

American Red Cross Support for ISBT 128

Frequently Asked Questions—February 2006

1. How is the American Red Cross working with the individual software vendors to assist in the transition to ISBT 128?

The American Red Cross will comply with the ISBT 128 labeling requirements of ICCBBA, Inc. To assist customers in the conversion to ISBT 128, the American Red Cross has provided copies of key documents issued by ICCBBA, which describe the technical aspects of the transition. Hospitals should go to the ICCBBA website to view a list of software vendors who have registered with ICCBBA (http://iccbba.com/reg_vendorlisting.htm). The American Red Cross is not working with individual software vendors.

Regional CEOs and regional account managers (RAMs) can provide the following reference documents, which hospitals may share with vendors:

A. United States Industry Consensus Standard for the Uniform Labeling of Blood and Blood Components Using ISBT 128

B. ISBT 128 Standard Technical Specification

Vendors should be directed to ICCBBA to obtain the most recent information on ISBT 128 labeling requirements and technical specifications.

2. What is the scheduled target date for complete development and launch of ISBT 128-labeled products?

The American Red Cross will be converting to the ISBT 128 labeling standard for blood products no earlier than October 2006, but no later than March 2007. The exact deployment date for ISBT 128-labeled products has not been finalized; however, American Red Cross will identify the specific timeframe by spring 2006.

In the meantime, CEOs and RAMs will assist in customer preparation using the estimated timeframes outlined in Question 7.



3. Will the American Red Cross produce a book of mock-up labels? Where can I see label examples in the meantime?

Yes. Once the FDA approves examples of the labels proposed for use by the American Red Cross, we will create a book of mock-up labels for our customers. To view a sample ISBT 128 label, hospitals may refer to *An Introduction to ISBT 128 2nd Edition*, available from ICCBBA.

4. Will the ISBT 128 labeling system apply to autologous units?

Yes. After ISBT 128 implementation, all units collected and labeled by the American Red Cross will use the new standard for labeling.

5. Will transfusion services (hospital blood banks) be required to pay registration fees to ICCBBA?

The American Red Cross does not control this activity. Hospitals should refer to the following guidance provided to us from ICCBBA:

If the facility manufactures, processes, repacks, or relabels blood or blood products intended for transfusion, and the facility is AABB accredited, the facility will have to use ISBT 128 labeling and register with ICCBBA no later than May 2008. The fee structure may be obtained from the ICCBBA website: www.iccbba.com

Once registered, the facility may obtain new product codes and current copies of all ICCBBA documentation. For facilities that do not collect, but only transfuse blood products, the ICCBBA Board of Directors has decided that registration and licensing are not required.

The following exceptions apply and registration is required for these facilities if the facility:

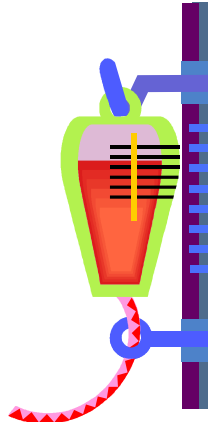
- ◆ Modifies blood products and relabels them using ISBT 128 data structures (bar codes)
- ◆ Wishes to receive all ISBT 128 documentation and updates and access the “licensees only” section of the ICCBBA website



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6. Many hospitals operate using manual systems and processes. Is it necessary for these hospitals to buy and install computers to meet the ISBT 128 labeling requirements? How should manual labeling processes be updated to account for the new, computer-based labeling standard?



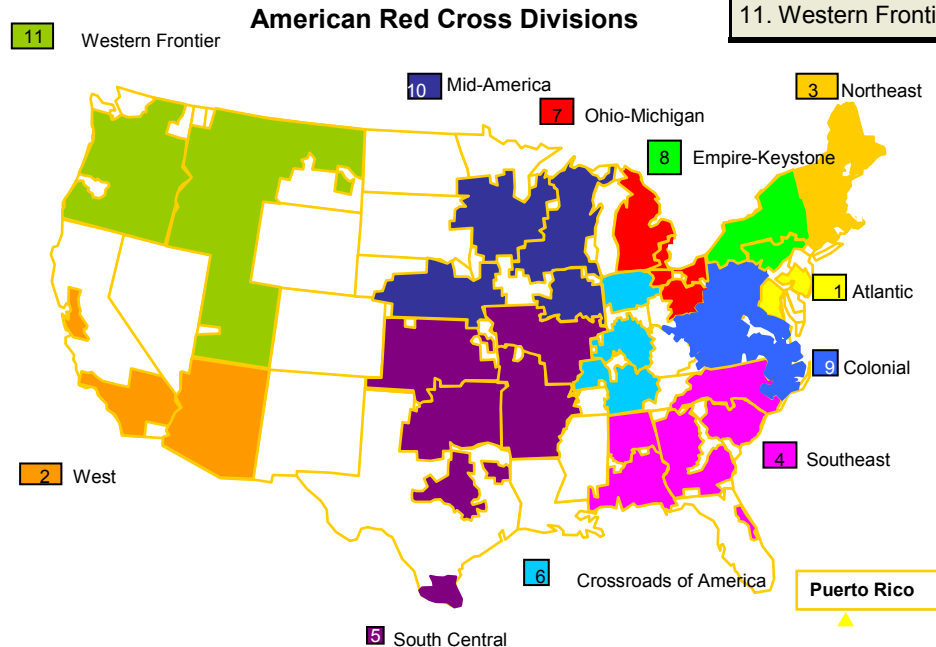
The American Red Cross does not control this activity and refers all hospital customers to IC-CBBA documents for official guidance. Although these customers will have different concerns, hospitals that do not use computers in the labeling process should be prepared to receive ISBT 128-labeled products.

