



Just the **facts**

Spring 2009 Newsletter

We recognize that participation in the FACT accreditation process is voluntary and that your participation reflects a commitment to quality outcomes for your patients.

C. Fred LeMaistre, MD

Draft 4th Edition Cord Blood Standards Under Development

FACT and NetCord began developing the draft fourth edition Cord Blood Standards last fall. The draft is scheduled to be published for public review and comment on July 1, 2009.

The [committee membership](#) encompasses a total of 585 years of experience in cord blood banking and cellular therapy. This expertise spans the entire continuum of cord blood banking, including cord blood bank directors, collecting health care professionals, processing scientists, quality management professionals, registry experts, and cord blood transplant physicians.

Major changes to the draft currently include integration of quality management requirements into applicable operational sections, reorganization of sections for clarity, and addition of requirements for directed cord blood units.

Further announcements will be distributed via the FACT website and email distribution list. To subscribe yourself or colleagues to the distribution list, visit the [FACT website](#).

Letter from the President

For the first time in nine years, we recently announced that we are increasing the fees for FACT accreditation. The decision to do so occurred only after a careful review of costs and fee structures and intense deliberation and discussion by the FACT Board of Directors.

The FACT Board of Directors is appointed by the parent organizations, ISCT and ASBMT. The Board members are all professionally active in our field and have first-hand experience with the difficult economic times our facilities have encountered. Fees were increased only after the Board was convinced that a fee increase was required to maintain the level of service you have come to expect from FACT.

We have made one additional change in fee structure we hope you will find helpful. The fees were adjusted to an annual schedule to facilitate the budgeting process. Most facilities have told us that establishing a line item in the annual budget is easier than requesting a lump sum every three years.

We recognize that participation in the FACT accreditation process is voluntary and that your participation reflects a commitment to quality outcomes for your patients that goes far beyond any accreditation fee. We will continue to support these efforts to the best of our ability in ways that both control costs but enhance value to your programs.

Sincerely,
C. Fred LeMaistre, MD

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New Cellular Therapy Fee Structure Emphasizes Ongoing Activities

FACT will begin implementing cellular therapy accreditation fees on an annual basis starting July 1, 2009. The annual fees will cover one year of FACT accreditation for all aspects of cellular therapy endeavors, including Clinical Programs in addition to cell collection and processing. The annual fees also include inspection costs, year-round assistance, and access to resources such as quality management tools, [press kit materials](#), [publications](#), [guidelines](#), [webinars](#), [tutorials](#), and many more. See the insert **2009 Annual Cellular Therapy Fees for FACT Accreditation** for details.

These smaller, routine expenditures will avoid large, unplanned fees at the beginning of each accreditation cycle.

Although the overall cost of accreditation experienced a modest increase, the smaller, routine annual expenditures will assist programs during the annual budgeting process and avoid large, unplanned fees at the beginning of each new accreditation cycle.

No additional fees will be charged at the time of a program's renewal inspection. Programs who have already submitted the previous three-year accreditation fee will not be assessed an annual fee until the beginning of their next accreditation cycle.

2009 Annual Cellular Therapy Fees for FACT Accreditation

Base Fee	Clinical Program Fee	Collection Facility Fee	Processing Facility Fee	Full Program Fee	Supplemental Fee
\$3,000	\$1,550	\$1,550	\$1,550	\$7,650	\$1,800

Note: The full program fee includes one clinical site, one marrow collection site, one peripheral blood progenitor cell collection site, and one processing facility. Programs comprised of additional sites will be charged the supplemental fee. Partial programs will be assessed fees based on the component parts (e.g., a stand-alone processing facility will incur an annual fee of \$4,550).

Examination of 4th Edition Standards Available to All Cellular Therapy Inspectors

FACT inspectors are required to maintain knowledge of the current Standards, which is verified by requiring inspectors to complete the written [Inspector Test](#) for each edition of the Standards as they are published. Before an individual is scheduled to conduct an inspection under the fourth edition of the [FACT-JACIE International Standards for Cellular Therapy Product Collection, Processing, and Administration](#), he/she must submit a completed test over the Standards to ensure knowledge of the Standards and the intent of the [Cellular Therapy Standards Development Committee](#).



Royal Brisbane and Women's Hospital including the Royal Children's Hospital Bone Marrow Transplant Program is the first transplant program outside of North America to receive FACT accreditation.

