



# APPLICANT'S GUIDE

JACIE Accreditation Process

Version 01

## Contact

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



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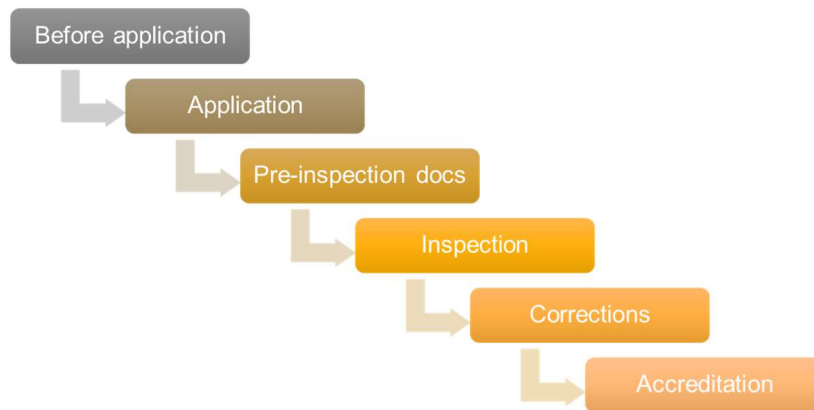
## Contents

INTRODUCTION	4
1. SECTION 1 – PRE-INSPECTION	4
1.1. Sending the JACIE Application	4
1.2. Signing the Standard Agreement	6
1.3. Preparing the preaudit documentation	6
1.4. Preparing for the Inspection	8
2. SECTION 2 – INSPECTION	9
2.1. Opening meeting	9
2.2. During the inspection	9
2.3. Exit meeting	10
3. SECTION 3 - POST-INSPECTION	10
3.1. After the Inspection	10
3.2. Summary Report	11
3.3. Evidence of corrections	11
3.4. Receiving the Accreditation Letter and Certificate	12
4. SECTION 4 – POST CERTIFICATION	13
4.1. Surveillance	13
4.2. Changes in accreditation	13
4.3. Reaccreditation	13

## Introduction

This Guide has been compiled to help applicants prepare for the JACIE inspection. The document should be read in conjunction with the current FACT-JACIE Accreditation Manual.

This Guide has been divided in sections in accordance to the accreditation process.



For more information about the JACIE Accreditation process please visit the EBMT web site at <https://www.ebmt.org/jacie-accreditation>

## 1. Section 1 – Pre-inspection

### 1.1. Sending the JACIE Application

Before submitting an application for accreditation, the applicant should ensure that they can clearly demonstrate compliance in all areas of the Standards but particularly in the following key areas:

- The programme functions as a Single Integrated Programme sharing common staff training, protocols, regular meetings and quality management systems.
- Minimum transplant activity – see the current version of the FACT – JACIE Standards. The programme is required to meet the minimum transplant activity numbers before getting accredited, but not at the time of application.
- EFI. If the clinical programme carries out allogeneic transplantations, it must use a HLA-typing laboratory accredited by the European Federation for Immunogenetics (EFI).

*First time applicants should provide the Application form and the Checklist.*

*Centres applying for Reaccreditation just need to submit the Application form*



*Remember to gather evidence*

### 1.1.1. Application form

If the applicant faces any challenges with the points above, they can always discuss these with the JACIE Office before applying. Once the programme is ready, they should send the completed Application form to [jacie@ebmt.org](mailto:jacie@ebmt.org).

When completing the Application form, the applicant should:

- Ensure that they have used the last version of the document by requesting it to the JACIE Office at [jacie@ebmt.org](mailto:jacie@ebmt.org)
- Include the most up to date information
- Pay special attention when defining the layout of the programme (Scope, number of sites, distance between sites, number of Quality Management Systems,...)
- Review that no sections have been left empty
- Indicate any Changes that have happened since the last accreditation cycle (Reaccreditations)
- All fields need to be completed, if it is not applicable please note N/A
- This information will determine invoicing, inspection team, scope of accreditation, location of the units (once the scope is set/approved no modifications will be allowed after the signature of the agreement)



Application form

Scope

Structure

Size

Team  
organisation

### 1.1.2. Checklist

First time applicants should also send a completed Checklist together with the Application form. The last version of the Checklist can also be found in the JACIE web site in the [Document Centre](#).

Applicant should self-assess compliance against all standards under the scope of their accreditation and indicate if they are compliant, non-compliant, partially compliant or if the Standard is not applicable. Applicant should make sure that they are able to document how they meet each standard, for example by noting a specific SOP, training record, meeting record, etc. These references and other information should be entered into the Inspection Checklist to help the inspector easily find supporting documents and evidence of compliance with the standards. It is also especially important to indicate the reason why Standards are Not applicable, Partially Compliant or Non-Compliant.



