IVV 14: Corrective and Preventive Action

Version: AI

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Note: The official version of this document is maintained in IV&V's internal IV&V Management System Website (https://confluence.ivv.nasa.gov:8445/display/IMS). This document is uncontrolled when printed.

Purpose

The purpose of this system level procedure (SLP) is to define the corrective and preventive action procedure for the NASA IV&V Program. This procedure governs the identification and resolution of existing or potential nonconformities (including customer complaints), and opportunities for improvement.
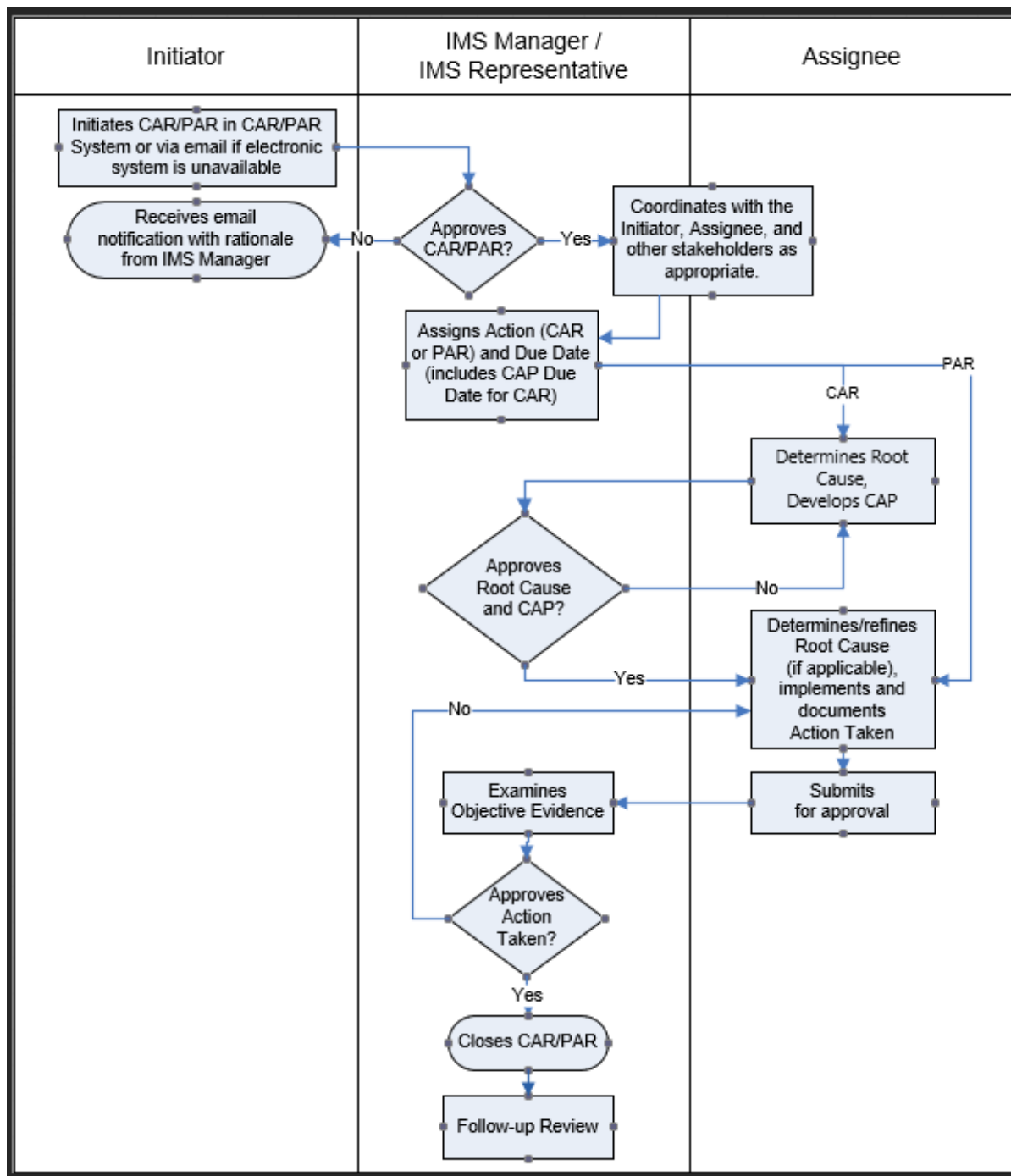
Scope

This SLP applies to all nonconforming or potentially nonconforming processes or procedures associated with the IMS products, and services; and opportunities for improvement pursuant to the NASA IV&V Management System (IMS).

