

# Component Recall

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## ISBT 128/Codabar Dual Label Implementation Regulatory Implications?

- Unique and unmistakable identification of each donation and its component products
- To ensure traceability through accurate donor, patient and laboratory identification procedures
- Effective recall procedures
- Demonstrate 100% traceability

# Component Recall

- Prevent the distribution or transfusion of an implicated blood component which may subsequently prove to be unsuitable for infusion
- Rapid Alert Notification System
- A recall must be processed promptly to ensure retrieval of components

# Recalls 2009 -NBC

- Number of Events: 252
- Number of Components: >600

# Component Recall

## Recall -Breakdown

- Suspected Platelet Bacterial Contamination: 132 (118)
- Donor notification post donation: 69
- Virology positive (subsequent donation): 13
- Suspected Adverse Reaction: 5
- Labelling/Distribution errors: 13
- Others: 20

# Component recall

- Verbal contact with receiving hospital
- IBTS will ask what Donation ID format is used by hospital and number given in that format
- IBTS Confirmation Recall Request Fax sent to receiving hospital will contain both Donation ID's formats if ISBT128 has been implemented

# ISBT 128/Codabar Dual Label Implementation

- ISBT128 Check digit calculator

<b>Codabar No</b>	5760011
<b>Year (YY) Bled</b>	10
<b>ISBT Number</b>	R000110576001X

- Codabar Check digit calculator

<b>ISBT Number</b>	
<b>Codabar No</b>	

# Re Routing/Traceability

- Traceability of Components issued to the receiving hospital – IBTS Responsibility
- Traceability of Components to the final disposition/patient – Hospital Responsibility



# Re Routing /Recall

- Verbal Contact with receiving hospital – Component re routed – receiving hospital to initiate recall with HUB/new receiving hospital
- IBTS Confirmation Recall Request sent to receiving hospital
- Receiving hospital to forward Fax to new receiving hospital
- Recall Completion Fax to be sent to IBTS asap by hospital that completed the recall