Review Change Order

1.0 PURPOSE

This procedure defines the responsibilities for a Change Implementation Board member to review a Change Order in Windchill.

This procedure applies to all locations that route Change Orders through Windchill.

2.0 REFERENCES

2.1 Applicable Documents

Number	Title
87143	Guide for Reviewing Change Order
87145	Change Order Proxy Review
87146	OEM Proxy Review

2.2 External References

Number	Title
N/A	N/A

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3.0 RESPONSIBILITIES

Function or Title	Responsibility
Change Implementation Board (CIB)	Reviews Change Orders and associated Change Activities for approval.

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 SJM 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 CO.
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 system search engine for content, attributes, document number, etc.
Lifecycle 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

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Term	Definition
	SAP updates to fields not integrated with Windchill.
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 and retained 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 review and approval.
Pre-Released	A lifecycle state where the object is available for development 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 CO.
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 CO release but before CO is Closed.
Released	A lifecycle state where the object is available for production activities.
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.

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5.0 FLOW CHART

N/A

6.0 INSTRUCTIONS

6.1 General Requirements

Step	Action
1	The Change Implementation Board (CIB) ensures the Change Order (CO) is complete based on the change Description and the proposed changes are appropriate. • See Appendix A for additional, functional focused responsibilities

6.2 Review Change Order

Step	Action
1	**Name** That the name clearly and concisely identifies the intent of the change.

2	**Description**
	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.
	
	Justification
	At a minimum, the Justification must:
	• Explain the reason the change is being implemented.
	• Explain why the change is occurring and how it affects the quality system, product and/or process.
	• Provide a brief summary of Supporting Evidence for the change.

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6.2 Review Change Order

Step	Action
	Additional considerations: • 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?
3	**Target State** Verify if the Target State is correct.
4	**CO Non Rev-Change** Verify if CO meets requirement of a Non-Rev change.
5	**Task Determination Questions** Review Task Determination for completeness and understanding of expected impact.
6	**Attachments** 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 • 56-0368, Analyzing the Impact of Design and Process Changes (NMD)

6.3 Review Change Activity

Step	Action
1	**Name** The CA name is specific to the task.
2	**Description** The CA description should be specific and concise. The description describes what needs to be updated as part of the CA.

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6.3 Review Change Activity

Step	Action

3	**Attachments**
	• Structure/Routing Creation Form for new BOM/Routing and new document structure.
	• Structure redlines for changing BOM/Routing and revised document structure.
	• Training Plan when the documents require training.
	• Implementation Plan for affected document(s), when applicable
	• Inactive (with the exception of Quality System documents) or Obsolete parts or documents:
	  ○ Keyword search with reconciliation of reference relationships stated.
	  ○ Where Used report from Windchill (both parts and documents)
	  ○ Structure report (both parts and documents)
	• Component Qualification Plan for purchased parts.
	• Part Extension Form and/or Part Data Form for updates to parts as applicable
	• Software Executable that is recorded on hard media external to Windchill (NMD only).
	  ○ Ensure two copies of the media are provided to Documentation Services group.
	Terumo Supplier Notice of Change Form for parts or documents that impact Terumo.

4	**Affected/Resulting Objects**
	• Documents and part objects undergoing change are added to the Affected/Resulting Objects section and are at the correct state.
	  ○ An object at Pre-Released or Released state is added to Affected Objects section.
	  ○ An Object at Draft or In Work state is added to Resulting Objects.
	  ○ Documents and part objects undergoing a change to Inactive or Obsolete target state are added to the Resulting Objects.
	  ○ For Non-Rev CO, an object at Pre-Released or Released state is added to the Resulting Objects section.
	• Document redlines are uploaded as primary content and set to state Redline. A final copy with changes accepted is then uploaded as primary content for review.
	• Part and document attributes are accurate.
	• Structure is accurate.

5	**Material Assessment** For Change Activities containing part object types that require Material Assessment ensures Material Assessment is complete and correct.
6	**Training Determination** For Change Activities containing document object types requiring training, ensure training determination is complete and correct.

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6.4 Review Peer Review Comments

Step	Action
1	The Peer Reviewer can provide feedback to the CA Assignee, or approve accept the work. Review the Votes and Comments provided by the Peer Reviewers, ensure updates are complete and correct.

6.5 Approve or Reject Change Order

Step	Action
2	**Approve** When approving, the entire CAs that fall under the CO is approved. If all requirements have been met, approve the Change Order using your User Name and Password.
3	**Reject** When rejecting, the entire CO is rejected. CIB have the ability to indicate which CAs are being rejected and which are acceptable (Review Complete). Windchill will retain the Review Complete items therefore only the rejected CA are required to review after resubmission. If the CIB decision is to reject the CO, select one or more rejection reasons and provide comment concerning the issues that need to be addressed. CIB should review rejection comments and resubmission comments to help with review after rejection.
4	**Proxy Approval** The Change Order 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.

