Corrective and Preventive Action

I PURPOSE

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

II APPLICATION

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

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

NOTE: Kooltronic recognizes an important distinction between preventive and corrective action in the phase of identifying the problem that needs to be corrected or prevented. Accordingly, the present procedure has separate sections for handling the two types of actions in this phase (Sections 1 and 2). However, in subsequent phases preventive and corrective actions are processed through the same system and both types of actions are referred to as corrective actions (Section 3).

III PROCEDURE

1. Preventive actions

1.1 Preventive actions are implemented where there is an increased risk for potential nonconformity. The need for a preventive action is identified on the basis of information regarding capability and performance of processes and work operations, product nonconformity rates, service and user feedback, customer complaints, and effectiveness of the quality system.

1.2 Quality Assurance is responsible for collecting, compiling and reviewing the pertinent information. At a minimum, Quality Assurance reviews:

- Reject and scrap rates
- Product nonconformity reports
- Service records and reports
- Production equipment maintenance records
- Customer complaints
- Quality system audit records

1.3 Preventive actions are initiated when quality performance data indicates that there are trends of decreasing quality capability and/or effectiveness of the quality system. For example, it may be increasing incidence of product nonconformities traceable to the same common cause, excessive equipment problems, or increasing number of audit findings against the same element of the quality system or department.

1.4 When a problem requiring preventive action is identified, the process of dealing with the problem follows the same steps that apply to corrective actions, as described in this procedure in Section 3, Requesting and Processing CARs. In subsequent processing stages both types of actions are referred to as corrective actions.

2. Corrective actions

2.1 Corrective action requests (CARs) can be directed to the company's internal departments and to its vendors.

2.2 Initiation of a CAR may be proposed by anyone in the organization, but all CARs must be authorized by Quality Assurance or the President. This is to prioritize and direct resources where corrective actions are most urgent.

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

2.4 Corrective actions may be requested in the following cases:

- Identification of product nonconformity, including products returned by the customer
- Problem with a process or work operation
- A nonconformity identified during a customer or third-party audit (internal audits have their own CAR system)
- Field performance problem reported by servicing
- Customer complaint (including late shipments)
- Nonconforming delivery from suppliers
- Identification of any other product or condition that does not conform with product specification, documented quality system or requirements of the ISO 9001 standard

3. Requesting and processing CARs (applies also to preventive actions)

3.1 Corrective and preventive actions are requested using Form K925, Corrective Action Request. The requests include description of the unsatisfactory condition to be corrected, and are addressed to the manager responsible for the condition. The same CAR form is also used to request corrective actions from suppliers.

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 (Quality Assurance or President) reviews and approves the proposed action.

3.3 On, or immediately after, the due date for implementation of a corrective action, Quality Assurance 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.

IV ASSOCIATED DOCUMENTS

- Form K925: Corrective Action Request
- Operational Procedure QOP-83-01: Control of Nonconforming Product
- Operational Procedure QOP-72-03: Customer Feedback and Complaints
- Operational Procedure QOP-85-01: Continual Improvement