TRAINING UPDATE

Update Number:	QDHOS707 v1	**Training Module #:**	**Date Implemented:**
Lab Location:		**Department:**	

DESCRIPTION OF PROCEDURE REVISION

Name of procedure(s):
FDA Reportable Event Notification Process (Supercedes Biological Product Deviation Reporting –FDA Reportable Event QDHBB601 v3)
Description of change(s):
Understands the following changes to SOP(s): **Section 1**—Added possible transfusion related fatality reporting to the purpose. **Section 2**—Added donor facilities to the scope. **Section 3**—Added responsibilities for reporting fatalities. **Section 5.A**— Added instructions for fatality reporting **Section 5.D**— Added more detail regarding internal report handling. Updated FDA reporting instructions to the preferred method (email). **Section 5.E.1**— Added specific report writing instructions for BPD reports. **Section 5.E.2**— Added specific instructions for initial fatality report. Added preparation for FDA inspection due to a fatality. **Section 5.E.3**— Added specific instructions for the seven (7) day fatality report. **Section 5.E.4**— Added required documentation. **Section 5.E.5**— Updated specific notification deadlines and addresses. **Section 6**— Updated retention requirement to indefinite. **Section 7**— Updated numbering convention for the Initial Notification of Suspected BPD Template. **Section 8**— Updated references

Electronic Document Control System

Document No.: SGAHQDHOS707[1.1]
Title: FDA Reportable Event Notification Process
Owner: LESLIE.X.BARRETT LESLIE BARRETT
Status INWORKS
Effective Date: 10-May-2015 **Next Review Date:**

Non-Technical SOP

Title	**FDA Reportable Event Notification Process**
Prepared by	Jill Hittinger **Date: March 2, 2015**

Laboratory Approval		**Effective Date:**
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		

Review		
Print Name and Title	**Signature**	**Date**

Corporate Approval		**Corporate Issue Date: March 20, 2015**
Print Name and Title	**Signature**	**Date**
Dianne Zorka, Owner **Director, Corp Quality Assessment**	*Approval on file*	**March 20, 2015**
Lee Hilborne, M.D., MPH **BPT Medical Advisor** **Medical Director, CP Quality**	*Approval on file*	**March 6, 2015**

Retirement Date:	*Refer to the SmartSolve EDCS.*
Reason for retirement/replacement:	

TABLE OF CONTENTS

1. PURPOSE

This document sets forth the process for recognition, classification, and reporting of biological product deviations, as prescribed by 21 CFR 606.171, for all Quest Diagnostics (owned or managed) manufacturing and/or transfusion service departments. This process will ensure timely investigation of exceptions in service and FDA notification of subsequent corrective actions, as described in 21 CFR 606.100, 211.192, and 211.198.

In addition, this document includes reporting steps for blood collection or transfusion related fatalities.

This process describes specific activities related to the filing of reportable events with the FDA and is to be used in concert with the corporate quality issue SOP that describes internal notification, investigation, root cause analysis, corrective actions, and preventive actions.

2. SCOPE

This process applies to all Quest Diagnostics hospital laboratories (owned or managed) that offer donor or transfusion services.

3. RESPONSIBILITY

Responsible Party	Task
Laboratory Director	• Approves the initial document and revisions. • Ensures that nonconforming events including Biological Product Deviations (BPDs), reportable or not reportable and blood collection or transfusion related fatalities are investigated and corrected when encountered. • Ensures that Biological Product Deviations are appropriately reported to the FDA. • Ensures that blood collection or transfusion related fatalities are appropriately reported to the FDA.

Responsible Party	Task
Laboratory Operations Director or Manager	• Ensures implementation of this Standard Operating Procedure (SOP) • Communicates the SOP to relevant laboratory areas.
Manager/ Supervisor	• Implements and maintains this SOP as part of local procedure manuals. • Ensures applicable training and competency. • Ensures departmental compliance with this process. • Participates in the investigation and correction of nonconforming events. • Completes the RQI, BPD Report, and fatality report in conjunction with the Quality Assurance Personnel.
Testing Personnel	• Comply with procedure. • Report nonconforming events immediately. • Participate in the investigation and correction of nonconforming events.
Quality Assurance Personnel / RQI Owner / Designee	• Facilitate in the investigation and correction of nonconforming events. • Monitor the effectiveness of the corrective action implemented. • Ensure the completion of the RQI, BPD Report, and fatality reports. • Obtain Quest Legal approval for documents prior to submission to the FDA. • Submit the RQI to DGX Hospital RQI; BPD Report and fatality report to the FDA.

