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# JACIE Accreditation *Guide*



# A Guide to JACIE

## CHAPTER 1

### Thinking of applying for JACIE accreditation? (page 1)

What is JACIE?  
What is JACIE accreditation?  
How much does it cost & what are the terms and conditions?  
Are there minimum levels of activity required to qualify for accreditation?  
Who should be responsible for coordinating JACIE within my unit?  
How does the JACIE accreditation process work?  
What is a realistic timeframe?  
Are there any courses or documents that can help me further?  
When should I apply?  
Where do I apply?  
What is the process of applying?  
What if one or all of the units are relocating?

## CHAPTER 2

### You have applied for JACIE accreditation, what next? (page 4)

What happens after my application is approved?  
What pre-inspection documentation is required?  
What language should my pre-inspection documentation be in?  
How long have I got to submit all of my pre-inspection documentation?  
What timeframe is realistic for working out my inspection date?  
Changes to documentation after it has been submitted to the JACIE Office

## CHAPTER 3

### The inspection (page 6)

How long does the inspection take?  
Who will inspect my centre?  
How are the Inspectors assigned?  
Which staff should be available during the inspection?  
Who covers the Inspectors' costs?  
What is the format of the inspection?

## CHAPTER 4

### Post inspection (page 8)

What should I do when the Inspectors have gone?  
Do I have the opportunity to feedback on the inspection experience?  
Who assesses the Inspection Report?  
What will the Inspection Report tell me?  
When will I receive the Inspection Report?  
If there are deficiencies, what should I do?  
If I disagree with the Inspection Report, what should I do?  
Who assesses the corrections?  
When we achieve accreditation, what's next?

## CHAPTER 5

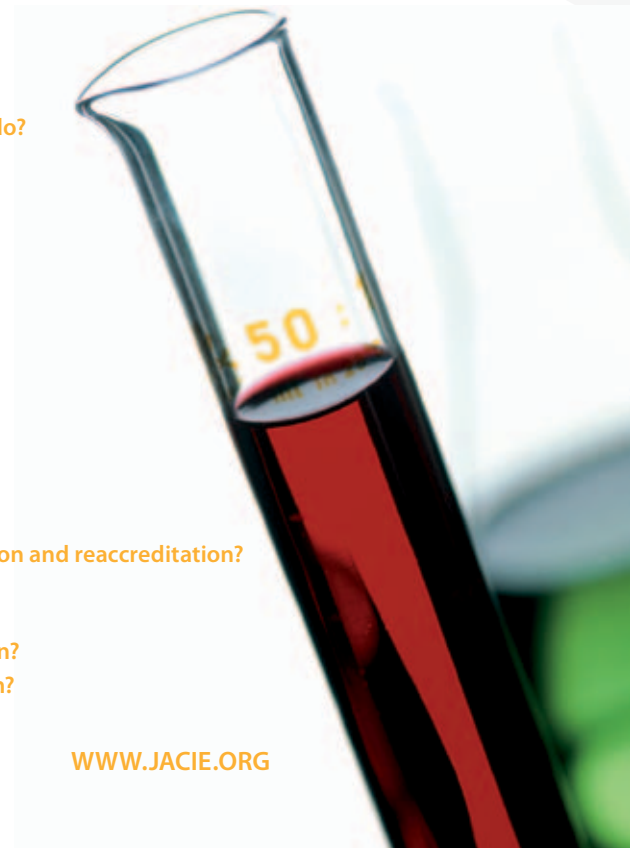
### Maintaining your accreditation (page 10)

Maintaining your JACIE accreditation  
Interim audit  
Annual reports  
Do I need to notify JACIE of any significant changes?  
Evaluation surveys

## CHAPTER 6

### Reaccreditation (page 12)

What's the difference between applying for accreditation and reaccreditation?  
How do I apply for reaccreditation?  
When do I apply for reaccreditation?  
What documents do I need to supply for reaccreditation?  
Can I re-use documents from my previous accreditation?





