To our valued hospital clients:

BloodworksNW (formerly known as Puget Sound Blood Center) has amended the process for hospital notification of non-conforming products (product withdrawals). As a reminder, AABB regulatory guidelines state that “Blood components that are determined after release not to conform to specified requirements shall be evaluated. In cases where quality may have been affected, the nonconformance shall be reported to the customer. Records of the nature of the nonconformance and subsequent actions taken, including acceptance for use, shall be maintained.”

Attached is a revised Product Withdrawal Form which will be implemented on 4/15/15. This form will continue to be faxed to your facility after an initial phone call about a nonconforming event. The grayed out sections of the form will be completed by BloodworksNW. This includes the reason for the product notification and the specific instructions on what to do with the product. In section 3 of the form hospitals will need to complete the sections highlighted in yellow. This includes documentation if and when the unit was transfused, is to be returned, or was discarded. The form must be returned to the Blood Center as soon as possible by fax or email. It is critical to document who completed the form and the date. Forms not fully completed will be returned to the hospital by BloodworksNW to ensure all documentation requirements have been met.

Also attached is a sample of a confirmatory notification letter to be sent to hospitals regarding specific units that have been withdrawn (example: TRALI investigation results, bacterial follow up testing results for Platelets). Please note that the confirmatory notification letter is not intended for the purposes of notification of recipient risk. A separate letter will be sent to a physician from the Blood Works Safety and Surveillance department should that be required.

As always, please feel free to contact me by phone or email if you have any questions regarding this change. Debbie Roslan (Product Control Supervisor) is also available to discuss questions or concerns and can be reached at [debbier@bloodworksnw.org](https://ap02.alpine.washington.edu/alpine/alpine/2.0/mailto?to=debbier%40bloodworksnw%2Eorg&pop=view/0/$f/28304) (425-656-7905).

Best regards,

Brian

**Brian Danforth**

*Director Hospital Services*

*(Puget Sound Blood Center has a new name!)*

*701 SW 39th Street, Renton WA 98057*

*P (425) 656-3080* *• C (206) 276-4902 F (425-656-3043)*

*briand@bloodworksnw.org • bloodworksnw.org*

Your Facility Name Blood Bank April 1, 2015

Fax: 206-584-6845

We are providing you notification of the reason for withdrawal of a product. This information was not available at the time of issue.

|  |
| --- |
|  **1. Product Notification Reason** |
| This product tested positive for a post issue test | Bacterial testing | **Comments****URGENT REQUEST** |

*NOTE: This letter is not intended for the purposes of notification of recipient risk. A separate letter will be sent from the Safety and Surveillance department, if applicable.*

|  |
| --- |
|  **2. Instructions for Product Disposition** |
| Please locate the implicated products(s) and take the following action(s).[x]  Quarantine products for return on the next delivery. [ ]  Quarantine products at your Facility, pending further instructions.[ ]  Discard products at your Facility. |

|  |
| --- |
|  **3. Document the Product Disposition ( if greater than 2 products document on the attached list)** |
|

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Unit number** | **Product** | **Suffix** | **Ship Date** | **Transfused** | **Transfusion Date**  | **To Be Returned** | **Discarded at Facility** | **Other****(See below)** |
| **W141600000000** | **RCL4** | **A0** | **3/15/15** | □ | 3/16/15 | □ | □ |  □ |
|  |  |  |  | □ |  | □ | □ |  □ |

 ***Other*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

|  |  |
| --- | --- |
| Customer Printed Name: | Date: |

 |
|  |

**Fax this form back to the Product Control Office at 425-656-3052 immediately.**

|  |
| --- |
| **Comments:** |

Customer Notified: \_\_\_\_\_\_Customer Name\_\_\_\_\_\_\_\_

Date/Time: \_\_\_\_\_\_\_\_Date and Time Faxed\_\_\_\_\_\_\_\_

[x]  Follow-up letter to be sent

***Product Control Office***

701 S.W. 39th St. Renton, WA. 98052

Phone (425) 656-*3050* • Fax (425) 656-3052

*productcontroloffice@bloodworksnw.org*

Additional Follow up Actions:

Your Facility Blood Bank April 1, 2015

Fax: 206-584-6845

We are providing you follow up information for a product notification form sent to your facility.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Unit number** | **Product** | **Suffix** | **Ship Date** | **Product Notification Date** |
| **W141600000000** | **RCL4** | **A0** | **3/15/15** | **3/26/2015** |

|  |  |  |
| --- | --- | --- |
| **Test:****Culture** | **Result:****Negative** | **Comments** |

*NOTE: This letter is not intended for the purposes of notification of recipient risk. A separate letter will be sent from the Safety and Surveillance department, if applicable.*

***Product Control Office***

**blood services | medicine | research**

701 S.W. 39th St. Renton, WA. 98052

Phone (425) 656-*3050* • Fax (425) 656-3052

*productcontroloffice@psbc.org*

Customer Notified:

\_\_\_\_\_\_\_\_\_Customer Name \_\_\_\_\_\_

Date/Time:

\_\_\_\_\_\_\_\_Date and Time Notified \_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_