

## Complete Change Activity

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### 1.0 **PURPOSE**

This procedure defines the requirements for completing a Change Activity.

### 2.0 **REFERENCES**

#### 2.1 **Applicable Documents**

Number	Title
87129	Guide for Completing Change Activity
87132	Complete Training Assessment
87136	Complete Material Assessment

#### 2.2 **External References**

Number	Title
N/A	N/A

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### 3.0 RESPONSIBILITIES

Function or Title	Responsibility
Change Activity Assignee	<ul style="list-style-type: none"> <li>• Completes the Change Activity.</li> <li>• Assigns Peer Reviewers.</li> <li>• Manages the Peer Review and determines action on feedback.</li> </ul>
Change Manager (CM)	<ul style="list-style-type: none"> <li>• Creates and manages the Change Order.</li> <li>• Assigns Change Activity Assignee and Peer Reviewer.</li> <li>• Assigns CIB, Pre- and Post-Release Task Assignee(s), and Material Dispositioner</li> </ul>
Creator/Editor (C/E)	Creates and revises Change Activity objects defined on the Description of the Change Activity.
Peer Reviewer	Provides a technical or feasibility review of redline changes or new objects.

### 4.0 DEFINITIONS

Term	Definition
Affected Objects	The primary object(s) that is undergoing change; this may include parts or documents.
Attachment	A document, data file, zip file, etc. that supports an object.
Attribute	Fields populated on an object that define its use.
Change Activity (CA)	A change implementation activity used to assign tasks for individuals to complete and be reviewed prior to Change Implementation Board review.
Change Order (CO)	An object that allows planning, managing, monitoring, and approval of new/revised objects of the change activities
Document Object	An object that consists of primary content (e.g., Word document, Excel file) for a controlled document.
Enterprise Change Request (ECR)	An object containing information relating to the scope of the proposed change(s). The ECR houses all Change Orders, and their associated Change Activities, used to implement the approved ECR. All of the change objects, and their current state, can be viewed all at once using the ECR change tree.
Inactive (Phase Out)	A lifecycle state when objects are no longer intended for use, but may be used to complete work in progress.
Keyword Search	PLM system search engine for content, attributes, document number, etc.

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Term	Definition
Lifecycle Map	Displays current position within the lifecycle.
Lifecycle State	The status of an object in Windchill.
Major Rewrite	Extensive changes to a document.
Notification Email	A Windchill system generated email that notifies the identified functional roles of the status change of an object.
Object	A document, part, ECR, CO, CA, etc., that is identified in Windchill.
Obsolete	A lifecycle state where the object is identified as no longer being used.
Part Object	A part controlled in Windchill.
Peer Review	Allows for feedback, input, and error correction prior to formal approval.
Pre-Released	A lifecycle state where the object is available for development activities.
Released	A lifecycle state where the object is available for production activities.
Resulting Object	Object which will become effective upon release of the Change Order.
Structure Report	A query that identifies parent/child, and object structures.
SAP	Enterprise Resource Planning (ERP), a business operating system used to manage finances, assets, costing, production operations materials, plants and executions of a common set of data and programs.
Version	An identifying letter or number which is used to identify the implementation, or pending implementation, of a change to a particular object as part of a Change Order.
Where Used	A query that identifies the parent of a dependent object.
Windchill (WC)	Product Lifecycle Management (PLM) system used to manage objects associated with the lifecycle of a product from its conception to its obsolescence.

### 5.0 FLOW CHART

N/A

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### 6.0 REQUIREMENTS

#### 6.1 General Requirements

Step	Action
1	<p>The Change Order (CO) is the implementation plan for a change. It is made up of Change Activities (CA) and is often referred to as the shell of the change. The CA is where the actual work associated with the change is executed. Several related CAs may come together under one CO. Peer Review takes place during the CA and is a way to get feedback from peers before Change Implementation Board (CIB) review.</p> <p>The CAs are reviewed and approved as part of the CO package.</p>
2	<p>The Change Activity Assignee (CA Assignee) is responsible for creating and managing the CA. The CA Assignee is also responsible for reviewing Peer Review feedback and determines how to act upon the feedback. If the CA Assignee incorporates changes, the CA Assignee resubmits for additional Peer Review, or can move forward without it.</p>
3	<p>The CA progress can be tracked by using the Lifecycle Map found at the top of the Details tab of the CA.</p>
4	<p>Refer to the following work instructions and guidance when completing the CA:</p> <ul style="list-style-type: none"> <li>• 87129, Guide for Completing Change Activity</li> <li>• 87113, Create and Maintain Parts</li> <li>• 87116, Create and Maintain Documents</li> <li>• 87132, Complete Training Assessment</li> <li>• 87136, Complete Material Assessment</li> </ul>

