1.0 Purpose of Procedure

This document describes Product Resources' preventive action process. It decribes the process of and provides instructions for requesting, initiating, acting on, and verifying preventive action. It assigns responsibility and authority related to preventive action, and it sets expectations for the completion of preventive actions.

.

2.0 Scope of Process

The scope of this process is the preventive action process.

3.0 Process Owner(s)

3.1 Quality Manager

3.2 QA

4.0 Preventive Action Request

4.1 Intiating

Requests for preventive action are created in the QMS system by employees. The same form is used for all types of requests but categorized as to type. In the QMS system, select ISO Functions, Preventive Actions, New Preventive Action to initiate.

The Preventive Action Types are listed below along with their descriptions:

- New Idea: The preventive action request represents a new idea that the company may choose to adopt. This new idea would improve process or product.
- Process Improvement: The preventive action request represents a way to improve a business process to be more effective, more efficient, or give better results.
- Potential Nonconformance: The preventive action request stems from an observation, formal or informal, that we have a condition that is nearly a nonconformance or has the likelihood to develop into a nonconformance.
- Audit Observation: The preventive action request comes from any type of audit, external or internal, that has yielding a finding that is not a nonconformance. These may be termed observations or opportunities for improvements or comments in audit reports.

The person initiating the preventive action request will determine, based on the information known up front, the preventive action type, however unlike corrective action types for which one must be selected, multiple types may be selected for preventive action – choose as many as describes the situation. The person initiating the preventive action, after determining the type, describes the situation that has lead to the request for preventive action (Description). There is other information to complete: A responsible party must be selected. The QA Manager can be selected as the initial responsible party; otherwise select someone with the knowledge to analyze the given situation. A priority level must be chosen. There are other fields available to assist in describing and managing the preventive action. One can also attach related files as example and evidence.

Submitting one of the above requests via the QMS system causes the QMS system to notify the QA Manager or other responsible party. The preventive action is serialized by the QMS system and the preventive action may be referenced by number.

The QA Manager has the authority to initiate preventive action based on the trending and review of Quality measurements as described in 91-9004, Objectives and Analysis of Data, based on periodic review of a product for in-process and field failures (recorded as RMAs), or based on any other internal, customer, supplier, QMS registrar, or regulatory body input that would warrant the taking of preventive action.

The QA Manager has the authority to assign responsible parties to preventive actions. Responsible parties have the responsibility for root cause analysis and/or action determination, and as appropriate the responsible party may change as the preventive action progresses from initiation to root cause to action determination.

4.2 Root Cause, Action, Approval, Verification, and Closure

Once the Preventive Action is initiated, further handling of it for root cause, action, approval, verification, and closure progress in an identical manner to that for Corrective Action. See these steps in 91-7002, Corrective Action, and apply them also to Preventive Action.

4.3 Risk

Responsible parties are to apply risk based thinking in the action, approval, and verification stages. No formal risk exercise is required.

4.4 Expectations on PAR Completion and Due Dates

Timely PAR completion is important to risk management and customer satisfaction. PARs are initiated with priorities of either Normal, Hot, or Cold, and for each of these the QMS system assigns default, company-selected due dates: Normal is 42 days, Hot is 28 days, and Cold is 70 days. All of these defaults for PARs permit for a longer time for completion than CARs (see also 91-7002).

These due dates refer to the time to bring a PAR from initiation to submitting for approval, encompassing investigation and root cause to determining and completing actions that will be completed inline with the PAR.

Note that there is no default due date concept for the verification step, as when a PAR can be verified for effectiveness is quite varied depending on the business cycle of what is being verified. For verifications, an approver will set the due date in accordance with when it is believed the given subject matter can be verified for effectiveness based on what the business cycle permits.

Once a due date is established, it is the expectation that the responsible party for PAR completion or verification will complete it by that due date.

To facilitate awareness of due dates, the QMS system has been set up to begin notifying responsible parties (by email) of approaching due dates. For PAR completion, this takes place when approximately a third of the time to the due date remains; this number of

days carries forward if a due date is rescheduled. For verification, notification comes 10 days before the due date.

Due dates can be changed with justification. QA can set a new due date as can other appointed QMS system administrators. In setting a new due date, the complexity of investigation and root cause determination and/or the time required to carry out determined actions is considered or having the means to assess effectiveness for a verification is considered.

5.0 Control of Records

The storage location and retention period for records referenced above are given in 91-6002, Control of Records.