



Letter from the President

This newsletter contains requests from organizations, including FACT, for comments regarding standards and regulatory information. We would like for you to tell us what you think about the draft fourth edition Cord Blood Standards. Feedback from you is critical to ensure proposed standards are relevant and helpful in assuring quality practice of cellular therapy and that patients receive the best possible care. FACT accreditation is a voluntary process, which means we are here to serve the needs of cellular therapy programs and cord blood banks. We recognize the best way to serve these facilities is to partner with our constituents in developing meaningful and useful standards. We hope that participation in the standard-setting process will both enhance your satisfaction with the inspection and accreditation process but ultimately help all of us improve patient outcomes.

FACT started as a team effort to identify minimum standards related to patient care and product manufacturing and develop an accreditation process that would allow us all to improve. There is no question that teams that work together are more successful. We appreciate the teamwork in making our process better and look forward to hearing your thoughts about the draft Standards. Thank you in advance for allowing FACT to be part of your team.

Sincerely,
C. Fred LeMaistre, MD

Feedback is critical to ensure proposed standards are relevant and helpful.

C. Fred LeMaistre, MD

Draft 4th Edition Cord Blood Standards Available for Public Comments

NetCord and FACT have published the 4th Edition of the *International Standards for Cord Blood Collection, Processing, Testing, Banking, Selection, and Release* for inspection and public comment for a 90-day period. The public comment period began July 1, 2009 and comments will be accepted through September 28, 2009.

The draft [Standards](#) and the [Accreditation Manual](#), which provides guidance for meeting the Standards, can be downloaded for review. A list of [significant changes](#) provides an overview of some of the changes.

Instructions for Submitting Comments

1. Download the [Comment Form](#).
2. Type in your contact information and comments on the form.
3. Save the comment form to your computer.
4. Email the comment form to fact@unmc.edu (Attention: Kara Wacker)*

**If you are unable to email the form, you may fax it to 1-402-559-1951 or mail it to:*

FACT Accreditation Office
Attention: Kara Wacker
University of Nebraska Medical Center
986065 Nebraska Medical Center
Omaha, NE 68198-6065
USA

In this Issue:

- Draft Cord Blood Standards Available for Comment
- Update on Standards Interpretation
- Accreditation Manual Updates
- Legal and Regulatory Affairs Update
- Coordinator Commentary
- ASHI Requests Public Comment
- Training Opportunities

Update on Standards Interpretation

High Resolution HLA Typing (CT Standard B6.7.2):

High resolution typing is required only for DRB-1. The implied interpretation requires high resolution typing only for DR genes because B6.7.2.1 is a substandard to B6.7.2, which only requires DR. Of the DR genes, DRB-1 is the one of importance in cell transplantation. This is a minimum requirement, and a Clinical Program may choose to use high resolution typing for other genes also. It is important to comply with ASHI, EFI, or equivalent organizations as applicable. NMDP also has more stringent requirements.

Control of Critical Collection Facility Parameters (CT Standards C2.3 and C2.4):

The intent of the Standards is to require Collection Facilities to determine if any facility parameters may affect product viability, integrity, contamination, sterility, or cross-contamination during collection. If parameters are identified, they must be controlled, monitored, and recorded to demonstrate ongoing compliance. **No specific parameters are dictated in this standard.** The following are two examples of how a Collection Facility could be noncompliant with the standard:

1. The Collection Facility did not perform an assessment to identify facility parameters that must be controlled, monitored, and recorded. It is possible that a facility may determine that no parameters need to be controlled; however, an assessment must occur before it is possible to arrive to that conclusion.
2. An inspector may disagree with the Collection Facility's assessment while touring the facility. If this happens, the Accreditation Committee will review the reasons for the citation.

Standard C2.4 is specific to collection methods that pose a greater risk to contamination or cross-contamination, such as the use of open collecting systems.

Accreditation Process Made Even More Transparent with Updates on Standards Interpretation

The FACT accreditation process emphasizes objectivity and consistency between all cellular therapy programs and cord blood banks. When Standards become effective, differences in interpretation may be identified. [Cellular Therapy](#) and [Cord Blood Accreditation Committees](#) use precedence to make decisions regarding Standards that are interpreted uniquely among individual inspectors to be sure all applicants are treated the same.

A new process will be used to proactively share precedent-setting decisions with inspectors, programs, and banks so that everyone is able to accurately apply the Standards in the same manner as the Accreditation Committees. This information will ensure the intent of the Standards is consistently applied by all programs and banks and subsequently assessed by inspectors.

The Accreditation Committees make precedent-setting recommendations to the Board of Directors for assessing compliance with a particular standard and may also ask the

Precedent-setting decisions will be proactively shared with inspectors, programs, and banks.

Standards Committee leadership for consultation regarding the intent at the time the Standards were written.

