

## ISBT 128 Implementation Plan

### Background Information

Drug manufacturing regulation 21 CFR 606.121 (c) 13 effective April 26, 2006 requires that all blood components be labeled with machine readable donation identification number, manufacturer, ABO/Rh type and product code. AABB Standards require that each accredited facility have a plan to convert to *ISBT 128* documented by November 1, 2006.

Units of (allo, auto, directed \_\_\_\_\_) are collected at \_\_\_\_\_ sites and processed and labeled in \_\_\_\_\_ (Codabar/*ISBT 128*).

Blood components are received from \_\_\_\_\_ (enter suppliers) \_\_\_\_\_. The(se) supplier(s) intend to begin shipping *ISBT 128* labeled components on or about \_\_\_\_\_.

### Current Blood Labeling

- \* Our facility is/is not computerized.
- \* We do/do not modify any components and will/will not need to re-label blood component bags.
- \* We irradiate, volume reduce, wash, pool, \_\_\_\_\_ components.
- \* We collect, process and label autologous, directed, allogeneic, stem cell donations.

### Description of Future Blood Labeling Process

- \* Blood components will /will not be modified and therefore will / will not need to re-label units following modification.
- \* Preprinted labels will be used when modifying blood components
- \* Blood component labels will print as needed.
- \* Labels will be printed from the Laboratory Information System
- \* Labels will be generated from a stand alone label generation program

### Implementation Team

The Chief Technologist/Blood Bank Manager/ \_\_\_\_\_ will chair an implementation team including the following representatives:

Blood Bank	
Nursing	
Laboratory Information System	
Medical Records	
Laboratory Administration	
Purchasing	

Sample 3

Risk Management	
Donor Center Representative	

**Time Line**

Goal: facility is ready to receive *ISBT 128* units before the receipt of the first unit expected on \_\_\_\_ (No later than May 1, 2008)\_\_\_\_\_.

**Attachments**

- Project Plan
- Documents from blood supplier(s)
- Equipment verification plans
- Validation plans
- Training plans
- Educational Materials
- Transition plan
- Training Aids
- PowerPoint® presentations
- Competency Assessment tools

Plan prepared by

Date

Plan Approved by

Date

**Project Plan**

Task	Assigned To	Due date	Completed
Register with ICCBBA and obtain facility identification number.			
Assemble and review information documents and materials			
ICCBBA documents			
US Guideline			
Blood Supplier communications			
Computer system specifications			
Form a team			
Notify Facility Administration Medical Director Transfusion Committee Other laboratories Anesthesiology Nursing Facility wide notice			
Modify forms			
Identify capital equipment needs Barcode readers Label printers LIS Programs			
Obtain funding			
Obtain labels			
Design new process			
Write SOP's			
Perform risk analysis			
Define Quality Assurance plan			
Define transition plan including look back			
Send letter to the FDA for exception use <i>ISBT 128</i> labeling			
Submit labels to FDA (licensed facilities) FDA form 2567			
Create/order any local use product codes (these begin with A,B,C or D)			
Verify computer changes			

Sample 3

Verify equipment operation			
Validate the new process			
Develop training materials			
Verify availability of supplies			
Train staff			
Nursing			
Blood Bank			
Anesthesiology			
Emergency Department			
Develop transition plan			
Re-labeling			
Dual processing			
Traceability			
Lookback			
Assess staff competency			
Begin Use			
Assess implementation			