Checklist

First-time  
Applicants  
Only!



*To complete the Inspection Checklist: assign someone to complete each section.*



*The Application form and Checklist will be reviewed by the JACIE Office, and the applicant will be contacted should any clarifications be needed.*



*JACIE fees and discounts available for centres that provide active inspectors are available at the website <https://www.ebmt.org/ebmt/news/jacie-fees-2019>*

## 1.2. Signing the Standard Agreement

When the application has been pre-approved by the JACIE Office, the applicant will be asked to sign a Standard agreement. By signing the agreement, the centre accepts the quotation, which can be found as an annex at the end of the document.

Once the Standard agreement has been signed by both the Applicant and EBMT, the application will be considered approved. **The applicant should not pay the Quotation attached to the agreement.** They will be directly contacted by the EBMT Finance office in regards to their invoice after the inspection.



*The applicant should sign and return the Standard Agreement to the JACIE Office within 30 days of receiving it.*

*When more time is needed to complete this task, the applicant should let the JACIE Office know in advance. Delays in your end will impact when scheduling your inspection and in the progress of your application.*

## 1.3. Preparing the preaudit documentation

### 1.3.1. Checklist

First time applicants will have already prepared the Checklist at the Application stage. Reaccreditations should also prepare the Checklist at this stage.

- The Checklist used should be latest version available and should not be reused from previous accreditations
- If a centre has more than one unit for the Clinical, Collection or Processing parts, the applicant should complete one tab of that part for each unit
- The applicant should define where the responsibility for the donors lies (clinical or collection)

### 1.3.2. Documentation

The applicant should provide all those documents required according to the “Pre-audit document list” and organise them following the folder structure previously provided by the JACIE Office (also available at JACIE web site in the [Document Centre](#)). The folder structure should correspond to the version of the Standards to which the applicant has applied.

- The selected documentation to be sent to JACIE should be the latest version available and up to date
- The documents should be well organised to allow easy identification of area-specific documents
- Folders from the Folder structure should not be deleted
- When an applicant cannot or does not need to provide a document for a specific folder, they should indicate the reason for this in a Text note/Word document stored in that folder
- Audits of MED A will not be performed by the JACIE Inspectors. Therefore, the applicant does not need to provide any information related to the MED A with the pre-audit documentation. However, JACIE inspectors will continue to assess that the applicant centre performs internal audits of accuracy of the data contained in the MED A.
- Please note that it is the responsibility of the centre to ensure that the documentation provided to JACIE has appropriate security measures in place before the transfer and to make certain that the respective national laws are followed

Staff at the JACIE Office will check the folder contents to make sure that a file or document is present, without assessing the quality of the documentation. If documents appear to be missing, the JACIE Office will contact the centre.

The applicant is responsible to send any updated documents to the JACIE Office before the Inspection.



To complete the Preaudit documentation, get the whole team on board.



The preaudit documentation will be prepared in the language of the centre. In those cases where there are no inspectors that speak the language of the centre available, the applicant will have to translate a list of documents into English. In order to compensate for the translation efforts required, centres will receive a discount (A €300 discount per area to be translated with a minimum of €500 per application). The translation is not aimed to be from a professional translator and the discount is not intended to cover professional translation costs but is a gesture within JACIE’s capacity while JACIE works on building/increasing its inspectors pool with more language skilled inspectors.



*The completed pre-audit documentation (Checklist and evidence documents) should be provided to the JACIE office within 90 days after the Standard Agreement has been signed by both parties. Approximately two months prior to the inspection applicants will be requested to update the pre-audit documentation if there have been any changes.*

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

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>.

#### 1.4. Preparing for the Inspection

Once the preaudit documentation has been received, and to start programming the inspection, the JACIE Office will ask the applicant to submit or prepare the following:

- Set of preferred dates for inspection (pending inspectors' availability and preaudit documentation approval)
- Notification of any inspectors who the applicant would prefer not to participate in the inspection due to Conflict of Interest (please provide name, last name and the reason why there is a conflict of interest)
- Additional documents, if required by the inspectors up until two weeks prior to the inspection.

Onsite inspections:

- Recommendations of accommodation for the inspection team in a convenient and reasonably-priced hotel (usually a good business class hotel)
- Information for the inspectors on how to get to the facility. When possible, make arrangements to pick up the team at their hotel. Otherwise, provide information about available transportation and estimate time that will be required to reach the facility to be inspected.
- Reservation of a room for the inspectors for the duration of the audit for reviewing case notes, procedures, manuals and documents. In addition, reservation of a room for the initial meeting and the exit interview that is adequate in size to accommodate the entire inspection team, key programme personnel and others that the team wishes to invite
- Arrangement of a modest business lunch for the inspection team. Most teams will want to utilise the lunch hour as a working lunch.



