JACIE

Joint Accreditation Committee

ISCT | EBMT

Inspector Handbook

Contact

In case of doubts or questions, please do not hesitate to contact the JACIE Office:

JACIE Accreditation Office
EBMT Executive Office
Edifici Dr. Frederic Duran i Jordà Passeig Taulat, 116,
08005 Barcelona
jacie@ebmt.org

Contents

1. Introduction

JACIE inspectors are volunteers who work in the field of stem cell transplantation in clinical, quality management (QM), nursing or scientific roles. There are specific entry requirements for would-be inspectors and defined job descriptions for the different inspector roles (Clinical, Collection, Processing and QM). Some inspectors may be qualified to inspect more than one area. For example, a clinician might be qualified to inspect both clinical and collection facilities. All inspectors are asked to commit to 1-2 inspections per year.

The JACIE approach to using volunteer subject matter experts has been vital to the transplant community accepting and embracing the inspection process, as the inspectors are part of the community and peers of the clinicians and Allied Health Professionals (AHPs) working within the centres. This has also allowed the transplant community to use JACIE to educate centres on quality management system working and best practice within the field of cell therapy. Moreover, it has helped to standardise practice and support an ethos of continuous improvement within transplant programmes.

This handbook is intended to be a ready reference for inspectors to help guide them through the tasks and responsibilities throughout all stages of a JACIE inspection. The JACIE accreditation phases are summarised below (Figure 1.) and the detail of the inspector's responsibilities are described in the relevant sections that follow. For more information about JACIE Accreditation please visit the EBMT website

Inspectors should contact the JACIE office if they have any questions about the inspection process.

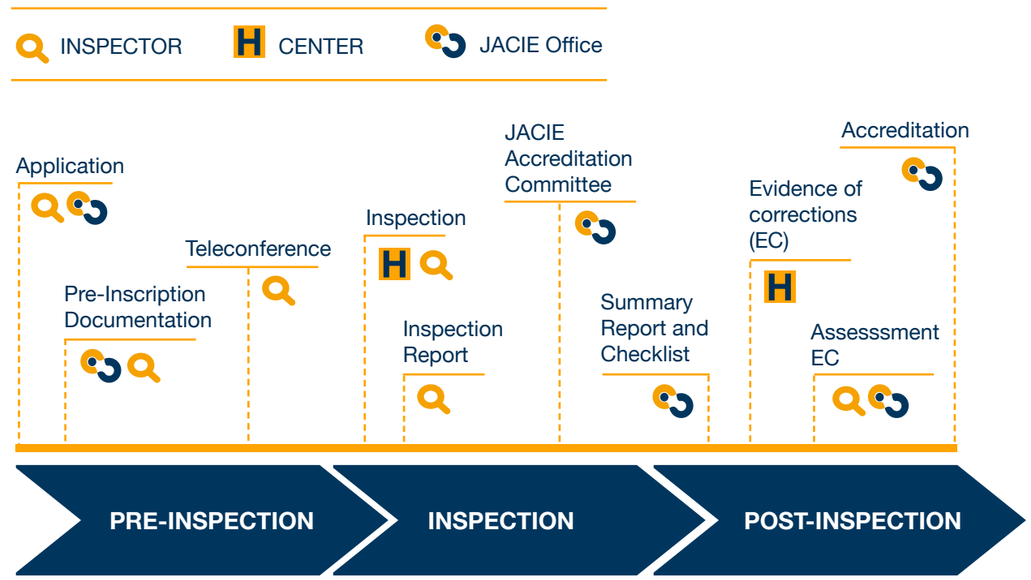


Figure 1. JACIE Accreditation process

2. Accreditation Scope

JACIE accreditation covers the following scope:

- Cell processing
- Collection of HPC, Apheresis
- Collection of HPC, Marrow
- Allogeneic transplantation in adult patients
- Allogeneic transplantation is paediatric patients
- Autologous transplantation in adult patients
- Autologous transplantation in paediatric patients
- Administration of Immune effector cells

3. Accreditation Process

The JACIE accreditation process consists of three phases and there are important processes within each phase that inspectors are involved in (Figure 2).

Figure 2. The three phases of the JACIE accreditation process.

4. Pre-inspection

This phase covers all activities from the time a centre submits an accreditation application to the JACIE office until the date of the inspection. The first activity is for the centre to apply to the JACIE office and set out the scope, structure, size of the programme, team organisation, distances between the sites, collaboration with other centres and particulars of the programme using the JACIE application form. Then comes the signing of an accreditation agreement and submission and review of the pre-inspection documentation.

The role of the inspector during the pre-inspection

Inspectors will liaise closely with the volunteers' coordinator and an accreditations' coordinator in the pre-inspection phase to ensure that they work collaboratively with their inspector colleagues to prepare and plan for the inspection.

The Inspection Team

The inspector teams typically include an inspector from each area included in the scope and one quality management inspector. The final number of inspectors will depend on the number of sites and quality management systems within a programme, and whether the inspection includes both paediatric and adult transplant facilities. One inspector will also be assigned the role of team leader. If needed, observers/trainees and/or language facilitators can be included in the team (Figure 3).

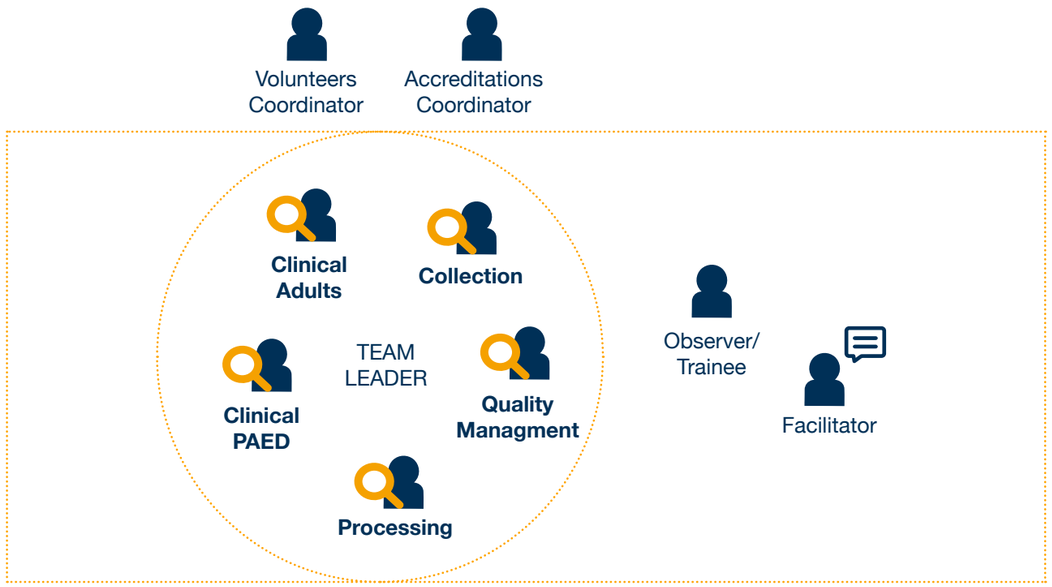


Figure 3. JACIE inspection team

Putting the Team Together

When the centre is ready for inspection, the volunteers' coordinator will contact the inspectors according to area of expertise, language, and availability. When a team has been formed, the volunteers' coordinator liaises with everyone to agree on dates, book dates in the diary and await final confirmation from the accreditation coordinator.

It is essential that potential inspectors respond promptly, ideally within a week, to the request to inspect and alert the JACIE office to any potential conflicts of interest including, but not limited to the ones listed below (see Table 1). The JACIE office will decide if the potential conflict of interest is sufficient to exclude them from the inspection. Transparency is key to the JACIE culture and an important part of ensuring the consistency and impartiality of the inspection process.

PERSONNEL	SCENARIO	ACTION
INSPECTOR	Inspector is or has been an employee of a centre that has applied for JACIE Accreditation.	Inspector shall not participate in the inspection of the centre.
	Inspector participated in the previous inspection of a centre that has applied for JACIE Accreditation.	Inspector shall not participate in the inspection of the centre.
	Family members of the inspector are part of the staff at the centre going through the JAC assessment.	Inspector shall not participate in the inspection of the centre.
	Inspector has a professional or personal relation with the centre.	Inspector shall not participate in the inspection of the centre.
	Personnel from the inspected centre being present at meals/ meetings when the inspection is being discussed.	Inspector shall report the incident to the AC.
	Reciprocal visits between inspectors and centres.	Inspector shall not participate in the inspection of the centre.
	Inspector has directly assisted centre with preparations.	Inspector shall not participate in the inspection of the centre.

Table 1 Conflict of interest scenarios and actions

The JACIE office understands that most inspectors will need to get authorisation from their employers to participate in an inspection and this might take a little time, however it is very helpful to get a prompt response about the inspector's intentions i.e., they are unable to participate or are seeking approval from their employer. Please note that centres with active inspectors i.e., that have performed an inspection in the past 4 years, get a discount on their accreditation fees. See LINK

Preparing for an Inspection

SharePoint

During the pre-inspection phase, centres share the pre-inspection documentation to a designated SharePoint1 space. Ideally, inspectors will be given access to this space four weeks before the inspection.

What is SharePoint

SharePoint is the file sharing platform that JACIE uses as a secure place to store, organise, share, and access information from any device. Inspectors need a web browser, such as Microsoft Edge, Internet Explorer, Chrome, or Firefox.

Here is a LINK to a Microsoft SharePoint training video

Inspectors should work collaboratively and online in the SharePoint space rather than downloading and creating copies of files. This is to ensure that the most up to date version of documents is always available to the whole inspection team.

How to Access SharePoint

The Accreditation Co-ordinator notifies the inspectors what USERNAME and PASSWORD to use to log in to SharePoint. The SharePoint login email has the following domain: @ebmtshare.onmicrosoft.com. Inspectors must not use their work or personal email to connect to SharePoint as this will not provide access. Inspectors must sign a Non-Disclosure Agreement and should not share their credentials with others.

SharePoint does not inform the accreditation coordinators when inspectors and centres have finished their tasks. It is important that inspectors and centres notify the accreditation coordinators by email or telephone when they are done with their tasks to help speed up the preparation process.

JACIE offers a licence free of cost for Microsoft Office 365. The aim is to use the services provided by Microsoft Office 365 to upload and exchange documentation related to the accreditation (SharePoint) and conduct remote inspections via teleconference (Microsoft Teams).

Review of pre-inspection documents

Pre-inspection documents include the checklist and other supporting documentation (see Box 1.). The supporting documents are in the language of the centre, and if necessary, the centre can be asked to translate them into English. When centres submit their pre-audit documentation, the JACIE office reviews its completeness, but it does not review the content. This is because documents are sent in the language of the centre. Inspectors should review pre-audit documentation before the inspection so that they are prepared in advance. If inspectors want to review additional documentation before the inspection, they must contact the accreditation coordinator to obtain this. The inspector can also request extra supporting documentation during the inspection. When reviewing the pre-audit documentation, inspectors can already start completing the assessment of the checklist, particularly those standards that can be reviewed based on documentary evidence. Ideally, inspectors will have reviewed the pre-audit documentation two weeks before the inspection.

- SOPs.
- Staff training and qualifications.
- Licenses and authorizations.
- QM Manual.
- QMS evidence.
- Transplant activity.
- Consent forms.
- Sample labels.
- Plans or maps.
- Third party agreements.

Box 1. Supporting documents submitted by the centre

Checklist

The checklist is formatted in an Excel spreadsheet and is a source of information and evidence to the inspection team, the JACIE office and to the JACIE accreditation committee. It is a self-assessment against the standards and the centre must indicate whether they are compliant or not. The checklist is slightly different depending on whether the applicant is being inspected against the 7th or 8th edition standards.

Distribution of the standards

Checklist distribution

The checklist for the 8th edition standards is divided into the following sections and inspectors will be responsible for the sections in the checklist dependent on their area of expertise.

- Part B Clinical
- Part B Clinical QM (quality management)
- Part CM Bone Marrow
- Part CM Bone Marrow QM (quality management)
- Part C Apheresis
- Part C Apheresis QM (quality management)
- Part B-CM-C Donors
- Part D Processing
- Part D Processing QM (quality management)
- Labels Collection
- Labels Processing
- Labels Shipping and Transport

Not all centres offer a full transplant program, therefore some sections will not be relevant to the application and will not be part of the checklist the inspection team receives from the JACIE office.

Inspector responsibility

Certain sections, such as Part B-CM-C Donors and Part CM Bone Marrow, can be inspected by either the clinical or collection inspector. It is therefore important to define who will assess each section to avoid an incomplete inspection and checklist (Figure 4.)

