

EOTA – Business Process

	<p><i>Document Title:</i></p> <p>Process Deviation</p>
	<p><i>Document Number:</i></p> <p>P-010 Rev 11-0304</p>
<p><i>Document Owner:</i> Elizabeth Sousa</p> <p><i>Backup Owner:</i> Melissa Otero</p>	<p><i>Approver(s):</i></p> <p>Melissa Otero</p>
<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> F-013 Process Deviation Form, P-008 Corrective/Preventive Action, F-014 Process Deviation Log, ADMP-001 Procurement Process</p>	

Revision History:

Rev.	Description of Change
A	Initial Release
08_0822	Process assigned to new owner. Process and flowchart modified to require completion of all items on F-013.
09_0122	Process and flowchart modified to reflect process modifications.
11_0304	Combined Steps 2.0 and 3.0 to streamline process and renumbered flowchart accordingly, reworded Steps to clarify process and made minor editorial updates.

I. Purpose

To define the process for deviating from an approved process.

II. Scope

This process applies to EOTA employees who require deviation from an approved process.

III. Responsibility

Program Manager (PM1)/Designee – Provides final approval for all process deviations. Conducts reviews for deviations affecting Procurement and Human Resource-related processes.

Quality Assurance Manager (QAM)/Designee – Responsible for monitoring and distributing Process Deviations, and metric generation relevant to the Process Deviation process.

Project Manager (PM2)/Designee – Reviews and approves for submission to PM1 process deviations requested by assigned personnel.

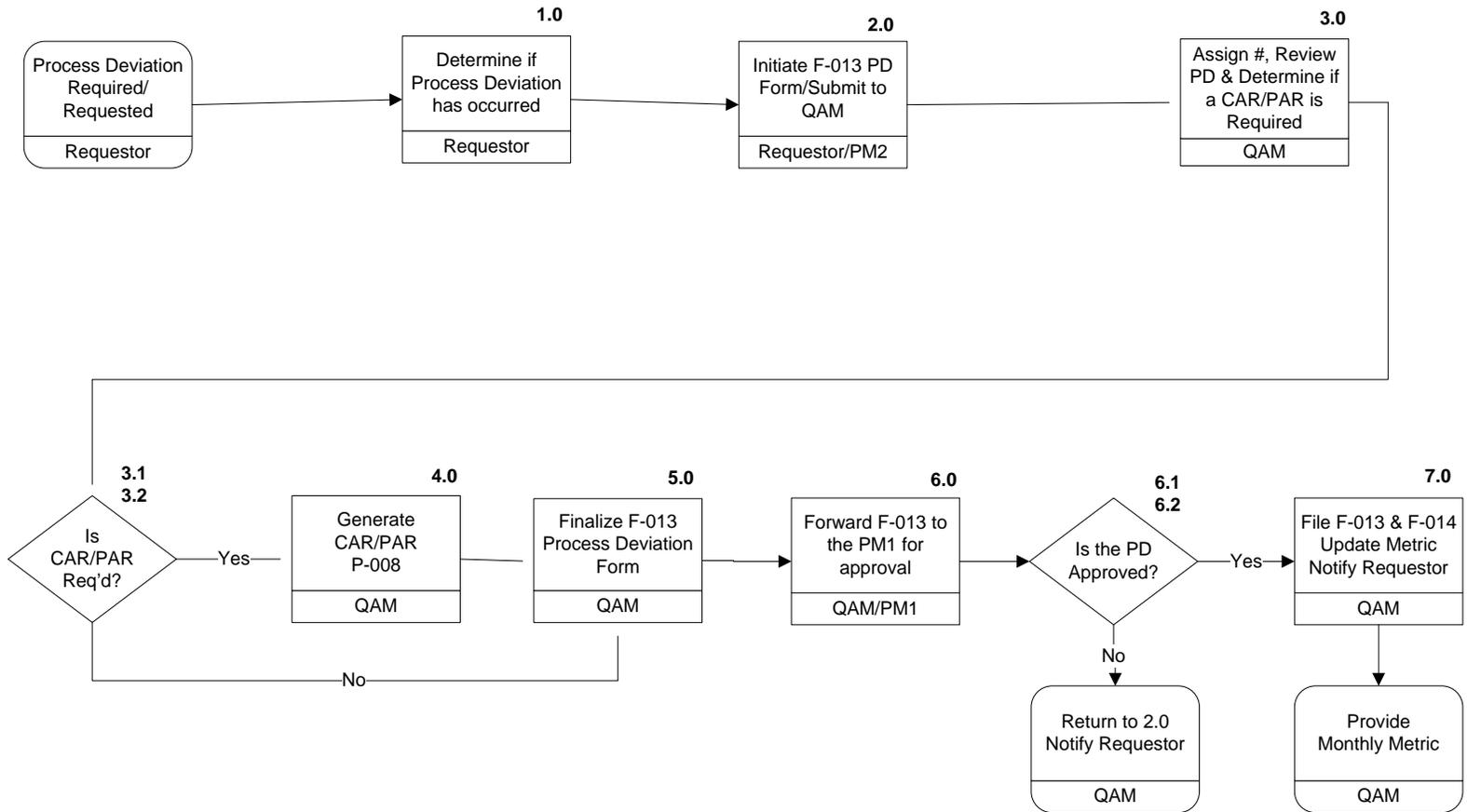
Requestor – Responsible for completing the Process Deviation Form when deviating from an approved process (QAM may be requested to assist). Note: The Requestor should discuss the Process Deviation request with the Project Manager (PM2) prior to completing F-013, Process Deviation Form.

