



Advancing Transfusion and
Cellular Therapies Worldwide

ASSOCIATION BULLETIN #05-12

Date: October 12, 2005
To: AABB Members
From: Paul D. Mintz, MD – President
Karen Shoos Lipton, JD – Chief Executive Officer
Re: ISBT 128 Implementation

Summary

The AABB Board of Directors has reaffirmed its continued commitment to implementation of ISBT 128. In July 2005, the AABB Board of Directors approved a timeline for the implementation of the United States Industry Consensus Standards for the Uniform Labeling of Blood and Blood Components using ISBT 128.

The timeline approved by the Board is associated with the development of the 24th and 25th editions of the *Standards for Blood Banks and Transfusion Services (BB/TS Standards)* and the 2nd and 3rd editions of the *Standards for Cellular Therapy Product Services (CT Standards)*. Accordingly, the plan calls for a gradual implementation of ISBT 128 labeling through *Standards*.

The timeline for implementation of ISBT 128 for facilities accredited under the *BB/TS Standards* is as follows:

- 24th edition (effective November 1, 2006) will require that facilities have a written plan for the implementation of ISBT 128
- 25th edition (effective May 1, 2008) will require implementation of ISBT 128 by accredited facilities

The timeline for the implementation of ISBT 128 for facilities accredited under the *CT Standards* is as follows:

- 2nd edition (effective March 1, 2007) will require that facilities have a written plan for the implementation of ISBT 128
- 3rd edition (effective September 1, 2008) will require implementation of ISBT 128 by accredited facilities

This bulletin provides background information on the rationale for the Board's decision and a summary of a recent survey of representatives from AABB institutional members. In addition, this bulletin highlights past and future educational content and guidance on the implementation of ISBT 128.

Background – *BB/TS Standards*

Since 1997, the *BB/TS Standards* has included the following language:

Labeling of blood component containers should be in conformance with the most recent version of the United States Industry Consensus Standard for the Uniform Labeling of Blood and Blood Components using ISBT 128. During the transition to ISBT 128, labeling that conforms with the 1985 Uniform Labeling Guideline (FDA) is acceptable.

With the publication of this requirement, the AABB Board of Directors agreed that continued discussion among AABB members and participation with the International Council for Commonality in Blood Bank Automation (ICCBBA), Inc. was critical regarding the timing of this implementation. As a result of these discussions, there is now agreement that every facility should be able to meet the new requirement identified in the proposed standards.

Background – *CT Standards*

The AABB Board approved a similar implementation timeline for the *CT Standards*. AABB is currently working closely with other accrediting organizations and is also represented on the Cellular Therapy Coding and Labeling Advisory Group convened by ICCBBA, Inc. AABB will continue to seek input and to keep the membership advised of progress in this area.

Rationale – Why Now?

AABB has monitored the status of ISBT implementation in its member facilities. Over the past few years, the reasons that originally led the Blood Bank/Transfusion Service Standards Program Unit (BB/TS SPU) and the Cellular Therapy Standards Program Unit (CT SPU) to consider the implementation of ISBT 128 have become more evident. While Codabar symbology was of great value to the medical community when it was originally implemented, advances in transfusion medicine and transplantation therapies have tested Codabar's capabilities. An insufficient number of product codes remain for new transfusion medicine and transplantation therapy products. In addition, ISBT 128 includes controls (lacking in Codabar) that are likely to further reduce errors and improve safety for the recipients of blood, components, and cellular therapy products. Further, the elements of ISBT 128 can be used in other bar code symbologies and in more advanced delivery mechanisms such as reduced space symbology (RSS) and radio frequency identification (RFID).

ISBT 128 ensures that all donation identification numbers are unique. In addition, the labeling scheme includes a center prefix so that a facility receiving a unit can easily determine the collecting blood center. As a result of international standardization, product codes can be read and interpreted anywhere in the world. Unlike Codabar, the product code structure is expandable and able to accommodate new products. Perhaps most important, ISBT 128 bar codes include check characters, which can be used to detect scanning errors.

