



IQPP Standard for Recording Donor Adverse Events

**Version 1.0
Approved September 11, 2014**



Background

The IQPP Standard for Recording Donor Adverse Events is part of a series of standards that comprise the Plasma Protein Therapeutics Association (PPTA) IQPP Standards Program. PPTA's Voluntary Standards Program provides global leadership for the plasma protein industry's goal of continuous improvement with a focus on safety and quality from the donor to the patient.

This voluntary IQPP Standard was developed by the PPTA IQPP Standards Committee, and was approved by the PPTA Source Board of Directors on September 11, 2014.

For questions about this PPTA Voluntary Standard contact IQPP@pptaglobal.org. For more information about the IQPP Standards Program or PPTA, visit www.pptaglobal.org.

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1. Introduction

In 2006, the United States Federal Advisory Committee for Blood Safety and Availability (“Committee”) recommended that the federal government engage in efforts to enhance safety monitoring for blood products, cell and tissue products and solid organs in partnership with private sector initiatives.^[1] These monitoring systems, collectively termed “biovigilance,” were viewed by the committee as important tools for improving outcomes related to transfusion and transplantation therapy. Donor biovigilance is integral to the total biovigilance program since donors provide the “raw materials” for biologic treatments, and because safety of living donors is a related and important public health issue.^[2]

All IQPP certified establishments have processes in place to monitor, manage, and document donor adverse events. This IQPP Standard serves as the foundation for establishing industry-wide requirements for adverse event definitions and classification.

This Standard is part of a series of standards that comprise the PPTA IQPP Voluntary Standards Program. For more information about the program, visit www.pptaglobal.org.

2. Scope

This standard applies to facilities that collect Source Plasma.

3. Terms and Definitions

3.1. BP

blood pressure

3.2. DAE

donor adverse event

^[1] Letter dated February 9, 2007, from Chair, ACBSA, to ASH John O. Agwunobi, <http://www.hhs.gov/ash/bloodsafety/advisorycommittee/recommendations/recommendations200608.pdf>

^[2] Biovigilance in the United States: Efforts to Bridge A Critical Gap in Patient Safety and Donor Health, report of PHS Biovigilance Task Group in Response to HHS ACBSA recommendations, http://www.hhs.gov/ash/bloodsafety/biovigilance/ash_to_acbsa_oct_2009.pdf



3.3. LOC

loss of consciousness

4. Requirements

4.1. General

Companies shall have a documented process for recording known DAEs considered to be associated with any part of a Source Plasma donation program (this includes initial screening, donation, immunization for high titer collections, etc.) following company approved SOPs.

All DAEs shall be classified using the DAE Classifications list in Clause 4.2 by a licensed center physician or physician substitute utilizing the available information and their best medical judgment. Each DAE shall be assigned to only one classification from the list. DAEs identified with an asterisk (*) shall be recorded in the facility’s documentation system. For those DAE’s not identified by an asterisk, each company shall determine if the event is to be included in its recording system and the level of detail required. DAEs, when occurring off-site and reported to the facility, shall also be documented using this process including whatever information is available, with the understanding that the information may be limited and not completely accurate.

Companies shall follow Attachment A, Donor Adverse Event Classification Guide, when reviewing and classifying each event in their process.

4.2. DAE Classifications

DAEs include the following:

Category	Recording Requirement (* = record)	Sub-Category
Hypotensive Event (vasovagal/Hypovolemia)		Prefaint, No LOC (Minor)
	*	Prefaint, No LOC (Moderate)
	*	LOC approximately less than 60 Seconds
	*	LOC approximately 60 Seconds or longer
	*	Severe (With or Without LOC)
	*	Injury



Category	Recording Requirement (* = record)	Sub-Category
Major Cardiovascular or Respiratory Event	*	
Local Injury Related to Phlebotomy Event		
	*	Nerve Irritation
		Hematoma/Bruise (Uncomplicated)
	*	Hematoma/Bruise (Complicated)
	*	Infection
	*	Arterial Puncture
		Infiltration
	*	Major Blood Vessel Injury
Citrate Reaction Event		
		Minor
	*	Moderate
	*	Severe
Hemolysis/Hemoglobinuria Event		
	*	Uncomplicated
	*	Complicated
Air Embolus Event		
		Uncomplicated
	*	Complicated
Allergic Event		
	*	Local
	*	Generalized
	*	Anaphylaxis
Hyperventilation Event	*	
Other Event	*	

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4.3. Donor Variables

The DAE recording process shall incorporate the following variables in accordance with company SOPs:

- a) The donor's age
- b) The donor's gender
- c) The donor's weight
- d) The donor's height
- e) The date of donation (mm/dd/yyyy)
- f) The time of donation (military)
- g) The name and title of the staff member recording the reaction
- h) The pre-donation Diastolic BP
- i) The pre-donation Systolic BP
- j) The pre-donation pulse
- k) The timing when the reaction was first known to begin, either:
 - o Pre-donation;
 - o During Donation;
 - o Post-donation on-site; or
 - o Post-donation off-site
- l) Special observations relating to the donor reaction event (For example, when applicable,):
 - o Change in Systolic and Diastolic BP
 - o Change in pulse
 - o Collected volume at the time of the DAE)
- m) Transport and/or hospitalization within 24 hours

4.4. Inspection and Compliance Verification

At the Corporate Audit, inspectors shall request the company SOPs related to DAE recording, and review the company's documented process for recording known DAEs.



