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Revision History

Rev No	DCN #	Changes	Effective Date	Approved
01		Initial Release	08/06/04	
02	0007	Footer changed	10/08/04	J. Rao
03	0080	Modification of flow chart	01/11/05	J. Rao
04	0724	Revised flow chart, detail change category	08/03/09	N. Guo
05	0821	Clarify change category	02/05/10	Y. Chen
06	0891	Clarify the flow, responsibility, and requirements.	08/31/10	Y. Chen
07	1003	Simplified the flow chart, emphasize section 6.2	06/29/11	A. Qin
08	1164	Yearly Review, Added three requires for ECN initial	05/15/13	A. Qin
09	1172	Specify Customer Specification Review and Release Process in section 6.2	07/12/13	A. Qin
10	1177	Modification of CRB Member Responsibility	10/11/13	A. Qin


Engineering Change Control Procedure

Process Owner: Nancy Guo

Date: 10/09/2013

Department Manager: Alex Qin

Date: 10/10/2013

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1.0 Purpose


This procedure defines the process flow to ensure that all engineering changes are properly reviewed, verified and validated, as appropriate, and approved before implementation.

2.0 Scope


This procedure applies to all Optoplex products, materials, test software and associated manufacturing processes.

3.0 Authorities and Responsibilities

<ul style="list-style-type: none"> Divisional Engineering 	<ul style="list-style-type: none"> Initiates the request of engineering change(s) Provide the required information for engineering change(s) Perform test to verify and validate proposed change To ensure product integrity and manufacturability Conducts initial assessment on the impact of the proposed change to production process, product quality/reliability, inventory and supplier status.
<ul style="list-style-type: none"> Responsible Manager 	<ul style="list-style-type: none"> Reviews the request of engineering change(s) Review the required information for engineering change(s) Review the plan and results of validation test(s) Reviews the initial assessment conducted by divisional engineer.
<ul style="list-style-type: none"> CRB 	<ul style="list-style-type: none"> Reviews the proposed ECN, Reviews and verifies the plan and results of validation test(s) Reviews and verifies the change classification.
<ul style="list-style-type: none"> Document Control 	<ul style="list-style-type: none"> Assigns an ECN number. Manages ECN process, make pre-view on change proposal, and coordinate approval status Chairs the CRB review meeting, present ECN information and maintain accountability of process owner. Documents records upon ECN closure.


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<ul style="list-style-type: none"> • Sales/ Marketing 	<ul style="list-style-type: none"> • Clarifies the request of PCN for the changes. • Join the CRB to review the request of ECN. • Notify customer about PCN and obtains approval when necessary. • In charge of Customer Specification pre-review process
<ul style="list-style-type: none"> • Process Engineer 	<ul style="list-style-type: none"> • Performs necessary test to verify and validate any changes associated with the manufacturing process • Review; approves and implements the ECN. • Makes associated changes with ECN such as BOM, W/I. Travel card, etc. • Records/Maintains the traceability info associated with the change
<ul style="list-style-type: none"> • Quality Assurance 	<ul style="list-style-type: none"> • Conducts qualification and reliability assessment test when necessary. • Determines the required departments to involve the ECN process • Approves the ECN if the results are satisfactory. • Makes changes associated with ECN such as inspection standard, etc.
<ul style="list-style-type: none"> • Production & Material Control Planning 	<ul style="list-style-type: none"> • Cooperates with Production Plan on the disposition of materials. • Notifies supplier of change or adjusts the PO if necessary. • Works with Accounting if there is a cost concern on changes. • Works with ECN Owner for the impact of the change as it affects the production plan, inventories, WIP and disposition of materials. • Provides the effective date for material/assembly changes
<ul style="list-style-type: none"> • Manufacturing /Production 	<ul style="list-style-type: none"> • Verifies the necessity of the change • Ensures that manufacturing is prepared for the change in the process • Implements the changes on ECN effective date
<ul style="list-style-type: none"> • Contract Manufacturing 	<ul style="list-style-type: none"> • Report the inventory information disposition plan • Verifies the necessity of the change for CM • Implements the changes in CM on ECN effective date
<ul style="list-style-type: none"> • R&D Engineering 	<ul style="list-style-type: none"> • Review and approve the ECN that product in design and develop phase include technical documents • In charge of NPI product document transfer from Engineering to Production based on approved ECN. • Support production for ECN change in production phase

