

Letter from the President

We are all excited about the new FACT website and the promise it offers for the future. This website is the first major milestone of FACT's vision to use information technology to make the inspection and accreditation process efficient and cost-effective. Change can be hard, but it is often worthwhile and things end up better in the end. Small steps have been taken in the past three years to make submissions and checklists electronic, and the benefits of those changes should excite us for what is to come.

It will take a concerted effort among inspectors and programs to make the new website function as it should. The first step is for inspectors to create an online profile and complete the online inspector application. This is simply to add you to the new online database so that the website provides you free access to inspector tools and educational sessions. We understand our inspectors are busy professionals and appreciate everyone's cooperation in this endeavor to make the website work for you.

Sincerely,

C. Fred LeMaistre, MD

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Join us on facebook!

FACT has a facebook page intended to be another resource for FACT inspectors and accredited and applied organizations. This page will provide continuous updates and tips from FACT that may not fit in one of its traditional publications or educational events. So far, information regarding pertinent journal articles, the inspection process, IT advancements, and regulatory announcements has been shared with viewers.

The page can be found via the facebook link at the top of the FACT website's home page. Because this page will be a source of invaluable, timely information, we think everyone will "like" it! The first 100 people to join our facebook page will be entered into a drawing for a FREE online training session worth up to \$100!

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Editor: Kara Wacker, MBA

Accreditation Report

One new blood and marrow transplant program earned accreditation and five additional facilities received accreditation renewal during the third quarter of 2010. The complete report of accredited organizations in the third quarter is available at www.factwebsite.org.

Cellular Therapy Programs	Cord Blood Banks
199 Programs Registered	39 Banks Registered
183 Programs Accredited	27 Banks Accredited
16 Applications Pending	12 Applications Pending

FACT Launches New Website

FACT is proud to announce the launch of its newly designed website! As part of the goal to use technology to make the inspection and accreditation process more efficient with your time and resources, the first step is the redesign of the website to make it the one-stop resource for FACT news, tools, and purchases. Purchase FACT Standards and educational sessions via a streamlined point of purchase in the Store, submit questions via the Ask FACT feature, and register for workshops completely online.

Can't find what you're looking for? The "I want to . . ." menu on the home page will point you in the right direction!

Other exciting features of the website include:

- **Standards and Resources:** provides details regarding the scope of the Standards and links to regulatory and industry resources.
- **Accreditation Process:** includes general information pertinent to obtaining initial or renewal accreditation, including accreditation timelines, process overview, and fees.
- **Become an Inspector:** lists the benefits and expectations of inspectors and provides directions on how to apply to become an inspector.
- **FACTWeb:** enables users to create a personal profile for updating demographic information, tracking participation in FACT education, and managing downloads. This is the first phase of the online accreditation system . . . stay tuned for more!

Create your profile today! Creating a personal profile will provide access to member-only content and discounts for ASBMT and ISCT members. To take advantage of the powerful tools of the new FACT website, FACT volunteers and Directors of accredited organizations have already been given a personal profile. If you haven't updated your profile already, please contact FACT for your username, password, and further instructions.

Case Studies Requested from Accredited Organizations

The new FACT website features case studies written by and about FACT accredited organizations. A case study is a short narrative intended to highlight accredited organizations and give them an opportunity to share their experience with the FACT accreditation process. This is an excellent way to showcase your organization and help your colleagues!

In addition to providing a brief description of your accredited organizations, please submit an approximately one page document (3-4 paragraphs) describing a significant aspect of the accreditation process for your organization. This may include:

- The extent of involvement by your organization's administrative leadership and its impact on FACT accreditation.
- The impact of FACT accreditation on your organization.
- Suggestions for programs going through the process.
- The biggest reward of FACT accreditation.
- Experiences with the renewal process.

Case studies will be chosen for publication based on their relevance to FACT's audience. An effort will be made to ensure that case studies from varying types and sizes of organizations are published.

To complete the submission of the case study to FACT, please complete the case study submission form on the FACT website. This form can be found by logging into your FACTWeb profile and selecting "Case Study Submission" under Resources.

