

**NHS SCOTLAND DOCUMENT**  
Model SOP to Meet Requirements of OIG Quality Management  
System



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**Procedures for Carrying out a Recall of Blood Components and Other  
Products**

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## 1. Introduction

It is a fundamental requirement of the Operational Impact Group (OIG) blood bank Quality Management System that all products and components, which are considered to pose a risk to patients, are withdrawn from use. This SOP describes the procedures in use for recall of blood components.

There are 2 different kinds of component recall, internal recall and external recall. In both cases, a procedure must be in place which ensures that components are withdrawn rapidly from use to ensure that patients are not placed at risk. The procedure should be robust and it should be possible to initiate a recall at all times.

This SOP provides a mechanism for carrying out recalls. In particular, this SOP describes how to: -

- (a) Identify the fate of suspect components.
- (b) Identify where these components are to be located.
- (c) Quarantine the suspect components.

## 2. Objective

The initiation of a formalised and documented procedure, which allows the department to quickly and efficiently, trace and withdraw a recalled component.

## 3. Staffing Requirements

Qualified BMS staff will carry out this procedure

## 4. Related Documents

OIG Quality Management System

## 5. References

Computer Users manual  
CPA Standards D3 &E4  
The Blood Safety and Quality Regulations 2005  
EC Guide to Good Manufacturing Practice (Orange Guide) Chapter 8

## 6. Personal Protective Equipment

Laboratory coat  
Gloves

## 7. Procedure

The basic principles of acceptable component issue and use is that all elements of the QMS must be in place and implemented. In particular, the transportation of blood components must be in accordance with the

laboratory's local policy for safe transportation of blood components and must ensure that the cold chain is not broken. There are however, instances where the quality of a component is clearly compromised and a recall must be initiated.

All components, if recalled, should be quarantined. If possible this should be done electronically using the laboratory's computer system.

## **7.1 Reasons For Recall**

### **7.1.1 Internal recall**

In all cases any returned blood components must be processed through the laboratory computer system.

a) Suspected Transfusion Reaction

When notified of a suspected transfusion reaction, the ward or department must be instructed to retain all used components for return. Any unused components should also be returned immediately. The laboratory's local procedure for transfusion reactions should then be followed.

b) Failure of Cold Chain

If it is found that issued components have been subjected to unacceptable conditions during storage or transportation, they should be recalled.

### **7.1.2 External Recall**

On occasions, the laboratory may be asked by an external source to trace and withdraw components and return to requesting source e.g. SNBTS.

An external component recall may be initiated for many reasons, including the following:

- a) Donation(s) considered to be, a microbiological risk
- b) Donation(s) found to have been collected from donor who did not meet standard acceptance criteria, e.g. following post donation notifications
- c) Problems identified with donation testing
- d) Problems identified with quality of raw materials e.g. blood bag faults

## **7.2 Recall Procedure**

- 7.2.1 The request for a component recall is usually by phone initially, and followed up by a written request.

All details from the phone request must be recorded on the laboratory's' telephone request form and should be signed by the person receiving the telephone call.

- 7.2.2 The BMS in charge must be notified of all component recall requests whether written or phoned.
- 7.2.3 The recall may relate to blood component units or a batch of plasma product.  
The laboratory computer system should be interrogated with the components unique unit number to determine the status of the component.  
e.g. Free Stock  
Reserved Stock  
Issued to patient/ward/dept/Hospital  
Used/Transfused  
Expired  
Due for return to SNBTS (i.e. pigtails used up)
- 7.2.4 If the recalled component is free in existing stock, the product should be traced and withdrawn immediately. Wherever possible an electronic quarantine should be applied to prevent recalled stock from being re-issued in error. The withdrawn component should then be returned to requesting source as instructed along with the completed documentation. A copy of the documentation should be kept.  
The return of the recalled component must be recorded on the laboratory's computer system.  
If necessary, replacement stock should be ordered.
- 7.2.5 If the recalled component is blood, FFP, Cryoprecipitate or platelets and have been issued for a patient but unused, the recalled component must be traced and withdrawn from issue.  
The ward/dept should be notified of any delay to the issue to the patient arising from the 'product recall'.  
Replacement stock should then be reserved for the patient and processed accordingly (i.e. if unit of blood, then compatibility testing should be done etc).  
The recalled product should be returned to requesting source as per instructed along with the completed documentation. A copy of the documentation should be kept.  
The return of the recalled component must be recorded in the laboratory's computer system. Where multiple components are recalled, a reconciliation should be carried out to confirm the fate of each individual component.  
If necessary, replacement stock should be ordered

7.2.6 If a batch product (eg. Anti-D, ALBA) has been issued, each ward the product has been issued to must be notified immediately and the status of the product determined i.e. used or unused.

All unused products must be retrieved immediately . A reconciliation should be carried out to ensure that all received product can be reconciled against the local receipt records.

Replacement stock should then be either reserved for patients as required (if issued on a named patient basis) or issued as stock to the relevant Dept (if issued as a batch).

The recalled product should be returned to requesting source as per instructed along with the completed documentation. A copy of the documentation should be kept.

The return of the recalled component must be recorded in the laboratory's computer system.

If necessary, replacement stock should be ordered.

7.2.7 If the recalled component has been used/transfused then this should be recorded on the component recall documentation and returned to the requesting source. A copy of the documentation should be kept.

## 8 Limitations/Pitfalls

Wrong details entered into the computer system.

Not recording the return of recalled components to requesting source on the laboratory computer system.

Not copying the documentation, which is returned to the requesting source.