

Create and Manage Enterprise Change Request

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1.0 **PURPOSE**

This procedure defines the requirements for creating and managing an Enterprise Change Request.

2.0 **REFERENCES**

2.1 **Applicable Documents**

Number	Title
87120	Guide to Create and Manage Enterprise Change Request
87121	Review Enterprise Change Request
87123	Create and Manage Change Order
87144	Enterprise Change Request Proxy Review

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2.2 External References

Number	Title
N/A	N/A

3.0 RESPONSIBILITIES

Function or Title	Responsibility
Change Manager (CM)	Creates and manages Enterprise Change Requests. Assigns Change Review Board and Functional Assessor(s).
Change Review Board (CRB)	Reviews the scope and impact of an Enterprise Change Request for approval.
Functional Assessor	Completes the functional Impact Assessment for the assigned functional area. The Functional Assessor may need to work with other functional areas to complete the assessment thoroughly.
Notification Role	This role allows individuals to be informed of proposed changes and status throughout the ECR process. This is an informational, non-voting role and the individuals notified assume no review responsibilities.

4.0 DEFINITIONS

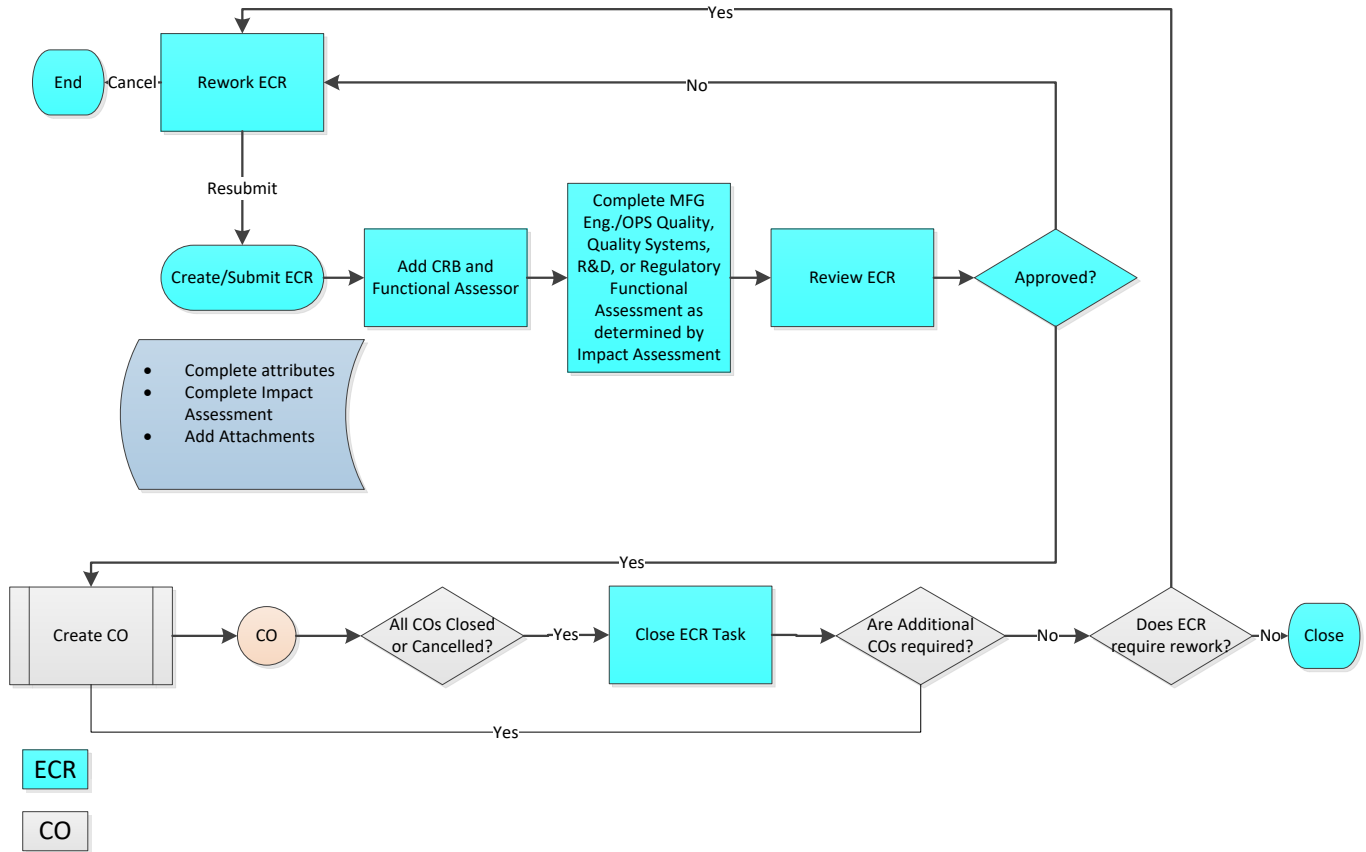
Term	Definition
Affected Object	Released or Pre-Released Objects which can be added to the ECR to communicate scope and support functional impact assessments.
Attachment	A document, data file, zip file, etc. that supports an object
Attribute	Fields populated on an object that define its use.
Cancelled	A lifecycle state where there will be no further activity.
Change Order (CO)	An object that allows planning, managing, monitoring, and approval of new/revised objects of the change activities.
Closed	A lifecycle state after all objects' activities have been completed.
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.