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APPENDIX A: FUNCTIONAL ROLE RESPONSIBILITIES

Functional Role	Typical Responsibilities
Finance	Review may be performed by an individual(s) cognizant of the applicable requirements and who is able to assess the financial aspects of the proposed change.
Additional Reviewer	Technical review may be performed by an individual(s) cognizant of the applicable requirements and who is able to assess the technical aspects of the proposed change.
CAD	Assess impact, and accuracy with regard to: • Format • Revisions of tabulated parts • Tolerance stack-ups • Dimensioning
Calibration	Assess impact, and accuracy with regard to: • Calibrated equipment drawing and specifications • Calibration test procedures
Clinical	Assess impact, and accuracy with regard to: • Clinical data, clarity and accuracy for users of the product and the welfare of the patient. • Evaluate proposed change and assess the impact of investigational devices and notification of Clinical Trial Investigators as required.
Customer Service	Review may be performed by an individual(s) cognizant of the applicable requirements and who is able to assess the Customer Service aspects of the proposed change
Documentation Systems	Assess impact and accuracy with regard to: • Conformance to Change Control Procedures • Configuration management requirements (Structure) • Non-Rev changes
Environmental Health and Safety	Review may be performed by an individual(s) cognizant of the applicable requirements and who is able to assess the Environmental Health and Safety aspects of the proposed change
Environmental Management Representative	Assess the impact, accuracy, and need with regard to continued compliance with the Environmental Management System and other applicable global regulatory requirements.
Evaluator - Microbiology (Non-Voting)	A member of the Microbiology function. Consider proposed changes and assess the impact and accuracy with regard to the Instruction for Use and the impact on inbox sterilization

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Functional Role	Typical Responsibilities
Evaluator - Packaging Engineering (Non-Voting)	A member of the Packaging Engineering function. Consider proposed changes and assess the impact and accuracy with regard to form, fit and function of packaging components and the impact on inbox sterilization.
Facilities	Assess the impact, accuracy, and need with regard to: • Production layout and facility capabilities • Effect of the Environmental Management System
Human Resources	Review may be performed by an individual(s) cognizant of the applicable requirements and who is able to assess the Human Resources aspects of the proposed change
Information Technology	Review may be performed by an individual(s) cognizant of the applicable requirements and who is able to assess the Information Technology aspects of the proposed change
Labeling	As applicable, assess the impact of the change(s) with regard to: • Symbol and translation alignment between the IFU and label • Regulations and business requirements • Packaging materials affecting device label design • Printing (e.g., set up in SAP ZCONFIGLABEL)
Legal	Assess impact, and accuracy with regard to: • Compliance with product trademarks • Product liability concerns • Intellectual property issues
Manufacturing Execution System -1 (MES Review 1)	• Update MES attributes on Part or Document. • Extract MES Data from Windchill.
Manufacturing Execution System -2 (MES Review 2)	Add proof of testing evidence to the Change Activity.

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Functional Role	Typical Responsibilities
Manufacturing Engineering/ Process Development	Assess impact, accuracy, and need with regard to: • Manufacturability and cell flow integration • Operator training and certification • Manufacturing documents such as Manufacturing Procedures/Forms, Shop Floor Paperwork, etc. • Material dispositions • Labeling • Labeling setup in SAP via ZCONFIGLABEL and implementation plan for label changes as appropriate • Laser Engraving Artwork is accurate and called out appropriately as necessary • Impact to remote manufacturing sites • Tooling, equipment and fixtures • Special handling and/or storage defined • Tool qualifications are completed prior to final release of the change. • Validation of process and software • Implementation of dispositions at all locations, excluding Field Returns • Product structures of released products. • Tooling, equipment and fixture drawings are at Alpha Released state prior to use in Production, and available for use • Update product configuration, and manufacturing and inspection procedures as required during process validation and verification activities. • Document and release all equipment and process validation protocols and reports as required. • Review SAP – Change Master – The Change Master should include a list of all the object types and objects that are included on the CM and that match up to the change in the Change Order. • Product Related • Work with Research and Development (R&D) to ensure that product configurations are correct for product builds. • Review document/part attributes for connection to Terumo and when Terumo items are changing, an approved Terumo Supplier Notice of Change is attached to the CO. On shared parts or documents, a change will be initiated by Terumo in the Terumo Windchill library.
Manufacturing/ Operations	Assess impact, and accuracy with regard to: • Shop Floor Paperwork • Material Disposition / Implementation plans • Training impact

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Functional Role	Typical Responsibilities
Marketing	Assess impact, and accuracy with regard to: • Compliance with product identification schemes (label/labeling) • Compliance to Market Specification and advertising claims • Overall content accuracy, graphics and verbiage • Image presented to the customer • Impact to existing marketing literature • Impact to customer requiring retraining and/or notification
Microbiology/ Sterilization	Assess impact, and accuracy with regard to: • International and domestic regulatory standards and specific divisional procedures. • Verification/validation activities affecting sterilization processes or sterilized products. Ensure the correctness of the decision regarding validation prior to approval. • Pyrogenicity testing of new or modified materials. • Sterilization requirements. • Labeling claims that involve the type of sterilization used on the product, sterility claims, or pyrogenicity claims. • Instructions for sterilization or re-sterilization in the product Instruction for Use manuals. • Microbiology test procedures.
Notification	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.
Packaging Engineering	Assess impact, and accuracy with regard to: • Packaging and labeling processes and requirements.
Planning	Consider the impact of the changes to current inventories, lead times, resources, costs, etc.
Preventative Maintenance	Assess impact, and accuracy with regard to: • Equipment maintenance procedures • Maintenance/equipment requirements
Product Service	Assess impact, and accuracy with regard to: • Evaluating the impact to the field • Product Service procedures

