PROCEDURE

Title: Biological Deviation

Procedure #: 2015BLOODBANK87

Institution: Highlands Regional Medical Center

Address: 3600 Highlands Avenue, Sebring Florida 33870

Prepared by: Anita Smith Date: 6/12/2015

Title: Laboratory Administrative Director

Accepted by: _____ Date: 6/12/15

Title: Laboratory Medical Director

Date Patient Testing Implemented: 2/1/2009

Review of procedure every two years

Reviewed by: _____ Date: _____

Reviewed by: _____ Date: _____

Reviewed by: _____ Date: _____

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Reviewed by: _____ Date: _____

Reviewed by: _____ Date: _____

Discontinued testing date: _____

Highlands Regional MEDICAL CENTER

Policy Name: Reporting Biologic Product Deviation	Department: Blood Bank-Lab
Departmental Review:	Policy #:

INITIATE DATE	DATE REVIEWED/REVISED	PAGE 1 of 2
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POLICY:
Transfusion facilities are required to report to FDA any deviations or unexpected events associated with manufacturing that may affect the safety, purity or potency of a distributed product as soon as possible but not to exceed 45 calendar days from the date of discovery of information reasonably suggesting a reportable event has occurred. Manufacturing in a transfusion service may include compatibility testing, component preparation, labeling, storage, and distribution of units for transfusion. A BPDR (Biological Product Deviation Report) is reportable to CBER if the transfusion service releases a blood product from its control and the error has the potential to affect the safety, potency or purity of the product, even if it is not administered to a patient. The reporting establishment is the establishment who had control over the product at the time the BPD occurred.

PROCEDURE:
1. Obtain form FDA 3486 Biological Product Deviation Report.
2. Complete all sections that apply to your report
3. If exact dates are not known, make your best guess.
4. Complete a separate form for each BPD. If a BPD involves more than one product, only one form needs to be completed listing all distributed products potentially affected.
5. Only submit completed pages of the report. Do not submit blank pages if additional space is not needed.
6. Do not include donor, patient, or employee personal identification information or other confidential information.
7. Do not use this form to report fatalities that occur as a result of collection or transfusion of blood or blood products. See Reporting of Transfusion Related Fatalities Procedure.
8. Send amended or follow-up reports or information to CBER via regular mail or e-mail to bp_deviations@cber.fda.gov. When submitting the amended or follow-up report via regular mail, please identify the report as an amended or follow-up report and highlight the changes and/or the additional information.
9. See Guidance for Industry and General Instructions for Completing the Biological Product Deviation Report Form FDA 3486 for detailed instructions
10. Mail report to:
    Director, Office of Compliance and Biologics Quality
    (HFM 600)
    Center for Biologics Evaluation and Research
    Food and Drug Administration
    1401 Rockville Pike, Suite 200N
    Rockville, MD 20852-1448
11. Contact CBER at 301-827-6220 if there are any questions about reporting BPD

REFERENCES:
US Food and Drug Administration Biologic Product Deviation Reporting
www.fda.gov/cber/biodev/biodev.htm. 21CFR 600.14 and 606.171
CAP TRM.30950

Highlands Regional MEDICAL CENTER

Policy Name: Reporting Transfusion Related Fatalities **Department:** **Blood Bank-Lab**

Departmental Review: **Policy #:**

INITIATE DATE **DATE REVIEWED/REVISED** **PAGE 1 of 3**

POLICY:
The current good manufacturing practice (CGMP) regulations for blood and blood components require that you report fatalities related to blood collection or transfusion to CBER (21 CFR 606.170(b)). Section 606.170(b) states: When a complication of blood collection or transfusion is confirmed to be fatal, the Director, Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research, shall be notified by telephone, facsimile, express mail, or electronically transmitted mail as soon as possible; a written report of the investigation shall be submitted to the Director, Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research, within 7 days after the fatality by the *collecting facility* in the event of a donor reaction, or by the *facility that performed the compatibility tests* in the event of a transfusion reaction. (Emphasis added)

