Engineering Change Control Procedure

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Document History

Version	Date	Summary of Changes
1.0	Refer to the signature page	Original Release
2.0	2022/06/10	1. Improvised the procedure by adding detailed responsibilities of creator, verifier, reviewer and approver. 2. Updated the process map.
3.0	2023/02/23	Update to revise the Purpose, and procedure, include reference to Solidworks Product Data Management (PDM), revise the Process Map, add definition for product manager responsibilities.

*Note: Add row as necessary

1 Purpose

It is important that everyone involved in buying, inspecting, building, testing, storing, and shipping products know exactly what they need to do to ensure that a high quality, consistent product is produced. The description and instructions for what a product is and how it is built may take many forms and may need to be changed as time passes. Additionally, it is important to be able to look back at how, when, and why products have changed as time passes.

Enconnex has developed a digital compendium that contains all the information necessary to ensure quality products are built. It is critical that this information be accurate and that the affected parties know how to find and use the information.

The Engineering Change Order (ECO) process is used to update the information in the compendium and ensure that all relevant parties know and understand what and when changes are made. The compendium is defined here: Compendium Definition

2 Scope

The procedure applies to all ECOs originating at Enconnex that affect in-house projects as well as subcontracted projects from suppliers.

3 Procedure

The Process Map defines the process to release an ECO. All ECO's are created in Odoo. A step by step guide to create ECO's in Odoo is here: ECO Creation in Odoo

The ECO is the process used to implement changes and to ensure that all parties are notified, but the actual change will often result in new files, documents, procedures, drawings, etc.

3.1 Attachments:

Responsible parties may need to see exactly what changes are being made, it is therefore important that they have access to the modified files. Links to the files can be placed either in the Notes tab on Odoo, or attached in the message box. Note: documents attached to the ECO do not propagate through Odoo, so they are considered for reference only. The released documents are available in the Compendium. Exception: BOM's may have attached instructions that are presented to the operators. These documents should be verified as correct by the author and verifier.

3.2 ECO Author Responsibilities

- The ECO Author accepts responsibility for communicating the information to all department leads at Enconnex, and that they are a subject matter expert related to the change they are making.
- In the "Notes" field, the author is expected to document and write a concise description that explains why a change is being made as well as any known impacts the change may make. The note should include:
  - Product description
  - Why it is changing
  - When the change needs to happen.
  - Links to the updated documents

  Note: Odoo provides a way to make the change automatically based on release (ASAP) or a date, but if it can't be easily identified clarification should be done in the notes field.
    - The ECO creator will evaluate If the change could impact any of the following situations

- Parts on order
- Parts in stock
- Productions in process
- Finished goods
- Product at customer locations
- Returns

The information need not include specific quantities of components if they are not known, but it should include the information so that the responsible party can figure out exactly which and how many components are affected.

- The ECO creator will utilize the following keywords:
  - **Release** - used to indicate a new part/product/assembly. Identify what new files will be stored as active.
  - **Revise** - used to indicate a change to a current part/product/assembly. Identify which files will be archived, and which will be moved to Active.
  - **Obsolete** - used to indicate that a part will no longer be produced or available. Identify which files will be archived.
- Versions of the file that are easily viewable (for example .pdf files) should be attached to the ECO if possible; however, only certain formats are possible to attach in Odoo. The original editable form must also be archived and the directory and or links to the applicable documents will be included in the description
- Indicate what files should be moved into archived, and/or saved in the compendium, and which files will be moved to “Release” or “Obsolete” status.
- Note on BOM’s these traditionally mean “Bill of Materials” however for Enconnex /Odoo (the Enterprise. Resource Planning or ERP) program we use. The BOM is more complicated, it includes: a list of what components and how many are being used, what process steps are utilized, and what the resulting product(s) are.
- It is the Authors responsibility to ensure that the ECO completes the process in a timely manner. This may require reminders to other approvers. If action continues to be neglected the approvers manager should be notified.

