ISBT 128: What You Need to Know Now

With the approval of the 25th edition of *Standards for Blood Banks and Transfusion Services* by the AABB Board of Directors, implementation of ISBT 128 labeling will be required by May 1, 2008. The final language of standard 5.1.6.3.1(1) will read:

Labeling of blood and component containers shall 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. Units conforming to 1985 FDA Uniform Labeling Guidelines are acceptable if collected and labeled before May 1, 2008.^*

> *United States Industry Consensus Standard for the Uniform Labeling of Blood and Blood Components Using ISBT 128 - 11/2005.
> ^ Units collected and labeled prior to ISBT 128 implementation may be relabeled using Codabar.

As accredited facilities may have concerns regarding the conversion to ISBT 128, below are some answers to some of the most frequently asked general and technical questions.

What if my supplier will not meet the May 1, 2008, deadline? Can my hospital delay implementation of ISBT 128 accordingly?
No. Either your facility will have to implement ISBT 128 independently of your supplier's status, or you will need to request a variance. Because all commercially available scanners used in blood bank software have maintained reverse compatibility between ISBT 128 and previous labeling systems such as Codabar, all hospitals should plan to meet the deadline. A hospital that does not implement ISBT 128 by May 1, 2008, would run the risk of not being able to receive and transfuse units from ISBT 128-ready suppliers without investing significant time and resources into a manual workaround for ISBT 128-labeled units. If a catastrophic event requiring massive regional mobilization of blood were to take place, your hospital might run the risk of being unable to provide blood when and where it will be needed the most.

In addition, regional shortages may require your hospital to supplement its blood inventory with units from a different supplier, or other mitigating circumstances may develop that would compel your hospital to seek a new blood supplier.

What if my computer software vendor will not meet the May 1, 2008, deadline?
Your facility would need to request and receive a variance. Any facility that will not implement ISBT 128 by May 1, 2008, is expected to request a variance from the *Standards for Blood Banks and Transfusion Services* before the requirements become effective.

In the absence of an approved variance, failure to implement ISBT 128 by the deadline will result in a nonconformance. Corrective action plans should include a detailed timeline for implementation, and the AABB Accreditation and Quality Department may require evidence of successful implementation before a certificate of accreditation is issued. Failure to provide this information or to adequately respond to the nonconformance may result in a reassessment or loss of accreditation.

Who can apply for variances?
Any accredited facility can request a variance from the 25th edition of *Standards for Blood Banks and Transfusion Services*. The variance request should explain the internal operational challenges that have caused the delay. Facilities also should indicate their timeline for full implementation, and whether they will implement interim policies, processes and procedures such as a manual workaround in the event that the facility receives ISBT 128-labeled units. Variances to delay implementation because of external factors, such as those caused by another facility in the "chain of supply" not being ready to meet the May 1, 2008, deadline, are unlikely to be granted. A description of the variance process is available under Members Area > Standards.

My supplier will not be ready by May 1, 2008. What constitutes "implementation" of ISBT 128, considering that my facility may not relabel some units originally labeled in Codabar?
If your hospital gets all of your blood from a supplier who will not meet the deadline, and if you do not modify any components in a manner that would require them to be relabeled, you should be prepared to show an assessor that you have validated your software system and that you have the ability to scan ISBT 128-labeled units. In the event that you modify and need to relabel products, you can apply ISBT 128 labels to the product or you could choose to relabel the product in Codabar. Note that the "footnote" in the language above allows facilities to relabel products collected prior to ISBT 128 implementation (i.e., the implementation by your blood supplier — which may or may not be prior to May 1, 2008) in Codabar. Relabeling would be necessary in the event that a product is modified (e.g., thawed, irradiated or washed) or in the event that it is further processed (e.g., aliquotted).

Each facility will have to decide how to handle rare frozen inventory collected prior to ISBT 128 implementation. This decision may be

based on operational criteria, such as the size of the frozen inventory or the expected frequency of use of frozen products. Some facilities may choose to keep a legacy system operating for this very reason, while others may prefer to create a manual workaround to allow the product to be relabeled in ISBT 128.

In the case of a triple plateletpheresis donation, the units have the same donor identification number with different product codes. Each unit will be used for pediatric transfusion and split into four units. The products are then irradiated for in-house use. How should this be reflected in ISBT 128 labeling?
Products that are divided or split will be handled much differently under the ISBT 128 labeling system. The main shift is that facilities will now be changing product codes rather than donor identification numbers.

Products collected with ISBT labeling will retain the same donor identification number (unit number) for the "life" of the product, including after the product is modified. Once the product is modified, the product code will change — but not the donor identification number.

If the product is split into "subunits," the triple apheresis product is first divided into three units. The divisions can then be split. The last two characters of the product code will reflect this information. The first character reflects the division and appears as an uppercase letter (e.g., A, B, C). The second character is for splitting and is a lowercase character (e.g., the second split of A would be Ab). This allows for a potential 26 divisions (A through Z), each of which can have 26 splits (a through z). In this case, the products would be relabeled with the same donor identification number but with different product codes.

If the products are irradiated at a later time, they would need to be relabeled with a new product code that also would reflect this modification.

How does a facility pooling platelets across different ABO /Rh types meet the requirement to identify the ABO and Rh of units in a pool after implementation of ISBT 128 labeling? The ISBT label says "mixed types," but the label itself will not include the specific groups and types of the units in the pool.
Item 18 in Reference Standard 5.1.6A in the 24th edition of *Standards* required that the pooled product labels reflect the ABO and Rh of units in a pool. A footnote that is new to the 25th edition of *Standards* will read: "For pooled cryoprecipitate, plasma or platelets of mixed types a pooled type label is acceptable. The specific ABO group and Rh types in the pool may be put on a tie tag. Standard 5.7.4.3 applies." In accordance with requirements for traceability, the specific ABO/ Rh information for each unit in the pool would have to be identified in records.

Before implementing the pooled ABO type for product labeling, you also should verify with your laboratory information systems software vendor that its computer system can accommodate this change.