HIM.2.1  Report an Issue/Complaint

Purpose

To communicate any type of issue/complaint, including those that relate to components, customer service, and requests for credit.

Scope

All customers and partners

Materials

✓ Computer workstation
✓ HemaControl

Procedure Notes

- In order to receive a credit for a variant component, the component returned must have an obvious variance and the variant component must be physically returned. However, if the component is damaged or leaking (not safe for transport) or has been manipulated/ altered (e.g., irradiated), do not return the component.
- A credit will not be issued for a variant component without the signed Issue/Complaint Report.
- Variant component must be reported in a timely manner to receive credit.

Procedure Steps

Follow sub-procedures that applies to your workflow to report an issue or complaint:

- Report an issue or complaint via the Issue/Complaint Report according to 2.1.1, Report an issue or complaint via the Issue/Complaint Report.
- If the units need to be returned, report an issue or complaint via HemaControl according to 2.1.2, Return a product via HemaControl.

2.1.1, Report an issue or complaint via the Issue/Complaint Report

1. Complete the Issue/Complaint Report as follows:
   a. Enter the report details in Part 1 as applicable.
   b. Provide issue details in Part 2 as applicable; note the following:
      (i) Select the issue type in the Description of issue section.
      (ii) Indicate whether returning a component.

<table>
<thead>
<tr>
<th>If this</th>
<th>Then this</th>
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<tbody>
<tr>
<td>Returning an unbroken/undamaged component</td>
<td>Check Returning a Component; however, components must only be returned if they were stored at the proper temperature at your site. By signing, you are verifying that proper temperature was maintained.</td>
</tr>
<tr>
<td>Not returning a component due to breakage/damage</td>
<td>Check Discarded at facility; will not return. By signing, you are confirming that the component was properly discarded at your facility.</td>
</tr>
<tr>
<td>Not returning a component</td>
<td>Component was transfused; check the Transfused box. By signing, you are confirming that the component no longer exists in your inventory as it</td>
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(iii) Sign the Issue/Complaint Report in the Consignee Signature field.

2. Send the completed Issue/Complaint Report to the Quality Assurance department as indicated on the Issue/Complaint Report form.

3. Arrange to return the component, if applicable (see 2.1.2, Report an Issue/Complaint in HemaControl). Make a copy of the Issue/Complaint Report for your records, and enclose the original Issue/Complaint Report with the returned component.

2.1.2, Return a product via HemaControl

1. Log into HemaControl.
2. Select Returns.
3. Select Return as the Type.
4. Select Complaint as the Reason.
5. Scan or enter the unit number and product code.
6. Select Add.
7. Select Review Return.
8. Select Return Blood.
9. Print a copy to send with the units.
**HIM.2.1 Report an Issue/Complaint**

**Procedure Area:** Hospital Inventory Management Procedures (HIM)  
**Version:** 3.0

### 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>
| 3.0| Changed instructions to handle issues/complaints in HemaControl.                                                                                                                                                    | Dr. Juan Merayo, Medical Director  
Dr. Chris Lough, VP of Medical Services  
Lori Masingil, VP of Quality Assurance | 08 Mar 2024  
26 Mar 2024 |  

| 2.0| • Removed instructions to specifically fax the Issue/Complaint Report form to QA; form can be faxed or emailed.  
• Removed instructions to note whether a blood component is involved.  
• Added procedure note to report variance in timely manner in order to receive credit.                                                    | Dr. Juan Merayo, Medical Director  
Dr. Chris Lough, Medical Director  
Lori Masingil, VP of Quality Assurance | 29 May 2019 | 18 Jun 2019  

| 1.0| • Updated title; previously Return Variant Products.  
• Replaced Hospital Reportable Event Form and Request for Credit form with the Issue/Complaint Report.  
• Incorporated information from discontinued procedures, HIM.2.2 and HIM.3.1.  
• Added version information.  
**Note:** Prior versions of this document may exist; version numbers were applied to policies and procedures beginning in ~Jan. 2015. | Dr. Juan Merayo-Rodriguez, Medical Director  
Dr. Marek Fried, Medical Director  
Richard Jones, QA Manager  
CBCC Medical Director | 03 Jun 2015 | 23 Jun 2015  

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