

[Company Name]

[Company Group, Division, Location]

Document Title: Corrective and Preventive Action

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1.0 Purpose

To ensure that corrective and preventive action is a vital closed loop system of root cause analysis, documented action, verification of effectiveness, and prevention of recurrence.

2.0 Scope

This procedure applies to identified product, process, system nonconformities and problematic performance with respect to internal quality, manufacturing, customer complaints, work safety issues and discrepancies cited during internal audits and external audits (e.g., FDA, Supplier, ISO) at all facilities of [Company Name].

3.0 Definition Of Terms

3.1 Corrective / Preventive Action Notice (CPAN)

A unique # assigned to a Corrective / Preventive Action Notice for easy identification and tracking purposes.

3.2 Corrective Action

Action taken to eliminate the root cause(s) and symptom(s) of an existing undesirable deviation or nonconformity to prevent recurrence.

3.3 Nonconformity

A departure or deviation of a quality characteristic from its intended level or state that occurs with severity sufficient to cause an associated product, process, system or service not to meet a specified requirement.

3.4 Preventive Action

Action taken to eliminate potential nonconformance

3.5 Objective Evidence

Verifiable qualitative or quantitative information, observations, records or statements of fact pertaining to the quality of the product, process or system.

3.6 Root-Cause

A fundamental deficiency that results in a nonconformance which must be corrected to prevent recurrence of the same or similar nonconformance.

4.0 Responsibilities and Requirements

4.1 Quality Assurance

- Initiate and/or issue Corrective / Preventive Action Notice(s);
- Review documented root cause and Corrective / Preventive Action Plan for approval;
- Initiate follow-up verification (audit) of completed Corrective / Preventive Actions for effectiveness;
- File and maintain all Corrective / Preventive Action documentation.
- Facilitate the preparation and implementation of Corrective/ Preventive Action Plans

4.2 Quality Auditors

Perform follow-up verification of completed Corrective / Preventive Actions resulting from internal audits

4.3 Departmental Manager or Designee

- Participate in review or respond to Corrective / Preventive Action Notice(s) when requested;
- Investigate potential causes of nonconformance(s);
- Assist in the development and implementation of a Corrective / Preventive Action Plan.

4.4 [Company Name] Personnel

Responsible for reporting problems and nonconformance to Quality Assurance on the Corrective/ Preventive Action Notice form.

5.0 References

- Customer Complaint Processing
- Customer and Supplier Audits
- Internal Quality Audits
- Recall Procedures
- Quality Records
- MDR/MDVS Reports
- Quality System Report to Senior Management

6.0 Procedure

6.1 Preventive Action

Quality Assurance will determine the appropriate tools to detect, analyze and eliminate potential causes of nonconformance. Use of Failure Mode and Effect Analysis (FMEA), process mapping, Cause and Effect Diagrams and/or Statistical Process Control may be applied to monitor the process. Information and/or data is collected to determine areas needing preventive action.

6.2 Corrective Action

Both external and internal rejections of nonconformities require root-cause analysis and corrective action. If the problem stems from a processing practice, appropriate departmental personnel are contacted to initiate an investigation to determine the root-cause of the nonconformance. After the root-cause of the nonconformance is determined, corrective action is initiated to implement improved practices.

6.3 Originating a Request for Corrective / Preventive Action

Any [Company Name] employee who identifies a potential or actual problem or nonconformance may request corrective / preventive action by completing the Originator section of a Corrective / Preventive Action, and submitting the form to Quality Assurance as soon as possible after identifying the potential or actual problem or nonconformance. For a Corrective / Preventive Action resulting from an internal quality audit, SOP-XXXX INTERNAL AUDITS states the time period and method for submitting the form to Quality Assurance. If the Corrective / Preventive Action concerns a problem with a defective item, when possible the defective item shall accompany the Corrective / Preventive Action.

Corrective / Preventive Action may be requested as a result of:

- Internal and external audits;
- Recall of product either voluntary or mandatory;

- Review of product service records;
- Feedback that identifies problematic performance with respect to manufacturability of product or process operations;
- Customer complaints due to dissatisfaction of products or services that may or may not lead to the return of goods;
- Review of NCMRS;
- Medical Device Report (MDR) or Medical Devices Vigilance System (MDVS) report;
- Product, process, or system nonconformance;
- Other.

