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Kaiser Permanente Medical Center, San Francisco
Northern California Region
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Work Instruction

Title:	**TQ-Biological Product Deviation Reporting**	**WI Number** SFOWI-0156 **Revision:** 11
Department: Immunohematology **Area:** 2425 Geary Blvd SFO Hospital Lab	***Document is in the Final Approval Process. 2 - approvals are required***	
Type of Document: Policy		**Review Period -** 340 **Days**

PURPOSE

A. The Code of Federal Regulations require that the Center for Biologics Evaluation and Research (CBER) be notified promptly of errors or accidents in the manufacture of products that affects the safety, purity or potency of any product.

B. The term "Biological Product Deviation" (BPD) includes unexpected events as well as deviations.

C. This procedure defines the reportable and non-reportable events that may occur in the transfusion service when a deviation occurs, and the steps to be followed when a report must be submitted.

REAGENTS

Not Applicable

EQUIPMENT

A. Computer with internet access

B. Biological Product Deviation Report Form – electronic form available

C. General Instructions for Completing the Biological Product Deviation Report (BPDR) Form

D. Biological Product Deviation Codes and Blood Component Codes

PROCEDURE

A. Staff, performing or reviewing Transfusion Service operational steps, identifies unexpected events and deviation of cGMPs, applicable regulations, or established specifications that may affect the safety, purity, or potency of those products.

B. Staff files Variance Log. Responsible Reporting Form is also filed if needed.

C. The Transfusion Service Supervisor or designee determines if the unusual occurrence is reportable to the FDA as a Transfusion Service based on the following criteria:

1. Was the event associated with manufacturing of both licensed and unlicensed blood or blood components?

a. Manufacture means the collection, preparation, processing, or compatibility testing or manipulation, sampling, testing or control procedures applied to the final blood product.

2. Was there a deviation or unexpected event that may affect the safety, purity, or potency of the product?

a. Change in the manufacturing process that would prevent a product from meeting all:
   i) Current good manufacturing practices (cGMP)
   ii) Applicable standards
   iii) Established specifications of defined product or process parameters (SOP)

b. Unexpected event affects the product despite that a blood establishment followed all required procedures.
   i) Post donation information discovered that donor does not provide all information, but was asked all history questions.
   ii) Patient sample used for compatibility testing was collected from the wrong patient.
   iii) Materials used in the collection or processing did not meet all requirements or specifications.

3. Did it occur in your facility or at your contract facility?

a. Blood establishment
   i) Licensed manufacture of blood and blood components, including source plasma
   ii) Unlicensed registered blood establishment
   iii) Transfusion Service

b. Contract establishment
   i) If you contract out any manufacturing step, that step is performed under your control.

c. Supplier

d. Consignee

4. Did you have control over the product when the deviation occurred?

a. Control means having
   i) Responsibility for maintaining the continued safety, purity, and potency and for
   ii) Compliance with applicable product and establishment standards, and for
   iii) Compliance with cGMPs.

5. Was the product distributed?

a. The blood or blood component has left the control of the licensed manufacturer, unlicensed blood establishment or Transfusion Service.

b. The licensed manufacturer has provided Source Plasma or any other blood component for use in the manufacture of a licensed biological product.

D. **Report as soon as possible but not to exceed 45-calendar days** from the date you acquire the information.

1. The date when you acquire the information reasonably suggesting that a reportable BPD event has occurred.
2. The date when your manufacturer, supplier, or contractor learns of the deviation or unexpected event.

E. **Report to FDA CBER**

1. Electronically through CBER's website using the eBPDR system: http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ReportaProblem/BiologicalProductDeviations/ucm134534.htm
2. Mail to:
   Food and Drug Administration
   Center for Biologics Evaluation and Research
   Document Control Center
   10903 New Hampshire Avenue
   Building 71, Room G112
   Silver Spring, MD 20993-0002.
   NOTE: Verify that the address is current by going to the FDA CBER website prior to mailing.
3. Send amended or follow-up reports to CBER via regular mail or e-mail to bp_deviations@fda.hhs.gov.
   Include the establishment identification number, P#, first listed unit or lot number, and the date the report was submitted.
4. If you need assistance, you may contact CBER via phone call to 800-835-4709 or 240-402-9160 **during regular working hours** or email to bp_deviations@fda.hhs.gov.
   NOTE: If phone# no longer works, obtain the current contact# from CBER website.

