

CORRECTIVE AND PREVENTIVE ACTION

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Abstract:

This document describes the procedures used to correct and prevent nonconformities.



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1.0 PURPOSE

This document provides details and procedures for the process governing the discovery, reporting, resolution and recording of actions taken to correct or prevent nonconformities.

2.0 THEORY

Corrective action is taken to correct nonconformities, which could be product defects found during production, errors found in documents, equipment problems or problems related to how the Company performs functions in its processes. "Corrective action" is simply the "fix" that corrects the problem.

Whenever we take corrective action we also attempt to prevent the problem from recurring, which is known as "preventive action". There are times when preventive action is a standalone activity, specifically when reporting a problem that does not exist at the moment but could exist if something isn't done. Sources for preventive action opportunities include risk management, error proofing, failure mode and effects analysis and reports of product problems by external sources. Having a formal system to record and resolve both existing and potential problems ensures that these problems do not occur or reoccur, thereby improving our products, processes and work environment.

3.0 PROCEDURE: INTERNAL REPORTS

3.1 The Company utilizes a Request for Support (RFS) form to record both nonconformances related to its products, process and quality system as well as compliments or positive feedback. The form and system are used for [REDACTED]

3.2 ALL employees are empowered with the ability to report sources of problems and nonconformances.

3.3 No disciplinary action may be attached to the submission of RFS's.

3.4 The Quality Manager has been assigned the role of RFS Administrator.

3.5 For the processing and routing of RFS's see Process Map.

3.6 If the responsible manager determines they are not responsible for the issue involved, they [REDACTED]

3.7 Actions taken shall [REDACTED]

3.8 The Quality Manager shall monitor the RFS Log to determine overdue RFS's and take appropriate action to see that such RFS's are resolved.

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3.9 In addition to corrective action efforts, management shall utilize [REDACTED]

3.10 The management review process shall [REDACTED]

3.11 Where product is suspected of a nonconformance, the Company shall take preventive action that includes [REDACTED]

4.0 PROCEDURE: INVESTIGATION & CORRECTIVE ACTION REQUESTS (ICAR's)

4.1 Any purchasing agent may submit an Investigation and Corrective Action Request (ICAR) to a Supplier that has shown delivery issues, quality problems or the potential for nonconformity.

4.2 ICAR's are processed through the same steps as the RFS but are routed to the Supplier for root cause analysis and action planning. ICAR's are logged separately.

4.3 Failure of a Supplier to respond to an ICAR or to respond with an insufficient action plan may [REDACTED]

[REDACTED]

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5.0 PROCESS MAP

