

STANDARD OPERATING PROCEDURE

(Name of the Blood Centre)

Number	Effective Date	Pages	Author	Authorised by
SP 033		3		
Version	Review Period	No. of Copies	Approved by	Date
1	1 Year	2		

LOCATION	SUBJECT
Quality Assurance Laboratory	Incident Report
FUNCTION	DISTRIBUTION
Mechanism for correction and Prevention of error and incidents	- Quality Assurance Manager - Supervisor in charge of Donor Area - Supervisor- Red Cell Serology Laboratory - Supervisor- TTI Testing Laboratory - Supervisor- Quality Control Laboratory - Supervisor- Component Laboratory - Master File

1. SCOPE & APPLICATION

The procedure covers all incidents that would affect the quality of blood products & services. The procedure applies to all incidents, adverse reactions, equipment used in collection, testing & storage of blood products. The incident reporting process should be clearly defined so that information is tracked and acted on and feed back provided.

2. RESPONSIBILITY

- (i) It is the responsibility of all the technical staff to report any incident/accident to the section supervisor who will submit the report to the Quality Assurance Supervisor/Manager.
- (ii) The Quality Assurance Supervisor/Manager is responsible to review the completed report and report to the Director for further investigation and implementation of remedial measures if any.

3. REFERENCES

1. Technical Manual of American Association of Blood banks 13th Edition, 1999, Pages 3, 14-15.

4. DEFINITIONS

Incident Reporting:

- Is a process improvement tool that is used to identify problems, analyse the

cause, develop solutions, execute the solution and track the effectiveness.

Corrective Action:

- Is required for error and accident reports and is usually connected to a process improvement activity. It is an immediate remedial action taken to correct the effect of a defined event.

Preventive Action:

- Follow up action taken to prevent a defined event from re-occurring.

Incident:

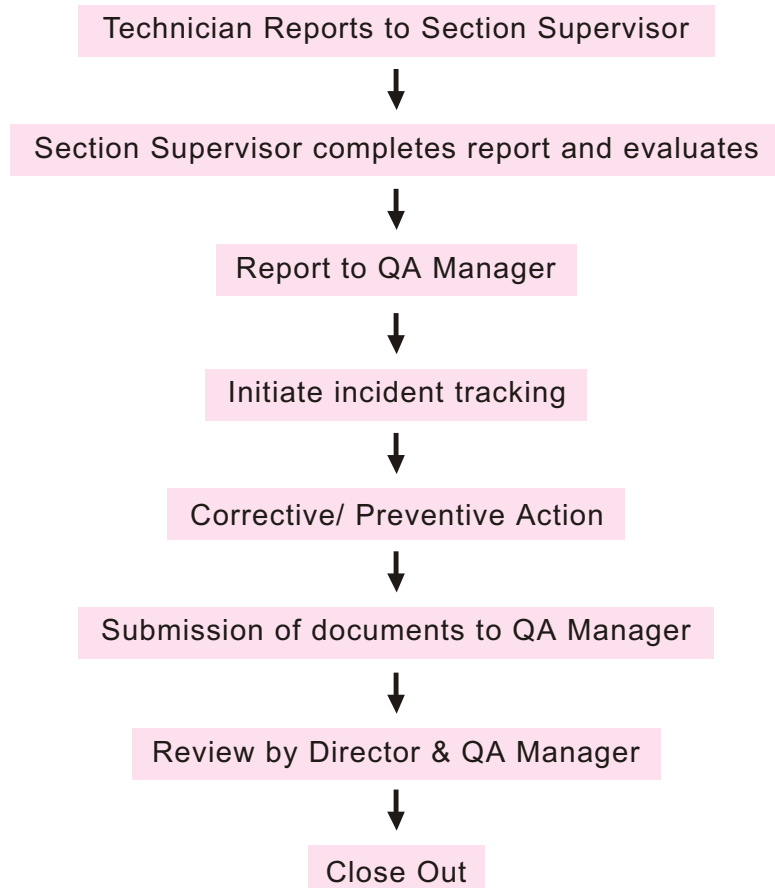
- An Event that results from a deviation from a system, process or procedure that may affect the:
 - (i) Safety, purity, potency or effectiveness of the product.
 - (ii) Health or safety of a donor, product recipient, member of staff/public.
 - (iii) Trace ability of records.

This event may have been identified either prior to or after distribution of a product or service.

5. PROCEDURE

- (i) Document all incidents on the standard form (Incident Report Form).
- (ii) Forward the incident summary report to the section supervisor for evaluation and completion.
- (iii) Initiate incident tracking.
- (iv) Develop corrective/preventive Action in consultation with Section Supervisor, QA Manager and the Director.
- (v) Forward original documents to the QA Manager within 3 working days of the event.
- (vi) The QA Manager reviews the report for completeness and appropriateness of corrective action.
- (vii) The status of an event remains active until effective action is taken and closed out. Record the details, date of action and close out and get the reports form signed by the Director.
- (viii) Notify the Director immediately in case of critical incidents such as those that could result in loss of life, product recall, failure to operate or adverse publicity
- (ix) Provide monthly summary reports to the Director.

5. FLOW CHART FOR INCIDENT REPORTING PROCESS



6. DOCUMENTATION

Record all incidents on a incident report form. File all record forms.

7. END OF DOCUMENT