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Compliance with the new requirements for labeling of aliquots and pooled components

A Transfusion Service Technical Coordinator in Georgia wonders what it would take to comply with the new requirement for labeling of aliquots and pooled components, as announced by AABB 'Association Bulletin #06-03: Bar Coding Regulations'. Has anyone developed a label that prints all these components?

Editor's Note: Allene Carr-Greer, MT(ASCP)SBB, Deputy Director, Regulatory Affairs at AABB (attribution used with permission), reports that the information which must be machine-readable is described below and is listed in [21 CFR 606.121 \(c\) Container label](#)

(13) The container label must bear encoded information in a format that is machine-readable and approved for use by the Director, Center for Biologics Evaluation and Research.

(i) *Who is subject to this machine-readable requirement?* All blood establishments that manufacture, process, repack, or relabel blood or blood components intended for transfusion and regulated under the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act.

(ii) *What blood products are subject to this machine-readable requirement?* All blood and blood components intended for transfusion are subject to the machine-readable information label requirement in this section.

(iii) *What information must be machine-readable?* Each label must have machine-readable information that contains, at a minimum:

- (A) A unique facility identifier;
- (B) Lot number relating to the donor;
- (C) Product code; and
- (D) ABO and Rh of the donor.

(iv) *How must the machine-readable information appear?* The machine-readable information must:

- (A) Be unique to the blood or blood component;
- (B) Be surrounded by sufficient blank space so that the machine-readable information can be scanned correctly; and
- (C) Remain intact under normal conditions of use.

(v) *Where does the machine-readable information go?* The machine-readable information must appear on the label of any blood or blood component which is or can be transfused to a patient or from which the blood or blood component can be taken and transfused to a patient.

The following comments have been received.

ADDENDA Apr. 7, 2006

1. **Editor's Note:** The information at [Frequently Asked Questions: Bar Code Label Requirements for Blood and Blood Components \(FDA/CBER\)](#) is germane to the present discussion.

ADDENDA Apr. 21, 2006

2. **A California colleague** reports that her hospital's blood supplier **uses Codabar** (see [HERE](#) and [HERE](#)) for product labeling and will not be converting to **ISBT 128** until close to the 2008 deadline. Consequently, they have to comply with the bar code labeling requirement using Codabar labels. In particular, they prepare blood for neonatal exchange transfusion by pooling **CPD or CPDA1 Leukocyte Reduced Red Blood Cells with thawed Fresh Frozen Plasma to create a "Reconstituted Whole Blood"**. Currently, they print a label in-house for the aforementioned pooled product which they call "CPD (or CPDA-1) RED BLOOD CELLS LEUKOCYTE REDUCED RECONSTITUTED WITH FFP". Unfortunately, the current label lacks a bar code! They plan to switch to a custom label, as soon as they figure out what bar code to assign to this product. The inquiring colleague would like to know if other sites prepare a similar product by pooling and, **if using Codabar labels, what bar code is assigned.**
3. **Cynthia Borneman, MT(ASCP)SBB of the VA San Diego Healthcare System** (attribution used with permission) reports that her institution has **asked the FDA for guidance** on what product codes can be used for barcoding of unlicensed blood products and what follows is reportedly their response: "**Local product Codabar codes may be assigned to blood products for which there are no assigned product Codabar codes.** These products are usually products that have not been licensed by the FDA since data has not been submitted to prove that the product is effective and safe. (Thawed Plasma is in this category as this is not a recognized product). **Local Codabar product codes may be picked from anywhere in the range of 27100 through 29599.**"

ADDENDA June 12, 2006

4. **Debbie Rushing, CLS MT(ASCP)SBB, Supervisor of the USC/Norris Cancer Center transfusion service laboratory** (attribution used with permission), reports that her hospital recently went 'live' on [Cerner Millennium](#). In response to the new requirement to use machine readable labeling for pooled blood products, they set up a barcode label function using a Z4MPlus Zebra printer. This was set up in "DISCERN EXPLORER" as a "Discern prompt for Blood bank Zebra barcode labels". Using the aforementioned plan, they can now **create simple barcode labels for the pooled product number and for the hospital name** ([example attached](#)). The hospital transfusion service is neither FDA registered or licensed. To print an "on-demand" label, the "Explorer Menu" button is added to the Application bar for access to print the barcode label.

ADDENDA Aug. 9, 2006

5. **David Pollock, MT(ASCP)SBB, DLM who is the Blood Bank Supervisor at the Children's Medical Center in Dayton, Ohio** (attribution used with permission) reports that he has created an internet-based process for **fonts and templates to print barcoded labels** at <http://www.geocities.com/dmpollock>. Mr. Pollack acknowledges that these labels are **designed for in-house use**. Use by FDA Licensed facilities should be coordinated with the FDA. It is the responsibility of the user's facility to validate the labels and ensure that all requirements are met.

ADDENDA Nov. 12, 2006

6. **A Consulting Technologist** reports that she works with several **rural hospital laboratories in Maine**. In gearing up for the ISBT-128 changes, she anticipates that there would be very few instances when relabeling of blood products would be needed. One would be for **pooling** cryoprecipitate, but supposedly there will be a pooled product available in the future. The other would be when **splitting** units (for infants, etc). She wonders if there is any **easy way to comply with labeling such products without having to invest quite a bit of money in hardware and software that would be used infrequently?**

ADDENDA Dec. 27, 2007

7. **A supervising technologist in Los Angeles** reports that her hospital's transfusion service staff currently manufacture two kinds of blood products that must be labeled by their staff: 1) Thawed Plasma, which expires 5 days from thaw date, and 2) Pooled Cryoprecipitate. She reports that she checked the [ICCBBA website](#) to learn how to properly label these products but found the information confusing. She wonders if any colleagues would **share their approach to labeling Thawed Plasma and Pooled Cryoprecipitate in a manner that is compliant with federal and state regulations.**

Please submit comments to the [e-Network Forum](#).

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