After approval from the Board of Directors, the interpretations will be included in updated versions of the applicable Accreditation Manual, included on the FACT website, and announced in the *Just the FACTs* newsletter.

Accreditation Manual Updates to Provide Further Guidance

The Accreditation Manuals for the [Cellular Therapy Standards](#) and [Cord Blood Standards](#) are now routinely published at the same time as the Standards themselves. As inspections are conducted under an edition of Standards, it becomes evident that some requirements are in need of additional guidance information. In these situations, updates will be made to the manuals on a quarterly basis if necessary.

Inspectors, programs, and banks will be notified of updates via the newsletter. Similar to the Standards, the version on the FACT website prevails over any printed copies of the manuals. An appendix outlines the changes with each version, which is also listed under Amendments in the applicable Document Library.

The fourth edition Cellular Therapy Accreditation Manual has been updated! Download the [current version](#) and review the [changes](#).

ISCT North America Legal and Regulatory Affairs Committee

One of the goals set by the ISCT North America Legal & Regulatory Affairs Committee for 2009 is to improve the educational relevance of committee activities. The members of the committee remain vigilant in their quest for updated information regarding regulatory requirements and act to inform the ISCT membership when updates are available.

The committee will sponsor four webinars by the end of this year. Webinars have already been conducted on batch records and risk-based quality assurance, which are available for [purchase on a CD](#). Upcoming webinars include a presentation on Stability Requirements on September 9, 2009 and an FDA inspection update on October 21, 2009. Visit the [ISCT webinar web page](#) to register.

Did you know?

A watchdog subcommittee monitors the regulatory environment for updates pertinent to cellular therapy programs. The ISCT membership is updated via the [ISCT website](#) and email bulletins. The committee will submit comments on behalf of organization's members, so remember to send any comments or concerns regarding these updates to ISCT!

ASHI Requests Public Comments

ASHI is requesting public comments on its proposed [standards](#). Accreditation by ASHI is required for programs and banks in the United States, and it is in their interest to review the proposals. Of particular concern to programs last year were new requirements for confirmatory typing. The proposed Standards clarify the timing of these tests. An outline of [changes](#) is available for review.

Send your comments to Kathy Miranda at ASHI Headquarters via email (kmiranda@ahint.com) before August 28, 2009. All comments will be addressed and ASHI's responses will be posted on its [website](#) late this year.

Coordinator Commentary: TED Forms and the Patient Log

Programs preparing to submit pre-inspection documentation often have questions regarding the Transplant Essential Data (TED) forms and the patient log. These items are needed for the data management review. The Program selects the consecutive records for review from its recent 12-month patient log. It is important to include records that have follow-up information. *In some instances, the patient log timeframe may need to be expanded to include at least half of the records with follow up for the Post-Transplant Essential Data form.*

For each consecutive record selected, a Pre-Transplant Essential Data form and a Post-Transplant Essential Data form (if available) need to be submitted. For current information regarding the appropriate forms, please visit the Center for International Blood & Marrow Transplant Research (CIBMTR) website. *As the forms are long, pages without any selections do not need to be submitted.*

Since the CIBMTR assigns the Universal Recipient ID, it is not always easy for the FACT coordinator and inspector to match the TED forms submitted to the patient log. *Including the CIBMTR ID on the patient log or writing the Program's unique patient identifier on the TED forms help avoid confusion.*

If you have any questions regarding TED forms or another topic, please feel free to contact your Accreditation Coordinator at 1-402-559-1950. Direct [contact information](#) is listed on the FACT website.

ACCREDITATION REPORT

Cellular Therapy

198 Registered
173 Accredited
25 Applications Pending

Cord Blood

47 Registered
18 Accredited
31 Applications Pending

Read the [Quarterly Accreditation Report](#) for details regarding accreditation activity in the previous quarter.

FACT Training and Development: Applying Accreditation to Real Results

FACT committees have joined forces in a collaborative effort to address training needs from a variety of angles. The training and development program continues to provide a variety of educational opportunities to inspectors, cellular therapy programs, and cord blood banks in enjoyable, accessible formats meant to engage participants, address current issues, exercise practical application, and clarify common questions and misinterpretations.

Webinars

Online, peer-to-peer seminars

Webinars address individual FACT requirements during specific sessions. Stay tuned for the new Virtual Roundtables: an online peer networking session enabling collaboration and idea sharing.

Tutorials

Online, role-based instruction

Tutorials are based upon roles in the FACT community. They are directly applicable to viewers and accessible when most pertinent to them.

Workshops

In-person educational conferences

Workshops include sessions on current accreditation issues and tips for preparing for and conducting inspections. Interactive presentations encourage participation and application of ideas to real world examples.

QM Series

Modules of related QM training sessions

Modules are discounted, related sets of QM training sessions that enable inspectors, programs, and banks to obtain detailed information regarding FACT QM requirements.

