When the 24th edition of American Association of Blood Banking’s (AABB’s) Standards for Blood Banks and Transfusion Services becomes effective on November 1, 2006, every AABB-accredited blood bank and transfusion service will be required to have a written plan for implementing ISBT 128. This plan must define specific tasks the facility will complete in order to ensure a smooth transition to the new labeling standard.

Some organizations assume that because they are not computerized, this change does not apply to them or will not affect them, but that assumption is incorrect. Every AABB-accredited blood bank and transfusion service must develop a written plan and communicate with local blood suppliers to arrive at an implementation date for the new standard. Hospital transfusion services do not need to have the same implementation date as their blood suppliers, but it is essential for both entities to work together to ensure that hospitals will be able to receive components into their inventory that are numbered differently and have a label that uses the new format.

While each facility will have its own unique implementation plan, there are a number of major tasks that most will have to address as their plans take shape. Following is a list of “action items” to consider during the planning process.

**Determine whether ICCBBA registration is required**

The first question to address is whether or not your facility should register with the International Council for Commonality in Blood Banking Automation (ICCBBA), the organization that manages the ISBT 128 international information standard for use in transfusion and transplantation. All blood collection centers, whether free standing or within a hospital, must register because their ICCBBA facility identification number (see the diagram on the final report, p. 43) will become an integral part of the unit identification number on the label.

For transfusion services (facilities that do not collect but only transfuse blood products), registration and licensing with ICCBBA is required if they apply ISBT 128 labels. This encompasses facilities that pool, aliquot, or modify products and label them with ISBT 128 bar codes. Registration/licensing is also required if a facility uses ISBT 128 data structures in applications other than labeling products. Examples of these other applications include patient-identification wristbands, crossmatch tags, or electronic messaging. A facility may also wish to register and pay licensing fees in order to receive all ISBT 128 documentation and updates and access the Registered Users section of the ICCBBA website. All new product codes, other updates, and current copies of the ICCBBA databases are maintained in this section of ICCBBA’s website. Information on how to register can be found on the organization’s website at www.iccbba.org. Facilities that do not apply an ISBT 128 label do not need to register with ICCBBA.

**Discuss relevant issues with the medical director**

As your organization moves forward with its implementation plan, your medical director will likely be asked a number of questions by the medical staff. Consequently, it is important that he or she understands why the organization is transitioning to the new labeling standard, and is prepared to answer any questions or concerns the medical staff might have. The medical director will also provide support should there be financial challenges in implementing ISBT 128.

**Notify other laboratory supervisors**

Even though they may not be directly involved in making the transition to ISBT 128, other laboratory supervisors may be affected by the change and should be notified about it. Here are three examples of how the transition to ISBT 128 could potentially impact other departments:

- Hematology analyzers may be used to perform quality-control testing of units collected or manufactured at your facility. The unit identifier will have to be entered into the system being used by hematology and must be able to translate appropriately — not only in the instrument, but also through the interface — to the computer system and the final report. Clearly, this process will need to be validated.
- The chemistry laboratory may perform viral marker tests. Equipment in the chemistry department that will read, store, transfer, or transmit the unit identifier information will need to be validated to ensure that the data are readable, and translate to the computer system and all reports appropriately.
- The microbiology lab may perform testing for bacterial contamination on components manufactured or distributed by your facility or may be involved in the investigation following a transfusion reaction. In each case, the blood unit identification number will need to be accurately reflected on the final report.

**Get approval from laboratory administrators**

It is essential to work with laboratory administrators on ISBT 128 implementation plans that require system changes or the allocation of additional resources. They must be involved in initiating a budget for the additional costs associated with the transition, including potential computer upgrades. Lab administrators can also facilitate the assessment of computer systems to determine their capabilities to read ISBT 128 bar-code symbology, and the testing of interfaces to ensure that information can be transferred
accurately. If your current software is developed in-house, lab administrators also must allocate sufficient resources and time for planning, designing, building, and validating the system.

**Notify anesthesiology, nursing, and other ancillary services**

Why is the notification of nursing staff, anesthesiology, and other ancillary services in the hospital an important factor in developing a plan for implementing ISBT 128? First of all, forms used by nursing personnel may need to be revised to accommodate the longer unit number on the new label. These forms include flow sheets, intake and output records, operative notes, and dialysis records.

Second, individuals involved in the administration of blood components, including physicians, perfusionists, and anesthesiologists, will need to receive training in the new labeling system. ISBT 128 is more than a unit number; the blood bag looks different, and the location of the information people are accustomed to verifying is not the same. During training, it is important to stress that it is not acceptable to record only the last few digits of the unit number, and that the entire 13-digit unit identification number must be used. Recording only the terminal sequence of numbers may lead to an apparent duplication of donor unit identification numbers. Abbreviating the unit number becomes particularly problematic when blood is obtained from multiple sources. The facility identification code, the year, and the donation number sequence work together to identify a specific donation.