# Thinking of applying for JACIE accreditation?

## What is JACIE?

The Joint Accreditation Committee ISCT-Europe - EBMT (JACIE) was established in 1998 with the aim of establishing a voluntary, internationally recognised accreditation scheme for cellular therapy programmes. Using the US-based Foundation for the Accreditation of Cellular Therapy (FACT) as its model, JACIE is the result of international collaboration among cellular therapy professionals. Based on an independent on-site inspection, JACIE certifies programmes that demonstrate that they comply with the International Standards for Cellular Therapy Collection, Processing and Administration, jointly developed by FACT and JACIE. JACIE is supported by the European Group for Blood and Marrow Transplantation (EBMT) and the International Society for Cellular Therapy (Europe) (ISCT), the two leading scientific organisations in Europe dedicated to cellular therapy.

## What is JACIE accreditation?

Accreditation is the means by which a centre can demonstrate that it is performing in accordance with internationally agreed standards. It is a peer-review process based on a philosophy of support and facilitation. The Standards are developed by professionals active in the field and the Inspectors are volunteers who work full-time in their respective areas of expertise. The Standards take into account regulatory requirements and endeavour to bring programmes to the necessary level but in a manner that encourages collaboration and exchange of experience between centres and individuals working in the area of cellular therapy.

## How much does it cost & what are the terms and conditions?

The JACIE fees consist of a registration fee and a fee per part which is based on the number and type of facilities e.g. clinical unit, apheresis unit, processing laboratory. Full details of the current fees and terms and conditions can be found on the JACIE website [www.jacie.org](http://www.jacie.org)

## Are there minimum levels of activity required to qualify for accreditation?

The Standards specify minimum numbers of transplants and cell collection procedures. The requirements should be checked in the current edition of the FACT-JACIE Standards.

## Who should be responsible for coordinating JACIE within my unit?

Applying for JACIE accreditation requires a lot of planning, time and dedication – but it will be worth it! It is important to keep this in mind when planning for JACIE accreditation, especially if this is on top of a high workload. Depending on the centre, the JACIE coordinator may be a quality manager, nurse, physician, external consultant, administrative assistant, data manager or someone who is capable of understanding the requirements of the Standards and how they affect the day-to-day work in the transplant programme. The responsible person could be working on JACIE full or part-time.

On the JACIE application form, you are asked to nominate one person as the JACIE contact. It is very important that JACIE has only one main contact to avoid duplication and confusion.

## How does the JACIE accreditation process work?

A centre seeking accreditation first carries out a self-check of its practices and procedures. This check may identify areas that require additional resources, changes in systems or staff training needs.

When a programme considers that it meets the criteria, it may then apply to JACIE. When the application is approved by the JACIE Office, the centre needs to prepare and provide a variety of pre-inspection documentation e.g. quality manual, list of SOPs, evidence of staff training.

When all pre-inspection documentation has been submitted, the JACIE Office will then start to determine the date for the on-site inspection. This date will depend on the availability of the JACIE Inspectors, and is usually scheduled with a minimum of 2 months notice.

For the on-site inspection visit, a team is assigned made up of experts in clinical practice, laboratory processing and cell collection who have attended a JACIE Inspector Training Course. The team spends between one and two days on-site checking documentation and records, interviewing staff and observing real procedures.

