Create and Manage Change Order

Create and Manage Change Order

1.0 PURPOSE

This procedure defines the requirements for creating and managing a Change Order.

2.0 REFERENCES

2.1 Applicable Documents

Number	Title
86927	Document Translation
87124	Guide for Creating and Managing Change Order
87125	Complete CAD, LMS, or MES Pre-Released Task
87128	Complete Change Activity
87130	Complete Pre- and Post-Release Task
87138	Complete Peer Review
87140	CIB Approval Requirements
87145	Change Order Proxy Review
87146	OEM Proxy Review
87166	Verification/Validation Assessment
87274	SAP Master Data Field Task List
87375	Translation Attachment Identification
90236083	Repack for Superficial Package Damage
94-2285	Form, Change Analysis (NMD)

2.2 External References

Number	Title
N/A	N/A

3.0 RESPONSIBILITIES

Function or Title	Responsibility
Business Owner	Responsible for the content, release, and revision of any document, BOM, part object, etc.
Change Activity Assignee	• Completes the Change Activity. • Assigns Peer Reviewers. • Manages the Peer Review and determines action on peer feedback.
Change Manager (CM)	• Creates and manages the Change Order. • Assigns Change Activity Assignee and Peer Reviewers. • Assigns CIB, Pre and Post Release Task Assignee, and Material Dispositioner, consulting with a Change Specialist or functional representatives as needed.
Change Implementation Board (CIB)	Reviews Change Orders and associated Change Activities for approval.
Creator/Editor (C/E)	Creates and revises Change Activity objects based on the Change Activity description.
Notification Role	This role allows individuals to be informed of proposed changes and status throughout the CO process. This is an informational, non-voting role and the individuals notified assume no review responsibilities.
Peer Reviewer	Provides a technical or feasibility review of redline changes or new objects.
Pre-Release Task Owner	Completes the assigned Pre-Release tasks (e.g., SAP updates, Translations)
Post-Release Task Owner	Completes the assigned Post-Release tasks (e.g., Update LMS, Document Distribution, GUI updates)

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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.
External Approvers	An approver external to Abbott who is required to approve changes and be notified of changes made.
Fast Track	A path in the Windchill workflow which allows certain document types to bypass Pre-Release and Post-Release activities and release immediately upon approval of the Change Order.
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	Windchill search engine for content, attributes, document number, etc.
Life Cycle Map	Displays current position within the lifecycle.
Lifecycle State	The status of an object in Windchill.
Major Rewrite	Extensive changes to a document.
Non-Rev Change	A Non-Rev change executes iteration-only (“non-rev”) changes (e.g. 1.1 to 1.2 or B.5 to B.6) on document and part objects with Pre-Released or Released states. Typically used to correct typos, create document to document structure, and SAP updates to fields not integrated with Windchill.

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Term	Definition
Notification Email	A Windchill 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.
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.
Pre-Release Task	Windchill generated tasks defined from the objects types, attributes, states, and task determination questions upon approval of the Change Order. Tasks must be completed prior to release of the Change Order
Peer Review	Allows for feedback, input, and error correction prior to formal review.
Post-Release Task	Windchill generated tasks defined from the objects types, attributes, states, and task determination questions upon release of the Change Order. Tasks are completed after Change Order release but before Change Order is Closed.
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.
Target State	The lifecycle state at which all objects on the Change Order will be once the Change Order has closed.
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.

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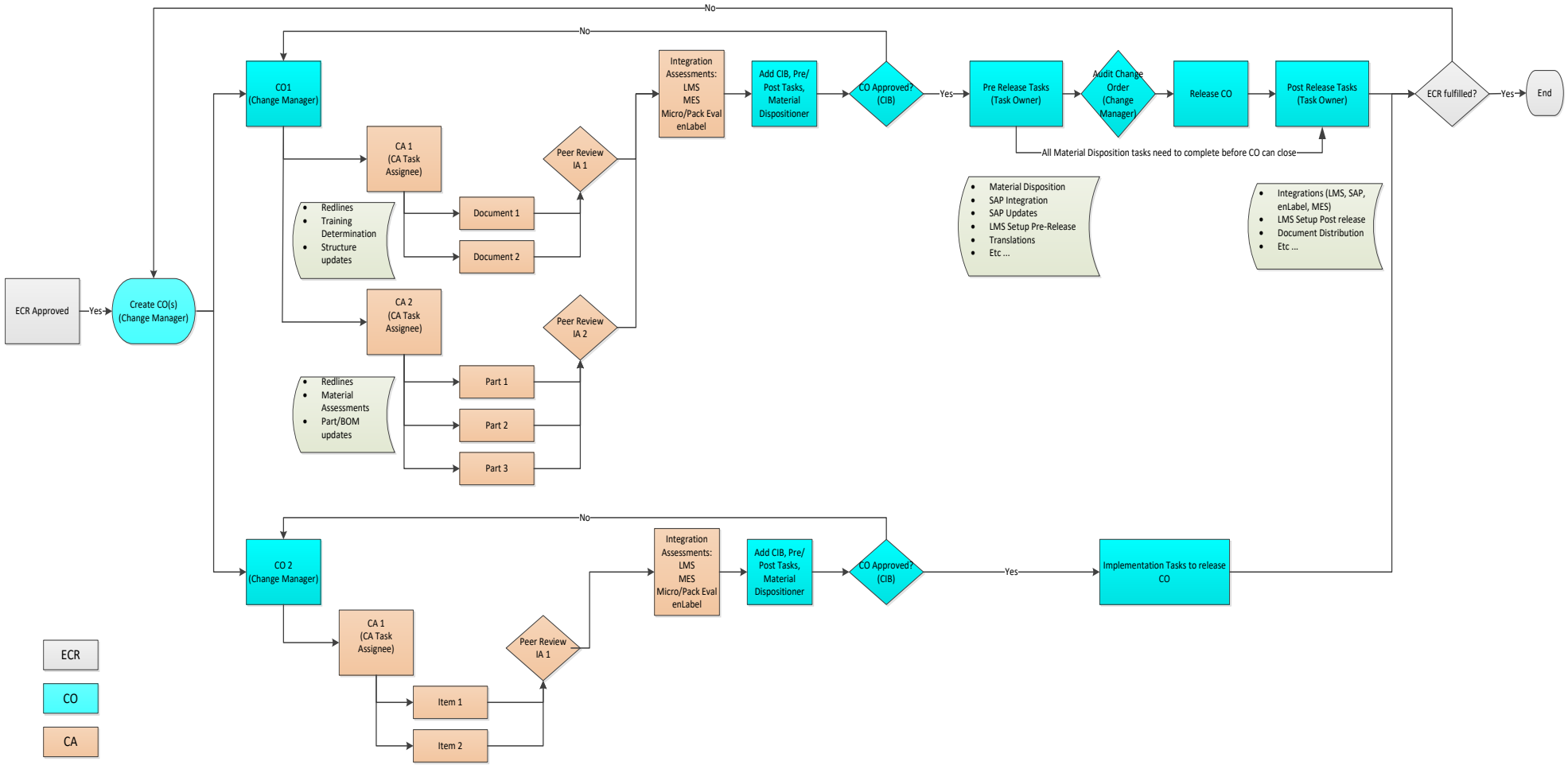
5.0 FLOW CHART

