

Oklahoma Blood Institute



ISBT 128

Implementation Plan

October, 2006

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INTRODUCTION

The International Society for Blood Transfusion (ISBT) 128 uniform labeling standard was designed to capture additional and more complex information regarding the identification and content of blood and blood products on the label and to make that information universally accessible to the international blood banking community. The standard was later expanded to address labeling of hematopoietic progenitor cells and tissues, as well as allow for electronic data interchange. This information transfer system, with its internationally recognized data structures and content, provides advanced capabilities for manufacturing process control, inventory control, and automation in an industry with ever-increasing demands for global distribution. All of these are benefits resulting from ISBT's aim to enable improved efficiencies, documentation, and most important, transfusion and transplantation safety.

As with the introduction of any novel approach or technology, however, the blood banking and transplant communities recognized a need to carefully consider the ability of users to implement the new standard. Considerations included its impact on existing systems, the training and resources that would be required, and any unforeseen obstacles that might be encountered. In July 1997, the American Association of Blood Banks (AABB) hosted a workshop to discuss issues surrounding the implementation of the new uniform labeling standards for blood and blood products using ISBT 128. The participants at that meeting represented all segments of the blood banking community. Several issues were identified that required further exploration and analysis and AABB appointed an ISBT 128 Task Force to address specific concerns, including the need to:

- Determine a realistic implementation date for conversion to ISBT 128
- Establish a repository of existing information and determine mechanisms for disseminating that information to the AABB membership and to nonmember hospitals
- Generate additional information and experience regarding implementation and to assess the impact on other hospital systems

The International Society for Blood Transfusion (ISBT) 128 uniform labeling standard with its internationally recognized data structures and content, provides advanced capabilities for manufacturing process control, inventory control, and automation in an industry with ever-increasing demands for global distribution.

The Oklahoma Blood Institute Implementation Plan consists of a timeline and Gantt chart that we will follow or use as a reference as we undertake the process of ISBT 128 implementation. The narrative information will be used in conjunction with the Implementation Plan.

IMPLEMENTATION PLAN

The AABB has formed an ISBT 128 Task Force to address the issues confronting the blood banking community with regards to implementing ISBT 128 within their various facilities. The Oklahoma Blood Institute has developed an ISBT 128 Implementation Plan that consists of a timeline and Gantt chart that we may follow or use as a reference as we undertake the process of ISBT 128 implementation.

The narrative information in this section provides some detail for selected steps in the time line. It will be used in conjunction with the Implementation Plan. The timeline may or may not contain all the steps required for implementation. It is intended to be used as a guideline, to be modified as necessary.

Identify Project Champion (Step 2)

John Armitage, MD has been identified as the project champion for Oklahoma Blood Institute as the orchestrator in this facility's conversion to ISBT 128. He is committed to the project and willing to get acceptance and commitment for participation from all areas and individuals whose involvement will be mandatory for ISBT 128 implementation success.

Assemble and Review Educational Materials (Step 3)

The project manager assembled all necessary education materials that are readily available regarding ISBT 128. These materials will be carefully evaluated. The various resource materials were acquired by contacting the AABB and the ICCBBA. The contact information is listed below:

American Association of Blood Banks
8101 Glenbrook Road
Bethesda, MD 20814-2749
Fax 301-907-6895
E-mail aabb@aabb.org
<http://www.aabb.org>

ICCBBA
204 St. Charles Way, Unit 179E
York, PA. 17402
717-845-9727
E-mail iccbba@iccbba.com
<http://www.aabb.org> <http://www.iccbba.com>

Medical Director/President Buy-in (Step 7)

John Armitage, MD, the President/CEO for the Oklahoma Blood Institute and the project champion for our ISBT 128 implementation, understands ISBT 128 labeling and the impact it will have on the Institute, its transfusion service, and the many outside client institutions we serve. Educating those medical directors and informing him/her of the benefits of ISBT 128 will enable him/her to accept the change and give it the support necessary for implementation.

Administration and Laboratory Management at the Oklahoma Blood Institute have been informed about the change to ISBT 128. Conversion (Step 8)

Informing the laboratory administration and other laboratory supervisors about the change to ISBT 128 has been done as well. They have been alerted to the fact that their areas will be affected, but that a plan has been drafted to assist the entire institution in the implementation process. They are aware that Dr. John Armitage, MD is in full support of our implementation of ISBT 128 facility wide.

Get Management Approval to Develop Implementation Plan (Step 9)

The appropriate laboratory personnel and assistant/associate medical directors have been informed of the change to ISBT 128. They understand that the plan will take many months and involve multiple persons from various areas, such as all personnel working with blood products, bags, computer software, etc.

Develop a Business Plan (Step 10)

The implementation of ISBT 128 will involve expenses that will need to be justified with a business plan. We will evaluate all possible expenditures and whether they can be funded with current budgets or will require additional funding. A business plan template has been included if our institution chooses to use this one or one we already have in-house. Refer to Addendum A.

Approval from Administration to Proceed (Step 14)

Once the business plan is completed, approval from the Oklahoma Blood Institute Executive Management will be acquired to begin the implementation process, keeping in mind that the business plan may need budgetary approval and this may not occur immediately. Tasks will proceed that will not require an outlay of money.

Register with ICCBBA (Step 15)

All computerized transfusion services that will scan the bar codes on blood product labels, vendors, and blood collection facilities will be required to register with the ICCBBA. Contact the ICCBBA office by fax to request registration information. Once you register, you will be given access to the US Consensus Standard, the ISBT 128 Standard Technical Specification, version 2.0.0, and the databases for ISBT 128.

