Procedure Corrective and Preventive Action P8.5.2/3-1 Rev. H

Approved By: Mike Orsini, Quality Manager

Purpose: To document procedure for corrective and preventive action.

Scope: All corrective and preventive action for customer complaints, audit findings, and

product non-conformity.

Authority: The Quality Manager has the authority to change or modify this procedure.

Reference Documents and Records

Policy Element 8.5.2 Corrective action and 8.5.3 Preventive action

• DMR Procedure P8.5.2/3-3

Quality Records Procedure P4.2.4

Change History

Date	Change	Rev	Ву
12/01/96	Revised typos	В	MO
12/10/96	Revised for typos	C	MO
12/12/96	Updated to reflect all CARS for preventative action.	D	MO
03/03/97	Removed Low Risk Log. Added use of database QCICAR.MDB	Е	MO
11/13/98	Revised name of database. Added forms and reports generated by Harrington Group Software. Revised method of initiating a CPAF request. Revised method of closing CAR's. Revised initial filing method for CAR's. Added review of open CAR's to step 9. Added databases to Preventive Action section.	F	MO
10/29/2002	Updated to the ISO 9001:2000 requirements and flowcharted. Defined two types of preventive actions.	G	МО
8/27/2003	Added method for tracking Preventive Actions. Use of category field in CAR program to identify Preventive Actions.	Н	МО

Corrective and Preventive Action P8.4.2/3-1 Rev. H - Corrective Action Supervisor. **QMRB** Responsible Person/ Management or Quality Manager Member Team Auditor Review need for Investigate the cause of Address problem corrective and Opinion: High magnitude or preventive action. Determine the the non-conformities risk? relating to product, process, and quality magnitude of the End system, and record the problem and Yes result on the Summary . amount of risk. and Notes section of the Enter the problem into the Corrective Action Software for Corrective Customer Request Problem and Action for Corrective and Preventive Actions. The database used for CAR is called "Internal Detail Reports.(CAP-XXX Actions shall also & CAI-XXX) Use all be cause for implementing the CPAF procedure. appropriate sources of information such as If DMR is reason for corrective or preventive action then document the process and work DMR number as part of the reference material to be used by the CAR operations which affect product quality, concessions, audit results, quality records, Log CPA into the database. The computer will generate a CAR number. This number will be used to track and record the and customer complaints effectiveness of the CAR. to detect, analyze, and eliminate potential causes DMR related? of non-conformities. Assigns responsibility for CAR and documents in the CAR software program. Generate initial copies of the Problem Detail Report (CAP-XXX) and the Action Detail Report (CAI-XXX). (Action may be assigned after investigations.) Distributes copies of the initial problem and action detail reports Submits a Determine corrective to appropriate CAR team members. Places copies request to action needed to in the CAR file (book). generate a CAR eliminate the causes of to the QA non-conformities or steps Manager or QMRB member Review corrective or preventive actions taken. May require needed to deal with any problems requiring preventive action. This additional actions be to be taken or may close out the CAR through the use if evidence is provided that problem is resolved. of a memo or includes assigning actions that need to be Determines if there is a need for follow-up actions and note or through can assign additional actions for the purpose of a verbal request. investigating the effectiveness of a given CAR. (Follow-up). taken to insure effective CAR. These actions should be submitted to Review all CAR's and insures that they are entered into the CAR database. Reviews all actions associated with The the QA Manger so that additional Action Detail Reports can be CAR to insure that they have been closed. Once a CAR generated for the initial has been deemed to be effective and is closed the QA problem (CAR number). Manager or QMRB member signs and dates the completed problem detail reports and action detail reports. All of the listed actions on Submit a copy of Generates a Problem Summary Report (CAP-XXX). a given CAR must be the DMR with completed in order to request. DMR's are close out a CAR. conducted per the Place copies of all documentation in the CAR File (Book). DMR Procedure (P8.5.2/3-3). A copy of all documentation generated for a CAR is placed with a summary report (CAP-XXX) into the CAR file (Book). Initial written copies of the problem detail report and action detail reports may be discarded once all the information on them has been transferred to the database and new reports (with previously written info) have been generated. File CPAF according to Quality Records Procedure (P4.2.4). Begins step 3 for distribution purposes on re-assignments of dates and updates the database to reflect the changes. Reviews all CAR's on a minimum monthly basis to insure they are closed in a timely manner or determines that there is a need to revise initial due date for the CAR. **END**

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