documentation of knowledge in the procedural skills listed in Standard B3.3.5.	B3.3	-	-	<input type="checkbox"/>
	Advanced practice provider/professional: Physician Assistant, Nurse Practitioner, or other licensed Advanced Practitioner authorized by the applicable legal authority to provide primary patient care with physician oversight. Physician Assistants are formally trained and licensed or certified by the applicable authority to provide diagnostic, therapeutic, and preventive health care services with physician supervision. Advanced Nurse Practitioner includes certified nurse anesthetists, nurse practitioners, certified nurse midwives, and clinical nurse specialists.	B3.5	/	/	/
68.	Copies of national certification/license to practice as required by the jurisdiction of the Programme.	B3.5.1	-	-	<input type="checkbox"/>
69.	Documentation of training and competency in transplant related cognitive and procedural skills they routinely practice, including but not limited to skills listed in Standards B3.5.2-B3.5.5	B3.5.2	-	-	<input type="checkbox"/>
70.	Written documentation of regular participation in	B3.5.3.1	-	-	<input type="checkbox"/>

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Consulting Specialists		B3.9			
71.	Documentation of appropriate credentialing of the consulting specialists and/or specialist groups. Clinical Programs are not required to submit documentation for individual consultants unless requested by the inspector.	B3.9.1, B3.9.2	-	-	<input type="checkbox"/>
72.	Surgery	B3.9.1.1	-	-	<input type="checkbox"/>
73.	Pulmonary Medicine	B3.9.1.2	-	-	<input type="checkbox"/>
74.	Intensive Care	B3.9.1.3	-	-	<input type="checkbox"/>
75.	Gastroenterology	B3.9.1.4	-	-	<input type="checkbox"/>
76.	Nephrology	B3.9.1.5	-	-	<input type="checkbox"/>
77.	Infectious Diseases	B3.9.1.6	-	-	<input type="checkbox"/>
78.	Cardiology	B3.9.1.7	-	-	<input type="checkbox"/>
79.	Pathology	B3.9.1.8	-	-	<input type="checkbox"/>
80.	Psychiatry	B3.9.1.9	-	-	<input type="checkbox"/>
81.	Radiology	B3.9.1.10	-	-	<input type="checkbox"/>
82.	Radiation oncology with experience in large-field (e.g., total body or total lymphoid) irradiation treatment protocols, if radiation therapy is administered.	B3.9.1.11	-	-	<input type="checkbox"/>
83.	Transfusion medicine	B3.9.1.12	-	-	<input type="checkbox"/>
84.	Neurology.	B3.9.1.13	-	-	<input type="checkbox"/>
85.	Ophthalmology	B3.9.1.14	-	-	<input type="checkbox"/>

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86.	Obstetrics/Gynecology	B3.9.1.15	-	-	<input type="checkbox"/>
87.	Dermatology	B3.9.1.16	-	-	<input type="checkbox"/>
88.	Palliative and end of life care	B3.9.1.17	-	-	<input type="checkbox"/>
Nurses		B3.7			
89.	Document describing the following: <ul style="list-style-type: none"> ○ 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 haematology 	B3.7	-	-	<input type="checkbox"/>
Pharmacists		B3.8			
90.	Copy of current license.	B3.8.1	-	-	<input type="checkbox"/>
91.	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 <ul style="list-style-type: none"> ○ 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.3.8.4	-	-	<input type="checkbox"/>
Quality Manager		B3.10			
92.	Written documentation of regular participation in educational activities related to the field of hematopoietic progenitor cell transplantation, including the minimum information for each activity <ul style="list-style-type: none"> ○ Title of activity ○ Type of activity (for example, webinar, meeting, grand round, etc.) 	B.3.10.2	-	-	<input type="checkbox"/>

Name of Document: G-002-11-Pre-inspection documentation guide Approved by: Eoin McGrath Responsible: Eva Controle Entry: Pre-Inspection documentation list	Creation date: 08/05/2013 Effective date: 22/07/2013 Review date: 24/04/2019 Modification: Change of logo	
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DOCUMENTATION		STANDARD	COLLECTION	PROCESSING	CLINICAL
	<ul style="list-style-type: none"> ○ Topic of activity (for example, hematology, cell transplantation, etc.) ○ Date of activity ○ Approximate number of hours of activity 				
	Support Services Staff	B3.11			
	Documentation of appropriate credentialing of the support services staff. Clinical Programs are not required to submit documentation for individual consultants unless requested by the inspector.		-	-	<input type="checkbox"/>
93.	Dietary staff capable of providing dietary consultation regarding the nutritional needs of the recipient, including enteral and parenteral support, and appropriate dietary advice to avoid food-borne illness.	B3.11.1.1	-	-	<input type="checkbox"/>
94.	Social Services staff.	B3.11.1.2	-	-	<input type="checkbox"/>
95.	Psychology Services staff.	B3.11.1.3	-	-	<input type="checkbox"/>
96.	Physical Therapy staff.	B3.11.1.4	-	-	<input type="checkbox"/>
97.	Data Management staff sufficient to comply with B9.	B3.11.1.2	-	-	<input type="checkbox"/>