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	Title: Engineering Change Decisions and Tasks for Lab/Office Role		Page #: 1 of 5
Work Instruction Owner(s) – list functions: Manager of Solutions Engineering		Revision's Training Requirements – select one (per section #9): Awareness _ Formal ✘	

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1 Purpose


- 1.1 To supply instructions to the Lab/Office role regarding the steps to make decisions within the Engineering Change Management System. The instruction ensures decisions are reproducible and applicable requirements are met.

2 Scope – *applies to where & when the work instruction is used*

- 2.1 Applies to all activities the Lab/Office role performs within the Engineering Change Management System.
- 2.2 The scope of activities covered in this instruction for this role include: Approve, Accept, and Close.

3 Definitions and Acronyms (if needed)

- 3.1 ECM....Engineering Change Management.
- 3.2 Activities....These are the names of major sequences within the ECM process flow. REQUEST, APPROVE, ACCEPT, CLOSE, IMPLEMENT
- 3.3 ECN.....Engineering Change Notification
- 3.4 ECO.....Engineering Change Order
- 3.5 Factor...Item that has influence in engineering change. Each factor has a role assigned for responsibility
- 3.6 Requirements....contractual, regulatory, statutory and MTS Test

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4 Graphic (if needed)

5 Responsibilities

- 5.1 Approver is responsible for reviewing and approving or rejecting an ECN. If the ECN is approved, the approver sets the effectivity date and material disposition.
- 5.2 Acceptor is responsible for reviewing and accepting or requesting a re-plan of an ECN.
- 5.3 Closer is responsible for updating Bill of Materials, drawings and any additional documentation required by the QMS.

6 Instruction

- 6.1 Lab/Office approval considerations for engineering change:
 - 6.1.1 Alpha vs. Numeric revision control
 - 6.1.1.1 Numeric revision control – for development (for quoting purposes, for prototyping in a lab, cannot be delivered to stock)
 - 6.1.1.2 Alpha revision control – for manufacturing release
 - Decision: Numeric-to-Numeric revision (i.e. Rev. 1 to 2) – This is done when a new version of a development material is being created. No issues with inventory, installed base, etc. should exist.
 - Decision: Numeric-to-Alpha revision (i.e. Rev. 2 to A) – This should be done when the material is ready for release to manufacturing.
 - Decision: Alpha-to-Alpha revision (i.e. Rev. B to C) – This occurs when a material in Alpha control is being changed. Consider inventory, installed base, all other materials with where-used connectivity.
 - 6.1.2 Do the Rules of Interchangeability apply? If the answer to any of these questions is yes, then a new part number is required and the ECN should be Rejected.
 - 6.1.2.1 Will the change affect the form, fit, or function of the material?
 - Form: The unique and relevant physical characteristics (shape, size, mass) that characterize a part or assembly for a particular use.

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Fit: The ability of a part or assembly to physically mate with, interconnect to, or become integrated with another part.

Function: The action that a part is expected to perform in fulfilling its purpose.

6.1.2.2 Will the change affect performance or adherence to customer specifications?

6.1.2.3 Does the request compromise safety or regulatory requirements?

6.1.3 Is there existing inventory of the material? If yes, a disposition for each material number listed on the ECN must be defined, (Use as is, Rework, Scrap, or Other).

6.1.4 Determine the where-used status of each material. Is rework or retrofit of installed units required? Is significant rework required? Create a plan for rework or retrofit activity.

6.1.5 Is there an impact on service or repair parts? Note this in the plan.

6.1.6 Are there additional materials (with additional Lab Office persons) applicable to the change? What is the potential impact on them and their impact on the ECN?

6.2 When setting the effectivity date for an ECN, consider the following:

6.2.1 The number of factors applicable to the material being requested for change and the time lag required for gaining the approval/acceptance.

6.2.2 The time required to update the BOM/drawing(s).


6.2.3 The impact to production schedule & customer delivery.

6.2.4 The effect on inventory.

6.3 If multiple materials with multiple Lab/Offices are applicable, the first material listed will have the Lab/Office champion for the Engineering Change. The other Lab/Offices (for the additional materials) will need to accept the change recommended by the Champion Lab Office. If the other Lab/Office does not agree with the written instructions, then the ECN should be Re-Planned with comments about suggestions for improvement to the ECN. Otherwise it should simply be Accepted.

6.4 Preparing the Engineering Change for Closure:

6.4.1 The Lab/Office coordinates the updating of the BOM and the drawing/document associated with the ECN.

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6.4.2 The changes must be done prior to the effectivity date. Otherwise, the ECN must be Rejected and restarted.

7 Associated Quality Records – as stated in the Quality Records List

Required Record
ECN/ECO number

8 Reference Forms / Templates / Documents (if needed)

Form / Template / Document Title	Location
ECM System Procedure	QMS Quality, Document Control

9 Current Revision's Training Requirements


Training requirements are determined by the document owner – either awareness or formal.

Select One (mark X)	Training Type	Training Definition
	Awareness	Awareness training is conducted by communication, which is sent/delivered by the approver/author/owner of the document to the affected employees/groups.
X	Formal	Formal training requires the approver/author/owner to collect/store evidence that the affected employees/groups were trained.

Affected – Lab/Office

10 Revision History & Approval

REVISION HISTORY

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Rev	Description of Change	Author	Effective Date
A	Initial release to support ECM release 1	Jesse Gunderson	2012-04-23

APPROVAL OF CURRENT REVISION		
Name / Function	Signature	Date
Marvin Westerman/Solutions Engineering Manager	Marvin D. Westermann	4/20/2012
Bob Haapala/ECM Process Owner	Bob Haapala	4/21/2012