4. DEFINITIONS

Accident: an event that is not expected, foreseen, or intended.

Adverse event: any complication experienced by a donor or patient. Adverse events may occur in relation to blood donation, transfusion, diagnostic procedures, or therapeutic procedures.

Biological Product Deviation (BPD): an event that could affect the safety, purity, or potency of a biological product. It may represent a deviation from current "good manufacturing practices", applicable regulations, applicable standards, or established specifications, or it may be unforeseen and unexpected.

Blood Bank: a facility that performs any of the following: collection, processing, storage, and distribution of human blood and/or components that is intended for transfusion or transplantation.

Corrective Action: any combination of actions taken to prevent or diminish the probability that an event might recur in the future.

CQA: the Corporate Quality Assessment group within Quest Diagnostics.

Error: a mistake resulting from carelessness, inattention or misunderstanding by a person or persons.

Event: when used in the context of this document, is a nonspecific term intended to convey recognition that something has occurred that requires further investigation.

Reportable Quality Issue (RQI): A quality issue with known or potential effect on current or future patient care that is of sufficient priority to require the notification of Corporate Quality Assessment, Corporate Medical Regulatory Affairs, and the Corporate Legal Department.

Non-Conformance Event: An event that results in deviations from approved policies, processes and procedures or in failures to meet requirements, as defined by the facility, or applicable regulations.

QA: an abbreviation for Quality Assurance or Quality Assessment.

Remedial Action: any combination of actions taken to prevent or diminish the probability that an event might recur in the future.

Transfusion Service: a facility that performs one or more of the following activities: compatibility testing, storage of blood or components, or selection and issuance of blood or components to intended recipients. Transfusion services do not routinely collect blood for transfusion or process Whole Blood into components.

5. PROCESS

A. Recognition of an Unexpected Event or a Non-Conformance Event

Step	Action	
All department personnel will:		
1.	Notify the Manager/Supervisor IMMEDIATELY. The manager/supervisor is responsible for notifying the Medical Director and local QA team.	
	If	**Then**
	the event resulted in injury or harm to a patient (alleged or realized);	o notify the Laboratory Director or delegated M.D. CLIA Technical Supervisor and QA manager, IMMEDIATELY;
	AND the event resulted in a fatality possibly due to a transfusion reaction,	o notify CQA Manager via phone IMMEDIATELY; o notify the FDA with a Quest legally approved report, AS SOON AS POSSIBLE. **Note: See special instructions in Section 5.E.2 for filing the initial fatality report;**

Step	Action	
	AND the compatibility testing was performed by another blood bank (different CLIA number),	o notify the testing facility IMMEDIATELY via phone; **Note:** Both the transfusing facility and the testing facility must notify the FDA with initial information and submit a final report within seven (7) days of the fatality; this may be submitted as a joint report.
2.	Document the event on a PI/QV/variance form	
Manager/Supervisor will:		
3.	Notify the QA manager, as soon as possible.	
4.	Collect relevant information, evidence, and personnel interviews as soon as possible.	
QA Manager will:		
5.	Notify CQA Manager via phone as soon as possible.	
6.	Consult with CQA to determine the event classification.	
	If the event involves	**Then**
	o a fatality related to blood collection or transfusion	o **follow reporting instructions for the initial fatality report and the seven (7) day final report;** o **Refer to Section 5.E.2 and 5.E.3** o perform a thorough investigation ▪ Refer to Section 5.C o submit an RQI.
	o a deviation that **does not** require correction to patient results o **and** the event is corrected prior to any associated blood product distribution,	o follow local procedures for corrective and preventive actions of occurrences and/or non conformance events; o **do not** initiate the FDA reportable event process; o **do not** submit an RQI.
	o a deviation that requires correction to patient results, o **and** the event is corrected prior to any associated blood product distribution,	o submit an RQI; o **do not** initiate the FDA reportable event process.
	o a deviation that has the potential to affect the safety, purity, or potency of a biological product o **and** is not corrected prior to blood product distribution,	o initiate the FDA reportable event process; o **and** submit an RQI.
7.	Consult with the *Guidance for Industry – Biological Product Deviation Reporting for Blood and Plasma Establishments* http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/ucm073455.htm to determine the event classification. Examples of Biological Product Deviations (BPDs) are provided in Addendum A.	