See Section 7.0 for instructions on completing each step in the Change Order process.



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6.0 REQUIREMENTS

6.1 General Requirements/Information

Step	Action
1	Every Change Order (CO) must be associated with an Enterprise Change Request (ECR).
2	The Change Order (CO) is the implementation plan for a change. It is made up of Change Activities, and is often referred to as the shell of the change. The Change Activity (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 the formal CO Review and Approval stage. • The intent of the CO is to group items that need to release together and typically have the same, or similar, approvers. The CAs are reviewed and approved as part of the CO package. Change Manager (CM) is responsible for creating and managing the change. Most Pre- and Post-Release tasks are generated by Windchill as part of the routing process. There may be instances where a CM manually creates Pre- and Post-Release tasks. If all documents on the CO can be processed as Fast Track, the documents will release upon approval of the Change Order. See Appendices A and B for a list of document types and sub-types that can be processed via Fast Track.
3	Sections 6.1 thru 6.8 apply to all CO Target States; additional/specific requirements are listed in each CO Target State, sections 6.9 thru 6.12. The CO can be tracked using the Lifecycle Map found at the top of the Details tab for the change.

6.2 Pull Backs and Rejection

Step	Action
1	A CM can pull back a CO. Select the appropriate Routing Option (Pull back reason) and enter comments describing in more detail why the pullback was needed. Once corrections are made, resubmit the CO for review and approval. Only CIB members can reject. A CIB member should not request a Pullback. When the CO is rejected, review the feedback, make changes accordingly, and resubmit the change for review. **NOTE: Pull back option is unavailable until at least one CIB vote has been completed.**

6.3 Affected/Resulting Objects

Step	Action
1	Part objects undergoing a change are added to the Affected/Resulting Objects table, and need to be at the correct Lifecycle state. • A part object at Pre-Released or Released state is added to Affected Objects section. This allows for material disposition. • A part object at Draft or In Work state is added to Resulting Objects.
2	Documents undergoing a change are added to the Resulting Objects table, and need to be at the correct Lifecycle state. • A document object at Draft or In Work is added to Resulting Objects.
3	The Windchill document name should match the actual document name in the header as closely as possible given the Windchill character restrictions (limited to 60 characters).
4	Ensure document and part object attributes are correct (e.g., Affected Sites, Business Owner, Training Required).

6.4 Document/Part Structure

Step	Action
1	Confirm parts and documents meet stated Windchill structuring requirements as defined in 87117, Create and Maintain Document and Part Structure.

6.5 Document Revisions and Releases

Step	Action
1	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 then uploaded as primary content for review. • For complete rewrite a clean copy is uploaded as the primary content. **NOTE: 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.**
2	For tabulated BOMs, ensure that new part numbers are added or that updates are redlined on the affected drawing.
3	Documents are formatted per the current applicable template. If not, justification for that decision must be provided in the CO description.

6.6 Translations

Step	Action
1	Translations are based on Document Types and Affected Sites. Some translation tasks will be automatically initiated, see Appendix D – Document Types Requiring Translation. For translations of Quality Systems procedures, refer to 87375, Translation Attachments Identification for the required Language and Translation site. • If it is determined that the document requires translation, indicate on the CO for a CM to create a manual Pre-Released task. • If translation is necessary for a document that is at a Released state, a Non-Rev Change Order is required. **NOTE: For business critical needs, translation activities may be bypassed and performed on a subsequent Non-Rev CO. These COs should be completed under the same ECR as the original release.**

6.7 Training Determination

Step	Action
1	For COs containing document types that require training, Windchill generates a Make Training Determination task. Windchill does not allow completion of the CA until the task is complete.
2	For COs containing document types that do not normally require training, training materials can be created and distributed using LMS or classroom, if deemed necessary. For these situations, set the document object's training attribute to "yes" when entering the training determinations in Windchill.
3	The reasons training requirements are electronically entered into the CO: • Appropriate review and approval of the CO package by the CIB. • Communicate to LMS Administrators that training should be set up per the training plan attached to the CA. • Coordinate required classroom and/or hands-on training with the release of the CO. • Training materials are attached to the Attachment section of the Document objects (e.g., Knowledge Questions, Supplemental Materials). **NOTE: For COs containing documents that do not normally require training, and training is indicated, manually initiate completion of the training assessment task by including instructions in the CO description field.**

6.8 Material Assessment

Step	Action
1	For COs containing parts, Windchill generates a Make Material Assessment task. Windchill does not allow completion of the CA until the task is complete. The CA Assignee determines the proper interchangeability assessment and part disposition on the Pre-Released or Released version.