PROCEDURE:
1. Submit initial notification by telephone, email, facsimile, or express mail. E-mail notification is recommended. A follow-up report must be submitted 7 days after the fatality.
2. There is no required FDA form, provide at least the following information for the initial notification:
   a. Date and time of the notification.
   b. Your name, title, telephone number with area code, and fax number (if available).
   c. Your facility's name, mailing address
   d. Age and sex of the deceased.
   e. Date, time, and cause or suspected cause of death (briefly describe what happened).
   f. If an autopsy was or will be performed.
   g. Name and address of facility where the fatality occurred if different from your facility.
   h. Please also include in the initial notification the information listed
      - Transfusion date(s)
      - Blood/blood component(s) and unit number(s) of product(s) that may be implicated
      - Name and address of facility(ies) providing the blood
      - Brief description of events that led to the fatality - include underlying medical condition reason for transfusion, how the patient initially responded to the transfusion, any medical intervention taken or response to the reaction, and time from initiating the transfusion to patient's death.
3. Conduct a thorough investigation of the adverse event and submit a written report of the fatality investigation. The report can be amended by filing additional information but a follow-up must be submitted in 7 days after the fatality. Identify the report as a follow-up and include:
   - Discharge summary and/or death certificate
   - Autopsy report (if performed)
   - Conclusions and corrective action plan if appropriate
   - Complete transfusion reaction report, including the manufacturer and lot number of the blood collection system.
   - Additional relevant documents include laboratory, radiology, etc. reports and physicians' consults/opinions.
   - If replacement fluid(s) was given during the transfusion, indicate which fluid(s) and the unit or lot number(s), and include any other relevant information, manufacturer's notices, contamination warnings, or replacement fluid recalls.

- If responsibility for the fatality appears to be outside the blood bank, the nurses' and/or physicians' notes on the patient, radiology reports, and physicians' consults/opinions.
- Results of lookback investigation when the fatality was the result of transfusion transmitted infectious disease. Transfusion committee minutes and risk management summary of findings when the fatality was reviewed and discussed.

4. Submit initial and 7-day reports to:
   a. E-mail: fatalities2@cber.fda.gov
   b. Telephone/voice-mail number: 301-827-6220
   c. Fax number: 301-827-6748, Attn: CBER Fatality Program Manager
   d. Express mail address:
      Office of Compliance and Biologics Quality/CBER
      Attn: Fatality Program Manager (HFM-650)
      1401 Rockville Pike, Suite 200N
      Rockville, MD 20852-1448
5. If you have any questions about reporting fatalities, please contact the CBER Fatality Program Manager at 301-827-6220.

REFERENCES:

Food and Drug Administration. Current good manufacturing practice for blood and blood components. Records and reports. Adverse reaction file. Washington, DC: US Government Printing Office, 1999(Apr 1):[21CFR606.170(b)]

Notifying FDA of Fatalities Related to Blood Donation or Transfusion. September, 2003 CBER

CAP Requirements TRM.42185

Highlands Regional MEDICAL CENTER

Policy Name: Reporting Biologic Product Deviation **Department: Blood Bank-Lab**

Departmental Review: **Policy #:**

INITIATE DATE	**DATE REVIEWED/REVISED**	**PAGE 2 of 2**
02/2009	05/2013	

Reviewed by	Reviewed Date	Reviewed by	Reviewed Date

Initial Implementation Date: _____

Taken out of Service: _____

Reason:_____

Reviewed by: _____Signatures on file_____ Date: 5-27-15

Department Supervisor

Reviewed by: _____ Date: 5/29/15

Department Adm. Director

Reviewed by: _____ Date: _____

Department Chief Technologist

Reviewed and Approved by: _____ Date: _____

Department Medical Director

Highlands Regional MEDICAL CENTER

Policy Name: Reporting Transfusion Related Fatalities **Department:** **Blood Bank-Lab**

Departmental Review: **Policy #:**

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Reviewed by	Reviewed Date	Reviewed by	Reviewed Date
	8.6.14		
	5.28.15		
	5-29-15		

Initial Implementation Date: _____

Taken out of Service: _____

Reason: _____

Reviewed by: _____ Date: 7/10/13
Department Supervisor

Reviewed by: Angela Lawster Date: 7/8/13
Department Adm. Director

Reviewed by: _____ Date: _____
Department Chief Technologist

Reviewed and Approved by: _____ Date: 7/8/13
Department Medical Director

Highlands Regional MEDICAL CENTER

Policy Name: Reporting Biologic Product Deviation **Department: Blood Bank-Lab**

Departmental Review: **Policy #:**

INITIATE DATE 02/2009 **DATE REVIEWED/REVISED** 05/2013 **PAGE 2 of 2**

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Department Medical Director