

## 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	<ul style="list-style-type: none"><li>• Complete a <i>Hospital Return</i> form and arrange for return per <b>HIM.1.2</b>.</li><li>• On the <i>Blood Component Market Withdrawal/Recall Notification</i> form select the “Returned to Blood Center” disposition, and write the date you returned the component in the <b>Date of Final Disposition</b> field.</li><li>• Enclose a copy of the <i>Blood Component Market Withdrawal/Recall Notification</i> form with the component being returned.</li></ul>
Discarded/destroyed	Select the “Destroyed at your facility” disposition and write the date you discarded/destroyed the component in the <b>Date of Final Disposition</b> field.
Transfused	Select the “Transfused prior to notification” disposition and write the date the component was transfused in the <b>Date of Final Disposition</b> field.
Shipped	<ul style="list-style-type: none"><li>• Select the “Shipped to another facility” disposition and write the date you shipped the component in the <b>Date of Final Disposition</b> field.</li><li>• Indicate the facility that received the component in the <b>Additional Comments</b> field.</li></ul>
Kept	Explain why the component was kept in the <b>Additional Comments</b> field.

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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 \(Return Components for Normal Inventory Rotation\)](#)

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## Blood Component Market Withdrawal/Recall Notification

Lifesouth Community Blood Centers

Form Initiated by:	Region:
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**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**

<input type="checkbox"/> Bacterial testing failed <input type="checkbox"/> Co-component associated with a report of adverse transfusion event <input type="checkbox"/> Co-component has fibrin strands/clots <input type="checkbox"/> Co-component has visual signs of bacterial contamination (cloudy, clumps, frothy/unusual air bubbles) <input type="checkbox"/> Imported product: exporter initiated recall: _____ <input type="checkbox"/> Incorrect volume on product label	<input type="checkbox"/> pH out of range in component or co-component <input type="checkbox"/> Product QC: low platelet count: _____ x10e11 <input type="checkbox"/> Product QC failure noted after component shipped <input type="checkbox"/> QA Investigation: _____ _____ <input type="checkbox"/> Other reason: _____ _____ _____
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Email this form to [QA@lifesouth.org](mailto: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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
2	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
4	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Additional Comments:						

- As soon as possible, return this form to QA at [QA@lifesouth.org](mailto: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](http://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

Not Under Document Control if Printed

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### 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	<ul style="list-style-type: none"><li>Added "Component Kept" to the if/then table in step 3.</li><li>Updated step 5 so staff have the option to email the completed <i>Blood Component Market Withdrawal/Recall Notification</i> form.</li><li>Added example of completed <i>Blood Component Market/Withdrawal Notification</i> form</li></ul> <p><b>Note:</b> Prior versions of this document may exist; version numbers were applied to policies and procedures beginning in ~Jan. 2015.</p>	Phuc Huynh, Corporate Quality Assurance Coordinator	18 Mar 2021	18 Mar 2021