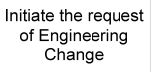
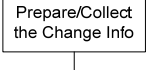
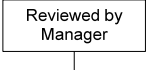
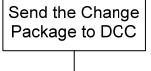
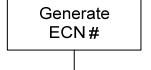
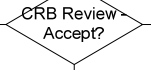
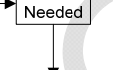
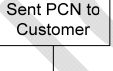

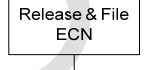
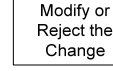
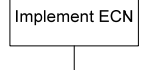
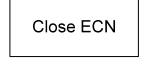
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4.0 Definitions and Acronyms

DCC	Document Control Center
ECN	Engineering Change Notice
CRB	Change Review Board CRB Member: Sales , R&D Engineering (Mechanical and Electrical), Process Engineering, Manufacturing, Optics Department Production and Material control Planning, Contract manufacturing , QA and Cost Accounting
PCN	Product Change Notice
Effective Date	Date when the proposed change(s) start to be implemented ECN can be effective starting from a particular lot or serial number if a clear cut-off date is not practical
ECN Owner	The person who responsible to implement the ECN.
Deviation	Any practice that is deviated from the current documented work instruction and process control.
NPI	New Product Introduction

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5.0 Flow Chart of Procedure


Flow Chart	Responsible	Notes	Record
	Engineer (Originator)	Fill out the ECN from, proposal change documents and supporting data	Engineering Change Notice (ECN) Change Documents Test Report
	Engineer (Originator)	Determine validation test plan and preliminary test report for supporting data	
	Manager of Requester Department	Review ECN. Review the evaluation and validation test plans and preliminary test report	ECN
	Engineer (Originator)		ECN
	DCC	Review the completeness of change package. Assign the ECN number	ECN
	CRB	Review and make decision on ECN.	ECN
			
	S/M, PLM QA,DCC	Based on change classification and customer request. Refer to PCN Procedure QP72004	ECN PCN Special Requirement
	Engineer (Originator) Customer	Feedback the result from customer	ECN
	DCC	Release ECN and file the documents	ECN
	Engineer (Originator)		
	Responsible Departments	Implement the ECN with related activities.	Related documents
	Responsible Departments	Provide actual implementation status of ECN	ECN

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6.0 General Requirements

6.1 Product and Process Change Classifications

Change Classification	Definitions	Examples
Level 1	<ul style="list-style-type: none"> Any minor change to a process, material, method, or product design that does not represent a fundamental change to the process technique, material components, or product functionality. No impact to product's performance and form, fit, and function. These changes typically require no formal qualification and customer notification 	<ol style="list-style-type: none"> Non-critical material and material supplier change Cosmetic change without appearance change Correct typo or clarify step in W/I Part number description change
Level 2	<ul style="list-style-type: none"> Any change to a process, material, method, process architecture, or product design that might impact device performance but not to form, fit and function. These changes represent a more fundamental change and typically require a formal qualification and customer notification based on agreements and contracts. Customer approval may be required. 	<ol style="list-style-type: none"> Design platform change Non critical Internal dimension change Critical material and material supplier change Work instructions step change Visual appearance change including weight, size, shape, general structure, color, surface finish Manufacturing site change
Level 3	<ul style="list-style-type: none"> Fundamental changes to process technique, material components or product design that might impact form, fit, and/or function of a product. As for product termination, a 12-months notification will be provided to customer. These changes need formal qualification and customer approval based on standard agreements and contracts. 	<ol style="list-style-type: none"> Correct safety or fire hazard related concerns Change affect functional parameters set Major firmware change Changes impact reliability New material and/or material supplier approved Changes affect external dimensions, associated tolerances and interface parameter Critical manufacturing equipment or methodology change Discontinuation of product

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6.2 Customer Specification Pre-review / Release Process

6.2.1 Sales and Marketing shall be in charge of the customer specification pre-review for both new product and existing product modification. Engineer and Production shall be involved in the review.

