Standard Operating Procedure

Change Control of Software and Computer Systems

This is an example of a Standard Operating Procedure. It is a proposal and starting point only. The type and extent of documentation depends on the process environment. The proposed documentation should be adapted accordingly and should be based on individual risk assessments. There is no guarantee that this document will pass a regulatory inspection.

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Controls:

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<th>Superseded Document</th>
<th>N/A, new</th>
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<tr>
<td>Reason for Revision</td>
<td>N/A</td>
</tr>
<tr>
<td>Effective Date</td>
<td>Jan 1, 2004</td>
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Signatures:

<table>
<thead>
<tr>
<th>Author</th>
<th>I indicate that I have authored or updated this SOP according to applicable business requirements and our company procedure: Preparing and Updating Standard Operating Procedures.</th>
</tr>
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<tbody>
<tr>
<td>Name:</td>
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<tr>
<th>Approver</th>
<th>I indicate that I have reviewed this SOP, and find it meets all applicable business requirements and that it reflects the procedure described. I approve it for use.</th>
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<tr>
<th>Reviewer</th>
<th>I indicate that I have reviewed this SOP and find that it meets all applicable quality requirements and company standards. I approve it for use.</th>
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<tr>
<td>Date:</td>
<td>____________________________________________________________________________________________________________________</td>
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</table>
1. **PURPOSE**

   Computer hardware and software are frequently changed. Insufficient documentation and uncontrolled changes can have a negative effect on the reliability of software and computer systems. This SOP should help ensure that changes of computer hardware, firmware, software and computer systems follow documented procedures. It describes procedures for initiation, implementation, approval and documentation of the changes.

2. **SCOPE**

   The procedure applies whenever computer hardware or software is changed. For a computer system this also includes accessories such as printers, network devices and cables.

3. **GLOSSARY/DEFINITIONS**

   For generic definitions on computer validation, see [www.labcompliance.com/glossary](http://www.labcompliance.com/glossary).

4. **REFERENCE DOCUMENTS**


   4.2. SOP ###: “Validation of Macro Programs and other Application Software” and exhibits listed in that SOP. (Available through [www.labcompliance.com/solutions/sops](http://www.labcompliance.com/solutions/sops))

5. **RESPONSIBILITIES**

   5.1. System Owner

      5.1.1. Submits change request.
5.1.2. Evaluates impact of change.

5.1.3. Typically acts as change owner.

5.2. Functional Supervisor

5.2.1. Evaluates business benefits of change.

5.2.2. Reviews risk as assessed in change request.

5.2.3. Approves or rejects request for change.

5.3. Validation Group

5.3.1. Evaluates need for validation/qualification of changed or new functions or components.

5.3.2. Evaluates need for qualification of components/functions that have not changed.

5.4. Change Advisory Board (CAB)

5.4.1. Approves/rejects change request.

5.4.2. Approves/rejects change release.

5.4.3. Reviews all changes on a weekly basis.

5.5. Quality Assurance

5.5.1. Checks if documented procedures are followed.

5.5.2. Approves or rejects test plan and protocols.

5.5.3. Checks if regulatory requirements are met.

5.5.4. Updates SOP inventory.

5.5.5. Notifies regulatory agency on the change, if necessary.

6. CHANGE PROCEDURE

6.1. Requesting the Change
The user makes a proposal for a change using the form in Attachment 7.1. The proposal should include:

6.1.1. Why the change is needed.
6.1.2. What the current problem is and how the change will solve that problem.
6.1.3. Technical and business impact.
6.1.4. Priority (high, medium or low).
6.1.5. Latest acceptable date if time dependent.
6.1.6. Information if a regulatory notification is required.

For some activities the requester may consult other professionals. For example for the technical impact, test plan and risk assessment.

6.2. Evaluating and Approving the Request

6.2.1. Functional Supervisor

6.2.1.1. Reviews the request and business impact.

6.2.1.2. Approves or rejects the request using the request form in Attachment Error! Reference source not found..

6.2.2. Validation Group

6.2.2.1. Determines the need for retesting of new or changed components or functions.

6.2.2.2. Determines the need for retesting of the entire system, including the functions that will not change.

6.2.2.3. If no testing is required, this should be stated together with a reason for not testing. For example, such a statement could be: "Based on our multi-year experience and risk assessment the change does not impact validation of the system".

6.2.2.4. Performs a risk assessment.

6.2.3. Change Advisory Board (CAB)

6.2.3.1. Reviews the change request.
6.2.3.2. Approves or rejects the change request.

6.3. Implementation and Testing

6.3.1. The request is submitted to the system owner.

6.3.2. The system owner arranges the ordering of hardware, software, accessories etc.

6.3.3. The system owner updates the master list database with initial setup or previous versions using the form: Template for Network/Computer System Identification.