B. Initiate the FDA Reportable Event Process

Step	Action
QA Manager will:	
1.	Complete the Initial Notification of a Suspected BPD Template (Form QDHOS302) and email to CQA Manager within three **(3) days** of discovery. **NOTE**: Required information includes: o Date of occurrence o Date of discovery o Statement of initial deviation o Brief description of what happened o Who discovered the deviation o How it was discovered o Type of blood products involved o If products were transfused o If the clinician was notified o If a transfusion reaction occurred o Laboratory Director assessment of patient impact
2.	Initiate the RQI form.
CQA Manager will:	
3.	Notify senior corporate staff via email of the FDA reportable event.
4.	Notify senior corporate staff via phone if the event resulted in injury or harm to the patient (alleged or realized).

C. Perform Investigation and Corrective Actions

Step	Action
CQA Manager/QA Manager/Manager/Supervisor will:	
1.	Perform root cause analysis as soon as possible, using collected information, evidence and interviews. The CQA Manager, QA Manager, Laboratory Manager/Supervisor, and other involved individuals will participate in the analysis. Often many causal factors are identified, in addition to a root cause, or there may be several root causes.
2.	Evaluate all potential or realized risks identified during the event investigation for appropriate corrective and preventive actions.
3.	Determine steps to adequately correct the problem, prevent recurrence, and include monitoring to ensure the continued effectiveness of the actions taken.
4.	Obtain the Laboratory Director's approval for the outcome of the investigation, including the determination of cause(s), corrective actions, and preventive actions.
5.	Initiate actions in a timely manner to ensure patient safety and to ensure the safety, purity, and potency of blood and blood products.

D. Complete the BPDR 3486

Step	Action
1.	The final report version is due to CQA within **30 days** of discovery.
CQA Manager will:	
2.	Schedule a meeting with the QA Manager/Manager/Supervisor approximately four (4) weeks after the date of discovery. o This will allow sufficient time to perform a thorough root cause analysis before determining effective corrective actions.
CQA Manager/QA Manager/Manager/Supervisor will:	
2.	Obtain a current BPDR 3486 form and instructions from the FDA website https://www.accessdata.fda.gov/scripts/cber/CFApps/Login/Index.cfm?CFID=2247731&CFTOKEN=37e7ee9193ceb1cf-EB8F766E-A2F5-D20F-82004396CE4A3819
3.	Write the report together.
4.	Adhere to the following report writing process: o There must be only one version of the report while in draft form. This draft version must reside on a designated local laboratory shared drive and be labeled with the local naming convention and the word DRAFT. ▪ **Note:** *Do not email draft versions. Do not save previous drafts.* o **See Section 5.E.1. for specific report writing instructions.** ▪ **DO NOT** include donor, patient, or employee personal identification information or other confidential information. ▪ Use concise, declarative statements. Do not include opinions. o Choose the most appropriate BPDR Product Deviation Code from the current list found at http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ReportaProblem/BiologicalProductDeviations/ucm129721.htm#blcd o List the products affected using the appropriate BPDR Blood Product Codes found at http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ReportaProblem/BiologicalProductDeviations/ucm129732.htm
5.	When complete, change the report label from DRAFT to FINAL and add the current date.
QA Manager will:	
5.	Generate a printed copy of the FINAL version and obtain the Laboratory Director's signature indicating approval of the root cause analysis and corresponding corrective actions.
6.	Email the final report to the CQA Manager.
CQA Manager will:	
7.	Distribute the report to Corporate Quality Assessment, Corporate Medical Regulatory Affairs and the Corporate Legal Department for approval.
8.	When approved, will email the QA Manager to submit the BPDR 3468 to the FDA,