#### Remote inspections:

- Arrangement of a quiet room for all teleconferences with proper sound, camera, internet connection, headphones.
- If the Agreement has already been signed, and it has been decided at a later stage that the Centre will go through a Remote Inspection, the signature of the amendment to the agreement for the remote inspections and the video consent form
- Video recording of the facilities using the Video requirement document

The JACIE Office will assign the Inspection Team by contacting one Inspector for each area to be inspected, plus a QM Inspector. One inspector will have the role of Team leader.

When the Inspection Team is finalised, the applicant will receive the Inspection Plan, indicating the different Inspectors and their roles, and the agenda with the schedule to be followed during the Inspection.

## 2. Section 2 – Inspection

The Inspection will follow the agenda indicated in the Inspection Plan.

### 2.1. Opening meeting

- Should include all key personnel of the HPC Programme and members of the Inspection Team
- The Programme Director should plan to introduce the members of the applicant HPC transplantation team, and present any other information to the inspection team about the programme that may be helpful, particularly any information that was not required on the checklist or required documents list. It is helpful to review the structure of the programme and the location of the applicant sites, particularly if these issues are complex and/or there are any off-site locations. This presentation should not exceed 10-15 minutes.

### 2.2. During the inspection

- Each inspection team member should have a knowledgeable member of staff available at all times to answer questions, find documents or procedures, etc. Appropriate individuals would include a quality manager, data manager, collection centre nurse supervisor, and laboratory supervisor.
- The following documents must be immediately available for the inspectors to review
  - Complete SOP manual for the clinical, collection and laboratory areas.
  - Documentation of training and continuing competency of the staff.
  - Quality assessment and improvement documents, including internal audits.
  - Validation studies.

- Be prepared to have someone escort the inspectors to each of the sites during an onsite inspection. If there are distant sites, be prepared to transport the inspectors there and accompany them at those sites.
- Inspectors will need to talk to key personnel at each of the sites. Be certain that they will be available during the scheduled time of the visit for each of the sites. For example, Clinical Programme - head nurse, social worker, pharmacy staff, any additional personnel who are needed to answer specific questions on the checklist
- Be prepared to gather additional documentation requested by the team during the time that they are present in your facility. If you try to send it in later, it delays the final report
- Assume that the inspectors will want some closed session time during the lunch hour, though they may also wish to use a portion of this time to communicate with the applicant. Be available. Be sure to check with the inspection team for questions or concerns related to completing the inspection visit before you leave for your own lunch break. Make sure inspectors have good internet connection and some drinking water available.

### 2.3. Exit meeting

- At the end of the inspection, the inspectors may wish to meet privately with the Programme Director and/or designated directors if there are issues to be raised that may be of a sensitive or confidential nature. Be available for this meeting
- The purpose of the Exit Interview is to allow the inspectors to summarise their major findings and to outline the remainder of the accreditation process. Remember that the Inspection Report observations are reviewed by the JACIE Accreditation Committee who will assess the applicant centre's current level of compliance and make recommendations for the correction of any deficiencies. The inspectors have specifically been instructed not to speculate on the level of compliance your programme will attain after Accreditation Committee review



In those cases where there are no inspectors available that speak the language of the centres and the inspection needs to be conducted in English, the centre will have to identify facilitators. The facilitators do not need to be professional translators and the only restriction is that they can't be from the transplant programme (other doctors/nurses from the other departments, like oncology, could be an option, and depending on their background they will be assigned to a specific area).

## 3. Section 3 - Post-inspection

### 3.1. After the Inspection

Once the Inspection is completed, the applicant will receive an Inspection Evaluation form. The form should be used by the applicant to formally state satisfaction or to raise any issues

that may have occurred during the inspection visit. It also gives the applicant an opportunity to give feedback on the process overall. It is important that this form be returned as quickly as possible. The evaluation by the centre will also be sent to the inspectors for their information and response where necessary.

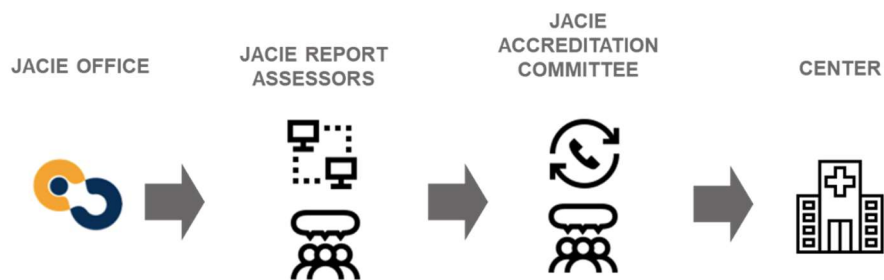


*Feedback and complaints can also be sent to [jacie@ebmt.org](mailto:jacie@ebmt.org) at any other time during the process.*

### 3.2. Summary Report

Once the Inspectors have submitted the completed Inspection Report and the Inspection Checklist to the JACIE Office, these will be reviewed and analysed by the JACIE Accreditation Committee. Sporadically, clarification may be required from the centre during this phase.

