Standard operating procedure (SOP) · PRO-SOP-006 · Version 1.0 · Approved by the ASF Expert Committee

Supports: 11.9

At a glance

- Each recall notice is received, logged and checked against stock and against patients treated.
- Each patient who received a recalled batch is contacted within the set time.
- Each adverse reaction is recorded (PRO-FRM-006) and reported where the rule requires.
- The batch register (PRO-REG-001) is the source for tracing patients.
- Stop and get help straight away if: a recalled batch is still in use, or a patient who received it is not contacted.

1. Purpose

To act on recalls and adverse reactions using the batch register (11.9).

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

A product recall is only effective if the centre knows which patients received the product. Checking notices against stock and against patients makes the recall reach the people affected.

5. Responsibilities

Role	Responsibility	Competence
Pharmacist or supply lead	Receives recalls and checks stock	Pharmacist
Medical director	Contacts patients and reports reactions	Clinician

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. Receive and check.

- Log each recall and check stock and the batch register at once.

Key point: At once.

Step 2. Contact.

- Contact each patient who received a recalled batch within the set time.

Key point: Within the set time.

Step 3. Record and report.

- Record each adverse reaction on PRO-FRM-006 and report it where required.

Key point: Recorded and reported.

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
Recalls checked against stock within 24 hours	100%	Each recall	Pharmacist or supply lead	Escalate to medical director

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 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
PRO-REG-001	Product batch register	Register
PRO-FRM-006	Adverse reaction record	Record

17. Evidence

Reference	Note
E-009	Based on the ASF Expert Committee consensus and the WHO Guidelines for Safe Surgical Care and Safe Procedures (2009).
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

E-learning for this document

- **Incident Reporting, Just Culture and Open Disclosure** (T-09)
- Medication Safety & Storage in Guest Facilities (MED-03)

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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