1. Purpose

To define the process for determining and implementing effective Preventive Actions.

2. Scope

This procedure applies to all Preventive Actions implemented in Technical Services at all locations.

3. Definitions

**CPA** - Corrective and Preventive Action

**CPAR** – Corrective/Preventive Action Request (form)

**Non-conformance** – A deviation from an expected result or standard.
- Observed practice or product does not equal documentation.
- Verbal description does not equal documentation.
- Documentation or practice does not meet the requirements of the ISO 9001 standard.

**Preventive Action** - Action taken to eliminate underlying causes to potential non-conformances to prevent them from occurring.

4. Responsibilities

**Quality Assurance Project Manager** - Responsible for implementing and maintaining the preventive action system.

**Management** – Responsible for providing resources to effectively address issues that are generated as a result of the preventive action system.

**All Employees** – Responsible for identifying non-conformances and suggesting improvement opportunities and for suggesting preventive actions when they identify a potential non-conformance.
5. Procedure

5.1. Initiating a request for Preventive Action
   5.1.1. In conjunction with the management team, the Quality Assurance Project Manager will determine criteria for how non-conformances are reviewed and communicated and when Preventive Action is required. They will also determine timeframe requirements associated with the steps of the process. These time requirements will be relative to the severity of the non-conformance encountered.

   5.1.2. Any employee can initiate a request for Preventive Action. This request can stem from a non-conformance that has been communicated by a customer, or from direct observation by the employee. This includes Supplier Corrective Actions.

   5.1.3. Internal auditors may generate CPAR’s as a result of the internal audit process.

   5.1.4. Preventive Action may also be generated as a result of the Management Review process.

   5.1.5. Details about the issue are recorded on the Corrective/Preventive Action Request form.

   5.1.6. The Quality Assurance Project Manager will assign an investigator and schedule based on the degree of the potential non-conformance.

5.2. Investigating a request for Preventive Action
   5.2.1. The investigator determines the cause of the potential non-conformance and designs the implementation plan to address the issue.

   5.2.2. The investigator is responsible for finding the root cause, and determining both short-term containment and permanent preventive actions as required.

5.3. Implementing a Preventive Action
   5.3.1. Upon investigation, the Quality Assurance Project Manager assigns an individual to implement the actions as required.

   5.3.2. This person is responsible for implementing or overseeing the implementation of actions to be taken. A summary of actions taken is recorded on the CPAR form.

5.4. Verifying a Preventive Action
   5.4.1. Following completion of the actions taken, the Quality Assurance Project Manager will assign and schedule follow-up.

   5.4.2. The responsible person will record the results of the action taken and determine whether or not the action was effective.
5.4.3. If the action was determined to not be effective a new Preventive Action Request may be issued.
5.4.4. If the action was determined to be effective the request will be forwarded to the Quality Assurance Project Manager for closure.

5.5. Closing Preventive Action Requests
5.5.1. Upon final review, the Quality Assurance Project Manager will close the Preventive Action Requests.

5.6. Periodic Review of Data
5.6.1. Periodically, the Quality Assurance Project Manager will review records of previously issued CPAR’s in order to summarize any trends and to initiate further action as needed.
5.6.2. The effectiveness of the Preventive Action system is reviewed as an agenda item during Management Review meetings.

6. Quality Records

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<thead>
<tr>
<th>Record Name</th>
<th>Record Number</th>
<th>Record Location</th>
<th>Record Access</th>
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<tbody>
<tr>
<td>Corrective/Preventive Action Request Form</td>
<td>TS-0022</td>
<td>QAcommon</td>
<td>Quality Assurance</td>
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<td>CPA Status Log</td>
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7. Reference Documents

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Printed copies of this document are considered uncontrolled documents.
8. Change Log

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<th>Approval</th>
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<td>October 15, 2012</td>
<td>Rick Meaney</td>
<td>Initial Release</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Rewrite to better meet the ISO 9001:2008 standard</td>
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