

SOP Template: Documentation, Record-Keeping, and Reporting Requirements

1. Purpose

This SOP details the **documentation, record-keeping, and reporting requirements** essential for maintaining accurate and timely records. It covers the processes for documenting operational activities, storing records securely, and generating reports in compliance with regulatory standards. The goal is to ensure transparency, accountability, and easy retrieval of information for audits, performance monitoring, and continuous improvement.

2. Scope

This SOP applies to all employees involved in documentation, record-keeping, and reporting processes within the organization.

3. Responsibilities

- **All Employees:** Ensure records are completed accurately and on time.
- **Supervisors/Managers:** Oversee record maintenance and timely reporting.
- **Compliance Officer:** Monitor compliance with regulatory and internal requirements.

4. Definitions

Term	Definition
Documentation	The process of recording operational activities, events, and decisions in written or electronic format.
Record-Keeping	The systematic retention and maintenance of documents for reference, compliance, and audit purposes.
Reporting	The creation and distribution of summaries, analytics, or other reports from documented records.

5. Procedures

5.1 Documentation

- Document all operational activities, decisions, and incidents promptly using approved templates or

electronic systems.

- Ensure that all entries are dated, signed, and include relevant details.
- Correct errors using approved correction methods (e.g., single line-through and initial, no erasures).

5.2 Record-Keeping

- Store records in designated secure areas (physical files) or approved electronic repositories (digital files).
- Retain records for the minimum period specified by applicable regulations or internal policy.
- Restrict access to records to authorized personnel only.
- Back up electronic records regularly and protect data from unauthorized access or alteration.

5.3 Reporting

- Generate required reports (e.g., monthly, quarterly, annually) as outlined in the reporting schedule.
- Verify the accuracy and completeness of data prior to report submission.
- Distribute reports to relevant stakeholders and retain copies for audit purposes.

6. Records Retention and Disposal

- Follow the records retention schedule to determine how long records must be kept.
- Dispose of records securely when the retention period expires, using approved destruction methods (e.g., shredding for paper, secure deletion for digital files).

7. Review and Continuous Improvement

- Review this SOP annually or when regulations or internal processes change.
- Implement corrective actions as identified during audits or process reviews.

8. References

- Title of Applicable Law/Regulation 1
- Organization Policy Manual
- Report and Record Retention Schedule

9. Appendix: Templates and Forms

- [Document Template](#)
- [Records Log](#)
- [Reporting Schedule](#)

