NTTA
NORTH TEXAS TOLLWAY AUTHORITY

Document Release Notice

Document Number:	QM-10	**Title:**	Corrective and Preventive Action
Current Revision #:	Rev 4	**Type of Change:**	☐ ORIG RELEASE ☑ REVISION ☐ ARCHIVE ☐ OBSOLETE
New Revision #:	5	**DRN Number:**	10204 ☐ MAJOR ☑ MINOR ☐ ADMIN
Date Submitted:	7/8/2010	**Document Type:**	QMS Document - QM (Choose from Drop Down Menu - left)

Summary of Proposed Changes:
- Include paragraph numbers or other references & attach a copy of the new or revised documents)
- For new documents, indicate "Original Release"

Section 6.4.1 updated to direct Quality Team to enter the response submital date into the proper field in EPDS

Reason for New Release / Revision / Obsolescence:

To support the metrics that have been devloped for the CAR/PAR program

Required Signatures:

Title:	Printed Name	Signature	Date:
Originator	Troy Federspiel		7/8/10
Process or Content Owner	Peter Claypool (Alt - Micki Ellis)		7/8/2010
Assistant Program Manager	Micki Ellis (Alt - Steve Knobbe)		7/9/10
Program Manager	Steve Knobbe (Alt - ~~Clif Davis~~)		7-13-10
Department Director	Elizabeth Mow (Alt - Mark Bouma)		7-13-10
Quality Manager	Peter Claypool (Alt - Micki Ellis)		7/8/2010
Document Control	Md Omar Faruk (Alt - Peter Claypool)		7/14/2010

Ehret, Sylvia

From: Ehret, Sylvia
Sent: Wednesday, July 14, 2010 3:20 PM
To: Ehret, Sylvia
Subject: QMS Manual Updates

Minor Revision

The following documents have been released into the QMS Manual as a minor revision. If your role requires your involvement in the execution of this procedure, it is now your responsibility to retrieve the latest version from the QMS manual published on www.ntta.org and familiarize yourself with the changes. Upon review, if you determine you require further clarification or training, it is your responsibility to contact the PMO Business Process Owner for the same.

Doc #	Document Title	Rev	Originator	DRN#	Changes
QM-10	Corrective and Preventive Action	5	Troy Federspiel	10204	Section 6.4.1 updated to direct Quality Team to enter the response submittal date into the proper field in EPDS
QM10-A1	Corrective Action Reference Card	2	Troy Federspiel	10203	Section 6.4 updated to direct Quality Team to input the response submittal date into the "Validation Due Date" field in EPDS.
QM-12-F1	Document Release Notice	7	Md Omar Faruk	10207	Revised Required Signatures List.

The QMS Manual is available at the below location:

http://www.ntta.org/WorkingWithUs/NTTA+QMS+Manual+and+Forms/

Thank You,

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DOCUMENT RELEASE NOTICE - CLOSEOUT CHECKLIST

DRN Number	10204

To be completed BEFORE the DRN is released	YES	NO	N/A
Latest revision of QM-12-F1 form used and submitted by the originator	☑	☐	☐
Soft copy of the new/revised documents has been submitted with QM-12-F1	☑	☐	☐
Soft copy inclusive of embedded files (pictures, visio flowcharts) has been submitted.	☑	☐	☑
All required information have been provided in QM-12-F1	☑	☐	☐
Proper document type has been selected in Document Type box of QM-12-F1	☑	☐	☐
Relevant type(s) of change have been marked in Type of Change box of QM-12-F1	☑	☐	☐
Process owner/originator submitted training record where change is classified as major	☐	☐	☑
A DRN number is assigned	☑	☐	☐
New/revised document was created/changed using current QM-12-F2 format	☑	☐	☐
Compared the word documents with source files to create redline as applicable	☑	☐	☐
All spelling has been checked and found correct	☑	☐	☐
Latest NTTA logo is available in the document if applicable	☑	☐	☐
Originator and all review team members have approved and signed QM-12-F1	☑	☐	☐
All requested changes have been incorporated in the source file	☐	☐	☑
All Forms/Attachments have been referenced in the parent procedure	☑	☐	☐
All Forms/Attachments/Procedures have been referenced in all other documents	☐	☐	☑
All external website hyperlinks are correct	☐	☐	☑
All the internal QMS links are correct and working fine	☑	☐	☐
All Forms/Attachments/Procedures have been linked to their associated documents	☑	☐	☐
New Forms/Records have been added to the Record Matrix	☐	☐	☑

