**CORRECTIVE - PREVENTIVE ACTION PROCESS**

**1.0 PURPOSE AND SCOPE**

The Corrective - Preventive Action process provides the necessary guidelines to correct and prevent quality-related problems. The process addresses:

* Corrective Action
* Preventive Action
* Customer Feedback
* Customer product returns

**2.0 AFFECTED DEPARTMENTS**

All departments of Larson Davis are affected by this procedure.

**3.0 REFERENCE DOCUMENTS**

SM012 Quality Concern/Suggestion Form

SM25 Customer Complaint Procedure

SCCD Syteline Customer Complaint Database

D0001.1021 Document Change Order

D0001.1022 Engineering Change Order

D0001.1012 Customer Communication

D0001.1150 Return Material Authorization (RMA)

PCB Quality Assurance Manual Section 10.2 and 10.3 found on R drive/ISO/QAM

**4.0 DEFINITIONS**

**Corrective-Preventive Action Request (QC/Quality Concern)** – Documented method that encompasses corrective, preventive actions, root cause investigation, resolution and customer satisfaction. The request is used for communicating customer and employee concerns about processes, procedures or products that may affect the quality and reliability of the finished product or service.

**Corrective Action** – An action that is taken to minimize or fix a concern that is affecting processes, procedures, product quality or reliability.

**Customer Satisfaction –** Actions proposed or taken to improve relationship with customer. The actions may include but are not limited to: discounts on goods or services, free accessories, free shipping, etc.

**DCO-** Document Change Order

**DRA-** Department Review Authority; generally this is the Division QA Manager who approves all action on QCs prior to being submitted for final approval.

**ECO** - Engineering Change Order

**Management -** Management may include but is not limited to the Engineering Manager, Sales Division Manager, and Director of LD Operations/General Manager.

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

**Preventive Action** – An action that is taken to prevent the occurrence of potential non-conformities.

**RMA (Return Material Authorization)** - For the purpose of this procedure, an RMA refers to any item being returned from a customer.

SCCD—Syteline Customer Complaint Database—location where customer complaints are logged and tracked as QCs.

**Verification –** The act of verifying that the corrective or preventive action was effective.

**5.0 RESPONSIBILITIES & AUTHORITY**

 **5.1 Submitter (Originator)**

LD employees are responsible to identify and report concerns that affect or have the potential to affect the quality of a process, procedure, product or service. The Submitter (originator) of a QC is an LD employee with the following responsibilities:

* Determine the nature of the quality concern.
* Complete SM012 or follow SM25 in as much detail as possible.
* If scanned documents are included as part of the QC, make note that documents are attached.
* Submit the QC to QA Department.
* Approve extensions of the resolution date and the final resolution.

**5.2 Assignee**

An “Assignee” is an employee assigned to resolve a "Corrective-Preventive Action Request" (QC) and is responsible to:

* Determine and document the “root cause” of the concern.
* Ensure that the concern is fixed or resolved.
* Resolve the concern within 30 days from date of assignment.
* Document the information about the resolution including the corrective action and preventive action that may be applicable.
* Obtain approval from management and the submitter for extension of the resolution date if needed.
* Submit the QC to department manager for approval and forward to DRA--LD QA Manager.

**5.3 PCB QA Department**

PCB QA department has the following responsibilities:

* Follow the procedures documented in PCB Quality Manual sections 10.2 and 10.3 for the purposes of tracking all corrective and preventative actions.
* PCB QA has oversight for the corrective/preventative processes and controls documents, follow up and storage of completed QCs.

 **5.4 Management**

Management includes department managers, supervisors and Division Management.

Management is responsible to:

* Verify that the QC process is being used effectively
* Determine and communicate the assignee for a QC within their group
* Approve extensions of resolution date
* Ensure that proper training is occurring

**5.5 Sales**

Customer communication is handled per the requirements of the Customer Communication procedure, D0001.1012. Corrective-Preventive Action Requests (QCs) are generated as indicated in this procedure.

Sales has the responsibility to:

* Follow the procedures documented in PCB Quality Manual sections 10.2 and 10.3.

 **5.6 Quality Assurance (QA) Larson Davis**

The QA Manager, or a designated representative, is responsible to:

* Provide oversight of the process at the LD plant
* Determine whether the process is working and being implemented as documented
* Report on the process to Management
* Act as DRA for LD plant
* Recognize, suggest and implement methods for improving the process

**6.0 SAFETY PRECAUTIONS**

No safety precautions are applicable to this procedure.

**7.0 EQUIPMENT & MATERIALS**

Current computer system capable of running the necessary software and templates used to write, edit, submit and control applicable information.

**8.0 CORRECTIVE - PREVENTIVE ACTION PROCESS**

A flow chart detailing the process flow is located at the end of Section 8.0.