Registration with ICCBBA (Step 16)

Registration with the ICCBBA is done by contacting them at fax number: (717) 845-9727. Request the registration information.

Review ISBT Guidance Document (Step 17)

The Oklahoma Blood Institute is computerized and will scan the bar codes on the labels of blood products. An important document, titled the US Consensus Standard, is available from the FDA on its website, <http://www.fda.gov/cber/gdlns/ISBT128Nov99.pdf>.

Understanding New Product Code Changes (Step 18)

The changes included in the new ISBT 128 product labeling are many. The Oklahoma Blood Institute will fully understand all product code changes and how they may affect our operations. The product code has increased in size to eight characters. It includes the product code (characters 1-5), intended use (character 6), and division/splits (characters 7 and 8). A brief description appears below and a sample label appears in Addendum B (page 13). The donation identification number has 13 eye-readable characters and is next to the ABO/Rh label. The ABO/Rh blood group label will appear in the upper right quadrant of the product label. The ISBT 128 blood product bar code will appear to the left of the expiration date. The expiration date and time will appear on the lower right quadrant of the product label. Facility identification and FDA license and registration numbers are on the top left of the label near the donation identification number. On-demand labels will be printed in black and white.

Contingency Planning (Step 19)

The Oklahoma Blood Institute will decide how to enter, process, dispense, and transfuse ISBT 128 labeled products if they are received into our institution before implementation. We will decide how frozen inventories of Codabar labeled products will be handled after the ISBT 128 implementation. We will begin assessing our computer system's capability to handle ISBT 128 (hardware and software) and this will be critical. We will begin discussions with all necessary vendors, manufacturers and blood product suppliers to ascertain their readiness to support ISBT

128. We will also remember to consider whether upgrades to current information systems will be needed and if they are going to be available. If not, we will consider our options for purchasing a new blood bank information system that will support ISBT 128. We will be sure to review labels from all of our suppliers to be sure we can read all bar codes on their product labels.

Implementation Plan (Step 20)

This section includes many, but possibly not all, issues that may need to be addressed by our institution for successful implementation of ISBT 128. A good way to obtain answers to more specific questions is to post questions on either the ICCBBA or AABB web sites.

Budget Approval (Step 38)

Preparation of a budget to support the implementation of ISBT 128 is an important part of the Implementation Plan. We will evaluate all hardware, software, and devices to ensure they will support ISBT 128. If they do not, we will work with our vendors and be sure any upgrade expenses for this are included in our budget. As soon as our budget is complete, we will take the necessary steps to obtain approval. Once again, our site's budget review and approval follows a specific cycle and we may have to wait to present it and have it approved. If budget approval does not occur immediately, we will refer to our Contingency and Implementation Plans. There may be areas or issues that can be addressed while awaiting approval of the budget.

Identify Transition Team (Step 40)

We will contact key individuals in all areas of the institute that will be affected by the conversion to ISBT 128 who would be willing to join our team. The persons selected will be aware of ISBT 128 and how it may affect their areas. Also, we will consider individuals outside of our organization that will play an important role in making our implementation of ISBT 128 a success. Team members to consider include personnel from the blood center, the transfusion services we are contracted with, laboratory information systems (LIS) department, nursing service, laboratory management, billing and the testing laboratory.

Update Contingency Plan (Step 42)

As progress is made and new issues arise, we will modify our Contingency Plan as necessary, keeping all persons on the transition team and management updated on any changes or additions to the Contingency or Implementation Plans.

Define Transition Plan (Step 43)

We will keep all persons on the transition team and management updated on any changes or additions to the Contingency or Implementation Plans. The support of both bar code symbologies will be essential during the overlap of label types during the phase-in period and for the receipt of products from non-ISBT compliant blood product suppliers.

To assist all areas affected by the implementation of ISBT 128, we will draft a plan on how the change will occur. This will include the date that products labeled with ISBT 128 are expected to be sent/received.

Questions to be considered include the following:

- Will the transition occur in phases? If so, how are those phases defined and what is the timeline associated with each phase?
- When will software be available to support ISBT 128?
- If software for the current computer system will not be upgraded (either by in-house development or by commercial vendor), what options are available for obtaining a new blood bank information system?
- If ISBT 128 products are received before software support is available, will manual data entry be possible?
- How will look-back be handled?
- What type of audit system will be needed for this plan?

Define Validation Plan (Step 48)

The Oklahoma Blood Institute will write a plan to validate our standard operating procedures (SOPs), hardware (label printers, bar code readers, etc), software that supports ISBT 128, interfaces, training of personnel, transition plan, and maintenance of ISBT 128 labeling of products.

Order and Receive Laboratory Software (Step 49)

If our transfusion service software cannot support the increased size of the donation identification number, changes to the ABO/Rh label, changes to product code label, or changes in expiration date, we will need to work with your vendor (whether the software was developed in-house software or commercially manufactured) to obtain these enhancements. Also, we will confirm with our vendor that the software can accommodate both Codabar and ISBT 128.

The support of both bar code symbologies will be essential during the overlap of label types during the phase-in period and for the receipt of products from non-ISBT compliant blood product suppliers. Frozen inventory that is labeled with Codabar should not be relabeled if the system can support both bar codes.