#### 6.2 Complete a Change Activity

Step	Action
1	<p>The CM creates a CA structured to the CO which identifies the task, the Assignee, and the Peer Reviewer(s). There may be more than one CA structured to the CO.</p>
2	<p>The CA Assignee is notified of the CA via email and the task also appears on the Home Page, My Tasks section. The CA Assignee completes the task per the CA Description.</p> <p>While the formal process begins with the CA task, the process of creating and editing documents and parts may begin prior to receiving the task.</p>

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### 6.2 Complete a Change Activity

Step	Action
3	<p><b>Name</b></p> <p>The CA Name is specific to the CA</p> <p>Examples:</p> <ul style="list-style-type: none"> <li>• Release of drawings for the Accu Cutter</li> <li>• Initial Release of MP 90260205</li> <li>• Update Product Hierarchy for Material 44-0187-01</li> </ul>
4	<p><b>Description</b></p> <p>The Description describes what needs to be updated as part of the CA. The CA Description serves as the directions to the CA Assignee to complete the CA.</p> <p>Examples:</p> <ul style="list-style-type: none"> <li>• Revise the part object 600005236 to update the BOM.</li> <li>• Structure the applicable documents to 86084.</li> <li>• Create a new document number and release IQ Protocol.</li> <li>• Create a new ZRAW Part and new Material Specification.</li> </ul>

### 6.3 Attachments

Step	Action
1	<p>Add attachments that support the change to the CA Attachments section as required. Attachments are dependent upon the changes. See Appendices A and B for the list of attachments based on the objects and target state. Examples include:</p> <ul style="list-style-type: none"> <li>• Structure/Routing Creation Form for new BOM/Routing and new document structure.</li> <li>• Structure redlines for changing BOM/Routing and revised document structure.</li> <li>• Training Plan when the documents require training.</li> <li>• Implementation Plan for affected document(s), when applicable             <ul style="list-style-type: none"> <li>○ Implementation Plans are used to communicate requirements when a change to a document cannot be implemented upon release without further explanation or activity. This information may be captured within the change description or may be a separate attachment.</li> </ul> </li> <li>• When inactivating (with the exception of Quality System documents) or obsolescing parts or documents:             <ul style="list-style-type: none"> <li>○ Keyword search with reconciliation of reference relationships stated.</li> <li>○ Where Used report from Windchill (both parts and documents)</li> </ul> </li> </ul> <p><b>NOTE: The requirement to include a Where Used, Keyword Search and Structure Report does not apply for QS documents moving to an Inactive state. Those requirements DO apply for QS documents moving to an Obsolete state.</b></p>

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### 6.3 Attachments

Step	Action
1	<ul style="list-style-type: none"> <li>• Attach the Component Qualification Plan for purchased parts.</li> <li>• Attach the Part Extension Form and/or Part Data Form for updates to parts, as applicable.</li> <li>• Attach the Software Executable that is recorded on hard media external to Windchill (NMD only).               <ul style="list-style-type: none"> <li>○ Ensure two copies of the media are provided to Documentation Services group.</li> </ul> </li> <li>• Attach the approved Terumo Supplier Notice of Change Form for parts or documents that impact Terumo.</li> </ul>

### 6.4 Affected/Resulting Objects

Step	Action
1	<ul style="list-style-type: none"> <li>• Part objects undergoing changes are added to the Affected/Resulting Objects section and must be at the correct state.               <ul style="list-style-type: none"> <li>○ A part object at Pre-Released or Released state is added to the Affected Objects section.                   <ul style="list-style-type: none"> <li>▪ The Make Material Assessment is required to disposition the prior Pre-Released or Released version.</li> </ul> </li> <li>○ A part object at Draft or In Work state is added to Resulting Objects section.</li> </ul> </li> <li>• A document object at Draft or In Work is added to the Resulting Objects section.</li> <li>• Documents and part objects undergoing a change to an Inactive or Obsolete target state are added to the Resulting Objects section.</li> <li>• For Non-Rev CO, an object at Pre-Released or Released state is added to the Resulting Objects section.</li> </ul> <p><b><u>NOTE:</u> Objects cannot be placed on multiple CAs.</b></p>
2	<p><b>Document Versions and Releases</b></p> <ul style="list-style-type: none"> <li>• Document redlines are based off the current Released document from Windchill. Document redlines are uploaded as primary content and set to state Redline once the final clean copy is uploaded. A final clean copy with changes accepted is uploaded for review.</li> <li>• For complete rewrite a clean copy is uploaded as the primary content.</li> <li>• Redlines and clean copy are uploaded to the Resulting Objects section of the CA.</li> </ul> <p><b><u>NOTE:</u> Options to indicate what has changed include attaching redlines, or for complete rewrites, the previous released version (“From” document), or To/From Description, to the Change Activity Attachments section.</b></p>
	<p><b>Document/Part Structure</b></p> <p>All parts and documents meet stated Windchill structuring requirements.</p> <ul style="list-style-type: none"> <li>• Refer to 87117, Create and Maintain Document and Part Structure</li> </ul>

