

EOTA – Business Process

	<p><i>Document Title:</i></p> <p>Corrective/Preventive Action Process</p>
	<p><i>Document Number:</i></p> <p>P-008 Rev 11_0414</p>
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<p><i>Parent Document:</i> Q-001, Quality Manual</p>	<p><i>Notify of Changes:</i> EOTA Employees</p>
<p><i>Referenced Document(s):</i></p> <p>P-004 Business System Management Review, F-017 Corrective Action Report Planning Worksheet or F-018 Preventive Action Report Planning Worksheet</p>	

Revision History:

Rev.	Description of Change
A	Initial Release
08_0310	Implemented Multiple reviewer of "Root Cause" into process.
08_0313	Changed verbiage in Process, Responsibility and Definitions for clarification. Assigned new Backup Document Owner.
08_0411	Changed process title, added directions to use Improvement Opportunity for non-PAR improvements/suggestions
08_0623	Changed process and verbiage to incorporate F-017 Corrective Action Report Planning Worksheet, F-018 Preventive Action Report Planning Worksheet and F-019 Improvement Opportunity Planning Worksheet.
09_0923	Changed verbiage in Process, Responsibility and Definitions for clarification. Modified CAR/PAR/IO templates in Q-Pulse module and added verbiage to process to ensure utilization of correct templates. (These changes address Opportunity for Improvement to PAR – Root Cause – from 9/18/09 External Audit.)
11_0119	Changed process to eliminate IO (added to P-012).
11_0414	Modified verbiage for clarification.

I. Purpose

To establish a process to investigate potential problems or non-conformity, to determine root cause, or to take Corrective or Preventive Action and follow up to prevent reoccurrence or occurrence.

II. Scope

This process applies to EOTA employees.

III. Responsibility

Assigned Verifier – Responsible for verifying whether the Short Term/Long Term Action taken is effective in eliminating the root cause, potential problem, or achieves the improvement goal and closing the CAR/PAR in a timely manner. The Assigned Verifier is identified in Q-Pulse as the owner of the “Follow-up” stage, and is different than the Person Responsible.

Integration Group (IG) – Consists of EOTA representatives and/or consultants who discuss issues concerning development, deployment, and data control of the Quality Management System.

Lead Auditor (LA) – Responsible for a CAR/PAR generation related to Internal Audit, Customer assessments, Customer feedback and others as defined by business need and/or Top Management.

Management Representative (MR)/Designee – Responsible for the management and control of the CAR/PAR records. The Management Representative will determine the validity/suitability of the submitted CAR/PAR and will work with the Requester regarding the CAR/PAR. The MR is responsible for Customer notifications when significant conditions adverse to quality, safety, or security are identified and the measures proposed to correct the deficiency.

Functional Area Manager – Working with the Management Representative and the Person Responsible, responsible for:

- Determining and initiating containment action(s)/Short Term Action
- Investigating the root cause
- Determining Long Term Action(s)
- Informing the Assigned Verifier that the CAR/PAR is available for verification.

Requester – Any employee who requests or initiates a Corrective/Preventive Action request. This person is responsible for interfacing with the Management Representative to complete a CAR/PAR.

Person Responsible – Individuals identified in a CAR/PAR document (in Q-Pulse) that has the responsibility for any action related to the specific CAR/PAR. The CAR/PAR “Person Responsible” will inform the Management Representative upon completion of applicable actions and the MR will inform the Assigned Verifier of the completion of the long-term action.

Reviewer – Responsible for reviewing the “Root Cause” with Person Responsible/Integration Group (IG) prior to input into Q-Pulse. Reviewer may be any EOTA member asked to provide input into determining the “Root Cause”.

IV. Definitions

Corrective Action Request (CAR) – used to eliminate the cause of actual non-conformities in order to prevent recurrence. Corrective actions will be appropriate to the effects of the non-conformities encountered. A CAR is identified when there has been a violation of the ISO 9001:2008 Standard, or EOTA process.

CAR/PAR Stage – Any of a variety of action areas related to completion of CAR/PAR, this could be “Containment”, “Root Cause”, “Follow-up”, etc.... Each stage has an identified “Owner” which indicates the Person Responsible for completion of actions associated with that stage.