	Prepared by:	Checked by:
Date:	07-14-2010	
Name:	SYLVIA EHRET	
Signature:	S. Ehret	

To be completed AFTER the DRN is released

Revised/New document is available in updated online version of QMS Manual	☑	☐	☐
All links in the new/revised documents are working fine	☑	☐	☐
All flowcharts in the document are visible/readable	☑	☐	☐
An e-mail notification has been sent to the distribution list	☑	☐	☐
Scanned e-mail notification and inserted into DRN number	☑	☐	☐
Updated DRN tracking log with release information	☑	☐	☐
Moved DRN working folder to Archive folder	☑	☐	☐
Filed hard copy of the DRN package	☑	☐	☐
Spreadsheet for Controlled Document Numbers has been updated	☑	☐	☐
Spreadsheet for Document Linking updated as applicable	☐	☐	☑

Verified By:	Date:	Name:	Signature:
	07/14/2010	SYLVIA EHRET	S. Ehret

6.4 Response Review

Upon receipt of the CAR / PAR response, the Quality Team / EOP shall evaluate the root cause and corrective action plan provided. This evaluation will conclude if the true root cause or causes has been identified, and if the proposed action plan is sufficient to prevent recurrence of the nonconformance. The Quality Team / EOP shall:

6.4.1 If approved, forward the approved CAR / PAR to the Responsible Party for implementation of the action plan.

~~6.4.1~~6.4.1.1 Quality Team shall enter the actual date of the provided response into the "validation" field in EPDS to allow calculation of the Response Time metric.

6.4.2 Reject and suspend the CAR / PAR back to the Responsible Party when the evaluation determines:

- The root cause or causes has not been correctly identified
- The action plan is not sufficient to prevent recurrence

6.5 Implementation of the Corrective / Preventative Action Plan

Upon receipt of an approved CAR / PAR (or resubmission) the Responsible Party shall execute the approved action plan by the submitted implementation date. Any problems or issues that could cause a delay in the implementation of the CAR / PAR shall be reported to the Quality Team / EOP as soon as they are identified to request an extension. Once the action plans in the CAR / PAR are completed the Responsible Party shall contact the Quality Team / EOP to schedule review and verification activities.

6.6 Implementation Review / Verification

Upon notification by the Responsible Party that a CAR / PAR has been completed, the Quality Team / EOP shall review and verify the implementation of the action plan. The Quality Team / EOP shall:

6.6.1 Confirm the action plan has been completed by the indicated date.

6.6.2 Verify the actions identified in the plan have been implemented. Any changes to the action plan should be noted as part of the verification.

6.6.3 Recommend CAR / PAR for closure.

6.6.4 Determine and schedule follow up when additional time is needed to generate objective evidence.

6.6.5 Reject the CAR / PAR to the Responsible Party for revision when the approved action plan has not been implemented correctly (see 6.5)

6.6.5.1 The Responsible Party shall be given 5 working days to correct the issues.

6.6.6 When the action plan has not achieved the intended results of eliminating the identified root cause it shall be rejected to the Responsible Party to determine a new action plan (see 6.3).

6.7 Validation / Closure

The Quality Team shall validate and close all CAR / PAR after verification of the actions has been completed. The Quality Team shall:

6.7.1 Validate that the actions implemented have achieved the intended results of eliminating the identified root cause.

6.7.1.1 Schedule follow-up, when advised by the Quality Manager, to determine long term effectiveness of the action taken.

6.7.2 Close the CAR / PAR and notify the Responsible Party.

6.1.2 **Internal / External Audit Findings –** Auditors will submit requests for CAR / PAR based on the findings that have resulted from audits that have been conducted.