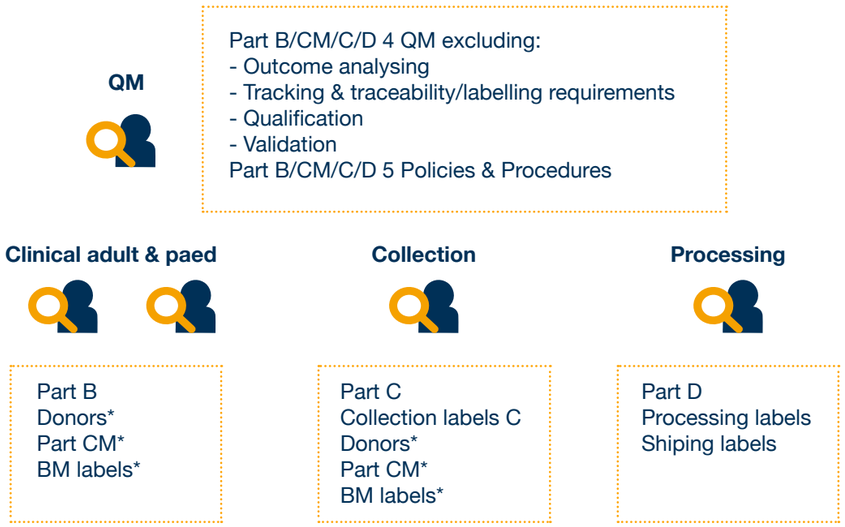


Figure 4. Define inspectors' scope of responsibility

Inspection Organisation

Inspection Plan

Team leaders are ultimately responsible for preparing the inspection agenda / plan from a template provided by the JACIE office.

Team leaders liaise with the other members of the inspection team to agree on the timetable and list of staff to interview during the inspection. Inspectors base the interview plan on the organigram (included in the pre-inspection documentation) provided by the centre. It is the responsibility of all inspectors to contribute to the inspection plan for their area/scope to ensure that the centre and its personnel are available on the day and the inspectors can make the most of their time.

It is important that inspectors complete the inspection agenda at least two weeks before the inspection. Once the agenda is completed by the inspectors it must be sent to the Accreditation Co-ordinator who will share it with the centre. The centre adds information about the location and names of the personal that need to be interviewed. Once confirmed, the agenda is sent back to the accreditation coordinator who will share it with everyone (inspectors and centre).

Below is the agenda for the onsite inspection (Figure 5).

TIME	LOCATION To be completed by APPLICANT	ACTIVITY	INSPECTORS	ACCOMPANYING STAFF To be completed by APPLICANT
08:00-08:30		Meet inspection team and accompany them to meeting room	All	
09:00-09:30 approx. 30-60min		Opening Meeting	All	
09:30-10:30 approx. 30-60min		Tour around facilities demonstrating linksn between facilities[1]	All	
10:30-12:00 approx. 30-60min		Document review	All	QM to be available during the review of documentation
12:00-13:00		WORKING LUNCH	All	
13:00-17:00		Document review and Interviews **See 7.0 Interviews Details*	All	QM to be available during the review of documentation **See 7.0 Interviews Details*

AREA / SCOPE	POSITION / ROLE To be completed by INSPECTION TEAM Insert or delete positions as necessary	NAME + LAST NAME To be completed by APPLICANT
	Programme Director	
	Transplant physician/Consultant/Specialist	
	Physician in training	
	Quality Manager	
	Senior Nurse	
	Nurses in training (or newest nurse in the unit)	
	Other BMTu nit nurses	
	Pharmacist	
	Intensive Care Lead	

Figure 5 Inspection plan template for onsite inspections

Remote Inspection Plan

Due to logistics, the agenda for remote inspections differs from the onsite inspection.

The Accreditation Co-ordinator will provide the inspectors with the links to the Teams calls (Figure 6). The General room meeting has a public link, so must only be shared with people within the organisation. The rest of the meeting room links have a 'lobby' and require a name to access. The inspectors or liaison person from the centre will be able to bypass this lobby and accept any guest into the meeting room. Finally, the inspectors' room is set up to be invitation only.

ROOMS	LINK
Inspector room	
General room	
Area room - Clinical room	
Area room - Collection room	
Area room - Processing room	
Area room - QM room	

Figure 6 Links to Teams calls

Below is the daily agenda template (Figure 7) and interview schedule (Figure 8) for remote inspections. An important point is that the remote inspection agenda needs to be very well defined because it does not allow for much improvisation during the day, and timings need to be respected.

DAY 1 Click or tap to enter a date.

TIME To be determined by TEAM LEADER	Connection See links above – Section 5	ACTIVITY	INSPECTORS	ACCOMPANYING STAFF To be completed by APPLICANT
08:00-08:30	Inspectors room	Meet to review the inspection plan to assess if any minor changes are needed	Inspectors: All JACIE staff: AC[1]	N/A
08:30-09:00	General room	Opening Meeting	Inspectors: All JACIE staff: AC[1]	
09:00-09:30	Areas rooms	Discussion of the pre-recorded video tour or alive video tour of the facilities	Inspectors: All JACIE staff: AC[1]	
09:30-09:45	Break			
09:45-11:15	Areas rooms	Document review and Interviews 1	Inspectors: All JACIE staff: AC[1]	See 8.0 Interviews Details
11:15-11:45	Inspectors room	Inspectors meeting	Inspectors: All JACIE staff: AC[1]	N/A

1 - AC will be available at the beginning of each meeting to ensure that participants that can connect APPLICANT please indicate if there are scheduled infusions, collections or processing of products during the inspection days as the team will be interested in observing the procedures.

Figure 7 Inspection agenda template for remote inspections

AREA / SCOPE	POSITION / ROLE To be completed by INSPECTION TEAM Insert or delete positions as necessary	NAME + LAST NAME To be completed by APPLICANT	TIME
Cellular Therapy Product Administration & Clinical Facilities – ADULT	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		
	Intensive Care Lead		

Figure 8 Interview schedule for remote inspections

The time slots are a suggestion and can be modified. A total time of 11 hours is expected over the course of 3 days. Hours are shown in the applicant's time zone and inspectors will identify the personnel to interview and will prepare the schedule for their sessions (to be filled out by inspectors).

Teleconference

The Accreditation Co-ordinator liaises with the team leader and wider team to set the date for the teleconference. The team leader chairs the pre-inspection team meeting. It is important that the teleconference takes place 2 weeks before the inspection date, otherwise it loses its purpose and there may not be sufficient time to act on anything proposed. The team leader, along with the other inspectors and the JACIE accreditation coordinator meet using Microsoft Teams[1]. It is expected that the whole inspection team, including trainees, must actively participate in the teleconference. This helps with planning and gaining a deeper understanding about the centre and how the inspection will be organised.

The topics included in the teleconference agenda are:

- Pre-audit documentation
- Open discussion
- Extra documents to be requested
- Distribution of standards among the inspection team
- Agenda / plan for the inspection
- Logistics

1 - JACIE offers a licence free of cost for Microsoft Office 365. The aim is to use the services provided by Microsoft Office 365 to upload and exchange documentation related to the accreditation (SharePoint) and conduct remote inspections via teleconference (Microsoft Teams). For further explanation and how to connect please check JACIE 86

Travel arrangements

JACIE recognises the considerable effort made by inspectors when performing site visits. Therefore, to ease the burden, travel arrangements and trips are booked directly by the travel agency named by the JACIE office. Once the inspection has been confirmed, inspectors will be contacted by the travel agency by email. Inspectors should communicate their preferences to the travel agency as soon as they are contacted as a delay means there will be less options available. If they do not receive an email from the travel agency, they should let the coordinator know.

If changes (including cancellations) to the reservations are necessary, the inspector must contact the travel agency directly by email or by phone: asturias.empresas@bcdtravel.es, 902 995 365 (calls from Spain) or 0034 971 070 551 (calls from abroad). Inspectors are responsible for obtaining any entry VISA, if needed. Inspectors are responsible for any necessary vaccination when travelling to countries where compulsory immunisation is required for travel or to enter the territory. JACIE will reimburse any cost related to vaccinations and VISAs.

Inspectors should not book their own travel, as the travel agency can arrange trains and planes directly. The only exception is when travelling with their personal car and inspectors can then claim the mileage.

Per diem payments

Inspectors and trainees participating in onsite inspections should not be out of pocket and JACIE provides a daily allowance to cover expenses. The total amount depends on the duration of the inspection. For example, three days are usually awarded for a two-day inspection to take into consideration travel and preparation. If any other refunds are needed the inspector should submit the request within 2 weeks.

If inspectors are participating in their first inspection, the Accreditation Co-ordinator will ask that they complete a 'Per Diem' form which will ask for the bank details. If a returning inspector, it is essential that the Accreditation Co-Ordinator is informed if the bank details have changed since the last inspection.

Summary

REQUEST TO INSPECT

Potential inspectors shall respond promptly, ideally within a week, to the request from the Volunteers' Co-ordinator to inspect and alert the JACIE office to any potential conflicts of interest.

SHAREPOINT

Inspectors shall access the pre-inspection documents and standards they are responsible for using the SharePoint login credentials. They shall work collaboratively, confidentially, and online in the SharePoint space.

PRE-AUDIT DOCUMENTATION

Inspectors shall review the pre-audit documentation (checklist and other supporting documentation provided by the centre) two weeks before the inspection.

INSPECTION PLAN

All inspectors shall liaise with the team leader and accreditation's co-ordinator to contribute to the inspection agenda for their section. The inspection plan shall be completed two weeks before the inspection.

PRE-INSPECTION TELECONFERENCE

It is expected that the whole inspection team, including trainees, shall actively participate in the pre-inspection teleconference using Microsoft Teams at least two weeks before the inspection.

TRAVEL ARRANGEMENTS

Inspectors shall communicate their preferences for travel as soon as they are contacted as a delay means there will be less options availables. If they do not receive an email from the travel agency, they shall let the coordinator know.

PER DIEM PAYMENTS

Inspectors shall complete a 'Per Diem' form which ask for bank details. If a returning inspector, it is essential that the accreditation co-ordinator be informed if bank details have change since the last inspection performed. If any other refunds are needed the inspector shall submit the request within two weeks.

5. Inspection

The JACIE inspection model, based on on-site inspections, was understandably exposed during the COVID pandemic and inspections had to be paused for a significant period. As a result, JACIE had to develop a remote inspection model to restart the inspections during the pandemic as well as build in resilience for the future. JACIE now has an on-site and remote inspection format. The duration and method of JACIE inspections may vary according to the preference of the applicant and the type of accreditation being applied for.

On-site inspections are currently used for first-time accreditation inspections and if there have been significant amendments to a programme since the previous inspection such as changes to facilities, infrastructure, and buildings.

Remote inspections might currently be used for reinspection. The onsite tour and staff interviews are replaced with pre-recorded videos of the facilities and with remote interviews with facility staff in combination with the document review. During these inspections the full checklist is reviewed resulting in a full four-year period of accreditation.

A hybrid inspection, where some inspectors visit the facilities and other areas are done remotely, can be considered if a contingency is needed. These situations are discussed case-by-case and the inspection team must determine if the conditions are suitable for a hybrid inspection.

On-site and Remote Inspection differences

The duration of on-site and remote inspections is the same in total (1.5 days) but remote inspections are ideally spread over three half days. The differences between on-site and remote inspections are listed below (Figure 9):

	ON-SITE INSPECTION	REMOTE INSPECTION
DURATION	1-2 days	3 half days
LOCAL	Centre	Teleconference – Teams Specific room for each area
AGENDA	Opening meeting Tours Interviews Document review Closing meeting	Similar to on-site meeting The tour of the facilities will be done by video or streaming
IMPLICATIONS FOR INSPECTORS	Travel required (one day before the inspection) Ability to physically see the facilities	Inspect from anywhere Laptop, camera, microphone and good internet connection Strong planification required due to complexity about last minute changes
ATTENDANTS	Inspector team Centre team	Inspector team Centre team JACIE accreditation coordinator

Figure 9: The differences between on-site and remote inspection

On-site and Remote Inspection agendas

For both inspection formats (on-site and remote) the agendas are similar (Figure 10). The inspection team should be given a separate room to use as a base to ensure privacy.

For remote inspections, JACIE will set up the rooms in “Microsoft Teams’ so that inspectors and the centre can connect. Links to connect will be embedded in the agenda. Inspectors are encouraged to connect to ‘Teams’ before and ensure that the audio / video works well.

	ONSITE INSPECTION	REMOTE INSPECTION
1ST HALF DAY / DAY 1	Opening Meeting Tour of the facilities	
2ND HALF DAY / DAY 1	Document review Interviews key personnel of each unit Observation of procedures and if they are according to checklist	
3RD HALF DAY / DAY 2	Closing meeting	Continue tour Document review Interview key personnel of each unit Closing meeting

Figure 10. On-site and remote inspection agendas

Format of opening meeting

Applicant:

During the opening meeting, the applicant presents the programme and describes the structure of the organisation, location of sites, presents any information that may be helpful to the team, particularly items not included on the checklist or required documents list.