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Term	Definition
Impact Assessment	Questions to determine how the proposed change affects specific functional activities to indicate the scope of impact and resources needed.
Implementation	A lifecycle state within the ECR that identifies implementation activities are occurring.
Lifecycle State	The status of an object in Windchill.
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.
Notification Email	A Windchill system generated email that notifies the identified functional roles of the status change of an object.
Open	A lifecycle state where the object is created.
Pending Approval	A lifecycle state where the object is routed for approval.
Pending Close	A lifecycle state after CO activity completion where Windchill generates a task asking to close the ECR.
Rework	A lifecycle state where the object needs to be updated or clarified.
Proxy Approval	A method of approval that can be used by a reviewer who does not have access to Windchill.
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..
Windchill	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



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6.0 CREATE AN ENTERPRISE CHANGE REQUEST

6.1 General Requirements

Step	Action
1	<p>The Enterprise Change Request (ECR) is the top-level change and represents a significant set of work (e.g, a development phase) or an entire project. The ECR can be made up of many Change Orders and may span an extended period of time until the work associated with the scope of the ECR is complete.</p> <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 Change Activity 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 Change Activity and is a way to get feedback from peers on the actual change before the formal Review and Approval stage.</p> <p>For non-project type ECRs which are kept open for an extended period of time to group together changes it is important to ensure that the COs created within the ECR are within its scope.</p> <p>See Appendix A for examples of ECR types that could be created.</p>
2	<p>The Change Manager (CM) is responsible for creating and managing the ECR.</p> <p>Additional ECR Change Managers are added to the Change Manager role upon creation of the ECR. These Change Managers will manage the COs associated with the ECR.</p> <ul style="list-style-type: none"> • If additional ECR Change Managers are needed at Implementation, contact Documentation Services.
3	<ul style="list-style-type: none"> • An ECR created in the following libraries can only have affected objects from their own library. <ul style="list-style-type: none"> ○ Puerto Rico Quality Systems ○ Clinical Validation IT Marketing and Legacy Corporate • An ECR created in the following libraries can have affected objects from any of the listed libraries. <ul style="list-style-type: none"> ○ Production ○ Product Development ○ Atlanta Quality Systems ○ CATD Quality Systems ○ NMD Quality Systems ○ SJM Quality Systems
4	<p>If a new Enterprise Change Request (ECR) is being considered, the Change Manager (CM) searches for an existing ECR within Windchill.</p> <p>If one exists, follow 87123, Create and Manage Change Order</p> <p>If one does not exist for the scope of work being undertaken, the CM creates a new ECR. Refer to 87120, Guide to Create and Manage Enterprise Change Request.</p>

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6.2 Attributes

Step	Action
1	When creating a new ECR, the CM completes the required attributes and Impact Assessment questions.
2	<p>Name The ECR name uniquely identifies the ECR object.</p>
3	<p>Description Describe the scope of the ECR. 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.</p> <p>At a minimum, the ECR Description must:</p> <ul style="list-style-type: none"> • List what is being affected: <ul style="list-style-type: none"> ○ Project Name ○ Product Family • 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. <p>An effective Description of the change will describe the overall expectation of what the change will consist of (e.g., scope, resources needed), and if the change is associated to an approved project.</p> <p>Before submitting, ask:</p> <ul style="list-style-type: none"> • Is it clear and concise? • Does it effectively describe the scope of work that will be completed under the ECR? • Will it withstand the passage of time? • Will it hold up in an audit? • Is it easily understood by a non-technical person?