It may also be prudent to consider if the transition to ISBT 128 provides an opportunity to have “boxes” or other tools on forms to assist in documenting every digit in the unit identification number. These kinds of tools may help prevent the omission of a digit. Individuals involved in the documentation of blood administration can provide valuable insights into the redesign of these forms.

**Evaluate supply and ordering issues**

Since the label will change when your facility begins using the ISBT 128 standard, it may be a good idea to evaluate your ordering process for labels. Is there a “standing order” for pre-printed labels? Does the vendor assess current inventory levels and reorder to a minimum level? The answers to these questions are important, and should be addressed in your transition plan.

**Validate computer changes**

Transitioning to ISBT 128 may require several computer changes. Here are some things to remember about the new label:

- The unit number is now a 13-digit number, which may necessitate lengthening the space or the number of characters allowed by the computer system;
- The component code has increased in length, and is now an eight-digit code; and
- The "field" for the expiration date now includes the time of expiration.

Also, it is essential to verify the transfer of information to computer reports (operational, statistics, workload, billing, etc.), and validate the electronic transfer of information (e.g., from testing laboratory to collection site). Verifying that components (including aliquots, splits, pools, and those that are irradiated or leukoreduced, etc.) are billed appropriately is important as well.

**Validate equipment**

Follow protocols for implementation and validation of equipment — such as bar code readers — related to the use of ISBT 128 bar-code symbology.

**Validate processes**

Verify that applicable processes have been considered, including the following: collection; aliquoting; pooling; unit labeling; preparing a new component by washing, irradiation, leukoreduction, etc.; and label ordering. Since the year is now included as an integral part of the unit number, the “schedule” for ordering labels must be able to accommodate the collection of units labeled W XXXX 06 XXXXX in the year 2006. A grace period of one month has been established to reduce wastage of labels. The unit identification labels that include “07” may be used between December 1, 2006, and January 31, 2008. The inclusion of the year in the donor identification number is to ensure a unique number every 100 years and is not intended to establish a collection or expiration date. Even with the “grace” period for use of unit-identification numbers, each facility will need to evaluate how many unit numbers are used within a defined period, and allow for an unexpected mass influx of donors. Also, remember that standard operating procedures may need to be revised since they may include examples of labels and forms used in any process.

**Modify forms in the transfusion service**

Investigate to determine where the blood unit identification number is recorded. Is it on work cards, transfusion slips, or transfusion-reaction reports? Check component preparation records, including the following:

- sterile connection device logs;
- pooling logs;
- irradiation logs;
- aliquot logs;
- saline wash logs;
- freezing/deglycerolization logs;
- final disposition logs;
- shipping logs for recovered plasma; and
- specimen shipping logs (if specimens are sent to an outside testing agency).

Evaluate the ability of all forms used during “computer downtime” to accommodate the increase in the length of the unit number. All manual back-up paper records a facility would require to continue operations during downtime, and documentation of all processes should also be assessed. Other forms that may require review include emergency release forms (e.g., release of blood that is not crossmatched); transfusion-reaction reports; look-back forms; and recall/market-withdrawal forms.

**Determine what inventory issues may arise during the transition period**

Every facility will need to be able to “read” both Codabar and ISBT 128 bar-code symbology for an extended period of time. Frozen plasma components expire in one year, and frozen red cells can have an expiration date that is as long as 10 years out. Units (particularly units with a rare phenotype) could be made available for distribution as dictated by patient need. Computer systems will need to be able to read and interpret both bar-code languages in order to enter, process, dispense, and transfuse units labeled by either bar-code symbology.
Address distribution concerns
Can the agency that receives your recovered plasma read units labeled by ISBT 128 bar code symbology? If you further distribute units or provide blood to a “sister hospital,” are your implementation dates coordinated? These issues should also be addressed in your transition plan.

At this point, the blood-banking and transfusion-medicine community has had extensive experience controlling and monitoring change, and a good way to avoid being overwhelmed by planning for the transition from Codabar to ISBT 128 is to think of it as just another change. This article has highlighted some of the issues to address when developing a transition plan, but is not intended to be an all-inclusive list. For more information on ISBT 128, visit the websites listed under ISBT 128 Resources (see sidebar).

Marianne A. Silva, MS, MT(ASCP)SBB, CQA(ASQ), is a consultant for AABB Consulting Services. This division of AABB operates independently from the AABB Accreditation and Standards Division and offers expertise in regulatory and professional association requirements to helping facilities develop quality systems and solutions for all medical, technical, and business processes.

Editor’s Note: When the 24th edition of AABB’s Standards for Blood Banks and Transfusion Services becomes effective on November 1, 2006, every AABB-accredited blood bank and transfusion service will be required to have a written plan for implementing ISBT 128. The 25th edition of AABB’s Standards for Blood Banks and Transfusion Services, effective May 1, 2008, will require implementation of ISBT 128 by accredited facilities. This article was originally published in the March 2006 issue of AABB News. For more information, visit the AABB website at www.aabb.org.

Sample ISBT 128 Label

ISBT 128 Resources

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