**A Letter to Inspectors from Mark Litzow, MD, FACTWeb
Oversight Committee Chair**



Dear Inspector,

Thank you for volunteering as a FACT inspector. In this collegial organization built upon peer-developed ideas, the time and expertise you devote to the mission of quality cellular therapy is greatly appreciated. We could not do this without you.

As previously announced, FACT has unveiled its new website, which has powerful capabilities to streamline the inspection and accreditation process. We believe the changes you will continue to see will make your role as an inspector even more enjoyable. The FACTWeb Oversight Committee has worked diligently to transfer the paper-based accreditation process to FACTWeb, the online accreditation portal accessible to members only.

To make use of the website's new capabilities, it is necessary for FACT inspectors to create an online profile and complete the new inspector application. In addition to adding you to the new inspector database, this will enable the system to recognize you as an inspector and provide you with the valuable education and resources you deserve free of charge.

If you have not already done so, please complete the following steps by December 20, 2010. If you have any questions or difficulty, you can contact Ramona Repaczki-Jones, IT Manager, directly for assistance at rrepaczki@unmc.edu or 1-402-559-1972.

1. Create a personal profile. This profile will create your record in FACT's new inspector database and provide you with access to free education and resources.
2. Complete the online inspector application. This application requires you to complete certain documents and then upload them to an online form. Before you start the inspector application, ensure that you have gathered all your documents and completed the forms listed on the Inspector Application Instruction page. The online inspector application form will take less than ten minutes to complete.

We understand your time is valuable, and appreciate the effort you put into the transition to FACTWeb.

Sincerely,

Mark Litzow, MD

**Fun Facts about the new FACT
Website**

One of the goals of the new FACT website is to create an online presence as a reliable resource for information on the FACT inspection and accreditation process. The following are usage statistics from the new website since it was launched on September 15, 2010:

There have been a total of 7,649 total visitors, with 3,566 new visitors and 4,083 returning visitors

The visitors spend over 3 minutes on the site and view an average of 4 pages.

7,003 visits were from a Windows computer, 525 visits were from a Macintosh computer, and 39 visits were from iPad.

A total of 1,050 individual FACTWeb profiles have been created.

A total of 463 organizations have a FACTWeb profile.

Individuals from accredited organizations account for 641 individual profiles.

397 primary contacts from accredited organizations have a profile.

So far, 46 individuals, including existing and prospective inspectors, have submitted the online FACT inspector application.

Of the individuals with a FACTWeb profile, 164 are committee members who serve in one of 14 FACT committees. Many of these individuals serve on more than 1 committee.

Helpful Hints from the FACT Accreditation Coordinators

Although FACT encourages organizations to submit documents electronically, we still currently accept paper submissions. If you are submitting documents by mail, here are some helpful hints from the FACT Accreditation Coordinators:

Do not use staples, sheet protectors, or colored paper as these items make it difficult to scan or copy.

It is best to use binder clips as notebooks often open during transport, scattering the contents.

Remember to include relevant forms, appendices, and attachments if referenced in the submitted policy or procedure.

Follow the order in the Document Checklist and indicate if a particular document applies to more than one facility (i.e. Collection and Processing Facilities). Also indicate if certain documents are not applicable.

Do not include outdated documents or documentation of continuing education from over three years prior.

Do You Know Who Your FACT Accreditation Coordinator Is?

FACT Coordinators are here to help you throughout the accreditation process. Our goal is to help you meet the Standards. We can answer technical questions, review documents, and work with you to stay in compliance. All organizations are assigned a FACT Coordinator for their current accreditation cycle. Their contact information is as follows:

Nancy Abraham, BSMT (ASCP)

phone: 402.559.1954 e-mail: nabraham@unmc.edu

Linda Cave, MS MIS, BSMT (ASCP)

phone: 402.559.1961 e-mail: lfcave@unmc.edu

Sarah Litel-Smith, BSMT (ASCP)

phone: 402.559.1959 e-mail: slitelsmith@unmc.edu

Cathy Matuella, BSMT (ASCP)

phone: 402.559.1955 e-mail: cmatuella@unmc.edu

Quality Corner

Continuous Operations Safeguards

S. Elizabeth "Sam" Sharf, RN, BSN, CHTC, Quality Manager of Bone Marrow and Stem Cell Transplant Program, Chapel Hill, North Carolina

You know you do it....Continuous Operations Safeguards, that is! Safety is an intrinsic part of the bone marrow transplant world whether our patients are in the hospital, in the outpatient setting, collecting their cells or having them processed. Every program has 'safety nets' in place and these are the very safeguards we rely upon on a daily basis.