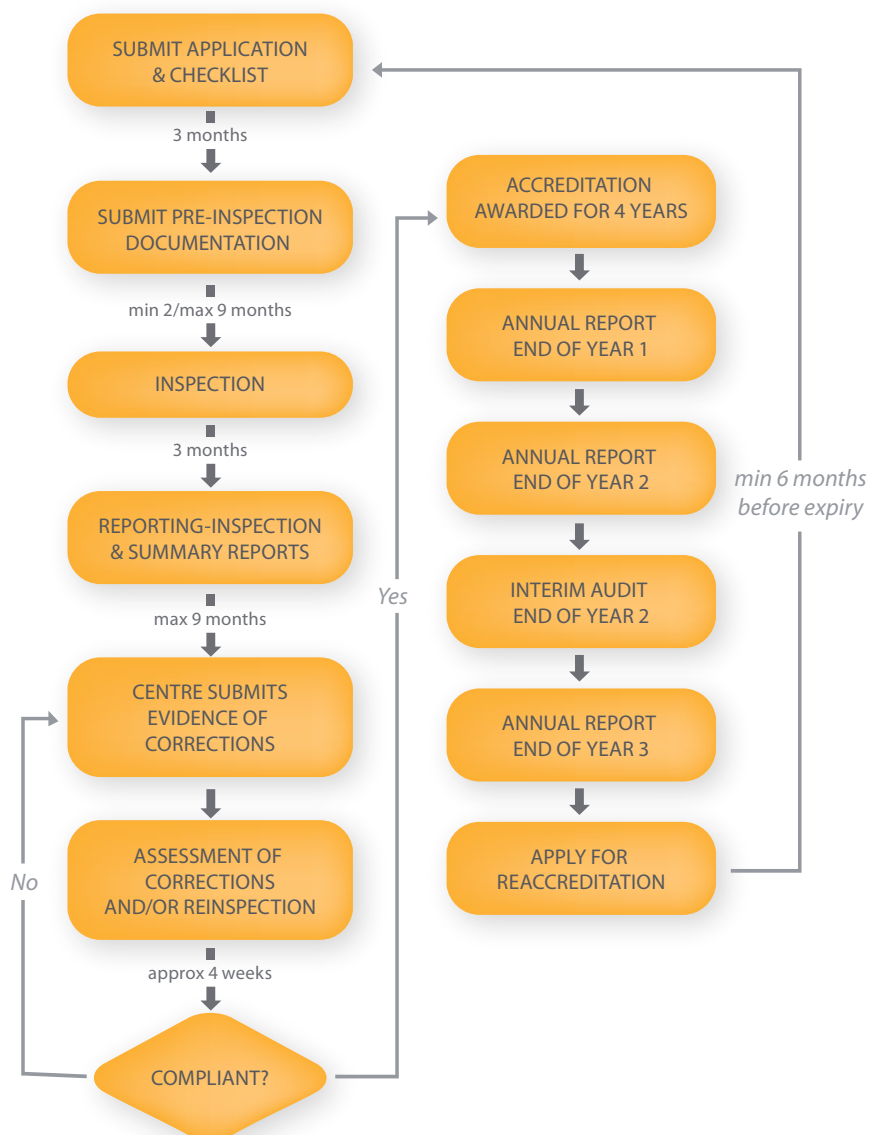
A report of the inspection is submitted by the Inspectors to the Report Assessors who collate the information for assessment by the JACIE Accreditation Committee. Following this assessment, the centre receives a detailed analysis of the deficiencies identified including recommendations for actions the programme must take in order to comply with the Standards. The centre is required to submit documentary evidence of corrections and/or undergo a re-inspection visit.



Once all deficiencies have been satisfactorily corrected, the Accreditation Committee awards accreditation. Accreditation is awarded for four years from the date of approval. A shorter interim audit with a focus on the quality management system will take place at the end of the second year of accreditation.

### What is a realistic timeframe?

The time from application to accreditation will depend on the size and complexity of the transplant programme as well as the amount of time and staff that can be dedicated to JACIE.



### Are there any courses or documents that can help me further?

There are many different sources of help available to make the process easier for you.

For example, there are many documents available to assist you with preparing your centre located in the Document Centre on the JACIE website [www.jacie.org](http://www.jacie.org).

Also, JACIE runs Centre Preparation Courses (subject to demand). These courses are a great way to understand the JACIE process and how to work towards acquiring JACIE accreditation.

We also participate in congresses and national meetings throughout Europe. These include the EBMT Annual Congress where we have dedicated JACIE sessions and a stand so that you can meet JACIE staff and discuss accreditation related issues in person.

Don't forget to use the JACIE Office as a resource – we are more than happy to assist you with any queries.

### When should I apply?

Complete a self-assessment using the Inspection Checklist (Excel) to determine your readiness. This document can be downloaded from the Document Centre on the JACIE website [www.jacie.org](http://www.jacie.org).

Once you have applied, keep in mind the time necessary to complete the stages - to submit all documents, prepare your team for the inspection, and the time necessary for the JACIE Office to determine an inspection team.

### Where do I apply?

In general, all application forms must be submitted to the JACIE Office. The JACIE Office will advise you if there are specific procedures to be followed in your country.





### What is the process of applying?

1. **Review the word application form** to assess if you are eligible to apply, and if so what information is required.
2. **Complete the application form.** On this application form you will be asked for specific information about your centre such as main contact names, emails and telephone numbers, activity numbers and your institution's taxation number. All of this information is important and must be completed before the JACIE Office can approve the application.
3. **Complete the Inspection Checklist** Download the latest version of the Inspection Checklist from the Document Centre on the JACIE website [www.jacie.org](http://www.jacie.org). Complete the section marked "applicant's response".
4. **Submit the application form and the checklist to the JACIE Office for review and approval.** JACIE may request further information or clarification from you, if needed.
5. **Approval of your application form.** JACIE will notify you and your National Representative when the application has been approved.


