

Adverse reaction report

Form | BLD-FRM-003

Document type	Form
Title	Adverse reaction report
Document ID	{{facility.code}}-BLD-FRM-003
Version and status	1.0 Issued for use. Pending ASF Expert Committee ratification
Prepared by	{{roles.quality_lead.name}}, Quality lead
Reviewed by	{{roles.clinical_director.name}}, Clinical director Date: _____
Approver and signature	{{roles.clinical_director.name}}, Clinical director Signature: _____ Date: _____
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 5 (Blood Bank), criterion 5.7
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.

Use this form when

Records a reaction in a donor or a recipient, its investigation and its report.

1. How to complete

- Complete at once.
- Record the investigation outcome.
- Record the report number.

2. Items to check

#	Item	Standard or evidence	Yes	No	N/A	Action if No
1	Donor or recipient	Yes	☐	☐	☐	Action and who to tell
2	Unit number and time	Yes	☐	☐	☐	Action and who to tell
3	Reaction described	Yes	☐	☐	☐	Action and who to tell
4	Investigation outcome and action	Yes	☐	☐	☐	Action and who to tell
5	Reported to the national system (number)	Yes or N/A	☐	☐	☐	Action and who to tell

Completed by (name and role): _____ Date/time: _____ Signature: _____

3. Evidence

ID	Source and status
E-009	Based on the Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood

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

EC = ASF Expert Committee consensus.

4. Change history

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