3.3 ECO Verifier Responsibility:

- The verifiers are the subject matter experts for the product in question, and they must be aware of how the product is currently being built, and how the change should be correctly implemented.
- The verifier acknowledges that If they aren't an expert, they are agreeing to learn and understand the product, by discussing with any respective parties.
- The verifier/approver will consider the following questions before approving a change
  - Why are we making these changes?
  - What are the changes?
  - Is all the necessary information present in the ECO?
  - Is this the correct change to make?
  - Do the component descriptions correctly match what the components are?
- Ensure that the “Note” field correctly describes the changes being made, and why they are being implemented.
- The design change has been correctly made. Form Fit and Function changes are correct and valid.
- Verify that the BOM has the correct components, and quantity of components needed for the build of the product.

- The verifier/approver will verify whether the ECO description correctly describes the changes, and why they are being implemented.

3.4 ECO Approver Responsibility:

- The approvers accept responsibility for communicating the information to the team they represent, and that they are the subject matter experts for their department.
- ECO approvers are responsible to read all ECO descriptions.
- ECO approvers will decide if there is any relevance to them or the team you represent, the list provided below may not be all inclusive.
- Create a Log entry in the ECO note area as to what steps are required based on your ECO evaluation. If additional action is to be monitored, describe how, and references to any actions plans or tools used to monitor implementation.

3.4.1 Product Manager:

- Responsible to evaluate the effect on any related product usage
- Responsible to evaluate cost implications for the product, and update Odoo with appropriate sales pricing
- Responsible for ensuring that any marketing materials are created, updated, or obsolete.
- Responsible to ensure that ECO timeline meets sales needs
- Creates a log entry in the note area indicating what steps are required based on the ECO evaluation, and how any additional actions will be accomplished and/or monitored including links to action plans or tools used to monitor implementation.

3.4.2 Purchasing:

- Responsible for identifying any open purchase or sales order associated with the ECO.
- Responsible for adding appropriate notes on components and purchase order associated with the ECO.
- The purchasing department is responsible to revise the purchase orders based on the changes necessary for the components.
- Create a Log entry in the ECO note area as to what steps are required based on your ECO evaluation. If additional action is to be monitored, describe how, and references to any actions plans or tools used to monitor implementation.

3.4.3 Quality control

- Evaluate changes in the BOM for inspection criteria
- Evaluate if there are any effects relevant to material for quarantine
- Develop or revise inspection protocols for the affected products and components.
- Develop or revise process inspection protocols to ensure that production is following any new or revised assembly instructions
- Update the training program as needed.
- Work with purchasing and production to remove any unnecessary or obsolete stock (including raw material, WIP, and Finished goods)
- Evaluate for effects on the training program.
- Create a Log entry in the ECO note area as to what steps are required based on your ECO evaluation. If additional action is to be monitored, describe how, and references to any actions plans or tools used to monitor implementation.

3.4.4 Production

- Understand the effects of the changes to the production process.
- Inform all appropriate workers of any updates to the assembly, test, program, build, etc. instructions
- Evaluate how component changes affect the production process (part stocking locations, assembly steps, etc.)
- Evaluate how Instruction changes affect the production process.
- Develop any new test equipment or fixtures necessary for production.
- Effect on current production orders
- Effect on Sales orders.
- Create a Log entry in the ECO note area as to what steps are required based on your ECO evaluation. If additional action is to be monitored, describe how, and references to any actions plans or tools used to monitor implementation.

