SOP: Incident and Deviation Reporting Protocols

This SOP details **incident and deviation reporting protocols** to ensure timely and accurate documentation of any irregularities, accidents, or non-conformities within operational processes. It covers the identification, reporting, investigation, and corrective actions to maintain compliance, improve safety, and enhance overall organizational performance.

1. Purpose

To establish standardized procedures for the identification, reporting, investigation, and resolution of incidents and deviations to ensure compliance and continuous improvement.

2. Scope

This procedure applies to all employees, contractors, and third parties involved in operations where incidents or deviations may occur.

3. Definitions

Term	Definition
Incident	Any unplanned event that results in or could result in injury, illness, damage, or loss.
Deviation	A departure from standard operating procedures, specifications, or regulations.
Non-conformity	Failure to meet a specified requirement.

4. Responsibilities

- **All Employees:** Immediately report incidents and deviations as per this SOP.
- **Supervisors/Managers:** Ensure reports are completed, investigated, and corrective actions are implemented.
- **Quality/Safety Team:** Oversee reporting, monitor trends, and verify effectiveness of corrective actions.

5. Procedure

1. **Identification**
   - Recognize and confirm the occurrence of an incident or deviation.
2. **Immediate Actions**
   - Ensure safety, contain hazards, and provide first aid if required.
3. **Reporting**
   - Fill out an Incident/Deviation Report Form within 24 hours.
   - Notify Supervisor/Manager immediately.
4. **Investigation**
   - Supervisors/Managers lead investigation within 48 hours, involving relevant departments.
   - Determine root cause using appropriate methodologies (e.g., 5 Whys, Fishbone Diagram).
5. **Corrective Actions**
   - Document corrective and preventive actions (CAPA), assign responsibility, and set deadlines.
6. **Documentation & Review**
   - Archive completed reports in accordance with document control procedures.
   - Review trends periodically for continuous improvement.

6. Incident/Deviation Report Form (Sample Fields)

Date/Time	Description of Event	Immediate Actions Taken	Reported By	Supervisor Review	Corrective Actions

7. References

- Company Policies & Procedures
- Relevant Regulatory Requirements
- Incident and Accident Investigation Standards

8. Revision History

Version	Date	Description	Approved By
1.0	YYYY-MM-DD	Initial creation	