

Product recall and adverse reaction response

Standard operating procedure (SOP) | PRO-SOP-006

Document type	Standard operating procedure (SOP)
Title	Product recall and adverse reaction response
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Prepared by	{{roles.quality_lead.name}}, Quality lead
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Effective date	{{document.effective_date}}
Next review	{{document.review_date}} (12 months, or sooner after any incident or change)
Replaces	None (new document)
Standards and criteria supported	Standard 11 (Procedure Units), criterion 11.9
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 recall notice is received, logged and checked against stock and against patients treated.
2. Each patient who received a recalled batch is contacted within the set time.
3. Each adverse reaction is recorded (PRO-FRM-006) and reported where the rule requires.
4. 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 {{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 act on recalls and adverse reactions using the batch register (11.9).

5. Responsibilities

Role	Duties in this SOP	Competence needed
Pharmacist or supply lead	Receives recalls and checks stock	Pharmacist
Medical director	Contacts patients and reports reactions	Clinician

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	Receive and check.	• Log each recall and check stock and the batch register at once.	At once.
2	Contact.	• Contact each patient who received a recalled batch within the set time.	Within the set time.
3	Record and report.	• Record each adverse reaction on PRO-FRM-006 and report it where required.	Recorded and reported.

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

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

16. Evidence

ID	Source and status
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.

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