6.1.3 **Trends -** Quality Management may generate a CAR / PAR when PMO activities indicate systemic failure, or when repetitive NCRs are observed

6.1.4 **Customer Complaints or Feedback -** Quality Management may generate CAR / PAR as a result of customer complaints or other customer feedback to address serious or repetitive customer concerns.

Originators shall:

6.1.4.1 Clearly describe the problem / issue

6.1.4.2 Make reference to failed sections of stated requirements

6.1.4.3 Make a recommendation for the individual who will be assigned as the Responsible Party

6.1.4.4 Activate a potential Corrective or Preventive Action Request (CAR or PAR).

6.2 Review of Potential Corrective / Preventative Action Requests

Within 5 days of receiving a CAR / PAR request the Quality Team shall determine if the request is valid. The criteria to be used in determining the validity of a request will be based on the provided supporting data/evidence and its relevance to failed requirements related to procedures and processes used in the PMO Quality Management System or other provided documentation.

6.2.1 When the Quality team finds that a CAR / PAR request is not valid they may:

6.2.1.1 Close the request and notify the Originator.

6.2.1.2 Request clarification from the Originator.

6.2.2 When the Quality Team finds that a CAR / PAR request is valid:

6.2.2.1 The Quality Team shall determine if the CAR/ PAR request will be assigned to an external person for oversight who will act and manage the process on behalf of the Quality Team in steps 6.3 through 6.6

6.2.2.2 The Quality Team shall Assign the Responsible Party (owner)

6.2.2.3 Ensure that the Responsible Party and EOP have access to EPDS to perform their assigned task.

6.2.2.4 Notify the Responsible Party that a CAR / PAR have been assigned to them.

6.2.2.5 Ensure that the Responsible Party is aware that a response is due 10 business days after the CAR / PAR has been assigned.

6.2.2.6 Notify the Responsible Party and the EOP that subsequent communication shall be addressed to the EOP for steps 6.3 through 6.6.

6.3 Response to CAR / PAR

Upon receipt of a CAR / PAR the Responsible Party shall:

- Determine the root cause of the nonconformance to achieve the aim of preventing recurrence.
- Establish the actions needed that will correct the nonconformance and prevent future recurrence
- Submit the action plan to the Quality Team / EOP with the date upon which the corrective action will be implemented
- The Responsible Party shall be given 5 working days to correct the issues on rejections

Proposed new revision

NORTH TEXAS TOLLWAY AUTHORITY

QMS MANUAL
Procedure Definition

NTTA Projects	Original Issue Date: 06/05/2008	QM-10
Resource: Quality Management	Revision 5 Issue Date: TBD	Page 1 of 7
Title: Corrective and Preventive Action		

1. PURPOSE:

The purpose of this document is to define the procedure for processing requests for corrective or preventive actions within the Program Management Office (PMO).

2. RESPONSIBILITIES:

2.1 Quality Management – It is the responsibility of Quality Management to monitor:

- NCRs for trends that may require systemic corrective action
- Customer complaints, or other customer feedback to identify needs for corrective or preventive action requests
- Internal Audit results for trends that may require systemic corrective action

2.2 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
- Make a recommendation for the individual who will be assigned as the Responsible Party

2.3 Quality Team – Quality personnel 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 process. The Quality Team shall:

- 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 an individual responsible for limited process oversight when the CAR / PAR is generated by someone outside of the PMO office, or more familiar with the subject matter, in the judgment of the Quality Team
- Validate the actions taken for all CAR / PAR and schedule follow-up, when advised by the Quality Manager, to determine long term effectiveness of the action taken
- Approval and closing all completed CAR / PAR

2.4 External Oversight Person (EOP) – Responsible for limited oversight of CAR / PAR and shall:

- Review the CAR / PAR submitted by the Responsible Party 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
- Recommend CAR / PAR to the Quality Team for closure

2.5 PMO Staff and Corridor Managers – PMO staff and CMs shall be responsible to monitor:
- NCRs generated on NTTA projects for trends that may require systemic corrective action
- Customer complaints, or other customer feedback to identify needs for corrective or preventive action requests
- Provide input on potential corrective or preventive action requests to the PMO Quality Manager

