Form Approved
OMB No. 0920-0666
Exp. Date: 12/31/2026
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Hemovigilance Module
Monthly Incident Summary

*Required for saving

*Facility ID#: _____ *Month: _____ *Year: _____

All reporting is facility-wide. Include numbers of individual incident reports in the totals.

*Process Code	*Incident Code	*Total Incidents	*Total Adverse Reactions
PC: Product Check-In (Transfusion Service) Events that occur during the shipment and receipt of products into the transfusion service from the supplier, another hospital site, satellite storage, or clinical area.	PC 00 Detail not specified		
	PC 01 Data entry incomplete/incorrect/not performed		
	PC 02 Shipment incomplete/incorrect		
	PC 03 Products and paperwork do not match		
	PC 04 Shipped/transported under inappropriate conditions		
	PC 05 Inappropriate return to inventory		
	PC 06 Product confirmation incorrect/not performed		
	PC 07 Administrative check not incorrect/not performed (record review/audit)		
	PC 08 Product label incorrect/missing		
US: Product Storage (Transfusion Service) Events that occur during product storage by the transfusion service.	US 00 Detail not specified		
	US 01 Incorrect storage conditions		
	US 03 Inappropriate monitoring of storage device		
	US 04 Unit stored on incorrect shelf (e.g., ABO/autologous/directed)		
	US 05 Incorrect storage location		
IM: Inventory Management (Transfusion Service) Events that involve quality management of the blood product inventory.	IM 00 Detail not specified		
	IM 01 Inventory audit incorrect/not performed		
	IM 02 Product status incorrectly/not updated online (e.g., available/discarded)		
	IM 03 Supplier recall/traceback not appropriately addressed/not performed		
	IM 04 Product order incorrectly/not submitted to supplier		
	IM 05 Outdated product in available inventory		
	IM 06 Recalled/quarantined product in available inventory		
PR: Product/Test Request (Clinical Service) Events that occur when the clinical service orders patient tests or blood products for transfusion.	PR 00 Detail not specified		
	PR 01 Order for wrong patient		
	PR 02 Order incompletely/incorrectly ordered (online order entry)		
	PR 03 Special processing needs not indicated (e.g., CMV negative, autologous)		
	PR 04 Order not done		
	PR 05 Inappropriate/unnecessary (intended) test ordered		
	PR 06 Inappropriate/unnecessary (intended) blood product ordered		
	PR 07 Incorrect (unintended) test ordered		
	PR 08 Incorrect (unintended) blood product ordered		
OE: Product/Test Order Entry (Transfusion Service) Events that occur when the transfusion service receives a patient order. This process may be excluded if clinical service uses online ordering.	OE 00 Detail not specified		
	OE 01 Order entered for wrong patient		
	OE 02 Order incompletely/incorrectly entered online		
	OE 03 Special processing needs not entered (e.g., CMV-, autologous)		
	OE 04 Order entry not done		
	OE 05 Inappropriate/unnecessary (intended) test order entered		
	OE 06 Inappropriate/unnecessary (intended) blood product order entered		
	OE 07 Incorrect (unintended) test ordered		
	OE 08 Incorrect (unintended) blood product ordered		

Clearance Officer, 1600 Clifton Rd., MS H21-8, Atlanta, GA 30333, ATTN: PRA (0920-0666).