F. **To submit BPDR online**

Go to the FDA CBER website or the following url
http://www.fda.gov/cber/biodev/biodev.htm

1. Click on Electronic Submission of Biological Product Deviation Reports (eBPDR).
2. Click on the CBER On-line Login Screen. Our user name is tpmg_sfo.
3. Enter the password.
4. On Application, select (eBPDR) Biological Product Deviation Reporting.
5. Use CLIA# 05D0689947 for Establishment ID. (Use FEI # 1000135033 only if the facility is actively registered with FDA).
6. Create a Tracking Number based on the date of event, using the following format: YY_MMDD.
7. Enter all required information including the appropriate BPD Code, Description, Contributing Factor(s), Follow-up or Corrective Action, Unit number and Component Code.
8. Print report before Logout. The report will have a P# and is automatically saved by the system. Do Not submit the report at this time.
9. Send the report to the following individuals for review and approval before submitting to the FDA.
   a. The Transfusion Service Medical Director, Assistant Laboratory Administrative Director and the hospital AR&L before final submission to the FDA.
   b. If there is difficulty in finalizing root cause and corrective action plans, contact the NCAL Laboratory Quality and Compliance department at the TPMG Regional Laboratory for assistance. Contact by email to NCAL LQC-KPNC, or phone the NCAL Blood Bank Quality Practice Leader at 510-559-4938.
   c. Email a PDF to NCAL LQC-KPNC or FAX a copy to 510-559-5215 for review and regional tracking. If there is no difficulty in finalizing root

cause and corrective action plans, do not wait for LQC department's response before submission to the FDA.

10. If computer is not available, use Form FDA-3486 Biological Product Deviation Report Form to report BPD
    a. Obtain the form by downloading from the CBER website or the following http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ReportaProblem/BiologicalProductDeviations/default.htm
    b. Use General Instructions for Completing the Biological Product Deviation Report (BPDR) - Form FDA 3486
    c. Refer to CBER website for the appropriate Biological Product Deviation Code to use.
    d. Submit the completed form for review and approval before submitting to the FDA. Follow steps 9.a.- c. above.

G. **Comments**

1. DO NOT include donor, patient, or employee personal identification information or other confidential information.
2. **DO NOT use this form to report Fatalities** that occur as a result of collection or transfusion of blood or blood products. Refer to SFOWI-0155 Unusual Occurrence Management.
3. DO NOT use this form to report Adverse Experiences related to biological products other than blood or blood components.

PROCEDURE NOTE(S)

Refer to CBER website for BPD codes and descriptions to determine if an event or deviation is reportable.

REFERENCE:

A. O'Callaghan, Sharon, FDA Focus on Hospital Transfusion Services, AABB Audioconference, March 14, 2001.

B. General Instructions for Completing the Biological Product Deviation Report (BPDR) - Form FDA 3486, Biological Product Deviation Reporting.

Associated Documents:

External Documents

Associated Quality System Documents - None

Documents Generated:

Document Revision History:

Revision: 11	**Date Created:** 10/02/2005 **Date of Last Revision:** 01/31/2019	**Last Approval Date:** 01/03/2017

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Reason for Change:

Revision:	Sec/Para Changed	Change Made:	Date
1	N/A	Initial Issue of Document	7/30/06

2	Approver	New Lab Director	1/15/07
3	Approver	New Lab Director	7/31/07
4	Equipment D	Typo corrected.	4/26/10
5	Approver	New Lab Director	06/11/11
6	Procedure D., E., & F. Procedure F.2. Procedure E. & F. Procedure F.5. & 6.	Switched order. Changed user name. Updated CBER's web address, email address and mailing address. New.	11/28/12
7	Approver Procedure Procedure B1.d. & e. Procedure D.1.e.v) to viii), h. & i.	New BB Medical Director. Reformatted numbering and sections. New. Added missed QC and sample labeling error as criteria. New. Added more criteria.	10/4/13
8	Procedure Note(s) D.1.f. Procedure Note(s) D.1.g., i. & 1.e.(vii) Procedure Note(s) D.1.e. Procedure F.5. Procedure F.9.	Revised wordings to match exactly with CBER description. New. Added three categories. Revised. Added CBER deviation description. Revised. Added instructions to use CLIA# unless actively registered with FDA. Added 2 reviewers, Transfusion Service Medical Director and the hospital AR&L before final submission to the FDA. Also added sending a copy to Regional LQC for review and tracking.	11/19/13
10	Procedure E.	Updated FDA CBER's contact information for BPD.	9/12/14
11	Approver	New CLIA Director.	12/29/16
12	Procedure E. Procedure Notes.	Updated CBER's contact information for BPD. Deleted outdated BPD descriptions and added instructions to refer to CBER website to determine reportable events and deviations.	1/31/19

Notification List:

Approvals:

First Approver's Signature

Name: Maria F Serrano/CA/KAIPERM
Title: Transfusion Service Medical Director

Second Approver's Signature

Name: Eric Suba/CA/KAIPERM
Title: Chief of Pathology; CLIA Director

Document History Section