

Standard Operating Procedure (SOP)

Error Reporting and Corrective Action Protocols

This SOP details **error reporting and corrective action protocols**, encompassing the identification, documentation, and communication of errors, root cause analysis, implementation of corrective and preventive actions, monitoring effectiveness, and continuous improvement measures. The goal is to ensure timely resolution of issues, minimize recurrence, and enhance overall operational quality and safety.

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1. Purpose

To provide a systematic approach for reporting, investigating, and addressing errors to prevent recurrence and promote operational excellence.

2. Scope

This protocol applies to all staff and processes within [Department/Organization].

3. Responsibilities

- **All Employees:** Promptly report observed errors.
- **Supervisors/Managers:** Oversee investigation, documentation, and resolution.
- **Quality Assurance (QA):** Review reports, track corrective actions, and monitor effectiveness.
- **Management:** Ensure resources and support for corrective actions and continuous improvement.

4. Procedure

1. Identification of Errors

- Staff members identifying actual or potential errors must report them immediately.
- Use the designated error reporting form or system.

2. Documentation

- Record the error in the Error Log including date/time, location, description, and persons involved.
- Attach any related supporting documents or evidence.

3. Communication

- Notify relevant supervisors/managers as soon as practicable.
- Inform affected parties as appropriate.

4. Root Cause Analysis

- Conduct a thorough investigation using tools such as Fishbone Diagram, 5 Whys, etc.
- Document findings and contributing factors.

5. Corrective and Preventive Actions (CAPA)

- Develop action plans addressing immediate corrections and long-term preventive measures.
- Assign responsibilities and due dates for completing actions.
- Document all steps taken.

6. Implementation

- Execute corrective and preventive actions as specified in the action plan.
- Update relevant procedures, training, or resources if required.

7. Effectiveness Monitoring

- Monitor outcomes to ensure the error does not recur.
- Conduct follow-up audits or observations as needed.

8. **Continuous Improvement**

- Analyze trends in error reports for recurring issues.
- Review and update SOPs and training periodically.

5. **Documentation and Records**

- Error Reports and Logs
- Root Cause Analysis Documents
- Corrective and Preventive Action Records
- Follow-up/Audit Reports

6. **References**

- [List any applicable guidelines, standards, or regulatory documents]

7. **Revision History**

Version	Date	Revision Details	Author
1.0	[YYYY-MM-DD]	Initial Release	[Name]