1.0 Purpose

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

2.0 Associated Form

QT9 / ISO Functions/Corrective Actions

3.0 Policy

A planned and documented program for corrective 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 Assurance Manager is responsible for the investigation and analysis of nonconformities relating to product, process, and quality systems and for the cause determination and corrective action process. All employees have the obligation to identify and report nonconformities to the Quality Assurance Manager.

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 an investigation of a nonconformity shall be corrected in accordance with the Control of Documents procedure 90-2000-4.2.3.

7.0 Corrective Action Request and Initiation

7.1 Requests for corrective action are created in QT9 by employees. The same form is used for all types of requests. In QT9, select ISO Functions, Corrective Actions, New Corrective Action.

The **Corrective Action Types** are listed below:

- **Audit Issue – do not use**

- **Customer Complaint** - This corrective action type may be used by any employee who receives a complaint from a customer. The QA Manager should be selected as the initial responsible party.

- **Inspection Issue -** This corrective action type may be used by any employee who discovers a product/item issue at incoming or outgoing inspection. The QA Manager should be selected as the initial responsible party.

- **Internal Audit major/minor** - This corrective action type may be used by the internal audit committee to record a corrective action found during an internal audit. The committee shall discuss the type, minor or major and the responsible party.

- **Management Review -** This corrective action type may be used as part of the management review process.

- **Nonconforming Product -** This corrective action type may be used by any employee who discovers a product/item issue at any time in the production process. The QA Manager should be selected as the initial responsible party.

- **Process Issue – do not use**

- **Supplier Issue –** This is initiated by QA to request action/analysis for a nonconforming condition that originates external to Product Resources at the supplier level. Returned product may or may not accompany the Supplier Corrective Action Request. A copy will automatically be emailed to the supplier via the QT9 system. The Purchaser of the part shall be listed as the responsible party. It is the

joint responsibility of QA and Purchasing to follow the Supplier Corrective Action Request through to completion.

- **Surveillance audit major/minor** are to be entered when the audit non compliance is generated by an external auditor. The QA Manager should be selected as the initial responsible party.

The person initiating the corrective action request must determine, based on the circumstances and investigation of the incident the corrective action type. 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 corrective 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 The QA Manager works with the most knowledgeable parties to determine and document the root cause. QA holds twice-a-month meeting with other participants when beneficial. The purpose of this session is to review open corrective actions, assign corrective actions to the best party for root cause determination and action determination when it is not QA (setting appropriate Approvers in the process), answer to root cause and actions for those ultimately assigned to QA, and facilitate verification and closure. These sessions are ongoing and have the purpose of maintaining the corrective action process as current.

8.2 After the implementation date, QA reviews 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 for effectiveness. 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 corrective action request can be closed.

9.0 Documentation and Record

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