

# SOP: Incident Reporting and Adverse Event Management

This SOP details the procedures for **incident reporting and adverse event management**, covering the identification, documentation, analysis, and resolution of incidents and adverse events in the workplace. It emphasizes timely reporting, clear communication, root cause analysis, corrective actions, and continuous improvement to ensure safety, compliance, and risk mitigation across all operations.

## 1. Purpose

To establish a systematic process for the identification, reporting, investigation, and management of incidents and adverse events, ensuring safety, compliance, and continuous improvement.

## 2. Scope

This procedure applies to all employees, contractors, and visitors at all company workplaces and operational sites.

## 3. Definitions

Term	Definition
Incident	An unplanned event that results in, or could have resulted in, injury, illness, property damage, or environmental impact.
Adverse Event	An incident that leads to unintended harm to an individual or damage to property/environment.
Root Cause Analysis	A systematic process for identifying the primary cause of an incident or adverse event.

## 4. Responsibilities

- **All Staff:** Identify and promptly report incidents/adverse events.
- **Supervisors/Managers:** Ensure incidents are documented, investigated, and appropriate actions taken.
- **HSE/Compliance Team:** Oversee incident management, analysis, and continuous improvement efforts.

## 5. Procedure

### 5.1 Identification

- All personnel must remain vigilant for incidents or adverse events in the workplace.
- Any observed incident must be reported immediately to a supervisor or via the designated reporting system.

### 5.2 Reporting

- Complete the Incident Reporting Form within **24 hours** of occurrence or discovery.
- Include date, time, location, individuals involved, detailed description, and any immediate actions taken.

### 5.3 Documentation

- Ensure all details are recorded in the incident management system, with supporting evidence where applicable (photos, witness statements, etc.).

### 5.4 Investigation and Analysis

- Supervisors initiate a preliminary review to classify severity and escalation needs.
- The incident investigation team conducts a root cause analysis using appropriate tools (e.g., 5 Whys, Fishbone Diagram).

### 5.5 Corrective and Preventive Actions (CAPA)

- Based on analysis, corrective and preventive actions are identified, assigned, and tracked for implementation.
- Actions are documented and communicated to relevant stakeholders.

## 5.6 Resolution and Follow-up

- Verify completion and effectiveness of corrective actions.
- Update documentation and close the incident record.

## 6. Communication

- Timely notifications to relevant staff and authorities as required by law or policy.
- Periodic summary reports shared with management for oversight and improvement.

## 7. Training

- All employees receive incident reporting and response training annually, and during onboarding.

## 8. Records Management

- All incident records and investigative reports will be retained securely for a minimum of [X] years, in compliance with regulatory requirements.

## 9. Continuous Improvement

- Periodic review of incident reports to identify trends and improve procedures.
- Lessons learned and best practices to be shared organization-wide.

## 10. References

- Applicable laws and regulations
- Company Health & Safety Policy
- Incident Reporting Form/Template