IV Definitions

CAR/PAR – Corrective Action Request and/or Preventive Action Request

PD – Process Deviation

V. Process



1.0 Determine if Process Deviation is Planned in Advance

When a PD is required/requested, the Requestor will determine if the PD of an approved process has already occurred or if the PD of an approved process is planned in advance (before the deviation has occurred).

2.0 Initiate F-013, Process Deviation Form and Submit to QAM

Based on Step 1.0 determination, the Requestor/PM2 will gather information and initiate F-013, Process Deviation Form. The Requestor/PM2 will complete all information available as to why the PD is being requested. The “Explanation” section **does not** need to be completed if the PD has not already occurred. The “Explanation” section **does** need to be completed if the PD has already occurred. The form will be submitted to the QAM in either paper or electronic format. Proceed to Step 5.0.

Note: Only the Program Manager (PM1) can approve process deviations.

3.0 Assign Process Deviation Number & Determine if a CAR/PAR is Required

The QAM will review the PD, assign a PD number using F-014, Process Deviation Log, and determine if a CAR/PAR is required. A CAR/PAR may be required based upon evidence that the PD is an indicator of systemic issues within the Business Management System.

3.1 If a CAR/PAR is required, the QAM will proceed to Step 4.0.

3.2 If a CAR/PAR is not required, the QAM will proceed to Step 5.0.

4.0 Generate CAR/PAR – Monitor thru Completion

The QAM will generate and monitor the CAR/PAR thru completion using P-008, Corrective Action/Preventive Action Process.

5.0 Finalize F-013, Process Deviation Form

The QAM will finalize the PD by ensuring all necessary items on F-013, Process Deviation Form are completed. Non-applicable items should be identified with “N/A”. Add additional comments as required or enter “N/A” in “Comments” section. Update F-014, Process Deviation Log.

6.0 Forward F-013, Process Deviation Form To PM1

The QAM will forward the finalized F-013, Process Deviation Form to the PM1 for approval.

6.1 If the PD is approved, the QAM will proceed to Step 7.0.

6.2 If the PD is not approved, the QAM will notify the Requestor who will then proceed to Step 2.0 for editing and reprocessing. If the reason for non-approval is based on determination that a planned PD should NOT occur, document the reasons for non-approval and notify the Requestor.

7.0 File F-013 & F-014, Update Metric, Notify Requestor

The QAM will file the F-013, Process Deviation Form and F-014, Process Deviation Log as defined on the Record Register. The QAM will notify the Requestor of the Process Deviation approval.

On a monthly basis, the QAM will update the Process Deviation metric using data from F-014, Process Deviation Log, and ensure the metric has been forwarded to the PM1, for review.