6.9 Pre-Released State

Step	Action
1	A CO with Pre-Released target state can only be completed in the Product Development and Production Libraries.
2	For Pre-Released state, the following criteria must be met: • The affected object state is Draft. • Document redlines are uploaded and set to state Redline. A final copy with changes accepted is uploaded for review and approval.
3	For COs that have CAs containing part objects, the Make Material Assessment is required. **NOTE: Does not apply to first Pre-Released version.**
4	If the documents on the CO need training, attach the Training Plan. The training task will need to be created and assigned manually. Training Determination or Pre- and Post- Release Tasks are not system generated. An instruction must be included in the CO description to create a training task.

6.10 Released State

Step	Action
1	A CO with Released target state is used when all resulting objects are being released for production use.
2	The CA resulting objects must be at an In Work state (both documents and part objects) before submission of the CO. If objects at a state other than In Work are added as resulting objects, a warning box will be displayed. The Change Activities cannot begin until the errors are corrected.
3	For COs that have CAs containing part objects, the Make Material Assessment is required. **NOTE: Does not apply to first Released version.**
4	Regulatory should evaluate if the change is reportable to any specific geography. This is documented in the Regulatory assessment at the CO level.

6.11 Inactive State

Step	Action
1	A CO with Inactive target state is used when all resulting objects on the CAs for the CO are being set to an Inactive state. **NOTES:** ➢ **Target State Inactive is used for inactivating the specification and all parts listed in the specification.** ➢ **If all of the materials on a specification are being inactivated, a new revision to the part or specification is not required.** ➢ **For LMS, a manual Post- Release task is created to complete activity. Refer to 87130, Complete Pre- and Post-Release Task.**
2	For Inactive state, the following criteria must be met: • The state of Resulting Objects must be Released or In Work. • A Where Used and Keyword Search are included showing proper upward, downward and reference relationships have been addressed, with the exceptions stated in the following notes. **NOTES:** ➢ **QS documents moving to an Inactive state** • **Do not require a Where Used and Keyword Search.** • **Do not need to be removed from any Product Structure.** ➢ **Parts moving to an Inactive state:** • **Do not require a Keyword Search.** • **Require a Where Used to verify that Parent Parts using this Part in their Product Structure meet one of the following conditions:** ○ **Latest version lifecycle state = Inactive** ○ **Latest version lifecycle state = Obsolete** ○ **Latest version lifecycle state = In Work or Draft, and no previous version has reached Pre-Released or Released.** ○ **Latest version lifecycle state in any other state, but is also included on the same CO's Affected Objects.** • **Where-used must also be verified via SAP. All higher level materials that contain the material with an inactive target state must either be on the same CO or already be at cross plant material status of Z1, Z5, or Z6.** • **If the part object is used in a bill of material, the part object needs to be removed from the structure.** • If Parent is moving to Inactive, the structure will remain in place. • If Child is moving to Inactive, the inactive Child must be removed from the structure except for QS Documents and Parts as stated above.

6.11 Inactive State

Step	Action
3	Check Submit Rules for Target State – Inactive: • An Inactive CO has limited check submit rules since it is a “state change” CO. • If an Inactive CO contains part objects, a Make Material Assessment is required.

6.12 Obsolete State

Step	Action
1	A CO with target state of Obsolete is required when a resulting object is set to a target state of Obsolete. **NOTES:** ➢ **Target State Obsolete should be used to obsolete the specification and all parts listed in the specification.** ➢ **If all of the materials on a specification are being obsoleted, a new revision to the part or specification is not required.**
2	For Obsolete state, the following criteria must be met: • The affected objects can be in any state. • A Where Used and Keyword Search are included showing proper upward, downward and reference relationships have been addressed. This is to ensure that obsolete items are no longer referenced or used. Refer to 87124, Guide for Creating and Managing Change Order. • If Parent is set to Obsolete, the structure will remain in place. • If Child is set to Obsolete, the obsoleted Child must be removed from the structure. • For documents being replaced with a new document, a watermark or note should be added to the header indicating that the document is obsolete and list the replacement document. If the document is not being replaced, the watermark/note is optional.
3	Where Used The latest version of a parent that uses the child is reported. • Where used is required to be attach to the CO. • Obsolesced item is removed from the parent document and structure.
4	Keyword Search Keyword searches are performed against an index of keyword data. The search index includes keyword data taken from all object attribute values and the content of document files that have been uploaded to Windchill. • Keyword search is required to be executed and exported. The results are reconciled and attached to the CO. • A new column is added to the spreadsheet to reconcile, suggested title: *Reconciliation.*

6.12 Obsolete State

Step	Action
	• References from the search results are reconciled and documented within the new column, with one of the following; ○ **CO Number**: CO used to remove the reference of the document being obsolesced if reference is within document that is Released or Pre-Released, Typically, the same Change Order is used. If there are additional COs listed, a manual Post-Release task is required to ensure activities are closed. ○ **N/A – Record**: If reference is within a document this is a record (e.g., Report, lifecycle state is Obsolete) ○ **N/A**: Provided justification if reconciliation of reference is not required (e.g., reference to the document being Obsolesced is PLM meta-data and does not exist in document).
5	Check Submit Rules for Target State – Obsolete: • A CO with Obsolete target state has limited check submit rules since it is a "state change" CO. • If an Obsolete CO contains part objects, a Make Material Assessment is required.