Step	Action
QA Manager will:	
9.	Submit the BPDR 3486 to the FDA within **45 days** of event discovery (with the exception of a fatality; see Guidance for Industry: http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/ucm073455.htm
8.	The report can be submitted: o electronically at: https://www.accessdata.fda.gov/scripts/cber/CFApps/Login/Index.cfm?CFID=2247731&CFTOKEN=37e7ee9193ceb1cf-EB8F766E-A2F5-D20F-82004396CE4A3819 or o by mail: Food and Drug Administration Center for Biologics Evaluation and Research Document Control Center 10903 New Hampshire Avenue WO71-G112 Silver Spring, MD 20993-0002

E. Documentation and Reporting Guidelines

1. Biological Product Deviation Report

Report Field	Documentation Instructions
Description of the BPD	1. Start with a single sentence that states the deviation. 2. Add enough details to provide a clear, succinct picture of **what happened.** 3. End with a statement of impact to the patient and its justification.
Description of Contributing Factors or Root Cause	1. Provide a statement regarding the adequacy of current affected procedures. 2. Provide a statement regarding the adequacy of LIS and/or instrumentation functionality, if applicable. 3. If procedures are adequate, state why written instructions were not followed. 4. Add enough details to provide a clear, succinct conclusion of why the deviation happened.

Report Field	Documentation Instructions
Follow Up	1. For corrective actions involving a new or revised procedure: ▪ Describe briefly the new/revised procedure that will be implemented with the tentative effective date. ▪ Describe the process to initially alert all staff of identified gap(s) and specific new or corrected work instructions. 2. For corrective actions involving adequate procedures requiring retraining, state what will be reviewed and tentative completion date. Use the following customizable phrase: ▪ "The critical steps/elements of _____ will be reemphasized with the involved tech and all employees with a tentative completion date of _____."

2. Initial Notification of Fatality to the FDA

Step	Action
QA Manager will (prior to submission):	
1.	Obtain the required information.
2.	Record information on laboratory letterhead document.
3.	Adhere to the following report writing process: o There must be only one version of the report while in draft form. This draft version must reside on a designated local laboratory shared drive and be labeled with the local naming convention and the word DRAFT. ▪ *Do not email draft versions. Do not save previous drafts.* o **DO NOT** include donor, patient, or employee personal identification information or other confidential information. ▪ Use concise, declarative statements. Do not include opinions.
4.	**Required Information**
	1. Your name, title, telephone number, and fax number (if available)
	2. Your facility's name, mailing address, and FDA registration number (if applicable)
	3. Names and addresses of the following facilities, if applicable: a. where the fatality occurred b. where the compatibility testing was performed, if applicable c. from where the blood was donated d. where any interim manufacturing was performed on implicated transfused units (ie. irradiation)
	4. Age and sex of the deceased
	5. Date, time, and cause or suspected cause of death
	6. If an autopsy was or will be performed

7. Brief description of events that led to the fatality a. include underlying medical condition or disease and circumstances necessitating this hospitalization b. reason for transfusion c. how the patient initially responded to the transfusion d. any medical intervention taken or response to the reaction e. time from initiating the transfusion to patient's death	
If the event involves a	**Then provide the following information**
Patient/Recipient Fatality	o Transfusion date(s), o Blood/blood component(s) and unit number(s) that may be implicated
Donor Fatality	o Collection date o What product was collected or attempted to be collected o Whether this was a manual or automated collection o If automated, the name and model of collection device and device manufacturer
Therapeutic Apheresis or Therapeutic Phlebotomy **Note:** a report is required *only* if: o blood products were given as part of the procedure for a therapeutic apheresis fatality; or o a blood product was collected for manufacture into transfusable biologics from a therapeutic phlebotomy	o date o if product was collected and its disposition o manual or automated collection o if automated, include manufacturer, name and model of collection device o if any blood product was transfused, identify the unit number or lot number o brief description of events that led to the fatality—include underlying condition and circumstances necessitating the therapeutic apheresis or therapeutic phlebotomy o any medical intervention to the reaction and time from initiating the procedure to the patient's death.
fatality not associated with a reportable biological product deviation occurring at the transfusion service	o an explanation of why a BDP report will not be filed; o the name of the facility which will file a BPD report, if available.

