

Submit Applications for ISBT 128 Label Variance

The following is an updated reprint of an article that appeared in the June 2007 issue of BloodNews.

To better serve our customers, United Blood Services has moved our ISBT 128 transition date to April 28, 2008. We want to ensure that all facilities that plan to label blood products are moving forward with their plans for implementation

and will be ready to switch to the new labeling April 28. In order to comply with US Food and Drug Administration regulations, all facilities requiring a variance to any type of ISBT 128 blood label will need to submit their labels to FDA

for approval prior to the new deadline. The FDA approval process may take several months. Here are some guidelines for submitting your labels:

1. Acquire a list of FDA-approved ISBT 128 label types, US Labels to be Submitted to the FDA. The list is available on our Web site at www.UnitedBloodServices.org/HH/isbt-labeltypes.asp. It is also available on the Members side of the ICCBBA Web Site: www.iccbba.org. (Click on "US Labels to be Submitted to the FDA.")

2. If any of your labels vary from the list of FDA-approved label types, you will need to apply for a variance. Print out samples of all ISBT 128 labels that your facility will need to submit for variance.

3. Fill out FDA Form 2567, Transmittal of Labels and Circulars. (Available at www.fda.gov/opacom/morechoices/fdaforms; then scroll to Form 2567.)

4. Submit your sample labels and Form 2567 along with a cover letter requesting a variance to the wording of the component description. Include this verbiage in your cover letter: "We are requesting a variance under 21 CFR 640.120 for [your facility name]

to use the United States Industry Consensus Standard for the Uniform Labeling of Blood and Blood Components using ISBT 128 Version 2.0.0 instead of 21 CFR 606.121(e)(1)(ii)."

5. The FDA will respond with either approval, rejection or suggestions for changes to the application.

Please keep in mind that the variance approval process could take several months and therefore your application will need to be submitted well in advance of the April 28 deadline. As always, if you need any help with your application submission or have any other questions regarding the ISBT 128 transition, contact your local United Blood Services representative or Helen Pleasant at hpleasant@bloodsystems.org.



BBT applications due March 15

March 15 is the deadline for applications for the online Blood Bank Technology Program presented by The University of Texas Southwestern Medical Center in cooperation with Blood Systems Laboratories. For information about the program and an application, please visit <http://www.bloodsystemslaboratories.org/blood-bank-technology-program.shtml>. Program graduates are awarded a post-baccalaureate certificate in blood bank technology or a continuing education certificate and are eligible to take the certification examination for Specialist in Blood Bank Technology administered by the Board of Registry of the American Society for Clinical Pathology.



BloodNews is published by United Blood Services for the hospitals we serve. Media inquiries can be made to Barb Kain at (480) 675-5664. The United Blood Services network is one of the nation's oldest and largest non-profit blood service organizations, and is a founding member of America's Blood Centers and the AABB.

'On Q' Training Schedule

On Q is our quality training program designed to help transfusion services conform to today's complex regulatory environment while providing your employees with practical, easy to understand knowledge of quality and regulatory concepts.

February	Las Vegas, NV
April	Albuquerque, NM Reno, NV
May	Billings, MT Fargo, ND Cheyenne, WY
August	Scottsdale, AZ

PACE Programs Now Online

Hospitals that choose United Blood Services as their blood provider get more than blood delivered to their doors. You get personalized service, a myriad of resources and educational opportunities for your staff. One of the educational opportunities is United Blood Services' PACE®-accredited programs. (United Blood Services is an approved PACE provider.)

The PACE programs allow hospital staff to earn continuing education credits at their convenience with timely and relevant information on topics that are vital to their lifesaving work. The programs are a few hours long and each class carries one or more Continuing Education Units (CEUs).

United Blood Services debuted the PACE program in 2003 with two courses. That year, 56 certificates of completion were issued. This year, staff at hospitals throughout our 18-state service area earned nearly 2,000 certificates and attendees at our Quality School earned another 1,148.

There are seven PACE programs that were originally packaged on CD. They are now available online: <http://www.bloodsystemseducation.org>.

Hospital staff who take the PACE courses give them high marks. Post course evaluations show mostly 4 and 5 ratings (on a 1-5 scale, with 5 being the highest).

United Blood Services Researcher to Advise HHS on Blood Stem Cell Transplantation

HHS Secretary Mike Leavitt has appointed a United Blood Services researcher to the new HHS Advisory Committee on Blood Stem Cell Transplantation (ACBST). Elizabeth J. Read, MD, is the Director of Cell and Tissue Therapies at Blood Systems Research Institute (BSRI), the internationally acclaimed transfusion medicine research division of United Blood Services' non-profit parent organization, Blood Systems. She joins 22 other leading scientists on the new advisory council that will study and make recommendations on issues pertaining to blood stem cell transplantation.

Dr. Read is a world-renowned authority on human cellular therapy. Much of her career has involved translational "bench to bedside" research and she has particular expertise in cellular product development as well as regulatory and safety issues.

Before joining BSRI in 2006, Dr. Read was Chief of the Cell Processing Section in the Clinical Center Department of Transfusion Medicine at the National Institutes of Health (NIH). In that position she was responsible for a large and active core laboratory whose mission was to support development and manufacturing of cell and tissue products for NIH clinical trials in blood stem cell transplantation, immunotherapy and gene therapy.

Faster Turnaround for Final Case Reports

Our Immunohematology Reference Laboratory now faxes Final Case Reports to your laboratory. Customers have requested faster turn-around time on these reports to facilitate patient billing and this change shaves several days off the process. Please verify that your facility fax number is accurately documented on the Reference Laboratory Request form (BS313) submitted with the samples. The fax number on your request must allow reports to be retrieved by laboratory personnel 7 days a week, 24 hours a day.