**Model SOP**

**Standard Operating Procedure**

**Name of the facility / activity : Incident Report**

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| **SOP no.**  | **Effective Date** | **Pages** | **Prepared by**  | **Authorised by**  |
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| **LOCATION** : Quality Assurance Laboratory |
| **SUBJECT** : Incident Report  |
| **FUNCTION** : Mechanism for correction and Prevention of error and incidents |
| **DISTRIBUTION**: 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.  |

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:**

1. 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/Incharge Blood bank.
2. The Quality Assurance Supervisor/Manager is responsible to review the completed report and report to the Incharge of blood bank for further investigation and implementation of remedial measures if any.

**3. 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
1. Safety, purity, potency or effectiveness of the product.
2. Health or safety of a donor, product recipient, member of staff/public.
3. Trace ability of records.

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

**4. PROCEDURE:**

1. Document all incidents on the standard form (Incident Report Form).
2. Forward the incident summary report to the section supervisor for evaluation and completion.
3. Initiate incident tracking..
4. Develop corrective/preventive Action in consultation with Section Supervisor, QA Manager and the Incharge blood bank.
5. Forward original documents to the QA Manager within 3 working days of the event.
6. The QA Manager reviews the report for completeness and appropriateness of corrective action.
7. 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.
8. Notify the Incharge blood bank immediately in case of critical incidents such as those that could result in loss of life, product recall, failure to operate or adverse publicity
9. Provide monthly summary reports to the Director.

***Flow Chart for Incident Reporting Process*:**

Technician Reports to Section Supervisor

Section Supervisor completes report and evaluates

Report to QA Manager

Initiate incident tracking

Corrective/Preventive Action

Submission of documents to QA Manager

Review by Incharge blood bank & QA Manager

Close out

**5. DOCUMENTATION:**

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

1. **REFERENCES:**
2. Technical Manual of the American Association of Blood Banks – 15th edition 2005.
3. Introduction to Transfusion Medicine – Zarin Bharucha and D.M. Chouhan; 1st Edition, 1990.
4. Training module for laboratory technologists. National AIDS Control Organization, Ministry of Health and Family Welfare, Govt. of India publication, 1995.

**7. END OF DOCUMENT**