

SOP Template: Standardized Procedure for Implementing Process Changes

This SOP defines the **standardized procedure for implementing process changes**, covering the assessment, approval, communication, documentation, training, and monitoring steps required to ensure changes are effectively integrated into existing workflows. The goal is to maintain process consistency, minimize disruptions, and improve operational efficiency while ensuring compliance with organizational standards and regulatory requirements.

1. Purpose

To provide a consistent and effective method for making changes to organizational processes, safeguarding operational stability, regulatory compliance, and improvement objectives.

2. Scope

This procedure applies to all process changes affecting operational workflows, quality, safety, or regulatory compliance within the organization.

3. Responsibilities

Role	Responsibilities
Process Owner	Initiates change request, conducts initial assessment, oversees implementation.
Change Control Board (CCB)	Reviews and approves/rejects changes.
Quality Assurance	Ensures documentation and compliance with standards.
Training Coordinator	Organizes and implements training.
All Staff	Participates in training and follows new procedures.

4. Procedure

- Assessment**
 - Identify the need for change and define its scope.
 - Assess impact on stakeholders, workflows, safety, quality, and compliance.
 - Document risks and mitigation plans.
- Approval**
 - Submit change proposal with supporting documentation.
 - Obtain formal review from the Change Control Board (CCB).
 - Decision (approve, reject, revise) is documented and communicated.
- Communication**
 - Notify all affected stakeholders of the upcoming change.
 - Provide a summary of the change, timeline, and expected impact.
- Documentation**
 - Update all SOPs, manuals, and records reflecting the change.
 - Archive obsolete documents per retention requirements.
- Training**
 - Identify staff requiring training on updated processes.
 - Deliver training and maintain attendance records.
- Implementation**
 - Carry out the approved change according to the planned schedule.
 - Monitor initial execution for unforeseen issues.
- Monitoring & Review**
 - Monitor performance indicators related to the change.
 - Document findings and take corrective actions if required.
 - Conduct post-implementation review for continuous improvement.

5. Documentation & Records

- Change request forms and assessment documents
- Approval/rejection records
- Training attendance logs
- Updated SOPs and manuals
- Post-implementation review reports

6. Compliance & References

- All changes are to comply with relevant regulatory and organizational standards.
- Reference applicable quality management system (QMS) documents as needed.

7. Revision History

Version	Date	Description	Author/Approver
1.0	2024-06-13	Initial SOP template issued	[Name/Title]