

Letter from the President

This newsletter highlights new developments in FACT requirements for cellular therapy programs and cord blood banks. Not only have the 4th edition Cord Blood Standards been published, but new information regarding the appropriate grade of reagents has been published in the Cellular Therapy Accreditation Manual. As programs and banks take the necessary steps to be compliant with these requirements, we encourage you to view the tasks as patient care issues, not just FACT compliance issues. The ultimate goal of FACT's Standards and inspection and accreditation process is to improve the direct care received by patients. FACT's mission of promoting quality medical and laboratory practices drives what this peer organization does, and as developments advance the field of cellular therapy, the requirements should keep up. We appreciate the effort that many of you have made in drafting and reviewing the new standards and guidance embodied in these documents as well as validating the relevance of existing standards.

FACT's new cellular therapy guidance information lays out specific ways that reagents that are not clinical or pharmaceutical grade can be qualified to be appropriate for their intended use. This document was a subject of broad input and considerable debate on both sides of the Atlantic. The result is an approach to a difficult subject in our field which should not restrict research nor create financial hardships; in fact, it should encourage programs to responsibly update their practices to provide the best care possible, while supporting research and the responsible provision of care.

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C. Fred LeMaistre, MD

4th Edition Cord Blood Standards Published

The fourth edition of the NetCord-FACT International Standards for Cord Blood Collection, Processing, and Release for Administration and its associated Accreditation Manual and Inspection Checklist have been published and are available on the FACT website. Other accompanying documents that are available include the Document Checklist, a list of significant changes, and crosswalks between the third and fourth editions.

All banks must be in compliance with the fourth edition by March 31, 2010. If your bank has an upcoming inspection and has already submitted the third edition checklist with all required documentation, you must be inspected by March 30, 2010, before the fourth edition Standards becomes effective. We appreciate your involvement with FACT and understand the effort required to become compliant with new requirements. It is our goal to make this transition as smooth as possible for all accredited and applicant banks. If there is any way we can be of assistance to you, please contact the FACT office.

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Accreditation Report

One new blood and marrow transplant program earned accreditation and thirteen additional facilities received accreditation renewal during the fourth quarter of 2009. The complete report of accredited organizations is available at www.factwebsite.org.

Cellular Therapy Programs	Cord Blood Banks
197 Programs Registered	45 Banks Registered
175 Programs Accredited	21 Banks Accredited
22 Applications Pending	24 Applications Pending

CB Inspectors Requested to Complete 4th Edition Inspector Test

Cord blood inspectors are required to take an updated Inspector Test upon the publication of a new edition of Cord Blood Standards. The 4th edition Cord Blood Inspector Test is available, and inspectors are encouraged to complete this test by March 31, 2010. By completing the test prior to the effective date of the Standards, inspectors will increase their proficiency with the new

Standards and help facilitate their own banks' transition to the new requirements.

All inspectors will receive a printed copy of the 4th edition Cord Blood Standards and Cord Blood Accreditation Manual. In the meantime, the online versions can be used to assist you with taking the Inspector Test.

Keeping Up With Accreditation Manual Updates

Updates to the Accreditation Manuals are intended to be helpful to inspectors and organizations by clarifying commonly misunderstood or misinterpreted requirements. While it can be daunting to keep up with all of the changes, it is important to do so in order to ensure organizations comply with the requirements and inspectors appropriately assess compliance. FACT intends to limit updates to only those that are necessary to minimize burden on organizations and inspectors. The following are tips to keep up with the changes:

1. Read the Just the FACTs newsletter, as updates will be announced in this publication. Be sure to forward the newsletter to all staff affected by the content.
2. Review the list of changes in the appendix of the manual or in the Cellular Therapy or Cord Blood Document Library, and review the changed text in its entirety.
3. Assess whether or not your organization (or the organization you are inspecting) complies with the clarified intent; if not, enact process improvement procedures to ensure compliance.

Updates to the Accreditation Manual are intended to be helpful to inspectors and organizations.

Using a Printed Copy?

While the electronic version of the Accreditation Manual is the official version, many inspectors and organizations consult their printed copies. The following are suggestions for keeping printed copies current with the electronic version:

- Print the list of amendments and attach it to the cover of your printed copy. The list of changes is cumulative, so you only need one copy of the list at a time.
- Flag updated sections of your printed copy as a reminder that updated information is available online.
- Add or strike information with pen on your printed copy.

