SOP: Documentation, Recordkeeping, and Release Authorization Process

1. Purpose

This SOP details the **documentation, recordkeeping, and release authorization process**, encompassing the accurate creation, maintenance, and storage of records, ensuring data integrity and compliance. It covers procedures for document control, secure record retention, access management, and the proper authorization required for releasing information or materials. The objective is to streamline operations, uphold regulatory standards, and guarantee transparency and accountability throughout the documentation lifecycle.

2. Scope

This SOP applies to all employees involved in handling, creating, storing, or authorizing the release of documents and records within the organization.

3. Responsibilities

- **Document Owner:** Responsible for initial document creation, accuracy, and ongoing updates.
- **Records Custodian:** Ensures secure storage and retrieval of records, monitors retention schedules.
- **Access Manager:** Grants or revokes access permissions based on role and need.
- **Authorizing Official:** Reviews and approves release of documents or information.
- **All Staff:** Follow this SOP and report discrepancies or unauthorized access.

4. Procedure

4.1. Document Creation & Control

- Generate documentation following applicable templates and standards.
- Assign a unique identifier (document number, version, date).
- Review for completeness and accuracy before finalization.
- Track revisions and maintain version control log.

4.2. Recordkeeping & Storage

- Store records in designated secure locations (physical or digital repositories).
- Implement backup procedures and disaster recovery measures for digital records.
- Archive records according to retention policies and regulatory requirements.
- Protect records against unauthorized access, alteration, or destruction.

4.3. Access Management

- Restrict document access to authorized personnel in line with defined roles.
- Regularly review and update access permissions.
- Maintain an access log of who views or edits records.

4.4. Release Authorization

- Requests for document or information release must be submitted in writing.
- The Authorizing Official reviews request, assesses compliance, and grants or denies approval.
- Document all approvals, including reason, date, and recipient.
- Release only redacted or anonymized information when required by policy.

4.5. Monitoring & Compliance

- Periodically audit recordkeeping systems for compliance with policies and regulations.
- Report and investigate any discrepancies, breaches, or unauthorized releases.

5. Documentation, Logs, and Forms

Document/Form	Description	Retention Period	Owner
Document Control Log	List of documents, versions, and status	Permanent	Records Custodian
Access Authorization Log	List of who has accessed documents	5 years	Access Manager
Release Authorization Form	Approval for releasing documents/information	7 years	Authorizing Official

6. References

- Company Record Retention Policy
- Applicable Regulations (e.g., GDPR, HIPAA, ISO 9001, as relevant)
- Document Control Policy

7. Revision History

Version	Date	Description	Author
1.0	2024-06-12	Initial SOP release	SOP Team

Prepared by: _____ Date: _____

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