#### NON-CONFORMANT MATERIALS, PRODUCTS OR SERVICES

**1.0 PURPOSE AND SCOPE**

The primary purpose of this document is to ensure that when a non-conformance is identified that action is taken to eliminate the non-conformance, the product or service is prevented from unintended use or delivery, that the problem is fixed such as to make it unlikely that the problem will occur again, and that actions taken are appropriate to the effects or potential effects of the non-conformance i.e. an MRB is called in serious situations. The methods for resolving non-conformities are defined in general terms to allow management the flexibility to determine the best course of action to meet the needs of the customer and the company. It is expected that when a non-conformance is discovered that notification and resolution is executed promptly and in a timely manner.

**2.0 AFFECTED DEPARTMENTS**

Engineering

Production

Logistics

Purchasing

Quality Assurance

Sales

**3.0 REFERENCE DOCUMENTS**

Applicable drawing(s) and/or specification(s) for the non-conformant material or product

D0001.1012 Process for Customer Communication

D0001.1020 Corrective-Preventive Action Process

D0001.1034-1 Non-Conformity Notification form

D0001.1120 Surface Mount Assembly Inspection

D0001.1168 Statistical Techniques

D0001.1168-1 SPC Technician Inspection form

D0001.1150 Return Material Authorization Process

SM012 Quality Concern Form

ISO/IEC 80079-34 Potentially explosive atmospheres, Application of quality systems

**4.0 RESPONSIBILITIES & AUTHORITY**

**4.1 Engineering**

Engineering participates as a member of the “Material Review Board” (MRB) to provide expertise concerning the design and specification for the material or product that is being reviewed and to offer possible options to resolve the non-conformity.

 **4.2 Manufacturing**

The Production Manager has the responsibility to schedule the MRB meeting based on the extent of impact the non-conformity has on customers, suppliers, processes, etc. An MRB meeting is not held for each non-conformity, but at the discretion of the Production Manager or at the request of a member of the MRB or Management.

 **4.3 Logistics**

Logistics provides information to the MRB as requested concerning product or material stock, location, etc. Logistics has the responsibility to protect materials and products in their control to prevent non-conformities due to handling, storage, packaging or transportation to other departments. Logistics does not typically attend the MRB meeting but is invited as needed.

 **4.4 Purchasing**

Purchasing provides information to the MRB as requested concerning vendor performance, current orders, material or product information (from vendors), etc. Purchasing has the responsibility for processing vendor related non-conformities and working with the vendor to reduce the incidence of non-conformant materials. Purchasing does not typically attend the MRB meeting but is invited as needed.

 **4.5 Quality Assurance (QA)**

QA participates as a member of the MRB to ensure that corrective and preventive actions are discussed and that the ultimate resolution of the non-conformity includes provisions for both. QA has the responsibility to work with all departments to improve quality by working to reduce and/or eliminate the occurrence of non-conformities.

 **4.6 Sales**

Sales Management attends MRB meetings as invited (dependent on the non-conformity) and acts as an advocate for the customer. Sales evaluate the non-conformity in light of how it affects the customer and/or the form, fit, or function of the finished product. Sales assist QA in notifying customers of approved recalls.

 **4.7** **Employees**

LD Employees have the responsibility and authority to notify their supervisor, manager, or QA when a suspected non-conformity is identified. If a process is the problem, the employee has the authority to stop the process to prevent further creation of non-conformant product or materials.

 **4.8 Management**

Management is notified of MRB meetings and participates in those meetings where a recall is being recommended and/or when the actions require signing authority or as desired.

**5.0 DEFINITIONS**

**QC –** Quality Concern

**LD –** Larson Davis a division of PCB Piezotronics, Inc.

**Material –** includes parts, processes, etc.

**MRB -** Material Review Board

**NCN -** Non-Conformity Notification

**Non-conformity** – a variation from the specifications of the part or product that affects form, fit or function

**Product –** A finished good manufactured or purchased by Larson Davis

**QA –** Quality Assurance

**Recall –** The issuance of a notification that product or material may not meet specifications and should therefore be returned to the factory or other designated location.

**RMA –** Return Material Authorization

**Signing Authority:** The granting of authority by the General Manager or Corporate Officer to a Larson Davis employee to authorize purchases or payments up to a pre-determined dollar value.

**6.0 SAFETY PRECAUTIONS—N/A**

**7.0 EQUIPMENT**

Access to a computer and/or the form used for reporting the non-conformities is required.

**8.0 INSTRUCTIONS**

Larson Davis has identified four primary sources of non-conformities:

* Vendor – materials, products or services purchased from an outside source by LD
* Product design – Engineering or software design
* Manufacturing – processes that are used to assemble and test the finished product
* Service – repair & calibration of customer owned product

Vendor non-conformities are reported on the "Non-Conformity Notification" (NCN) form, D0001.1034-1. Vendor non-conformities have the potential to be identified at any stage of the receiving or manufacturing process. (This paragraph does not apply to surface mount or wave-solder vendors; non-conformities from those processes are reported on the SPC Technician Inspection form, D0001.1168-1. The analysis of those non-conformities is reported on the Statistical Process Control (SPC) report that is provided to the General Manager, Production Manager and vendors when applicable.)