5.	Contact the CQA Manager via phone to review the report.
6.	Email the reviewed report to the CQA manager.
CQA Manager will:	
7.	**Obtain approval from Legal.**
8.	Contact the QA Manager via phone and forward report approval from Legal via email.

Step	Action
QA Manager will:	
9.	Send the email with attached template, to the FDA (preferred method), or phone the FDA and report the information verbally. ▪ **Note: See 5.E.5 for Notification Guidelines** ▪ **Do not delay notification if all of the details cannot be obtained immediately.** • Indicate "to be determined" (TBD) if necessary. • This information can be communicated on the seven (7) day final report.
Laboratory Director/CQA Manager/QA Manager/Manager/Supervisor/Hospital staff will:	
10.	Proceed with thorough investigation.
11.	Prepare for unannounced FDA inspection.

3. Final Report (7 day follow up) of Fatality to the FDA

Step	Action
QA Manager will (prior to submission):	
1.	Identify this report as a follow up to the initial fatality report.
2.	Add the initial fatality report submission date.
3.	Obtain the required information. Refer to the current *Guidance for Industry: Notifying FDA of Fatalities Related to Blood Collection or Transfusion.*
4.	Contact the CQA Manager via phone to review the report.
5.	Email the reviewed report to the CQA manager.
CQA Manager will:	
6.	**Obtain approval from Legal.**
7.	Contact the QA Manager via phone and forward report approval from Legal via email.
QA Manager will:	
8.	Send the email with attached report, to the FDA (preferred method), or send report by mail. ▪ **Note: See 5.E.5 for Notification Guidelines** ▪ Send any additional information collected after the seven (7) day final report is submitted, referencing the earlier reports

4. Documentation

Document and compile all activities related to the event.	
Activities can include but are not limited to:	▪ Initial information and evidence ▪ Interviews ▪ Initial Notification of Suspected BPD Template ▪ Root Cause Analysis ▪ RQI report ▪ Correspondence between lab and hospital administration, if required ▪ BPD report ▪ Transfusion Committee Minutes ▪ All compatibility information including reagent lot numbers, QC records, checks, etc ▪ All tranfusion information including the manufacturer and lot number of blood administration sets, clinical documentation, transfusion reaction documentation, relevant laboratory test results, etc. ▪ Results of lookback investigations ▪ Donor records ▪ Equipment details used for donor collection, etc.

5. Notification Guidelines

Step	Action
1.	Event reporting must be reviewed by the laboratory management, the QA Manager and the CQA Manager, and approved by the Laboratory Director, prior to submission to the Medical Regulatory and Legal Departments.
2.	Report contents must be reviewed by Corporate Quality Assessment, Corporate Medical Regulatory Affairs and the Legal department prior to submission to the FDA.
3.	Biological Product Deviation reporting deadlines: ▪ Initial notification to CQA—**as soon as possible** ▪ FDA Reportable Event Template to CQA—within **3 days of discovery** ▪ BPD Final Report to CQA—**within 30 days of discovery** ▪ BPD Final Report to FDA—**within 45 days of discovery**
4.	The FDA must be notified of any changes to information contained in BPD reports already filed. This includes changes to patient outcomes, corrective actions, etc. Send relevant information by email with reference to the original confirmation number or tracking number to: ▪ CBER BP_Deviations [BP_Deviations@fda.hhs.gov]

Step	Action
5.	**Transfusion Related Fatality** If a complication of a transfusion was confirmed to be fatal, the transfusing facility and the facility that performed the compatibility testing must notify the FDA o **regardless of whether or not a BPD occurred** o as soon as possible ▪ via email (preferred): fatalities2@cber.fda.gov or ▪ via phone: 301-827-6220 o within 7 days by submitting **a fatality report** ▪ via email (preferred): fatalities2@cber.fda.gov or ▪ via the U.S. Mail: U.S. Food and Drug Administration Center for Biologics Evaluation and Research Document Control Center 10903 New Hampshire Avenue WO71, G112 Silver Spring, MD 20993-0002

6. RECORDS MAINTENANCE

Records are maintained according to the requirements published in the Quest Diagnostics *Records Management Program Reference Guide.*
For transfusion related documents, the retention requirement is "indefinite."

