Sutter Health
Sutter Roseville Medical Center

Origination:	*N/A*
Effective:	*Upon Approval*
Final Approved:	*N/A*
Last Revised:	*N/A*
Next Review:	*2 years after approval*
Owner:	*Irene Wittkop: Coord, Transfusion Service*
Policy Area:	*Lab - Transfusion Service*
References:	
Applicability:	*Sutter Roseville Medical Center*

Completing a FDA Biological Product Deviation Report

Completing a FDA Biological Product Deviation Report

Purpose	This procedure describes how to complete and submit an electronic Biological Product Deviation Report (eBPDR).
Policy	• Each BPD will be assigned a facility tracking number using the format: *SQ site code-month/year (mm/yy)BPD discovered-sequence number for the year* (Example: RV05/01-1) • The Biological Product Deviation Report (BPDR) will be completed by the Transfusion Service Supervisor/specialist and approved by the Lab Medical Director preferably prior to submission. The BPDR will be submitted to the FDA within 45 days following discovery of the BPD.
Establishing a User Account	A User Name and Password are needed to file eBPDRs. To establish a user account: • Access the FDA website (refer to Procedure step 1). • Click on the *Create New Account* link. • Enter requested information.
Other FDA Contact Information	FDA/CBER Director, Office of Compliance and Biologics Quality (HFM-600) 1401 Rockville Pike, Suite 200 N Rockville, MD 20852-1448
Procedure	Follow the steps below to complete eBPDR.

Step	Prompt	Action
1	Access the FDA FURLS eBPDR Electronic Biological Product Deviation Report on the **FDA Industry Systems (FIS)** website *https://www.accessdata.fda.gov/scripts/cber/CFApps/Index.cfm*	
2	User Name	Enter your User Name <Tab>.
3	Password	Enter your password, then click on the *Enter CBER On-line* button.
4	From the FDA On-line Account Menu screen, click on CBER *Biological Product Deviation Reporting (CBER eBPDR)hyperlink* under Other FDA Systems header	
5.	Click Menu and select My Reports	
6		

If…	Then…
Entering a new report.	Click on *+Create Report* button.
Retrieving an Unfinished Report.	• Follow on screen instructions to complete or submit an Unfinished Report

7.	Select you establishment by highlighting it from the drop down box.	
8.	Click Next button	
9.	Verify that the facility information displayed is correct.	
10.	Telephone	Enter the telephone number of the facility contact person (Supervisor/Specialist or Medical Director). <Tab>
11	Point of Contact	Enter the name of the contact person. <Tab>
12	E-mail	Enter e-mail address of the contact person. <Tab>
13	Establishment Tracking Number	Enter the facility BPD tracking number. See policy section above for format instructions. <Tab>
14	Please check here if the Deviation did not occur at this Reporting Establishment?	Click box if applicable.
15	Click **Save & Continue**	
16	Date BPD Occurred	Enter date (mm/dd/yyyy) BDP occurred. <Tab>

17	Date BPD Discovered	Enter the date (mm/dd/yyyy) BDP was discovered. <Tab>
18	Date BPD Reported	<Tab>
19	Type of Product	Click • ***Blood Product*** <Tab>, or • ***Non-Blood Product*** (ie Rhlg) <Tab>
20	BPD Code	• Click Select BPD Code box • Select code that corresponds to category of where in process error occurred • Select BPD code that best fits source of error from list *Note: There are separate code lists for Blood vs Non-Blood deviations.*
21	Description of BPD	Enter event details (maximum of 3999 character spaces allowed), including description of what happened and summary of all relevant information. Click Continue. *DO NOT include any confidential information, such as patient or employee name.*
22	Description of Contributing Factors or Root Cause	Enter all contributing factors or root causes (maximum of 3999 character spaces allowed).
23	Follow-up	Enter follow-up action taken or planned, if applicable (maximum of 999 character spaces allowed). *Note: Corrective action identified does not have to be completed at the time the report is filed.*
24	Click **Save & Continue**	
25	Enter Total Number of Units involved in reportable event	
26	Enter number of Components or Lots	
27.	Click Update Product Grid	
28	Enter the following information for the first unit	

	If…	**Then enter ….**
Blood product	• Unit number • Collection date • Expiration date • Blood product code *Click Blood Product Code for listing)* • Disposition (select from drop down menu) • Notification • Comments, if needed
Non-blood product	• Lot number • Expiration date • Product type • Non-blood product code *(refer to Attachment)* • Disposition • Notification • Comments, if needed

	Note: Additional comments if needed (up to 1500 characters), can be entered in the Comments section.
29	Repeat step 28 for each unit to be reported.
30.	Click **Save & Continue**
31	When finished, review the report for accuracy.

	If the report….	**Then click….**
needs correction.	• Click Edit • Change Information
needs Medical Director review	• Print the BPD Pre-confirmed report, and • Submit to Medical Director for review. *Note: a saved report will be deleted after 30 days if not submitted to the FDA.*
approved by Medical Director	• BPD pre-confirmed report is signed & dated by the Medical Director indicating his/her approval • **Submit to FDA**, • Print the BPD Receipt Confirmation page, and • Retain in appropriate TS file. *Note: The Receipt Confirmation page contains all the information entered **and** a confirmation number that should be used if additional correspondence is needed.*
needs to be deleted	• Return to home Menu • Click the X on the line that corresponds to the Unfinished report that needs to be deleted.

32	• Click *Logout* at top of Account Management screen to exit system, or • Click **+Create Report** to enter another report.

End

All revision dates:

Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
Laboratory Director	Lindsey Westerbeck: Dir, Lab	pending