Development Process Deviation Management

RCCAC-ENG-M-000

Rev. 1.2

Rockwell Collins CETC Avionics Co., Ltd.

Approval

	Name	Title	Approval	Date
Prepared by:	Di Zhang	Quality Engineer	On File	03/31/2017
Reviewed by:	Ben Yan	System Manager	On File	06/09/2017
Reviewed by:	Yang luo	Product Line manager	On File	06/09/2017
Reviewed by:	James Zhang	Quality Manager	On File	06/09/2017
Approved by:	Richard Hackett	CTO	On File	06/09/2017
Approved by:	Yifei Wang	GM	On File	06/09/2017

Revision History

Revision	Originator	Description	Date
1.0	Kevin Chen	New Release	06/26/2015
1.1	James Zhang	Added the Signature column in the Approval page	10/12/2015
1.2	Di Zhang	Updated few sections per RCCAC's situation and peer review results (PRI_0085)	03/31/2017

Table of Content

List of Table

1 Introduction

1.1 Purpose

This method establishes the criteria for requesting a deviation from a Company process or procedure related to design and development activities and Rockwell Collins CETC Avionics Co., Ltd. (hereafter refers to “RCCAC”) Document Management System (RDMS).

1.2 Applicability

Location: RCCAC, Chengdu, Sichuan, China

1.3 Requirements Implementation

This method meets the requirements for Design and Development as defined in AS9100: 2016 and ISO 9001: 2015.

1.4 Industrial Standards

Table 1-1 Referenced Industrial Standards

Standard	Description
AS9100: 2016	Quality Management System – Requirements for Aviation, Space and Defense Organizations
ISO9001: 2015	Quality Management Systems – Requirements

1.5 Company Documentation

Table 1-2 Referenced Company Documentation

Document #	Description
RCCAC-QMS-P-905	Corrective Action
RCCAC-ENG-P-020	Design Assurance Center

1.6 Acronyms & Terms

Table 1-3 Acronyms

Acronym	Definition
RCCAC	Rockwell Collins CETC Avionics Co. Ltd.
DAC	Design Assurance Center
DRB	Deviation Review Board
RDMS	RCCAC Document Management System
SCL	Software Control Library

2 Definitions

- Deviation – Departure from standard procedures resulting in nonconforming processes or where there have been unusual or unexplained events which have the potential to impact customer product quality, system or process integrity, or personal safety.

3 General

3.1

The Deviation Review Board (DRB) shall review deviation requests upon request.

3.2

The cognizant Design Assurance Center (DAC) Focal representative, refers to the document RCCAC-ENG-P-020 Design Assurance Center, shall ensure the Deviation Request form (Exhibit B) is complete and submit to the DRB.

3.3

The DRB chair will review the Deviation Request for completeness. If errors are found, the Deviation Request will be returned to the DAC Focal representative for correction.

3.4

When DRB Chair accepts the Deviation Request, the DRB Chair shall invite all applicable stakeholders for review. The cognizant DAC Focal representative is a mandatory participant.

3.5

The Deviation Request will be processed when all stakeholders have provided their approval.

4 Entry Criteria

Project or product is unable to meet Company processes that are related to design and development activities.

5 Inputs

Business case to justify the Deviation Request. The business case should include the cost, schedule, customer satisfaction, potential impact to the product's quality, and/or other factors that will clearly describe the business case.

6 Requirements for Process Deviation

6.1

The requestor shall complete the questionnaire located in Exhibit B.

6.2

The cognizant DAC Focal representative shall track the Deviation Request via their Quality Documented Information database.

6.3

The cognizant DAC Focal representative shall approve the Deviation Request and provide Software Control Library (SCL) with the following items:

a) DAC Focal Quality Documented Information

b) Completed Deviation Request form
c) Appropriate file(s) to update, if applicable (e.g., markups, source, deliverables)

6.4

All stakeholders shall approve the Deviation Request.

6.5

The cognizant DAC Focal representative shall submit the Deviation Request to the DRB.

6.6

The DRB Chair shall review the Deviation Request for completeness. If missing or incomplete information exist, the Deviation Request shall be returned to the cognizant DAC Focal representative for correction.

6.7

The DRB Chair shall submit the Deviation Request to the DRB for their review.

6.8

The DRB shall perform one of the following actions:
a) Approve – The Deviation Request will be implemented.
b) Reject – More information is required to process the Deviation Request.
c) Deny – Deviation Request is not allowed.

6.9

The cognizant DAC Focal representative is responsible for the following:
a) Maintain documented information of the Deviation Request.
b) Track the progress of the planned actions identified in the Deviation Request.
c) Verify the Deviation Request has been correctly implemented.
d) Create a Corrective Action, in accordance with RCCAC-QMS-P-905, if the planned actions are not addressed.

