

Blood bank quality system

Policy | BLD-POL-001

Document type	Policy
Title	Blood bank quality system
Document ID	{{facility.code}}-BLD-POL-001
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 5.8
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. The blood bank has a written quality system for procedures, equipment, audit and training.
2. Each procedure has an owner and a review date.
3. Equipment is checked and calibrated on schedule.
4. The quality system is audited each year and reported to the governing body.

Stop and get help straight away if: a procedure is in use with no owner or past its review date, or an audit finding is open past its due date.

1. Purpose

To make sure the blood bank works the same way every day, and that its quality is checked (5.8).

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 make sure the blood bank works the same way every day, and that its quality is checked (5.8).

5. Responsibilities

Role	Duties in this SOP	Competence needed
Blood bank director	Owns the quality system	Clinician
Quality manager	Runs the audit and training plan	Quality

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	Write.	Keep the procedures, equipment list and training plan written and current.	Written, owned, dated.
2	Audit.	Audit each procedure each year against its written standard (BLD-FRM-004 for the emergency release audit, and others as set).	Audit finds the gap before the patient does.
3	Act.	Close each finding by its due date and report the status to the governing body.	Findings close.

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
Procedures in date	100%	Quarterly	Quality manager	Escalate to governing body
Audit findings closed by due date	At least 90%	Quarterly	Quality manager	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
STF-SOP-001	Staff credential verification and recheck	Staff
GOV-PLN-002	Quality improvement plan	Plan

16. Evidence

ID	Source and status
E-009	Based on ISO 15189:2022 for medical laboratories.
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