7. RELATED DOCUMENTS

- BPDR Product Deviation Codes
  http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ReportaProblem/BiologicalProductDeviations/ucm129721.htm#blcd
- BPDR Blood Product Codes
  http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ReportaProblem/BiologicalProductDeviations/ucm129732.htm
- BPDR Form 3486
  https://www.accessdata.fda.gov/scripts/cber/CFApps/Login/Index.cfm?CFID=2247731&CFTOKEN=37e7ee9193ceb1cf-EB8F766E-A2F5-D20F-82004396CE4A3819
- Initial Notification of a BPD Template (QDHOS302), see Attachments pane of SmartSolve

8. REFERENCES

1. *Process for Notification of Reportable Quality Issues* (QDMED708)
2. *Notification of Federal and State Agency Laboratory Performance Investigations, Inspections, Complaints or Adverse Media* (QDMED724)

3. U.S. Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research, Guidance for Industry – Biological Product Deviation Reporting for Blood and Plasma Establishments, October 2006
4. U.S. Department of Health and Human Services, Food and Drug Administration Center for Biologics Evaluation and Research, Guidance for Industry--Notifying FDA of Fatalities Related to Blood Collection or Transfusion, September 2003
5. Code of Federal Regulations, 21, parts 600.14 and 606.171, 607.3(d), 606.3(k), 606.3(l), 640.74, 211.192, 211.198, June 8, 2000.
6. AABB Standards for Blood Banks and Transfusion services, 28th Edition, 2012.
7. AABB Technical Manual, 17th Edition, 2011.

9. DOCUMENT HISTORY

Version	Date	Section	Revision	Revised By	Approved By
3	2-1-2014	All	Updated to current corporate template	J. Hittinger	L. Hilborne, M.D.
		1	Reworded Purpose; removed "tracking and trending"	J. Hittinger	L. Hilborne, M.D.
		3	Changed Laboratory Director responsibilities to include approval of SOP revisions and to ensuring that BPDRs are reported to the FDA; Removed "tracking and trending" from the Laboratory Operations Director/Manager's responsibility	J. Hittinger	L. Hilborne, M.D.
		4	Changed NQA to CQA	J. Hittinger	L. Hilborne, M.D.
		5	Process rewritten. Initial notification template changed. Removed mention of Occurrence Management. New process for writing the report described. Added Laboratory Director approval of corrective actions. Added instructions for amended reports. Moved Examples of BPDs to Addendum A.	J. Hittinger	L. Hilborne, M.D.
		7	Updated. Removed Occurrence Management documents	J. Hittinger	L. Hilborne, M.D.
		10	Removed Process Flow and Event Template; Added Examples of BPDs.	J. Hittinger	L. Hilborne, M.D.
4	3/2/2015	All	Title changed to reflect inclusion of fatality reporting; Corporate SOP ID and version changed; **This SOP supersedes Biological Product Deviation Reporting –FDA Reportable Event QDHBB601 v3**	J. Hittinger	L. Hilborne, M.D.
		1	Added fatality reporting	J. Hittinger	L. Hilborne, M.D.
		2	Added donor facilities	J. Hittinger	L. Hilborne, M.D.

