

Dockets Management Branch (HFA-305)
FDA
5639 Fishers Lane, Room 1061
Rockville, MD 20852
September 13, 2001

3649 '01 SEP 27 12:17

Dear Sir:

In reference to Docket # 01D0220, I would like to add a suggestion for inclusion in the guidelines. For transfusion services, under the *Quality Control and Distribution* system for reporting deviations, I would suggest that under IV. F, which I have reprinted below, that the distribution of a unit of rbc's that violates the "3 day rule" for compatibility testing, AABB Standard 5.12.3.2, be added to the list of SOP failures. The suggestion appears in bold at the end of the list.

For *transfusion services*, this also includes the distribution of products not in accordance with SOP's which may affect the safety, purity, or potency of a product, such as:

- The transfusion service receives an order for a unit requiring special processing or testing, such as irradiation, leukoreduction, CMV negative, and fails to perform that processing and distributes the unit
- Wrong unit issued for a specific patient
- The transfusion service received an order for a specific type of product, but distributes an incorrect product, such as an order for platelets is filled with Fresh Frozen Plasma
- Improper ABO or Rh type selected for patient
- Issuing the wrong filter for use in transfusion
- ***The transfusion service distributes a unit of red blood cells more than 3 days from the date the patient's sample was used for compatibility testing on a patient who was transfused or pregnant in the preceding three months***


Also, while you do have a section for Quality Control and Distribution BPDR codes, there is no specific section under that heading for distribution variances, such as:

QC-98-** Distribution

QC-98-01 Distribution of product for transfusion not in accordance with SOP

Most of the BPDR codes seem to apply to donor centers/blood banks. It would be helpful to have a category specifically for Transfusion Services. We find it somewhat difficult to code our variances, one of them being a violation of the three day rule as mentioned above. We coded it as QC-94-01.

Thank you,


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01D-0220



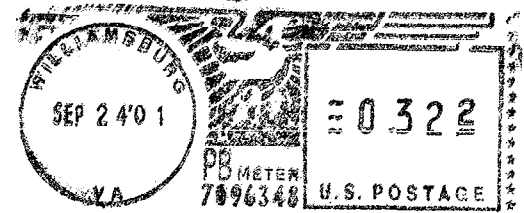
Blood Bank

**WILLIAMSBURG
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