New Quality Management Series to Provide Comprehensive Training

The [QM Series](#) consists of discounted, bundled QM-related topics to encourage inspectors and applicants to participate in each QM session. The individual sessions are designed to have a very specific focus, enabling in-depth instruction, collaboration, and peer involvement during each session. Participating in the entire series creates a more comprehensive understanding.

Bundles are modules comprised of related sessions on QM topics. Programs who register for an entire module will have access to each related QM training opportunity at a discounted price. Inspectors can register for modules free of charge in the Inspector Area. (To register for individual QM-related sessions, visit the [webinar](#) and [tutorial](#) pages.)

It is never too late to purchase a module! Registrants who purchase a module after a session has already taken place will have access to the recordings to share with other personnel in their programs or banks.

Module 1: Administrative Aspects of Quality Management

This module begins in Fall 2009 and focuses on establishing and implementing a QM program. It includes educational sessions related to structuring the program, roles within the program, and applying resources to the program. The following sessions are included in this module (details can be found on the webinar and tutorial web pages as applicable):

- Webinar: The Role of the QM Supervisor; August 26, 2009 at 2 pm ET
- Webinar: Establishing and Implementing a QM Plan; September 23, 2009 at 2 pm ET
- Virtual Roundtable: Time, Effort, and Resources for FACT Accreditation; October 2, 2009 at 1 pm ET
- Tutorial: The SOP for SOPs; November 2009

FACT Related Opportunities Web Page

FACT encourages inspectors, programs, and banks to utilize educational activities to maintain knowledge of industry practices and regulations. A [related opportunities](#) web page was created to provide topical lists of opportunities from a variety of organizations related to the daily operations of programs and banks. For training specific to FACT accreditation, see the [FACT Training Page](#) for more details.

Register today for upcoming webinars!

(Note: These can also be purchased with the new Quality Management Series Module 1!)

The Role of the QM Supervisor

August 26, 2009, 2 pm ET

Establishing and Implementing a QM Plan

September 23, 2009, 2 pm ET

Encourage Your QM Supervisor to Attend!

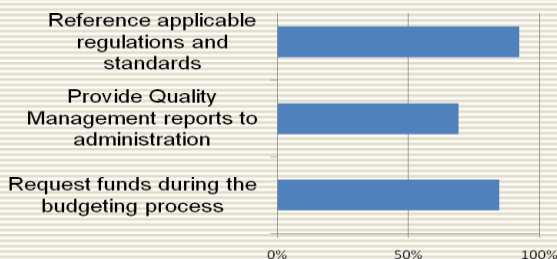
Information from Interaction . . . Content Directed by Our Readers

Give us the FACTs Poll

What question would you like addressed in the next newsletter's Quality Corner?

Give us the
FACTs!

Last month's poll: How do you garner support from administration for Quality Management resources?



In Your Opinion . . .

What example documents related to QM would be most helpful?

In Your
Opinion . . .

Last month's survey: Would your program be willing to provide example documents for QM education?

100% of respondents said their programs would be willing to provide example documents for QM Education. Please send documents your program is particularly proud of to Jill Hempel at jhempel@unmc.edu, FACT Accreditation Office, 986065 Nebraska Medical Center, University of Nebraska Medical Center, Omaha, NE 68198 USA. Programs will be contacted before their examples are used for educational purposes.



You Ask We Answer

FACT often receives several questions about similar issues from inspection evaluations and direct feedback. A common question is, "What information do applicants need to include during the on-site introductory presentation?"

Applicants should include the following information:

- length of time the program has been in operation,
- services provided,
- overview of the QM program,
- organizational chart,
- outstanding or unique, characteristics of the program, and
- unusual elements of the program or bank's structure (for example, contracted services).

Did you find this newsletter helpful? We strongly encourage programs and banks to have all personnel [subscribe!](#)

The FACT Quality Corner

Continuous
Quality
Improvement

Not only is a QM program essential for the organization to ensure quality practices, it should be of a sufficient maturity level to encompass the broad level of quality required to stand out in the cellular therapy community and to achieve long-term excellence with positive outcomes. Mature QM programs are well integrated into the daily work activities of everyone in the program, and are not simply limited to policies and procedures maintained by the quality management supervisor. Integration of the QM program into the cellular therapy program or cord blood bank allows the cooperation and input of everyone to achieve the program's objectives.

Continuous improvement plays a large role in all mature QM programs. Below are some continuous improvement steps that are general in nature and can be utilized in all aspects of continuous improvement:

1. Select the process to improve.
2. Review current performance.
3. Identify improvement needs or opportunities.
4. Implement process changes.
5. Evaluate progress.

To achieve maximum benefits and positive patient outcomes, it is important that a cellular therapy program or cord blood bank has a mature culture of QM that supports continuous quality improvement and an approach that encourages flexible implementation.