Do your bedside nurses double check the dosage calculations prior to administering chemotherapy? Does your harvesting team make sure that the product is seamlessly passed from the hands of the collection team to the hands of the processing team with recipient and donor identifiers intact? At its most basic, do staff members always wear gloves while handling biologic specimens? All of these are examples of safety measures, yet they have become so routine that we still have to think at times about what truly defines Continuous Operations Safeguards.

When preparing for a FACT inspection, imagine you're on the Inspection Team. Follow one of your patients through the pre- peri- and post-phases of his or her transplant. This trail should have identifiable safety measures in place, applicable to the FACT standards, at every junction. Providing the inspectors with actual examples of how your program guarantees safety will allow them to move through the assessment efficiently. Ensure that your SOPs are clearly written and guide staff logically through whatever steps are necessary toward an endpoint of safety. And when an unsafe circumstance is identified, provide evidence to the inspectors of the process your program underwent in order to rectify the situation.

Continuous Operations Safeguards are at the core of what FACT represents as well as what protects us all. Make sure that your safety systems are clearly defined and in place for a smooth inspection, successful accreditation and a safer experience for everyone!

Documents to Translate for Non-English Speaking Cord Blood Banks

Under the 4th Edition of the NetCord-FACT Standards, the list of cord blood banking policies and procedures that must be translated into English and submitted for the inspection binder has decreased in size. All documents in the Document Checklist must be translated into English. The Document Checklist can be found in the Cord Blood Bank Library in FACTWeb.

Translations do not have to be performed by a certified translator. Bank personnel who have a working proficiency in English can perform the translation. There are online tools that can assist with translation in the event a phrase is difficult to translate. FACT does not promote nor require certain translation programs, but two examples include Microsoft Word's translating feature and Google. The following are guidelines for translating documents:

- The translator should confirm that the English version document can be translated back to the original language and still match the original document.
- The concepts and ideas should be clear to the inspector. Perfect grammar is not required, but should be adequate enough for the inspector to understand the document.

If the FACT office or FACT inspector does not understand a translated document, the FACT Accreditation Coordinator will work with the inspector and bank to clear up misunderstandings.

Although not all documents within your bank need to be translated, the FACT inspector will ask personnel to read non-translated documents on-site. Banks need to have an individual accompany the inspector at all times who can translate and interpret in English the banks' verbal responses and written documents. This can be bank personnel or a hired interpreter.

All other correspondence with FACT before, during, and after the inspection is conducted in English. This includes email messages and telephone calls, the inspection report and response, and the final accreditation letter.

FACT makes an effort to minimize the burden of non-English speaking cord blood banks; however, it is important that the information shared with the inspector is clear enough to enable the inspector to verify compliance with the Standards. If an inspector is not able to verify compliance with a standard he or she will cite this as a deficiency in the inspection report. It is possible that inspector questions were unclear or that needed information was in a non-translated document. In these situations, simply include in your inspection report response how you comply with the standard and submit supporting documentation.

Congratulations to our new cellular therapy inspectors!

Andres Barrera, BS

Wilford Hall Medical Center

Suanne Dorr, MBA, MT(ASCP)

Karmanos Cancer Institute

Chris Fraser, MBBS, FRAC

Royal Brisbane Hospital

Parameswaran Hari, MRCP, DRCPATH, MS

Medical College of Wisconsin

Gemini Majkowski, BSMT

Alexandria, Virginia

David Szwajcer, MD

CancerCare Manitoba

Ellen Tambini, RN, BSN, OCN

Hackensack University Medical Center

Julia Walker, MT(ASCP)CLS

MD Anderson Cancer Center

What is the difference between transporting and shipping cellular therapy products?