We will ask our suppliers/vendors about the availability of software that supports ISBT 128 and confirm dates of delivery and installation if applicable. If there is delay, we will update our Contingency Plan accordingly.

Order and Receive New Hardware (if necessary) (Step 50)

We will evaluate our bar code scanners to determine if the scanner can read ISBT 128. Can it autodiscriminate between ISBT 128 and Codabar? Can our scanner concatenate ISBT 128 bar code symbols? If not, we may need to order new scanners for our laboratory. This purchase or upgrade will be included in our business plan and budget.

We will ask our supplier about the availability of hardware that supports ISBT 128. Confirm dates of delivery and installation. If there is delay, we will update our Contingency Plan accordingly.

Install Hardware (if necessary) (Step 51)

We will prepare our site for the hardware installation. We will ensure appropriate personnel are on-hand for the process. We will perform preliminary installation checks to ensure hardware functionality.

Install Software; Perform Preliminary Validation of Software (Step 52)

We will install the software and run checks to ensure that the software is loaded correctly and the system is accessible to those who will perform the validation.

Formal Software, Hardware, and System Validation (Step 53)

Following a comprehensive plan, we will perform validation for the hardware, the software, and then the entire system. We will document all results and follow up with vendors for issues that need attention. We will also perform revalidation for any corrections provided by our vendors or process changes that may occur as a result of previous validation.

We will be sure management and/or administrative acceptance of the validation is received and documented.

Modify Standard Operating Procedures/Forms (Step 54)

When validation of our system has been performed and accepted, review all SOPs (including laboratory and all other areas affected with this implementation) and will update as necessary.

This will include the quality program and its inclusion of ISBT 128 labeling as well as our procedure manuals, forms, and training documents.

Define Maintenance Plan (Step 55)

We will define how our site will maintain ISBT 128 and implement upgrades. We will also identify how our institution will support migration to standardized data elements to support current good manufacturing practice (cGMP) and quality system requirements (QSRs). We will review all SOPs and update as necessary. This will include the quality program and its inclusion of ISBT 128 labeling as well as our procedure manuals, forms, and training documents.

We will identify who will need to be trained and what materials will be required for each group being trained. We will identify how a trainee will be accessed for competency and what information must be recorded and maintained from the training process.

Define Quality Assurance Plan (Step 56)

Quality Assurance unit will review the Implementation and Contingency Plans. The Quality Assurance unit will evaluate the plan for its inclusion of ISBT 128 labeling and determine how ISBT 128 will affect the Quality Plan in areas in which process control is needed. The Quality Plan will be evaluated as to the impact of change to ISBT 128 for each GMP and each system.

We will modify and monitor incident/error/accident review policies.

Preparation of FDA Notification Packet (Steps 57-60)

See Addendum C for a sample letter we may use to when notifying the FDA. All facilities must notify the FDA. The same letter may be used for unlicensed unregistered, registered, and licensed facilities. Note that additional information is required for licensed facilities.

Submit 510(k) Application (Step 61)

Oklahoma Blood Institute will determine if any of our in-house developed software will meet these criteria:

- If your site develops its own software and your site is regulated by the FDA as a device manufacturer, you must identify whether a 510(k) application or an addendum to the current 510(k) submission will be required for any changes made to your software.
- The same procedures used for evaluation of software changes with regards to 510(k) submission should be applied to the changes made to support ISBT 128.

Develop Training Materials (Step 62)

The Oklahoma Blood Institute will review all documentation acquired from the AABB and ICCBBA. We will review all user guides that have been provided by our software and hardware vendors. We will identify who will need to be trained and what materials will be required for each group being trained.

All SOPs will be updated and approved prior to personnel training. Identification of how a trainee will be assessed for competency and what information must be recorded and maintained from the training process will be determined.

Staff Training (Step 63)

Staff training will begin at a time that will allow ample time to educate all persons involved but not too far removed from the actual implementation date.

We will continue communication with our vendors and suppliers. They may be willing and able to assist in certain training aspects. Training is an on-going process that may be a part of many steps within the timeline.

Begin Use (Step 64)

Monitor the ICCBBA web site for additional information. As more facilities begin to use ISBT 128, more information will be posted on the web site.

Assess Progress (Step 65)

As a part of our Quality Assurance Plan, we will track the implementation progress and success. We will evaluate whether it has increased errors and accidents. This information may be very important when writing up and or identifying corrections for the errors and accidents identified. The FDA has suggested tracking all errors for the first 5000 labels printed.

Addendum A. Business Development—Project Definition Form (Continued)

Description of Capital Equipment Required (estimate dollar amount): _____

Description of Expertise Required (Consultant, Training, Validation, FTE, Time Commitment [estimate dollar amount]): _____

Key factors required for program to be successful: _____

How is this project consistent with mission, strategic plan and business objectives:

Who is the market/audience for this particular program/service? _____

How should the success of this program/service ultimately be measured? _____

Addendum B. Sample Label—Codabar and ISBT 128 Comparison

ABC CODABAR vs ISBT 128 Blood Component Labels

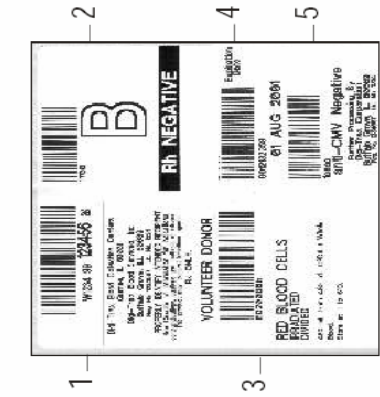
ABC CODABAR vs ISBT 128 Blood Component Labels

An Example of an ABC CODABAR
Red Blood Cell Label



1) Donation Identification Number—up to 2 alpha characters followed by 5 numerics. 2) ABO/Rh Blood Group—color coded. 3) Blood Product Code—red, black & white colors. 4) Product Expiration Date/Time. 5) Special Testing (eg, CMV Negative) (Note: Facility ID, FDA License & Registration Numbers on bottom right of label).