### What if one or all of the units are relocating?

If your programme is planning to relocate, check first with the JACIE Office before proceeding to apply. It may be better to wait until after the move. For further information on procedures, the additional documentation required and time-frames please refer to the JACIE Inspection Guide, which can be downloaded from the Document Centre on the JACIE website [www.jacie.org](http://www.jacie.org).


### Is there anything else I should know before I start?


- Familiarise yourself and your team with JACIE
- Attend JACIE courses and sessions at congresses
- Allow yourself plenty of time
- Don't be afraid to ask questions
- Set realistic deadlines and stick to them
- If you are the coordinator, keep the team updated


## TOP TIPS


 Review the Word version of the application form to familiarize yourself with what information is required to complete the application form


 Access the JACIE website and the Document Centre


 Review the Quality Management Guide


 Access the JACIE events page and check for up-and-coming Centre Preparation Training Courses


 Download and review the 'accreditation fees and terms and conditions' document. After your application has been accepted, the JACIE Office will issue the appropriate invoice which must be paid by bank transfer

 Determine the National Representative for your country. Your National Representative will be able to assist you with any specific national issues

 Have a clear description of roles and responsibilities of anyone involved in preparing for JACIE

 Do an audit against the Standards using the Inspection Checklist to determine which areas require attention

 Using the pre-inspection documentation list (see the Inspection Guide), begin to prepare and locate the documents that you will submit prior to the on-site inspection

 Remember that you are not alone! The JACIE Office is available to assist you and to help you achieve accreditation

# You have applied for JACIE accreditation, what next?

## What happens after my application is approved?

Once the JACIE Office has notified you that your application is approved, you will be sent an invoice for payment by bank transfer. We will also request that you start collating the pre-inspection documentation to be submitted to the JACIE Office.

## What pre-inspection documentation is required?

JACIE requires documentation to be submitted in advance. This is so that the Inspectors can review it before the on-site inspection, and make the best use of their time on-site. For a complete list of the documentation please refer to the Inspection Guide.

When submitting your pre-inspection documentation ensure that the documents are presented logically. This will greatly assist the Inspectors who will be reviewing your documents. It is recommended that documents are saved in PDF format.

## What language should my pre-inspection documentation be in?

Pre-inspection documents should be in the working language of the centre. The Inspector that will be reviewing the documents and performing the on-site inspection will have the necessary knowledge of your centre's spoken language. In some cases, if there is no availability of Inspectors with the language of your centre, JACIE may request that some of the documentation is translated in advance and that a translator is available during the inspection.

## How long have I got to submit all of my pre-inspection documentation?

JACIE allows up to 3 months to submit the pre-inspection documentation as there is a large amount of documents to prepare. Please note that an inspection team or date will not be determined until ALL documents are received. If you require more than 3 months, you should contact the JACIE Office.

## What timeframe is realistic for working out my inspection date?

JACIE estimates that it takes on average 8 months from when you apply to the inspection date. This includes the time necessary to compile and submit the pre-inspection documentation, search for inspectors and schedule the inspection date with sufficient notice. If you think that you will require additional time, please contact the JACIE Office.

## Changes to documentation after it has been submitted to the JACIE Office

The JACIE Office must be made aware of any changes made to the pre-inspection documentation between the time of submitting the documents and your on-site inspection. New documentation should be submitted within a reasonable timeframe to ensure that the Inspectors have sufficient time to review the new documents.

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*We organised a mock inspection with another programme who had achieved accreditation. This was enormously helpful in keeping us focused and also practically in ensuring that we had collated all the relevant documents. It clarified what to expect.*



*We felt that this was a positive process which helped us to understand areas of practice in which we can improve, and areas which are acceptable and good but which need to be maintained.*

## TOP TIPS

**i** Determine if there are any JACIE Inspectors in your country as they may be willing to assist you with a mock inspection. If you do approach an inspector and they conduct a mock inspection you must inform the JACIE Office as this Inspector will subsequently not be considered for participation in the real inspection

**i** Take time to plan and prepare!

**i** Being organized when preparing for JACIE will save everyone a lot of valuable time, including yourself!

**i** Begin to think of dates that would be suitable for the on-site inspection. Discuss this with your team members as meetings or annual leave may be planned

**i** Remember that the Inspector is not familiar with your programme, therefore presenting organised documentation will assist them greatly

**i** Determine which other staff members will assist you in collating the documentation from each unit e.g. do you have a contact within each unit, for example the laboratory, who will assist with collating their documentation, or a contact in Human Resources for copies of current CVs?