6.13 Non-Rev

Step	Action
1	A Non-Rev CO executes iteration-only ("no content revision) changes (e.g. 1.1 to 1.2 or B.5 to B.6) on document and part objects with Pre-Released or Released states. See Appendix G for information on what types of changes can be completed using a Non-Rev CO.
2	A Non-Rev CO cannot be used to change the following integrated attributes:
3	For Non-Rev COs, the following criteria must be met: • List the Non-Rev change reason in the description of the CO. **NOTE: This is necessary in order to understand why the Non-Rev Target State is appropriate and to verify that the appropriate approvers are included.**

Part Attributes	
Base Qty	Lab Office
Base Unit of Measure	Material Type
Description/Name	Number
BOM Attributes	
Base Qty	BOM Quantity
BOM Component	BOM Unit of Measure
BOM Line Number	BOM Usage
BOM Reference Designator	MES Route Step
BOM Phantom	Substitute Component

6.13 Non-Rev

Step	Action
	• The affected objects (both document and parts) state must be at Released or Pre-Released. Do not promote objects to In Work or Draft states, thereby “revving” the object. • The attachments depend upon the type of required changes. Some examples include: ○ Typographical corrections should have a redline version of the released document. ○ Extension to SAP plant should have a Part Extension Form. ○ Structure changes should have the revised structure information. ○ Affected Site(s) revisions information should be detailed in the CO Description field. No attachments are required. ○ Affected Site(s) attribute changes on document subtypes that require training, a training plan is required. ○ Training updates should have a completed training plan attached to the Change Activity.
4	Check Submit Rules for Non-Rev • A Non-Rev CO has limited Check Submit Rules.

6.14 Records Retention Flow

Step	Action
1	A Records Retention workflow allows for release of completed record objects in Windchill following an abbreviated processing path. See Appendix C for a list of the types of documents that can be completed using a Records Retention Change Order. If a Records Retention workflow is rejected, it returns to the CM for rework assignment.
2	The path for Records Retention workflow is: **Creation→Submission→CIB Review→Approval→Release**
3	For Records Retention workflow, the following criteria must be met: • The resulting object state is either Draft or In Work. • The primary file must display a clean, digital image, with no redlines. Signed and dated corrections on the original record are allowed. • Structure for Records Retention objects are completed by the Change Manager prior to submission.
4	When the Records Retention workflow is approved, Windchill automatically sets the objects to Pre-Released or Released state (depending on the initial state), and the workflow moves to Resolved state. No further action is needed.
5	A Records Retention workflow will not generate a Translation Task. A Non- Rev CO is required to update or create translation documents.

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7.0 CREATE A CHANGE ORDER

7.1 General Requirements

Step	Action
1	A CM creates a CO structured to an open ECR or revises an existing CO. The CM also creates CAs structured to the CO and assigns tasks to identified roles. The CO must align with the scope of the ECR and comply with the functional assessments. A CM creates and manages the CO, assigns Approvers to the CIB, and also assigns Task Owners and a Material Dispositioner, as well as Audits the CO. A CM creates and manages the CA, assigns the CA Assignee to complete the CA, and assigns Peer Reviewers.
2	A CM is responsible for managing the change. This includes: • Tracking the progress of the change and interacting with those involved with the change. • Completing tasks as required to keep the process moving. • Reassigning tasks if needed. Once a change is started, Windchill will continue to route the change; CM may need to follow up with Assignee(s) to facilitate progress. • Follow-up is an important part of managing the change. CM needs to follow up with Assessors, Approvers, CA Assignees, and other Task Owners.

7.2 CO Attributes

Step	Action
1	When creating a new CO, the CM completes the required attributes and task determination questions.
2	**Name** The CO name clearly identifies the intent of the change. Examples: Update to <title of document here> or Initial Release of <title of document here>

7.2 CO Attributes

Step	Action

3	**Description**
	Describe the changes being implemented by the CO. Provide as many details as necessary to write a complete description, but be concise. If the description exceeds the field character length, include as an attachment and indicate the name of the attachment in the field.
	
	At a minimum, the CO description must:
	• List what is being affected:
	  ○ Model/Reorder Numbers, if applicable
	  ○ Software revision, if applicable
	• Describe what is changing.
	• Describe the current state and future state.
	• List changes made to each affected document or part.
	• List changes made to document or part structure.
	• Explain the attachments required in support of the change.
	• Indicate the Approver for whom a designated Proxy Approver will be approving, his or her role, and that a Change Specialist from Documentation Services will act as a Proxy, if applicable.
	• List additional Pre- or Post-Released tasks.
	• List additional Translation Tasks.
	
	An effective description of the change typically starts with action verbs: release, update, change, revise, correct, etc.
	
	Examples:
	• Releasing ZFINs and associated specification for product family Advisor HD Mapping.
	• Updated the Change Control Process Work Instructions as part of Quarter 4 2016 enhancement.
	• Releasing qualification of new manufacturing and service lines for the Agilis product family.
	
	Before submitting, ask:
	• Is it clear and concise?
	• Does it address all objects included in the CO?
	• Will it withstand the passage of time?
	• Will it hold up in an audit?
	• Is it easily understood by a non-technical person?

7.2 CO Attributes

Step	Action
4	**Justification** Explain the reason the change is being implemented. Provide as many details as necessary to write a complete Justification, but be concise. If the Justification exceeds the field character length, include as an attachment and indicate the name of the attachment in the field. At a minimum, the Justification must: • Explain why the change is needed and how its impact to the quality system or validated state of the product and/or process has been mitigated. Provide a brief summary of Supporting Evidence for the change (note referenced documents must be in Released or Pre-Released state).
5	**Target State** Select the desired Target State: • Pre-Released • Released • Inactive • Obsolete
6	**CO Non- Rev Change** Select Yes if CO is Non-Rev

7.2 CO Attributes

Step	Action

7	**Task Determination Questions**
	It is important how the questions are answered as the answer determines Pre- and Post-Release task assignment.
	• Was product testing performed to justify implementation of the change?
	  ○ Select None Required or Testing Complete
	• Does Change impact a Packaging BOM?
	  ○ Select Yes to generate a Implement changes impacting Repack Rules Configurator in SAP task in order to update ZRPK_RULESCONFIG01 table in SAP.
	• Does change require an update to the eIFU website?
	  ○ Select Yes to generate a Implement Changes to eIFU Webste task in order to update eIFU website with new content.
	• Does change require the Packaging Validation Configurator be uploaded to SAP?
	  ○ Select Yes to generate a Implement Changes Impacting Packaging Validation Configurator ZPVCONFIG01 task in order to upload the barcode validation template to reflect the correct items to be scanned.
	• Does change require a Shelf Life Extension in SAP?
	  ○ Select Yes to generate a Implement Changes Impacting Shelf Life Extension ZSLEXTCONFIG01 task in order to convert ZFIN shelf life extension
	• Does change require an update to a Drawing?
	  ○ Select Yes to generate a Implement CAD Changes task to replace redlined CAD drawing content in WC with the final drawing.
	• Does change require any documents to be retyped?
	  ○ Select Yes to generate a Retype and Move a Document to the Appropriate Library task in order to update the document type/sub type and move the document if necessary.
	• Is this change revising documents with no change to training audience or materials?:
	  ○ Select No, if training is required. Task will be assigned to LMS to update.
	  ○ Select Yes, if training is not required. Task will not be assigned to LMS to update.
	• Does this change require an update to the LMS training audience?
	  ○ Select Yes to generate a LMS Update Training for Non-Rev changes.
	• Is Label (enLabel integrated) being added to or being changed in a BOM?
	  ○ Select Yes to generate a Changes Impacting ZCONFIGLABEL in ERP in order to update and verify the ZCONFIGLABEL.

7.2 CO Attributes

Step	Action
8	**Project Name** Select a Project Name, if applicable. **NOTE: To request additional Project Name be added to the list, email WCQualitySupport@sjm.com.**

7.3 CO Attachments

Step	Action

1	Attachments can be added to the CO to support the entire change. This may include:
	• Additional Description or Justification if characters exceed the limitation.
	• 87166, Verification/Validation Assessment Form
	  ○ Form is required for document types listed on Appendix F.
	  ○ Not required if Plano, Portland, or Liberty are the only affected sites.
	  ○ Not required for Non-Rev CO.
	• 94-2285, Form, Change Analysis (NMD)
	  ○ Form is required for Plano, Portland, or Liberty. If other sites are impacted, 87166 is also required.
	  ○ Not required for Non-Rev CO.

7.4 Create a Change Activity

Step	Action
1	The CM creates one or more CA structured to the CO which identifies the task, the Assignee, and the Peer Reviewer(s). The CA should be created so that Peer Reviews are completed within the same functional group, for examples:

Change Activity	Assignee	Peer Review
CA -1 consists of all Parts	ME	ME, Supply Chain
CA -2 consists of MP	ME	OPS, ME, QE
CA - 3 Rename Documents or Parts	Library Admin	CM

7.4 Create a Change Activity

Step	Action
2	**Name** The CA name should be specific to the CA: Examples: • Release of drawings for the Accu Cutter • Initial Release of MP 90260205 • Update Product Hierarchy for Material 44-0187-01
3	**Description** The CA description should be specific and concise. Describe 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. Use relevant items from the CO description, if applicable. Examples: • Revise the part object 600005236 to update the BOM. • Structure the applicable documents to 86084. • Create new document number and release IQ Protocol. • Create new ZRAW Part and new Material Specification.

7.5 CA Assignee

Step	Action
1	The CM assigns the CA Assignee. The CA Assignee is notified of the CA and completes the task per the Description. • To complete the CA task, refer to 87128, Complete a Change Activity.

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7.6 Peer Review

Step	Action
1	The Peer Review provides an opportunity to verify that the requirements have been met. Peer Reviewers are selected by the CM. The CA Assignee can bypass Peer Review, however **a justification must be provided to skip Peer Review**. Documents that reside in the SJM Quality System Library require a cross-functional Peer Review that includes impacted site representatives and functional areas. Peer Reviewers may include: • Final CIB Approvers • Technical Reviewers • Individuals requesting inclusion • Site representatives • Should include functional groups impacted
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. • To complete the Peer Review task, refer to 87138, Complete Peer Review.
3	**Feedback** 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.