Process Flow Diagram

The following diagram depicts the process described in this document and the responsibilities and actions that shall be performed by process participants. Any information supplemental to the depicted process will appear after the diagram.

Procedure

Corrective and Preventive actions may be identified as a result of internal or external audits, customer complaints, Quarterly Management Reviews (QMRs), or through identification of IMS related nonconformances or observations in day-to-day operations.

IVV 14 Process Flow Diagram -- 04-24-2023.vsd

Initiation

The Initiator shall create the action in the JIRA "CAR/PAR's" Dashboard using the "Create" button located at the top of the page.   More information can be found in the user guide here. If the JIRA CAR/PAR System is not available, an email to the IMS Manager or other similar method shall be used as an alternative.

Required fields:

- Project (must be "SCO")
- Issue Type (must be "CAR/PAR")
- Summary: Title or short description
- Description: Description of the Corrective or Preventive action request

Optional fields:

- Suggested Action
- IMS Document
- CAR/PAR Type
- Major/Minor (Note: Use the "Major/Minor" field to indicate, if appropriate, whether the CAR is a major or minor nonconformance. In addition to the "Major/Minor" field, there is also "Priority" field that allows for the selection of major and minor (and trivial, critical, and blocker). These fields are not the same. The "Priority" can be adjusted and is available for use if helpful. Otherwise it can be ignored.) By default, "Priority" for all CARs/PARs are "Major" unless changed, regardless of whether it is a major or minor nonconformance.

The IMS Manager shall:

- Approve action.
- Ensure "IMS Document" is selected, if appropriate.
- Ensure "CAR/PAR Type" is selected.
- Designate as "Major" or "Minor" (in the "Major/Minor" field) if appropriate.
- Assign CAR/PAR number.
- Determine assignee.
- Determine due date for CAP (if applicable). Note: If a CAP is required, the "Due Date" field in JIRA becomes the due date for the CAP. Once the CAP is completed, the "Due Date" field in JIRA returns to the due date for the closure of the action.
- Determine due date for closure of action.

  - When determining the due date, the IMS Manager shall consider input from the Initiator, the Assignee, and any impacted stakeholders (including the customer if the CAR is driven by a customer complaint or customer appeal). Drivers for completion (e.g. an upcoming event by which closure is needed or appropriate) and Assignee availability (including other tasking, program priorities, etc.) should be taken into consideration.
  - Offer support and assistance to the Assignee. Send a follow-up notification, either by a 'Comment' in the CAR/PAR system or through email, to the Assignee, 30 to 60 days prior to the due date for closure of action. Offer to help assess status and provide support for thinking through next steps, etc. (e.g. by scheduling a working session or equivalent).
    - When applicable, working sessions are best practice for mitigations to CAR/PARs that may be at risk of missing due dates and should be utilized throughout the life of the CAR/PAR.
    - When assessing CARs and PARs and determining if/how to take action, it may be beneficial to leverage an assessment approach like this.

The Assignee shall communicate with the Initiator throughout the process of CAR/PAR resolution to ensure the action being taken is sufficient to address the documented CAR/PAR issue.

If the CAR is driven by a customer complaint or customer appeal, the Assignee shall communicate with the customer to ensure the action being taken is sufficient to address the customer's complaint/appeal and communicate (provide) "progress reports" to the complainant or appellant.

Evaluation

CARs

The Assignee shall evaluate the nonconformance to determine the root cause. To determine the root cause, the Assignee may consider the following questions:

- What are the potential causes of the nonconformance?
- What sequence of events and conditions are causal factors that led to the nonconformance?
- Why do the identified causal factors exist?
- Note: The Assignee should also determine if similar nonconformances exist or could potentially occur.

The Assignee shall document in the CAR/PAR system the root cause of the nonconformance and a Corrective Action Plan (CAP) to correct the nonconformance and minimize risk of reoccurrence. The IMS Manager shall approve the root cause and CAP. If the IMS Manager is also the Assignee, the IMS Representative shall approve the root cause and CAP (the IMS Manager shall document IMS Representative approval in the Root Cause or CA Plan field).

- **Minor Nonconformance**

  A CAR with a minor nonconformance requires a Corrective Action Plan to be submitted within 30 calendar days of assignment.

