

Procedure

Corrective and Preventive Action P8.5.2/3-1

Rev. H

Approved By: Mike Orsini, Quality Manager

Date: 10/29/2002

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.

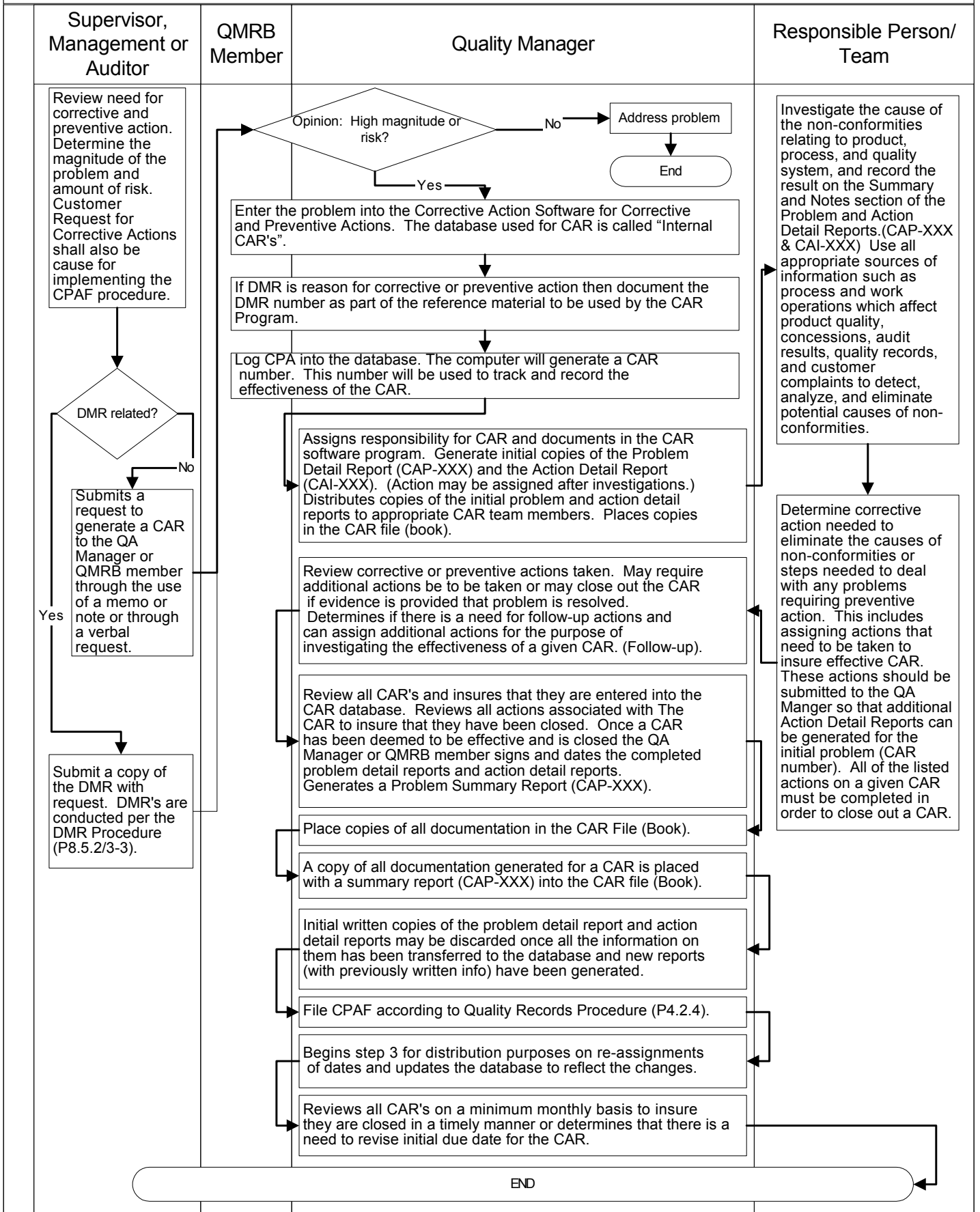
Reference Documents and Records

- 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	By
12/01/96	Revised typos	B	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	E	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	MO
8/27/2003	Added method for tracking Preventive Actions. Use of category field in CAR program to identify Preventive Actions.	H	MO

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Corrective and Preventive Action P8.5.2/3-2 Rev. H - Preventive Action

Management

Quality Manager

There are two methods to determine a preventive action. One is discovered through trend analysis and the second is through identification of any other potential nonconformance.

Trend or Potential nonconformance?

Trend

Potential Nonconformance

A potential nonconformance is discovered

Prior to Management review meetings perform an analysis of all corrective action systems including CARs, DMRs, and Supplier Corrective Actions. This analysis is done through the use of the Harrington Group Software Program.

The analysis shall be conducted on the Internal CAR and the Supplier CAR databases. A Pareto Analysis will be performed on both databases to determine trends in the corrective action problems.

Data may be sorted by type of problem, area, ISO element affected or any other manner deemed appropriate by the Quality Manager or member of the QMRB.

Trend detected?

Yes

No

Record in the Corrective and Preventive Action database using process on Page 2.
Any CAR's that are a result of a Preventive Action will be classified in the CAR Program as category PREVENTIVE. This will allow all Preventive actions to be reviewed individually from all other CAR's.

END