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7.7 Affected/Resulting Objects

Step	Action

1	• Part objects undergoing changes are added to the Affected/Resulting Objects section and must be at the correct state.
	  ○ A part object at Pre-Released or Released state is added to the Affected Objects section.
	  ▪ The Make Material Assessment is required to disposition the prior Pre-Released or Released version.
	  ○ A part object at Draft or In Work state is added to the Resulting Objects section.
	• A document object at Draft or In Work state is added to the Resulting Objects section.
	• Documents and part objects undergoing a change to an Inactive or Obsolete target state are added to the Resulting Objects section.
	• For Non-Rev CO, an object at Pre-Released or Released state is added to the Resulting Objects section.
	NOTES:
	➢ **Objects cannot be placed on multiple CAs.**
	➢ **Objects are not required to be added when creating a CA.**

7.8 Integration Assessments

Step	Action
1	Upon approval of the CA, Windchill moves the CA to the Integration Assessment state. This consists of the following activities, which are created by Windchill, depending on the document type and attributes of the affected objects on the CA. Task Owners are responsible for completing the following tasks, as applicable. • Submit/Update Labeling • Review Training Plan for LMS • MES Setup • Microbiology/Packaging Assessment

7.9 Submit Change Order for Approval

Step	Action
1	The CM is assigned the Start Change Activity Management task to add CIB members. The CM also adds Pre- and Post- Released Task Owner(s), and Material Dispositioner. The CM identifies individuals for each of these roles.
2	• Each Affected Object on the CO requires approvers based on the Target State, Document Types, and Attributes (e.g., Business Owner, Affected Sites, and Source). If there are multiple Affected Objects, add all required approvers to cover all affected object types, attributes, etc. • For information on which approver roles to include refer to the 87140 CIB Approval Requirements. Depending on the CO, additional approvers may be included as part of the CIB. **NOTE: If there are questions on identifying CIB members using the approval requirements document, especially for complex changes, consider consulting with a Change Specialist or a functional subject matter expert. This will minimize the potential for rework or additional CO activity.** • For objects shared, a member of the Sylmar Documentation Services team needs to be added as an additional approver to ensure a change is also initiated to update the part in TeamCenter. Part objects are identified using the Shared PLM System attribute. Documents are identified by affected site, and if controlled by TeamCenter are entered in the Description attribute of the document.

7.9 Submit Change Order for Approval

Step	Action
3	**Proxy Approval** • Proxy approval is necessary when a required approver does not have Windchill Approver permissions (including external approvals). In this instance, the Documentation Services personnel designated as the proxy approver electronically signs for the functional role. The Change Manager adds the Documentation Services individual to the appropriate approver role. **NOTE: Proxy approvals may also be used when it is not possible to obtain approvals within Windchill (e.g., individual is traveling without their computer).** • In the Description field of the Change Order, indicate the role the person approving by proxy is filling and that Documentation Services will sign electronically for the role. • Following submission of the CO, forward the following to the individual approving via proxy: o Proxy Review Form o Change Order Workflow Report o Copy of each file in the Resulting Objects (Redline and Clean) o Copy of each file in the document attachments o Copy of each file in the Change Activity attachments • Change Manager forwards the signed copy of the Proxy Approval to the designated Documentation Services individual. **NOTE: Documentation Services does not sign for the role in Windchill until a signed copy of the proxy is received from the CM. Documentation Services will then attach the signed proxy to the CO Attachments.**

7.10 Route for Change Implementation Board

Step	Action
1	• The CM sends the CO package to the CIB for review. • The CIB member is tasked with ensuring the CO, and all contained CAs, are correct and complete. • Regulatory assessment is completed by the Regulatory approver, if required. NOTE: If cancellation is required, CO can be canceled.
2	**Approval by CIB** To approve the CO, the CIB member selects Approve and signs the CO with their user name and password. Once all CIB members have approved the CO, it moves forward through the workflow.
3	**Rejection by CIB** A CIB member may reject the CO by selecting one or more Rejection reasons, entering comments providing more information about the rejection, and signing the CO rejection with their user name and password. Upon one vote by a CIB, the CM has the ability to pull back the CO or wait for all CIB members to vote. If the CO is rejected, the change will go back in the process to be updated and then go through review again.
4	**Proxy Review** The CO can be approved or rejected via proxy form using the following methods: • Physically signing a paper copy and providing a scan electronically • Electronically using a validated system.

7.11 Pre-Release Task

Step	Action
1	Windchill may generate Pre-Release Tasks after Change Order (CO) approval. A Pre-Released task is used to assign activities which need to occur prior to the CO releasing. Some examples are: SAP updates, translation, MES Setup, CAD updates, etc.
2	CM may manually create additional Pre-Release tasks, using the Create Pre-Released Ad hoc Task. • 87130, Complete Pre- and Post-Release Task

7.12 Audit Change Order

Step	Action

1	• Verify the following during completion of the Audit Change Order Task:
	  ○ Documents are updated and redlines have been accepted.
	  ○ Part and document attributes are accurate
	  ○ Structure has been updated correctly
	  ○ SAP is correct and complete, applicable BOM, route, cost and planning data are verified, and the effectivity date is correct.
	  ○ Translation tasks are complete and attached to the document object.
	• The scheduled release date can be entered. If a date is not entered the CO releases immediately.

7.13 Release Change Order

Step	Action
1	Upon completion of the Audit Change Order, the CO immediately releases unless a scheduled released date is entered.
2	COs that impact enLabel are scheduled to release at 11:00pm Central Time on the date selected.
3	For production related COs, consider the impact to production before allowing the COs to release immediately.