6.3.4. The validation group develops a test plan with test cases, test protocol, acceptance criteria and schedules.

6.3.5. Users test the performance of software and/or complete systems.

6.3.6. Validation group reviews and approves test protocols.

6.3.7. QA reviews and approves the test protocols.

6.3.8. The system owner initiates the release of the change using the form in Attachment 7.2.

6.3.9. The Change Advisory Board decides if the implemented change gets final approval or not.

6.4. Documentation and Communication

6.4.1. The system owner enters the change in the change history log using the form in Attachment 7.3.

6.4.2. QA notifies all impacted users on technical impact of the change and training requirements.

6.4.3. QA notifies regulatory bodies on the change, if required.

6.4.4. The Change Advisory Board reviews the change in the next meeting.

6.4.5. QA considers the inclusion of the change in the timetable for internal audits.

6.5. Records

All of the following should be retained:
6.5.1. Change request form (Attachment 7.1).

6.5.2. Change release form (Attachment 7.2).

6.5.3. Updated inventory list. (Form: Template for Network/Computer System Identification)

6.5.4. Test plan and protocols.

6.5.5. Updated change history log (Attachment 7.3).

6.6. Approvals

6.6.1. Approval of the request by the user’s departments and Change Advisory Board.

6.6.2. Approval of the release by the user’s and quality assurance departments, Change Advisory Board and validation group.
7. ATTACHMENTS

7.1. Attachment - Change Request Form

<table>
<thead>
<tr>
<th>Form ID:</th>
<th>Change ID:</th>
<th>Item ID:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Item Location:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Change Initiator:</td>
<td>Enter name.</td>
<td>Date of request.</td>
</tr>
<tr>
<td>Description of Change:</td>
<td>Enter a summary and a reason for the change and the business benefit.</td>
<td></td>
</tr>
<tr>
<td>Change Priority:</td>
<td>High O</td>
<td>Medium O</td>
</tr>
<tr>
<td>Latest Acceptable Date:</td>
<td>Only necessary if the change is time critical.</td>
<td></td>
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<tr>
<td>Risk Assessment:</td>
<td>Risk:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Likelihood:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Severity:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Recovery:</td>
<td></td>
</tr>
<tr>
<td>Test Plan:</td>
<td>Describe test efforts.</td>
<td></td>
</tr>
<tr>
<td>(Validation Group)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Regulatory Notification Required:</td>
<td>Yes O</td>
<td>No O</td>
</tr>
<tr>
<td>(Done by QA)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Change Approval:</td>
<td>Accepted O</td>
<td>Rejected O</td>
</tr>
<tr>
<td></td>
<td>Comments or reasons for rejection:</td>
<td></td>
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<tr>
<td>Signatures:</td>
<td>Name:</td>
<td>Signature:</td>
</tr>
<tr>
<td>Functional Mgt.</td>
<td></td>
<td></td>
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<tr>
<td>Change Adv. Board</td>
<td></td>
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<tr>
<td>QA Mgt.</td>
<td></td>
<td></td>
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7.2. Attachment – Release Request Form

<table>
<thead>
<tr>
<th>Form ID:</th>
<th>Change ID:</th>
<th>Item ID:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Item Location:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Change Initiator:</td>
<td>Enter name.</td>
<td>Date of request.</td>
</tr>
<tr>
<td>Name of System Owner:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Planned Release Date:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tests Passed:</td>
<td>Make a statement that all tests have passed acceptance criteria.</td>
<td></td>
</tr>
<tr>
<td>Known Problems:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recommendations for Release:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Change Release:</td>
<td>Accepted O</td>
<td>Rejected O</td>
</tr>
<tr>
<td>Comments or reasons for rejection:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Signatures:</td>
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<tr>
<td>Functional Mgt.</td>
<td>Name:</td>
<td>Signature:</td>
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<tr>
<td>QA Mgt.</td>
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<tr>
<td>Change Adv. Board</td>
<td></td>
<td></td>
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<tr>
<td>Validation Group</td>
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7.3. Attachment – Change Summary Log

<table>
<thead>
<tr>
<th>System ID</th>
<th>Name: ____________________________</th>
<th>Number: ____________________________</th>
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</thead>
<tbody>
<tr>
<td>Date</td>
<td>Type of Change</td>
<td>Change ID</td>
</tr>
<tr>
<td></td>
<td>(Include item and nature of change)</td>
<td></td>
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