Team leader:

The team leader introduces the inspection team and explains the purpose of the inspection and working methodology. The team leader will explain that inspectors are the eyes and ears of the JACIE accreditation committee and that they do not make the final decision as to whether accreditation is awarded. The inspection agenda is confirmed, and the programme is reassured that the information obtained during the inspection is strictly confidential.

Format of closing meeting

Three meetings are held to bring the inspection to a close:

Inspection team meeting

Only the members of the inspection team attend and it's a time to discuss and compare findings within the team. This is a good time to start completing the report and ensure all the parts were inspected and share the information between the inspectors.

Exit meeting with programme director

This is usually conducted in between the team leader and programme director and is an opportunity to brief the centre about any sensitive and important issues. Other members of the inspection team can be invited and should also be prepared to discuss findings with the programme director.

Closing meeting

This meeting closes the inspection and is led by the team leader, with the support of all inspectors. It is attended by the full inspection team, the programme director, facility and medical directors, anyone who accompanied the inspection team during the inspection; supervisors; and any other facility personnel invited by the programme director.

This is a time to thank the departments involved and to present the main findings of the inspection so there are no surprises when they receive the final report. It is recommended to indicate first the areas for improvement and then the centre's strong points. Finishing with the best part can leave a better impression with centres. Centres should be able to start addressing the deficiencies based on the closing meeting.

Important notes for inspectors:

- Avoid making promises or speculations. Specifically, do not guess about the likelihood of the applicant's "passing" the inspection. The JACIE accreditation committee will make this decision.

- Explain that you will report your observations; these are reviewed the JACIE Report Assessors and then summarised for presentation to the JACIE accreditation committee. The JACIE accreditation committee makes the final decision on accreditation.

- If you do not know the answer to a question, say so. Notify the JACIE office immediately if there are unanswered questions from the applicant that require answers before a final report is available. You should include applicant questions in your report.

6. Post-inspection

Feedback through online survey

Once the inspection is completed, the applicant and the inspection team will receive an inspection evaluation form. It is important that this form is returned within 2 weeks.

The form should be used to formally state satisfaction or to raise any issues that may have occurred during the inspection. It also gives the applicant an opportunity to give feedback on the process overall, identify strengths and areas for improvement.

The evaluation by the centre will also be sent to the inspectors for their information and response where necessary.

For specific issues, the feedback can also be sent to jacie@ebmt.org at any other time during the process.

Inspection report format

The Inspection Report has two parts:

1. The Inspection Summary which includes the basic information about the centre, the programme structure, team leader summary and overall impression of the inspection. Data, numbers, and the names of staff reflected in the Application Form may be outdated by the time inspectors are completing the inspection report. **It is important that inspectors ask for the latest information during the inspection.**

2. The completed Excel Inspection Checklist that includes the specific observations on each of the individual items in the checklist.

The inspectors need to submit the final Inspection Report and the checklist within 2 weeks of the inspection. The report is the fundamental part of the process, and all the decisions are based on the information presented within it.

How to complete the inspection summary and checklist

Inspection Summary

All inspectors should complete Sections A, C and D for the section they visited. The Team Leader should complete sections A, C and D for the facility he/she inspected and Section B with his/her summary. The Team Leader is responsible for reviewing the other team member's comments and observations and collating these in the Summary

Report before completing it in SharePoint. This final report is expected within **2 weeks** of the actual inspection. The summary should allow the reader to understand the overall impression of the Inspection Team.

Section A

Section A (Figure 11) contains general information about the programme or facility visited. It is the team leader's responsibility to ensure that all the fields are filled in. All information provided by the centre must be validated for consistency and accuracy during the inspection. Separate sections for adults and paediatrics must be completed and it is important to verify the interactions between facilities as seen in real-time. Inspectors must always be checking for consistency. It is also important to note the distances between a centre's facilities to include all three component parts.

SECTION A. GENERAL INFORMATION AND OVERVIEW

Programme/Institution name:	
City:	
Country:	
Type of inspection:	□ Initial / □ Reaccreditation / □ Re-inspection
Format of the Inspection	□ On-site / □ Remote / □ Hybrid
Edition of standards used for inspection:	□ 7th □ 8th

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

Accreditation goal (mark as appropriate):

AREA	PATIENT	HSCT		Immune Effector Cells	
		Allogeneic	Autologous	Allogeneic	Autologous
Clinical	Adult				
	Paediatric				
HPC, Marrow Collection	Adult				
	Paediatric				
HPC, Apheresis Collection	Adult				
	Paediatric				
Processing					

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:					

ADULTS	
Team Leader:	
Clinical:	
Marrow Collection:	
Apheresis Collection:	
Donors:	
Processing:	
Quality Management:	
Observer(s) and their organisation	
PAEDIATRICS	
Team Leader:	
Clinical:	
Marrow Collection	
Apheresis Collection:	
Donors:	
Processing:	
Quality Management:	
Observer(s) and their organisation:	

Figure 11. Section A General information and overview

Section B

Section B (Figure 12) is an objective, de-personalised description of the transplant programme and is the responsibility of the team leader. It should include an overview of what happens, where it happens and who makes it happen. It is important to state inter-facility and organisational relationships and include the catchment area. The team leader should set out the main deficiencies from the last inspection and evidence of on-going compliance. This is often called the 'helicopter' overview and should give a sense of whether you would want to be transplanted at 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 overall impression of the programme. This 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]

Figure 12. Section B Team leader on-site inspection summary

Section C

Section C (Figure 13) contains the individual inspector observations for each area inspected as listed under the inspection goals. All inspectors must complete the section relevant to their scope. Inspectors must note down the activity data, who they interviewed and include a brief description of the main strengths and areas for improvement. Observations must be referenced to the checklist for consistency.

SECTION C. OBSERVATIONS

PERSONS INTERVIEWED DURING THE INSPECTION: *This section appears under the heading of each section (see below) and should be completed with the names and roles of the persons interviewed during the course of the inspection*

MAIN STRENGTHS & AREAS FOR IMPROVEMENT: *This section appears below each section (see below) and describes the main strengths and areas for improvements e.g. well-trained team, excellent document management, need for more regular audits, etc.*

Cellular Therapy Product Administration & Clinical Facilities - ADULT	
Persons interviewed during the Inspection [*Insert or delete positions as necessary]*	
Position/role	**Name**
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	
Intensive Care Lead	

Numbers of transplants for 12 months up to inspection date		
	Allogeneic	Autologous
Adults	[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, population served, relationships with other organisations, etc. but not specific deficiencies or observations. These should be entered into the Inspection Checklist]

Main Strengths & Areas for Improvement	
Strengths	[This section should be for general suggestions. Specific deficiencies should be detailed in the Inspection Checklist]
Areas for improvement	[This section should be for general suggestions. Specific deficiencies should be detailed in the Inspection Checklist]

Figure 13. Section C Observations

Completing the inspection summary is a team effort and all inspectors should complete the sections that they inspected. Box 2 provides a summary of what must be included in the Inspection Summary.

The following must be included in the Inspection Summary:

✓ The number of:
- Transplants for 12 months up to inspection date
- Bone marrow harvests for 12 months up to inspection date
- Apheresis procedures for 12 months up to inspection date
- Processing procedures for 12 months up to inspection date

✓ The facilities visited

✓ The names of the directors of the service(s) visited

✓ A brief description of the programme or facility e.g., years functioning, main activities, relationship with other hospitals and services

✓ The clinical inspector should include the percentage of the data-points reviewed that were incorrect (if any)

✓ A description of the services provided to other facilities not visited during the inspection including donor registries

✓ A comment on the interactions between the different parts of the transplant programme

✓ An indication of the distance between the sites

✓ Any additional information you think relevant to the report

✓ Any comments on the documentation received and reviewed prior to the on-site visit

Box 2. Information to be included in the Inspection Summary

Checklist

The checklist is currently in an Excel spreadsheet format with a total of 14 worksheets. These worksheets include a cover page (Figure 14), a snapshot with activity numbers (Figure 15), eight parts of the FACT-JACIE standards, donors and three label worksheets. The checklist is first completed by the applicant and then validated by the inspectors.

JOINT ACCREDITATION COMMITTEE -ISCT & EBMT (JACIE)

Name of Facility/Programme:	0
Institution:	0
City:	0
Contact person:	0
Contact telephone	0

For JACIE Office use only
Inspector name:
Part B Part C HPC(M) Part C HPC(A) Part D Part(s) QM

Contact the JACIE Office at +34 93 453 8570 (office) or email jacie@ebmt.org

Figure 14. Cover tab in the FACT-JACIE standards checklist

	FOR COMPLETION BY THE APPLICANT
Name of Facility/Programme	
Institution:	
City:	
Contact person:	
Contact telephone	

Part B: CLINICAL			
Type of transplants	***Autologous***	*Yes/ No*	
	Allogeneic	*Yes/ No*	
Patients	***Adults***	*Yes/ No*	
	Paediatrics	*Yes/ No*	
	Adults	***Paediatrics***	
Total Transplants in 12 months prior to completing this checklist — **Total Allogeneic Related**			
Total Allogeneic MUD			
Total Autologous			
Type of application	*Initial/ Reaccreditation*	*Initial/ Reaccreditation*	
More than 1 clinical site?	*Yes/ No*	*Yes/ No*	
Is Extracorporeal Photopheresis a part of therapy for GvHD or other indications?	*Yes/No/ Only occasionally*	*Yes/No/ Only occasionally*	
Is Radiation Therapy administered?	*Yes/No/ Only occasionally*	*Yes/No/ Only occasionally*	
Does this application include Collection (bone marrow and/or apheresis)	*Yes/ No*	*Yes/ No*	
Is the Clinical Unit primarily responsible for donor selection, evaluation and management?	*Yes/ No*	*Yes/ No*	

Part D: PROCESSING		
Type of cellular therapy products	***Autologous***	*Yes/ No*
	Allogeneic	*Yes/ No*
Type of application	*Initial/ Reaccreditation*	
More than 1 processing site?	*Yes/ No*	

Part CM/C: Cell Collection	**Apheresis**		**Bone Marrow**	
Type of donors	***Autologous***	*Yes/ No*	***Autologous***	*Yes/ No*
	Allogeneic	*Yes/ No*	***Allogeneic***	*Yes/ No*
Type of application	*Initial/ Reaccreditation*		*Initial/ Reaccreditation*	
Donors	***Adults***	*Yes/ No*	***Adults***	*Yes/ No*
	Paediatrics	*Yes/ No*	***Paediatrics***	*Yes/ No*
More than 1 collection site?	*Yes/ No*		*Yes/ No*	
Is the Cell Collection Unit primarily responsible for donor selection, evaluation and management?	*Yes/ No*		*Yes/ No*	

Figure 15. Snapshot tab in the FACT-JACIE standards checklist

QM Standards

There are four separate quality management worksheets (QM-Part B, QM-Part CM, QM-Part C and QM-Part D) to be assessed by the quality management inspector. Where no quality management inspector is available, the clinical inspector will assess QM - Part B and QM - Part CM. The collection inspector will assess QM - Part C and the processing inspector will assess QM - Part D in addition to the corresponding sections of their area of expertise.

B/CM/C 6 Allogeneic and Autologous Donor Selection, Evaluation, and Management

The B/CM/C 6 Allogeneic and Autologous Donor Selection, Evaluation, and Management worksheet is usually assessed by the collection inspector for all facilities unless otherwise agreed by the inspection Team. Where only a clinical unit is being inspected, the clinical inspector will assess these standards.

CM/C/D 7 Coding and Labelling of Cellular Therapy Products

The standards for labels are found on three separate worksheets: Labels-Collection, Labels-Processing and Shipping & Transport Labels. The Collection Labels are assessed by the collection inspector and the Processing Labels and Shipping & Transport Labels are usually assessed by the processing inspector unless otherwise agreed by the inspection team. Where only a collection unit is being inspected, the collection inspector will assess these standards.

Assessment of compliance

Inspectors can assess the compliance of standards as follows:

- Compliant – all aspects of the standard are met
- Partially compliant – some, but not all aspects are met. Figure 16 shows where standards have been made partially compliant.
- Non-compliant – none of the aspects are met. Figure 17 shows where standards have been made non-compliant.
- Not applicable - where the standard is not applicable to the specific activity in the applicant facility or programme. (NOTE: this should not be used for something that is not compliant). Standard B3.9.2 is an example of a standard that can be not applicable if a centre does not treat paediatric donors (Figure 18).

B3.2.2	Attending physicians shall participate in a minimum of ten (10) hours of educational activities related to cellular therapy annually.	**COMPLIANT**	**PARTIALLY COMPLIANT**	We have seen this for two years of the five in the accreditation cycle.
B3.2.2.1	Continuing education shall include, but is not limited to, activities related to the field of HPC transplantation.	**COMPLIANT**	**PARTIALLY COMPLIANT**	We have seen this for two years of the five in the accreditation cycle.