7.14 Post-Release Task

Step	Action
1	Windchill may generate Post-Release Tasks after the Change Order is Released. A Post-Release Task is used to assign activities which need to occur after CO Release. Some examples are: LMS updates, document distribution, GUI updates, etc.
2	CM may manually create additional Post-Release tasks, using the Create Post-Released Ad hoc Task. • 87130, Complete Pre- and Post-Release Task

7.15 Completion of Change Order

Step	Action
1	Upon completion of the Post-Release Tasks, the Change Order state is set to Closed.

8.0 APPENDICES

Appendix A: Reference List of Fast Track Doc Types – Product Development Library

Appendix B: Reference List of Fast Track Doc Types – Production Library

Appendix C: Record Retention Doc Types – Production Library

Appendix D: Document Types Requiring Translations

Appendix E: Document Types Requiring Validation/Verification Assessment

Appendix F: Non-Rev Changes

Create and Manage Change Order

APPENDIX A: REFERENCE LIST OF FAST TRACK DOC TYPES – PRODUCT DEVELOPMENT LIBRARY

Product Development Library – Fast Track	
Document Type	**Document Sub Type**
Design and Development Other	Additional Release Authorization
Design and Development Other	Design History File
Design and Development Other	Design Review
Design and Development Other	Design Transfer
Design and Development Other	Development Installation Qualification
Design and Development Other	Development Equipment / Tooling / Fixture
Design and Development Other	Development Equipment Specification
Design and Development Other	Development Technical Report
Design and Development Other	Integrated Business Plan
Design and Development Other	Market Release
Design and Development Other	Miscellaneous DHF
Design and Development Other	New Technology Assessment
Design and Development Other	Inspection Validation
Design and Development Other	Clinical Evaluation
Design and Development Other	Clinical Product Qualification Plan
Design and Development Other	Clinical Product Qualification Protocol/Report
Design and Development Other	Physician Access Release Authorization
Design and Development Other	Supplier Assessment
Design and Development Other	Device Plan
Design and Development Other	Device Design Document
Design and Development Other	Additional Clinical Authorization
Design and Development Other	Clinical Trial Authorization
Design and Development Other	Special Release Authorization
Design and Development Other	Limited Market Release
Design and Development Other	Non Device Software Executable
Design Validation	Clinical
Design Validation	Design Validation
Design Verification	Biocompatibility
Design Verification	Design Verification

Create and Manage Change Order

Product Development Library – Fast Track	
Document Type	**Document Sub Type**
Design Verification	Distribution Test / Package Verification
Design Verification	Packaging Validation
Design Verification	Shelf Life / Accelerated Aging
Design Verification	Design Test Method
Design Verification	Design Test Method Validation
Process Validation	Process Validation
Requirements Documents	Applicable Standards Document
Requirements Documents	Customer Requirements
Requirements Documents	Design Input/Design Output Summary
Requirements Documents	Product Requirements
Requirements Documents	Device Requirements
Risk Management	Cybersecurity
Risk Management	FMEA, Design
Risk Management	FMEA, Process
Risk Management	FMEA, Use
Risk Management	Risk Analysis/Hazard Analysis
Risk Management	Risk Management Plan/Report

Create and Manage Change Order

APPENDIX B: REFERENCE LIST OF FAST TRACK DOC TYPES – PRODUCTION LIBRARY

Production Library – Fast Track	
Document Type	**Document Sub Type**
Manufacturing	Manufacturing Quality Report
Misc Production	Facilities
Misc Production	Firmware Executable
Misc Production	Marketing Literature - Inventoried
Misc Production	Non Production Marketing Literature
Qualification	Analytical Instrument Qualification
Qualification	Environment Qualification
Qualification	Industry Standard Assessment
Qualification	Inspection Method Validation
Qualification	Installation / Operations Qualification
Qualification	Installation Qualification
Qualification	Master Validation Plan/Report
Qualification	Microbiology Equipment Qualification
Qualification	Operational Qualification
Qualification	Other Qualification/Study
Qualification	Process Characterization
Qualification	Performance Qualification Plan/Report
Qualification	Product Performance Qualification
Qualification	Production Test Method Validation
Qualification	Purchased Component Qualification Report
Qualification	Software Validation
Qualification	Software Verification
Qualification	Sterilization Validation
Qualification	Technical Report
Specification	Non Device User Requirements Specification
Specification	Quality Service Specification
Specification	Software Design Document
Specification	Software Requirements Specification
Specification	System Requirements Specification
Testing	Test Method Transfer
Testing	Test Method Validation

Create and Manage Change Order

APPENDIX C: RECORDS RETENTION DOC TYPES – PRODUCTION LIBRARY

Production Library – Records Retention	
Document Type	**Document Sub Type**
Records Retention	Field Action Closure Requests
Records Retention	Field Action Consignee Lists and Communications
Records Retention	Field Action Government Communications
Records Retention	Field Action Govt Report
Records Retention	Field Action Govt Supporting Docs
Records Retention	Field Action Reconciliation
Records Retention	Field Action Reference Document
Records Retention	Field Action Sales Packet
Records Retention	Lab Notebook
Records Retention	Manufacturer Manual
Records Retention	Measurement Template
Records Retention	NRTL Report
Records Retention	REACH
Records Retention	RoHS
Records Retention	REACH/RoHS
Records Retention	Windchill Training Record