6.4 Quality Assurance Review

Quality Assurance will review the requested Corrective / Preventive Action Notice as soon as possible after receipt, and approve or disapprove the request. For a Corrective / Preventive Action Notice resulting from an internal quality audit, INTERNAL AUDITS states the time period and method for Quality Assurance review. If the request is not approved, the reason is documented on the Corrective / Preventive Action, the form is signed and dated, the originator is notified, and the form is filed.

If the request is approved, Quality Assurance determines if immediate or special action is required, and if so, the immediate or special action and when due are documented on the Corrective / Preventive Action. The Director of QA/RA or Quality Engineer then determines and records on the form the responsible department and area manager, assigns a Corrective / Preventive Action number (CPAN#), signs and dates the form, enters the information in the Corrective / Preventive Action Database, notifies the Originator of request approval and CPAN#, retains a copy of the form, and sends the original to the responsible department.

6.5 Responsible Department Action

The department manager or designee that receives a Corrective/Preventive Action Notice must implement immediate or special action (if noted on the Corrective/ Preventive Action Notice form) in the time period specified by the Director of QA/RA. Upon receiving a Corrective/Preventive Action, the recipient must perform the following:

- Investigate the potential root-causes of the nonconformance;
- Analyze suspect processes and/or operations to determine the specific root cause, then document on CPAN form;
- Develop, in conjunction with Quality Assurance, a Corrective/Preventive Action Plan to eliminate the root cause and prevent its recurrence;
- Document on the CPAN form, sign and date the form. The plan must include a projected date of completion.

For a Corrective / Preventive Action Notice resulting from an internal quality audit, Internal Audits, states the time period and method for responsible department action.

6.6 Corrective/Preventive Action Implementation

The responsible department manager implements the plan as prescribed by the projected completion date.

- Changes in procedures and/or processes resulting from Corrective/Preventive Actions are documented and recorded.
- Communication and training of the changes, for affected individuals, are performed, documented and retained as Quality Records.

When implementation is complete, the responsible department manager attaches or references objective evidence of implementation on the Corrective / Preventive Action Notice form, signs and dates the form, and sends the form to Quality Assurance.

6.7 Corrective / Preventive Action Follow-up Verification

Once implementation of Corrective / Preventive Actions are complete, Quality Assurance (or Quality Auditor(s) for Corrective / Preventive Action resulting from an internal audit) performs a follow up verification to assess and determine its effectiveness. Documented objective evidence of effectiveness is required for closure and is attached to or referenced on the Corrective / Preventive Action Notice form. If the Corrective / Preventive Actions are not implemented in a timely manner, Quality Assurance will review the situation with the department manager and establish a new priority. If the Corrective / Preventive Actions are not effective, the responsible department is notified to develop a new action plan.

Once verification of effectiveness is complete, Quality Assurance or the Quality Auditor signs and dates the Corrective / Preventive Action Notice form, and checks the CPAN Closed checkbox. Quality Assurance updates the Corrective / Preventive Action Database, notifies the originator and the responsible department that verification is complete, and files the completed Corrective / Preventive Action form.

