

8501 Corrective and Preventive Action Procedure

1. Purpose

The purpose is to establish controls for taking corrective and preventive action on identified problems or negative trends identified through analysis of quality records.

2. Scope

This procedure applies to internal or external concerns relating to quality, reliability, safety, or performance of any product or service offered by the company. Specifically, this procedure covers action to be taken when there are nonconforming product (including purchased product), customer complaints, audit findings, and negative trends identified from analysis of quality records (to include complaints, findings, nonconforming product reports, work processes, concessions, and service reports).

3. Responsibilities

All employees have the responsibility to initiate corrective/preventive action requests for known problems. The quality assurance manager is responsible for establishing, implementing, and maintaining the ongoing effectiveness of the corrective/preventive action program.

4. Reference Documents

Purchasing Procedure 7.401

Control of Nonconforming Product Procedure 8.301

Internal Quality Audit Procedure 8.201

CAR form F8.508

5. Definitions

Remedial action: an action taken to alleviate the symptoms of existing nonconformities or any other undesirable situation.

Corrective action: an action taken to eliminate the cause(s) of existing nonconformities (problems) or any other undesirable situation in order to prevent recurrence.

Preventive action: an action taken to eliminate the cause(s) of potential nonconformities (problems) in order to prevent occurrence.

6. Procedure

6.1 The person who detected the problem (originator) should initiate a corrective/preventive action request (CAR) form. Problem sources include supplier nonconformances, internal nonconforming product, customer complaints, audit findings, HACCP program and the results of analysis of records. The CAR form should be forwarded to the quality assurance manager.

6.2 The quality assurance manager logs and reviews the CAR to assess the magnitude (importance) of the problem. If the problem is assessed as significant, the quality assurance manager then assigns an employee to resolve the problem and requests a corrective action plan within a certain time frame (depending on the complexity and importance of the problem). The CAR is forwarded to the employee assigned the corrective action. For audit findings, the CARs are automatically assigned to the area that was audited.

Example ends here.