

# SOP Template: Investigation and Root Cause Analysis Process

This SOP defines the **investigation and root cause analysis process**, covering the systematic approach to identifying incidents, collecting and analyzing evidence, determining underlying causes, and implementing corrective actions. The goal is to prevent recurrence by understanding all contributing factors and improving organizational processes and safety measures.

## 1. Purpose

To establish a standardized procedure for investigating incidents and identifying root causes to ensure timely corrective actions that prevent recurrence and enhance continual improvement.

## 2. Scope

This SOP applies to all reported incidents, near misses, and non-conformities within the organization.

## 3. Responsibilities

- **Incident Owner:** Reports incidents and collaborates with investigators.
- **Investigation Team:** Conducts investigations and root cause analyses.
- **Department Heads:** Ensures corrective actions are implemented within their areas.
- **Quality/Safety Manager:** Monitors investigations and maintains records.

## 4. Definitions

Term	Definition
Incident	An unplanned event that results in or could have resulted in injury, damage, or loss.
Root Cause Analysis (RCA)	A systematic process for identifying the underlying causes of an incident.
Corrective Action	Action taken to eliminate the cause(s) of a detected nonconformity or incident.

## 5. Procedure

1. **Incident Identification**
  - All incidents and near misses must be reported immediately using the company's Incident Report Form.
2. **Initial Assessment**
  - Assess severity and initiate containment actions if necessary.
3. **Investigation Initiation**
  - Investigation Team is assigned within 24 hours of the incident report.
4. **Evidence Collection**
  - Gather relevant documents, photos, witness statements, and physical evidence.
5. **Analysis**
  - Use recognized methods (e.g., 5 Whys, Fishbone Diagram) to analyze collected evidence and identify root causes.
6. **Root Cause Identification**
  - Determine the fundamental cause(s) that contributed to the incident.
7. **Corrective Action Plan**
  - Develop actions to eliminate root causes, assign responsibility, and set deadlines.
8. **Implementation and Monitoring**
  - Track the implementation and effectiveness of corrective actions taken.
9. **Documentation and Reporting**
  - Document the entire process and report findings to management.

## 6. Records

- Incident Report Forms

- Investigation and RCA Documentation
- Corrective Action Tracking Logs

## 7. Review and Continuous Improvement

The investigation process and SOP should be reviewed annually or following any major incident to enhance effectiveness and incorporate organizational learning.

## 8. References

- ISO 9001: Quality Management Systems
- ISO 45001: Occupational Health and Safety
- Company Policies and Procedures

## 9. Revision History

Version	Date	Changes
1.0	2024-06-10	Initial issue