TRAINING UPDATE

Lab Location:	SGMC & WAH	**Date Distributed:**	5/8/2017
Department:	Blood Bank	**Due Date:**	5/24/2017
		Implementation:	**5/24/2017**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:
FDA Reportable Event Notification Process SGAH. QDHOS707v2.1
Description of change(s):
We are adopting the new corporate version. Refer to Revision History section to see their changes. Note: staff do not perform this SOP, non-conformances are reported through PI / quality variance process This revised SOP will be implemented on May 24, 2017

Document your compliance with this training update by taking the quiz in the MTS system.

Non-Technical SOP

Title	**FDA Reportable Event Notification Process**
Prepared by	Jill Hittinger/Linda Lowe/Mollie Kircher **Date**: February 20, 2017

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: April 20, 2017**	
Print Name and Title	**Signature**	**Date**
Dianne Zorka, Owner **Director, Corp Quality Assessment**	*Approval on file*	
Ronald Kennedy, M.D.**BPT Medical Advisor** **Medical Director, CP Quality**	*Approval on file*	

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 Hospital Reportable Quality Issues Process, (QDHOS708) 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.
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. • Submit the RQI to DGX Hospital RQI; BPD Report and fatality report to the FDA.
Corporate Quality Assessment (CQA) Manager	• Facilitate the investigation of FDA reportable events • Review FDA reports • Obtain Quest Corporate approval for documents prior to submission to the FDA

4. DEFINITIONS

Biological Product Deviation (BPD): is a deviation from current "good manufacturing practices", applicable regulations, applicable standards, or approved local procedures, or it may be unforeseen and unexpected. The deviation represents an event that either does or has the potential to, affect the safety, purity, or potency of a biological product.

Biological Product Deviation – Reportable: represents a BPD event that is not corrected prior to blood product distribution. Or

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.

CQA: the Corporate Quality Assessment group within Quest Diagnostics.

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.

QA: an abbreviation for Quality Assurance or Quality Assessment.

QA Manager: local quality assurance personnel assigned to each facility, i.e. the QHL QA manager, the business unit QA manager, or other responsible QHL personnel.

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 – REPORTING BLOOD PRODUCT DEVIATION TO FDA

Step	Action	
1.	All department personnel will notify the Manager/Supervisor IMMEDIATELY in the event of a blood product deviation. 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;

Step	Action	
	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 6 for filing the initial fatality report;**
	AND the compatibility testing was performed by another facility (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. o notify CQA Manager via phone IMMEDIATELY;
2.	Document the event on a PI/QV/variance form	
3.	Department Manager/Supervisor will notify the QA manager, as soon as possible.	
4.	Department Manager/Supervisor will collect all relevant information, evidence, and begins personnel interviews as soon as possible.	
5.	QA Manager will notify appropriate CQA Manager via phone as soon as possible.	
6.	QA Manager will consult with CQA to determine reporting requirements.	
	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 6** 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; **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.	QA Manager will initiate the RQI form.	

Step	Action
8.	CQA Manager will notify the following senior corporate staff via phone if the event resulted in injury or harm to the patient (alleged or realized). Dianne Zorka Dr. Ronald Kennedy Christine Vernusky Jim Ruger
9.	CQA Manager will schedule a meeting with the QA Manager/Manager/Supervisor approximately two (2) weeks after the date of discovery. This will allow sufficient time to perform a thorough root cause analysis before determining effective corrective actions.
10.	QA manager will document of all activities will be via the RQI process.
11.	QA manager will compile all records related to the event. Records can include but are not limited to: ▪ Initial information and evidence ▪ Interviews ▪ 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 transfusion information including the manufacturer and lot number of blood administration sets, clinical documentation, transfusion reaction documentation, relevant laboratory test results, etc. ▪ Results of look-back investigations ▪ Donor records ▪ Equipment details used for donor collection, etc.
11.	QA Manager will 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.
12.	QA Manager will draft the Blood Product Deviation Report on the CBER website – DO NOT SUBMIT.
13.	QA Manager will adhere to the following report writing process: o There must be only one version of the report while in draft form. This draft version resides on the FDA website, emailed versions are for approval only. o **DO NOT** include donor, patient, or employee personal identification information or other confidential information. o Use concise, declarative statements. o Do not include opinions.