**i** Work to a realistic timeline, keep your team members updated on the progress of your application

# The Inspection

## How long does the inspection take?

The inspection is a thorough examination of all aspects of the programme in accordance with the accreditation checklist and is a verification of the applicant's self-check. The inspection usually takes between one and two days, depending on the characteristics of your centre.

## Who will inspect my centre?

Inspectors are volunteers who work full-time in their respective areas of expertise. They have received training from JACIE and are familiar with the Standards. Inspectors may be from other countries. The JACIE website has a list of Inspectors that can be searched without restriction.

## How are the Inspectors assigned?

JACIE assigns Inspectors according to their language, area of expertise and where they are located. Inspectors from the same city as the applicant are generally not assigned and the applicant has the right to reject proposed Inspectors where they feel there is a conflict of interest.

## Which staff should be available during the inspection?

A timetable will be agreed and finalised in advance of the inspection. However, the Inspector may decide to interview additional staff members on the day if needed. ALL members of staff can be interviewed by the Inspector.

Depending on the programme the key members of staff that should be available are as follows:

1. Programme / Transplant Director
2. Facility / Medical Directors for each facility
3. Apheresis Technician
4. Laboratory Technician
5. Transplant Physician
6. Quality Manager(s)
7. Ward Manager
8. Nurse
9. Nurse Training Coordinator
10. Facility Manager / Matron
11. BMT Nurse Specialist / BMT Coordinators
12. Pharmacist
13. Representative from the Intensive Care Unit

## Who covers the Inspectors' costs?

JACIE requests that the centre reserves a suitable hotel nearby for all of the inspection team as well provide catering for the Inspectors while they are on-site. Accommodation should be reserved in a good business class hotel convenient to the centre. JACIE will pay the expenses of the Inspectors (flights, transport, accommodation, dinner)

## What is the format of the inspection?

The timetable for the inspection is decided and agreed in advance. However the inspection team may decide to alter the timetable on the day if they feel it is necessary and in discussion with the inspected team / centre.

There will be an opening meeting at the beginning of the inspection. At the end of the inspection there will be an exit interview where the inspectors will summarise their findings.

## What practical aspects do I need to take care of for the inspection?

- Reserve hotel rooms for the Inspectors
- Arrange a meeting point with the Inspectors – either in the hotel lobby and escort them on-site, or alternatively at the reception area of the main site
- Book a room in advance for the Inspectors to meet and work in private. This is a good place where the Inspectors can be served a working lunch
- Double-check that the room is booked
- Arrange sufficient catering – lunches, coffee/tea, light snacks - for the Inspectors
- Ensure that there are writing materials available and electricity connection points. Ideally the inspectors should also be able to access the internet
- Ensure all key personnel will be available on the day of the inspection



*The Inspectors were very thorough, but professional and courteous. They were friendly with great respect for the working of the unit and the needs of patients.*





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*The inspection team was fantastic - very thorough, friendly and encouraging us to reflect on our procedures and best practice. You truly felt that you were working with the inspection team for a common goal. Also the JACIE Office has been incredibly helpful and supportive. -Thank you!*



## **i TOP TIPS**

**i** Have paper copies of your pre-inspection documentation available on the day of inspection

**i** Prepare your patient notes for the on-site inspection. You should identify the data points in advance for easy reference during the inspection e.g. using 'post-its', bookmarks, etc

**i** Take notes during the exit interview so that you can start working on your deficiencies straight away

**i** Remember that practically all centres have demonstrated deficiencies

**i** Also remember that your team has achieved a lot so far! Well done!

# Post inspection

## What should I do when the Inspectors have gone?

Have a meeting with the team and pass on the information that was provided during the exit interview. Remember to remind them that they have already achieved a lot! You can also start working on your deficiencies.

## Do I have the opportunity to feedback on the inspection experience – praise, complaints, problems etc?

Yes. After the Inspection the JACIE Office will ask you to complete an on-site inspection evaluation form which will be confidential. Your feedback is very important to the JACIE Office and we appreciate your comments.