An Example of an ISBT 128
Red Blood Cell Label



1) Donation Identification Number—has 13 eye-readable characters and is next to the ABO/Rh, 2) ABO/Rh Blood Group. 3) ISBT 128 Blood Product Code—next to expiration date. 4) Expiration Date/Time. 5) Special Testing (eg, CMV Negative) (Manufacturers' bar code are on primary bag base labels but have been overlaid in this example. Note: Facility ID, FDA License & Registration Numbers are on top left of label near Donation ID Number. On-demand printed labels are black and white).

Addendum C. Sample Letter for FDA Notification

To: Director, Division of Blood Applications (HFM-375)
Food and Drug Administration
Center for Biologics Research and Review
Woodmont Office Center, Suite 200N
1401 Rockville Pike
Rockville, MD 20852-1448

From: Oklahoma Blood Institute
1001 N. Lincoln Blvd
Oklahoma City, OK 73104

Subject: Request for variance for conversion to ISBT 128

Our establishment requests a variance under 21 CFR 640.120 to delete the modifiers preceding the proper name of the blood products [21 CFR 606.121(c)(1)] in order for our establishment to convert our labels to the ISBT 128 format.

Sincerely yours,

(Authorized Person)

Note: Licensed establishments should submit, in addition, FDA Form 2567: "Transmittal of Labels and Circulars," and copies of labels (in duplicate) of licensed products for approval.

SYSTEM FOR SIMULTANEOUS USE OF BOTH CODABAR AND ISBT 128 DURING THE TRANSITION PERIOD

Question: What do I do if my blood supplier changes to ISBT 128 labels before my computer system is ready to accept these bar codes?

Option 1: Manually enter the ISBT data fields into your computer system.

- PROS: Does not utilize unit number relabeling so it maintains traceability.
- CONS: Manual data entry of unit identification number on initial receipt and probably on each computer entry and the possibility of duplicate unit numbers.
-

Option 2: Relabel units with unique, transfusion service assigned, unit identification numbers.

- PROS: Less manual data entry of unit identification numbers both on receipt of the unit and during subsequent unit handling.
- CONS: Possible loss of unit traceability if ISBT numbers are not included in the product's computer record.

Option 3: Build a computer program to convert ISBT 128 to Codabar labels and print labels.

- PROS: No manual keying. Good traceability.
- CONS: Cost of hardware and software development; requires most lead time to implement. Resources to develop, validate, and train staff for this option may be better invested in implementing ISBT 128. Hospital nursing staff may find double labeling (unit label and tie tag) confusing.

Discussion—Option 1

Option 1: Manually enter the ISBT data fields into your computer system. Take out the example of the ISBT 128 label and lay it side by side with your unit face label to be able to compare data fields.

Question: Does your computer system require the scanning of the collection facility's FDA registration number (lower right corner of Codabar label) to uniquely identify the unit by the collection center and unit number? If yes, you'll now manually enter the facility and year identification portions, the first seven digits of the ISBT 128 donation identification number (upper left corner of the ISBT label) in this field.

1. If this field accepts seven alpha/numeric digits, enter the first seven digits of the ISBT 128 identification number. Enter the country code (W), the facility identification digits (1234) and the year (04): W123404.
2. If this field will not accept an alpha/numeric designation but will accept six digits, enter the facility identification digits (1234) and the year (04): 123404.

3. If this field will accept seven (7) numeric but no alphabetic designations, enter 0, then the facility identification number (1234) and the year (04): 0123404.
4. If your system does not identify the collection facility in this manner, enter whatever combination of alpha/numeric digits is needed, being sure to include the facility identification number (1234) and year (04): 123404. If your system does not specifically use the identification code of the collection or shipping facility in blood product identification (facility identification directly tied to the unit number in the product's computer record or file), you may be better off renumbering the units to obtain more unique unit identification. The original unit number must also be tracked.
5. If you use only one or a few supplying centers, Codabar bar codes can be created for these facilities (using an on-demand printer or computer and laser printer) and either added to the unit or an attached tie tag, or scanned straight from a data sheet. Blood centers may be able to supply these labels for their unconverted transfusion services.
6. Note: Use of the new ISBT facility codes will require table maintenance to relate collection facility addresses to their new ISBT identification numbers vs their FDA registration numbers. When generating reports by facility, the computer system may have to be queried on two identification numbers.

Question: Does your computer require you to scan the Codabar unit identification number? If yes, you'll now manually enter the last six digits of the ISBT label's donation identification number.