 **8.1 Preventive Action**

Preventive Action is a process that allows the elimination of the possible causes of potential non-conformities in order to prevent their occurrence. The preventive action is proportional or appropriate to the effect of the potential problem. For example, if a piece of tile in the floor becomes cracked there is the potential that the tile will eventually break apart and become a trip hazard. A preventive response that would be proportional to the level of risk would be to replace the cracked tile. An out of proportion response would be to replace all of the tile flooring.

The potential for non-conformities and thereby the need for preventive action is identified through data analysis, process records, employees, etc.

When an area is identified that may benefit from preventive action, a quality Concern (QC) SM012 is generated and processed. The QC process provides a method:

* For determining root cause
* For evaluation of the need for action (risk management)
* For implementing appropriate action
* For documenting the action taken
* For reviewing the implementation to determine effectiveness

The method used for processing preventive actions is detailed in Section 8.3 of this document.

**8.2 Corrective Action**

Corrective action is the elimination of the causes of non-conformities in order to prevent recurrence. The corrective action implemented is proportional to the effect of the non-conformity encountered. The types of non-conformity that are reported through the corrective action process include but are not limited to:

* Product related non-conformities
* Customer complaints
* Warranty returns
* Order entry errors
* Training needs

The method used for processing corrective actions is detailed in Section 8.3 of this document.

 **8.3 Corrective – Preventive Action Process**

**8.3.1 Usage**

The Quality Concern (QC) form, SM012, is used to document a variety of concerns including but not limited to:

* Customer action items forwarded from Sales or Technicians per the Customer Communication procedure, D0001.1012
	+ Order entry errors
	+ Dissatisfied customer concerns—SM25 procedure
* Shipping problems e.g. wrong product, wrong location
* Product defects
* Internal problems that represent systemic problems enough to warrant corrective or preventive action
	+ Continuous reject rates
	+ Negative trends in metrics
	+ Repeated process or product nonconformance
* Employee suggestions for improvement

**8.3.2 Complete the Corrective-Preventive Action Request form**

The “Submitter” is an employee who submits a QC form or follows SM25, with as much information as possible, to QA.

**8.3.3 Submit the QC Form**

The preferred method of submission is using the electronic form.

The QC form is sent to QA in “Word” format. Attachments are submitted as pdf or Word files.

SM25 uses the current Syteline Customer Complaint Database (SCCD) as the method to document the concern specifically for customer complaints.

**8.3.4 PCB QA**

PCB QA administers the QC process by reviewing and distributing as indicated in the QAM 10.2 and 10.3.

**8.3.5 QC Assignment**

QCs are assigned to a department dependent on the nature of the request. The department manager is then responsible to resolve or assign responsibility for resolution.

*If the resolution requires more than 30 days to complete then the assigned individual contacts their manager for agreement to extend the due date.* The manager works with the LD Plant DRA to extend the QC.

**8.3.6 QC Tracking and Reports**

QCs are tracked by the PCB QA Department or through the current SCCD PCB QC Customer CARs forms.

The QA Manager/DRA reviews and prepares a report that documents trends and resolutions (monthly and/or quarterly report) and discuss with Director of LD Operations/General Manager.

**8.3.7 Investigation and Determination of Corrective - Preventive Action**

The results of the investigation are documented, by the assignee, on the completed form along with the name of the individual who performed the investigation.

The assigned individual conducts a “Root Cause” investigation and determines a possible solution.

If after investigation of the QC, it is determined that there is no viable solution or the documented issue is not a corrective or preventive concern, then the investigating employee reports his findings on the QC and seeks department manager approval and DRA approval to close the QC by sending it along to PCB QA Department.

**8.3.8 QC Completion**

A QC is completed when the assigned employee has finalized a resolution and the completed QC form, SM012 or SM25 process, documenting the action taken, has been filed with PCB QA Department and accepted.

If resolved through ECO or DCO then that information is on the QC.

 **8.3.9 Corrective or Preventive Action:**

If the QC was not resolved through a DCO or ECO, include the details of the resolution in the appropriate space (preventive and corrective). The details of the resolution are written using language and terminology that can be understood by any employee. If the resolution includes a:

* Production stop order, then indicate on Containment Checklist
* Product Recall, then fill out appropriate sections

**8.3.10 Customer Satisfaction with QC Resolution**

All QCs that affect customers require that Sales contact the customer and takes a response from the customer regarding the resolution and their satisfaction with the resolution.

This contact follows procedures outlined in PCB QA sections 10.2 and 10.3.

If the request originated with a supplier, the individual responsible for resolution has the option to work directly with the supplier or may involve the appropriate LD employees such as Purchasing, QA, Engineering, etc. Follow-up with the supplier is the responsibility of QA or the individual assigned to resolve the initial QC.