## Who assesses the Inspection Report?

The Inspectors' findings are forwarded to Report Assessors who will collate and prepare the report for the Accreditation Committee. Once the Accreditation Committee has assessed and approved the report, it is returned to the centre via the JACIE Office.

## What will the Inspection Report tell me?

The Inspection Report should not contain any surprises and should be a reflection of the exit interview. It will contain an overall assessment of your centre and highlight any deficiencies that the Inspector finds as well as suggestions for improvements that they may have. It will also include recommendations from the Accreditation Committee that will guide you on what is required to correct the deficiency. The report and the Inspectors' observations refer directly to the Standards.

## When will I receive the Inspection Report?

The JACIE Office aims to send you the report within 3 months from the inspection date, although usually it is returned before this. Bear in mind that it will depend on how quickly the Inspectors can return their report to JACIE and the complexity of the deficiencies observed.

## If there are deficiencies, what should I do?

Put a realistic plan and timeline together to correct the deficiencies. Work with your team and identify who will be responsible for each corrective action.

## If I disagree with the Inspection Report, what should I do?

When you receive the Inspection Report it is important that you read it carefully. Contact the JACIE Office and confirm that you have received the report. If you do not agree with the report, outline the areas / deficiencies and explain why you don't agree. This must be done shortly after receiving the Inspection Report.

## Who assesses the corrections?

The original Inspectors will review the corrective actions. If there is a large amount of corrective actions, or if some of the deficiencies are complex then the original Inspector may be asked to revisit the centre. A revisit should not be considered negative as this can be the most efficient way to assess the centre's improvements.

## When we achieve accreditation, what's next?

Party! You should celebrate this achievement with the team! Well done and congratulations!

Make sure that the great news is communicated to the team and as widely as possible throughout the centre. You will receive a certificate and letter of accreditation shortly after accreditation has been awarded.



*We found it an extremely positive experience overall. JACIE is certainly a genuine 'quality driver'!*



# IMPORTANT

**Remember your JACIE accreditation does not end here - it is a continuous process.**

Naturally people may be less motivated after this point, but it is extremely important that observation of the Standards continues. Therefore the regular meetings on the run up to the inspection should continue. Documentation including SOPs should continue to be updated and developed. Audits should continue to be planned and carried out. Information about JACIE developments should continue to be circulated among the team. All this will help you educate the staff and help them realise that JACIE is a continuous process and needs to continue to live within the programme – this will also make your interim audit and reaccreditation process easier.

## Maintaining the system

If you don't continue to develop and maintain JACIE, all of your hard work in achieving accreditation will become redundant and you will find yourself back at the beginning when applying for reaccreditation. It is essential that you maintain JACIE within the programme.



# Maintaining your accreditation

## Maintaining your JACIE accreditation

JACIE is not something that should be forgotten about until getting ready for the next accreditation cycle. It is essential that JACIE continues to grow and develop in your centre. You need to maintain your quality management system, making JACIE a part of the everyday life of the centre. In doing so, you will find achieving reaccreditation easier to manage.

## Interim audit

Your centre will be subject to an interim audit at the end of the second year of accreditation. The interim audit focuses primarily on the quality management system in the Clinical Units. Collection and Processing facilities must submit evidence that they are currently licenced/authorised by the appropriate regulatory authority(s). The interim audit will be based on a review of documents requested from the centre and assessed by the same inspector(s) who performed the most recent full Inspection. Where an inspector is no longer available, a substitute will be appointed.

The interim audit will be based on the same edition of the Standards used for the preceding accreditation of the centres.

The audit will focus on the functioning of the quality management system. For more information, please refer to the Inspection Guide

## Annual reports

Each year prior to the anniversary of your accreditation, JACIE will send you an annual report form for you to complete. This report is similar to the application form, and is used to describe ongoing activities and significant changes.

## Do I need to notify JACIE of any significant changes, for example - change in program director, moving buildings etc?

JACIE needs to be aware of any major changes that occur during the accreditation cycle. The significance of the change and when it occurs within the accreditation cycle will dictate what steps you will need to take, for example, submit CVs and evidence of qualifications, building plans etc.

For further information please refer to the Inspection Guide.

## Evaluation surveys

From time to time JACIE may request your feedback as to how your centre is performing or as an evaluation of the JACIE accreditation process. Such information could be used in the publication of papers or for JACIE to identify areas of improvement in the accreditation process. Your input is very important to the JACIE Office and your assistance and comments are appreciated.

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*Our programme found the experience to have been very positive, and we are very glad to have embarked upon the process.*




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*Compared to other inspections that we have had, we find JACIE to be the most aware of clinical practice and patients' needs. Many thanks for helping us improve our services to patients.*

## TOP TIPS

 Attend the JACIE session at the EBMT Annual Congress and other JACIE workshops

 Join the JACIE mailing list at <http://eepurl.com/jLxRz>. You will receive the JACIE newsletter and important announcements from the JACIE Office

 Encourage qualified colleagues to become JACIE Inspectors



# Reaccreditation

## What's the difference between applying for accreditation and reaccreditation?

There is no large difference between accreditation and reaccreditation. Accreditation is the first time that you apply for JACIE accreditation. All subsequent accreditations after the first are reaccreditations.

## How do I apply for reaccreditation?

Applying for reaccreditation is the same process as applying for accreditation. Application forms must be submitted to the JACIE Office for approval.

## When do I apply for reaccreditation?

Reaccreditation is the responsibility of the centre. JACIE does not impose a penalty on the centre if there is a break in their accreditation cycle. Bear in mind your time frame, especially if you have relationships with external organisations that require your transplant programs to be accredited. JACIE recommends to submit your application form at end of year 3. We would aim to have the on-site inspection during the first part of year four (around six months before the expiry of your current accreditation cycle). This would give you time to undergo the inspection, make corrections and have these assessed before the current accreditation expires, therefore avoiding gaps in your accreditation.

This is how you initiate the application for reaccreditation – your preparation for reaccreditation really begins after your previous accreditation is awarded.



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*Thank you to the JACIE Office -  
great help and support  
throughout the process!*



### What documents do I need to supply for reaccreditation?


Once your application form has been reviewed and accepted, you will be requested to submit your pre-inspection documentation. There is no difference between the documents requested for accreditation and reaccreditation and they can be found in the Inspection Guide.


### Can I re-use documents from my previous accreditation?


You can use some of the original documents if they are current, up-to-date and valid. However in most cases new documentation is necessary. For example, CVs – while it is perhaps unlikely that the person has changed their main role, they may have taken on new responsibilities, authored new articles or attended training events and scientific meetings, all of which imply that the CV should be updated.


## TOP TIPS

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 Attend the JACIE session at the EBMT Annual Congress and other JACIE workshops

 Make a note of your accreditation dates in your diary. This will assist you in planning for your annual reports and next accreditation cycle

 Encourage qualified colleagues to become JACIE Inspectors

 Contact the JACIE Office if you have any questions or queries

# Become a JACIE Inspector Today!

The inspection is an excellent learning mechanism, both for the centre and the Inspector as you will have a unique opportunity to see how other centres solve problems and observe their procedures up close and to transfer your own experience.

JACIE requires that all Inspectors attend a JACIE-approved training course in order to ensure uniformity and consistency in interpretation of the Standards and performance of the inspection. The course includes assessing a quality management system, interpretation of the Standards and how to prepare and perform an inspection.

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***Being a JACIE Inspector gives me the opportunity to see other centres and to raise quality awareness.*** JACIE Inspector



## The following are the minimum criteria for a JACIE Inspector:

Each inspector shall have completed a training course for new inspectors, passed the associated exam based on the Standards and complete periodic inspector training modules as prepared by JACIE.

### Training & Experience:

- An inspector of a Clinical Transplant Program shall hold a medical degree and be licensed to practice medicine, and have a minimum of five years of clinical blood and marrow transplant experience
- An inspector of a Haematopoietic Progenitor Cell Collection Facility shall hold a medical degree or degree in a relevant science and have five years experience in haematopoietic cell collection procedures, including apheresis; or, shall have five years experience as the nurse or technician supervising the collection of peripheral blood progenitor cells by apheresis
- An inspector of a Cell Processing Laboratory shall hold a medical degree or PhD or a professional degree in biological sciences or medical technology, and have five years experience as a Laboratory Director, Medical Director, or Supervisor of an HPC Laboratory

The inspector shall complete and sign a statement to the effect that she/he is qualified by medical/scientific training and experience to be a JACIE inspector. The inspector shall be a member of ISCT, EBMT, or similar society or association.



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