EPDS - Corrective Action Process Flow

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<td><strong>6.1 CAR/PAR Origination</strong></td>
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<tr>
<td>6.2 Review</td>
<td>Quality Team ONLY</td>
<td>6.2.1.1 Close CAR / PAR</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.2.1.2 Clarification</td>
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<td>6.2.3 Assignment of Responsible Party</td>
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<td>6.1 ACTIVATE</td>
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<td>6.3 Response</td>
<td>Responsible Party</td>
<td>Input: Root Cause</td>
<td>6.3 Ad-hoc Forward</td>
<td>CC: External Oversight (*)</td>
</tr>
<tr>
<td>6.4 Response Review</td>
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<td>6.3 REACTIVATE</td>
<td>CC: Quality Team (*)</td>
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<td>6.4.2 Rejected</td>
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<td>Implementation Date</td>
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<td>Responsible Party</td>
<td>Input: Completion date</td>
<td>6.5 Ad-hoc Forward</td>
<td>CC: Quality Team (*)</td>
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<td>6.6 Verification</td>
<td>Quality Team (*)</td>
<td>Review: Date completed</td>
<td>6.6 Ad-hoc Forward</td>
<td>CC: Quality Team (*)</td>
</tr>
<tr>
<td>6.6.6 Rejected</td>
<td></td>
<td>Implementation evidence</td>
<td></td>
<td></td>
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<tr>
<td>6.6.3 Approved</td>
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<td>Conclusion comments</td>
<td></td>
<td></td>
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<tr>
<td>6.7 Validation Closure</td>
<td>Quality Team ONLY</td>
<td>Input: Validation date</td>
<td>6.7 SUSPEND</td>
<td>CC: Responsible Party External Oversight (*)</td>
</tr>
<tr>
<td>6.7.3 Rejected</td>
<td></td>
<td>Conclusion comments</td>
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<td></td>
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<tr>
<td>6.7.2 Close CAR / PAR</td>
<td></td>
<td>Attach Supporting documentation</td>
<td></td>
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</tr>
</tbody>
</table>

(*) To be completed by External Oversight person when designated by the Quality Team (see 6.2)

Notes:
- For all rejections notify the Responsible Party that the revision must be completed and returned within 5 days.
- If Rejected: Revise above items.
- When Rejected: Revise above items by date indicated. Reactivate revised CAR/PAR to Quality Team.
- Input: Title Clearly describe the problem / issue Propose the Responsible Party Attach supporting info
- If Rejected: Revise above items.

Close CAR

PAR

Revise above items

PAR request

Title

Clarity describe the problem

Issue

Propose the Responsible Party

Attach supporting info

Notes:

Custom MSG

Conclusion comments

Input

Implementation evidence

Conclusion comments

Notes:

Custom MSG

Conclusion comments

Input

Date completed

Implementation evidence

Conclusion comments

Notes:

Custom MSG

Conclusion comments

Input

Validation date

Conclusion comments

Notes:

Custom MSG

Conclusion comments

Input
CAR/PAR QUICK NOTES

Purpose: The purpose of this document is to define the procedure for processing requests for corrective or preventive actions within the Project Delivery (PD) office.

Definitions:

- A corrective action is the process used to identify, correct and eliminate reoccurrence of root cause (or causes) of a nonconformance in procedures, processes or PD related activities.
- A preventive action is the process used to identify the actions needed to eliminate the cause of a potential nonconformance or other undesirable potential situation in procedures, processes or PD related activities before it occurs.
- Internal Audit Findings – CAR / PAR as a result of audit findings in accordance with QM-08 Quality Audit procedure or other observances of process, or procedural noncompliance within the PD or its consultants.
- External Audit Findings – CAR / PAR resulting from audits that have been conducted on behalf of the PD / NTTA.

Responsibilities:

CAR / PAR Originator – Any NTTA stakeholder may originate a corrective or preventive action (CAR or PAR) request. A CAR or PAR request may be created and activated by the Originator, and submitted to the Quality Team for review. The Originator shall clearly define the identified nonconformance and provide supporting data / evidence.

The Quality Team shall:

- Be responsible to review submitted requests for a CAR or PAR to determine if they are valid and best suited to resolution through the CAR / PAR process
- When opening a CAR / PAR, clearly define the identified nonconformance and provide supporting data / evidence
- Identify and assign the responsible party for effective resolution of the CAR / PAR
- Review submitted CAR / PAR to determine if the true root cause has been addressed and if the proposed action plan is sufficient to prevent recurrence
- When a CAR / PAR is completed, verify the action plan has been implemented
- Designate External Oversight Person (EOP) for limited process oversight when the CAR / PAR is generated by someone outside of the PD office, or more familiar with the subject matter, in the judgment of the Quality Team
- Validate the actions taken for all CAR / PAR
- Approval and closing all completed CAR / PAR

External Oversight Person shall:

- Act in the role of the Quality Team in steps 6.4 and 6.6 when a CAR / PAR has been assigned to them for management oversight.

Responsible Party shall:

- Provide a response to Quality Team within the time allowed and identifying the true root cause or causes of the nonconformance
- Provide a corrective / preventive action plan to prevent recurrence
- Determine the implementation date when the action plan will be completed
- Ensure the approved corrective action plan is completed by the indicated implementation date
- Notify the Quality Team when implementation is complete and ready for verification

Classification, Response Due Date and Description:

<table>
<thead>
<tr>
<th>Classification</th>
<th>Response*</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Critical</td>
<td>5 days</td>
<td>To be used when the nonconformance deals with an unsafe condition presenting hazard to life or health.</td>
</tr>
</tbody>
</table>
| Major          | 10 days   | To be used when a nonconformance has resulted in:  
|                |           | - A complete breakdown of a documented process  
|                |           | - Multiple minor nonconformance in the same discipline  
|                |           | - Systemic failure of a process required by the Quality Management System |
| Minor          | 10 days   | To be used for a single lapse within a documented process. |
| Observation    | N/A       | Observations shall be utilized as the PD vehicle for accomplishing Preventive Action as required by the Quality Management System. To be used when observing a potential nonconformance. |

* Business days, Monday through Friday

Table 1

FOR REFERENCE ONLY – Refer to QMS procedure QM-10 for controlled version

FOR PROCESS QUESTIONS – Md Omar Faruk – ofaruk@ntta.org

FOR EPDS TECHNICAL QUESTIONS – EPDShelp@ntta.org
FOR URGENT EPDS QUESTIONS – 214-224-2405