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:

<table>
<thead>
<tr>
<th>If component is</th>
<th>Do this</th>
</tr>
</thead>
</table>
| 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. |
### HIM.2.3 Respond to Market Withdrawals and Recalls

<table>
<thead>
<tr>
<th>Procedure Area:</th>
<th>Hospital Inventory Management Procedures (HIM)</th>
<th>Version:</th>
<th>2.0</th>
</tr>
</thead>
</table>

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)*
HIM.2.3  Respond to Market Withdrawals and Recalls

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

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

<table>
<thead>
<tr>
<th>#</th>
<th>DIN</th>
<th>Product Code</th>
<th>ABO/Rh</th>
<th>Date Shipped</th>
<th>Date Expires</th>
</tr>
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<tbody>
<tr>
<td>1</td>
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Reason for Market Withdrawal/Recall

☐ Bacterial testing failed  ☐ pH out of range in component or co-component
☐ Co-component associated with a report of adverse  ☐ Product QC: low platelet count: _____x10^11
transfusion event  ☐ Product QC failure noted after component shipped
☐ Co-component has fibrin strands/clots  ☐ QA Investigation:
☐ Co-component has visual signs of bacterial contamination (cloudy, clumps, frothy/unalusual air bubbles)  ☐ Other reason:
☐ Imported product: exporter initiated recall: ________
☐ Incorrect volume on product label

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):

<table>
<thead>
<tr>
<th>#</th>
<th>Returned to Blood Center</th>
<th>Destroyed at your facility</th>
<th>Transfused prior to notification</th>
<th>Shipped to another facility (designate where)</th>
<th>Component Kept (include comment)</th>
<th>Date of Final Disposition</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
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Additional Comments:

- As soon as possible, return this form to QA at QA@lifesouth.org or fax at (352) 334-7762.
- 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.

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

<table>
<thead>
<tr>
<th>#</th>
<th>Significant Changes</th>
<th>Approved by</th>
<th>Approved</th>
<th>Implemented</th>
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</thead>
</table>
| 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 |