Figure 16. Standards made partially compliant with inspector's reason

B6.3.5	A pregnancy test shall be performed for all female donors with childbearing potential within seven (7) days prior to starting the donor mobilisation regimen or undergoing anaesthesia, and, as applicable, within seven (7) days prior to the initiation of the recipient's preparative regimen.	**COMPLIANT**	**NON-COMPLIANT**	Pregnancy is tested when a donor could be pregnant, but is not tested in all, patients using anti conception
C6.3.4; CM6.3.4	A pregnancy test shall be performed for all female donors with childbearing potential within seven (7) days prior to starting the donor mobilisation regimen (if mobilised donor is used) or undergoing anaesthesia, and, as applicable, within seven (7) days prior to the initiation of the recipient's preparative regimen.	**COMPLIANT**	**NON-COMPLIANT**	Pregnancy is tested when a donor could be pregnant, but is not tested in all, patients using anti conception
C6.3.4.1	For collections without mobilization, a pregnancy test shall be performed within seven (7) days prior to cellular therapy collection.	**COMPLIANT**	**NON-COMPLIANT**	Pregnancy is tested when a donor could be pregnant, but is not tested in all, patients using anti conception

Figure 17. Standard made non-compliant with inspector's reason

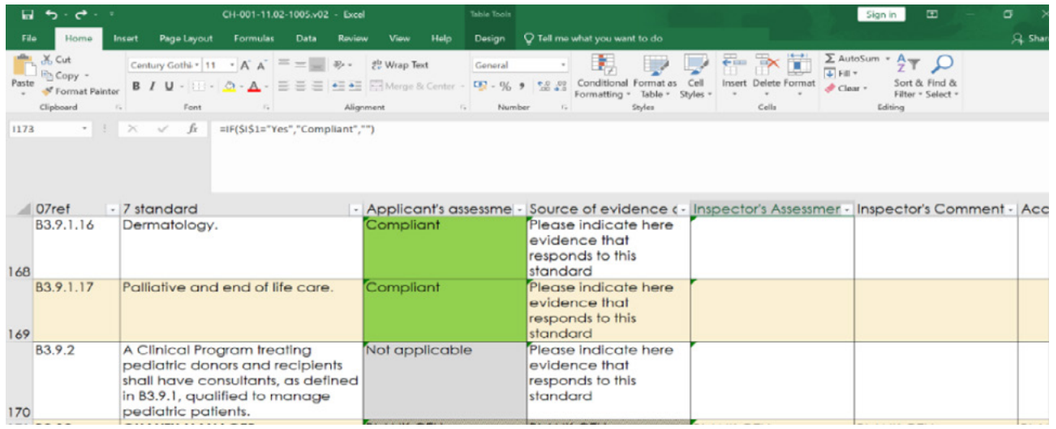


Figure 18. Standard B3.9.2 is not applicable to applicants treating only adults

There are situations where an inspector will find differently to an applicant and change the compliance on the checklist. In these instances, the inspector must always provide a clear supporting comment (Figure 19).

C	When using collection methods that may result in contamination or cross-contamination of cellular therapy products, critical environmental conditions shall be controlled, monitored, and recorded, where appropriate, for air quality and surface contaminants.	**NOT APPLICABLE**	**PARTIALLY COMPLIANT**	Please provide a supporting comment. The confusion here seems to be the use of collection method. When reading the explanation, I think this is as explained in C2.4, C2.4.1 and C2.4.2. Changed to PC.

Figure 19. Changing the centre's self-assessment

Applicability of standards

The JACIE standards cover the full scope of stem cell transplantation. There will be times, depending on the accreditation goals and service provision of an applicant, when the full set of standards do not apply. A few examples include clinical programmes that do not have physicians-in-training posts, do not treat paediatric patients, do not administer radiation therapy, do not administer ECP or utilise an electronic record system.

If an inspector has stated that a standard or set of standards is not applicable, a reason must be given to ensure that the JACIE accreditation committee is aware of the centre's way of working and that 'not applicable' has been correctly selected.

Another one, which is sometimes tricky, is in the case where the applicant has assessed a standard as 'not applicable'. The inspector should stand back and assess if the standard 'could' be applicable in certain circumstances and assess whether the centre would be compliant if the situation were to arise.

Inspectors must take care to ensure that they inspect all the standards that are applicable to a centre.

Variables affecting the reporting process

Not fully completed reports

If an applicant and inspector have found a standard not applicable, a reason must be given. Figure 20. shows an example of when the JACIE office had to refer a report back to the inspector to provide explanatory text which delayed the completion of the report.

C11.1.1.2- For cellular therapy products that are to be distributed for use at another institution, the Apheresis Collection Facility shall inform the receiving institution of the tracking system and requirement for tracking the product in writing or electronic format at or before the time of product distribution.

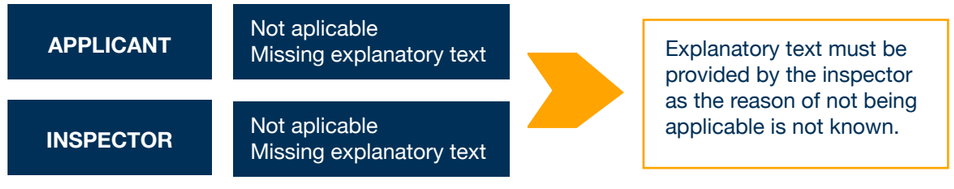


Figure 20. Standards that have been found not applicable must have explanatory text

If an applicant and inspector have assessed the compliance of a standard differently, a reason must be given. Figure 21. shows an example of when the JACIE office had to refer a report to the inspector to provide explanatory text which delayed the completion of the report.

B7.6.5 - For transplants utilising cellular therapy products from more than one (1) donor, the first cellular therapy product shall be administered safely prior to administration of the second cellular therapy product.

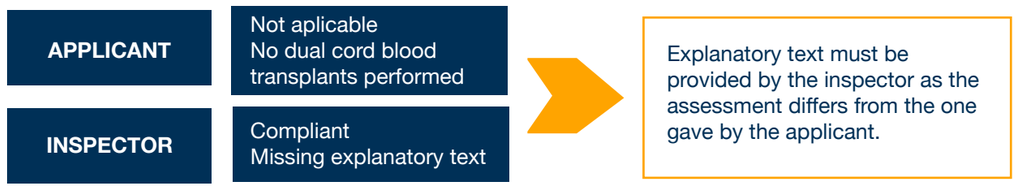


Figure 21. Standards that have been assessed differently by the inspector and applicant must have explanatory text

Inconsistencies

It is important that information provided by the inspector in the summary report and/or checklist is consistent with the information in the application form. If the information is different, a reason must be provided so that the JACIE office does not have to refer a report back to the inspector for clarification. Figure 22. shows an example of when a report had to be referred to the inspector for an explanation.

Information shown in the application form did not match the information provided by the inspector in the inspection report/checklist.

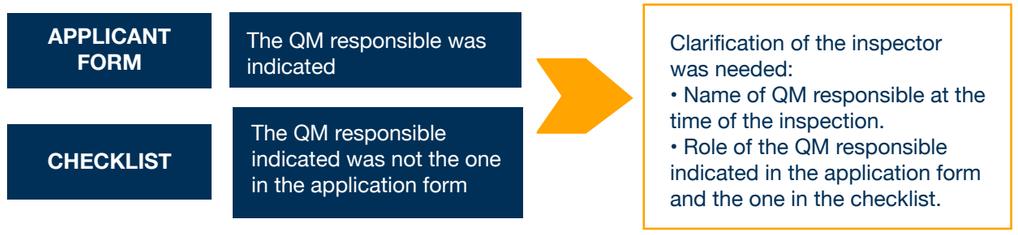


Figure 22. Information in the application form must be consistent with the checklist and/or summary report

Another point is that there must be consistency across standards. As some general quality standards are applicable across all standards, B, C, CM and D, it is important that the quality management inspector takes some time when they have completed the checklist to do a cross-check across the standards to ensure they have consistently reported the same findings where appropriate.

It is also good practice for the Team Leader to check that all standards have been assessed by the individual inspectors and for some standards where e.g., the collection inspector and the quality management inspector are reviewing similar standards e.g., training, supplies management, equipment management; that the respective assessment in each section is consistent. As an example, a collection inspector might review the storage of the collection supplies (apheresis collection kits or the bone marrow harvest kits) and the quality management inspector might look at the standard operating policies for these areas. The assessment of these affiliated standards should be similar between inspectors.

The information provided by the inspector in the summary report and checklist must also be consistent so that the JACIE office does not have to refer a report back to the inspector for clarification. Figure 23. shows an example of where the report had to be referred to the inspector for amendment.

D4.7.3 - For HPC products intended for haematopoietic reconstitution, time to engraftment following cellular therapy product administration measured by ANC and platelet count shall be analysed.

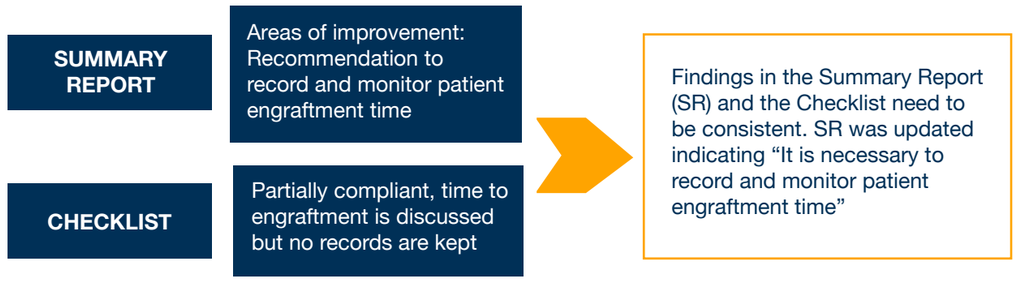


Figure 23. Information in the summary report must be consistent with the checklist

Interpretation of standards

Standards are compliant if the centre provides evidence as stated in the manual. Standards must be assessed against the requirement of the standard and cannot be found non-compliant or partially compliant if they have provided evidence that they meet the requirements. Figure 24 shows an example of this.

Information shown in the application form did not match the information provided by the inspector in the inspection report/checklist.

Figure 24. Standards are compliant if the centre provides evidence that they meet the requirements as stated in the manual

Standards are not applicable if they are not mandatory, and the centre does not include them in the service. See Figure 25. which shows that not all centres have advanced practice professionals in post.

B3.5.1- APPs shall be licensed to practice in the jurisdiction of the Clinical Program and shall be limited to a scope of practice within the parameters of their training and licences.

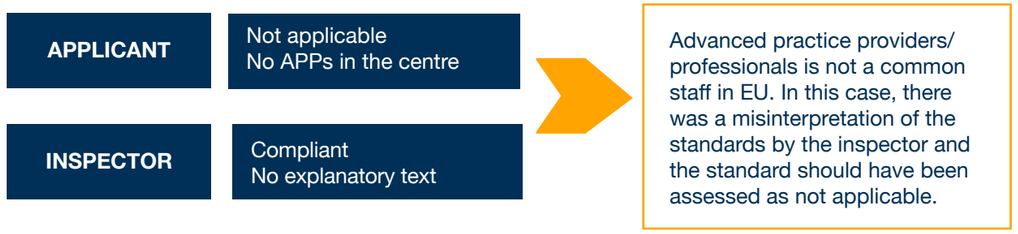


Figure 25. Standards are not applicable if they are not mandatory, and the centre does not include them in the service

JACIE standards must be followed if they are more stringent than the local / national regulations. Figure 26 shows an example of a centre not being compliant against the requirement for pregnancy testing.

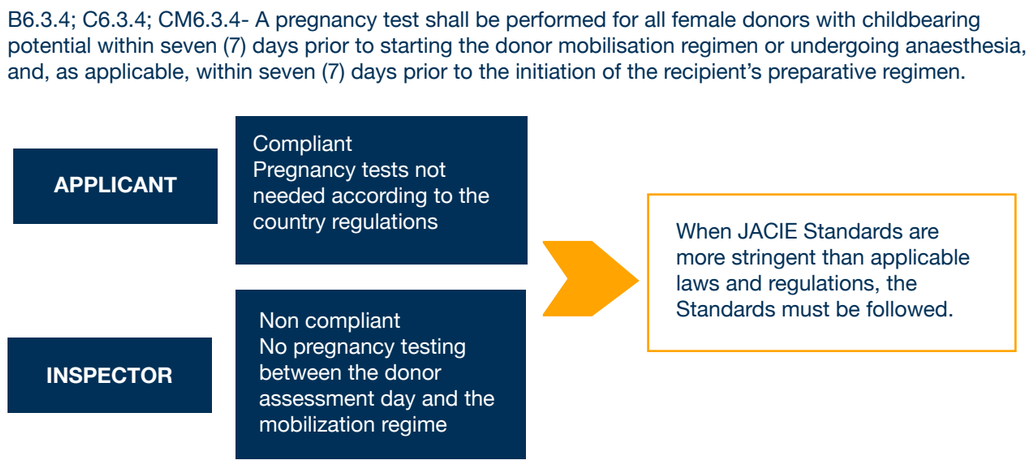


Figure 26. JACIE standards must be followed if they are more stringent that the local / national laws and regulations.

