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| **University of Washington,** **Harborview Medical Center****325 9th Ave. Seattle, WA, 98104****Transfusion Services Laboratory****Policies and Procedures Manual** | **Original Effective Date:** **July 15, 2011** | **Number:** **1703-1** |
| **Revision Effective Date:** | **Pages:** **4** |
| **TITLE: FDA—CBER BIOLOGICAL DEVIATION REPORTING** |

**Purpose:**

To provide guidance on the use of the FDA Biological Product Deviation Report (BPDR) and to standardize the documentation, investigation, reporting, implementation of corrective actions, and monitoring of the BPDR by the Harborview Medical Center Transfusion Service.

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| **Role** | **Responsibility/ Requirement** |
| **FDA-CBER** | * On November 7, 2000, the Food And Drug Administration (FDA) published a final rule to amend the requirements for the reporting of errors and accidents in the manufacture of blood products. The rule amended the regulation at 21 CFR 600.14, and added a requirement at 21 CFR 606.171, applicable to all manufacturers of blood and blood products.
* In August 2001, the FDA published draft guidance on Biological Product Deviation Reporting for Blood and Plasma Establishments. This guidance to the Blood Industry outlines biological product deviation reporting requirements for licensed blood donor centers and unlicensed registered transfusion services. The FDA finalized the draft guidance in October 2006, same title dated August 2001.
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| **Medical Director** | * Consults with Care provider about patient care
* Interacts with Care provider if reporting fatality.
* Consults with Manager when there are questions about whether an event meets the reporting criteria.
* Reviews reports.
* Together with manager, makes decisions about corrective action.
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| **Manager** | * Acts as facility contact with FDA
* Reports incidents that meet the reporting criteria.
* Prepares report for Quality Review.
* Implements and monitors corrective actions.
* Coordinates reporting of incident to HMC quality/risk as indicated.
* Performs Timely investigation of incident. Fatality must be reported in 24 hours, Others must be reported within 45 days of occurrence.
* Development of corrective action plans both short and long term, to prevent recurrence.
* Retrieval, Quarantine, and final disposition of any unsuitable products.
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| **Criteria for Reporting** | Any deviation or event (planned or unplanned) to include post donation information associated with manufacturing of both licensed and unlicensed blood or blood products that:* Were manufactured with a deviation from current good manufacturing practices (cGMPs) or applicable regulations or established specifications (Policies and Procedures) that may affect the safety, purity, or potency of the product AND such deviation occurred while the product was under the control of the Transfusion Service.
* Were distributed at Harborview Medical Center or a facility contracted to HMC.
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| **Definitions** | * **Manufacturing:** The collection, preparation, processing, compatibility testing, or other procedures of any blood product that meets the definition of a drug and including manipulation, sampling, testing or control procedures applied to that final product.
* **Deviation:** Change in the manufacturing process that would prevent a product from meeting all cGMPs, applicable standards or regulations and facility procedures.
* **Event:** Any occurrence that may affect the product and that might occur even if the facility has followed all required procedures. Examples include:
	+ post donation information (reportable by the collecting facility)
* patient sample used for compatibility testing was collected from the wrong patient
* materials used in the collection or processing did not meet all requirements or specifications,
* **Control:** Having responsibility for maintaining the continued safety, purity, and potency of a product and for complying with applicable product and establishment standards and cGMPs.
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**Reporting Procedure**

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| **Step** | **Action** | **Related Documents** |
| **1.** | Document deviation or event according to Occurrence Management Policy. | Occurrence Management  |
| **2.** | Inform management according to Occurrence Reporting protocol  | Occurrence Reporting |
| **3.** | Initiate investigation, describing the event in detail in the QIM form and attach any documentation.  |  |
| **4.** | Identify products affected and perform a look-back:* Determine disposition, quarantine if in date and notify consignee and/or recipient and/or physician in accordance with testing and look-back policies.
* Document notification if performed.
 | Look-Back Process |