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Functional Role	Typical Responsibilities
Project Management Office	Core Team Leaders/Project Managers represent this role. Consider the impact of proposed changes to the design history file / device master record, document structures, and assess the impact and accuracy of the proposed changes with regard to: • Strategic direction • Business philosophies and preferred practices • Guiding principles
Purchasing	Consider the impact of the changes to current inventories, lead times, resources, costs, etc. • Ensure that the source (manufacturer) tied to purchased or subcontracted parts is correct. • Work with Change Managers to determine disposition actions regarding open purchase orders. • Communicate changed specifications to manufacturers or suppliers as required upon Change approval.
Quality Engineering / Development Quality	Assess impact, and accuracy with regard to: • Rationale associated with the need for verification/validation of the change and the effectiveness of any applicable verification/validations. Ensure the correctness of the decision regarding validation prior to approval. • Ensure rework instructions/procedures are properly validated or justified. • Disposition of field and return product • Inspection and tests, as required, are completed prior to the change being implemented and are adequate to justify the change. • Risk management actions relevant to the device or that the risk management relevant to the device has been properly updated. • Design history file / device master record document structures. • Accuracy of Product Structures. • Establish, validate and verify all Quality Control requirements. • Review SAP – Change Master – The Change Master should include a list of all the object types and objects that are included on the CM and that match up to the change in the Change Order. • Impact assessment/analysis • Impact to site(s) is accurate • Training requirement • Review document/part attributes for connection to Terumo and when Terumo items are changing, an approved Terumo Supplier Notice of Change is attached to the CO.

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Functional Role	Typical Responsibilities
Quality Systems	Consider the necessity of proposed changes related to the Quality Management System and assess impact and accuracy with regard to: • Continued compliance with the Quality System and other applicable global regulatory requirements.
Receiving Inspection	Technical review may be performed by an individual(s) cognizant of the applicable requirements and who is able to assess the technical aspects of the proposed change.
Records Management	Consider the necessity of proposed changes related to Records Management document types.
Regulatory Affairs	Consider the necessity of proposed changes and assess impact and accuracy with regard to: • Previously submitted information to affected regulatory agencies or governing bodies. • Continued compliance with specific country requirements. • Investigational device product with regard to Clinical Trial Investigations. • Shelf life date requirements.
Research & Development	Consider the necessity of proposed changes and assess impact and accuracy with regard to: • Product and performance specifications and requirements. • Safety and effectiveness of the device • Reorder number changes • Shelf life dating requirements • Design history file / device master record document structures • Request new part and document numbers • Document changes to product design, manufacturing and inspection procedures during new product development. • Document Product Development activities and produce required deliverables. • Work with Manufacturing Engineering to ensure product configurations are correct. • Review assigned Changes to product configurations • Impact assessment/analysis • Impact to site(s) is accurate • Interchangeability of a part or component is reviewed • Labeling instructs user to use the product in a manner that has been fully verified and validated. • Part(s) meets the product specifications/requirements. • Change(s) are feasible and does not compromise the design or safety of the design.

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Functional Role	Typical Responsibilities
Science & Technology	Consider the proposed changes and assess impact and accuracy with regard to: • R&D Laboratory Test Procedures and requirements • Validation / qualification of R&D laboratory testing, material characterization • Biocompatibility requirements
Shipping/Handling	Review may be performed by an individual(s) cognizant of the applicable requirements and who is able to assess the Shipping/Handling aspects of the proposed change.
Software Quality Engineering	Consider the proposed changes and assess impact and accuracy with regard to: Quality System related software procedures and requirements (configuration, version, validation, document structures, etc.).
Supplier Quality Assurance	Consider the proposed changes and assess impact and accuracy with regard to: • Material Specifications and Inspection Procedures. • First Article inspection requirements relating to purchased materials. • Supplier management and compliance of purchased parts to specification. • Product structures as related to new or changing components. • Establish, qualify, and maintain documentation for manufacturers of purchased items. • Ensure that the source is assigned the appropriate level and Source ASL Part Status is properly maintained.
Supply Chain	Review may be performed by an individual(s) cognizant of the applicable requirements and who is able to assess the Supply Chain aspects of the proposed change.
Technical Publications	As applicable, assess the impact of the change(s) with regard to: • Symbol and translation alignment between the IFU and label • Regulations and business requirements • Packaging changes affecting IFU design • Electronic publication • Correct IFU part and/or artwork numbers
Training	Review may be performed by an individual(s) cognizant of the applicable requirements and who is able to assess the Training aspects of the proposed change.