Regulatory Requirements for Labeling Neonatal Blood Components.

Mary A. Lieb MT(ASCP)SBB, CQA(ASQ)

Quality Source by Blood Systems
Scottsdale AZ
Objectives

- List the regulatory requirements and standards for labeling blood components for neonates.
- Identify the how labeling can be used to meet requirements and standards.
- List risks of improper labeling.
- List Resources available for guidance to labeling
- Provide opportunity to discuss questions and concerns
21CFR 606.120
Labeling - General Requirements

Must have a separate area designated for labeling.
Labeling controls must include review and proof against a final copy for assurance of accuracy.
Storing labels must be in manner to prevent mixups and obsolete labels destroyed.
All necessary checks in labeling procedures shall be used to avoid errors in translating test results to container labels.
All labeling shall be clear and legible.
5.1.6.3 General Labeling Requirements.
The blood bank or transfusion service shall have a labeling process. This process shall include steps taken to:

1. Identify the original unit, any components, and any component modifications
2. Complete the required reviews
3. Attach the appropriate labels
(c) The container label shall include the following information, as well as other specialized information as required in this section for specific products:

(13) The container label may bear encoded information in the form of machine-readable symbols approved for use by the Director, Center for Biologics Evaluation and Research.
Subpart 3

- The original label and added portions of the label shall be attached to the container and shall be in clear, eye-readable type.
- ABO/Rh, unit number, component name, and facility identification shall be in machine-readable format.
AABB Standards 5.1.6.3.1

Subpart 6

- If a component is modified and new labels are applied, a method to ensure the accuracy of all labels including the unit number, ABO/Rh, and expiration date (as appropriate) and the component label(s).

Subpart 7

- Labeling process shall include a second check to ensure the accuracy of affixed label(s) including the correct unit number, ABO/Rh and expiration date.
Responsibilities

Who is subject to this machine-readable requirement?

All blood establishments that

- manufacture,
- process,
- repack,
- relabel

blood or blood components intended for transfusion
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.
**Requirements**

*What information must be machine-readable?*

Each label must have machine-readable information that contains, at a minimum:

- A unique facility identifier
- Lot number relating to the donor
- Product code
- ABO and Rh of the donor.
Requirements

How must the machine-readable information appear?

The machine-readable information must:
- Be unique to the blood or blood component
- Be surrounded by sufficient blank space so that the machine-readable information can be scanned correctly
- Remain intact under normal conditions of use
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.
Reducing Risk

When labeling blood products or inspecting blood products at any step of the production process the component must be visually inspected to ensure suitability for release.

Guidelines/SOP’s should be available to provide specific criteria for inspecting unlabeled components or inspecting components prior to and including labeling.
Tracking and Traceability

Retain lot numbers of all supplies
- Transfer bags
- Syringes
- Sterile Dock

Maintain a component log for labeling and component preparation
**ISBT 128 Labeling**

1. Donation Identification Number
2. ABO/Rh Blood Groups
3. Product Code
4. Expiration Date and Time
5. Special Testing
ISBT 128 Labeling

• AABB accredited facilities must implement by end of April 2008
• Facilities may be required to register with ICCBBA
• Commonly uses on-demand label printing
• May require hospital software upgrades
• Complies with FDA barcode rule
• References:
  www.iccbba.org
  www.aabb.org
Collection Date 27GY 27098/1
Expires 08-01-00

CPD RED BLOOD CELLS
LEUKOCYTES REDUCED

From 450 mL CPD Whole Blood.
Store at 1 to 6°C.

See circular of information for indications, contraindications, cautions and methods of infusion.

VOLUNTEER DONOR
This product may transmit infectious agents. Caution: Federal law prohibits dispensing without a prescription.

PROPERLY IDENTIFY INTENDED RECIPIENT

Processed by CONEMAUGH VALLEY MEMORIAL HOSPITAL BLOOD BANK
1086 Franklin Street Johnstown, Penna. 15905
Registration # 2673663
CMV NEGATIVE
Summary

• Labeling Process must be
  – Segregated
  – Controlled
  – Accurate
And Have
  – Second Check
    • Manual
    • Computer
<table>
<thead>
<tr>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>• <a href="http://www.geocities.com/dmpollock/">http://www.geocities.com/dmpollock/</a></td>
</tr>
<tr>
<td>• <a href="http://www.fda.gov/cber/summaries/bldreg011706dm2.pdf">http://www.fda.gov/cber/summaries/bldreg011706dm2.pdf</a></td>
</tr>
<tr>
<td>• Guideline for the Uniform Labeling of Blood and Blood Components; FDA :August 1985</td>
</tr>
</tbody>
</table>
References

• Guidance for Industry: Bar Code Label Requirements
  Questions and Answers
  Additional copies are available from:
  Office of Training and Communications
  Division of Drug Information, HFD-240
  Center for Drug Evaluation and Research
  Food and Drug Administration
  5600 Fishers Lane
  Rockville, MD 20857
  (Tel) 301-827-4573
  http://www.fda.gov/cder/guidance/index.htm
References

- Office of Communication, Training and Manufacturers Assistance, HFM-40
  Center for Biologics Evaluation and Research
  Food and Drug Administration
  1401 Rockville Pike
  Rockville, MD 20852-1448
  [http://www.fda.gov/cber/guidelines.htm](http://www.fda.gov/cber/guidelines.htm)
  Phone: the Voice Information System at (Tel) 800-835-4709 or 301-827-1800