It is not necessary for hospitals to have a computer to accept ISBT 128 products. However, whether or not they have computers, all hospitals will experience significant change when converting to ISBT 128-labeled blood products. Each hospital is responsible for training staff, as well as updating procedures and forms, with changes that will occur when the American Red Cross converts. The American Red Cross is available to guide hospitals in identifying the ISBT 128 impacts.

7. Will there be a period of transition when the Codabar and ISBT 128 labeling systems will be used?

Yes. During the 14-month deployment schedule, the American Red Cross will produce and distribute blood products with both Codabar and ISBT 128 labels. After deployment to all American Red Cross regions, ISBT 128 labeling will be the American Red Cross standard. All blood products produced by the American Red Cross will have only ISBT 128 labels. However, frozen blood products with an expiration date of one year or more will continue to be distributed until those supplies are exhausted. Hospitals should use the table and chart below to plan for ISBT 128 label readiness:

Division	Earliest target date for hospitals to receive ISBT 128-labeled products
1. Atlantic & Puerto Rico	September 2006
2. West	November 2006
3. Northeast	November 2006
4. Southeast	November 2006
5. South Central	April 2007
6. Crossroads	April 2007
7. Ohio-Michigan	April 2007
8. Empire-Keystone	April 2007
9. Colonial	July 2007
10. Mid-America	July 2007
11. Western Frontier	July 2007



American Red Cross and ISBT 128

Frequently Asked Questions—July, 2005

What is ISBT 128?

The International Society of Blood Transfusion (ISBT) developed a replacement for the ABC Codabar bar code symbology, which has reached its limit of usefulness in a world of increasing information complexity. The new bar code symbology, ISBT 128, allows every blood product to be identified and tracked anywhere in the world through the use of a donation identification number (DIN). The conversion to ISBT 128 is not just a Red Cross initiative, but one that is occurring industry-wide. We are not the first provider to convert in the US; there are several other US blood providers that are currently converting, including the military.

Why is the American Red Cross converting to ISBT 128?

The American Red Cross has agreed with the recommendations of ISBT, AABB and the FDA to convert to ISBT 128. The conversion process will begin with the transition to our new blood processing software starting in late summer



2006. ISBT 128 provides the following benefits:

- Uniform label format
- Unique donation ID number
- Donation type information
- Expanded descriptive product codes
- Capture special test information
- Data identifiers for bar code

Why is ISBT 128 important to the hospital customer?

- ISBT 128 is more than a new label. It is an end-to-end transfusion process and quality improvement standard
- ISBT 128 will help hospitals comply with recent FDA guidance about machine-readable labels on blood products

Will hospitals have adequate time to prepare for the change?

- If a hospital does not have a computer, they will have adequate time to upgrade their processes, forms and records to accommodate new ISBT 128 data structures



such as Donation Identification Number and Product Codes

- The hospital will have adequate time to resolve issues such as:
 - ◆ *New product codes used by billing service*
 - ◆ *Nursing and staff education on new ISBT 128 labels and terminology*
 - ◆ *Assessment of bar code readers and label printers for compatibility with ISBT 128 bar codes*

Most importantly, the hospital needs to be ready when the American Red Cross starts providing ISBT 128-labeled blood products or products obtained from non-American Red Cross centers that have converted to ISBT 128.

How will The American Red Cross be able to assist with ISBT 128 conversion?

- The American Red Cross Region will provide hospitals with a map of Codabar to ISBT 128 Product codes

- The American Red Cross Region will provide hospitals with ISBT 128 labels
- The American Red Cross Region will provide an ISBT 128 tool kit with background information and technical specifications
- If a hospital computer is not ISBT 128 compatible, the American Red Cross will provide adequate time to upgrade prior to the transition to ISBT 128

Where can hospitals find more information about ISBT 128?

- <http://www.iccbba.com>
 - ◆ The International Committee for Commonality in Blood Banking Automation (ICCBBA) is an international organization formed specifically to manage, expand and extend the ISBT 128 standard.
 - ◆ On the main page, click on "ISBT 128" for general ISBT 128 information
- Review the documents provided on the ISBT 128 tool kit CD, given to you by your Account Manager

For further information:
Contact your Regional Account Manager or send email to isbt128@usa.redcross.org



Together, we can save a life