

Traceability and recall

Standard operating procedure (SOP) | BLD-SOP-003

Document type	Standard operating procedure (SOP)
Title	Traceability and recall
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Prepared by	{{roles.quality_lead.name}}, Quality lead
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Next review	{{document.review_date}} (12 months, or sooner after any incident or change)
Replaces	None (new document)
Standards and criteria supported	Standard 5 (Blood Bank), criterion 5.3
Evidence basis	E-006, E-009
Status of this document	Recommended best-practice model. A hospital may adopt, adapt or replace it with an equivalent that meets the same criteria.

At a glance: what to do

1. Each donation has a unique number that follows it through testing, storage, issue and transfusion.
2. Each product made from a donation keeps that number.
3. Any unit can be traced from donor to recipient, and back.
4. A recall is run from the traceability record within the set time.

Stop and get help straight away if: a unit cannot be traced from donor to recipient, or a recall is not started when a unit is found to be unsafe.

1. Purpose

To find every patient who may be affected if a unit is unsafe, and to reach them (5.3).

2. Scope

Applies to	Clinical and support staff in the hospital
Locations	All wards, clinics and departments of {{facility.legal_name}}
When	Whenever the activity described is carried out
Does not apply to	Activities covered by another document listed in section 15

3. Definitions and abbreviations

Term	Meaning in this SOP
Clinical lead	The doctor or nurse in charge of the area at the time

4. Background and rationale

To find every patient who may be affected if a unit is unsafe, and to reach them (5.3).

5. Responsibilities

Role	Duties in this SOP	Competence needed
Blood bank director	Runs and closes each recall	Clinician
Laboratory scientist	Keeps the traceability record	Scientist

6. Equipment, materials and resources

Item	Specification or standard	Check before use
Records and forms named in this document	Current version	Checked before use

7. Safety and infection prevention

- Stop and call for help if a patient is at immediate risk. Do not delay urgent care to complete paperwork.

8. Before you start

- Confirm the forms and equipment named in this document are available and current.

9. Procedure

Follow the steps in order. Where a step says "If", take the action for the case that applies. Do not skip a step. If a step cannot be done, use section 11 and section 12.

Step	Action	How to do it	Key point
1	Number.	• Give each donation and each product a unique number, and record it at every step.	The number follows the unit.
2	Trace.	• Trace a unit from donor to recipient, and from recipient to donor, using BLD-REG-002.	Both directions.
3	Recall.	• When a unit is found to be unsafe, start the recall within the set time and tell each clinician.	Recall is started, then tracked to closure.

Decision points

- No decision points in this procedure.

10. Special situations

Situation	What to do
Out of hours	Follow the same steps. Use the on-call contact on the wall of the area.

11. Problems and escalation

- Any serious problem goes to the duty clinical lead at once and to the clinical director the same day.

12. Monitoring and compliance

What is checked	Target	How often	Who	If the target is missed
Units traceable in a test trace	100%	Quarterly	Blood bank director	Escalate to governing body
Recalls started within the set time	100%	Yearly	Blood bank director	Escalate to governing body

13. Records

Record	Where it is kept	Kept for
Record named in this document	Patient record or the area file	{{facility.records_retention_years}} years

14. Training and competence

- Staff are trained in this document at induction and refreshed each year, with a recorded competency check.

15. Related documents

ID	Title	Relationship
BLD-REG-002	Donation traceability register	Register

16. Evidence

ID	Source and status
E-009	ASF Expert Committee consensus.
E-006	ASF Policy Framework v1.2. Adapted.
E-009	ASF Expert Committee consensus.

EC = ASF Expert Committee consensus. Items marked EC are reviewed by the Committee each year.

17. Change history

Version	Date	What changed	Approver and signature
1.0	{{document.effective_date}}	First version	Pending Expert Committee approval