



Advancing Transfusion and  
Cellular Therapies Worldwide

ASSOCIATION BULLETIN  
#09-05

Date: July 24, 2009  
To: AABB Members  
From: Jay E. Menitove, MD – President  
Karen Shoos Lipton, JD – Chief Executive Officer  
Re: ISBT 128 Implementation

After careful consideration and input from the standards and accreditation program committees, the AABB Board of Directors has determined that any AABB-accredited facility that has not implemented ISBT 128 by November 1, 2009, as required by the 25th edition of *Standards for Blood Banks and Transfusion Services (Standards)*, will be placed on Conditional Accreditation status. Included in this edition of *Standards* that is effective May 1, 2008 until November 1, 2009 is Standard 5.1.6.3.1(1), which mandates the use of ISBT 128 for labeling of all blood and blood components.

This bulletin provides background information on the rationale for the board's decision and details the implications for those facilities that fail to comply with this standard.

Association Bulletins, which are approved for distribution by the AABB Board of Directors, may include announcements of standards or requirements for accreditation, recommendations on emerging trends or best practice, and/or pertinent information. Although intended solely for informational purposes, this bulletin does reference a standard that is required for accreditation.

**Rationale**

ISBT 128 is an important tool in ensuring safe transfusions for patients. ISBT 128 is an alphanumeric, high-density, widely supported symbology that can improve inventory control and reduce errors. The previous labeling standard, Codabar, is no longer supported and has significant problems. Specifically, Codabar does not include a check-digit function to protect against substitution errors, and donation numbers in Codabar are not necessarily unique. Continued use of the Codabar symbology also creates a national blood supply that is divided by two labeling systems, which poses serious concerns in the event of a disaster. Facilities that have not converted to ISBT 128 may not have the ability to receive blood with ISBT 128 labels or will have to resort to manual methods, which are more error prone and time consuming.

AABB has recommended conversion to ISBT 128 for more than a decade. In 2005, AABB laid out a specific timeline for implementation in Association Bulletin #05-12, stating that the 24th edition of Standards—effective November 1, 2006—would require all facilities to have a written plan for implementation, while the 25th edition—effective May 1, 2008—would require full implementation. An Association Bulletin distributed in 2008, just prior to the effective date of the 25th edition of Standards, emphasized the upcoming deadline, clarified the scope and applicability of the implementation requirement, provided guidance on how to request a variance and what types of variances were likely to be granted, and referred members to additional resources to help ensure that they remained in compliance.

In addition to giving significant advance notice, AABB, along with the Food and Drug Administration and ICCBBA, has provided guidance to the community to assist with this transition. Information resources, including answers to frequently asked questions, a sample letter to bring this issue to the attention of senior hospital management, and links to sample labels, all have been posted online at [http://www.aabb.org/Content/Members\\_Area/Labeling/ISBT\\_128/isbt128plan.htm](http://www.aabb.org/Content/Members_Area/Labeling/ISBT_128/isbt128plan.htm). The topic has also been covered extensively in association publications such as *AABB News* and through educational sessions at the AABB Annual Meeting.

### **Conditional Accreditation**

Pursuant to the “Accreditation Program Policy Manual,” a facility is placed on Conditional Accreditation when it has “partial or limited conformance with requirements. Conditional status is removed when the facility satisfactorily responds to nonconformities or a focused reassessment results in adequate resolution.”<sup>1</sup>

Facilities with Conditional Accreditation status are not listed as accredited institutions on the AABB Web site and may not ship blood or blood products through the National Blood Exchange. In addition, appropriate regulatory agencies and accrediting bodies are advised of this accreditation status.

Variances granted to facilities that were not in compliance with ISBT 128 on May 1, 2008 will expire on November 1, 2009. Facilities with an existing variance relating to ISBT 128 may be placed on Conditional Accreditation if they have not submitted documentation of implementation by November 1, 2009. If placed on Conditional Accreditation, facilities with previous variances will require reassessment, at the facility’s expense, to ensure compliance with the requirement before full accreditation can be reinstated.

Similarly, facilities that were not scheduled for assessment during the effective dates of the 25th edition of *Standards* must supply evidence to AABB of compliance with the ISBT 128 requirement by November 1, 2009, or they may be placed on Conditional Accreditation. The facility will be evaluated for compliance during its assessment within the facility’s regularly scheduled assessment quarter. If the facility is able to demonstrate that it has successfully implemented ISBT 128, full accreditation status will be reinstated.

**Assistance**

Questions or comments about the information referenced in this Association Bulletin should be directed to AABB's Department of Accreditation and Quality at [accreditation@aabb.org](mailto:accreditation@aabb.org).

**Reference**

1. Categories of accreditation (Appendix 4.4.2.A). Version 6.2. In: Accreditation program policy manual. In: Accreditation information manual (AIM). 6th ed. Bethesda, MD: AABB, 2006.