

Video requirements

PURPOSE OF THE VIDEO TOUR

The purpose of a recorded video tour for a JACIE inspection is to orientate inspectors when performing assessments remotely and to demonstrate compliance with a selection of standards, particularly those related to the adequacy of facility design and size, security, cleanliness, environmental conditions and monitoring, safety measures, access to support areas, supply and reagent storage, and workflow which would be difficult or impossible to demonstrate otherwise.

The tables below list the minimum elements that should be demonstrated during a tour of each area included in the centre and where applicable, the specific standards that address the requirements.

BEST PRACTICES FOR PREPARATION OF THE TOUR RECORDING:

- A separate recording can be made for each part of the centre (Clinical, Cell Collection and Processing).
- Be careful to not record patients or visitors. It is recommended to do the recording after normal working hours, during the weekend or during a low period of activity
- It is recommended to record normal functioning of staff to provide evidence of correct use of protective equipment, waste management. **Avoid recording faces where possible**
- During recording, inform staff and place signs to avoid interruptions
- The videos should be narrated to explain what is being shown, the purpose or function of each space or item that is being shown, and should describe the pathway of a patient, staff, or product. The videos can be broken up into sections if necessary.
- Pay particular attention to the pace of the recording. Ensure that there is enough time at each point to describe what is being shown and to explain how this element meets a certain standard. The more details the inspector can see clearly, the less will need to be requested during the inspection. Think through the standards list as you walk through the tour to help ensure completeness.
- Please be aware that during the accreditation process the inspectors assigned to your centre, the JACIE reports assessors, the JACIE Accreditation Committee and the Applicant's country National Representative will be involved and have access to information related to your application. You can refer to this page to consult the list of members involved: <http://www.ebmt.org/jacie-organization-office>
- The Applicant centre can delete the video once the accreditation process is concluded

Note: "Show or explain" below refers to explaining on camera how an activity or task is performed so that the viewing inspector can understand the configuration of the facilities and how activities are distributed. It is acknowledged that there may be restrictions on what can be shown e.g., where patients or donors are present and in those circumstances, an explanation is acceptable.

CLINICAL FACILITY TOUR	MARROW COLLECTION FACILITY TOUR	APHERESIS COLLECTION FACILITY TOUR	PROCESSING FACILITY TOUR
<p>Show or explain space, size, and design of the:</p> <ul style="list-style-type: none"> ▪ Inpatient Unit <ul style="list-style-type: none"> • An inpatient room • How patients are monitored by staff e.g., nurses station location and monitoring facilities ▪ Outpatient Area: <ul style="list-style-type: none"> • Waiting Room including how transplant patients are isolated • An exam / interview room • An Infusion Room ▪ Explain pathway to escalate care to Intensive Care Unit ▪ For IEC, the location of cytokine-blocking agents and corticosteroid administration 	<p>Show or explain space, size, and design of the:</p> <ul style="list-style-type: none"> ▪ Designated areas for cell collection ▪ For storage of equipment, supplies and reagents. ▪ Include the inside of refrigerators. 	<p>Show or explain space, size, and design of the:</p> <ul style="list-style-type: none"> ▪ Designated areas for cell collection ▪ Storage of equipment, supplies, and reagents ▪ Include the inside of refrigerators. 	<p>Show or explain space, size, and design of the:</p> <ul style="list-style-type: none"> ▪ The cell processing facility(s) including <ul style="list-style-type: none"> • How the facility is secured to prevent unauthorized entrance • Lightning, ventilation, sinks • Cell products storage area including O² sensors • Storage of equipment, supplies, and reagents
<p>Show how risks to the health and safety of employees, recipients, donors, visitors, and volunteers is managed e.g., hazard warning signs, gowning instructions, personnel using protective clothing</p>			
<p>Show or explain how</p>	<p>Show or explain labeling operations including the following:</p>	<p>Show or explain labeling operations including the following:</p>	<p>Show or explain labeling operations including the following:</p>

CLINICAL FACILITY TOUR	MARROW COLLECTION FACILITY TOUR	APHERESIS COLLECTION FACILITY TOUR	PROCESSING FACILITY TOUR
<ul style="list-style-type: none"> • The drug and dose in the bag or pill are verified against the orders and the protocol or standardized regimen (B7.4.4.1) • How the identity of the recipient and the product and the order for administration are verified prior to the administration of the cellular therapy product (B7.6.4) 	<ul style="list-style-type: none"> ▪ How version control of labels is managed (CM7.2.4) ▪ Explain how label information accuracy and completeness is verified (CM7.2.5, CM7.2.7) ▪ How the label is validated as reliable for storage under the conditions in use (CM7.2.12) ▪ How a unique numeric or alphanumeric identifier is assigned (CM7.3.1) 	<ul style="list-style-type: none"> ▪ How version control of labels is managed (C7.2.4) ▪ Explain how label information accuracy and completeness is verified (C7.2.5, C7.2.7) ▪ How the label is validated as reliable for storage under the conditions in use (D7.2.12) ▪ How a unique numeric or alphanumeric identifier is assigned (C7.3.1) 	<ul style="list-style-type: none"> ▪ How version control of labels is managed (D7.2.4) ▪ Explain how label information accuracy and completeness is verified (D7.2.5, D7.2.7) ▪ How the label is validated as reliable for storage under the conditions in use (D7.2.12) ▪ How a unique numeric or alphanumeric identifier is assigned (D7.3.1) ▪ If relevant, how supplementary identifiers are applied (D.7.3.1.4) ▪ Contents of partial labels (D7.4.6)
	<p>Show or explain</p> <ul style="list-style-type: none"> ▪ how cell product storage including temporary storage areas are controlled to prevent mix-ups, deterioration, contamination, cross-contamination, and improper distribution of cellular therapy products (CM9.1) 	<p>Show or explain</p> <ul style="list-style-type: none"> ▪ how cell product storage areas including temporary storage are controlled to prevent mix-ups, deterioration, contamination, cross-contamination, and improper distribution of cellular therapy products (C9.1) 	<p>Show or explain</p> <ul style="list-style-type: none"> ▪ how cell product storage areas including temporary storage are controlled to prevent mix-ups, deterioration, contamination, cross-contamination, and improper distribution of cellular therapy products (D9.1)
	<p>Show or explain</p> <ul style="list-style-type: none"> • How the cellular therapy product is transported or shipped to the Processing 	<p>Show or explain</p> <ul style="list-style-type: none"> • How the cellular therapy product is transported or shipped to the Processing 	<p>Show or explain</p> <ul style="list-style-type: none"> • How the cellular therapy product is packaged and transported or shipped (D10.2, D10.3).

CLINICAL FACILITY TOUR	MARROW COLLECTION FACILITY TOUR	APHERESIS COLLECTION FACILITY TOUR	PROCESSING FACILITY TOUR
	Facility Operating Procedure (CM10.3).	Facility Operating Procedure (C10.3).	