2.6 Responsible Party – CAR / PAR owner are assigned as the Responsible Party shall be responsible for:
- Providing a response to Quality Team / EOP within the time allowed and identifying the true root cause or causes of the nonconformance
- Provide a corrective / preventive action plan to prevent recurrence
- Determining the implementation date when the action plan will be completed
- Ensuring the approved corrective action plan is completed by the indicated implementation date
-

3. SCOPE / APPLICABILITY:

This procedure shall apply to potential and confirmed process nonconformances or repetitive NCRs within the PMO and its consultants operations.

4. REFERENCES:

- QM-08 *Quality Audit* procedure

5. DEFINITIONS & ACRONYMS

5.1 **Corrective Action** - Actions taken to correct and eliminate recurrence of root causes for deficiencies and/or ineffective controls from specified requirements

5.2 **Preventive Action** - Actions taken to eliminate the causes of potential deficiencies from specified requirements and/or risks not yet addressed

5.3 **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 PMO or its consultants.

5.4 **External Audit Findings –** CAR / PAR resulting from audits that have conducted on behalf of the PMO / NTTA.

6. PROCEDURES:

In cases where the PMO Quality Team designates process oversight / management (see step 6.2) to an External Oversight Person (EOP), they shall have responsibility to complete all the actions specified for the Quality Team, with the exceptions of steps 6.2 and 6.7. In no case shall the designated individual close the CAR / PAR.

6.1 **Potential Corrective / Preventive Action Request Submittals**

6.1.1 **Observed Process / Procedural –** Based upon observed process / procedural nonconformance within PMO operations or that of its consultants.

6.1.2 **Internal / External Audit Findings –** Auditors will submit requests for CAR / PAR based on the findings that have resulted from audits that have been conducted.

6.1.3 **Trends -** Quality Management may generate a CAR / PAR when PMO activities indicate systemic failure, or when repetitive NCRs are observed

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6.7.1 Validate that the actions implemented have achieved the intended results of eliminating the identified root cause.

6.7.1.1 Schedule follow-up, when advised by the Quality Manager, to determine long term effectiveness of the action taken.

6.7.2 Close the CAR / PAR and notify the Responsible Party.

6.7.3 Reject the CAR / PAR to the Responsible Party for revision (see step 6.3) when the action plan has not achieved the intended results of eliminating the identified root cause.

6.7.3.1 Notify the EOP when assigned for oversight.

6.8 Escalation

The Quality Team may escalate any issues to PMO management when users of do not adhere to the requirements of this processes.

7. REGULATORY REQUIREMENTS:

N/A

8. RELATED BOARD POLICY:

N/A

9. COMPONENT DOCUMENTS:

- QM-10-A1 Corrective and Preventive Action Reference Card

10. REVISION HISTORY:

Revision	Revised by:	Date Issued	DRN	Reason for Revision
0	Micki Ellis	06/05/2008		Original Issue
1	Troy Federspiel	05/12/2009	10004	Global changes to procedures Added Table 1 Added flowchart
2	Troy Federspiel	09/25/2009	10025	6.0 Procedure Updated to reflect the designation of the individual to oversee CAR / PAR 6.6 Implementation Review / Verification Updated and clarified actions 6.7 Validation / Closure Section added to clarify process 6.8 Escalation Updated for clarification 9 Changed to "FORMS" 11 Flowchart Updated to reflect process changes
3	Troy Federspiel	11/20/2009	10063	New release of: QM-10-A1 Corrective Action Reference Card Revision of QM-10 Corrective and Preventive Action. Adding QM-10-A1 attachment to the Section 9.0 Component Documents
4	Troy Federspiel	05/19/2010	10152	5.2 Updated Definitions & Acronyms 6.2.3 Deleted Table 1
5	Troy Federspiel	TBD	10204	6.4.1 updated to direct Quality Team to enter the response submittal date into proper field in EPDS

11. FLOWCHART: