

# JACIE Newsletter



April 2010

Issue 2

## Welcome

2010 marks the 10th anniversary of the first JACIE inspection performed in Europe. On 15th December 2000, Hospital Sant Pau, Barcelona, Spain opened its doors to an external inspection team that assessed the compliance of the programme with the then FACT Standards which have subsequently become the FACT-JACIE Standards. The JACIE accreditation model has grown to become a clear demonstration of the HPC transplant community's openness to improving practices and procedures in the pursuit of product and patient safety and ultimately improved patient outcome. We look forward to celebrating further success in the coming years!

Best wishes

Catherine Foggo  
On behalf of the JACIE Office Staff

## Standards

### 5th edition overview

Preparation of the 5th edition of the FACT-JACIE Cellular Therapy Standards will commence this summer. Final release is expected at the beginning of 2012.

FACT and JACIE invite you to complete a [short survey](#) focusing on general concepts of interest related to the Standards. You are also encouraged to promote this survey in your national or regional professional society. The results of this survey will be reported to the Standards Steering Committee for review and consideration. Please submit your responses by May 31, 2010.

A public consultant on the draft text will also open in 2011 and we will circulate the invitation to participate as widely as possible. All comments and input will be gratefully received.

Please watch out for other requests for your input. Further details will be posted at [www.jacie.org](http://www.jacie.org).

### Updated Guidance on Reagents

*(This text first appeared in Just The Facts, Winter 2010. Reproduced with kind permission of FACT)*

Processing facilities should use reagents of the appropriate grade (clinical or pharmaceutical) when they are available, and only allow reagents not of the appropriate grade to be used if qualification determines they are the only suitable reagents for the intended use. To read more, please click [here](#) or see the guidance for D4.13.2 in the Accreditation Manual version 4.1 on page 153 and D6.8.4 on page 167.

### Circular of Information – new edition November 2009

The Circular of Information (Circular) for the Use of Cellular Therapy Products is intended to be an extension of the cellular product label. Cellular products are biologic products and, in the form of cellular products, living human tissue intended for use in patient treatment. Professional judgment based on clinical evaluation determines the selection of products, dosage, rate of administration, and decisions in situations not covered in this general statement. The Circular can be accessed from the AABB web site [http://www.aabb.org/resources/bct/Pages/aabb\\_coi.aspx](http://www.aabb.org/resources/bct/Pages/aabb_coi.aspx)

## Accreditation Statistics

Total centres  
registered: **212**

Inspections in  
preparation:  
First time: **59**  
Reaccreditation: **19**

Total completed  
inspections:  
First time: **146**  
Reaccreditation: **27**

Accreditations: **90**

Facilities correcting  
deficiencies: **26**

Number of countries  
registered: **17**

### CONTACT US

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## News

### Overview

Since 2000, JACIE has received applications from centres in 17 countries. This is testimony to the global appeal and relevance of the FACT-JACIE standards.

### EBMT Annual Meeting, Vienna

JACIE was well represented at the EBMT Annual congress in Vienna, Austria. This included an Inspector Workshop and the JACIE Session. We were also available on the stand, helping with enquiries. See below for more details on the Quality Management Meeting.

Alois Gratwohl presented very interesting data on the impact of introducing a quality management system along JACIE lines on patient outcome. The abstract taken from the 2010 EBMT Annual Congress can be found on the JACIE website [www.jacie.org](http://www.jacie.org)

### Interim Audits Description Announced

This has been added to the Inspection Guide version 4.5.3, pages 30-31. Please download this version of the guide from the Document Centre on the left hand side of [www.jacie.org](http://www.jacie.org) for further information.

## Surveys

### Quality Indicator Survey of Accredited Centres

This survey aims to collect data from all JACIE accredited centres to assess the benefits associated with adoption and implementation of the JACIE standards. The results of this survey could potentially provide important data to support requests to their institutions for the human and logistical resources necessary to maintain a quality management system. *For further details, please click [here](#).*

### Access to Intensive Care

Under the 4th edition of the Standards, a new requirement for intensive care access was introduced. Standard B2.1.1 states "The inpatient program shall have an intensive care unit or equivalent coverage within the institution." In order to assess the potential impact of this requirement on centres applying for accreditation, a short survey is ongoing and we would appreciate your participation.

Please click on the following link <http://www.surveymonkey.com/s/V796CT7>

Thank you in advance for your valuable time and assistance.

## Quality Management

### 2nd EBMT Quality Management Meeting

On Wednesday 24 March, 2010, 150 people attended the 2<sup>nd</sup> EBMT Quality Management Meeting. The meeting was a mixture of plenary sessions and thematic group discussions. The meeting was organised by the EBMT Quality Management Group who were pleased with the overall meeting. They will soon start to prepare for the 2011 meeting in Paris and would be happy to receive suggestions for topics or speakers. The slides from the meeting are available to download from [www.jacie.org](http://www.jacie.org).

## Important dates for your diary

### Congresses and Annual Meetings

**23 -26 May 2010** - Philadelphia, USA - ISCT Annual Meeting [www.celltherapy2010.com](http://www.celltherapy2010.com)

**11-14 Sep 2010** - Belgirate, Italy ISCT Annual Meeting [www.isct-europe.eu/2010/](http://www.isct-europe.eu/2010/)

### Training Courses and Events

**1-2 June 2010** - Athens, Greece - Centre Preparation Course

**3-4 June 2010** - Athens, Greece - Inspector Training Course

**10-11 Sep 2010** - Belgirate, Italy - Inspector Training Course

**18-19 Nov 2010** - Barcelona, Spain - Internal Audit Training Course

If you are interested in attending a JACIE Training course and wish to register or would like further information, or if you would like us to consider promoting an upcoming event here, please do not hesitate to contact us [jacie@ebmt.org](mailto:jacie@ebmt.org)

## JACIE Office

Feel free to contact us if you have any questions or queries about obtaining your JACIE Accreditation, becoming a JACIE Inspector or attending a JACIE Training Course. We would be more than happy to assist you.

## TOP TIPS

In this issue our TOP TIPS are for those -

### *Preparing for the arrival of the onsite Inspection Team*

Reserve hotel rooms for the Inspectors

Arrange a meeting point with the Inspectors – either in the hotel lobby and escort them onsite. Or alternatively at the reception area of the main site

Book a room on site in advance for the Inspectors to work from. This is also usually where the Inspectors will have a working lunch

Double check that the room is booked

Arrange suitable lunch and refreshments for the Inspectors

Ensure that there are writing materials available

Have access to all of the pre-inspection documentation or hard copies available

Ensure that all relevant staff will be available on the Inspection day



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