Non-conformities due to product design include software bugs, omissions on drawings or other documentation, etc. A Quality Concern (SM012) may be generated to initiate action by the appropriate department to fix the cause of the non-conformance if it is deemed necessary. An alternative to generating a Quality Concern for software and firmware bugs is to enter the non-conformity into the defect tracking system used by engineering, TestTrack.

Non-conformities due to manufacturing processes are reported on the SPC Technician Inspection form, D0001.1168-1. If the occurrence of the non-conformity becomes a trend or is suddenly pervasive then the problem is reported using the QC process. Process non-conformities are also submitted via the QC process.

If a service repair is made but the customer reports that the problem has not been fixed, a QC is completed and a RMA is generated to return the equipment.

**8.1 Reporting a Non-Conformance**

Non-conformities that are tracked during the manufacturing processes are recorded on the following form:

* SPC Technician Inspection form, D0001.1168-1

Refer to Section 3.0 for the parent documents and to reference how the non-conformities are recorded. Non-conformities identified during the manufacturing processes are isolated and resolved and then the resolution is verified prior to returning the items to production operations.

Non-conformities that involve purchased parts i.e. LCD displays, printed circuit boards, custom metal work, cases, keypads, etc., are reported on the Non-Conformity Notification form (NCN), D0001.1034-1, if they are identified before reaching the customer. These items are isolated and returned to the vendor or the non-conformance is resolved prior to being returned to inventory or production operations.

Non-conformities that suggest a trend are identified during the review of the reported information or through employee comment. The QA and/or Production Manager review the information and determine the extent of the affect. After the extent of the effect of the trend has been reviewed, QA or the Production Manager has the option of submitting a QC, SM012, for trends that have a minor affect or convening a MRB meeting for trends with the potential for having a major effect on quality, the ability of the company to supply product or to meet product specifications.

**8.1.1 Purchased Part Non-Conformities**

If a non-conformance involves purchased parts i.e. LCD displays, printed circuit boards, custom metal work, cases, keypads, etc.

Once a non-conformity is identified or suspected:

* Segregate and mark (tag, arrow, bag, shelf, etc.) the non-conformant parts and place on the Containment Shelf.
* Complete the Problem Description section of the NCN form, D0001.1034-1, and email it to the QA Manager (or representative)..
* QA Manager (or representative) will number the NCN and complete Material Disposition section of the NCN with Purchasing and Engineering (if needed) to develop a preferred action for resolution.
* An MRB meeting may be requested by any member of the MRB or company management. If an MRB meeting is needed the Production Manager is provided details of the non-conformity.
* Purchasing will contact the supplier for a response and resolution to the non-conformance.
* If the vendor authorizes us to return the part to them, Purchasing will submit a completed Shipping Request form (D0001.1044-2) to Inventory Control. The part will then be returned against the PO in the BSD.
* The non-conformant part and the completed Shipping Request form (D0001.1044-2) will be delivered to Shipping to be returned to the supplier.
* Purchasing will complete the Vendor Response section and discuss the proposed resolution to the problem with QA Manager (or representative).
* After a resolution has been agreed upon with the vendor, Purchasing documents the details in the Resolution section on the NCN form and reviews the resolution with QA and Engineering (if needed). The completed form can be forwarded to those departments directly affected by the non-conformity. A copy of the NCN and completed Shipping Request form (D0001.1044-2) will be sent to the Accounts Payable department. Accounts Payable needs this information in order to process vendor invoices properly and so that they are aware of discrepancies between the BSD PO receiving data and the Vendor invoice(s).
* Purchasing files a copy of the completed NCN in the appropriate vendor file.
* QA files the NCN in an appropriate folder.

Once the non-conformance has been resolved the item is verified to comply with product requirements prior to being returned to inventory or production.

**8.1.2 Other Non-Conformities**

Once a non-conformity is identified or suspected:

* Segregate the non-conformant parts and/or stop the process.
* Each person shall have a clearly marked area for both rework and scrap parts to be stored.
* Rework should be looked at and resolved within 60 day from the time it is placed in rework.
* Scrap should be moved to the recycle area at the earliest convenience.
* In process non-conformities are recorded per the Surface Mount Assembly Inspection, D0001.1120, Statistical Techniques, D0001.1168, or Corrective-Preventive Action Process, D0001.1020, procedures.
* If the non-conformance is identified by a customer, a QC, SM012, is submitted.
* If the non-conformance was identified in the Manufacturing process, submit the information to the Production Manager.
* The Production Manager reviews the non-conformance and notifies QA and other departments that are affected by the non-conformance as necessary.
* A MRB meeting may be requested by any member of the MRB or Management. If MRB meeting is needed, the Production Manager is provided the details of the non-conformity.
* Once the non-conformance is resolved the item is verified to comply with product requirements prior to being returned to inventory or production.

**8.2 Material Review Board (MRB)**

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An MRB meeting may be requested by any member of the MRB or Management. If an MRB meeting is needed, the Production Manager or representative is provided details of the non-conformity and has the responsibility to create the agenda, initiate and chair the meeting.