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### 6.5 Training Determination

Step	Action
1	<p>For CA containing document types that require training, Windchill generates Make Training Determination task. Windchill does not allow completion of the CA until the task is complete. The CA Assignee determines the training requirements for the documents undergoing a change.</p> <p>The Training Plan is attached to the Attachments section of the CA.</p> <p>Training materials are attached to the Attachment section of the Document objects (e.g., Knowledge Questions, Supplemental Materials).</p> <ul style="list-style-type: none"> <li>• Refer to 87132, Complete Training Assessment</li> </ul>

### 6.6 Material Assessment

Step	Action
1	<p>For CAs containing parts, Windchill generates Make Material Assessment task. Windchill does not allow completion of the CA until the task is complete.</p> <p>The CA Assignee determines the proper interchangeability assessment and part disposition on the Pre-Released or Released version.</p> <ul style="list-style-type: none"> <li>• Refer to 87136, Complete Material Assessment</li> </ul> <p><b><u>NOTE:</u> Initial Pre-Released or Released part does not require Material Assessment.</b></p>

### 6.7 Peer Review

Step	Action
1	<p>The Peer Review provides an opportunity to verify that the requirements have been met. Peer Reviewers are selected by the CM and CA Assignee. The CA Assignee can move forward without a Peer Review. A justification is required to skip Peer Review.</p> <p>Peer Reviewers could include:</p> <ul style="list-style-type: none"> <li>• Approvers</li> <li>• Technical Reviewers</li> <li>• Individuals requesting inclusion</li> <li>• Site representatives</li> <li>• Should include functional groups impacted</li> </ul>

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### 6.7 Peer Review

Step	Action
2	The completed CA is forwarded to the identified Peer Reviewer. The Peer Reviewer can provide feedback to the CA Assignee, or accept the work.
3	<p><b>Feedback</b></p> <p>If the Peer Reviewer provides feedback to the CA Assignee, the Assignee can incorporate the changes and resubmit to the Peer Reviewer or move to CO review and approval.</p>

### 6.8 Pull Back Change Activity

Step	Action
1	A CA Assignee can pull back a CA while Pending Peer Review. Select the appropriate Routing Option (Pull back reason) and enter comments describing in more detail why the pullback was needed. CA Assignee determines to how to act upon the feedback. If the CA Assignee incorporates changes, the CA Assignee resubmits for additional Peer Review, or can move forward without it.
2	If it is determined that Peer Review is not required, the CA Assignee can skip Peer Review while the CA is Pending Peer Review. The CA Assignee will select Skip_Peer_Review on the Pull Back Change Activity Task.

## 7.0 APPENDICES

Appendix A: Document Attachments Guide

Appendix B: Part Attachments Guide



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### APPENDIX A: DOCUMENT ATTACHMENTS GUIDE

Non-Rev	X	X		X				X	
Inactive				X			X	X	
Obsolete	X			X			X	X	
Pre-Released				X	X			X	X
Released	X		X	X	X	X	X	X	X
Records Retention				X					
CAPA Document				X					
<b>CA Attachment</b>									
<b>Change Assessment</b>	Training Plan	Redlines	Document Implementation Plan	Applicable Reference Documents & Supporting Forms	External Approval	Redlines, Previous Released version, or To/From Description	Where-Used/Keyword Search	Structure, Documents should be linked to a parent or sibling	Routing Creation Form or redlined markups of existing routing
Complete rewrite						X			
Change to Document Name/Description							X		
Obsolete documents							X		
Impact Shop Floor Paperwork generated from SAP									X
Impact Existing Intended use, Indications, Clinical Use, or Marketing Claims				X					

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### APPENDIX B: PART ATTACHMENTS GUIDE

Use the table below as a general guidance for CA attachments to consider based on the Windchill part type, and whether the part is New/Revised, or Make/Buy.

New	X	X	X		X	X	X	X	X
Revised	X	X	X	X	X	X	X	X	X
Make	X	X	X	X		X	X	X	X
Buy	X	X		X	X	X	X		X
<b>CR Attachment</b>	Part Data Form	Part Extension Form	Routing	Where-Used/Keyword Search	Component Quality Plan	Structure-Bill of Materials	Parent Structure	ZCONFIGLABEL Form	Model Numbers (ZMOD Re-Order #s)
<b>Windchill Part Type</b>									
ZFIN - Finished Good	X	X	X	X	X	X	X	X	X
ZLIT - Literature	X	X							
ZNVL – Non-Valued Material	X	X		X	X		X		
ZRAW - Raw Material	X	X		X	X		X		
ZSMI - Semi-finished Good	X	X	X	X	X	X	X		
Equipment	X	X		X	X	X	X		