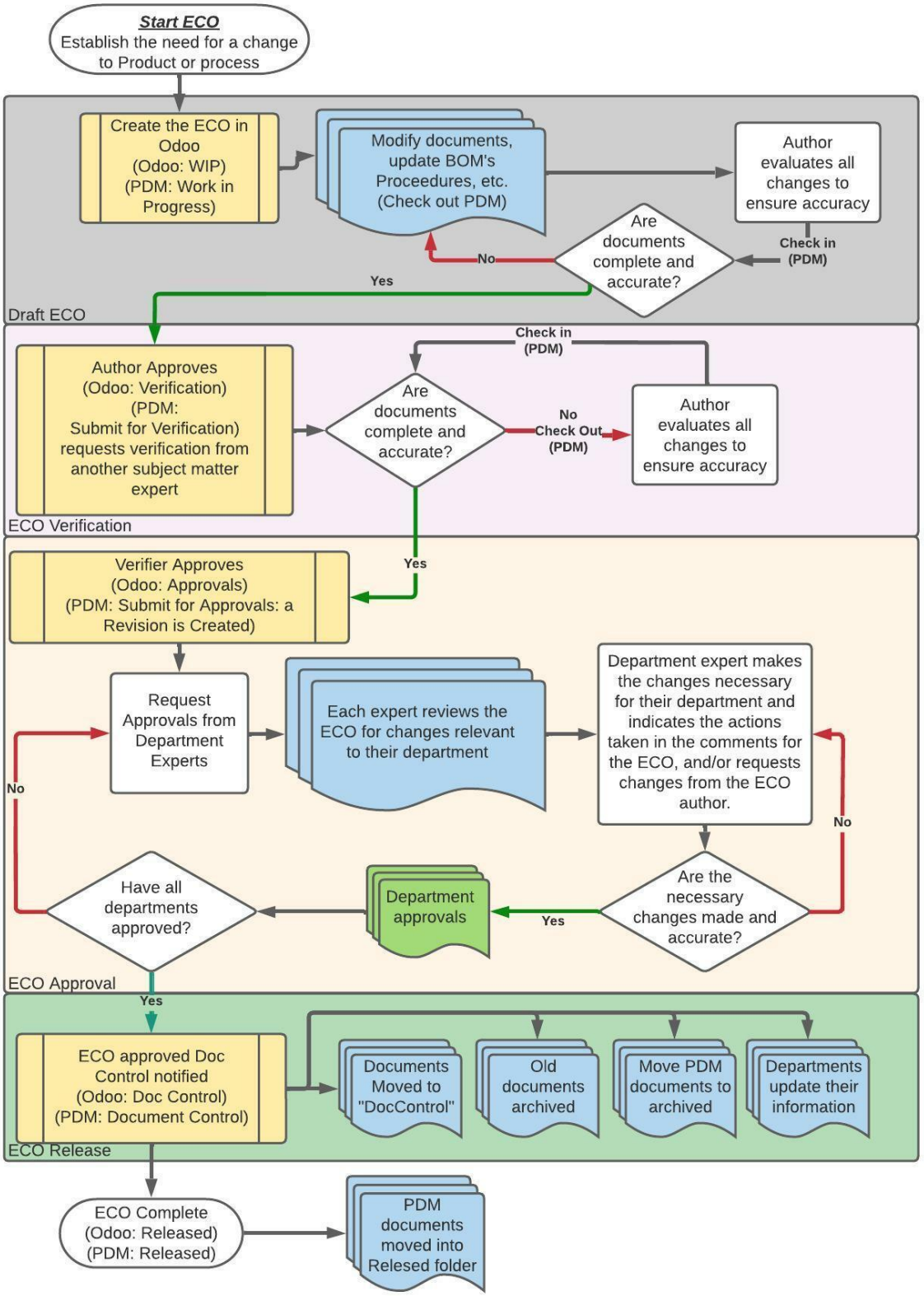
3.4.5 Engineering

- Evaluate how the change to the process affects any in progress, or upcoming designs, or enhancements
- Evaluate if any training is needed by or for the engineering department.
- Create a Log entry in the ECO note area as to what steps are required based on your ECO evaluation. If additional action is to be monitored, describe how, and references to any actions plans or tools used to monitor implementation.

3.4.6 Document control.

- Verify that appropriate documents exist and are correctly attached to the ECO.
- Move the appropriate documents in the Doc Control Directory according to the instructions on the ECO.
- Change the state on the appropriate documents in the PDM software
- Archive the appropriate documents to ensure only the active/released documents are available for use by respective personnel.

4 Process Map



5 Signature Page

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