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| Policy Statement | When notified by a supplier of biological products, Saint Agnes Hospital Transfusion Services maintains a process to identify and notify recipients who may have been exposed to a potentially infectious agent from the donor of a biological product. |
| Purpose | This procedure is designed to provide the necessary instructions to respond to a market withdrawal/recall or look-back notification from a biological product supplier.  |
| Scope | This procedure applies to, but is not limited to, the following departments: Laboratory Services, Perioperative Services, Materials Management, Quality and Patient Safety, Risk Management, Infection Control and Medical Records. The procedure also affects those patients who have received biological products during their encounter at Saint Agnes Hospital. |
| **Responsibility** | The associate who receives a notification from a biological product supplier is responsible for:* Determining the disposition of affected product(s)
* Quarantining any product(s) in the available inventory
* Completing TRAN 8005 Fa Recall Form documentation for the Transfusion Service Medical Director/Lead Technologist to investigate and review.

The Transfusion Services Medical Director, Lead Technologist or designee are responsible for:* Review of TRAN 8005 Fa Recall Form
* Determination of need for patient or physician notification
* Patient or physician notification process, if indicated.
* Recall Conclusion and medical record documentation as needed.
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| **Related Documents** | * TRAN 0000 QP Transfusion Services Quality Plan
* TRAN 5001 R Tissue Bank Process and Procedure
* TRAN 5065 R Tissue Disposition
* TRAN 5020 Fa Quarantine Log
* TRAN 8005 Fa Recall Form
* TRAN 8005 Fb Physician Receipt Verification Form
* CMS 42 CFR 482.27
* DHMH/AABB Standard 7.4.6.2
* CAP TRM.42120, TRM.42135, TRM.42170, and TRM.45125
* TJC PC.05.01.09 EP 1 & 2, TS.03.03.01 EP 4 & 5
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## Procedure

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| **Notification from Biological Product Supplier** |
| Notifications may be received by different modes of communication* E-mail
* Fax
* Surface mail letter
* Phone call

When an e-mail notification is sent to multiple associates, the associate responding to the notification should reply to all associates copied in the e-mail indicating that the notification has been addressed.  |

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| **Determination of the Disposition for Affected Product(s)** |
| Check the current database for the disposition of product(s)* For blood and blood components, perform a unit inquiry in Meditech.
* For tissue products, perform an advanced search in TRACS4Life.
* If no record is found, complete product information section of TRAN 8005 Fa for the Lead Technologist or designee to review and follow up.
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| **Respond to the Disposition** | **Products in the Available Inventory** |
| * Physically remove the product and place in quarantine
* Document the product on TRAN 5020 Fa Quarantine Log
* Document the quarantine in the current database
* Complete product information and disposition sections of TRAN 8005 Fa for the Lead Technologist or designee to review and follow up.
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| **Products with a Final Disposition** |
| * Complete product information and disposition sections of TRAN 8005 Fa for the Lead Technologist or designee to review and follow up.
* For product with a final disposition of transfused, implanted, or ingested, include the patient information on TRAN 8005 Fa.
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| **Review and Determination of Need for Patient or Physician Notification** |
| If no record was found for the affected product(s) during the initial inquiry, the Lead Technologist or designee must check previous databases for the affected product(s)* For blood and blood components, perform a search in the access database of products that didn’t transmit from the previous LIS.
* For tissue products, perform a search in the tissue access database that was previously used to track products.
* Complete documentation on TRAN 8005 Fa.
* If a product is still unable to be located, notify the supplier of the discrepancy and follow up as appropriate.

The Lead Tech or designee must ensure that all relevant information is recorded on TRAN 8005 Fa.* If the recall was for product that was transfused, the Lead Tech or designee must forward TRAN 8005 Fa and all accompanying documentation to the Transfusion Services Medical Director for review.
* If the recall was for product in the available inventory or previously discarded, there is no need for review by the Medical Director and the Lead Tech or designee must sign off for the conclusion of the recall.

The Transfusion Services Medical Director or designee must review the nature and timeline of the recall as well as the potential impact on the patient to determine whether the patient and/or physician should be notified. |

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| **Notification Process for Possible HIV/HCV** |
| * A registered letter from the Transfusion Services Medical Director along with instructions for testing and counseling resources will be sent to the patient’s last known address via surface mail.
	+ This letter will include the name of the attending or ordering physician to enable the patient to contact them for additional information.
* A certified letter will be mailed to the attending or ordering physician to make them aware that their patient was notified of exposure to a potentially infectious biological product and that they may be contacted for additional information.
* If the initial effort to contact the patient was unsuccessful within 30 days, a second certified letter will be sent to the attending or ordering physician.
	+ This letter will request assistance in contacting the patient and include a verification form for the physician to complete and return to the transfusion services, TRAN 8005 Fb.
* Once contact has been made and confirmed with either the patient or the physician, the recall may be concluded and signed off by the Medical Director.
* If the patient or physician was unable to be contacted at 12 weeks from the date of the recall, the recall may be concluded and signed off by the Medical Director.
	+ The extenuating circumstances will be documented.

Notes for special circumstances* If the patient is adjudged incompetent, the notification process will follow through a legal representative.
* If the patient is a minor or deceased, the notification process will follow through a legal representative or relative.
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| **Notification Process for All Other Circumstances** |
| * A certified letter from the Medical Director along with any applicable instructions will be sent via surface mail to the attending physician.
* Once receipt of the letter is confirmed, the recall may be concluded and signed off by the Medical Director.
* If no confirmation is received after 12 weeks, the recall may be concluded and signed off by the Medical Director.
* If the patient is deceased and it is determined that it was not related to the transfusion, the recall may be concluded and signed off by the Medical Director.
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| **Recall Conclusion and Medical Record Documentation** |
| All documentation related to the recall will be retained by the transfusion services for no less than ten years.Any notification letters will be scanned into the patient’s medical record by the Lead Tech or designee at the conclusion of the recall.If a patient was deceased and the fatality was determined to be related to the transfusion, a report to the FDA must be submitted. |