6.10

The DRB core membership shall have representation from the following organizations:
a) Configuration Management
b) Design Assurance Center for Quality Focal
c) Design Support Group (e.g., SCL)

6.11

The DRB shall elect a chair from the core membership for a term not to exceed two years.

7 Outputs

A quality documented information has been established to track the actions from the processed Deviation Request.

8 Exit Criteria

The Deviation Request has been approved, denied, or rejected and the results captured via RCCAC Document Management System (RDMS)

Exhibit A: Deviation Flow Diagram

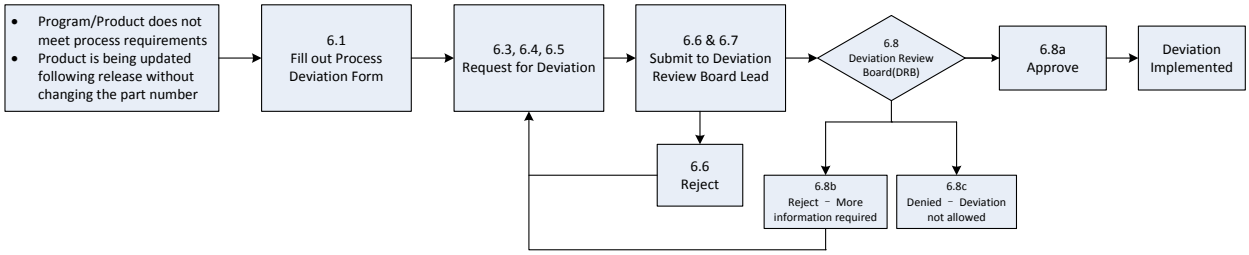

Exhibit B: Deviation Request Form

Quality Documented Information Number	e.g. RCCAC-0001	
Project Name	e.g. TCP-2110	
Equipment Type	e.g. COMAC C919	
Program Name	e.g. TCP-2110 SW	
Submittal Date	e.g. 26/01/2016	
Affected Part Numbers		
Business Case for Deviation (Enter summary of request) (Business case should include the cost, schedule, customer satisfaction, potential impact to the products quality)		
Answer the following questions:		
1.	Are there any other mechanisms in place to solve this issue with less risk? (An in-depth discussion with your configuration management analyst and DAC will most likely be necessary to determine this.)	
2.	Does the deviation identify the configuration (part number/revision letter)?	
3.	Has the product been delivered internally?	
3a.	If the product has been delivered, have all items been recovered? Please provide evidence.	
4.	Has the product been delivered externally?	
4a.	If the product has been delivered, have all items been recovered? Please provide evidence.	

5.	Have all internal customers been informed of this deviation?	
6.	Have all external customers been informed of this deviation? Please attach evidence of conversation to the deviation (i.e. email).	
7.	How will the customers be notified of the changes (i.e. coordination memo)?	
8.	Is customer approval required prior to release?	
9.	Is TSO or PMA in process?	
10.	Have all the spare parts of boards been updated with this change (if applicable)?	
11.	What is the cost impact analysis associated with implementing this deviation? Without implementing this deviation?	
12.	What is the risk analysis associated with implementing this deviation? Without implementing this deviation?	
13.	What is the schedule impact analysis with implementing this deviation? Without implementing this deviation?	
14.	Provide a list of all the **documents/drawing numbers** that will be affected if this deviation is not approved.	
Plan for Correction Action/Expected date of compliance or completion (include attachment, if needed)		
The following questions must be addressed:		
15.	What process steps are being requested of the design support organization (i.e. CM, DAC, SCL, etc.)?	
15a.	identify artifacts (document/drawing/software/data file, etc.) being changed Replaced or Revised	
15b.	Is a new rebuild required?	
15c.	Is a new software listing required?	
15d.	Are new CRCs required (if Software Deliverable or Altered Item Drawing)?	
16.	If the part number does not change, what action will be taken to ensure the correct software is loaded?	
17.	What specific action(s) will be taken to prevent reoccurrence (corrective action)?	

18.	Who will verify that the process steps taken by the design support organization are correct?	
19.	Are there actions to be completed following this deviation to be verified by the DAC representative?	

DRB Review Minutes and Follow up Action (This section to be completed during DRB review)

DRB Date:	
DRB Attendees:	
DRB Minutes:	
Actions:	

Stakeholder Representation Approvals (include representatives from all relevant stakeholder groups)

Role	**Name**	**Email Address**
DAC Focal Representative		
CM Representative		
DRB Chair		
Project Manager		
Engineering Manager		
Engineering Process Member (Deviation Author)		
Design Support Representative (e.g. SCL)		