- **Major Nonconformance**

    A CAR with a major nonconformance requires a Corrective Action Plan within 14 calendar days of assignment.

PARs

The Assignee shall evaluate the potential nonconformance or opportunity for improvement. Given the nature of a Preventive Action, a root cause cannot always be identified, but it is recommended that a root cause be identified if possible and documented in the CAR /PAR system.

Note: When assessing CARs and PARs and determining if/how to take action, it may be beneficial to leverage an assessment approach like this.

Implementation

The Assignee shall implement and document action taken in the CAR/PAR System. The IMS Manager shall review objective evidence and approve or disapprove the action taken. If the IMS Manager is also the Assignee, the IMS Representative shall review objective evidence and approve or disapprove the action taken (the IMS Manager shall document IMS Representative approval in the Action Taken field or in the "Comments" field). If the CAR was driven by a customer complaint or customer appeal, the IMS Manager shall ensure that the customer is notified of CAR closure.

The Assignee shall request a due date extension, when applicable, by adding a "Comment" to the CAR/PAR. When requesting an extension, it may be beneficial to leverage an assessment approach like this. Considering drivers for completion, risk, priority, Assignee availability, etc. The IMS Manager shall approve or disapprove the extension request.

In the event that the electronic CAR/PAR System is unavailable, an email sent to the IMS Manager or other similar method may be used as an alternative collection method. When the CAR/PAR System resumes availability, the IMS Manager shall enter this information into the CAR /PAR System.

The IMS Manager shall ensure a follow-up review is conducted of CAR/PARs to validate the effectiveness of the corrective actions taken, or preventive actions of potential nonconformities.

Please consider that any CAR or PAR may also be indicating that a Lesson Learned exists. If a Lesson Learned is discovered, please document per our SLP: IVV 23, *Lessons Learned* and Organizational Learning.

Additional Information and Guidance

Additional information and guidance regarding creation and analysis of CARs and PARs, including root cause analysis, can be found at IV&V's CAR/PAR Training Confluence page: http://confluence.ivv.nasa.gov:8090/pages/viewpage.action?pageId=9175276

Metrics

Any metrics associated with this SLP are established and tracked within the NASA IV&V Metrics Program.

Records

The following records shall be generated or updated and filed in accordance with this SLP and IVV 16, *Control of Records*, and in reference to NASA Procedural Requirement (NPR) 1441.1, *NASA Records Management Program Requirements*.

Record Name	Original	Essential	Responsible Person	Retention Requirement	Location
CAR/PAR	Y	N	IMS Manager	Destroy when 7 yrs old (1/26.5A)	CAR/PAR System

The current CAR/PAR System is housed in JIRA and accessed on the CAR/PAR's Dashboard in JIRA at:

https://jira.ivv.nasa.gov:8444/secure/Dashboard.jspa?selectPageId=21101

Definitions and Acronyms

Official NASA IV&V roles and terms are defined in the Quality Manual. Specialized definitions identified in this SLP are defined below.

- **Assignee/Delegate**
  - The Assignee or Delegate is the person responsible for addressing a corrective action request (CAR) or preventive action request (PAR).

- **Corrective Action Plan (CAP)**
  - A Corrective Action Plan is a plan constructed to describe the course of action to be taken to resolve a CAR in the CAR/PAR System. A CAP is required of CARs expected to take more than 30 calendar days to resolve.

- **Corrective Action Request (CAR)**
  - A CAR is the documentation of a nonconformance, and the root cause and action taken to correct that nonconformance. CARs can result from multiple activities or come from multiple sources (e.g., internal or external audits, actions from Program Management's review of the IMS, or customer feedback). Customer appeals (i.e. customer disagreements with IV&V that are not addressed via TIM or Risk resolution processes) and customer complaints are considered CARs.

- **Initiator**
  - The Initiator is any NASA IV&V civil service or contract employee who originates a CAR/PAR for change or improvement in the IMS.

- **Nonconformance**
  - A nonconformance represents a lack of compliance with a specified process or procedure (requirement) associated with the IMS or a nonconforming product in the IMS. For the purposes of this SLP, nonconformances are categorized into two levels of severity.

    - **Major Nonconformance**
      - A major nonconformance is characterized by one or more of the following:
      - A lack of a documented procedure, or a documented procedure that is not being implemented consistently.
      - An issued nonconforming product that has a significant effect on customer success, safety, or resources.
      - A series of minor nonconformances that indicates an overall IMS deficiency that may have an adverse effect on overall product quality or customer satisfaction.