Version	Date	Section	Revision	Revised By	Approved By
4	3/2/2015	3	Added responsibilities for reporting fatalities	J. Hittinger	L. Hilborne, M.D.
		5.A	Added instructions for fatality reporting	J. Hittinger	L. Hilborne, M.D.
		5.D	Added more detail regarding internal report handling Updated FDA reporting instructions to the preferred method (email)	J. Hittinger	L. Hilborne, M.D.
		5.E.1	Added specific report writing instructions for BPD reports	J. Hittinger	L. Hilborne, M.D.
		5.E.2	Added specific instructions for initial fatality report Added preparation for FDA inspection due to a fatality	J. Hittinger	L. Hilborne, M.D.
		5.E.3	Added specific instructions for the seven (7) day fatality report	J. Hittinger	L. Hilborne, M.D.
		5.E.4	Added required documentation	J. Hittinger	L. Hilborne, M.D.
		5.E.5	Updated specific notification deadlines and addresses	J. Hittinger	L. Hilborne, M.D.
		6	Updated retention requirement to indefinite	J. Hittinger	L. Hilborne, M.D.
		7	Updated numbering convention for the Initial Notification of Suspected BPD Template	J. Hittinger	L. Hilborne, M.D.
		8	Updated references	J. Hittinger	L. Hilborne, M.D.
1	4/9/2015	Cover page	Adopting corporate issued version 1. Update Local Effective Date message, minor changes to header & footer	L Barrett	N Cacciabeve M.D.
		7	Add template location		
		9	Minor formatting changes		

10. ADDENDA

Addendum	Title
A	**Examples of Reportable and Non-Reportable Biological Product Deviations**
B	**FDA Electronic Submission Tips**

ADDENDUM A

BPD is NOT REPORTABLE	BPD is REPORTABLE
• The affected product was not distributed. • Prior to distribution, it was determined that the safety, purity, or potency of the product was not affected. • The event was detected and corrected prior to distribution of product. • Timeframes for lookback, retrieval or consignee notification were not met. (i.e., proper notification procedures were followed but were not completed in the timeframe established in the procedure.)	
COMPONENT PREPARATION • A recordkeeping deviation, such as a missing signature of the person preparing the unit, or other documentation that would not affect the safety, purity, or potency of the product.	COMPONENT PREPARATION • The component was not prepared within the allotted time frame after collection. • Air contamination or bacterial contamination occurred. • The SOP for component preparation is inadequate or was not followed. • The platelet count or yield was not acceptable. • The collection time was extended beyond that allowed. • Freezing time requirements were not met. • The resting time requirement for platelets was not met. • Specific procedures (irradiation or leukoreduction) were not performed or were improperly performed. • The incorrect dosage was used for irradiation. • The product was not washed/deglycerolized properly.

TESTING • A documentation deviation, if other information indicates that testing was performed appropriately. • Appropriately invalidated assays (run failures or QC failures) for which the affected samples were retested in an acceptable run and tested negative.	TESTING • Testing was not performed in accordance with instructions. • An incorrect incubation time or temperature was used. • Incorrect reagents were used or reagents from different lots were used without appropriate QC testing prior to use. • Reagents were added incorrectly. • Incorrect testing for ABO, Rh, antibody screen, antigen type, or compatibility. • The incorrect sample was tested or the sample was misidentified. • An initially reactive sample was not repeated in duplicate (viral marker). • An unsuitable sample was used for testing. • The sample was improperly stored. • The sample was diluted (by IV fluids, for example). • The sample was not identified appropriately and could not be traced back to the donor or patient. • Testing was performed using expired reagents. • Patient samples were mislabeled or collected from the wrong patient. • Mistyped or misinterpreted patient samples if the sample was used in crossmatching a product that was distributed. • Only an immediate spin crossmatch is performed when a patient's history or testing protocol indicate that an indirect antiglobulin test is required.

LABELING • A unit is labeled with a shortened expiration date. • Any of the following information is missing or incorrectly stated on the label (provided that the product is otherwise acceptable): o collection date (provided that the expiration date is correct) o facility identification. • An unlicensed product is labeled with a license number.	LABELING • A product is labeled with an incorrect ABO, Rh, antigen, antibody, product type, anticoagulant, volume, weight or unit number. • Information is missing for ABO, Rh, product type, expiration, date, unit number, weight, volume or platelet count (for platelet products). • Unit is labeled with an incorrectly extended expiration date, even if the product was transfused within the correct dating period. • Additional information on an autologous unit is missing or incorrect. • The SOP for labeling was not followed or is inadequate. • The unit is labeled with incorrect information regarding leukoreduction, irradiation, washing, crossmatch, antigen/antibody, donor number or recipient number. • Unit is not labeled as a biohazard, when indicated.