7. Key in the last six digits of the donation identification number as the unit number. This is a sequential number assigned to a donation. This number sequence is repeated starting at the first of each year for each collection facility.
8. If you use these last six digits as the unit number, you must have it related in your system in some way to the facility identification digits and the year. These numbers work together to identify a specific donation. See section above.
9. If your computer must have seven numeric digits in the unit number, place a 0 before the six-digit number.
10. Note, the ISBT check digit will not work with this method of data entry.
11. If your system identifies a specific product only by its unit identification number and doesn't require an associated facility identification code, you may be better off renumbering with a local unique number, since manual entry of only the last six digits of the ISBT identification number could cause duplicate unit numbers. Since these last six digits are repeated each year, you could have frozen products with the same identification number.
12. Your system may automatically convert the leading digits of a bar coded unit number to alpha characters, depending on instruction codes that may be imbedded in the Codabar facility identification number. When creating Codabar facility identification bar codes as outlined in #1 above, be sure the correct start and stop codes are used so that unit identification numbers are not converted. You can get this information from your supplying facility.

Question: Does your computer system require you to scan in a product code from the units face label (usually lower left corner)? If yes, you will need to have some way of converting ISBT 128

product codes to Codabar product codes, since your computer's tables won't recognize the ISBT codes.

13. Create a table, which will be used to relate ISBT 128 product code labels to their corresponding Codabar bar code labels or facility acronym (eg, RBC). Either write the ISBT 128 product names or paste ISBT 128 product code labels on a sheet of paper or card. Place the corresponding Codabar labels or facility acronym next to the ISBT 128 labels. Be aware that there may be more than one ISBT 128 product code for a given Codabar code or acronym (eg, Codabar product code 18200, or FFP, may be CPDA-1 FFP, CP2D FFP or CPDA-1 FFP in ISBT 128).
14. When a product is received, you can use the table to identify the correct Codabar code or acronym. The Codabar label can be scanned straight from the created table data sheet or the acronym can be keyboard entered. The Codabar codes can also be entered manually, if necessary.

Question: Does your computer system require you to scan in an ABO/Rh type from the unit face label (usually upper right corner)? If yes, you will need to have some way of converting ISBT 128 ABO/Rh codes to Codabar ABO/Rh codes since your computer's tables won't recognize the ISBT codes. You can create a table for ABO/Rh labels just as you did above for the product code labels.

Question: Does your computer system require you to enter the product's expiration date? If yes, key in the product expiration date, or if the capability exists to create Codabar expiration date bar codes, you may scan from another sheet of paper on which the Codabar expiration date has been placed.

NOTE: No created Codabar bar code label should be placed directly on top of any ISBT bar code labels on the blood unit face label.

Discussion—Option 2

Option 2: Unit Number Relabeling

1. Relabel the unit with a unique, transfusion service assigned, product identification number.
 - a. That number must be affixed firmly to the container and there must be some way (on the new unit number label or on the tie tag) to identify the transfusion service assigning the additional unit identification number. This number should be placed directly on the container and not solely on the tie tag, since the tie tag may become separated from the product container.

- b. The original ISBT donation identification number must not be obscured or removed and no more than two unit numbers may be visible on the container.
 - c. If the unit is shipped from a transfusion or interim shipping facility and the shipping documents utilize the relabeled unit number, both the added unit number and the original collection facility ISBT donation identification number must be visible on the container even if the tie tag is removed.
 - d. The added unit identification number should also be annotated (written or using an additional number label) next to the original ISBT unit identification on the retained copy of the packing list received with the shipment.
2. For the collection facility identification number, the FDA facility registration number can be used. Codabar facility registration number labels can be created and placed on the unit, an attached tie tag, or scanned from a data sheet.
3. NOTE: The entire ISBT donation identification number must be put into each product's computer record or file comment section along with sufficient information to provide an audit trail of who renumbered the unit and when it was relabeled. In addition, some facilities might want to maintain a separate manual or database log with corresponding ISBT and transfusion service newly assigned unit identification numbers.
4. Product code, ABO/Rh, and expiration dates can be handled per paragraphs 13 and 14 of Option 1 above.

Discussion Option 3

Option 3: Automated Relabeling in Codabar

1. For this option, a computer program that translates ISBT 128 into Codabar is required. A bar code scanner, personal computer, and label printer are needed.
 - a. The ISBT 128 bar codes for the following data items are scanned: donation number, ABO/Rh, product code, expiration date.
 - b. The translation software will need to capture the data and assign a new unique donation number, in Codabar format, to the record.
 - c. The translation software will translate the ISBT 128 data to Codabar format.

In cases where the ISBT 128 product code could be translated into more than one Codabar product code, the system will list the choices and prompt the user to select the correct product code.

2. A two-part label will be generated.
 - a. Part 1 will contain the following information, both in eye-readable and Codabar format: Collection facility FDA registration number, donation number, ABO/Rh, product code, and expiration date. It will be applied to a tie-tag attached to the unit.
 - b. Part 2 will contain a Codabar donation number. It will be applied directly to the blood bag in the area immediately above the ISBT 128 donation number.
 - c. The Codabar bar codes on the tie tag are scanned into the facility's computer system in the usual manner.

The translation system will allow searching of donation numbers using either the Codabar or the ISBT 128 format.

HARDWARE/SOFTWARE ISSUES RELATED TO ISBT 128 IMPLEMENTATION

Introduction

ISBT 128 was developed as an international standard for the labeling of blood, blood components, tissues and hematopoietic progenitor cells. It is intended to replace the current guideline for labeling blood and blood components using American Blood Commission (ABC) Codabar. ISBT 128 increases the accuracy of labeling, enhances the safety of blood transfusion and tissue and progenitor cell transplantation, and facilitates the exchange of blood, tissue and hematopoietic progenitor (stem) cells between countries around the world. The implementation of ISBT 128 requires that consideration be given to the hardware and software used in the blood center and transfusion service.