*Process Code	*Incident Code	*Total Incidents	*Total Adverse Reactions
SC: Sample Collection (Service collecting the samples) Events that occur during patient sample collection.	SC 00 Detail not specified		
	SC 01 Sample labeled with incorrect patient ID (intended patient drawn)		
	SC 02 Sample not labeled		
	SC 03 Wrong patient collected (sample labeled for intended patient)		
	SC 04 Sample collected in wrong tube type		
	SC 05 Sample quantity not sufficient (QNS)		
	SC 06 Sample hemolyzed		
	SC 07 Sample label incomplete/illegible for patient identifiers		
	SC 08 Sample collected in error (e.g., unnecessary/duplicate)		
	SC 09 Patient sample not collected (in error)		
	SC 10 Patient wristband incorrect/not available		
	SC 11 Sample contaminated		
SH: Sample Handling (Service collecting the samples) Events that occur when a patient sample is sent for testing.	SH 00 Detail not specified		
	SH 01 Sample sent without requisition		
	SH 02 Requisition and sample label don't match		
	SH 03 Patient ID incomplete/illegible on requisition		
	SH 04 No Patient ID on requisition		
	SH 05 No phlebotomist/witness identification		
	SH 06 Sample sent with incorrect requisition type		
	SH 07 Patient information (other than ID) missing/incorrect on requisition		
	SH 08 Requisition sent without sample		
	SH 09 Data entry incorrect/incomplete/not performed		
	SH 10 Sample transport issue (e.g., sample broken/inappropriate conditions)		
	SH 11 Duplicate sample sent in error		
SR: Sample Receipt (Transfusion Service) Events that occur when a sample is received by the transfusion service.	SR 00 Detail not specified		
	SR 01 Sample accepted in error		
	SR 02 Historical review incorrect/not performed		
	SR 03 Demographic review/ data entry incorrect/not performed		
	SR 04 Sample incorrectly accessioned		
ST: Sample Testing (Transfusion Service) Events that occur during **patient sample** testing by the transfusion service.	ST 00 Detail not specified		
	ST 01 Data entry incomplete/incorrect/not performed		
	ST 02 Appropriate sample checks incomplete/incorrect/not performed		
	ST 03 Computer warning overridden in error or outside SOP		
	ST 05 Sample test tube incorrectly accessioned		
	ST 07 Sample test tubes mixed up		
	ST 09 Sample test tube mislabeled (wrong patient identifiers)		
	ST 10 Equipment problem/failure/not properly QC'd		
	ST 12 Sample testing not performed		
	ST 13 Incorrect sample testing method chosen		
	ST 14 Sample testing performed incorrectly		
	ST 15 Sample test result misinterpreted		
	ST 16 Reagents used were incorrect/inappropriate/expired/not properly QC'd		
	ST 17 ABO/Rh error caught on final check		
	ST 18 Current/historical ABO/Rh mismatch		
	ST 19 Additional testing not performed		
	ST 20 Confirmatory check incorrect/not performed (at time work performed)		
	ST 21 Administrative check incorrect/not performed (record review/audit)		
	ST 22 Sample storage incorrect/inappropriate		