The difference in distribution methods makes a difference in FACT requirements!

Inspectors and cellular therapy programs alike need to have a firm understanding of the difference between transport and shipping, and what requirements exist for each. Both are distribution methods – they get the product from point A to point B. During transport, the product does not leave the control of trained personnel. During shipping, the product does leave the control of trained personnel. For example:

Transport: A trained staff member from the collection facility takes a product to a transplant center via airplane.

Shipping: A processing facility sends a product to a transplant center via a FedEx truck.

The Standards Committee took considerable effort to be clear on when a requirement applies to one or both of these distribution methods. If a standard specifically references both transport and shipping, or does not mention either, it applies to both. If a standard only references shipping, it only applies to shipping. For example:

Both: C10.1 Procedures for transportation and shipping of the cellular therapy product shall be designed to protect the integrity of the product and the health and safety of facility personnel.

Both: D10.2.1 The primary product container for non-frozen products shall be placed in a secondary container and sealed to prevent leakage.

Shipping only: D10.4.3.1 The temperature of shipping containers bearing cryopreserved products shall be continuously monitored during shipping.

Transport only: D10.5.2 If the intended recipient has received high-dose therapy, the cellular therapy product shall be transported by a qualified courier.

Escorting FACT Inspectors to Off-site Locations

Many organizations who are inspected by FACT conduct operations in multiple sites, such as off-site collection facilities, processing facilities, or storage facilities. Sometimes the same inspector will visit two or more of these sites. When this is the case, the applicant must provide the inspector transportation. It is not sufficient to simply have a person meet the inspector at each location. The inspector should be escorted at all times, including during transit between facilities.

Public Comments on HLA Typing Terms Requested

The purpose of the Harmonization of Histocompatibility Typing Terms Statement, posted on the FACT website, is to recommend and to initiate discussion regarding terminology, definitions of resolution levels, format for reporting HLA assignments and match reporting for transplantation. This collaborative initiative among many organizations, including ASHI and FACT, began in February of 2010. We now request and welcome your participation in this effort.

Please respond with your comments and suggestions to Kathy Miranda (kmiranda@ahint.com) at the ASHI office no later than December 31, 2010. In the subject line indicate that you are responding to the Harmonization of Histocompatibility Typing Terms Statement. The Harmonization Group will review all comments in January 2011. The collective Harmonization of Histocompatibility Typing Terms statement will then be made public. It is our hope that each organization will incorporate the terminology and match reporting recommendations into their standards and guidance documents.

New ICCBBA Website Designed for Ease of Use

The new ICCBBA website features a new platform that allows our users to access the documents they need quickly and easily. Items are arranged and sorted based on subject areas (Blood, Cellular Therapy, Tissues, Eye Bank, and Vendors) via the "Subject Area" tab at the top of each page. The "Registered Users' Area" was removed, with the documents visible and accessible in their respective areas after logging in. User IDs and passwords used on the old site will work on this new site. A discussion forum is available as an extra way for our users to ask questions and search on hot topics.

There is a new ISBT 128 cellular therapy area on this site, in which the Standard Terminology document referenced in the FACT Standards can be found.

ISCT joins forces with Roche and Genzyme to launch Cell Therapy Industry Partnership

Many companies in the cell therapy regenerative medicine market including Roche, Genzyme, Athersys, Miltenyi Biotec, Hospira, Lonza and Life Technologies will join ISCT to launch a series of new initiatives that will create greater strategic alignment within the industry and drive late stage clinical development. The ISCT Industry Task Force (ITF), comprising these major corporations along with internationally renowned clinicians and academics in cell therapy translation, rolled out a series of recommendations to re-charter the ISCT Commercialization Committee to drive the creation of forums for discussion of shared concerns on process and product development, business models, and clinical development, and to catalyze the development of consensus standards.

