

Standard Operating Procedure (SOP)

Periodic File Audit and Quality Control Process

This SOP details the **periodic file audit and quality control process**, encompassing scheduled file reviews, accuracy verification, compliance checks with organizational standards, identification and correction of discrepancies, documentation of audit findings, continuous improvement measures, and reporting protocols. The objective is to maintain high-quality file management practices, ensure data integrity, and support operational efficiency through systematic audits and quality control activities.

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Prepared by	[Name/Department]
Approved by	[Name/Department]

1. Purpose

To establish a standard operating procedure for conducting periodic audits and quality control reviews of files to ensure compliance, data integrity, and continual improvement of file management practices.

2. Scope

This SOP applies to all electronic and physical files maintained by [Organization/Department] and covers all personnel responsible for file management and quality control.

3. Responsibilities

- **File Managers:** Conduct scheduled audits and implement corrective actions.
- **Quality Control Team:** Review audit findings, verify compliance, and recommend improvements.
- **Supervisors/Management:** Oversee implementation and ensure accountability.

4. Definitions

- **File Audit:** Systematic examination of files for accuracy, completeness, and compliance.
- **Quality Control:** Procedures implemented to ensure files meet established standards.
- **Discrepancy:** Any deviation from standards, procedures, or regulatory requirements.

5. Procedure

1. **Audit Scheduling**
 - Determine audit frequency (e.g., monthly, quarterly, annually).
 - Prepare audit schedule and notify relevant staff.
2. **File Selection**
 - Randomly or systematically select files based on risk assessment or compliance priorities.
3. **Audit Process**
 - Review files for completeness, accuracy, and adherence to organizational standards.
 - Verify that documentation is up-to-date and properly authorized.
 - Check for compliance with legal, regulatory, and organizational requirements.
4. **Identification of Discrepancies**
 - Document all identified errors, missing items, or non-compliant records.
5. **Correction and Follow-up**
 - Notify responsible personnel to address and correct discrepancies.
 - Confirm corrections are made and document actions taken.
6. **Documentation of Findings**

- Complete an audit report summarizing findings, corrective actions, and recommendations.

7. Continuous Improvement

- Analyze recurrent issues to identify root causes.
- Update procedures, provide training, or propose process changes as needed.

8. Reporting

- Submit audit report to management and retain documentation as per the records management policy.

6. Records

- Audit schedules
- Audit checklists and completed forms
- Audit reports
- Corrective action logs
- Continuous improvement records

7. References

- Records Management Policy
- Quality Control Guidelines
- Relevant Regulatory Standards

8. Revision History

Version	Date	Description of Change	Author
1.0	[Insert Date]	Initial Release	[Name]