

SOP: Critical Incidents or Adverse Event Reporting and Escalation Status

This SOP defines the process for **critical incidents or adverse event reporting and escalation status**, ensuring timely identification, documentation, and communication of incidents that may impact safety, operations, or compliance. It establishes clear guidelines for reporting criteria, roles and responsibilities, escalation protocols, and follow-up actions to mitigate risks and support continuous improvement within the organization.

1. Scope

This SOP applies to all staff and departments within the organization who may encounter or become aware of critical incidents or adverse events impacting safety, operations, or compliance.

2. Definitions

- **Critical Incident:** An event that poses an immediate threat to health, safety, or significant organizational operations.
- **Adverse Event:** An incident resulting in unintended harm or negative impact, which could affect personnel, assets, reputation, or compliance.

3. Reporting Criteria

- Events resulting in injury, illness, or fatality
- Significant disruption to business operations
- Non-compliance with regulatory or legal requirements
- Security breaches or data loss
- Other incidents at management's discretion

4. Roles and Responsibilities

Role	Responsibility
All Employees	Promptly report any observed or suspected critical incidents or adverse events via established channels.
Supervisors/Managers	Assess reported incidents, ensure proper documentation, and initiate escalation as per protocol.
Incident Response Team	Coordinate investigations, implement corrective actions, and communicate status updates.
Compliance Officer	Monitor incident trends, ensure regulatory reporting, and drive continuous improvement.

5. Reporting and Escalation Protocol

1. Immediately report incident to direct supervisor or designated point of contact.
2. Supervisor/Manager evaluates severity and determines required actions.
3. If incident meets escalation criteria, notify Incident Response Team or higher management within **1 hour**.
 - Severe injury/fatality: Escalate immediately to executive leadership and compliance.
 - Operational disruption: Escalate to department head and response team.
4. Document all actions taken in the incident log.
5. Update stakeholders as the status changes (initial notification, ongoing updates, resolution, and follow-up).

6. Follow-Up and Documentation

- Complete an Incident Report Form within 24 hours of occurrence.
- Conduct root cause analysis as applicable.
- Implement corrective and preventive actions (CAPA).
- File incident details securely and maintain records for a minimum of 5 years.

- Review incident trends during periodic management reviews.

7. Continuous Improvement

- Regular training on incident reporting and escalation for all personnel.
- Periodic review and update of escalation criteria and SOPs.
- Encourage open communication to foster a no-blame culture for reporting.

8. References

- Relevant organizational policies and procedures
- Regulatory requirements (e.g. OSHA, Data Protection Laws)
- Incident Report Form Template

9. Revision History

Version	Date	Description of Change	Approved By
1.0	2024-06-12	Initial SOP release.	Compliance Officer