Advantages of Code 128 Symbology

ISBT 128 is based on the bar code symbology, Code 128. The code is more secure than ABC Codabar, because it has three self-checking features per character. Thus, misreads due to substitution errors are extremely rare with Code 128. The symbology allows the encoding of the entire ASCII character set, including alphanumeric and special characters. Codabar does not support the encoding of alphabetic characters. Code 128 consists of three subsets, A, B, and C. Subset C allows double-density encoding of numeric characters, which means that more information can be encoded in a given space. This is of particular importance on both container labels and sample tubes, where space is limited. Code 128 can also be used with new bar code symbologies and allows for other means of data capture to be used in the future.

Data Structures in ISBT 128

ISBT 128 was developed using discrete “data structures.” A data structure is the organization of information within a bar code. Each data structure consists of a data identifier and data characters.

Data Identifier

Each bar code on a blood product begins with two data identifiers, which, through international agreement, are reserved for use on blood products only. The data identifier is used to indicate the type of bar code that is represented. For example, the characters “=%” indicate a bar code for the ABO/Rh blood group and the characters “&>” indicate a bar code for the expiration date and time. These characters are not eye-readable and, therefore, will not be seen by the user. They are used by the bar code scanner to identify the type of bar code structure.

Data Characters

The data characters include the information within the bar code that also appears in eye-readable format adjacent to the bar code. The following bar code structures have been developed (not all bar codes will be used on all products):

- **Donation Identification Number.** This unique 13-character donation identification number includes the country code, collection facility code, and donation year. This bar code also contains flag characters and a check digit for keyboard entry.
- **ABO/Rh Blood Group.** This code consists of a two-character numerical representation of the blood group and the donation type, as well as two additional characters, which in some countries may be used for Rh, Kell, and Miltenberger phenotypes.
- **Product Code.** This eight-character product code includes the actual five-character product code, the intended use/donation type, and the two-character designation for divisions/splits. The first letter indicates the type of product (“E” is a blood component, “S” is a hematopoietic progenitor cell product, and “T” is a tissue product).
- **Expiration Date/Time.** This structure includes the expiration date, expressed in the following format, “cyyjjhhmm” where c is the century, yy is the year, jjj is the Julian date, hh is the hour and mm is the minute. The eye-readable expiration date is printed in the following format: “DDMMYYYYHHMM” (eg, 04 MAY 2004 0915).
- **Collection Date/Time.** This code indicates the date and time of collection of the product and follows the format for expiration date/time.
- **Production Date/Time.** This code indicates the date and time of production of the product and follows the format for expiration date/time.
- **Special Testing: General.** This contains the results of special testing, such as CMV antibody status.
- **Special Testing: Red Blood Cell Antigens.** The bar code indicates the red cell antigen phenotype of the red cells as well as CMV antibody status.
- **Special Testing: Serologically Determined Platelet HLA and Platelet-Specific Antigens.** This bar code contains information regarding HLA and HPA phenotypes, CMV antibody, and IgA status for platelet products.
- **Special Testing: Genomically Determined (PCR) HLA-A and -B Alleles.** This bar code contains information about HLA-A and -B alleles for HPC and tissue products.
- **Special Testing: Genomically Determined HLA-DRB1 Alleles.** This bar code provides information regarding HLA-DRB-1 alleles for HPC and tissue products.
- **Container Manufacturer’s Identification and Container Description.** This code concerns the manufacturer’s container information regarding the container set, anticoagulant, etc.
- **Container Manufacturer’s Lot Number.** This code represents the container manufacturer’s lot number.

These new data structures will have an impact on both hardware and software used within each blood center or transfusion service. Implementers of ISBT 128 must ensure that bar code scanners can read ISBT 128, that the information management system can receive and process the information transmitted from the bar code scanner, and, if desired, transmit the necessary product information to a bar code label printer to enable on-demand printing of blood component labels.

Bar Code Scanners

The benefits of using bar code scanners are well known to the blood banking industry. A bar code scanner can scan six (6) characters/second, which is three times faster than manual entry. Scanners are much more accurate than manual entry, as proven by the fact there is less than one error in every 30-40 million characters scanned. Bar code scanners are also very easy to use and require minimal training.

Types of Scanners

There are three types of scanning devices available for use in scanning the ISBT 128 labels. These include hand-held light pens or wands, CCD scanners, and laser scanners. The advantages and disadvantages of each are summarized below.

- **Hand-held light pens or wands**

Advantages:	Low cost, low maintenance Easy to use, minimal training required
Disadvantages:	Performance may be compromised by bag or label surface and/or condensation
*Price Range:	\$100 - \$500

- **CCDs or Video Scanners**

Advantages:	Fast scan rate (2X laser scan rate) Easy to use, minimal training required Moderately priced, durable
Disadvantages:	Limited depth of field; length of scan limited by housing geometry
*Price Range:	\$150 - \$500

- **Lasers or guns**

Advantages:	Makes 30-40 scan attempts/second, virtually eliminating misreads Label contact not required; can read irregular surfaces and from a distance
Disadvantages:	More expensive than contact wands May require more training
*Price Range:	\$800 - \$2,000

*The price range listed is the approximate price range and is included only to provide an approximate price for each type of bar code scanner.

