1.0 Purpose

The purpose of this procedure is to describe the process of requesting, initiating, implementing, and following up on preventive action.

2.0 Associated Forms

- QT9 / ISO Functions/ Preventive Actions

3.0 Policy

A planned and documented program for preventive action shall be established to ensure that conditions adversely affecting quality are promptly identified. The causes of discrepancies shall be determined, and positive steps shall be taken and later reviewed to prevent recurrence.

4.0 Responsibility

The Quality Manager is responsible for the investigation and analysis of nonconformities relating to product, process, and quality systems and for the cause determination and preventive action process. All employees have the obligation to identify and report situations that may lead to nonconformities to the Quality Manager. The Quality Manager is also responsible for identifying opportunities for preventive action.

5.0 Feedback Data

Use shall be made of feedback data generated by customers as well as information generated internally to correct the potential causes of nonconformities that might otherwise go unnoticed (for specific examples of data and trends collected by management see 7.3). The Quality Dept. shall apply statistical techniques to the feedback data in order to detect changes in processes and will analyze quality records within the company.

6.0 Procedural Change

Any deficiency found in quality procedures resulting from preventive action activities shall be corrected in accordance with the Control of Documents procedure 90-2000-4.2.3.

7.0 Preventive Action Request and Initiation

7.1 Requests for preventive action are addressed to the Quality Manager. To request a preventive action, a new action is generated via QT9

The form is described below:

- QT9 / ISO Functions/ New Preventive Action: Any employee may report a condition or make a suggestion and thereby request a preventive action using this form. It is available on the company intranet (QT9 QMS Software).

The person initiating the preventive action request must determine, based on the circumstances and investigation of the incident the preventive action type; New Idea, Process Improvement, Potential Nonconformance, Audit Observation. The Responsible Party, Description and Root Cause information should also be completed

Submitting one of the above requests via QT9 causes an e-mail message to be forwarded to the QA Manager or other responsible party. The form is serialized by QT9 and may be referenced by number.

7.2 The QA Manager has the authority to initiate preventive actions based on the form described above or based on the trending and review of Quality measurements (see 7.3 below).

7.3 QA charts and reviews the following items, no less than once per year

- Audit noncompliances
- Customer Complaint Reports
- Corrective Action Request Activity
- Corrective Action (Overall) Activity
- Problems detected at outgoing inspection
- Quality and Delivery Reports from participating customers
- On Time Shipping Performance
- Noncomforming Material
- Warrenty Returns

8.0 Implementation and Follow-Up

8.1 If preventive action is required, the QA Manager works with the appropriate department manager or area supervisor to determine the root cause and to propose an action and implementation date. The manager or supervisor then becomes responsible for carrying out the action.

8.2 After the implementation date, QA verifies that the action has been implemented and is effective. This follow up can take the form of an extra internal audit, an inquiry, comparing new measurements to old, or any other appropriate method of verification. If the action is not effective or is not yet implemented, an additional action is proposed or a revised implementation date is agreed upon. When the action is completed and is deemed to be effective, it is closed by the QA Manager.

8.3 The Responsible Party (generally QA Manager) completes the additional training, procedure review or verification etc. and indicates this in the QT9 form, Action Taken. Upon completion, documentation and verification, the preventive action request can be closed.

9.0 Documentation and Record

The storage locations and retention periods for documents discussed in this procedures are specified in procedure 90-2000-4.2.4, Control of Records.