If a non-conformity that affects form, fit, function, or if the traceability of a product is identified after delivery to the customer, a MRB meeting is held. Participants review the facts and options for resolving the non-conformity. The resolution options available are reviewed and a resolution determined. Resolution includes a range of options from using the product “as is” for minor discrepancies to issuing a product recall for major non-conformities or safety concerns. The minutes of the meeting document the resolution and how it is implemented including assignments pertinent to the resolution.

* + The Production Manager schedules a meeting of the Material Review Board as needed.
	+ The Material Review Board (MRB) consists of representatives from Production, Engineering, and QA. Logistics, Purchasing or Sales participate in the MRB meeting as required at the invitation of the Production Manager. The MRB has the authority to implement resolutions that do not exceed the signing authority of the members of the MRB.
	+ The Production Manager, or designated representative, publishes the minutes of the MRB meeting including decisions, resolutions and assignments. Document Control maintains a copy of the minutes.
	+ The Sales department provides and or approves any communication documents that are to be sent to customers regarding the resolutions of the MRB. They also assist in contacting customers when needed.

**8.2.1 Non-Conformity Process**

Stop process and/or segregate product

Notify QA and/or immediate supervisor

Record and assign resolution through the NCN Form D0001.1044-2 or QC form SM012. Notify assignee of urgency.

Gather data / research

Present evidence and recall proposal to Management

Affects customer product?

Approval?

No

Yes

Problem identified or suspected

Immediate customer notification?

Is a recall needed?

Material Review Board meeting

Resolve issue

Resolve per Management instructions

Notify customers

No

Yes

Yes

Yes

No

**8.3 Customer Notification**

This section provides the guidelines necessary for notifying customers when problems are identified that may affect the ability of their instrument to operate as specified, affect health & safety, or if the validity of the calibration of the instrument may be questionable.

A list of customers that are affected by a non-conformity is prepared. If the non-conformity does not require a recall but does require notification and information to be distributed to customers then a document is prepared and reviewed by the QA Manager and Sales management. When the document is acceptable to QA and Sales management, Sales distributes the document to the affected customers.

**8.3.1 Product Recall**

If Management authorizes a recall of the affected products:

* Management determines the criteria for the recall.
* If the recall is due to a required change to the product then the recall action is listed on the ECO to make the change.
* A list of affected customers including, contact name, company, mailing address, telephone number, sales order #(s) for the product(s) being recalled as well as the affected product serial numbers is compiled. A copy of the list is distributed to the departments that are affected by the recall process.
* The QA Manager composes a letter of recall that includes the details of the recall and the RMA numbers for the customer (Return Material Authorization Process, D0001.1150).
* Management reviews the recall letter for content and intent.
* The approved recall letter is signed by the QA Manager and then provided to Sales for distribution to the affected customers.

**9.0 INSPECTION**

The Material Review Board meeting is the inspection step for those non-conformities requiring a more extensive review or level of action.

QA reviews the Non-Conformity Notifications as received and the Corrective Action Requests per the Corrective-Preventive Action Process, D0001.1020.

**10.0 RECORDS**

The following records are maintained in Document Control:

* Minutes of the MRB meetings
* Completed Document Change Orders (procedure D0001.1021)
* Completed Engineering Change Orders (procedure D0001.1022)
* Copies of the recall letter and the affected customer list

The Recall letter and affected customer list are maintained a minimum of two years after the notification is sent. Recall notifications involving possible safety hazards are maintained for a longer period of time, the length of which is determined by management.

Purchasing maintains the printed copies of the completed Non-Conformity Notification forms, D0001.1034-1, in the related vendor files for a minimum of one year.

For all non-conforming products that have been supplied to a customer and fall under ISO/IEC 80079-34 requirements (i.e. ATEX units) all records shall be maintained for a minimum of 10 years. This shall include:

* Serial numbers
* The customer who received the product
* Action taken to inform customer and relevant notified body
* Action taken to implement corrective/ preventative actions

**11.0 DISTRIBUTION**

Distribution and access of this procedure is via the online Document Control area.

**12.0 ATTACHMENTS**

None

**13.0 REVISION HISTORY**

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| --- | --- | --- | --- | --- |
| **DCO #** | **REV** | **DATE** | **INITIALS** | **CHANGES MADE** |
| 561 | C | 6/16/03 | JEB | Total re-write. |
| 1108 | D | 5/27/08 | DAR | Update |
| 1210 | E | 5/14/09 | DAR | ISO9001-2008 updates |
| 1279 | F | 1/28/10 | DSM | Update to meet EN13980 clause 8-3 (e) |
| 1364 | G | 2/17/12 | DSM  | Update to include defect tracking system |
| 1501 | H | 6/30/14 | DSM | Updated to satisfy audit findings from EO0214 |
| 1472 | I | 8/13/14 | CDR | Added instructions to 8.1.1 for NCN to be submitted to Accounts Payable |
| 1549 | J | 5/14/15 | CDR | Added clarification for processing parts being returned to vendor |
| 1616 | K | 3/30/16 | CDR | Added statement to Section 1.0 Purpose and Scope, and to Section 8.0 Instructions |