6.2.2 Follow the instruction on Customer Specification Review Sheet (Form S001) and assign an engineer who will be responsible for the preparation of all related documents update and the submission of the ECN for releasing the specification through ECN approval process.

6.2.3 Refer to PRD-DC-001 Revision Control Procedure for the revision assignment.

6.3 Initiate the Request of Engineering Change


Based on company business needs such as process enhancement, yield improvement, cost reduction, regulation requirement and upgrade safety issue, an engineering change proposal will be initiated.

The responsible engineer shall fill out the ECN form in the early stage of the change proposal. The information required includes the following items. (Not limited)

- 1.Type of Change
- 2.Product affected
- 3.Reason(s) for change(s)
- 4.Change Category and PCN request verification
- 5.Description of Reason For ECN
- 6.Description of Change
- 7.Final Product Impacted
- 8.Total Cost For ECN Changes (Estimate)
- 9.ECN Implemented Owner
10. ECN Effective Date (Proposal)
11. Validation Test Requirement and report
12. PCN Requirement
13. Disposition Plan for all change parts

6.4 Make Preliminary Decision on the Change Levels

Beside the changes that assigned from customer, the ECN change initiator shall make preliminary review on the PCN requests based on the classification of the levels on section 6.1.

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If it is in a concern on the level classification, the initiator shall consult with the members of CRB in advance.

The change level and the requested qualification plan will impact the implementation of the ECN. Sufficient lead time should be identified and prepared for the test samples preparation, test times and other activities that will impact the ECN implementations.

6.5 Make Early Pre-notification to the Production Planners

If there is a ECN request (Not belong to initial relapse) to overcome the current claims and make further improvement, the change initiator shall keep closely communication with Production Planner for the inventory control and P/O release issues to prevent over-stocked for the changed parts.

6.6 Provide Sufficient Info on the Contents on the ECN Forms

[Change Reasons]


Each of the items on the ECN form shall be filled out with clear information. The change reasons shall be clearly identified and explained that will help the technical accumulations and traceability for the teams.

No blurred wording such as “quality improvement” or “dimensions change” is allowed.

[Disposition Plans]

The disposition plan shall apply to the raw material, WIP, finish goods products, parts in supplier site, parts in transportation, parts/devices in Contract Manufacturing and open P/O. The disposition plan includes:

1. Use as it (Running changes). Used up the parts of current revision and then switch to the parts of new revision.
2. Scrap the parts with current revision.
3. Re-work on the parts of current revisions. The work instruction of re-work shall be prepared by

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Engineering. If the re-work or adjustments are performed on the Production, the instruction shall be prepared.

4. Due to purchasing lead time, Open P/O should be cancelled or take other disposition plan such as re-work by supplier, etc for immediacy change.

[Change Documents]

The change documents such like specification, drawing, BOM, Work Instruction and Traveler should provide with ECN package.

The changed documents and directly reported BOM must be listed in ECN as well. All supporting data documents have to include in ECN package if this change required the validation test.

[Evaluation and Validation Test(s) of the Change]

Based on the proposed change, the responsible engineer shall set up the test plan and perform the evaluation and validation assessment. All of the results shall be recorded and collected.

6.7 Perform the Preview by Department Manager

The change packages shall be reviewed and approved by department manager before sending to DCC.

6.8 Submit/collect All Required Information to DCC


The ECN responsible engineer shall update the information on the ECN form and provide all required information to DCC.

The ECN package with originator signature, department manager approved signature and related documentations will be forwarded to DCC.

6.9 Check the completeness and Assign ECN # by DCC

DCC shall conduct the checking on ECN for completeness, the following areas shall be checked:

1. Manager approval is required.
2. Provide related data in softcopy and hardcopy.
3. Check all marked areas on necessary requirement. PCN, Validation test reports provided (if required).