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6.2 Attributes

Step	Action
4	<p>Justification Explain the reason the change is being proposed. 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.</p> <p>At a minimum, the Justification must:</p> <ul style="list-style-type: none"> • Explain why the change is occurring and how it affects current finished product and/or process. • Provide a brief summary of Supporting Evidence for the change. <p>Before submitting, ask:</p> <ul style="list-style-type: none"> • Is it clear and concise? • Will it withstand the passage of time? • Will it hold up in an audit? • Is it easily understood by a non-technical person?
5	<p>Reason for Change Select at least one value from the drop-down menu to identify the reason for change. Depending on the reason that is selected, a text box may appear to allow a reference to be added. For example, selecting CAPA as a reason will prompt for the CAPA reference.</p>
6	<p>Product Line Select at least one value for product related change.</p> <ul style="list-style-type: none"> • N/A is used for QS documents. • Other Product Not Listed is for a product not on the dropdown list. <p><u>NOTE:</u> To request additional Product Lines be added to the list, email WCQualitySupport@sjm.com.</p>
7	<p>Affected Site(s) Select the site(s) that will be affected by the change.</p>
8	<p>Non-Recurring Cost of Change Enter information, if applicable .The information helps the CRB in their review and approval.</p>
9	<p>Project Name Select a Project Name, if applicable.</p> <p><u>NOTE:</u> To request additional Project Name be added to the list, email WCQualitySupport@sjm.com.</p>

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6.3 Affected Objects

Step	Action
1	<p>Affected objects are not required, but may be added as needed. The purpose of adding Affected Objects is to further convey the expected scope of the ECR on objects that already exist in Windchill.</p> <p>NOTE: Adding Affected Objects to an ECR does not initiate any change activity or change the object's Windchill state.</p>

6.4 Attachments

Step	Action
1	<p>Attachments which support the ECR, e.g., Project plan that was approved outside of Windchill, may be added to the ECR as needed.</p>

6.5 Impact Assessment

Step	Action
1	<p>The CM answers questions to determine how the proposed change will affect specific functions and the work needed to implement the change.</p>
2	<p>Question 1: Has this project/change been approved in another system? If Yes, enter project/change number and the approval system. If No, continue to question 2.</p>
3	<p>Question 2: Will a design change plan, integrated business plan, quality plan, or other master plan be written for the proposed change? If Yes, a regulatory assessment is required. No further questions need to be answered. If No, system displays questions 3 through 5.</p>
4	<p>Question 3: Will this change impact Quality Systems documents? If Yes, Quality Systems impact assessment is required. If No, continue to Question 4.</p>
5	<p>Question 4: Will this change affect product dimensions, requirements (specifications), characteristics, or customer use? If Yes, an R&D/Design Quality impact assessment and a Regulatory assessment are required. If No, continue to Question 5.</p>
6	<p>Question 5: Will this change affect how the product is processed (i.e. procedures, tooling/equipment, environment), inspected, or reworked? If Yes, a Manufacturing Engineering/Operations Quality impact assessment and a Regulatory assessment are required. Note: If all of the answers to Questions 3, 4 and 5 are No, Question 6 is displayed.</p>

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6.5 Impact Assessment

Step	Action
7	<p>Question 6: Will all COs under this ECR fall under the definition of a non-rev change?</p> <p>If Yes, impact assessments are not required.</p> <p>If No, done.</p>

6.6 Check Submit Rules

Step	Action
1	<p>The CM Checks ECR Submit Rules to determine the roles which need to be populated for the functional impact assessments. The Business rules for Submitting/Resubmitting the Enterprise Change Request are also checked to determine if the ECR can be submitted.</p> <ul style="list-style-type: none"> • Errors found need to be corrected before the ECR can be submitted/resubmitted. • Once errors have been corrected, a message stating the ECR is ready to be submitted will be displayed when checking the submit rules.
2	<p>The CM assigns an individual for each role identified in the Impact Assessment.</p>
3	<p>The CM assigns CRB approver(s). The ECR requires a minimum of one approver. The minimum is typically applied to projects that have been approved through another business process or the ECR has a limited scope or impact.</p> <p>Additional approvers should be added when the project has not been approved in another business system, considering:</p> <ul style="list-style-type: none"> • Significance of change impact (e.g., multiple functions affected, risk of change). • Achieving consensus for proposed scope of change.
4	<p>Proxy Approval</p> <ul style="list-style-type: none"> • 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 in Windchill. <p>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).</p> <ul style="list-style-type: none"> • In the Description field of the ECR, indicate the name of the proxy approver and the role they are approving for. Also indicate that Documentation Services will be completing the vote in Windchill. • Following submission of the ECR, forward the following to the individual approving via proxy: <ul style="list-style-type: none"> ○ 87144, Enterprise Change Request Proxy Review Form ○ ECR Workflow Report