Once the Accreditation Committee has assessed the level of compliance and made recommendations for the correction of deficiencies, the Summary Report and Checklist will be sent back to the centre.

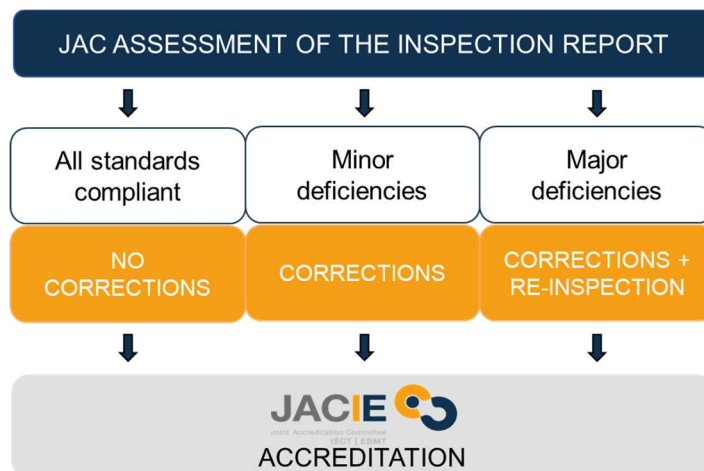


### 3.3. Evidence of corrections

The Summary Report and Checklist will identify those areas that were found to have deficiencies. The applicant will have the chance to work on these deficiencies and will send further evidence to demonstrate that they have been corrected. The applicant will receive instructions on how to provide their response.

When documentary evidence of corrections is submitted, this will be reviewed by the original inspection team. If this evidence is satisfactory and the centre has achieved all compliance, a final recommendation for accreditation will be sent to the JACIE Accreditations Committee Chair for approval and the centre will be informed of the outcome.

### 3.3.1. Potential Inspection outcomes



In some cases, a reinspection may be required to look at a very specific aspect of the programme or where a wider review is necessary. This will be arranged by the JACIE office on a date that is convenient for the applicant centre and the inspectors but should take place within 1 year of the Inspection Report being issued.

Costs arising from the focussed reinspection will be payable by the centre. These costs will be limited to the inspector's travel, accommodation and subsistence costs.



*The timeline for submitting the Evidence of corrections will be stated in the Summary report. Centres are asked to submit their corrections within 6 months after receiving the Summary Report. If that is not possible, the applicant should submit a summary of any issues that may delay or obstruct corrections and estimate the time required for consideration by JACIE.*

*Where an applicant delays in submitting evidence of corrections to the JACIE Office more than 9 months after receiving the Summary Report, accreditation will be awarded starting from the date of inspection, not from when the corrections were approved.*

*Where an applicant delays more than 12 months in demonstrating full compliance with the FACT-JACIE Standards after receiving the Summary Report, the accreditation process of the centre will be considered expired and the centre must restart the process. The calculation of 12 months will be made from the date when the Summary Report was emailed from the JACIE Accreditation Office to the applicant*

### 3.4. Receiving the Accreditation Letter and Certificate

Once the centre has been granted Accreditation, it will be listed in the List of Accredited Centres in the JACIE website.

A DRAFT version of the Accreditation Letter and Certificate will be sent to the applicant, who should check whether all details are correct or modifications are needed and communicate

these to their JACIE contact. Subsequently, the applicant will receive hard copies of the Accreditation Letter and Certificate.

Additionally, the applicant will receive the JACIE accredited logo and the guideline for its use. This logo is to be used strictly for the accredited units of the programme only.

Please note that in order to grant the accreditation the centre has to be up to date with the payment of the accreditation fees.

## 4. Section 4 – Post certification

### 4.1. Surveillance

During the period of your accreditation the JACIE office might contact you to perform some surveillance activities in order to assess the maintenance of your QM system.

### 4.2. Changes in accreditation

Accredited centres are no longer required to submit an Annual Report. They are, however, required to proactively inform JACIE of any changes (e.g. facilities, staff, etc) in their centre or to their program by filling out a Report of Changes. The Report of Changes can be requested at [jacie@ebmt.org](mailto:jacie@ebmt.org) or downloaded at the JACIE Document centre.

### 4.3. Reaccreditation

It is recommended that proceedings for reaccreditation are initiated one year prior to expiry in order to minimize the possibility of lapses between accreditation expiry and reaccreditation. Please bear in mind that such lapses are subject to the timing of document submission, availability of inspectors, the findings of the inspection and the applicant's submission of documentary evidence of corrections