

SOP Template: Record-keeping and Schedule Audit Trails

This SOP details the procedures for **record-keeping and schedule audit trails**, encompassing accurate documentation of all operational activities, maintenance of audit logs to track schedule changes, verification processes to ensure data integrity, and systematic review to support accountability and compliance. The aim is to establish a reliable and transparent record management system that facilitates effective monitoring, reporting, and continuous improvement.

1. Purpose

The purpose of this SOP is to define standardized procedures for record-keeping and the management of schedule audit trails to ensure compliance, transparency, and data integrity across all operational areas.

2. Scope

This SOP applies to all personnel involved in operations, administration, and IT systems management requiring the creation, maintenance, and review of records and schedule logs.

3. Responsibilities

- **Operations Staff:** Record all relevant activities accurately and promptly.
- **System Administrators:** Maintain automated audit trails for all schedule-related activities.
- **Supervisors/Managers:** Periodically review records and audit logs for accuracy and completeness.
- **Compliance Officers:** Ensure adherence to policy and regulatory requirements.

4. Definitions

Term	Definition
Record-keeping	Systematic process of documenting and preserving information related to operations.
Audit Trail	A chronological set of records providing documentary evidence of the sequence of activities or changes to schedules.
Schedule	A plan for carrying out a process or procedure, giving lists of intended events and times.

5. Procedures

1. **Creation of Records:**
 - Document all operational, maintenance, or schedule-related activities using standardized forms or digital systems.
 - Include date, time, responsible personnel, and description of the activity.
2. **Audit Trail Maintenance:**
 - Ensure that all changes to schedules (e.g., creation, modification, cancellation) are automatically logged by the system, capturing user ID, timestamp, and description of change.
 - Prevent unauthorized access to audit logs.
3. **Verification and Integrity Checks:**
 - Regularly review records and audit logs for completeness, consistency, and evidence of tampering.
 - Confirm that any schedule adjustments have appropriate approvals documented.
4. **Storage and Retention:**
 - Store records and audit logs securely, following relevant regulatory and organizational retention policies (e.g., retain for minimum 3 or 5 years).
5. **Systematic Review:**
 - Supervisors conduct quarterly audits of both manual records and digital audit trails, documenting findings and initiating corrective actions where required.
6. **Incident Reporting:**
 - Report discrepancies in records or audit trails immediately to the Compliance Officer.

6. Documentation

- Record Log Forms
- Audit Trail Export Reports
- Schedule Change Authorization Forms
- Audit Review Checklists and Reports

7. References

- Organizational Record-keeping Policy
- Regulatory Compliance Standards (e.g., 21 CFR Part 11, GDPR)
- IT Security Guidelines

8. Revision History

Version	Date	Description of Change	Author
1.0	2024-06-20	Initial SOP creation	[Your Name]

Note: This is a template and should be customized to reflect organization-specific policies, systems, and regulatory requirements.