During the transition to the fourth edition, inspectors were asked to submit the completed Inspector Tests as they were scheduled for inspections. Since inspectors now have their printed copies of the Standards and the accompanying Accreditation Manual, FACT is requesting all inspectors to complete the test and submit it to the FACT office via email at fact@unmc.edu or via fax to 1-402-559-1951.

ISCT North America Legal and Regulatory Affairs Committee

The FACT Program Relations Survey results, published in the Winter 2009 newsletter, reported that accredited and applicant programs desired more support regarding regulatory issues. In response, FACT has teamed up with one of its parent organizations, the International Society for Cellular Therapy (ISCT), to promote the use and benefit of the [ISCT North America Legal and Regulatory Affairs Committee](#)'s current mission and objectives.

This committee, chaired by Kurt Gunter, MD, those working in cellular therapy by providing information regarding regulations, standards, guidance, and best practices in the U.S., Canada, and worldwide. It engages in several activities that are beneficial to FACT accredited and applicant programs such as [webinars](#) throughout the year, which can be found on the ISCT website. In addition, the committee provides updates regarding regulatory announcements and submits comments on behalf of the field to regulatory agencies. These announcements can be found on the Bulletin Board on the [ISCT home page](#).

FACT teamed up with one of its parent organizations to promote the use and benefit of the ISCT North America Legal and Regulatory Affairs Committee.

Future editions of the Just the FACTs Newsletter will provide updates of the committee's activities, specifically how they benefit FACT accredited and applicant programs. FACT encourages programs to take advantage of the assistance the ISCT North America Legal and Regulatory Affairs Committee provides.

Several FACT Training Workshop Opportunities Remain

Three more inspection and accreditation workshops are scheduled for 2009. This year's format has been a success, with participants agreeing again that presentations are interesting, effective, and organized.

New information for the cellular therapy workshop includes updates on the fourth edition Standards and information on how to maintain accreditation. The cord blood workshop added several case study exercises throughout the day to provide hands-on, practical experience applying the Standards to actual scenarios.

Upcoming FACT Inspection and Accreditation Workshops – REGISTER TODAY!

Cellular Therapy (ISCT Annual Meeting)	May 3, 2009	San Diego, California
Cellular Therapy Collection Inspector (ASFA Annual Meeting)	May 19, 2009	San Diego, California
Cord Blood (CB Symposium)	June 7, 2009	Los Angeles, California

ACCREDITATION REPORT

Cellular Therapy

197 Registered
171 Accredited
26 Applications Pending

Cord Blood

59 Registered
17 Accredited
42 Applications Pending

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

Information from Interaction . . . Content Directed by Our Readers

Give us the FACTs Poll

How do you garner support from administration for Quality Management resources?

Give us the
FACTs!

In Your Opinion . . .

Would your program be willing to provide example documents for Quality Management education?

In Your
Opinion . . .



You Ask We Answer

FACT often receives several questions about similar issues from inspection evaluations and direct feedback. A common question is, *“If a Processing Facility uses its institution’s blood bank disaster plan, is it in compliance with FACT Standards?”* This is compliant if:

- The plan contains enough detail so that the cell processing staff would know what to do in case of a disaster.
- The processing lab staff has access to the plan.
- The processing lab staff is notified and re-trained when the plan is modified.
- The plan is reviewed at least every two years after implementation.

To Do List:

Remember to update FACT with any updates to addresses, phone numbers, or credentials. An updated Curriculum Vitae is always welcome.

Introducing . . . The FACT Quality Corner

FACT has implemented a new quality section in upcoming newsletters that will feature a variety of experts in the area of Quality Management. This section will be used as a forum to discuss current Quality Management topics that are relevant to the transplant community. As previously noted in the Winter 2009 Special Report on the Program Relations Survey Results, development of a comprehensive Quality Management Program is often one of the most challenging and time-consuming exercises that a program encounters when preparing for a FACT inspection. This new section will create awareness and clarity to commonly misunderstood aspects of a Quality Management Program as applicable to FACT Standards.

In addition, the Quality Corner will also provide suggestions and examples of how various accredited programs tackle the featured issues to maintain compliance with the current FACT Standards.

If you have a Quality Management question or topic you would like to see addressed in upcoming issues, please contact Jill Hempel, FACT’s Quality Assurance Coordinator, at 402-559-1968 or jhempel@unmc.edu.