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6.6 Check Submit Rules

Step	Action
	<ul style="list-style-type: none"> ○ Copy of each file in the Affected Objects of the ECR ○ Copy of each file in the Attachments section of the ECR ● Change Manager forwards the signed copy of the Proxy Approval to the designated Documentation Services individual. <p>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 ECR Attachments.</p>
5	<p>Delegations</p> <p>It may be necessary for an employee to delegate their tasks to another employee to perform in their absence. Delegating the tasks should be within the functional group.</p> <p>Refer to 87150, Guide to Create and Manage Delegation.</p> <p>NOTE: Ensure the assigned delegate has the appropriate training and Windchill access (equal to or higher than the Delegator) to complete the tasks.</p>

6.7 Functional Assessment

Step	Action
1	The individual functional assessors complete the assessments identified during the Impact Assessment. Once all functional assessments that are required have been completed, the ECR is routed to the CRB for review.

6.8 Route for CRB Review

Step	Action
1	The Change Manager sends the ECR to the CRB for review. The CRB Approvers are responsible for ensuring the ECR is correct and complete.
2	<p>Approval by CRB</p> <p>If the ECR is approved it is ready to move forward with Change Orders.</p>
3	<p>Rejection by CRB</p> <p>If the ECR is rejected, the change returns to Create/Submit ECR to be updated. The CM must address the feedback, determine if impact assessment tasks need to be reviewed and updated, and provide resubmission comments outlining what changes were made before sending the ECR back to the CRB for review.</p>

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6.8 Route for CRB Review

Step	Action
4	<p>Pullback by CM</p> <p>The CM has the ability to pull back the ECR. The CM must select a pullback reason and go through the same steps as listed in Step 3.</p>
5	<p>Proxy Review</p> <p>The ECR can be approved or rejected via proxy form using the following methods:</p> <ul style="list-style-type: none"> • Physically signing a paper copy and providing a scan electronically • Electronically using a validated system.

6.9 Implementation

Step	Action
1	<p>After ECR is approved and in the Implementation state, individuals assigned to the CM role in the ECR may move forward with CO creation per 87123, Create and Manage Change Order.</p>

6.10 Close an ECR

Step	Action
1	<p>When all COs structured to the ECR are closed or cancelled, the CM is assigned a task to close the ECR. The CM determines if all implementation activities have been completed in order to satisfy the scope of the ECR. If not, the CM can return the ECR to an implementation state and create additional COs. If the scope of the ECR needs to be changed at this point the CM can rework the ECR and update it accordingly and get the changes approved. If the ECR has been implemented fully, the CM can close the ECR.</p>

7.0 APPENDICES

Appendix A: Examples of ECR Types

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APPENDIX A: EXAMPLES OF ECR TYPES

Changes that require a Unique ECR:	
Product Development	Covers a single product or family up to release to manufacturing. The scope could be for the entire development project, a development phase, or a significant set of work (e.g., Risk Management, Design Verification, Process Validation). <ul style="list-style-type: none"> • E.5 OCT Software Project • Dragonfly 5 Catheter Project
Product Update	Covers a single update effort <ul style="list-style-type: none"> • EOL Bluetooth dongle that required new ZFINs • Radio Equipment Directive compliance that requires new ZFINs, packaging and IFUs • 60601-1 4th Edition compliance that required new NRTL reports • Line Expansion for Catheter manufacturing
End-Of-Life Action	Covers a single EOL effort <ul style="list-style-type: none"> • DVD, SSD, etc. (PC components on PLM Only assembly)
Audit Action	Covers an individual audit
CAPA Action	Covers an individual CAPA
Changes that may be under a Generic ECR:	
Process Change	Covers 1 year for a single product or family <ul style="list-style-type: none"> • NCMRs • SCRs • SCARs • IQs • Line down that does not violate rules
Field Service Actions	Covers life of a single product or family <ul style="list-style-type: none"> • New or revised spare part replacement procedure • New or revised ZFINs for spare parts (Field Replaceable Units)
A Generic ECR may not be used if:	
<ul style="list-style-type: none"> • A Design Change Plan is required • Changes to Risk analysis or FMEA are required • New ZFINs are required for traceability (release of new spare parts is acceptable) • New labeling is required • New product software is required • Design Validation is required • Changes to REACH or RoHS status • Change to NRTL reports 	