



What You Need to Know Now - ISBT 128

The final language of the AABB 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 128.9 (United States Industry Consensus Standard for the Uniform Labeling of Blood and Blood Components Using ISBT 128 - 11/2005.) Units conforming to 1985 FDA Uniform Labeling Guidelines are acceptable if collected and labeled before May 1, 2008."

What if my supplier will not meet the May 1, 2008, deadline? Can my hospital delay implementation of ISBT 128 accordingly?

[AABB] "No. Either your facility will have to implement ISBT 128 independently of your supplier's status, or you will need to request a variance."

[S&P] The AABB includes the caveat that in the event of regional shortages or emergency situations your hospital may need to supplement its blood inventory therefore you should be ready to convert by May 1. Moreover, most currently available barcode readers can read both Codabar and ISBT; however the database needs to be updated to recognize the ISBT codes.

What if my computer software vendor will not meet the May 1, 2008, deadline?

[AABB] "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."

[S&P] Cerner Millennium® and Cerner Classic™ are both ISBT licensed. Database design must be completed however to be fully able to import units. Modifying product (thawing, pooling, washing) require the resultant component be labeled with ISBT labels, whether printed through an on-line printer or pre-printed purchased labels.

Who can apply for variances?

[AABB] "Any accredited facility can request a variance from the 25th edition of Standards for Blood Banks and Transfusion Services. 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"

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?

[AABB] "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."

[S&P] Note that the requested variance is for AABB Accredited facilities. Since many of the regulating agencies point to the AABB as the industry standard, the recommendation is that all facilities be ISBT capable as close to the May 1 date as possible.

Reference:

AABB News, December 2007.

If you would like more information contact us at 508-586-7850 or email us at info@spconinc.com