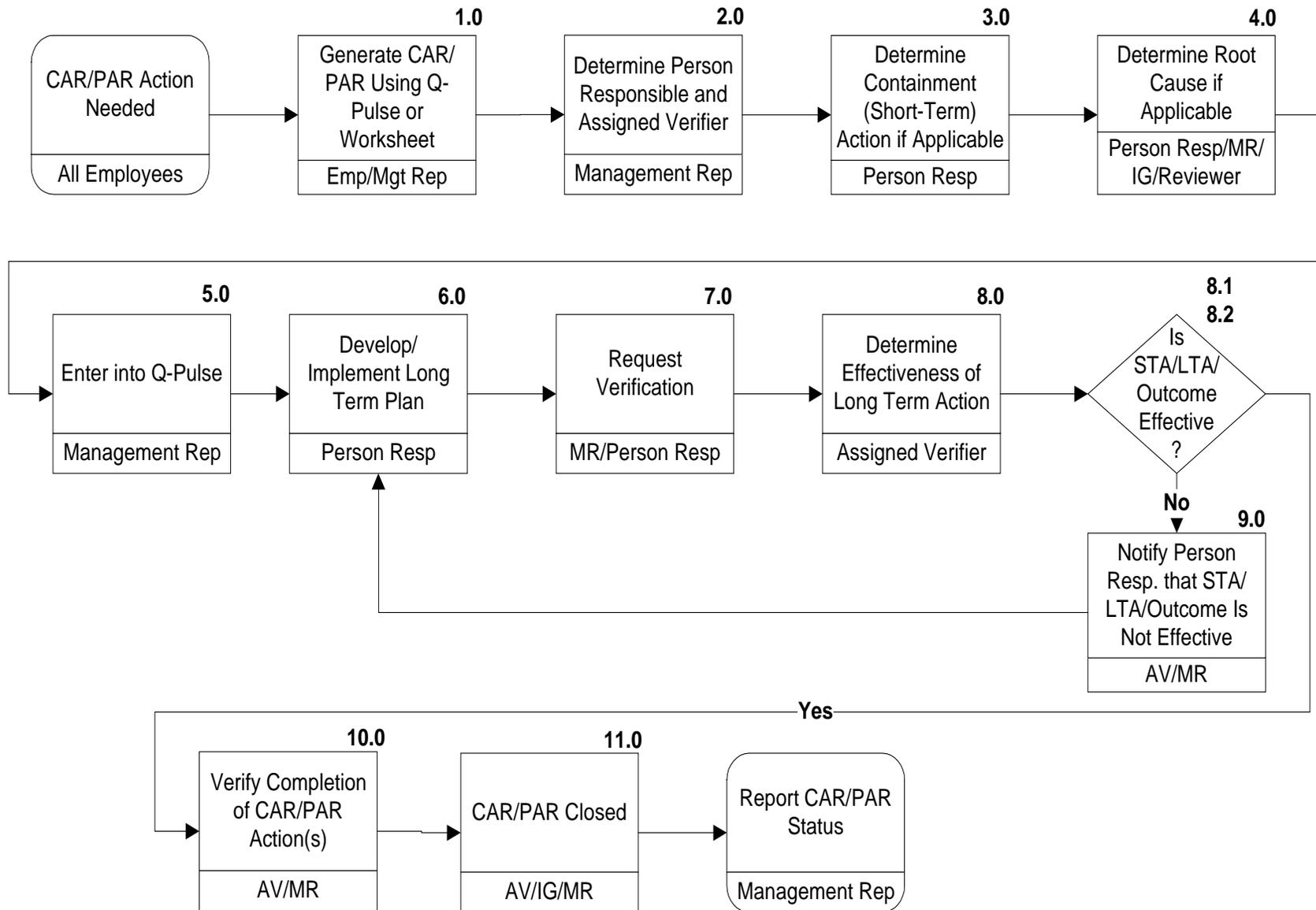
Containment Action – Also known as **Short Term Action (STA)**, this is an immediate containment of the problem to reduce the likelihood of recurrence until LTA is implemented. Containment may not always be necessary.

Long Term Action (LTA) – This is the action that is expected to eliminate the root cause or potential root cause.

Preventive Action Request (PAR) – Used to eliminate the perceived causes of potential/anticipated non-conformities in order to prevent their occurrence. Preventive actions will be appropriate to the effects of the potential problems. If the problem has already occurred a PAR is not appropriate; it must be addressed through a CAR.

Worksheets – Planning Worksheets refer to the F-017 Corrective Action Report Planning Worksheet and the F-018 Preventive Action Report Planning. Each of these worksheets can be used to submit a CAR/PAR to the IG for consideration/recommendation/implementation.

V. Process



1.0 Generate CAR/PAR

Any employee may interface with the EOTA MR or their FAM to generate a CAR/PAR when a non-conformance or potential non-conformance has been identified. Motivation for generation of a CAR/PAR should include internal audit results, safety issues, as well as process concerns with a systemic cause. Customer Complaints and Customer Audit results may also be handled through this process. CAR/PAR will be submitted to the MR on the appropriate Planning Worksheet (F-017 Corrective Action Report Planning Worksheet or F-018 Preventive Action Report Planning Worksheet or the employee may work directly with the MR to complete relevant sections of the worksheet.) At a minimum, CAR/PAR worksheets must include details of the problem. The CAR/PAR will be entered into the CAR/PAR Module of Q-Pulse by the MR utilizing the EOTA-Corrective Action or the EOTA-Preventive Action templates in Q-Pulse upon verification of problem and root cause by IG.

