

ISBT FREQUENTLY ASKED QUESTIONS

1. Who needs to register for ISBT 128?

Any facility that collects or modifies blood components or will apply ISBT 128 labels will need to register with ICCBBA and pay a registration fee. It is not necessary to be registered to receive ISBT 128 labeled blood products. ICCBBA website: www.iccbba.org.

2. Will my facility have to register if we modify blood components or aliquot in small volume quantities?

Yes, it is highly recommended that you register because each modification or aliquot will have a unique product code.

3. My hospital blood bank is not linked to the laboratory information system and all the blood bank records are manual; why should I be concerned about ISBT 128?

The donation numbers are larger and require more space, so forms may need to be changed to accommodate the new donation numbers. Hospitals will need to look at all of their systems in place (such as billing procedures) to ensure that their systems will accommodate the new, longer donation numbers and component codes that are part of ISBT 128.

4. What does my billing department need to know about ISBT labeling?

Hospital billing systems will need to accommodate the ISBT 128 structure and the new extended donation numbers and component codes. If necessary, the billing system will need to be changed to correctly interpret the new product codes.

5. Where can I get labels in advance so I can program our computer and bar code readers?

Sample bar codes (both valid and invalid) that can be used for validation may be found on the ICCBBA website. CBB will distribute labels after FDA approval is received (date to be determined).

6. Will I need to upgrade my scanners?

You will need to test your scanners with labels to determine if you need to upgrade them. You can also consult your instruction manual to determine if they are ISBT 128 compatible.

7. Is it acceptable to use just the 6-digit donation number when using our forms or in the computer system?

NO. The entire ISBT 128 donation identification number must be used.

8. I am a transfusion service that only thaws Fresh Frozen Plasma. Will I be required to relabel that unit and do I have to register with ICCBBA?

If your facility thaws FFP and transfuses it within 24 hours, then you are not required to relabel the unit and can just hand write the new expiration date/time. However, if your facility does not transfuse it and keeps it over 24 hours (up to 5 days), then you will have to relabel the unit as Plasma. You will only have to register if you apply an ISBT 128 label.

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9. Where does my FDA registration number and US license (if applicable) need to appear on the ISBT 128 label?

For collection facilities, the US license number can appear in either the upper left quadrant or the lower left quadrant, but not both. The FDA registration number should appear below the collection facility name in the upper left quadrant.

For modifying facilities, the FDA registration number and US license number (if applicable) should appear below the modifying facility's name in the lower right quadrant. See below.



10. What information am I required to have barcoded on my label?

At a minimum, FDA requires machine-readable labels for a unique facility identifier, lot number relating to the donor (unit number), product code and ABO/Rh. This is specified under 21 CFR 606.12 (c) (13) (iii).

11. Our current system assigns a suffix to the parent unit number when an aliquot is made. How will aliquots be handled with ISBT 128?

In ISBT 128, the product code data structure has 8 characters. The first 5 characters are considered the "product code", the 6th identifies the type of donation, and the 7th and 8th characters are for divisions and splits.

Let's take a CPDA-1 Red Blood Cell, 450 mL collection, leukoreduced. This has a product code of E0209. It's from a volunteer donor so the sixth character is V. Undivided, the full code is E0209V00. If you split this once, the codes go to E0209VA0 and E0209VB0. The "product description code" itself doesn't change, but the division codes do. If you take the E0209VA0 and divide it into three syringes, they become E0209VAa, E0209VAb and E0209VAc. Again, the E0209 part stays the same, but division codes reflect the daughter products. So, there remains a relationship between the parent and daughter products.

CBB will continue to attach the additional labels to the empty bags on a "Quad (Pedi)" Pak. Each bag will have a different product code.

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12. If I pool products that are collected from another facility, whose facility identification number is supposed to appear on the *ISBT 128* label and where?

Pooled products should be assigned a unique identification number by the modifying facility. This number will include the facility identification number of the pooling facility and be placed at the top of the upper left quadrant of a 4"x4" label. Beneath this number should appear the name and location of the pooling facility. Records of the units used in the pool should be maintained by the pooling facility

13. If I irradiate products that are collected from another facility, whose facility identification number is supposed to appear on the *ISBT 128* label and where?

The facility identification number of the collection facility should remain on the bag in the upper left hand quadrant of the label in order to maintain donation traceability.

When applicable, the modifying facility's information will appear in the lower third portion of the lower right quadrant of the label (see example).



14. When will ISBT 128 be implemented?

Currently, Community Blood Bank of Erie County, dba CBB of NW PA, and CBB of Western New York plans to implement ISBT 128 labeling on blood products sometime during the 2nd quarter of 2008. AABB requires facilities to implement by May 2008. While not requiring ISBT 128, the Code of Federal Regulations required machine-readable labels after April 26, 2006.