SOP: Incident Reporting and Quality Assurance Measures

This SOP details the **incident reporting and quality assurance measures** essential for maintaining a safe and efficient workplace. It outlines the procedures for accurately documenting and reporting incidents, identifying root causes, and implementing corrective actions. The SOP emphasizes continuous monitoring, regular audits, and employee training to uphold high-quality standards and prevent recurrence. The goal is to foster a culture of transparency, accountability, and ongoing improvement to enhance overall organizational performance and safety.

1. Purpose

To establish a standardized process for reporting, documenting, investigating, and resolving incidents, and for maintaining robust quality assurance across the organization.

2. Scope

This SOP applies to all employees, contractors, and visitors within the organization premises or during organizational activities.

3. Responsibilities

- All Employees: Report incidents promptly and truthfully; participate in training and quality initiatives.
- Supervisors/Managers: Ensure incidents are documented, investigated, and reported; initiate corrective actions.
- · Quality Assurance Team: Conduct audits, monitor trends, and support continuous improvement.
- Health & Safety Officer: Oversee incident investigations, maintain records, recommend safety enhancements.

4. Incident Reporting Procedure

1. Immediate Action:

- Ensure safety of all personnel; contain hazards if safe to do so.
- o Provide medical assistance if required.

2. Notification:

o Inform supervisor/manager as soon as possible.

3. Documentation:

- o Complete Incident Report Form within 24 hours, detailing:
 - Date, time, and location of incident
 - Parties involved and witnesses
 - Description of incident and immediate actions taken

4. Submission:

o Submit completed report to supervisor/manager and Health & Safety Officer.

5. Investigation & Root Cause Analysis

- 1. Assign investigation team (supervisor, QA, H&S officer).
- 2. Gather and review evidence (documentation, interviews, physical inspection).
- 3. Identify root causes using tools such as the "5 Whys" or Fishbone Diagram.
- 4. Document findings and recommendations.

6. Corrective and Preventive Actions (CAPA)

- 1. Develop and implement corrective actions to address the root cause.
- 2. Establish preventive measures to mitigate recurrence.
- 3. Assign responsibilities and timelines for implementation.
- 4. Document completion and verify effectiveness.

7. Quality Assurance Measures

- Regular internal audits and workplace inspections.
- · Monitor incident trends and identify areas for improvement.
- Ongoing employee training and refresher sessions.
- Review and update SOPs annually or as required.
- Maintain secure records of all incidents and actions taken for a minimum of 5 years.

8. Auditing and Continuous Improvement

- 1. Schedule periodic audits to assess compliance and effectiveness of incident management.
- 2. Analyze audit findings to guide process improvements.
- 3. Encourage employee feedback to enhance quality and safety measures.
- 4. Report performance metrics to management for strategic review.

9. Training

- · All employees must undergo incident reporting and quality assurance training at onboarding and annually thereafter.
- Training logs should be maintained and reviewed by the QA team.

10. References & Appendices

Document	Reference Number
Incident Report Form	APP-001
Root Cause Analysis Template	APP-002
Audit Checklist	APP-003
Training Record Log	APP-004

11. Revision History

Version	Date	Revision Summary	Author
1.0	2024-06-18	Initial release	QA Department