ATTACHMENT A – Donor Adverse Event Classification Guide

1. Hypotensive (Vasovagal/Hypovolemia)

Hypotensive reaction (vasovagal/hypovolemia) that falls into any of the following categories.

DAE Classification	Description	Signs/Symptoms/Findings
1.1 Hypotensive: Prefaint, No LOC (Minor)	This reaction: <ol style="list-style-type: none"> a. must resolve without medical staff (e.g., physician substitute) intervention, AND b. Involves signs and symptoms that resolved quickly (e.g. within approximately 10 minutes) 	May include one or more of the following: <ol style="list-style-type: none"> a. Cold Extremities, Chills/Shivering; b. Feeling of Warmth; c. Hypotension; d. Lightheaded/Dizziness; e. Pallor, Pale Skin or Lips; f. Sweating; g. Visual Disturbance; or h. Weakness.
1.2 Hypotensive: Prefaint, No LOC (Moderate):	This reaction: <ol style="list-style-type: none"> a. requires medical staff (physician substitute) intervention, OR b. involves signs/symptoms that did not resolve quickly (e.g. within approximately 10 minutes), OR c. additional signs/symptoms may be present. 	May include any in 1.1 AND any of the following: <ol style="list-style-type: none"> a. Nausea; or b. Vomiting.
1.3 Hypotensive: LOC (brief)	In this reaction, LOC lasts approximately less than sixty seconds.	May include any in 1.1 or 1.2.



DAE Classification	Description	Signs/Symptoms/Findings
1.4 Hypotensive: LOC (prolonged)	In this reaction, LOC lasts approximately sixty seconds or longer.	May include any in 1.1 or 1.2.
1.5 Hypotensive; Severe (With or Without LOC):	This reaction may or may not include LOC.	May include any in 1.1 through 1.4 AND any of the following: <ul style="list-style-type: none"> a. Carpopedal Spasms; b. Chest Pain; c. Convulsions/Seizures d. Loss of Bladder/Bowel Control; or e. Prolonged signs or symptoms that do not resolve.
1.6 Hypotensive; Injury	A hypotensive event that results in ANY type of injury such as: <ul style="list-style-type: none"> a. Closed Head Injury; b. Dental Injury; c. Fracture; d. Laceration; e. Soft Tissue Injury (not phlebotomy-related); or f. Other 	May include any of 1.1 – 1.5 as well as any signs/symptoms related to the injury itself.



2. Major Cardiovascular or Respiratory Event

Major cardiovascular or respiratory event that occurs within 24 hours of the completion of donation and which falls into the following.

DAE Classification	Description	Signs/Symptoms/Findings
2.1 Major Cardiovascular or Respiratory Event	Major cardiovascular or respiratory event that occurs within 24 hours of the completion of donation.	May include any of the below: <ol style="list-style-type: none"> Angina Pectoris; Cardiac Arrest; Cerebrovascular Accident; Myocardial Infarction; Transient Ischemic Attack; or Respiratory Arrest.

3. Local Injury Related to Phlebotomy

Local injury related to phlebotomy that falls into one of the following categories.

DAE Classification	Description	Signs/Symptoms/Findings
3.1 Local Injury Related to Phlebotomy: Nerve Irritation		May include any of the below: <ol style="list-style-type: none"> Immediate Intense Pain at Site; Paresthesias, Numbness/Tingling of Fingers, Hand, or Arm; Shooting Pain Down Arm; or Weakness of Arm.



DAE Classification	Description	Signs/Symptoms/Findings
3.2 Local Injury Related to Phlebotomy: Hematoma/Bruise (uncomplicated)	A hematoma/bruise that is approximately $\leq 2'' \times 2''$.	May include any of the below: <ol style="list-style-type: none"> a. Mild Pain; b. No Restriction of Movement; c. Skin Discoloration; or d. Swelling.
3.3 Local Injury Related to Phlebotomy: Hematoma/Bruise (complicated)	A hematoma/bruise that is approximately $>2'' \times 2''$.	May include any of the below: <ol style="list-style-type: none"> a. Significant Pain; b. Paresthesias, Numbness/Tingling of Fingers, Hand, or Arm; c. Pressure; d. Redness; e. Restricted Movement; f. Shooting Pain Down Arm; g. Swelling; h. Tenderness; i. Warmth; or j. Weakness of Arm.
3.4 Local Injury Related to Phlebotomy: Infection		May include any of the below: <ol style="list-style-type: none"> a. Drainage; b. Pain; c. Redness; d. Swelling; e. Tenderness; or f. Warmth.



