

Proposed Elements of an Effective Correction Action Program (CAP)

CAP Documentation and Scope

- Management formally defines the CAP, through the use of an approved plan, process description or standard operating procedure.
- The requirements of the CAP are clearly communicated to all responsible individuals.
- The scope of the CAP includes: the nature of findings and observations that would require corrective action, the time frame for responses to findings and observations, problem identification and reporting criteria, initial assessment and classification, roles and responsibilities, use of a graded risk approach, problem evaluation including an extent of condition as needed, investigation and causal analysis as appropriate, interim and permanent corrective actions, the assignment, implementation, tracking and verification of corrective actions, trending of reported conditions and corrective actions, and the system used to document the results of the CAP.

Graded Risk Approach

- The CAP is implemented through the use of a graded risk approach, based on the significance and severity of individual conditions adverse to safety.
- This graded risk approach is used to determine the level of effort, resources used and timeliness of response necessary to address a specific condition.

Initial Assessment and Classification

- Employing a graded risk approach, measures are established to ensure that conditions adverse to safety, such as failures, malfunctions, deficiencies, deviations, defective material, and equipment, and nonconformance's are promptly evaluated to determine the impact on safety, operability, regulatory compliance (reporting, etc.), and classified according to safety significance.

Problem Evaluation, Investigation and Causal Analysis

- Problem evaluations, investigations and causal analyses are conducted using a graded risk approach to determine the appropriate corrective actions (interim, compensatory and permanent) and preventive measures required to effectively eliminate or mitigate conditions adverse to safety.
- Significant issues or events are evaluated by personnel using causal analysis.
 - Individuals or teams use causal analysis to determine the primary and contributing cause(s) and corrective actions and preventative measures as appropriate to prevent recurrence.

- Additionally included within the causal analysis or completed as a separate investigation is an evaluation as to the extent of the condition which may exist in other areas of the facility.
- Minor or conditions that are of low significance are evaluated by a responsible individual to determine the need for corrective action. Some issues may be captured for trending with no action required.
- The results are approved by management and effectively implemented.
- An assessment of the effectiveness of the completed corrective and preventive actions for significant issues is conducted and reviewed by management.

Tracking, Verification and Reporting of Corrective Action Implementation

- Managing the timely and thorough implementation of corrective actions is important to CAP success.
- Roles and responsibilities clearly delineate who will implement corrective actions; and who will track and verify corrective action implementation.
- Appropriate information related to corrective actions is recorded in the CAP information system and reported regularly to management.

Adverse Trends are Identified and Corrected

- Trend analysis is performed on a regular basis, to identify and monitor adverse trends, repeat occurrences, generic issues, and to determine which trends need additional assessment and corrective action.

Audits/Assessments

- Audits/Assessments are conducted to evaluate the effectiveness of the CAP.
- The results are evaluated by management and corrective action is taken where needed.