

- (c) Lab 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.
 - (d) American Red Cross; variances involving blood or component unit quality or availability; severe adverse effects of transfusion.
 - (e) Product/ Equipment Vendors or Manufacturers; variances involving reagents, equipment or products.
 - (f) 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); fatal transfusion reactions
- (2) Communication of Concerns
- (a) Personnel with concerns about quality or safety are encouraged to communicate those concerns to Lab Administration or Hospital Executive Management. Anonymous communication of quality or safety concerns may also be made to CAP or Joint Commission. Contact information is in the Policy manual and posted in the laboratory.
- (D) References
- (1) AABB Standards for Blood Banks and Transfusion Services, current edition.

<p>Approved by:</p> <p>/s/</p> <hr/> <p>Lauren Stanoszek, M.D. Assistant Professor Director, Blood Transfusion Service</p> <p>3/1/2025</p> <hr/> <p>Date</p> <p>/s/</p> <hr/> <p>Russell Smith Pharm D, MBA, BCPS, CPEL, FACHE Senior Hospital Administrator</p> <p>3/3/2025</p> <hr/> <p>Date</p> <p><i>Review/Revision Completed by:</i> Danielle Weilnau MLS(ASCP)^{CM}</p>	<p>Policies Superseded by This Policy:</p> <ul style="list-style-type: none"> • <i>None</i> <p>Initial effective date: 06/1996</p> <p>All Review/Revision Dates:</p> <p>6/96 1/98 3/99 4/00 7/01 1/05 1/2008 6/9/2008 3/22/2011 3/01/2013 3/2/2015 3/1/2017 3/1/2019 3/1/2021 3/20/2023 03/03/2025</p> <p>Next review date: 03/03/2027</p>
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