Policy Statement	The Transfusion Service identifies, investigates, develops follow up, documents, and reports deviations and unexpected events which may impact the safety, purity or potency of blood and blood products it controls and distributes.
Purpose	This document provides direction to identify, investigate, take corrective action, report, and track biological product deviations.
Scope	This document applies to all products associated with manufacturing in the Transfusion Service. Manufacturing includes testing, processing, packing, labeling, storage and with the holding or distribution of blood or blood products.
Responsibility	All Transfusion Service associates are responsible for documenting deviations and unexpected events and applying immediate remedial action as appropriate. The Lead Technologist and Quality Coordinator are responsible for timely investigation and follow up. The Lead Technologist is responsible for submitting Biological Product Deviation Reports. The Transfusion Service Medical Director is responsible for ensuring the safety, purity and potency of all blood and blood products.
References	**Code of Federal Regulations:** Title 21, part 606, Current Good Manufacturing Practices for Blood and Blood Components **Guidance for Industry:** Biological Product Deviation Reporting for Blood and Plasma Establishments **CAP Accreditation Program:** Transfusion Medicine Checklist; TRM.30950

1. Deviations and unexpected events (also referred to as occurrences, nonconforming events, incidents, etc) are reviewed at regular intervals by the Lead Technologist, Quality Coordinator and Transfusion Service Medical Director.
2. The determination to submit a biological product deviation report (BPDR) is made when
    a. An occurrence is associated with manufacturing, to include testing, processing, packing, labeling, storage, or holding and distribution of blood and blood products; and
    b. The occurrence may affect the safety, purity or potency of the blood or blood products; and
    c. Occurs while the blood product is under the control of the transfusion service; and
    d. Involves a distributed blood or blood product (issued for transfusion or shipped out of the facility).
3. BPDRs are submitted as soon as possible but must be submitted within 45 days of discovery.
4. BPDRs are submitted electronically using Form FDA-3486.
    a. Form FDA-3486 and instructions for its completion are available at: http://www.fda.gov/cber/biodev/biodev.htm
5. Records of investigation and follow up are maintained as part of the occurrence management system.
6. BPDRs that may impact patient safety and/or represent interdepartmental deviations are reported through the appropriate medium.