Policy Statement	The Transfusion Service notifies the source facility when a blood or tissue product is suspected as the primary cause of an adverse event. The FDA is also notified in the event of a transfusion-related fatality.
Purpose	To provide direction when an adverse event is identified.
Scope	This program encompasses all patients who receive blood, blood products, donor milk, or tissue products which were issued by the Transfusion Service.
Responsibility	All Transfusion Service associates are responsible for referring possible adverse events to the Lead Technologist and Medical Director for review. The Lead Technologist and Medical Director are responsible for timely investigation and follow up. The Lead Technologist is responsible for reporting adverse events to the source facility and FDA as appropriate.
References	**Code of Federal Regulations:** Title 21, part 606, Current Good Manufacturing Practices for Blood and Blood Components **Guidance for Industry:** Notifying FDA of Fatalities Related to Blood Collection or Transfusion, Final Guidance **CAP Accreditation Program:** Transfusion Medicine Checklist; TRM.42100, TRM.42185

1. Adverse events are reviewed at regular intervals by the Lead Technologist, Quality Coordinator and Transfusion Service Medical Director.
2. The determination to report an event is made when a reaction is caused by a problem with manufacturing (which includes donor selection). Examples include but are not limited to
    a. Transfusion-related acute lung injury (TRALI).
    b. Septic reactions

   c. Severe allergic reactions
   d. Transfusion-transmitted infections
   e. Transfusion reactions related to compatibility problems when the reference laboratory performed the testing or provided specially selected products
   f. Death
3. Adverse events are reported to the supplier in as timely a manner as possible. Refer to specific supplier for their process and documentation requirements for reporting.
4. All fatalities confirmed to be caused by blood transfusion are reported to the FDA as soon as possible by e-mail. This initial notification should include
   a. Name, title, contact information for the reporting individual
   b. Facility identification
   c. Age and sex of the deceased
   d. Date, time and cause or suspected cause of death
   e. Date and time of transfusions
   f. Blood component information
   g. Brief description of the events leading to the fatality
5. A fatality follow-up report must follow within 7 days which includes the details of the investigation. Investigation details for a fatality generally should include (as appropriate)
   a. Discharge summary and/or death certificate
   b. Autopsy report
   c. Transfusion reaction workup
   d. Relevant clinical and diagnostic reports
   e. Relevant physician documentation
   f. Look Back documentation
   g. Meeting minutes from hospital oversight group(s) where the incident was reviewed
   h. Conclusions and follow-up actions
6. Contact information for reporting fatalities can be found here: http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ReportaProblem/TransfusionDonationFatalities/
7. All documentation will be retained as part of the occurrence management program.