

# SOP: Change Control Request and Approval Procedures

This SOP details the **change control request and approval procedures**, outlining the systematic process for submitting, reviewing, and approving changes to projects, products, or processes. It includes the identification of change requirements, documentation standards, impact assessment, approval hierarchy, communication protocols, implementation steps, and post-implementation review to ensure controlled and auditable modifications that maintain quality and compliance.

## 1. Purpose

To define the procedures for requesting, documenting, reviewing, approving, communicating, implementing, and reviewing changes to ensure all modifications are controlled, auditable, and in compliance with quality standards.

## 2. Scope

This procedure applies to all projects, products, or processes where changes, amendments, or enhancements are proposed or required within the organization.

## 3. Definitions

- **Change Request (CR):** A formal proposal for alteration to any product, process, or project documentation.
- **Change Control Board (CCB):** The committee responsible for reviewing and approving change requests.
- **Impact Assessment:** Analysis of potential consequences, risks, and benefits resulting from the proposed change.

## 4. Responsibilities

Role	Responsibility
Requester	Identifies need for change, prepares, and submits change request.
Project/Product Owner	Reviews initial request and forwards to Change Control Board (CCB).
CCB Members	Review, assess impacts, and approve or reject the change request.
Quality Assurance	Ensures change compliance with standards and documents the process.
Implementation Team	Executes approved changes and documents completion.

## 5. Procedure

1. **Identification of Change Requirement**
  - The requester identifies the need for change based on observations, audit results, regulatory updates, or process improvements.
2. **Submission of Change Request**
  - A Change Request form must be completed, including: description of change, justification, anticipated impact, risk assessment, and proposed timeline.
  - The completed form is submitted to the Project/Product Owner.
3. **Initial Review and Documentation**
  - The Project/Product Owner reviews for completeness and clarity. If satisfactory, the request is logged and forwarded to the CCB.
4. **Impact Assessment**
  - CCB conducts a thorough impact assessment, evaluating potential effects on scope, timeline, cost, resources, quality, and compliance.
  - Additional information may be requested from the requester as needed.
5. **Approval Process**
  - The CCB decides to approve, reject, or request modification of the change request.
  - Final decisions, including conditions for approval (if any), are documented.
6. **Communication**
  - Outcomes are communicated to all stakeholders. Approved changes are scheduled for implementation.
7. **Implementation**
  - The responsible team implements the approved change according to agreed-upon plans and timelines.

- Implementation steps are tracked and documented.

#### 8. Post-Implementation Review

- A review is conducted to confirm that the change was successful and objectives met.
- Lessons learned and any follow-up actions are documented.
- All related documentation is archived for audit and reference purposes.

## 6. Documentation Standards

- All change requests and supporting documents must be clear, complete, and stored in a centralized, accessible repository.
- Version control and traceability must be ensured at all stages.

## 7. Records

- Change Request Forms
- Impact Assessment Reports
- CCB Meeting Minutes and Approval Records
- Implementation Logs
- Post-Implementation Review Outcomes

## 8. Revision History

Version	Date	Description	Author
1.0	2024-06-05	Initial issue	SOP Team