Create and Manage Change Order

APPENDIX D: DOCUMENT TYPES REQUIRING TRANSLATIONS

Requires Translations	
Costa Rica	
Manufacturing	Form
	Inspection Procedure
	Manufacturing Procedure
	Work Instruction
	Shop Floor Paperwork
	Visual Standard/Aid
Misc Production	Facilities
	Training Document
Procedure	Equipment, Maintenance Procedure
	Equipment, Calibration Procedure
Quality System	Form
	Guidance Document
	QS Work Instruction
	Quality Manual
	Standard Operating Procedure
	Template
Specification	Equipment/ Tooling/ Fixture
	Equipment Specification
	General Specification
	Material Specification
	Process Specification
	Supply Specification
	System Requirements Specification
Testing	Test Method
	Test Method Validation
SJM Quality System	Form
	Guidance
	Manual
	Process SOP
	Standard Operating Procedure
	Template
	Work Instruction

Create and Manage Change Order

Requires Translations	
Brazil	
Manufacturing	ERP Routing
	Form
	Manufacturing Procedure
	Shop Floor Paperwork
	Manufacturing Quality Plan
	Manufacturing Quality Report
	Visual Standard / Aid
	Work Instruction
Misc Production	Training Document
Procedure	Equipment, Maintenance Procedure
	Equipment, Calibration Procedure
	Lockout / Tag out Procedure
	Receiving Inspection Procedure
Quality System	Form
	QS Work Instruction
	Quality Manual
	Standard Operating Procedure
Specification	General Specification
	Material Specification
	Artwork Specification
	Equipment/ Tooling/ Fixture
	Equipment Specification
	Instructions for Use
	Labeling Specification
	Packaging Specification
	Process Specification
	Quality Service Specification
	Supplementary IFU
	Supplementary IFU Artwork
	Supply Specification

Create and Manage Change Order

Requires Translations	
Testing	Test Method
	Test Method Validation
SJM Quality System	Form
	Guidance
	Manual
	Process SOP
	Standard Operating Procedure
	Template
	Work Instruction

Create and Manage Change Order

APPENDIX E: DOCUMENT TYPES REQUIRING VALIDATION/VERIFICATION ASSESSMENT

Library	Document Type	Doc Sub Type
Product Development	Requirements Documents	Applicable Standards Document
		Customer Requirements
		Product Requirements
Production	Manufacturing	ERP Routing
		Form
		Inspection Procedure
		Manufacturing Procedure
		Shop Floor Paperwork
		Visual / Standard Aid
Production	Manufacturing	Work Instruction
Production	Procedure	Equipment, Calibration Procedure
		Equipment, Maintenance Procedure
		Receiving Inspection Procedure
		Product Service Procedure
		Biomed Product Service Procedure
Production	Specification	Artwork Specification
		Equipment Specification
		Equipment / Tooling / Fixture
		Instructions For Use
		Labeling Specification
		Material Specification
		Packaging Specification
		Process Specification
		Quality Service Specification
		Software Requirements Specification
		Software Design Document
		Supplementary IFU
		Supplementary IFU Artwork
		Supply Specification
		System Requirements Specification
		General Specification
		Non Device User Requirements Specification
Production	Testing	Test Method

Create and Manage Change Order

APPENDIX F: NON-REV CHANGES

Non-Rev Changes	
Change Reason	**Description of Usage**
Add/Remove Affected Sites for LMS Training	To add/remove affected sites that requires LMS Training
Add/Remove Attachments	To add/remove attachments to an object (e.g. attaching translations).
Component Allocation	To request an update to the operation a component(s) is allocated to.
Component Qualification Change	To request an update to component qualifications within SAP.
Document Object Attributes	To request changes to attributes for a document object.
Document to Document Structure	To request structuring of a document to a document, with no content changes.
Document to Part Structure	To request structuring of a document to a part (or vice versa), with no content changes.
Implementation Errors	To request an update due to an error in implementation, including but not limited to matching document revision to WC revision.
Inventory Management	To convert inventory a) to a new/different part number and/or b) when numeric revision components go to alpha revision in SAP.
Load Error	To request a fix for an error created due to/during a load.
Load Manually Approved Docs	To document the load of manually approved documents.
Match SAP to Windchill	To request SAP data to be updated to match previously released Windchill data.
Material Disposition	To request material disposition be performed to align with a previously released CO (e.g. if a CO missed or incorrectly documented dispositioning).
Missed Approver	To document a signature of a missed approver.
Part Object Attributes	To request attributes changes to non-integrated fields for a part object.
Quality Information Record (QIR)	To request corrections to meet previously approved updates to QIR or to update Quality Management view for purchased parts.
Redlines Incorrectly Incorporated	To request corrections of a released document to meet the approved redlines, such that they didn't properly incorporate when "accepted".

Create and Manage Change Order

Non-Rev Changes	
Change Reason	**Description of Usage**
SAP Plant Extension (Buy)	To request an extension in SAP for a buy part number.
SAP Plant Extension (Make)	To request an extension in SAP for a make part number. This also includes BOM extension to non-integrated SAP plants (Manufacturing and Distribution).
SAP – Correct ZFIN to ZMOD Relationship	To request a correction to the ZFIN to ZMOD relationship to be made in SAP.
SAP – Phantom Set Up	To request the setup of a phantom within SAP.
SAP – Product Hierarchy Update	See 87274
SAP – Updating Router Times or Scrap, Work Center	To request an update for costing information within SAP Routing data including times, scrap, and/or WorkCenter.
Shelf Life	To update the shelf life listed within SAP to align to Released data/documentation. This is not for updating a shelf life listed in a released document/drawing/specification.
Training Plans	To request a change to a training plan for a released CO (e.g. adding/removing listed trainers).
Typos/Grammar/Formatting	To request fixes for typos, grammar, formatting that do not change the intention/usage of the Released documentation.
Update ZCONFIG table	To request an update to the ZCONFIG table within SAP.