FDA Releases Final Guidance for Industry: Cellular Therapy for Cardiac Disease

The FDA released "Final Guidance for Industry, Cellular Therapy for Cardiac Disease" to provide sponsors with recommendations on the design of preclinical and clinical studies, and on the chemistry, manufacturing, and controls (CMC) information to include in an Investigational New Drug application (IND) for cellular therapy for cardiac disease. This guidance also provides recommendations regarding the information that should be submitted regarding the product's delivery system. The guidance finalizes the draft guidance entitled "Guidance for Industry: Somatic Cell Therapy for Cardiac Disease" dated March 2009 (April 2, 2009, 74 FR 14992).

Give Us the FACTs Poll

How often do you contact your FACT Accreditation Coordinator and why?

Give Us the FACTs!

Last month's poll: What variables do you include when conducting the required validation studies?

Many variables were provided in response to this poll. The following are a listing of them for each required validation study:

Collection:

- **volume bacterial contamination**
- **TNC yield**
- **performance (expected CD34 collected vs CD34 collected)**
- **CFU**
- **viability**

Processing:

- **bacterial contamination**
- **CD34 and TNC yield**
- **pre and post CFU,**
- **viability**

Cryopreservation:

- **viability**
- **pre and post yield of TNC and CD34**

Labeling:

- **Adequacy and permanence of electronic and hand-written printing before and after freezing and after spraying with 70% alcohol**
- **Cryo glue sticks, biological glue sticks, other labels sticks on primary label,**

Storage conditions:

- **TNC and CD34 count and viability vs time at 4C and 22C**

Distribution:

- **Traceability**
- **Engraftment**

In Your Opinion ...

What is your favorite feature of the new FACT website?

In Your Opinion ...

Last month's survey: What labeling requirements are difficult to comply with while using the ISBT 128 technology?

Common difficulties include justifying the cost and integrating the ISBT 128 software into existing information technology (IT) systems.

Similar sentiments were echoed in the results of the international ISBT 128 survey. However, we believe your facility will find the long term benefits of using ISBT 128 worth the investment of resources needed to implement the system. Standardized labeling and bar coding can reduce costs by allowing your facility to eliminate or significantly reduce the need for expensive customized labels or label software, improve efficiency by allowing you to rapidly scan critical information into your computer system, and reduce the need for follow-up investigations caused by transcription errors.

FACT conducts workshop in conjunction with World Cord Blood Congress in Marseille

FACT conducted a Cord Blood Inspection and Accreditation Workshop in conjunction with the World Cord Blood Congress for the first time on November 3, 2010 in Marseille, France. This workshop proved to be an important venue for cord blood training and enabled FACT to reach out to new applicants for FACT-NetCord accreditation.

2011 FACT Workshop Schedule Released

The FACT workshop schedule for 2011 has been released! We invite you to join us for one of the following interactive, educational workshops:

February 16, 2011

Cellular Therapy Inspection and Accreditation Workshop

Registration Open!

in conjunction with the BMT Tandem Meetings in Honolulu, Hawaii
Two Tracks: Overall Cellular Therapy Program Track and Clinical Program Track

May 18, 2011

Cellular Therapy Inspection and Accreditation Workshop

in conjunction with the ISCT Annual Meeting in Rotterdam, the Netherlands
Held in collaboration with JACIE

May 31, 2011

Cellular Therapy Collection Inspection Workshop

in conjunction with the ASFA Annual Meeting in Scottsdale, Arizona

June 12, 2011

Cord Blood Inspection and Accreditation Workshop

in conjunction with the International Umbilical Cord Blood Transplantation Symposium in San Francisco, California

November 2011 (TBD)

Cord Blood Inspection and Accreditation Workshop

in conjunction with the World Cord Blood Congress in Rome, Italy

Online Education To Continue Its Valuable Offerings

Following a successful year in 2010, the FACT online education program will continue with more valuable offerings intended to help inspectors, cellular therapy programs, and banks around the world.

Donor evaluation tutorials are currently being recorded to assist programs with understanding the FACT requirements and how to use donor evaluation algorithms and tools.

The third module of the Quality Management Series will focus on reporting quality data and performance to staff, other facilities, and directors.

More details will be available soon!