

# SOP Template: Resolution Determination and Action Implementation

This SOP details the process for **resolution determination and action implementation**, covering the identification of issues, assessment of root causes, decision-making protocols, assignment of responsibilities, execution of corrective actions, monitoring of implementation progress, and evaluation of effectiveness. The goal is to ensure timely and effective resolution of problems to maintain operational efficiency and prevent recurrence.

## 1. Purpose

To establish a standardized procedure for determining resolutions to issues, implementing actions, and monitoring outcomes to sustain operational performance and continuous improvement.

## 2. Scope

This SOP applies to all departments and team members involved in identifying, analyzing, resolving, and preventing operational and process-related issues.

## 3. Definitions

- **Issue:** Any deviation from expected performance, policy noncompliance, incident, or process failure.
- **Root Cause:** The underlying factor(s) responsible for the occurrence of the issue.
- **Corrective Action:** Steps taken to eliminate the root cause and prevent recurrence.
- **Effectiveness Evaluation:** Assessment of whether the corrective actions successfully resolved the issue.

## 4. Responsibilities

Role	Responsibility
Process Owner	Oversees issue resolution, approves action plans, and monitors implementation.
Team Members	Report issues, participate in root cause analysis, and execute assigned actions.
Quality/Compliance	Facilitates investigations and effectiveness reviews.
Management	Supports resources allocation and reviews final outcomes.

## 5. Procedure

- 1. Issue Identification**
  - Document all reported issues in the Issue Log.
  - Assign a unique tracking number and initial priority rating.
- 2. Root Cause Assessment**
  - Convene a review meeting with relevant stakeholders.
  - Conduct root cause analysis using tools such as the “5 Whys” or Fishbone Diagram.
- 3. Decision-Making Protocol**
  - Evaluate possible corrective and preventive actions (CAPA).
  - Obtain necessary approvals as specified by policy.
- 4. Responsibility Assignment**
  - Assign action items to responsible individuals or teams with clear deadlines.
  - Document assignments in the Action Implementation Plan.
- 5. Execution of Actions**
  - Carry out corrective and preventive actions as per the plan.
  - Update progress in the Action Implementation Plan at each milestone.
- 6. Monitoring Implementation Progress**
  - Regularly review status in team meetings or via project management tools.
  - Address delays or obstacles promptly.
- 7. Effectiveness Evaluation**
  - Verify that actions taken have resolved the issue and prevented recurrence.
  - Document the evaluation and close the issue in the Issue Log.

## 6. Documentation

- Issue Log
- Root Cause Analysis Reports
- Action Implementation Plan
- Effectiveness Evaluation Records

## 7. Review and Revision

This SOP must be reviewed annually or upon identification of significant process failures, with revisions made as necessary to maintain effectiveness and compliance.

## 8. Appendix: Example Forms

Form Name	Description
Issue Log Template	Captures issue details, date, status, and assigned owner.
Root Cause Analysis Template	Documents methodologies, findings, and contributing factors.
Action Implementation Plan	Details action items, responsibilities, due dates, and progress notes.
Effectiveness Review Checklist	Guides and records the evaluation of corrective action outcomes.

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End of SOP Template