Please remember that the JACIE Accreditation Committee (JAC) does not have access to the documents, does not interview staff and does not visit the centre and therefore, the inspector must explain why they have assessed the compliance of the standards as they have.

Checklist summary

- **DO** add a comment if your assessment is anything but compliant, so that the JACIE Accreditation Committee, the JACIE office and the centre understands your assessment.
- **DO** add a comment if you change the centre's self-assessment.
- **DON'T** add a comment for standards that you and the centre have assessed as compliant.
- **DO** assess every standard.

The completion of the report should start before the inspection. It is important to start drafting the checklist with notes about what standards need more focus before the inspection and during the review of the pre-audit documentation.

During the inspection, make sure that all is reviewed and note down observations, fill in the checklist and report as much as possible.

Inspectors should never make a standard non-compliant because they did not have time to assess it during the inspection. Inspectors must manage the time so that they can assess all the standards.

Inspectors should not add questions or question marks to their comments in the checklist. If there are doubts or remaining questions during the inspection, the inspector must mark that standard as non-compliant or partially compliant and highlight in the comments what further information is needed in order to assess the standard. The JACIE office and JACIE accreditation committee do not assess standards, and inspectors must ensure they have enough information from the centre or set out what is missing and why the standard is not compliant. Inspectors are responsible to assess the standards and resolve issues related to them.

A good practice is to do a recap at end of the day and cross-reference the checklist and identify what is done and what still needs to be completed.

At the end of an inspection share conclusions with the inspection team to ensure consistency.

The template used should be the version provided by the JACIE accreditation coordinator.

Recommendations for improving the report process

- Complete the report as soon as possible after the inspection. A delay in preparing the report has a detrimental impact on the quality of the report and on the inspection process.

- It is **highly recommended** to draft the inspection report while still onsite. It is easier to remember key points and will ensure this task is completed outside of your normal work. JACIE will reimburse the costs of an additional night's accommodation if this facilitates writing the report.

- The checklist is an important document which is reviewed by the JACIE accreditation committee. If a standard has been assessed differently by the centre and inspector, a comment must be included so that the inspector's finding is clear. For example, if a centre has marked a standard compliant, but the inspector has found it rather non-compliant, then a reason must be noted in the comment section.

- Checklists, along with the inspection report, must be completed in SharePoint at the end of the inspection. If this is not possible, inspectors should aim to submit their reports within 3 days of the inspection.

- Inspectors are also required to assist with later phases of the inspection process. Once the centre has submitted evidence that they have corrected the deficiencies, inspectors must review this evidence.

-Although highly unlikely, inspectors may be needed to conduct a reinspection of the centre if major deficiencies were found.

JACIE process after inspection

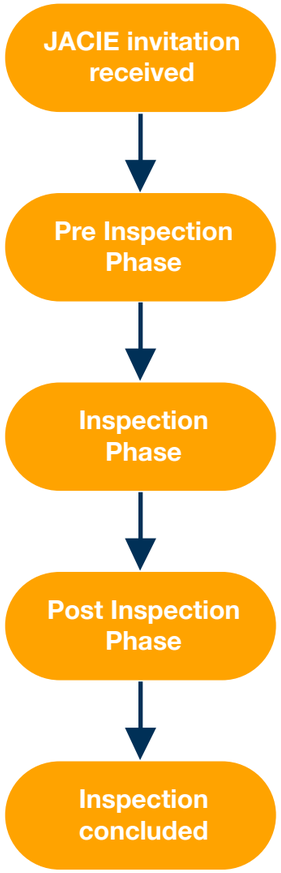
The inspection report is initially reviewed by the JACIE office to ensure that all standards have been assessed and are consistent across the different sections, where appropriate. The report is then reviewed by the JACIE accreditation committee whose members are experienced inspectors with expertise in all the sections of the standards. The JACIE accreditation committee will decide on the level of compliance against the standards based on the information provided in the report by the inspectors and set the time given to the centre to correct any deficiencies.

Subsequently, the JACIE accreditation committee report and annotated checklist are sent back to the Transplant Centre / Facility who must provide evidence of correction of any deficiencies within the allocated time period. This evidence is then reviewed by the initial inspection team and once it considers that all the deficiencies have been corrected, the final report will be approved by the Chair of the JACIE accreditation committee and the Centre / Facility will be notified of its accreditation.

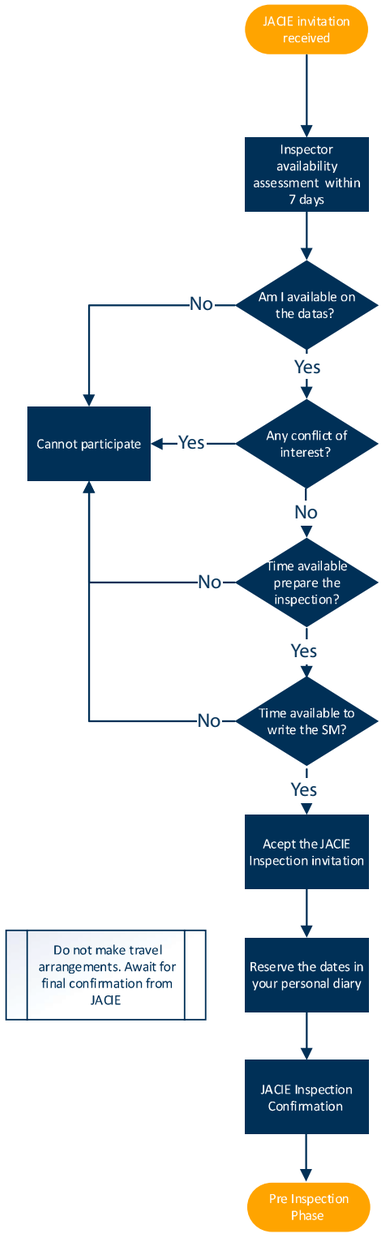
Accreditation timeframe

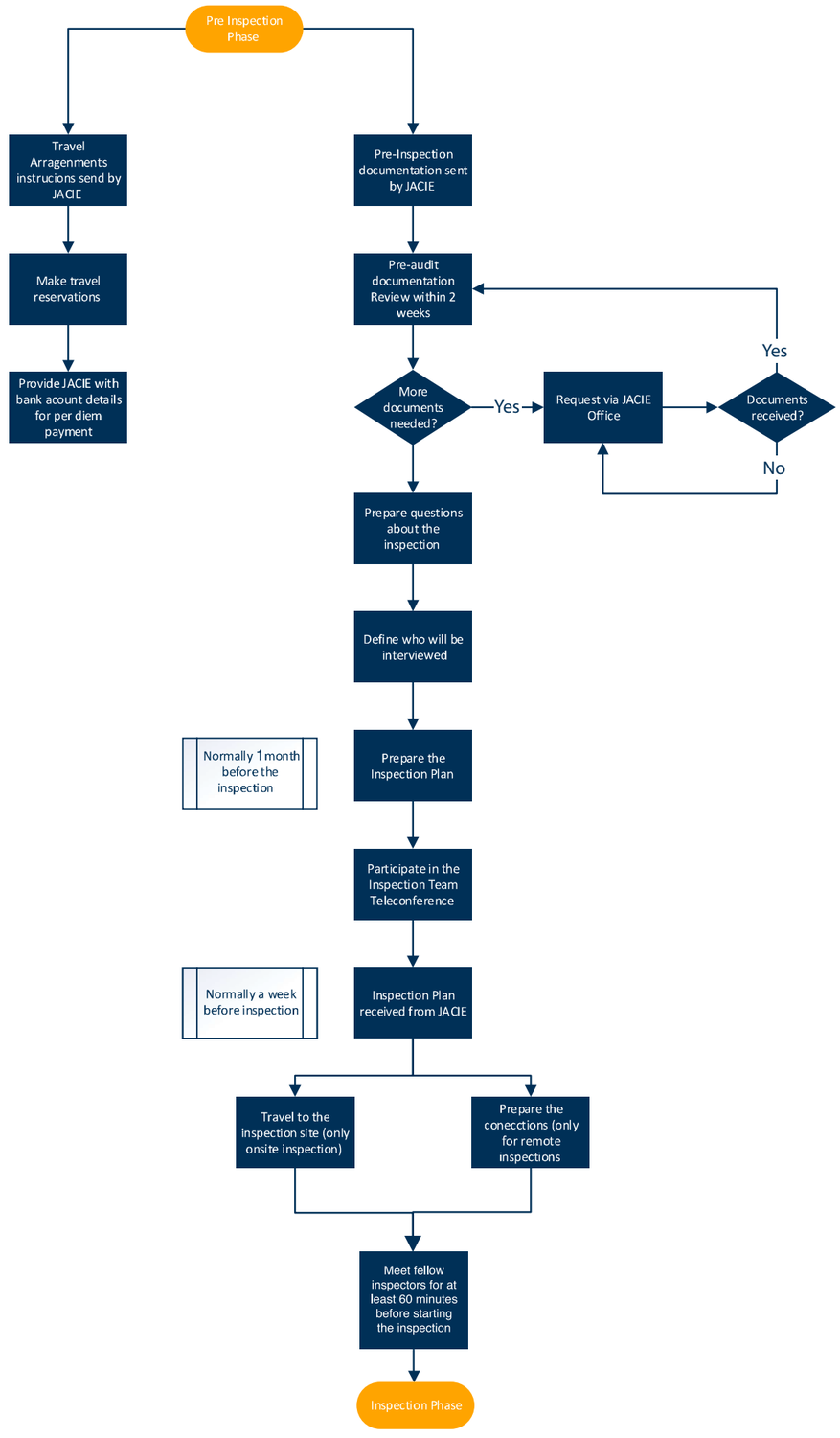
This accreditation is valid for four years following an on-site inspection (commencing from the date that accreditation is awarded), after which the centre is required to reapply to maintain accreditation. It is important to note that, unlike many Competent Authorities' processes, the JACIE accreditation process involves volunteer inspectors who have other time commitments, and this is reflected in the time to completion of some of the JACIE accreditation process steps. As the pre-inspection stage can take up to six months, and the JACIE accreditation committee can allocate up to 12 months to address the deficiencies identified by the inspection team, it is not unusual for the end-to-end accreditation process to take 12 -18 months, particularly for an initial accreditation.

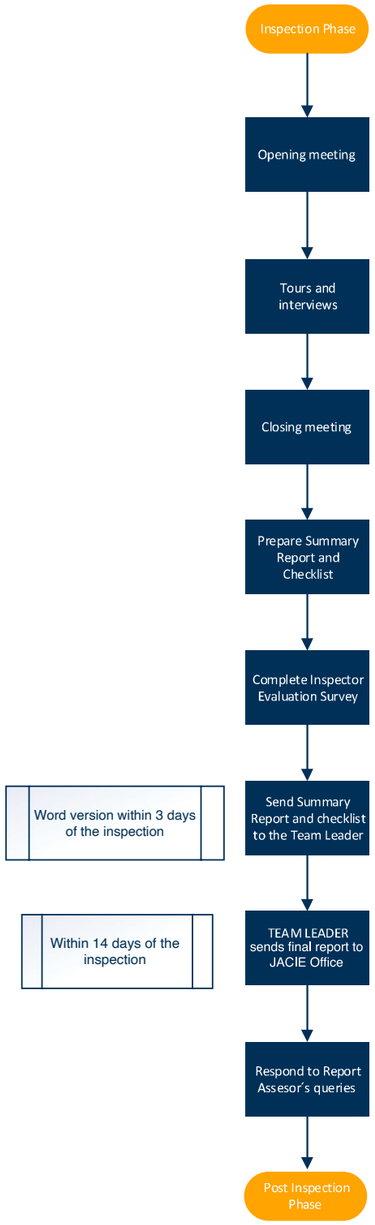
It is common for reaccreditation processes to proceed quicker, as the facilities, infrastructure and QMS have already been assessed as adequate. The challenges with reaccreditation usually occur, if there have been changes in the facilities (e.g., new ward/ laboratory) or staff (e.g. changes to the Transplant Program Director, Facility Director, Quality manager, significant staff turnover).

