


<b>Name of Policy:</b> <u>Incident/ Error/ Accident Review</u> <b>Policy Number:</b> 3364-108-106 <b>Department:</b> Pathology/Laboratory – Blood Bank <b>Approving Officer:</b> Associate Professor Director, Clinical Pathology/Hematopathology <b>Responsible Agent:</b> Core Lab Coordinator (Michelle Bartkowiak, MT(ASCP)SBB) Manager, Lab (Cynthia O’Connell) <b>Scope:</b> Pathology/Laboratory – Blood Bank	 <b>Effective Date:</b> 6/9/2008 Initial Effective Date: 6/1996
<input type="checkbox"/> New policy proposal <input type="checkbox"/> Major revision of existing policy	
<input type="checkbox"/> Minor/technical revision of existing policy <input checked="" type="checkbox"/> Reaffirmation of existing policy	

**(A) Policy Statement**

The Blood Transfusion Service has a process to capture, assess, investigate and monitor events that deviate from UTMC policy or procedure or other applicable regulations and requirements.


**(B) Purpose of Policy**

To capture and classify variant events; investigate and identify problems; implement corrective action and evaluate effectiveness of corrective action.

**(C) Procedure**

All errors (unplanned deviations) or variances from procedure detected in previously described reviews are documented on a Lab Occurrence Report.. Document all pertinent information including unit numbers, patient identification and detailed description of the problem. In addition, UTMC Occurrence Reports should be initiated for all serious errors that may adversely affect patient care or condition. Deviations from policy or procedure with prior approval from BTS-Medical Director (planned deviations) must also be documented. All variances are reviewed by the BTS supervisor and referred to the BTS Medical Director if warranted. Appropriate corrective actions and follow-up are recorded on Variance Log or Report. Recurrent variances by Blood Transfusion Service personnel are corrected by retraining. Repeated negligence or breach of policy or procedure will result in disciplinary action. Variance reports are referred as follows:

- ⇒ Hospital departments, Risk Management; variances involving personnel outside of Department of Pathology
- ⇒ Laboratory CQI Coordinator; variances involving specimen collection, delays, laboratory personnel
- ⇒ Blood Utilization Review Committee, Risk Management; serious variances requiring interdisciplinary approach for resolution; irregular blood ordering practices or blood usage for peer review. Incidents considered “Sentinel Events” will be investigated and reported to The Joint Commission by Risk Management.
- ⇒ American Red Cross; variances involving blood or component unit quality or availability; severe adverse effects of transfusion.
- ⇒ Product/ Equipment Vendors or Manufacturers; variances involving reagents, equipment or products.
- ⇒ Federal Drug Administration; biological product deviations (BPD) that occur while products are under UTMC control that affect the safety, purity, or potency of a blood product. See guidance documents and forms attached or to report electronically within 45 days, see CBER web site at [www.fda.gov/cber/biodev/biodev.htm](http://www.fda.gov/cber/biodev/biodev.htm)); fatal transfusion reactions.

<b>Approved by:</b>   6-6-08 _____ Robert L. Booth, Jr., M.D. Associate Professor Director, Clinical Pathology/Hematopathology  Review/Revision Completed By: Michelle Bartkowiak, MI(ASCP)SBB	<b>Review/Revision Date:</b> 6/96 1/98 3/99 4/00 7/01 1/05 1/2008 6/9/2008  <b>Next Review Date:</b> 6/1/2011
<b>Policies Superseded by This Policy:</b>	

*It is the responsibility of the reader to verify with the responsible agent that this is the most current version of the policy.*

**References:**

AABB Standards for Blood Banks and Transfusion Services, current edition.