    - **Minor Nonconformance**
      - A minor nonconformance is an issued nonconformance that has little or no effect on the customer.

- **Preventive Action Request (PAR)**
  - A PAR is the documentation of a potential nonconformance or opportunity for improvement. A PAR may be initiated to remove the causes of a potential nonconformance, or to improve the effectiveness and efficiency of processes, PARs can result from multiple activities or come from multiple sources (e.g., internal or external audits, actions from Program Management's review of the IMS, or customer feedback).

Acronyms

CAP	Corrective Action Plan
CAR	Corrective Action Request
DO	Document Owner
ECM	Enterprise Content Management
IMS	NASA IV&V Management System
NODIS	NASA Online Directives Information System
NPR	NASA Procedural Requirements
OBS	Observation
PAR	Preventive Action Request
PDF	Portable Document Format
QM	Quality Manual
SLP	System Level Procedure

References

REFERENCES	
Document ID/Link	**Title**
IVV QM	NASA IV&V Quality Manual
IVV 16	Control of Records
IVV 23	Lessons Learned and Organizational Learning
NPR 1441.1	NASA Records Management Program Requirements

If any procedure, method, or step in this document conflicts with any document in the NASA Online Directives Information System (NODIS), this document shall be superseded by the NODIS document. Any external reference shall be monitored by the Document Owner for current versioning.

Version History

VERSION HISTORY				
Version	**Description of Change**	**Rationale for Change**	**Author**	**Effective Date**
Basic	Initial Release		John Griggs IT/204	5/1/1998
A – X	Older revision information may be located in the Version History Overflow Document		Various	07/23 /1998 – 15 Sep 2010
Y	Replace Trackwise use with the new ECM workflow for CAR /PAR tracking		Richard Grigg	3/16 /2011
Z	Clarify Purpose, Definitions, roles, and Process Flows. Remove Lower Tier Action Item Tracking Systems		Natalie Alvaro	10/21 /2011
AA	Incorporate "opportunity for improvement". Made observation its own entity as it is not necessarily a type of nonconformance.		Natalie Alvaro	5/17 /2012
AB	Incorporate Follow Up Review for CAR/PARs in Section 4.1.3		Natalie Alvaro	7/31 /2012
AC	Removed Form 1005; replaced with email or similar method. CAP always used for CAR; flow and verbiage updated. Removed old TrackWise link; added location of downloaded PDF file of data.	Annual Document Review. Form 1005 rarely used; other methods are equally effective. Any CAR should have a CAP; even if it can be resolved quickly, it's still worth going through the planning process, considering recurrence control, etc.	Jeffrey Northey	11/26 /2013
AD	Add a link to initiate a CAR/PAR workflow. Correct flow to remove Form 1005. Correct section 6 link in Word version. Add hook to Lessons Learned.	CAR: 2013-C-394. It is always more user-friendly to include links instead of just a path someone will need to retype. A CAR or PAR is usually indicating a possible Lesson Learned.	Richard Grigg	12/12 /2013
AE	Adjust flow diagram and expand Initiation and Implementation sections to clarify due date determination and due date extensions.	2014-C-420, 2014-C-421. (1) Improve coordination prior to due date assignment, and (2) Simplify due date extension process.	Jeffrey Northey	1/29 /2015
AF	Include IMS Representative approval in situations when the Assignee/Delegate is also the IMS Manager: Sections 4.1.2, Evaluation, and 4.1.3, Implementation.	2015-P-428. In order to ensure there is no conflict of interest, have the IMS Representative review and approve key steps when the Assignee /Delegate is the IMS Manager.	Jeffrey Northey	6/23 /2015
AG	Update CAR definition (3.3) and key process steps (4.1.1 and 4.1.3) to more fully and explicitly address customer complaints and customer appeals.	2015-P-434. To ensure compliance with ISO 17020 (Section 7.5 and 7.6), we need to document a stronger connection between IVV 14 and the complaints/appeals requirements.	Jeffrey Northey	7/20 /2015

AH	Update to CAR/PAR procedures with moving from an ECM workflow to JIRA.	Moving CAR/PAR system to JIRA	Jeffrey Northey	03/04 /2019
AI	Update IMS Manager requirements to include following-up before a CAR/PAR due date and added language for working sessions and assessment approach as best practice. Clarified Major/Minor field.	To mitigate CAR/PAR risk for exceeding due dates.	Alex Ayers	06/15 /2021