SOP: Incident Follow-Up, Review, and Closure Documentation

This SOP details the process for **incident follow-up, review, and closure documentation**, ensuring all incidents are thoroughly investigated, analyzed, and resolved. It covers steps for collecting and documenting incident information, conducting root cause analysis, implementing corrective actions, and verifying their effectiveness. The procedure aims to promote continuous improvement, prevent recurrence, and maintain comprehensive records for compliance and organizational learning.

1. Purpose

To define a structured approach for managing post-incident activities, ensuring all incidents are investigated, documented, reviewed, and closed with appropriate corrective and preventative measures.

2. Scope

This procedure applies to all incidents that occur within the organization, including safety, security, operational, and information-related events.

3. Roles and Responsibilities

Role	Responsibility
Incident Owner	Leads the follow-up, investigation, and closure process; Ensures documentation is complete.
Investigation Team	Conducts incident investigation and root cause analysis.
Management	Reviews findings, approves corrective actions, and authorizes incident closure.
Compliance/Quality Team	Audits documentation and ensures procedures are followed for compliance.

4. Procedure

1. **Incident Recording**
   - Log the incident in the tracking system with all preliminary details.

2. **Assign Ownership**
   - Assign an Incident Owner responsible for managing the process.

3. **Data Collection**
   - Gather all relevant information, evidence, and timelines related to the incident.

4. **Root Cause Analysis**
   - Conduct a structured root cause analysis (e.g., Five Whys, Fishbone diagram).
   - Document contributing and underlying factors.

5. **Corrective and Preventative Actions (CAPA)**
   - Define actions to address root causes and prevent reoccurrence.
   - Assign responsibility and set deadlines for each action.

6. **Implementation and Verification**
   - Ensure corrective actions are implemented as planned.
   - Verify the effectiveness of actions taken (testing, monitoring, etc.).

7. **Incident Review and Approval**
   - Submit all documentation for management review.
   - Obtain approval for closure from appropriate authority.

8. **Closure Documentation**
   - Complete closure form including final review, lessons learned, and any residual risks.
   - Store records securely for future reference and compliance purposes.

9. **Continuous Improvement**
   - Periodically review incidents for trends.
   - Update policies and training as necessary.

5. Documentation and Records

- Incident Report Form
- Investigation Documents
- CAPA Register
- Closure and Approval Forms
- Audit and Management Review Records

6. References

- Company Incident Management Policy
- Regulatory Requirements (as applicable)
- ISO 45001 / ISO 27001 (as applicable)

7. Revision History

Version	Date	Description	Author
1.0	2024-06-20	Initial SOP release	[Your Name/Dept]