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UM: Product Manipulation/ Processing/Testing (Transfusion Service) Events that occur while testing, manipulating (e.g., pooling, washing, aliquoting, irradiating), processing, or labeling blood products.	UM 00 Detail not specified		
	UM 01 Data entry incomplete/incorrect/not performed		
	UM 02 Record review incomplete/incorrect/not performed		
	UM 03 Incorrect product (type) selected		
	UM 04 Incorrect product (patient) selected		
	UM 05 Product labeled incorrectly (new/updated)		
	UM 06 Computer warning overridden in error or outside SOP		
	UM 07 Special processing needs not checked		
	UM 08 Special processing needs misunderstood or misinterpreted		
	UM 09 Special processing needs performed incorrectly		
	UM 10 Special processing needs not performed		
	UM 11 Equipment problem/failure/not properly QC'd		
	UM 12 Reagents used were incorrect/inappropriate/expired/not properly QC'd		
	UM 13 Confirmatory check incorrect/not performed (at time work performed)		
	UM 14 Administrative check incorrect/not performed (record review/audit)		
No Blood	NB 01 Inventory less than usual par level due to supplier unable to meet usual steady demand		
	NB 02 Demand for blood product exceeding usual par inventory level		
	NB 03 Incompatible/inappropriate units issued due to inventory constraints when demand for blood product exceeds usual par inventory levels.		
	NB 04 Suboptimal dose (less than optimal quantity) transfusion or no transfusion due to inventory constraints when demand for blood product exceeds usual par inventory levels.		
RP: Request for Pick-Up (Clinical Service) Events that occur when the clinical service requests pick-up of a blood product from the transfusion service.	RP 00 Detail not specified		
	RP 01 Request for pick-up on wrong patient		
	RP 02 Incorrect product requested for pick-up		
	RP 03 Product requested prior to obtaining consent		
	RP 04 Product requested for pick-up, but patient not available		
	RP 05 Product requested for pick-up, but IV not ready		
	RP 06 Request for pick-up incomplete (e.g., patient ID/product type missing)		
	RP 07 Pick-up slip did not match patient information on product		
UI: Product Issue (Transfusion Service) Events that occur when the transfusion service issues blood product to the clinical service.	UI 00 Detail not specified		
	UI 01 Data entry incomplete/incorrect/not performed		
	UI 02 Record review incomplete/incorrect/not performed		
	UI 03 Product issued for wrong patient		
	UI 04 Product issued out of order		
	UI 05 Product issue delayed		
	UI 06 LIS warning overridden in error or outside SOP		
	UI 07 Computer issue not completed		
	UI 08 Issued visibly defective product (e.g., clots/aggregates/particulate matter)		
	UI 09 Not/incorrect checking of unit and/or patient information		
	UI 10 Product transport issues (e.g., delayed) by transfusion service		
	UI 11 Unit delivered to incorrect location by transfusion service		
	UI 12 Product transport issue (from transfusion service to clinical area)		
	UI 18 Wrong product issued for intended patient (e.g., incompatible)		
	UI 19 Inappropriate product issued for patient (e.g., not irradiated, CMV+)		
	UI 20 Confirmatory check incorrect/not performed (at time work performed)		
	UI 21 Administrative check incorrect/not performed (record review/audit)		
	UI 22 Issue approval not obtained/documented		
	UI 23 Receipt verification not performed (pneumatic tube issue)		

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CS: Satellite Storage (Clinical Service) Events that occur while product is stored and handled by the clinical service.	CS 00 Detail not specified		
	CS 01 Incorrect storage conditions of product in clinical area		
	CS 02 Incorrect storage location in the clinical area		
	CS 03 Labeling issue (by clinical staff)		
	CS 04 Floor/clinic did not check for existing products in their area		
	CS 05 Product transport issues (to or between clinical areas)		
	CS 06 Monitoring of satellite storage incorrect/incomplete/not performed		
	CS 07 Storage tracking/documentation incorrect/incomplete/not performed		
UT: Product Administration (Clinical Service) Events that occur during the administration of blood products.	UT 00 Detail not specified		
	UT 01 Administered intended product to wrong patient		
	UT 02 Administered wrong product to intended patient		
	UT 03 Transfusion not performed in error		
	UT 05 Bedside check (patient ID confirmation) incomplete/not performed		
	UT 06 Transfused product with incompatible IV fluid		
	UT 07 Transfusion delayed beyond pre-approved timeframe		
	UT 09 Transfused unsuitable product (e.g., outdated/inappropriately stored)		
	UT 10 Administered components in wrong order		
	UT 11 Appropriate monitoring of patient not performed		
	UT 14 Transfusion volume too low (per order or SOP)		
	UT 15 Transfusion volume too high (per order or SOP)		
	UT 16 Transfusion rate too slow (per order or SOP)		
	UT 17 Transfusion rate too fast (per order or SOP)		
	UT 18 Inappropriate preparation of product		
	UT 19 Transfusion protocol not followed (not otherwise specified)		
	UT 22 Order/consent check incorrect/not performed		
	UT 23 Transfusion documentation incorrect/incomplete/not performed		
	UT 24 Transfusion documentation not returned to transfusion service		
	UT 26 Transfusion **reaction** protocol not followed		
MS: Other	MS 99 Other		
	Total		