DAE Classification	Description	Signs/Symptoms/Findings
3.5 Local Injury Related to Phlebotomy: Arterial Puncture	An apparent arterial puncture	May include any of the below: a. Bright Red Blood; b. Pulse Sensation in Tubing; or c. Pulsing Blood Flow.
3.6 Local Injury Related to Phlebotomy: Infiltration	An apparent infiltration in the absence of bruising or hematoma	May include any of the below: a. Pain; or b. Swelling.
3.7 Local Injury Related to Phlebotomy: Major Blood Vessel Injury		May include any of the below: a. Arteriovenous Fistula; b. Brachial Artery Pseudoaneurysm; c. Compartment Syndrome; d. Deep Vein Thrombosis; e. Phlebitis; or f. Thrombophlebitis.

4. Citrate Reaction

Citrate reaction that falls into one of the following categories.

DAE Classification	Description	Signs/Symptoms/Findings
4.1 Citrate Reaction: Minor	Resolves quickly with or without reducing flow rate or providing calcium.	May include any of the below: a. Metallic Taste; b. Paresthesia (Peripheral – Lips Tingling/Numbness); or c. Paresthesia (Peripheral - Hands/Feet Tingling/Numbness).



DAE Classification	Description	Signs/Symptoms/Findings
4.2 Citrate Reaction: Moderate		Any of 4.1 that progress to the rest of the body AND any of the below: <ul style="list-style-type: none"> a. Carpopedal Spasms; b. Chest Pressure; c. Cold Extremities, Chills/Shivering; d. Muscle Tightness and/or Cramping; e. Nausea; f. Pallor, Pale Skin or Lips; g. Shortness of Breath; h. Sneezing/Nasal Congestion; i. Tetany (Transient); j. Tremors (Sensation of Vibration); k. Twitching; or l. Vomiting.
4.3 Citrate Reaction: Severe		Any of 4.1 or 4.2 that progress to the rest of the body AND any of the below: <ul style="list-style-type: none"> a. Bluish Tint to Skin (Cyanosis); b. Chest Pain; c. Heart Arrhythmia; d. Hypotension (Severe); e. Incontinence; f. Mental Confusion; or g. Tetany (Severe).



5. Hemolysis/Hemoglobinuria

Reaction that falls into one of the following categories.

DAE Classification	Description	Signs/Symptoms/Findings
5.1 Hemolysis/ Hemoglobinuria: Uncomplicated		Red/brown colored urine as the only sign
5.2 Hemolysis/ Hemoglobinuria: Complicated		Red/brown colored urine and any of the below: <ol style="list-style-type: none"> a. Back/Flank Pain; b. Bluish Tint to Skin (Cyanosis); c. Mental Confusion; d. Pallor, Pale Skin or Lips; or e. Shortness of Breath.

6. Air Embolus

Air embolus that falls into one of the following categories.

DAE Classification	Description	Signs/Symptoms/Findings
6.1 Air Embolus: Uncomplicated		None
6.2 Air Embolus: Complicated		May include any of the below: <ol style="list-style-type: none"> a. Back/Flank Pain; b. Bluish Tint to Skin (Cyanosis); c. Chest Pain; d. Mental Confusion; e. Nausea; f. Shock; g. Shortness of breath; or h. Vomiting.



7. Allergic

Allergic reaction that falls into one of the following categories.

DAE Classification	Description	Signs/Symptoms/Findings
7.1 Allergic: Local	In the antecubital area.	May include any of the below: <ol style="list-style-type: none"> a. Itching; b. Rash/Hives; or c. Redness.
7.2 Allergic: Generalized		May include any 7.1 AND any of the below: <ol style="list-style-type: none"> a. Itching, Generalized; b. Rash/Hives, Generalized; or c. Sneezing/Nasal Congestion.
7.3 Allergic: Anaphylaxis		May include any of 7.1 AND any of 7.2 AND any of the below: <ol style="list-style-type: none"> a. Anxiety, Restlessness; b. Arrhythmia; c. Bluish Tint to Skin (Cyanosis); d. Gastrointestinal Symptoms; e. Laryngeal Edema with Stridor; f. Scratchy Feeling in Throat; g. Shortness of Breath; h. Swollen Tongue, Throat, Eyes, and Face; i. Wheezing; or j. Hypotension.



8. Hyperventilation

Hyperventilation that results in any of the following signs and symptoms.

DAE Classification	Description	Signs/Symptoms/Findings
8.1 Hyperventilation		Any of the below: <ul style="list-style-type: none"> a. Anxiety; b. Carpopedal Spasms; c. Chest Tightness; d. Circumoral Paresthesia; e. Dry Mouth; f. Paresthesia (Perioral - Tingling/Numbness); g. Paresthesia (Peripheral - Hands/Feet); h. Respiration, Rapid; i. Restlessness; j. Shaking; k. Shortness of Breath; or l. Tetany.

9. Other

Reaction that does not fall into any other category listed above.

DAE Classification	Description	Signs/Symptoms/Findings
9.1 Other	A reaction that does not fall into any other category listed above	Any