HIM.2.3 Respond to Market Withdrawals and Recalls

Procedure Area:	Hospital Inventory Management Procedures (HIM)	Version:	2.0

Purpose

To respond to recalls due to post donation information about the donor or the blood component.

Scope

Customers

Materials

- ✓ Computer workstation
- ✓ HemaControl
- ✓ *Blood Component Market Withdrawal/Recall Notification* form (initiated in ***HS.5.2***)
- ✓ *Hospital Return* form, if needed (initiated in ***HIM.1.2***)

Procedure Notes

A credit will not be issued for components returned due to a recall without a completed *Blood Component Market Withdrawal/Recall Notification* form.

Procedure Steps

1. Receive the faxed *Blood Component Market Withdrawal/Recall Notification* form (see Figure 1). Note that you will receive a call alerting you that the form was faxed.
2. Determine the disposition of each blood component listed in the Component Details section of the *Blood Component Market Withdrawal/Recall Notification* form.
3. Complete the To Be Completed by Customer section of the *Blood Component Market Withdrawal/Recall Notification* form as follows:
   a. Enter your name as the **Person Completing Form**.
   b. Enter your job title as the **Title**.
   c. Indicate the **Final Disposition** of each component listed on the *Blood Component Market Withdrawal/Recall Notification* form, and handle as follows:

If component is	Do this
In inventory	• Complete a *Hospital Return* form and arrange for return per ***HIM.1.2***. • On the *Blood Component Market Withdrawal/Recall Notification* form select the "Returned to Blood Center" disposition, and write the date you returned the component in the **Date of Final Disposition** field. • Enclose a copy of the *Blood Component Market Withdrawal/Recall Notification* form with the component being returned.
Discarded/destroyed	Select the "Destroyed at your facility" disposition and write the date you discarded/destroyed the component in the **Date of Final Disposition** field.
Transfused	Select the "Transfused prior to notification" disposition and write the date the component was transfused in the **Date of Final Disposition** field.
Shipped	• Select the "Shipped to another facility" disposition and write the date you shipped the component in the **Date of Final Disposition** field. • Indicate the facility that received the component in the **Additional Comments** field.
Kept	Explain why the component was kept in the **Additional Comments** field.

4. Sign and date the *Blood Component Market Withdrawal/Recall Notification* form. By signing the form, you are assuring that the component disposition information indicated on the form is accurate.
5. Fax or email the completed *Blood Component Market Withdrawal/Recall Notification* form to the number or email address listed on the form as soon as possible.
6. Return the product in HemaControl, if applicable:
   a. Log onto HemaControl.
   b. Select **Returns**.
   c. Select **Recall** as the **Type**.
   d. Scan or enter the unit number and product code.
   e. Select **Add**.
   f. Select **Review Recall**.
   g. Select **Return Blood**.
   h. Print a copy to send with the units.

Related Documents

HIM.1.2 (Return Components for Normal Inventory Rotation)

Blood Component Market Withdrawal/Recall Notification

Lifesouth Community Blood Centers

Form Initiated by:	Region:

Customer Information

Notification Date:	Contact Name:
Facility:	Phone Number:
	Fax Number:

Component Details

#	DIN	Product Code	ABO/Rh	Date Shipped	Date Expires
1					
2					
3					
4					

Reason for Market Withdrawal/Recall

- ☐ Bacterial testing failed
- ☐ Co-component associated with a report of adverse transfusion event
- ☐ Co-component has fibrin strands/clots
- ☐ Co-component has visual signs of bacterial contamination (cloudy, clumps, frothy/unusual air bubbles)
- ☐ Imported product: exporter initiated recall: _____
- ☐ Incorrect volume on product label
- ☐ pH out of range in component or co-component
- ☐ Product QC: low platelet count: _____x10e11
- ☐ Product QC failure noted after component shipped
- ☐ QA Investigation: _____
- ☐ Other reason:

Email this form to QA@lifesouth.org at the same time that you fax or email this form to the customer

TO BE COMPLETED BY CUSTOMER*

Person Completing Form:	Title:
Signature:	Date:

Indicate the Final Disposition of each component listed (check applicable):

#	*Returned to Blood Center*	*Destroyed at your facility*	*Transfused prior to notification*	*Shipped to another facility (designate where)*	*Component Kept (include comment)*	*Date of Final Disposition*
1	☐	☐	☐	☐	☐	
2	☐	☐	☐	☐	☐	
3	☐	☐	☐	☐	☐	
4	☐	☐	☐	☐	☐	

Additional Comments:

- *As soon as possible, return this form to QA at QA@lifesouth.org or fax at (352) 334-7782.*
- *Credit for discarded components may be issued upon request. Request credit by submitting the* Issue/Complaint Form *(accessible at www.lifesouth.org).*

Contact the LifeSouth Quality Assurance department at 1-866-592-8678 if you have questions.

HS.5.2 Effective: 22 Feb 2022

Figure 1, *Blood Component Market/Withdrawal Notification* form

HIM.2.3 Respond to Market Withdrawals and Recalls

Procedure Area:	Hospital Inventory Management Procedures (HIM)	Version:	2.0

Version History

#	Significant Changes	Approved by	Approved	Implemented
2.0	Updated the steps to have staff respond to market withdrawals using HemaControl.	Dr. Chris Lough, VP of Medical Services Dr. Juan Merayo-Rodriguez, Medical Director Lori Masingil, VP of Quality	08 Mar 2024	26 Mar 2024
1.0	• Added "Component Kept" to the if/then table in step 3. • Updated step 5 so staff have the option to email the completed *Blood Component Market Withdrawal/Recall Notification* form. • Added example of completed *Blood Component Market/Withdrawal Notification* form ***Note**: Prior versions of this document may exist; version numbers were applied to policies and procedures beginning in ~Jan. 2015.*	Phuc Huynh, Corporate Quality Assurance Coordinator	18 Mar 2021	18 Mar 2021