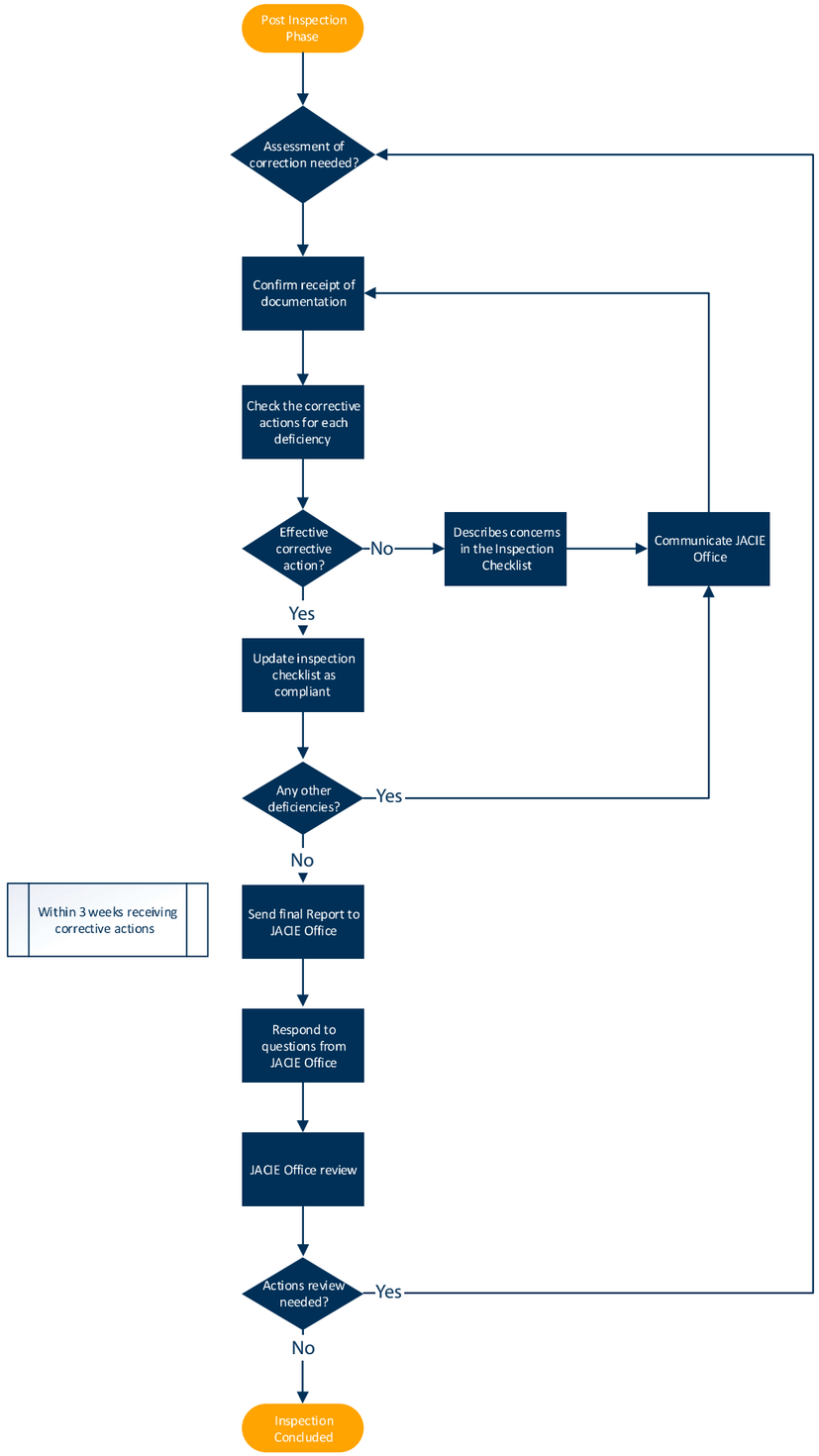


IH Flowchart


JACIE invitation received
Inspector availability assessment within 7 days
Am I available on the datas?
No
Yes
Cannot participate
Yes
Any conflict of interest?
No
Time available prepare the inspection?
No
Yes
Time available to write the SM?
No
Yes
Acept the JACIE Inspection invitation
Do not make travel arrangements. Await for final confirmation from JACIE
Reserve the dates in your personal diary
JACIE Inspection Confirmation
Pre Inspection Phase


Pre Inspection Phase
Travel Arragenments instrucions send by JACIE
Make travel reservations
Provide JACIE with bank acount details for per diem payment
Pre-Inspection documentation sent by JACIE
Pre-audit documentation Review within 2 weeks
More documents needed?
Yes
Request via JACIE Office
Documents received?
Yes
No
Prepare questions about the inspection
Define who will be interviewed
Normally 1 month before the inspection
Prepare the Inspection Plan
Participate in the Inspection Team Teleconference
Normally a week before inspection
Inspection Plan received from JACIE
Travel to the inspection site (only onsite inspection)
Prepare the conecctions (only for remote inspections
Meet fellow inspectors for at least 60 minutes before starting the inspection
Inspection Phase


Inspection Phase
Opening meeting
Tours and interviews
Closing meeting
Prepare Summary Report and Checklist
Complete Inspector Evaluation Survey
Word version within 3 days of the inspection
Send Summary Report and checklist to the Team Leader
Within 14 days of the inspection
TEAM LEADER sends final report to JACIE Office
Respond to Report Assesor's queries
Post Inspection Phase


Post Inspection Phase
Assessment of correction needed?
Confirm receipt of documentation
Check the corrective actions for each deficiency
Effective corrective action?
No
Describes concerns in the Inspection Checklist
Communicate JACIE Office
Yes
Update inspection checklist as compliant
Any other deficiencies?
Yes
No
Within 3 weeks receiving corrective actions
Send final Report to JACIE Office
Respond to questions from JACIE Office
JACIE Office review
Actions review needed?
Yes
No
Inspection Concluded

7. How to deal with unexpected events

Inspector illness

In the unfortunate situation that an inspector is unexpectedly unable to participate in an inspection, it is important the JACIE office is notified as soon as possible so that appropriate steps can be taken to mitigate for this.

Travel upheaval

In the unfortunate situation that there is travel upheaval and inspectors are unexpectedly delayed or unable to participate in an inspection, it is important the JACIE office is notified as soon as possible so that appropriate steps can be taken to mitigate for this.

8. Tricky standards

It has been noted that some standards are trickier to interpret than others and these are often queried by inspectors. Table 2. summarises these standards and provides guidance to inspectors to ensure these are consistently assessed. The cross-reference to other standards to which the clarification applies can be found in the column labelled ‘related standards’. This is not an exhaustive list and please contact the JACIE office if there are further queries.

Clinical

STANDARD	DESCRIPTION	CLARIFICATION	ALWAYS APPLI-CABLE	RELATED STAN-DARDS
B1.2	The Clinical Program shall use cell collection and processing facilities that meet FACT-JACIE Standards with respect to their interactions with the Clinical Program.	This is compliant if the application is for the reaccreditation of a full programme; it is partially compliant if the application is the initial accreditation of a full programme.	yes	CM1.2 C1.2
B1.3.1	The Clinical Program shall be licensed, registered, or accredited as required by the appropriate governmental authorities for the activities performed.	This standard refers to the local authority’s licence, not to the JACIE accreditation.	yes	CM1.3.1 C1.3.1 D1.2.1
B1.5	The Clinical Program shall comply with the minimum number of new patients for accreditation as defined in Appendix I.	The programme is required to meet the minimum activity numbers before getting accredited, but not at the time of application. See the current version of the FACT – JACIE Standards for more information about activity numbers.	yes	CM1.5 C1.5
B3.3.4.24	Diagnosis and management of HPC graft failure.	Always applicable - can happen in autos (rare) and allos.	yes	N/A
B3.3.4.33	Age-specific donor and recipient care.	Not only for paediatric patients, but also for elderly patients	yes	CM5.1.4 C5.1.4
B4.5.1.4	Labels	Always applicable, even if there is only a clinical unit. They need to have a provision and understanding of how and where the labels are produced.	yes	N/A

B4.13 (INCL. SUB STAN-DARDS)	The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for qualification of critical manufacturers, vendors, equipment, software, supplies, reagents, facilities, and services.	There is a difference between qualification and validation. According to GMP's definitions, validation refers to the total life cycle of a product from development through use and maintenance. The word 'validation' is sometimes widened to incorporate the concept of qualification that is part of the validation process. Qualification deals with components or elements of the process. Validation deals with the entire manufacturing process of the products. The Inspector should find evidence of qualifications of manufacturers, vendors, suppliers, equipment, facilities, services and critical reagents. Qualification procedures should include instructions for requalification and under which circumstances qualification is required. There are several ways to qualify a vendor of supplies, reagents and services. Practical methods, may include: review of a third party assessment by an accreditation organisation such as FACT, JACIE, CAP or others; remote audits by questionnaire; an ongoing dialogue regarding resolution of service complaints and process improvements; the sharing of internal audit findings and implementation of corrective action plans from the provider back to the facility is evidence that deficiencies have been recognised and corrected and a document review of the suppliers past performance history. In the rare case that a centre has determined that qualifications are not needed, they must have a written statement to support their assessment so that the inspector can determine compliance. These standards are applicable to the clinical unit, regardless of whether there is a BM unit (consider e.g., HEPA filters / infusion pumps). To note, B4.13.2 can be not applicable if there is no BM unit. For further information see Chapter 5 Qualification and validation written by Renza Monteleone and Dieter Klarmann in the JACIE Guide available: https://www.ebmt.org/education/jacie-guide	yes	C4.13 D4.13

B4.14	The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for validation or verification of critical procedures.	There is a difference between qualification and validation. According to GMP's definitions, validation refers to the total life cycle of a product from development through use and maintenance. The word 'validation' is sometimes widened to incorporate the concept of qualification that is part of the validation process. Qualification deals with components or elements of the process. Validation deals with the entire manufacturing process of the products. The Inspector should ask to see the SOPs for conducting validation studies and review a sample of validation studies that have been completed. Inspectors must note that studies are properly designed, the required data is objectively collected, the outcome, and intended actions are summarised and that both the finalised plan and report are reviewed and approved by the Clinical Program Director and the Quality Manager. In previous editions of the standards, re-evaluations were limited to validation studies. Inspectors should now have evidence of revalidation and risk analysis with change to process as well as how the introduction of new processes are made. For further information see Chapter 5 Qualification and validation written by Renza Monteleone and Dieter Klarmann in the JACIE Guide available: https://www.ebmt.org/education/jacie-guide	yes	C4.14 D4.14
B4.16.1	Feedback shall be obtained from associated Collection and Processing Facilities.	"Associated" means any unit, service, lab, clinical program that has an operational relationship with the unit inspected.	yes	C4.16.1 D4.16.1
B10.5.1	If two (2) or more facilities participate in the collection, processing, or administration of the cellular therapy product, the records of each facility shall show plainly the extent of its responsibility.	If a program consists of e.g., one clinical unit, one collection and one processing unit, then this is not applicable. If a program consists of e.g., two clinical units, then this is applicable.	no	C11.8.2 D13.5.3

Bone Marrow

STANDARD	DESCRIPTION	CLARIFICATION	ALWAYS APPLICA-BLE	RELATED STANDARDS
CM1.2	The Marrow Collection Facility shall use cell processing facilities that meet FACT-JACIE Standards with respect to their interactions with the Marrow Collection Facility.	This is compliant if the application is for the reaccreditation of a full programme; it is partially compliant if the application is the initial accreditation of a full programme.	yes	B1.2 C1.2
CM1.3.1	The Marrow Collection Facility shall be licensed, registered, or accredited as required by the appropriate governmental authorities for the activities performed.	This standard refers to the local authority's licence, not to the JACIE accreditation.	yes	B1.3.1 C1.3.1 D1.2.1
CM1.5	A minimum of one (1) marrow collection procedure shall have been performed in the twelve (12) month period immediately preceding initial accreditation, and a minimum average of one (1) marrow collection procedure per year shall be performed within each accreditation cycle.	The programme is required to meet the minimum activity numbers before getting accredited, but not at the time of application. See the current version of the FACT – JACIE Standards for more information about activity numbers.	yes	B1.5 C1.5
CM5.1.4	Donor age-specific and size-specific issues where relevant.	Not only for paediatric patients, but also for elderly patients	yes	B3.3.4.33 C5.1.4
CM5.1.10	Cellular therapy product storage.	It is a common issue that centres think that this standard does not include storage in the bone marrow unit. This standard is applicable.	yes	C5.1.11

