SOP: Periodic Review and Audit of Documentation

Objective:

To establish a systematic procedure for the periodic review and audit of organizational documentation to ensure accuracy, compliance, currency, and effective version control in alignment with regulatory and internal requirements.

Scope

This SOP applies to all controlled documents within the organization, including but not limited to policies, procedures, manuals, forms, and records.

Responsibilities

- **Document Owners:** Responsible for initiating and completing scheduled document reviews and necessary updates.
- **Quality Assurance (QA):** Oversees the review process, conducts audits, and verifies compliance with requirements.
- **Department Managers:** Ensure review tasks are assigned and completed in their department.

Definitions

- **Periodic Review:** A scheduled assessment of document content, accuracy, and relevance.
- **Audit:** An independent evaluation to ensure compliance with standards and regulations.
- **Version Control:** Management of document revisions and historical tracking.

Procedure

1. **Scheduling Regular Reviews**
   - Each controlled document must be reviewed at least once every *12 months*, or as required by regulation or internal policy.
   - Document Owners are to maintain a review schedule and notifications.
2. **Document Assessment**
   - Verify accuracy, completeness, and compliance with current regulations and internal standards.
   - Identify outdated, incorrect, or missing information.
3. **Updating Documentation**
   - Update necessary sections, referencing regulatory changes or operational improvements.
   - Ensure updates go through the required review and approval workflow.
4. **Version Control**
   - Assign new version numbers to updated documents.
   - Archive previous versions according to retention policy.
5. **Audit Process**
   - QA conducts periodic audits to verify review completion and proper document management.
   - Identify and record any gaps, inconsistencies, or non-compliance.
6. **Corrective Actions**
   - Document and implement corrective actions as needed to resolve identified audit findings.
7. **Audit Trails**
   - Maintain comprehensive audit trails for all document revisions, reviews, and approvals, including dates and responsible individuals.

Documentation and Records

- Maintain updated copies of all active documents in the designated document management system.
- Retain archived and obsolete versions according to the organization's record retention policy.
- Store records of reviews, approvals, and audit findings securely.

References

- Relevant regulatory guidelines
- Internal document management policy
- Record retention schedule

Revision History

Version	Date	Description of Change	Approved By
1.0	2024-06-01	Initial SOP Release	[Name/Title]