

American Red Cross Support for ISBT 128

Frequently Asked Questions—March 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 blood labeling requirements of ICCBBA, Inc. To assist customers in converting to the ISBT 128 labeling system, 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 Red Cross is not working with individual software vendors.

Regional CEOs and 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 not earlier than October 2006. The exact deployment date for ISBT 128 labeled products has not been finalized; however, Red Cross will identify the specific timeframe by Spring 2006.

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



3. Will the 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, re-packs, or re-labels 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 can 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 re-labels them using ISBT 128 data structures (bar codes).
- ◆ the facility wishes to receive all ISBT 128 documentation and updates and access the “licensees only” section of the ICCBBA website.

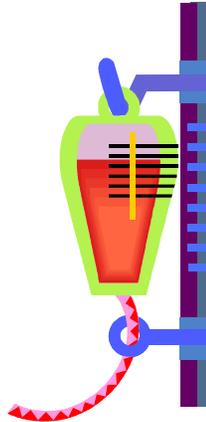


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6. Many hospitals operate using manual systems and processes. Is it necessary for these hospitals to buy and install computers to meet the ISBT 128 labeling requirements? How should manual labeling processes be updated to account for the new, computer-based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



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

It is not necessary for hospitals to have a computer in order 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 Red Cross converts. The American Red Cross is available to help guide hospitals in identifying the ISBT 128 impacts.

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

Yes, during the 14-month deployment schedule, American Red Cross will produce and distribute blood products with both Codabar and ISBT 128 labels. After deployment to all Red Cross Regions, ISBT 128 labeling will be the Red Cross standard. All blood products produced by the American Red Cross will only have ISBT 128 labels. However, frozen blood products with an expiration date of a 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	Date for hospitals to be compliant with ISBT 128
Atlantic & Puerto Rico	September 2006
West	November 2006
Northeast	November 2006
Southeast	November 2006
South Central	April 2007
Crossroads	April 2007
Ohio-Michigan	April 2007
Empire-Keystone	April 2007
Colonial	July 2007
Mid-America	July 2007
Western Frontier	July 2007

Red Cross Divisions