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| **Step** | **Action** | **Related Documents** |
| **5.** | Determine the cause of the event.* Meet with all parties involved.
* Recreate the event and check the process flow.
* Ask “Why” until the cause is determined.
* Review Policies and Procedures for clarity, completeness

 and contradictions.* Evaluate training process.
 | Process Improvement by Corrective ActionRoot Cause Analysis Process |
| **7.** | Develop and implement corrective action plan—involve staff. |  |
| **8.** | **Non Fatalities--Complete the BPDR online form. FDA Form 3486.** |  |
|  | * Submit through CBER website at [www.fda.gov/cber/biodev/biodev.htm](http://www.fda.gov/cber/biodev/biodev.htm).
* When submitting electronically, the user name and password for the institution is

 required. The user name and password are kept by the Manager in a secure  location.* Choose Facility name and address.
* Enter CLIA Test Site number.
* Enter Facility Tracking number (mm/dd/yy-1,2,3, etc.)
* Enter the date the deviation was discovered (dd/mm/yyyy). This is the date the

 information was received, suggesting that a deviation had occurred.* Enter the date the deviation or event actually occurred.
* Describe the event or deviation in detail, including description of what happened and

 a summary of all relevant information. DO NOT include confidential information such as patient, employee, or donor names.* Describe contributing factors or the cause of the event or deviation. Indicate if a root

 cause cannot be determined.* Describe all short-term and long-term corrective action and follow-up plans.

 Corrective actions do not have to be implemented at the time of the report.* Enter Six-digit BPD code (Appendix A). The first two digits identify a subset of the
* system, and the last two digits contain detailed information regarding the event.
* Select the code that most closely describes the deviation or event.
* Select Blood or Non-Blood.
* Blood: products manufactured by blood and plasma establishments.
* Non-Blood: products manufactured by a facility other than a blood establishment. (Such as vaccines, THIg, AHF)
* Blood Products—Enter the total number of Lots affected. A lot includes all products manufactured from a donor identification number. For each component provide the following:
* Unit Number
* Collection Date
* Expiration Date
* Blood Product Code (Appendix A)
* Blood Disposition Codes (Appendix A)
* Notification—Enter Y or N to designate whether consignee was notified. Enter RN if consignee notified you of the event.
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| **Step** | **Action** |
| **9.** | **Fatalities** |
|  | **Reporting Fatalities**Section 606/170(b) of the 21 CFR states that fatalities may be reported by telephone, fax, express mail, or electronically transmitted mail. It is recommended that initial notification be sent via email, and an email confirmation will be sent. If this is not feasible, notify by telephone or fax and complete a 7 day follow-up report by email, fax, or express mail.* E-mail: fatalities2@cber.fda.gov
* Telephone/voice-mail number: 301-827-6220
* Fax number: 301-827-6748, Attn: Fatality Program Manager (HFM-650)
* Express Mail address:

Office of Compliance and Biologics Quality/CBERAttn: Fatality Program Manager (HFM-650)1401 Rockville Pike, Suite 200NRockville, MD 20852-1448 |
| **Initial Notification of Fatality—within 24 hours of event**Provide the following information for proper evaluation of the potential public health significance of the event:* Date and time of the notification.
* Information on the person reporting the fatality:
* Name and Title
* Telephone number with area code and fax number
* Facility Information:
* Name
* Mailing address
* FDA Registration number, if applicable
* Date, time, and cause or suspected cause of death.
* Brief description of what happened.
* Whether an autopsy has been or will be performed.
* Name and address of the facility where the fatality occurred if different from the reporting facility.
* Transfusion dates(s)
* Blood product type(s) and unit number(s) of products that may be implicated.
* Name and address of Blood Supplier(s)
* Brief description of events that led to the fatality—include underlying medical condition or disease and circumstances, necessitating the hospitalization, reason for transfusion, how the patient initially responded to the transfusion, any medical intervention taken, and response to the intervention, and time from initiating the transfusion to patient’s death.
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**References**

BABB Standards for Blood Banks and Transfusion Services, Current Edition Page **4** of **4**

Code of Federal Regulations, 21, parts 606.171 Current Edition