CM7.1	ISBT 128 and EUROCODE coding and labelling	ISBT 128 / Eurocode / SEC This standard is not always well assessed. In the 8th edition of the JACIE standards, the labelling systems of ISBT 128 or Eurocode must be fully implemented. The labels may also include a Single European Code (SEC) at the bottom of both types of labels. Eurocode is mainly used in Germany. Evidence: Pre-printed or print-on-demand labels are used. A system for label version control shall be employed and must be reviewed by the inspector. For pre-printed or print-on-demand labels, the obsolete ones are archived minimally for 10 years. The products that are re-packed, and that is quite frequent in processing, shall be labelled with new labels before they are detached from the original container. The information that is entered on the label shall be verified by one qualified staff member if the procedure is validated, or by two qualified staff members if it's not. It is more frequent to use some electronic system for labels nowadays and this electronic labelling system must include a verification step. The product must be assigned a unique numeric or alphanumeric identifier to trace it. The process or partial label is the label that must be on the product at each step of the processing procedure. It must include at least the proper name of the product and the numeric or alphanumeric identifier. The code for these labels is included in the Appendix II of the standard. The content of all the labels is included in the Appendix II of the standards. Each label shall bear the appropriate biohazard and warning signs when it is required. Example: Inspectors must review the label samples and ensure they are representative of the product and contain all the necessary information.	yes	C7.1 D7.1

CM7.4.3	Each label shall bear the appropriate biohazard and warning labels as found in the Circular of Information for the Use of Cellular Therapy Products, “Table 2. Biohazard and Warning Labels on Cellular Therapy Products Collected, Processed, and/or Administered in the United States.	If the biohazard label is used indiscriminately on all products the standard should be assessed as non-compliant.	no	C7.4.4 D7.4.4 ‘Label at completion of collection’ ‘Label at completion of processing’
CM7.4.3.1	For cellular therapy products not collected, processed, or administered in the U.S., the appropriate Biohazard and Warning Labels shall follow Applicable Law.	If the biohazard label is used indiscriminately on all products the standard should be assessed as non-compliant.	yes	C7.4.4.1 D7.4.4.1 ‘Label at completion of collection’ ‘Label at completion of processing’
CM7.4.5	A cellular therapy product collected in or designated for use in the U.S. shall be accompanied by the elements listed in the Accompanying Documentation table in Appendix IV at the time it leaves the control of the Marrow Collection Facility.	Only applicable for collection facilities when they export to the US, they are in the U.S., or they receive BM collection from the U.S. (extremely rare).	no	C7.4.5 D7.4.5
CM7.4.7	For cellular therapy products distributed before completion of donor eligibility determination, there shall be documentation that donor eligibility determination was completed during or after distribution of the cellular therapy product and that the physician using the product was informed of the results of that determination.	In some rare cases, centres will need a statement in their standard operating procedure that explains their process e.g., that all products are cryopreserved (they then have time to complete eligibility) or in countries, like Germany, where it is against the law to do this.	yes	C7.4.7 D7.4.7

CM9.2	Marrow Collection Facilities shall establish policies for the duration and conditions of short-term storage prior to distribution to a Processing Facility or Clinical Program.	Frequently found not applicable by the applicant and inspector as ‘no storage’. However, any duration between the end of the collection and distribution to a processing facility / clinical program constitutes storage. The JACIE Accreditation Committee have previously found that a contingency process must be in place for when, however rare, a product cannot be distributed immediately. Evidence: Review of the established storage criteria for all relevant products / inspection of the storage conditions and space to confirm adequacy of separation to prevent contamination and mix-ups. Example: An end-of-collection label with all the information printed, including storage temperature and duration, should be kept on-site.	yes	C9.2

CM10	Cellular Therapy Product Transport and Shipping	Frequently there is confusion as to the difference between transport and shipping. In transport, the product does not leave the control of trained personnel, but for shipping, the product leaves the control of trained personnel at distribution. A standard operating policy is mandatory for both Transport and Shipping of products. Transport is always applicable. If a centre does not ship, they should state this in their policy as shipping is not applicable to all centres. Evidence: Review the established transport and shipping criteria for all relevant products / inspection of the shipping and transport containers to confirm adequacy to prevent damage and mix-ups. Example: The temperature of the shipping container shall be continuously monitored, and the shipment facility shall maintain a record of the temperature over the period of travel. For non-cryopreserved products, the outer container shall be insulated with all the appropriate labels, and a biohazard label if it is required. The conditions of transport shall be established to preserve the integrity and safety of the product during transport and shipping and the primary container for non-frozen products shall be placed in a secondary container and sealed to prevent leakage. The containers selected must be validated for the task they perform, and the outer container may be simple or more complicated e.g., when the products are cryopreserved. In both cases, the outer container shall be secured and labelled. Remember that, even if it is just an internal transport, a SOP is required. The outer container shall be secure, shall be labelled, shall be validated, etc. For the transport or shipping of cryopreserved cells, a cryo-shipper is required. It must maintain the temperature for at least 48 hours. Even after the transit time, the temperature monitor is required.	yes	C10 D10

Apheresis

STANDARD	DESCRIPTION	CLARIFICATION	ALWAYS APPLICA-BLE	RELATED STANDARDS
C1.2	The Apheresis Collection Facility shall use cell processing facilities that meet FACT-JACIE Standards with respect to their interactions with the Apheresis Collection Facility.	This is compliant if the application is for the reaccreditation of a full programme; it is partially compliant if the application is the initial accreditation of a full programme	yes	B1.2 CM1.2
C1.3.1	The Apheresis Collection Facility shall be licensed, registered, or accredited as required by the appropriate governmental authorities for the activities performed.	This standard refers to the local authority's licence, not to the JACIE accreditation.	yes	B1.3.1 CM1.3.1 D1.2.1
C1.5	A minimum of ten (10) cellular therapy products shall have been collected by apheresis in the twelve (12) month period immediately preceding initial accreditation, and a minimum average of ten (10) cellular therapy products shall have been collected by apheresis per year within each accreditation cycle.	The programme is required to meet the minimum activity numbers before getting accredited, but not at the time of application. See the current version of the FACT – JACIE Standards for more information about activity numbers.	yes	B1.5 CM1.5
C2.4.3	If using collection methods that may result in contamination or cross-contamination of cellular therapy products, critical environmental conditions shall be controlled, monitored, and recorded for air quality and surface contaminants.	There is no such a thing as a perfect closed system in this instance as patients are not within the system and there is always the need to insert a needle. However, using CE certified closed collection kits would make this not applicable.	no	N/A

C4.13 (incl. sub standards)	The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for qualification of critical manufacturers, vendors, equipment, software, supplies, reagents, facilities, and services.	There is a difference between qualification and validation. According to GMP's definitions, validation refers to the total life cycle of a product from development through use and maintenance. The word 'validation' is sometimes widened to incorporate the concept of qualification that is part of the validation process. Qualification deals with components or elements of the process. Validation deals with the entire manufacturing process of the products. The Inspector should find evidence of qualifications of manufacturers, vendors, suppliers, equipment, facilities, services and critical reagents. Qualification procedures should include instructions for requalification and under which circumstances qualification is required. There are several ways to qualify a vendor of supplies, reagents and services. Practical methods, may include: review of a third party assessment by an accreditation organisation such as FACT, JACIE, CAP or others; remote audits by questionnaire; an ongoing dialogue regarding resolution of service complaints and process improvements; the sharing of internal audit findings and implementation of corrective action plans from the provider back to the facility is evidence that deficiencies have been recognised and corrected and a document review of the suppliers past performance history. In the rare case that a centre has determined that qualifications are not needed, they must have a written statement to support their assessment so that the inspector can determine compliance. For further information see Chapter 5 Qualification and validation written by Renza Monteleone and Dieter Klarmann in the JACIE Guide available: https://www.ebmt.org/education/jacie-guide	yes	B4.13 D4.13

C4.14	The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for validation or verification of critical procedures.	There is a difference between qualification and validation. According to GMP's definitions, validation refers to the total life cycle of a product from development through use and maintenance. The word 'validation' is sometimes widened to incorporate the concept of qualification that is part of the validation process. Qualification deals with components or elements of the process. Validation deals with the entire manufacturing process of the products. The Inspector should ask to see the SOPs for conducting validation studies and review a sample of validation studies that have been completed. Inspectors must note that studies are properly designed, the required data is objectively collected, the outcome, and intended actions are summarised and that both the finalised plan and report are reviewed and approved by the Clinical Program Director and the Quality Manager. In previous editions of the standards, re-evaluations were limited to validation studies. Inspectors should now have evidence of revalidation and risk analysis with change to process as well as how the introduction of new processes are made. For further information see Chapter 5 Qualification and validation written by Renza Monteleone and Dieter Klarmann in the JACIE Guide available: https://www.ebmt.org/education/jacie-guide	yes	B4.14 D4.14
C4.16.1	Feedback shall be obtained from associated Clinical Programs and Processing Facilities.	"Associated" means any unit, service, lab, clinical program that has an operational relationship with the unit inspected.	yes	B4.16.1 D4.16.1
C5.1.4	Donor age-specific and size-specific issues where relevant.	Not only for paediatric patients, but also for elderly patients	yes	B3.3.4.33 CM5.1.4
C5.1.11	Cellular therapy product storage.	It is a common issue that centres think that this standard does not include storage in the apheresis unit. This standard is applicable.	yes	CM5.1.10

C7.1	ISBT 128 and EUROCODE coding and labelling	ISBT 128 / Eurocode / SEC This standard is not always well assessed. In the 8th edition of the JACIE standards, the labelling systems of ISBT 128 or Eurocode must be fully implemented. The labels may also include a Single European Code (SEC) at the bottom of both types of labels. Eurocode is mainly used in Germany. Evidence: Pre-printed or print-on-demand labels are used. A system for label version control shall be employed and must be reviewed by the inspector. For pre-printed or print-on-demand labels, the obsolete ones are archived minimally for 10 years. The products that are re-packed, and that is quite frequent in processing, shall be labelled with new labels before they are detached from the original container. The information that is entered on the label shall be verified by one qualified staff member if the procedure is validated, or by two qualified staff members if it's not. It is more frequent to use some electronic system for labels nowadays and this electronic labelling system must include a verification step. The product must be assigned a unique numeric or alphanumeric identifier to trace it. The process or partial label is the label that must be on the product at each step of the processing procedure. It must include at least the proper name of the product and the numeric or alphanumeric identifier. The code for these labels is included in the Appendix II of the standard. The content of all the labels is included in the Appendix II of the standards. Each label shall bear the appropriate biohazard and warning signs when it is required. Example: Inspectors must review the label samples and ensure they are representative of the product and contain all the necessary information.	yes	CM7.1 D7.1

C7.4.4	Each label shall bear the appropriate biohazard and warning labels as found in the Circular of Information for the Use of Cellular Therapy Products, "Table 2. Biohazard and Warning Labels on Cellular Therapy Products Collected, Processed, and/or Administered in the United States.	If the biohazard label is used indiscriminately on all products the standard should be assessed as non-compliant.	no	CM7.4.3 D7.4.4 'Label at completion of collection' 'Label at completion of processing'
C7.4.4.1	For cellular therapy products not collected, processed, or administered in the U.S., the appropriate Biohazard and Warning Labels shall follow Applicable Law.	If the biohazard label is used indiscriminately on all products the standard should be assessed as non-compliant.	yes	CM7.4.3.1 D7.4.4.1 'Label at completion of collection' 'Label at completion of processing'
C7.4.7	For cellular therapy products distributed before completion of donor eligibility determination, there shall be documentation that donor eligibility determination was completed during or after distribution of the cellular therapy product and that the physician using the product was informed of the results of that determination.	In some rare cases, centres will need a statement in their standard operating procedure that explains their process e.g., that all products are cryopreserved (they then have time to complete eligibility) or in countries, like Germany, where it is against the law to do this.	yes	CM7.4.7 D7.4.7

C9.2	Apheresis Collection Facilities shall establish policies for the duration and conditions of short-term storage prior to distribution to a Processing Facility or Clinical Program.	Frequently found not applicable by the applicant and inspector as ‘no storage’. However, any duration between the end of the collection and distribution to a processing facility / clinical program constitutes storage. The JACIE Accreditation Committee have previously found that a contingency process must be in place for when, however rare, a product cannot be distributed immediately. Evidence: Review of the established storage criteria for all relevant products / inspection of the storage conditions and space to confirm adequacy of separation to prevent contamination and mix-ups. Example: An end-of-collection label with all the information printed, including storage temperature and duration, should be kept on-site.	yes	CM9.2

C10	Cellular Therapy Product Transport and Shipping	Frequently there is confusion as to the difference between transport and shipping. In transport, the product does not leave the control of trained personnel, but for shipping, the product leaves the control of trained personnel at distribution. A standard operating policy is mandatory for both Transport and Shipping of products. Transport is always applicable. If a centre does not ship, they should state this in their policy as shipping is not applicable to all centres. Evidence: Review the established transport and shipping criteria for all relevant products / inspection of the shipping and transport containers to confirm adequacy to prevent damage and mix-ups. Example: The temperature of the shipping container shall be continuously monitored, and the shipment facility shall maintain a record of the temperature over the period of travel. For non-cryopreserved products, the outer container shall be insulated with all the appropriate labels, and a biohazard label if it is required. The conditions of transport shall be established to preserve the integrity and safety of the product during transport and shipping and the primary container for non-frozen products shall be placed in a secondary container and sealed to prevent leakage. The containers selected must be validated for the task they perform, and the outer container may be simple or more complicated e.g., when the products are cryopreserved. In both cases, the outer container shall be secured and labelled. Remember that, even if it is just an internal transport, a SOP is required. The outer container shall be secure, shall be labelled, shall be validated, etc. For the transport or shipping of cryopreserved cells, a cryo-shipper is required. It must maintain the temperature for at least 48 hours. Even after the transit time, the temperature monitor is required.	yes	CM10 D10