How to Choose a Bar Code Scanner

There are several factors to be considered during the evaluation of existing bar code scanners or the purchase of new scanners. First, determine if the bar code scanner can read Code 128 bar codes. Most scanners purchased since 1981 will be capable of decoding Code 128 symbology. Can the scanner autodiscriminate between Code 128 and Codabar? Since there will most likely

be an overlap between the use of Codabar labels and ISBT 128, it is helpful if the scanner can automatically distinguish between the two bar code symbologies. Most bar code scanners are capable of scanning many different bar code symbologies. Many parameters, such as beep volume, scan time, and bar code length, as well as the ability to read other bar code symbologies, can be configured relatively easily by following the manufacturer's directions. It is suggested that any feature that enables the scanner to read all other symbologies be disabled to prevent scanning of "illegal" bar codes.

Another consideration is the ability of the scanner to concatenate ISBT 128 bar code symbols. Code 128 bar code symbology supports concatenation, which is the joining together of data from two adjacent bar code symbols. The data from the two bar codes is interpreted and transmitted back to the host computer system as a single message. However, ISBT 128 concatenation requires customization within the scanner such that the concatenation occurs within a specific period and that only certain bar code structures can be concatenated. Concatenation adds control to the process of labeling by enabling the donation identification number and ABO/Rh bar codes to be concatenated and the product code and expiration date/time bar codes to be concatenated. Other pairs of bar codes may be concatenated, as well. By transmitting this information as a unit to the host system, the system can perform checks to ensure that the unit is labeled with the correct ABO/Rh label and that the correct expiration date has been applied to the unit based on the product code.

During the evaluation of bar code scanners, it is important to remember to include any automated equipment used by the blood center or transfusion service. Hardware or software upgrades may be required to read the new standard. Check with the equipment vendor for more information.

Assistance from a vendor who is familiar with the ISBT 128 standard is essential in assessing bar code scanning needs. The vendor can recommend the type of scanner most suited to the volume of blood components or samples scanned. The first pass read rate performance should be evaluated by trying various combinations of scanners and labels. Other considerations include ISBT 128 concatenation needs, training requirements of new scanners and, of course, the cost of the scanner.

Computer System Issues

There are many software issues that must be considered during the evaluation of the blood center or transfusion service computer system. Can the computer system accommodate the changes made to each of the quadrants of the blood component label? Based on the previous description of the new data structures, the computer system must be able to accommodate the major changes to the label, which are summarized below.

Donation Identification Number

The donation identification number has increased in size to 13 characters. This entire number, which includes the blood center identification number, the donation year, and the serial number of donation, is required for unique identification of the component. The use of only the serial

number will no doubt lead to duplicate donation identification numbers and is not considered to be a safe practice!

ABO/Rh Group

The ABO/Rh designation now includes the donation type. Therefore, based on the donation type, there are many ways to numerically represent a single ABO/Rh. Bombay and Parabombay have been added as possible ABO/Rh groups on this label. The system must be able to translate and process each blood type, which will have many different values based on donation type. The donation type may also affect the processing requirements of the component.

Product Code

The product code has increased in size to eight characters, which includes the actual product code, its intended use and any divisions or splits. The system must be able to store and process the product code information. There are over 5000 randomly assigned blood product codes, as well as about 700 hematopoietic progenitor cell codes and 200 tissue codes in the current ISBT 128 Product Code Database. Many other tables that utilize product codes, such as product modification tables and price or billing tables, may also be affected by the addition of these new product codes.

Expiration Date/Time

The bar code format for expiration date and time includes the century, year, Julian date, and hours and minutes. The system must be able to translate and store this information correctly. As illustrated by the examples above, evaluating the ability of the computer system to accommodate ISBT 128 is essential. Additionally, the system should be capable of handling both Codabar and ISBT 128 labeled components for some time during the implementation. System interfaces and the ability of the interfaced software to accept ISBT 128 data structures must also be assessed. These issues should be discussed with the software vendor to determine the capabilities of the software and when the software will be available.

On-Demand Printing of ISBT 128 Labels

The use of ISBT 128 with the large number of product codes lends itself to printing blood component labels on demand. However, there are many factors that will influence the decision to print labels on demand or purchase preprinted labels.

The bar code labels that are applied to a component can be divided into two broad categories: sequential and static. Donation identification labels fall into the category of sequential. Donation identification number sets differ from other labels in that the printer requires a high degree of numeric control, because the sequence is critical. This is a “must-read” label since there is a high

degree of liability associated with misidentification of donor. The decision to print these labels on demand must be made very carefully. Bar code labels in the category considered static include ABO/Rh, product code and expiration date. These labels are particularly good candidates for on-demand printing.

Printing Options

When assessing the feasibility of on-demand printing there are several printing options available depending upon the functional area where the labeling is to occur. The ISBT 128 label is based on quadrants. Quadrant 1 includes the donation identification number, quadrant 2 includes the ABO/Rh, quadrant 3 includes the product code, and quadrant 4 includes the expiration date/time. The most common printing options are to print quadrants 2 and 4 (ABO/Rh and expiration date) or quadrants 3 and 4 (product code and expiration date). The entire label can be printed, but must include a cutout for the donation identification, since this label should not be overlaid with another label. Individual quadrants, such as the ABO/Rh, product code or expiration date, may also be printed on demand. These printing options are summarized:

Full Face Label

4” x 4” stock with cut-out for Donation ID
 Quadrants 1, 2, 3, and 4

Individual Quadrants

2” x 2” stock
 Quadrant 2 OR
 Quadrant 3 OR
 Quadrant 4

ABO/Rh + Expiration Date

2” x 4” stock
 Quadrants 2 and 4

Product Code + Expiration Date

2” x 4” stock
 Quadrants 3 and 4

Donation ID Quadrant 1	ABO/Rh Quadrant 2
Product Code Quadrant 3	Expiration Date Quadrant 4

Types of On-Demand Printers

There are two different types of printing technologies: thermal direct and thermal transfer. Thermal direct printing involves label stock that is impregnated with a clear coating that changes to black when exposed to heat. The heaters are part of the print head and are controlled by logic in the printer.