<table>
<tr><th>Step</th><th colspan="3">Action</th></tr>
<tr><td></td><td>Report Field</td><td colspan="2">Documentation Instructions</td></tr>
<tr><td></td><td>Note</td><td colspan="2">This report is intended to include only the required elements as indicated. A more detailed record of the deviation, investigation, and follow up actions is filed as a corresponding Hospital Reportable Quality Issue.</td></tr>
<tr><td></td><td>Description of the BPD</td><td colspan="2">1. Start with a single sentence that states the deviation and includes:
a. Date of occurrence
b. Type of blood product involved
c. If the product was issued, or issued and transfused
2. Add enough details to provide a clear, succinct picture of what happened.
3. Indicate when, who and how the deviation was discovered.
4. End with a statement of impact to the patient and its justification including
a. If the clinician was notified
b. If a transfusion reaction occurred
c. Laboratory Director assessment of patient impact using the following guidelines:</td></tr>
<tr><td></td><td></td><td>Laboratory director’s Assessment of Patient Impact</td><td>Intended Use</td></tr>
<tr><td></td><td></td><td>Major patient impact documented</td><td>Use when significant adverse patient impact is known to have occurred.</td></tr>
<tr><td></td><td></td><td>Minor patient impact documented</td><td>Use when routine specimen types must be recollected and/or transfusion activities are slightly delayed due to the incident.</td></tr>
<tr><td></td><td></td><td>No patient impact at all</td><td>Use when it is unlikely that the patient was affected by the incident in any way.</td></tr>
<tr><td></td><td></td><td>Significant patient impact unlikely</td><td>Use when, in the judgment of the Laboratory Director, the incident would not have had significant adverse impact on patient care. To use this choice, specimen recollection would not be required and there was no delay in transfusion activities.</td></tr>
</table>

	Description of Contributing Factors or Root Cause	1. List all contributing factors. If human error is included, add "why the human made the error." 2. Provide a statement regarding the adequacy of current affected procedures. 3. Provide a statement regarding the adequacy of LIS and/or instrumentation functionality, if applicable. 4. If procedures are adequate, state why written instructions were not followed. 5. Add enough details to provide a clear, succinct conclusion of why the deviation happened.
	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 _____."
	Choose the most appropriate BPDR Product Deviation Code	Use the current list found at http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ReportaProblem/BiologicalProductDeviations/ucm129721.htm#blcd
	List the products affected using the appropriate BPDR Blood Product Codes	Use the current list found at http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ReportaProblem/BiologicalProductDeviations/ucm129721.htm#blcd
14.	QA manager will capture the information entered via screen shots (FDA website does not have a print feature).	
15.	QA Manager will print screen shots of the completed DRAFT version of the FDA report from the CBER website and obtain the Laboratory Director's signature indicating approval of the root cause analysis and corresponding corrective actions.	
16.	QA Manager will scan the Laboratory Director approved DRAFT report and send to the CQA manager for review within 30 days of discovery.	
17.	CQA Manager will review DRAFT report for the following: • Ensure that all items listed under QA manager Step 13 are complete • Root cause matches the root cause in the RQI report • Review for grammar, punctuation, and content	

18.	CQA Manager will forward the DRAFT report to the following senior corporate staff via email: Christine Vernusky Jim Ruger The email notification will include voting buttons to approve/not approve the DRAFT report. Any person not approving the report, will email required revisions to the CQA manager.
19.	Biological Product Deviation reporting deadlines (non-fatality): ▪ Initial notification to CQA—**as soon as possible** ▪ BPD Final Report to CQA—**within 30 days of discovery** ▪ BPD Final Report to FDA—**within 45 days of discovery**
20.	CQA Manager will email the QA manager with approval to submit the BPDR 3468 to the FDA. Email will be copied to Virginia Sturmfels who will maintain a copy of the report for the company.
21.	QA manager will 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 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
22.	QA manager will maintain the original (or scanned) report, with recorded signature approval by the laboratory director.
23.	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]

6. PROCESS – REPORTING FATALITY TO FDA

Step	Action
1.	QA Manager will obtain the required information – see Addendum C.
2.	QA Manager will record all information on the FDA fatality report form

3.	**Reporting Time Frames - 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
4.	QA Manager will 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. o **DO NOT** include donor, patient, or employee personal identification information or other confidential information. o Use concise, declarative statements. o Do not include opinions.
	Required Information (See Addendum C)
	IF the event involves a Donor Fatality - the following additional information must be included: 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)Your facility's name, mailing address, and FDA registration number (if applicable)
	IF the event involves a Therapeutic Apheresis or Therapeutic Phlebotomy - the following additional information must be included: **Note**: A report is required *only* if: 1. blood products were given as part of the procedure for a therapeutic apheresis fatality; or 2. a blood product was collected for manufacture into transfusable biologics from a therapeutic phlebotomy where any interim manufacturing was performed on implicated transfused units (ie. irradiation)