The Survey

AABB recently conducted a survey to gauge progress in the implementation of ISBT 128. A total of 529 facilities, including blood centers, hospital blood banks, and transfusion services, responded. Some of the participating facilities chose not to answer every question on the survey. As a result, the number of responses varies from one question to the next. Therefore, results are reported as numbers rather than in percentages.

Of the 529 facilities that responded to the survey, 463 identified their facility type. The breakdown was as follows:

- 54 blood centers
- 173 hospital blood banks
- 214 transfusion services
- 6 cellular therapy facilities
- 16 self-identified as “other”

Of the respondents, 30 (5.7%) have implemented ISBT 128. Their experiences include the following:

- Representatives of 11 facilities reported finding no major obstacles during the implementation.
- Of the facilities that encountered obstacles during the implementation, the most frequent logistical and operational obstacles involved the compatibility of existing software and hardware with the scanning/reading and printing of ISBT 128 labels. Another obstacle was the coordination of ISBT 128 implementation with a facility’s suppliers and customers.
- The most frequent administrative obstacles included validation of ISBT 128 and other related change control issues, including resources (allocating human resources needed to build computer tables, managing competing priorities, training staff, and updating the computer software).
- Seventeen of the facilities had a written plan for implementation of ISBT 128.
- One facility required more than 18 months to implement ISBT 128; 14 facilities completed implementation in less than 6 months.
- All 11 of the facilities that used the AABB ISBT 128 implementation plan (on the AABB Web site) found the plan useful.

Among the 499 facilities that have not implemented ISBT 128, the following findings are significant:

- Although 158 facilities plan to implement ISBT 128 within two years, 298 facilities were uncertain as to when they would implement ISBT 128.
- Among hospital based facilities, 405 of the facilities surveyed have a blood bank computer system. Among those facilities, 318 have computer systems that are compatible with ISBT 128.
- Although 77 facilities reported having budgeted for the cost of implementing ISBT 128, 267 have not. An additional 113 facility representatives did not know whether this cost was budgeted or not.

- When asked about implementation plans, 258 facilities indicated that their biggest obstacle in the eventual implementation of ISBT 128 is expected to be validation and other related change control issues (including resources and training). Another 223 facilities indicated their major obstacle would be “blood supplier not ready.”

Transitional Phase and Implementation

Survey responses also indicated quite clearly that additional written materials should be provided by AABB to assist with the implementation. The BB/TS SPU, the CT SPU, and the Information Systems Committee will endeavor to develop guidance geared toward different implementation scenarios. Guidance on compliance with AABB standards will continue to be published in *Standards Source*. The BB/TS SPU and the CT SPU will develop examples of how to satisfy the requirement for a written plan for implementation that will be published in *Standards Source*. AABB members are encouraged to begin this planning phase with the following initial steps in mind:

- 1) Develop an internal timeline for implementation of ISBT 128.
- 2) Review the bag labeling changes with transfusion service personnel and information systems staff.
- 3) Generate staff training schedules (to include staff and clinicians administering blood components and cellular therapy products).
- 4) Revise forms to accommodate a longer number.
- 5) Evaluate the need for information systems support and modifications.
- 6) Assess the ability of current bar code scanners to read (and the computer systems to interpret) ISBT 128 bar code labels.

Existing Resources

Several educational resources currently available to AABB members can be useful in the initial design phase of implementation. These include:

- ISBT Code 128 Implementation Plan (revised June 2004) available to all AABB members: http://www.aabb.org/members_only/archives/other/isbt128plan.htm
- Sessions at the 2005 Annual Meeting:
 - Information Systems Special Interest Group for Hi Tech (119-A)
 - ISBT 128: Lessons Learned (319-A)
 - Implementation of ISBT 128 (409-TC)
 - Ask the Standards Committee (427-TC)

Information can also be found on the ICCBBA, Inc., Web site: www.isbt128.org.

Assistance

In the coming months, AABB will continue to develop resources, including educational programs, to assist institutions in developing their ISBT 128 implementation plans. In addition to developing further educational resources, AABB will use existing print, email, and web-based communications such as this Association Bulletin, to provide members with additional information on ISBT 128. In the meantime, any questions or

comments should be sent to the Standards and International Affairs Department by email (standards@aabb.org) or fax (+1.301.657.0957).