SOP Template: Investigation and Root Cause Analysis Workflows

This SOP details the **investigation and root cause analysis workflows** designed to systematically identify, analyze, and address the underlying causes of incidents and non-conformities. It encompasses steps for data collection, evidence evaluation, problem identification, and corrective action planning to prevent recurrence and promote continuous improvement within the organization.

1. Purpose

To establish a consistent process for investigating incidents and non-conformities, identifying root causes, and implementing measures to prevent recurrence and support organizational improvement.

2. Scope

This SOP applies to all employees and contractors involved in reporting, investigating, or managing incidents, non-conformities, or process deviations.

3. Definitions

Term	Definition
Incident	An unplanned event or occurrence that could result in or has resulted in injury, damage, or loss.
Non-conformity	Non-fulfillment of a specified requirement or deviation from a standard or procedure.
Root Cause	The fundamental issue(s) that led to the occurrence of the incident or non-conformity.
Corrective Action	An action taken to eliminate the root cause and prevent recurrence.

4. Responsibilities

- **Process Owner**: Ensures investigations are conducted according to this SOP.
- **Investigators**: Carry out investigations, document findings, identify root causes, and recommend corrective actions.
- **Employees/Contractors**: Report incidents and non-conformities promptly.
- **Management**: Review investigation reports, approve corrective actions, and monitor implementation.

5. Workflow Steps

1. **Incident/Non-conformity Reporting**
    - Immediately report incidents or non-conformities through designated channels (forms/software/system).

2. **Initial Assessment**
    - Assess the event for severity and potential impact.
    - Determine if investigation is warranted.

3. **Investigation Planning**
    - Assign an investigation lead/team.
    - Define scope, objectives, and timeline.

4. **Data Collection**
    - Gather all relevant data, records, physical evidence, interviews, and documentation.

5. **Evidence Evaluation**
    - Analyze collected data for reliability and relevance.
    - Map out sequence of events (using tools like timelines, diagrams).

6. **Root Cause Analysis**
    - Apply root cause analysis methodology (e.g., 5 Whys, Fishbone Diagram, Fault Tree Analysis).
    - Document the underlying causes, not just immediate symptoms.

7. **Corrective and Preventive Action Planning**
    - Identify actions to address root causes and prevent recurrence.
    - Assign responsibility, set deadlines, and allocate resources.

8. **Implementation and Follow-up**
    - Monitor the completion and effectiveness of corrective actions.
    - Document and verify results.

9. **Closure and Documentation**
    - Ensure all steps are documented.
    - Close the incident/non-conformity in the tracking system.

6. Documentation and Records

- All investigation reports, evidence, analyses, and corrective actions must be recorded and stored according to the company's document management policy.

7. References

- ISO 9001: Quality Management Systems
- Company Document Control Policy
- Incident Reporting and Management Procedure

8. Review & Revision History

Date	Revision	Description of Change	Approved By
2024-06-01	1.0	Initial Issue	QA Manager