2.0 Determine Person Responsible and Assigned Verifier

The Management Representative, working with the appropriate personnel, will determine the Person Responsible for each CAR/PAR stage and an Assigned Verifier for the CAR/PAR. The MR will review the CAR/PAR for potential Customer notification. If the non-conformance or potential non-conformance is from an Internal Audit, the Assigned Verifier should be the Lead Auditor, whenever possible. Generally, the Assigned Verifier will be the MR, Requester of the CAR/PAR, or a member of management.

3.0 Determine Containment (Short Term) Action

The Management Representative working with the Person Responsible and/or Functional Area Management should take containment measures whenever possible to prevent further non-conformances and possible distribution of defective material to the Customer. If the issue warrants further investigation regarding the Short Term Action, and this investigation can be done without compromising the Customer or safety of the employees, the Management Representative may defer the definition of the Short Term Action to the Functional Area Manager and/or Integration Group member. The MR will document verification of containment actions in the CAR/PAR stage as applicable. PAR may not require containment depending on the potential they are identified to avoid.

4.0 Determine Root Cause

The Management Representative, working with the Integration Group and/or the Person Responsible, will investigate the Root Cause of the problem/non-conformity, or potential non-conformity. This can be done using a number of quality problem-solving tools (e.g., fishbone diagram, brainstorming, 5 Whys, etc). Root Cause determination should not be a restatement of the initial CAR/PAR detail statement and should be reviewed by the IG for correctness and clarity. PAR will require Root Cause determination based on the potential root cause they are identified to avoid.

5.0 Enter CAR/PAR into Q-Pulse

Upon review and approval of the problem statement and root cause by the IG, CAR/PAR will be entered into the CAR/PAR Module of Q-Pulse by the MR.

6.0 Develop/Implement Long Term Action Plan

Once the Root Cause has been determined, the Person Responsible, working with the Integration Group, MR and /or FAM, will develop and implement a Long Term Action Plan designed to eliminate the Root Cause to ensure the non-conformities or potential non-conformities do not recur or occur. For example, instructions may need to be changed, training may have to be performed, or equipment purchased. Corrective Actions must be appropriate to the effects of the non-conformance encountered and Preventive Actions should be appropriate to the effects of the potential non-conformance (actions must address the anticipated Root Cause for PAR).

7.0 Request Verification

The Management Representative is responsible for monitoring the completion and all stage actions that are required to satisfy the requirement of the CAR/PAR. The CAR/PAR “Person Responsible” will inform the MR and the Assigned Verifier of the completion of the applicable stage. The Assigned Verifier will be responsible for ensuring timely verification of the effectiveness of the LTA and coordinating closure of the CAR/PAR through the MR. Open CAR/PAR issues will be presented to the IG to ensure activities are accomplished to ensure all stages are completed on time.

8.0 Determine Effectiveness of Long Term Action

The Assigned Verifier will evaluate if LTA has been effective in eliminating the Root Cause, avoiding the potential occurrence.

8.1 If LTA/Outcome is effective the Assigned Verifier will go to Step 10.0.

8.2 If LTA/Outcome is not effective the Assigned Verifier will go to Step 9.0.

9.0 Notify Person Responsible that STA/LTA/Outcome is Not Effective

The Assigned Verifier will notify the Person Responsible that the LTA/Outcome has not been effective and that further action is now necessary. The Assigned Verifier should give clear reasons for the determination. Upon completion of notification that the LTA/Outcome is not effective, the Person Responsible will return to Step 6.0.

10.0 Verify Completion of CAR/PAR Action(s)

When the LTA/Outcome is determined to be effective, the Assigned Verifier, working with the MR, will document the method of verification and verification comments for the CAR/PAR in the Follow-up Stage.

11.0 CAR/PAR Closed

The Management Representative will review the CAR/PAR with the Integration Group for determination of closure and lessons learned, upon IG approval the CAR/PAR will be closed, its status in Q-Pulse updated, and identified improvement opportunities will be implemented as applicable. The status of CAR/PAR is periodically reviewed by the Management Staff and during Management review as defined in P-004, Business System Management Review.

Disposition: After a CAR/PAR is entered into Q-Pulse, or if a determination is made that no action will be considered, forms F-017 Corrective Action Report Planning Worksheet or, F-018 Preventive Action Report Planning Worksheet will be filed in the QAM office for a period of not less than 180 calendar days. After the 180 days, the forms may be disposed of by shredding.