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CORRECTIVE AND PREVENTIVE ACTION

Operational Procedure: QOP-14-01

Rev.: A

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I PURPOSE

The purpose of this procedure is to provide for a system and instructions, and to assign responsibilities for initiating, requesting, carrying out, and checking the effectiveness of corrective and preventive actions.

NOTE: Distinction between corrective and preventive action is that corrective action deals with actual nonconformities and preventive action deals with potential nonconformities. Procedure for handling both types of actions is the same. The only difference is in the way the need for a corrective or preventive action is identified. Therefore, this procedure does not distinguish between the two types and refers to both as corrective actions.

II APPLICATION

This procedure applies to correcting and preventing nonconformances and nonconformities related to materials, components, subassemblies, finished products, production processes, and the quality system.

This procedure concerns Quality Assurance and Management, and affects all other departments and functions in the company.

III PROCEDURE

1. Application and Responsibility

- 1.1 Corrective action requests (CARs) can be directed to the company's internal departments and to its subcontractors.
- 1.2 Initiation of a CAR may be proposed by anyone in the organization, but all CARs must be authorized and requested by QA or the President.

Written by:

Original Issue Date:

Approved by:

Date:

Approved by:

Date:

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1.3 Requests to initiate a CAR are made in writing to QA or, if QA or QC activities are involved, to the President. The requests contain a description of the unsatisfactory condition to be corrected and explain how quality is affected.

2. Initiation of a CAR

2.1 Corrective actions may be requested in the following cases:

- Identification of a major product nonconformance, including products returned by the customer;
- A trend of minor product nonconformances of a similar character;
- Recurring problem with a process or work operation;
- A noncompliance observed during an internal, customer, or third-party audit;
- Field performance problems reported by servicing;
- Customer complaints (including late shipments);
- Nonconforming deliveries from subcontractors; and/or
- Identification of any other condition that does not comply with the documented quality system and/or QS-9000 requirements.

3. Requesting and Processing CARs

3.1 Corrective actions are requested using the CAR form, a model of which is enclosed at the end of this procedure. The requests contain a description of the unsatisfactory condition that needs to be corrected and are addressed to the manager who is responsible for the area where the condition occurred.

3.2 Upon receiving a request for corrective action, the responsible manager investigates the cause of the problem that initiated the request, proposes a corrective action to be taken, and indicates the date by which the corrective action will be fully implemented. The party initiating the request (QA or President) reviews and approves the proposed action.

3.3 On, or immediately after, the due date for implementation of a corrective action, QA or the President follows up with an inquiry or an audit to determine if the corrective action has been implemented and if it is effective. When there is objective evidence that the corrective action is effective, the CAR can be closed out. If more work is needed to fully implement the action, a new follow-up date is agreed upon.

4. Problem-Solving Methods

4.1 Managers responsible for investigating causes of nonconformances and for implementing corrective actions use disciplined problem-solving methods. The methods include formal documentation of problems, cross-functional approaches to problem solving,

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organization of investigative and implementation activities, communication, reporting, and so forth. When required, analytical problem-solving techniques, such as Fault Tree Analysis, Design of Experiments, and Cause and Effect Diagrams are used.

5. Customer Returned Products

- 5.1 Nonconforming parts returned by customers are given special attention. Highest priority is given to establishing causes of nonconformances and implementing corrective actions to prevent recurrence. QC analyzes and/or tests the returned parts, and investigates root causes of the nonconformances. Results of the analysis are recorded, and may be made available to the customer upon request. Where appropriate, QA initiates and requests corrective actions in accordance with this procedure.

IV ASSOCIATED DOCUMENTS

- Control of Nonconforming Product — Oper. Proc. QOP-13-01
- Customer Complaints — Oper. Proc. MOP-14-02

Insert **CORRECTIVE ACTION REQUEST FORM** from file FRM1401.DOC