SOP Template: Critical Incident and Adverse Event Reporting

Purpose

This SOP details the process for **critical incident and adverse event reporting**, including identifying and documenting incidents, procedures for immediate response, roles and responsibilities of staff, communication protocols, root cause analysis, corrective and preventive actions, and compliance with regulatory requirements. The goal is to ensure timely reporting, thorough investigation, and effective management of incidents to enhance safety, accountability, and continuous improvement within the organization.

Scope

This SOP applies to all staff members, including temporary and permanent employees, contractors, and volunteers who work within the organization.

Definitions

Term	Definition
Critical Incident	An event that results in or has the potential to result in significant harm, injury, or loss.
Adverse Event	An unexpected event that causes or could have caused harm to a person, process, or property.
Root Cause Analysis	A methodical process to determine the underlying causes of an incident or adverse event.

Roles and Responsibilities

- **All Staff:** Promptly identify and report all critical incidents and adverse events.
- **Supervisors/Managers:** Ensure incidents are reported, initiate immediate response measures, and support investigations.
- **Risk Manager/Quality Team:** Lead root cause analysis, document findings, and implement corrective and preventive actions.
- **Compliance Officer:** Ensure adherence to regulatory requirements and reporting timelines.

Procedures

1. **Identification and Documentation**
    - Immediately identify and, if safe, secure the area of the incident.
    - Document all relevant information using the Incident Report Form within 24 hours.
2. **Immediate Response**
    - Provide first aid or medical assistance as needed.
    - Notify supervisor/manager and escalate per severity.
3. **Notification and Communication**
    - Communicate the incident to relevant internal stakeholders.
    - Inform regulatory authorities as required.
4. **Investigation and Root Cause Analysis**
    - Initiate investigation within 48 hours of incident.
    - Perform root cause analysis using accepted methodologies (e.g., 5 Whys, Fishbone Diagram).
5. **Corrective and Preventive Actions (CAPA)**
    - Develop and implement a CAPA plan based on investigation findings.
    - Monitor the effectiveness of actions taken.
6. **Documentation and Record Keeping**
    - Maintain records of all incidents, investigations, actions, and outcomes for a minimum of [X] years.
7. **Review and Continuous Improvement**
    - Conduct periodic reviews of incident reports to identify trends.
    - Revise SOP as necessary to reflect lessons learned and process improvements.

Compliance and Regulatory Requirements

- Ensure reporting aligns with local, state, and federal regulations.
- Submit required notifications within regulatory timeframes.
- Participate in audits and reviews as mandated by authorities.

References

- Regulatory Guidelines (e.g., OSHA, CMS, FDA, State Health Departments)
- Internal Policies and Procedures

Appendix: Incident Report Form (Sample)

Field	Description
Date/Time of Incident	_____
Location	_____
Description of Incident	_____
Immediate Actions Taken	_____
Persons Involved	_____
Reporter Name & Signature	_____
Date of Report	_____