

## Component Management of Unsuitable Units Indicated for Recall, Withdrawal

### **Product Recall**

A Product Recall occurs when a product discovered to have been unsuitable for release but distributed due to an error/accident in the manufacturing process. Once a Product Recall is determined, TBC QS immediately initiates recall and notifies consignee.

### **Market Withdrawal**

A Market Withdrawal occurs when a product was suitable for release following manufacture but later discovered to be unsuitable. Determination of Market Withdrawals may be the result of a donor call back, post transfusion reaction, or subsequent positive test (see table). TBC QS initiates withdrawal as soon as information becomes available. If the withdrawal is due to a positive test, facility notification must occur within 72 hours.

### **Recall Withdrawal Process:**

Component determined to be unsuitable due to:

- Subsequent Positive Test Result
- Positive Bacterial Test Result
- Transfusion Related Adverse Event
- Post Donation Information

Notification to consignees initiated and completion of notification forms routed to consignee for acknowledgement of the receipt of the information and appropriate component disposition. Forms: **FPD.QS.5200C** (Product Withdrawal Form – Subsequent Positive Test) and **FPD.QS.5200D** (Product Recall/Withdrawal Form – Selective) initiated by TBC QS staff with verbal notification of the event. If your establishment has requested Preliminary notification with information available at the time of verbal notification, the form is sent using the method determined to be best for your establishment (fax, email, or via courier). Upon obtaining final information for the notification, TBC QS staff complete required information on the recall/withdrawal forms and send Final Notification Report to establishment using the method determined to be best for your establishment. Consignee is required to review notification form, complete Section II providing verification of the component disposition and acknowledgement of notice for Final Notification reports. Return of Preliminary Reports is optional.

If at any time there are questions regarding the notification, please contact TBC QS staff at 864-751-1226, or 1-800-392-6551, Ext. 1226 or Ext 3104.

Notifications can be returned to TBC Quality Department via email:

[Qsnotifications@thebloodconnection.org](mailto:Qsnotifications@thebloodconnection.org) or fax 864-527-4498.