5.	**For initial notification:** QA Manager will contact the CQA Manager via phone to review the DRAFT report.
6.	QA Manager will print the completed DRAFT report and obtain the Laboratory Director's signature indicating review and approval.
7.	QA Manager will scan the Laboratory Director approved DRAFT report and email to the CQA manager for review.
	CQA Manager will review DRAFT report for the following: • Ensure that all items listed under Addendum C are included • Additional required items are included as needed • Review for grammar, punctuation, and content
8.	CQA Manager will send the initial fatality notification DRAFT report to the appropriate Legal and corporate medical via email. The email will contain voting buttons for approval of the document.
9.	CQA manager will follow-up on the email with a phone call to the appropriate corporate medical and legal staff (i.e. Jim Ruger, Christine Vernusky, and Virginia Sturmfels).
10.	CQA Manager will contact the QA Manager via phone and forward report approval via email.
11.	QA Manager will rename the report, changing DRAFT to FINAL. QA manager will send an email, attaching the FINAL report, to the FDA (preferred method), or phone the FDA and report the information verbally. ▪ **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. QA manager will maintain a copy of the email as confirmation of report submission and the original (or scanned) report, with recorded signature approval by the laboratory director.
12.	All staff will proceed with thorough investigation of the incident. This investigation will be documented via the RQI process.
13.	QA manager will compile all records related to the event. Records can include but are not limited to: ▪ Initial information and evidence ▪ Interviews ▪ 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 transfusion information including the manufacturer and lot number of blood administration sets, clinical documentation, transfusion reaction documentation, relevant laboratory test results, etc. ▪ Results of look-back investigations ▪ Donor records ▪ Equipment details used for donor collection, etc.

14.	**For seven day follow up notification:** QA Manager will update Addendum C with additional required information, indicating DRAFT in the file name, and send to CQA manager no later than 6 days following the initial notification.
15.	CQA Manager will send the follow up fatality notification DRAFT report to the appropriate legal and corporate medical via email. The email will contain voting buttons for approval of the document.
16.	CQA manager will review the follow up fatality notification DRAFT report for completeness and send to the appropriate legal and corporate medical via email. The email will contain voting buttons for approval of the document.
17.	CQA manager will follow-up on the email with a phone call to the appropriate corporate medical and legal staff (i.e. Jim Ruger, Christine Vernusky, and Virginia Sturmfels).
18.	CQA manager will return the approved final document to the QA manager no later than noon on day 7 following the event.
19.	QA Manager will rename the report, changing DRAFT to FINAL. QA manager will submit the FINAL report to the FDA via email no later than the end of business on the 7th day following the event. Maintain a copy of the email as confirmation of report submission.
20.	Prepare for unannounced FDA inspection.

7. 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.”

8. 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

9. REFERENCES

1. *Hospital Notification Process for Reportable Quality Issues* (QDHOS708)

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, 30th Edition, 2016.
7. AABB Technical Manual, 18th Edition, 2015.

10. DOCUMENT HISTORY

Version	Date	Section	Revision	Revised By	Approved By
1	2-1-2014		New	J. Hittinger	L. Hilborne, M.D.
2	1/9/2017	All	Separated the process for product deviation and fatality reporting	L. Lowe	R. Kennedy, M.D.
		5	Changed meeting to be scheduled within 2 weeks after discovery Added RQI guidance for LD assessment of patient impact Added email voting to corporate approving staff	L. Lowe	R. Kennedy, M.D.
		9	Updated References	L. Lowe	R. Kennedy, M.D.
		All	Removed details concerning RQI reporting	L. Lowe	R. Kennedy, M.D.
		Add C	Added addendum C – Template for Reporting Fatality to FDA	L. Lowe	R. Kennedy, M.D.
2	4/26/17	Cover page	Adopting corporate issued version 2. Update Local Effective Date message, minor changes to header & footer Correct numbering of sections 7-11	L Barrett	N Cacciabeve, M.D.

11. ADDENDA

Addendum	Title
A	Examples of Reportable and Non-Reportable Biological Product Deviations
B	FDA Electronic Submission Tips
C	FDA Fatality Report Template

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 • 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.	QUALITY CONTROL & DISTRIBUTION • 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.

ADDENDUM C

FDA Fatality Report

Date of Notification		**Name of Reporting Person**	
Time of Notification		**Title of Reporting Person**	
Facility Name		**Phone Number**	
Facility Street Address		**Did the fatality occur at this facility?**	□ **Yes** □ **No**
Facility City, State, Zip		**If no provide name of facility**	
FDA Registration Number (if applicable)		**If no provide address of facility**	
Age of Deceased		**Sex of Deceased**	
Date of Death		**Time of Death**	
Autopsy performed or planned?	□ **Yes** □ **No**		
Transfusion Date:		**Product Transfused:**	
Unit number(s) transfused			
Name of the facility that collected the blood product(s)		**Address of the facility that collected the blood product(s)**	
Deceased Patients Admitting Diagnosis			
Reason for patient transfusion			
Patient's initial response to the transfusion			
Medical intervention taken in response to the transfusion			
Elapsed time from initiating transfusion to patient death.			

Email Report to: fatalities2@fda.hhs.gov