**8.3.11 Verification of Corrective – Preventive Action**

This process follows procedures outlined in PCB QA section 10.2 and 10.3.

Corrective actions requiring follow-up verification, as indicated by quality assurance management on either the document or SCCD entry, are evaluated to ensure effective functioning of the internal corrective action system. Quality assurance employees shall verify effectiveness using Follow-up Effectiveness Verification Reports in the SCCD or appropriate sections of SM012. Verification of corrective action effectiveness may be based upon severity of issue, presence of any recurrent workmanship deficiency, need for continuous improvement plan evaluation, or to assure comprehensive coverage of all manufacturing center processes, products or services.

**8.3.12 Quality Review**

Quality Assurance, or an assigned employee, review randomly chosen QCs, that have been completed, for conformance to the QC process.

Quality Assurance/DRA reviews the QC process on a periodic basic to verify that the system is being used effectively, employees are adequately trained, procedures are being followed, and that the system is producing continual improvement.

The following flow chart defines the Corrective - Preventive Action Process.

External Input

(Customer, Supplier, Rep)

Employee

(Submitter)

Record customer communication per this procedure and “Customer Communication”

(D001.1012); Customer Complaint follow SM25

Employee

(Submitter)

Complete form per procedure

(SM012) of SCCD

Give to QA for assignment

Assigned individual provides a completion date to QA

(not more than 30 days following failure analysis)

Root Cause Investigation—use 5 Whys

Contact customer or supplier

Submit findings to LD Sales

QA updates files

QA completes the process

If the QC was of external origin, Sales communicates the resolution to the source and gets response

Implement per instructions on the form or associated documentation in SCCD

Update QC form

Assigned person determines resolution

Is this a valid QC?

Does Manager and DRA accept resolution?

No

No

Yes

Yes

DRA approves and forwards to QA

**9.0 INSPECTION / VERIFICATION**

See above sections.

\*If fixes, repairs or testing are ineffective or inadequate they will become evident through other means and a QC can be written. There are enough controls within the ECO and DCO procedure to verify that everyone accepts the solution that we don’t need anymore.

**10.0 RECORDS**

PCB QA department maintains all QC records.

**11.0 DISTRIBUTION**

This procedure is applicable to all departments and available through the online Document Control area or obtained in hard copy format from the Document Control Clerk.

**12.0 ATTACHMENTS**

None

**13.0 REVISION HISTORY**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **DCO #** | **REV** | **DATE** | **INITIALS** | **CHANGES MADE** |
|  | B | 9/29/99 | JEB | Deleted Technical communications flow chart, corrected company name, deleted references to Sensar, added supervisor / manager review prior to submission to QA. |
| 293 | C | 10/9/00 | JEB | Added reference to Customer Communication procedure, removed sections of flowchart that overlapped with Customer Communication, removed LD representatives from QC process, corrected grammar and clarified how to complete form. Added a new section 8.2.6. Changed references to "Senior Staff" to "Management Team". Defined Management Team in the definitions. |
| 470 | D | 10/15/02 | JEB | Changed Customer Feedback to Customer Communication, Added link from Customer Communication to an LD Employee in the flow chart, replaced "Repair & Calibration" in section 8.2.1 with Technicians, removed reference to weekly reviews and reporting and replaced with monthly review and reporting. Edited the CAR form and updated the drop-down lists to match current departments / groups. |
| 514 | E | 4/09/03 | JEB | Created a new form to incorporate needs from multiple departments as well as eliminate an RMA form. Rewrote procedure edited process flow chart. |
| 589B | F | 9/15/03 | JEB | Expanded Preventive action & Corrective Action sections to reflect requirements of ISO9000. Removed the requirement to retain paper copies of completed CAR’s, added reference to the Quality Records Matrix, D0001.1126-1. |
| 589D | G | 10/1/03 | SLB | Added CAR tracking log into the Procedure |
| 703 | H | 2/10/04 | JEB | Added and clarified the responsibilities associated with the CAR process. Standardized the term submitter through the rest of the document, added the requirement that electronic CAR’s be submitted in Word format and attachments in Word or pdf format. Clarified and corrected throughout the document. |
| 804 | I | 8/23/04 | JEB | Modified and clarified sections 4.0, 8.3 and the form D0001.1020-1 to help employees better understand the process and use the form. |
| 1108 | J | 5/23/08 | DAR | Update to integrate with corporate tracking of corrective and preventative actions. |
| 1322 | K | 1/17/11 | DSM | Rearrange sections for better clarification |
|  | L | 4/11/18 | DAR | Update to add new SM25 Customer Complaint Procedure. |