In the thermal transfer method, the image is produced by a dry ribbon, which is heated by heating elements in the print head. The dry ink is melted and transferred to label stock. This is the preferred choice of on-demand printing, because there is a wide variety of label stock available and because of the enhanced durability of the image produced by these printers.

On-demand printing may involve a “stand-alone” printer or an “on-line” printer. The stand-alone printer usually has a graphic user interface (GUI). On-demand printing requires user input of label requirements. The software in the printing application contains the product code database and the software logic to create the label based on user input.

On-line, on-demand printing requires a printer that is interfaced with the host computer system. Instructions are transmitted from the host system in the form of a “data stream,” which contains the label requirements. In this case, the software logic used by the printer is based on input from the host computer.

Choosing an On-Demand Printer

There are many factors to be considered when choosing an on-demand printer. These factors are summarized below.

- **Size of label to be printed.** The choice of printing options for the ISBT 128 label will dictate the maximum label width capacity required of the printer. Generally, if the institution elects to print full-face labels, donation identification number sets, product and expiration date/time quadrants, or the ABO-Rh and expiration date/time quadrants, then a printer with a label width capacity of no less than 4.25 inches (108 mm) should be chosen. Currently, the majority of thermal printers on the market have maximum label width capacities of 4 inches or more.
- **Batch printing vs single label.** Batch printing refers to a moderate to large volume of labels being printed at one time. The donation identification number set labels can be thought of as the prime candidate for batch printing operations. When batch printing large numbers of labels it may be desirable to purchase a printer option that provides for the rewinding of labels. However, in the case of donation identification number sets, rewinding (that is, double rewinding) can be entirely avoided by purchasing the blank donation identification label stock in fan-fold configuration. Single label printing refers to labels that are printed for a specific component, on demand, at the time of component labeling. With the increase in donation-specific information that is now carried in three of the four ISBT label quadrants, the majority of labels lend themselves to on-demand printing. In facilities where a large number of on-demand labels are being printed, it may be beneficial to purchase printers that offer a print and dispense option. In this case, the

labels are presented one at a time such that the label may be easily lifted from the carrier sheet (label liner).

- **Volume of labels to be printed:** The number of labels to be printed within a given time will determine which other characteristics of the printer are also of importance. The time required from label request to label delivery is important in high-volume applications. The label stock and ribbon capacity of the printer dictates how often the operator must replace these supplies. The ease or difficulty of making ribbon and label supply changes also affects label production capacity and efficiency.
- **Resolution (Density of Bar Code):** Printer resolution is measured as the number of pixels or dots per inch or millimeter that the print head is capable of producing. The factors that dictate printer resolution are: 1) the font size of the printed text, and 2) the x-element dimension of the bar codes to be printed. The x-element dimension is the measurement of the narrowest bar that may appear in a given bar code symbology and establishes the bar density. The 203 dots per inch (dpi) printers are very popular in many blood banks currently printing their own ABC Codabar compliant labels. While these printers are capable of printing the narrowest bar or element required by ISBT 128 on the container label, the legibility of the text that they produce begins to fail at font sizes less than 8 points. The 203 dpi printers are not capable of producing the ISBT bar coded donation identification number for the tube label. Because a 300 dpi printer is capable of printing the narrowest bar widths and offers superior resolution for text fonts, it should be generally accepted as the printer resolution of choice.

All labels, either preprinted or printed on demand, must be tested to ensure that the bar codes fall within a specific tolerance level of deviation from nominal, so that they can be read reliably by a bar code scanner. Commercial verifiers are available to do American National Standards Institute bar code quality testing. A label supplier or printer vendor who is familiar with the requirements of the blood banking industry should be consulted for assistance.

Planning for ISBT 128 Implementation

Successful implementation of ISBT 128 requires careful planning, and hardware and software issues are only one aspect of the implementation process. In review, it is necessary to evaluate the following:

- **Existing or New Bar Code Scanners:** Will your scanners read Code 128? Can the bar code scanners autodiscriminate? Do you intend to utilize concatenation? Which type of scanner meets the needs of the operation in terms of concatenation, training, and cost?
- **Blood Center or Transfusion Service Computer Software:** Can your computer system translate, store, and process the data within the new data structures? Can the system send a data stream to an on-demand printer? Can interfaced systems accept the new data structures?
- **On-Demand Label Printers:** Do you intend to print labels on demand? In which functional area will on-demand printing be used? Which printing option will be used? What volume of labels will be printed on demand? Will the printing occur in batch mode or one at a time?

It is the vendor's responsibility to ensure that the hardware and software functions in compliance with the ISBT 128 Applications Specification. It is the user's responsibility to establish validation protocols that will ensure that all hardware and software can accommodate the changes to ISBT 128 blood product labeling. Proper evaluation and testing of hardware and software are an essential part of implementing ISBT 128.