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4. Ensure the revision is correct. Any drawing change or replacement for existing product, reported BOM has to be updated.

An ECN number is assigned by DCC and forward the ECN to CRB members and/or appropriate department managers.

6.10 Conduct the Review on the ECN by CRB

The ECN package shall be forwarded to CRB for preliminary review.

CRB members shall review and confirm the request of Product Change Notification associated with the changes.

If there is no necessary for the PCN, the CRB meeting shall make the review on the contents such as:

1. The draft disposition plan shall be checked by CRB. Any Scrap, Re-work and Cancel P/O for material, WIP and Finish goods should add up the cost.
2. For those changes that need the evaluation and validation, CRB meeting will confirm the contents of the test data submitted.
3. CRB members shall review and evaluate ECN to determine whether the changes are valid and whether the proposed action achieves the expected improvement.
3. Accounting or upper level manager might involve approval for an ECN with high cost impact.


If the change proposal had been accepted after review from CRB , the further action on the ECN shall be conducted. Please skip to the section # 6.14.

If the ECN is held by CRB for further info, DCC shall notify the assigned engineer to modify or provide supporting documents and information.

If the ECN is rejected from CRB, DCC shall write the reasons; scan softcopy of ECN; file hardcopy, notify originator and requester the cancellation of the ECN.

6.11 Sent the PCN to Customer for Approval

If the change level meets the request of notification to customer, the PCN form shall be prepared and sent to customer via Sales/Marketing. The details please refer to Product Change Notification Procedure QP 72004.

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6.12 Receive the Feedback from Customer about the PCN

Once customer had agreed the PCN, the ECN will be forward to CRB for final approval.

If the PCN was rejected from customer, depend on the detail of the feedbacks, the following actions shall be taken;

1. The proposed engineering change will be cancelled.
2. Add more supporting information to meet the comment from customer.
3. Modify the change proposal.

6.13 Release the ECN and Filing the ECN Related Documents

DCC shall formal release the ECN once it gets the final approval by CRB.

DCC shall handle and file the ECN related documents, those activities such as updating BOM, WI, verify revision on drawing, update Master log, data stored to DCC system, and ensure the soft file located at suitable folders, file hardcopy of ECN.

6.14 Implement the ECN on Related Activities and Associated Document Changes


Individual department is responsible to implement changes in affected areas by effective date as notice to customer, material disposition plan, and production schedule, record the traceability information, and notice PCN implementation date or lot number.

The changes on the associated documents that had been impacted from the ECN such as inspection standard from the other departments or contract manufacturer shall be completed at timely basis.

6.15 Conduct the Deviation on the Urgent Changes

For urgent or temporarily engineering changes, there is no sufficient lead-time to complete the ECN cycle, a deviation process shall be conducted.

The responsible engineer shall fill out the deviation request form in order to get approval for implementing any deviation practice in Production or Contractor Manufacturer.

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For traceability, the deviation form shall be attached to the traveler of the device that applies to the change.

The effective spans of deviation have the following decisions:

1. The period of time. In general is 30 calendar days.
2. The number of lots. In general are three consecutive lots.
3. The total quantity. Specified by Optoplex for case to case bases.
4. Others, specified after team meeting

If the change is a permanent, the formal ECN process shall be initiated within 30 calendars (In general conditions).

6.16 Monitor the Close of ECN Implementations

All parties responsible for ECN implementation must provide actual implementation date of the ECN on their portion of the responsibility.

The respective department shall be the implementation coordinator to check all implementation status before formal closing of ECN.

The definition of the formal close of ECN is all of the activities related to specified ECN are implemented and changed products are shipped to customers.

7.0 Reference Documents

QM 001	Quality Manual
QP 72004	Product Change Notification Procedure
QP 75101	Process Control Procedure
QP 73002	Reliability Program Procedure
QP 42303	Document Control Procedure
Form E001	Engineering Change Notice (ECN)
Form P119	Deviation Request Notice
Form S001	Customer Specification Review Sheet