Organisation name Site or unit		STANDARD OPERATING PROCEDURE **Traceability and recall**	
Document ID	BLD-SOP-003	**Version**	1.0
Status	Blank form, to adapt	**Issue date**	
Review date		**Replaces**	
Owner		**Approved by**	
Signature			

Standards › Standard 5 › Standard operating procedures (SOPs)

Standard operating procedure (SOP) · BLD-SOP-003 · Version 1.0 · Approved by the ASF Expert Committee

Supports: 5.3

At a glance

- Each donation has a unique number that follows it through testing, storage, issue and transfusion.
- Each product made from a donation keeps that number.
- Any unit can be traced from donor to recipient, and back.
- 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 the facility

When	Whenever the activity described is carried out
Does not apply to	Activities covered by another document listed in section 15

3. Definitions

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

4. Background

If a donation is found to be unsafe after release, the blood bank must be able to find every product made from it and every recipient who received it. Without traceability, a recall is impossible.

5. Responsibilities

Role	Responsibility	Competence
Blood bank director	Runs and closes each recall	Clinician
Laboratory scientist	Keeps the traceability record	Scientist

6. Materials and equipment

Item	Requirement	Condition
Records and forms named in this document	Current version	Checked before use

7. Safety

- 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

Step 1. Number.

- Give each donation and each product a unique number, and record it at every step.

Key point: The number follows the unit.

Step 2. Trace.

- Trace a unit from donor to recipient, and from recipient to donor, using BLD-REG-002.

Key point: Both directions.

Step 3. Recall.

- When a unit is found to be unsafe, start the recall within the set time and tell each clinician.

Key point: Recall is started, then tracked to closure.

10. Decision points

- No decision points in this procedure.

11. Special situations

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

12. Escalation

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

13. Monitoring

Measure	Target	Frequency	Owner	If not met
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

14. Records

Record	Kept in	Retention
Record named in this document	Patient record or the area file	the period set by the facility's records policy, in years

15. Training

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

16. Related documents

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

17. Evidence

Reference	Note
E-009	ASF Expert Committee consensus.
E-006	ASF Policy Framework v1.2. Adapted.
E-009	ASF Expert Committee consensus.

18. Change history

Version	Date	What changed	Approval
1.0	the date of approval	First version	set Expert Committee approval

19. References

Accréditation Sans Frontières (2026). ASF Policy Framework v1.2. (E-006)

Accréditation Sans Frontières (2026). ASF Expert Committee consensus on Standard 1. (E-009)

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