QUALITY CONTROL & DISTRIBUTION	QUALITY CONTROL & DISTRIBUTION
• There is a discrepancy between the shipping form and the shipment. • A unit was shipped to the incorrect facility. • A unit was lost or the shipment was never received. • The final disposition of the unit is unknown. • A frozen product breaks during thawing and the product is discarded. • A product breaks or is damaged during shipment and the product is discarded. • An allogeneic unit is issued when an autologous unit is available. • A unit is returned to the blood bank, is determined to be unsuitable, and is discarded (e.g., out of temperature range). • Unlicensed product was distributed labeled with a license number.	• An unsuitable unit is distributed. • A unit or segment is clotted. • A unit or segment is hemolysed. • An outdated unit is distributed. • A unit is shipped or stored at an incorrect temperature. • Failure to quarantine a unit due to incorrect, incomplete, or positive testing. • Required testing is not performed or not documented. • The donor has an unsuitable medical history. • SOPs for quality control or distribution are not followed or are inadequate. • Product specifications are unacceptable or not documented. • An incorrect product is issued for a specific patient. • The wrong unit is issued for a patient. • An improper ABO or Rh is selected for a patient. • The wrong filter was issued for use in transfusion or a filter was not issued when required. • Visual check of the product was not performed prior to distribution. • Product was distributed based on testing that was not performed on a current sample (sample too old for testing).

ADDENDUM B

FDA Electronic Submission Tips

Establishing an eBPD Account:

An account can be established using a FDA Registration Number or a CLIA Number.

- The FDA requires a blood bank to register if it routinely collects or processes blood or blood components. Processing includes, but is not limited to, preparing components, irradiation, leukoreduction, washing of red cells, viral marker testing of blood donors (21 CFR 607.7).
- Contact the CBER to obtain a registration number at: http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/EstablishmentRegistration/BloodEstablishmentRegistration/ucm055484.htm
- Only use your CLIA Number if you do not have a registration number

Enter the Establishment Identification Number and select the Establishment Identification Number Type then press the **Add to My Establishments** button.

- A confirmation screen will appear if you have entered a valid Identification Number and Number Type. By pressing the **Yes** button, you are agreeing that you are a valid representative of this establishment and may legally submit Biological Product Deviation reports for this establishment. Press the **No** button to cancel your association request and return to the previous page.
- Repeat this process for each establishment with which you want to request an association.
- The establishment information corresponding to the Establishment Identification Number selected is automatically populated. Verify that this information is correct. If an incorrect establishment identification number was entered, return to Select Establishment page. If the establishment identification number is correct, but the information displayed is incorrect, Contact eBPDR Technical Support.

Upon selecting "New Report" for a CLIA facility, the system asks, "Is this facility actively registered with FDA? The user answering NO can proceed with creating the new report and is not required to answer the question again for that facility for 90 days. The user answering YES will see a screen requesting that registered facilities submit BPD Reports using their FEI number instead of their CLIA number.

Account Maintenance

Periodically check the **List of Active Users.** This page will display other users that are associated to the same establishment you have listed on your "My Establishments" page.

- Contact eBPDR Technical Support if you find unfamiliar names listed or need names removed.

- If one of your establishments is not listed, it means that you are the only user account associated to that establishment.
- If one of your establishments is listed it will display the following information:
  - Establishment Identification Number and Type
  - Establishment Name
  - Full Name (Last Name, First Name, MI) of other users associated with that establishment.

To remove your association with an establishment, select the establishment and press the **Remove From List** button.

- A confirmation screen will appear asking if you are sure you want to remove your association to this establishment. Press **OK** to remove the establishment or press **Cancel** to cancel your request.

To remove or change the name of an establishment:

- Contact eBPDR Technical Support.