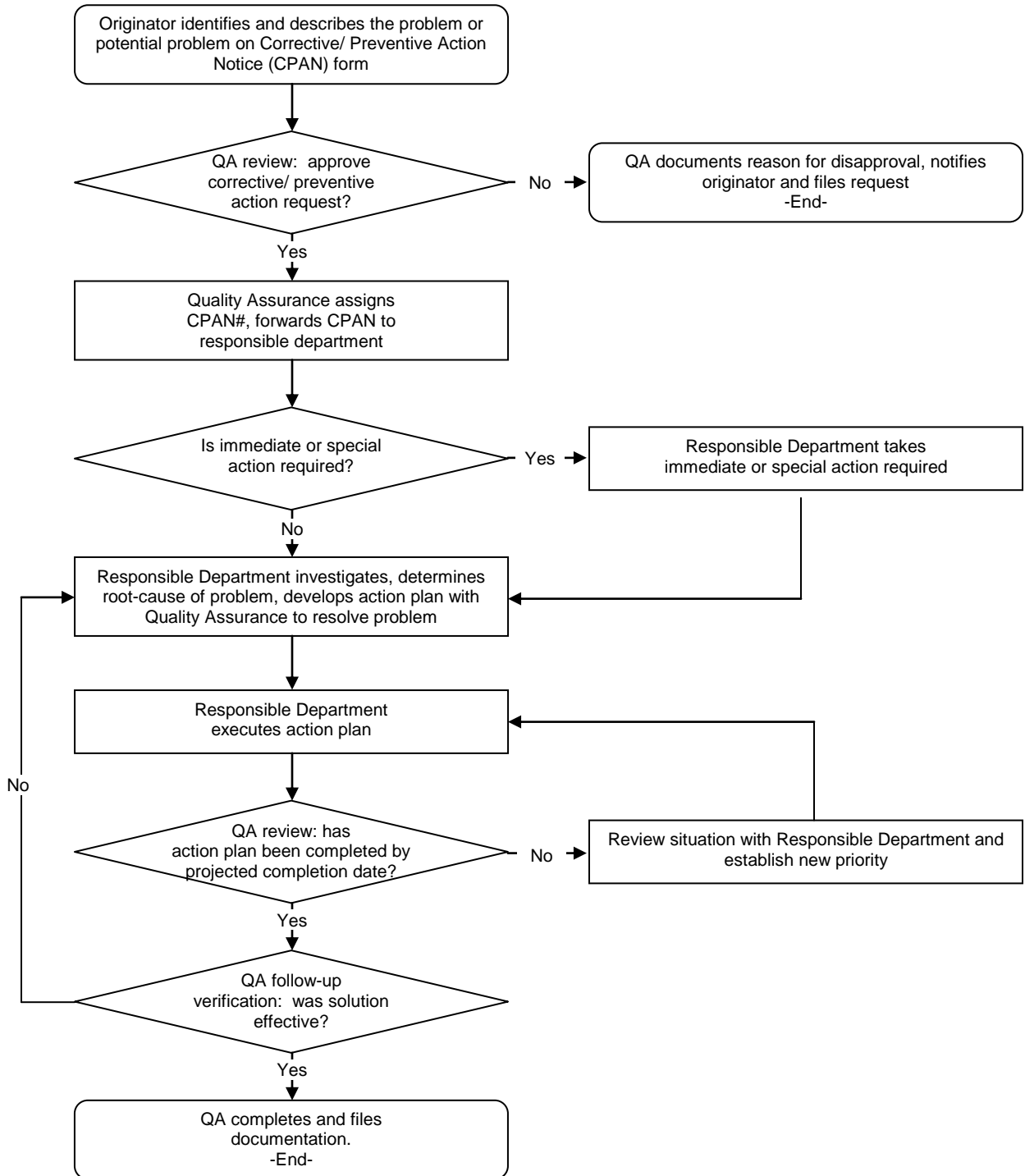
Timing and scheduling of such verifications are at the discretion of the Director of QA/RA, and depend on such factors as: criticality of the corrective / preventive action, time required to generate and gather objective evidence of effectiveness, and available resources. Verification may take place during an internal audit, or Quality Assurance may perform verification as soon as practical after the completion date. For a Corrective / Preventive Action resulting from an internal quality audit, Internal Audits, states the scheduling of follow-up verification.

Records are filed and maintained as Quality Records.

6.8 Corrective/Preventive Action Awareness

The Corrective / Preventive Action Database, maintained by Quality Assurance and available on the [Company Name] computer network, tracks and indicates the status of Corrective / Preventive Actions. The status or summary of Corrective / Preventive Actions will be included in the Quality System Report to Senior Management. Also, when pertinent the Director of QA/RA will report to Senior Management the status of Corrective / Preventive Actions at corporate staff meetings. Senior Management will review and initiate appropriate action.

7.0 Flow Chart



8.0 Corective/ Preventative Action Notice

ORIGINATOR DATA		
Name:		Date: / /
Subject:		
Description of Problem/ Condition:		
QUALITY ASSURANCE REVIEW		
<input type="checkbox"/> Disapproved		
Reason for Disapproval:		
<input type="checkbox"/> Approved		Due Date: / /
Immediate Action Required:		
Assigned To:	Location:	CPAN #:
MANAGEMENT ACTION		
Analysis of Root Cause:		
Corrective Action Plan (CAP):		Due Date: / /
Reviewed By:		Date: / /
QUALITY ASSURANCE FOLLOW-UP/ VERIFICATION		
Provide Documented Evidence of CAP Implementation/ Effectiveness:		
Corrective/ Preventative Action Notice Status: <input type="checkbox"/> Closed		Date: / /
Reviewed By:	Signature:	