C11.8.2	If two (2) or more facilities participate in the collection, processing, or administration of the cellular therapy product, the records of each facility shall show plainly the extent of its responsibility.	If a program consists of e.g., one clinical unit, one collection and one processing unit, then this is not applicable. If a program consists of e.g., two apheresis units, then this is applicable.	no	B10.5.1 D13.5.3

Donors

STANDARD	DESCRIPTION	CLARIFICATION	ALWAYS APPLICA-BLE	RELATED STAN-DARDS
B6.4.17	The use of an ineligible allogeneic donor, or an allogeneic donor for whom donor eligibility determination is incomplete, shall require documentation of the rationale for his/her selection by the transplant physician, urgent medical need documentation, and the informed consent of the donor and the recipient.	The use of a cellular therapy product from an ineligible allogeneic donor, or from an allogeneic donor for whom donor eligibility determination is incomplete, shall require documentation of urgent medical need that includes the rationale for the selection and documentation of the informed consent of the donor and the recipient.	yes	C6.4.8
C6.4.8	Collection of a cellular therapy product from an ineligible allogeneic donor, or from an allogeneic donor for whom donor eligibility determination is incomplete, shall require documentation of urgent medical need that includes the rationale for the selection and documentation of the informed consent of the donor and the recipient.	Collection of a cellular therapy product from an ineligible allogeneic donor, or from an allogeneic donor for whom donor eligibility determination is incomplete, shall require documentation of urgent medical need that includes the rationale for the selection and documentation of the informed consent of the donor and the recipient.	yes	B6.4.17

Processing

STANDARD	DESCRIPTION	CLARIFICATION	ALWAYS APPLI-CABLE	RELATED STANDARDS
D1.2.1	The Processing Facility shall be licensed, registered, or accredited as required by the appropriate governmental authorities for the activities performed.	This standard refers to the local authority's licence, not to the JACIE accreditation.	yes	B1.3.1 CM1.3.1 C1.3.1

D4.13 (incl. sub stan-dards)	The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for qualification of critical manufacturers, vendors, equipment, software, supplies, reagents, facilities, and services.	There is a difference between qualification and validation. According to GMP's definitions, validation refers to the total life cycle of a product from development through use and maintenance. The word 'validation' is sometimes widened to incorporate the concept of qualification that is part of the validation process. Qualification deals with components or elements of the process. Validation deals with the entire manufacturing process of the products. The Inspector should find evidence of qualifications of manufacturers, vendors, suppliers, equipment, facilities, services and critical reagents. Qualification procedures should include instructions for requalification and under which circumstances qualification is required. There are several ways to qualify a vendor of supplies, reagents and services. Practical methods, may include: review of a third party assessment by an accreditation organisation such as FACT, JACIE, CAP or others; remote audits by questionnaire; an ongoing dialogue regarding resolution of service complaints and process improvements; the sharing of internal audit findings and implementation of corrective action plans from the provider back to the facility is evidence that deficiencies have been recognised and corrected and a document review of the suppliers past performance history. In the rare case that a centre has determined that qualifications are not needed, they must have a written statement to support their assessment so that the inspector can determine compliance. For further information see Chapter 5 Qualification and validation written by Renza Monteleone and Dieter Klarmann in the JACIE Guide available: https://www.ebmt.org/education/jacie-guide	yes	B4.13 C4.13

D4.14	The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for validation or verification of critical procedures.	There is a difference between qualification and validation. According to GMP's definitions, validation refers to the total life cycle of a product from development through use and maintenance. The word 'validation' is sometimes widened to incorporate the concept of qualification that is part of the validation process. Qualification deals with components or elements of the process. Validation deals with the entire manufacturing process of the products. The Inspector should ask to see the SOPs for conducting validation studies and review a sample of validation studies that have been completed. Inspectors must note that studies are properly designed, the required data is objectively collected, the outcome, and intended actions are summarised and that both the finalised plan and report are reviewed and approved by the Clinical Program Director and the Quality Manager. In previous editions of the standards, re-evaluations were limited to validation studies. Inspectors should now have evidence of revalidation and risk analysis with change to process as well as how the introduction of new processes are made. For further information see Chapter 5 Qualification and validation written by Renza Monteleone and Dieter Klarmann in the JACIE Guide available: https://www.ebmt.org/education/jacie-guide	yes	B4.14 C4.14
D4.16.1	Feedback shall be obtained from associated Clinical Programs and Collection Facilities.	"Associated" means any unit, service, lab, clinical program that has an operational relationship with the unit inspected.	Yes	B4.16.1 C4.16.1

D7.1	ISBT 128 and EUROCODE coding and labelling	ISBT 128 / Eurocode / SEC This standard is not always well assessed. In the 8th edition of the JACIE standards, the labelling systems of ISBT 128 or Eurocode must be fully implemented. The labels may also include a Single European Code (SEC) at the bottom of both types of labels. Eurocode is mainly used in Germany. Evidence: Pre-printed or print-on-demand labels are used. A system for label version control shall be employed and must be reviewed by the inspector. For pre-printed or print-on-demand labels, the obsolete ones are archived minimally for 10 years. The products that are re-packed, and that is quite frequent in processing, shall be labelled with new labels before they are detached from the original container. The information that is entered on the label shall be verified by one qualified staff member if the procedure is validated, or by two qualified staff members if it's not. It is more frequent to use some electronic system for labels nowadays and this electronic labelling system must include a verification step. The product must be assigned a unique numeric or alphanumeric identifier to trace it. The process or partial label is the label that must be on the product at each step of the processing procedure. It must include at least the proper name of the product and the numeric or alphanumeric identifier. The code for these labels is included in the Appendix II of the standard. The content of all the labels is included in the Appendix II of the standards. Each label shall bear the appropriate biohazard and warning signs when it is required. Example: Inspectors must review the label samples and ensure they are representative of the product and contain all the necessary information.	yes	C7.1 CM7.1

D7.3.1.2	If a single cellular therapy product is stored in more than one (1) container, there shall be a system to identify each container.	It is usual to store a cellular therapy product in more than one container. Example: If you cryopreserve one product and store it in multiple containers, you need to identify these multiple containers.	yes	N/A
D7.4.4	Each label shall bear the appropriate biohazard and warning labels as found in the Circular of Information for the Use of Cellular Therapy Products, "Table 2. Biohazard and Warning Labels on Cellular Therapy Products Collected, Processed, and/or Administered in the United States.	If the biohazard label is used indiscriminately on all products the standard should be assessed as non-compliant.	no	CM7.4.3 C7.4.4 'Label at completion of collec-tion' 'Label at completion of process-ing'
D7.4.4.1	For cellular therapy products not collected, processed, and/or administered in the U.S., the appropriate Biohazard and Warning Labels shall follow Applicable Law.	If the biohazard label is used indiscriminately on all products the standard should be assessed as non-compliant.	yes	CM7.4.3.1 C7.4.4.1 'Label at completion of collec-tion' 'Label at completion of process-ing'
D7.4.7	For cellular therapy products distributed before completion of donor eligibility determination, there shall be documentation that donor eligibility determination was completed during or after distribution of the cellular therapy product and that the physician using the product was informed of the results of that determination.	In some rare cases, centres will need a statement in their standard operating procedure that explains their process e.g., that all products are cryopreserved (they then have time to complete eligibility) or in countries, like Germany, where it is against the law to do this.	yes	CM7.4.7 C7.4.7

D10	Cellular Therapy Product Transport and Shipping	Frequently there is confusion as to the difference between transport and shipping. In transport, the product does not leave the control of trained personnel, but for shipping, the product leaves the control of trained personnel at distribution. A standard operating policy is mandatory for both Transport and Shipping of products. Transport is always applicable. If a centre does not ship, they should state this in their policy as shipping is not applicable to all centres. Evidence: Review the established transport and shipping criteria for all relevant products / inspection of the shipping and transport containers to confirm adequacy to prevent damage and mix-ups. Example: The temperature of the shipping container shall be continuously monitored, and the shipment facility shall maintain a record of the temperature over the period of travel. For non-cryopreserved products, the outer container shall be insulated with all the appropriate labels, and a biohazard label if it is required. The conditions of transport shall be established to preserve the integrity and safety of the product during transport and shipping and the primary container for non-frozen products shall be placed in a secondary container and sealed to prevent leakage. The containers selected must be validated for the task they perform, and the outer container may be simple or more complicated e.g., when the products are cryopreserved. In both cases, the outer container shall be secured and labelled. Remember that, even if it is just an internal transport, a SOP is required. The outer container shall be secure, shall be labelled, shall be validated, etc. For the transport or shipping of cryopreserved cells, a cryo-shipper is required. It must maintain the temperature for at least 48 hours. Even after the transit time, the temperature monitor is required.	yes	C10 CM10

D12.1.1	A pre-collection written agreement between the storage facility and the designated recipient or the donor defining the length of storage and the circumstances for disposal of cellular therapy products.	Inspectors should look for evidence of the record of the discard of cellular therapy products with the storage conditions. Also, the consent to disposal and authorisation of the destruction of the product.	yes	N/A
D13.5.3	If two (2) or more facilities participate in the collection, processing, or administration of the cellular therapy product, the records of the Processing Facility shall show plainly the extent of its responsibility.	If a program consists of e.g., one clinical unit, one collection and one processing unit, then this is not applicable. If a program consists of e.g., two processing units, then this is applicable.	no	B10.5.1 C11.8.2

Table 2. Tricky standards guide

9. Frequently asked questions

When is the inspection happening?

Inspectors receive an invitation to take part in an inspection and dates are arranged once the team is complete. Dates are aligned with everyone's availability. Therefore, it is essential that potential inspectors respond promptly, ideally within a week, to the request to inspect and alert the JACIE office to any potential conflicts of interest.

What if I do not have time to review all the standards in the checklist?

It is important that you manage your time well during the inspection. A good tip is to review the checklist at the end of the first half day, also at the end of second half day, and in the middle of the third half day. Speak to your inspector colleagues if you have queries as they might have observed the area you have questions about. You cannot assess a standard as partially or non-compliant because you have not reviewed it. Therefore, review as much as possible before the inspection and keep on top of time-management during the inspection.

What if I do not know if a standard is compliant or not?

Ask the other inspectors for help, particularly the team leader. They may have seen something related to that standard that will help you with your assessment. If it is a particular issue related to the centre, you can query the matter with the JACIE office and your Accreditation Coordinator. If required, a query can be sent to JAC. In these cases, inform the centre that a further review by the team and JACIE must be done, and that the final decision will be in the report.

Can I request printed copies of the standards or manual?

JACIE does not provide printed copies of the Standards or Manual. You can of course download and print a copy yourself.

Should the centre collect inspectors from hotels/ airports?

No, this is not necessary. If the hotel is close to the centre, someone from the centre can pick the inspectors up from the hotel lobby and guide them towards the facilities to be inspected. However, this is not a requirement and inspectors can get the information about the best route from the hotel to the facilities (e.g., taxi, walking or bus) in advance of the inspection.

Should the key personnel from the centre join the Inspectors for meals during the Inspection dates?

No, the centre is required to arrange a modest business lunch for the inspectors. Considering that time is limited during the inspection, inspectors may want to consider this a working lunch and will usually use the time to go over notes and discuss them with the rest of their team. Similarly, although suggestions are welcome for where inspectors could go for dinner, centre personnel should not join them.

10. References for JACIE office use

JACIE 3	Recruitment of JACIE inspectors
JACIE 4	Inspectors feedback system
JACIE 7	Changes in the Accreditation
JACIE 9	Accreditation process
JACIE 19	Inspectors' Travel and Accommodation Arrangements & Expenses
JACIE 40	Inspection Plan - On-site Inspection
JACIE 42	Application Form
JACIE 60	Guidelines for Impartiality Management
JACIE 65	Inspection Checklist 7th ed
JACIE 71	Inspector tasks pre- and post-inspection
JACIE 75	Inspection Report
JACIE 86	Office 365 Access Request Guide
JACIE 95	Inspection Checklist 8th ed.
JACIE 97	Applicant´s Guide
JACIE 109	Inspection Plan - Remote Inspection

JACIE

Joint Accreditation Committee

ISCT | EBMT