This template contains the layout and styles that should be used for a CADV report. Italicized text is for guidance/instruction only and should be removed or replaced before routing any report.

Department	Printed Name	Signature	Date
Author		See electronic signature	See stamp
PQ		See electronic signature	See stamp
LSD		See electronic signature	See stamp
PDO		See electronic signature	See stamp
Systems Engineering		See electronic signature	See stamp
RA		See electronic signature	See stamp
Marketing		See electronic signature	See stamp
Medical		See electronic signature	See stamp
PDO		See electronic signature	See stamp
Risk		See electronic signature	See stamp
Human Factors Engineering		See electronic signature	See stamp
Other		See electronic signature	See stamp

ABSTRACT:

A high-level summary of the introduction, purpose and scope, and changes included in the CADV should be included in this section (approximately 2-3 sentences).

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1 INTRODUCTION

This section should identify the purpose/intent of this document, the scope, high level change summary, terms and definitions, and references used throughout the document. This section includes the Entities Impacted and Individuals Involved in the CADV.

1.1 Purpose and Scope

This section contains an identification of the system, sub-system or HW/SW component which is affected by the change and a brief description of the change. If applicable the section should contain a reference to the originating anomaly, change order, or project in which it is implemented, including field actions or Non-conformance reports.

The following note should be included in all CADVs.

Note: This CADV document only identifies and describes the changes being applied. Where necessary additional background material will be provided.

1.2 Summary

This section contains a brief description of the overall change including the reason for the change, as well as a brief listing of the individual changes (this list should correspond to the subsections in the description section).

1.3 Terms and Definitions

Term	Definition
<Term 1>	<Insert Definition>

1.4 References

No	ID	Title
[R1]	<Insert ID>	<Insert Title>

1.5 Entities Impacted

This section contains a list of documents impacted by the change.

Add additional important documents to the following list as applicable, such as cybersecurity and human factors assessments, part numbers, or changes to external interfaces such as electronic media definitions.

Document	Yes	No	Comments
RAD			
RCM			
TRS			
CRS			
PRD			
HRD			
SRS			
PDD			
SDS			

Document	Yes	No	Comments
Operator's Manual			
Service Manual			
Code			
Licensing			
Labeling			
Error Code List			
Test Protocols			
Other:			

1.6 Individuals Involved

The names of the primary individuals involved in the creation of this document are as follows:

Name	Section (CA, CD, or CV)

2 CHANGE ANALYSIS (CA)

Best practice is to complete change analysis (CA) in two steps, CA1 and CA2, with review (and preliminary release of this document) in-between.

2.1 Design Inputs (CA1)

This section provides reason for change, description of the CADV project, storyboards, risk analysis for existing and new RADs. Along with sections 2.1.1 – 2.1.6 below, sections 1 and sections 1.1-1.6 are also typically documented as part of CA1 development.

2.1.1 Reason for Change

This section contains a short description of the reason for the change, e.g. a description of a reported problem or the reason behind a request for new or changed functionality.

2.1.2 Description of Change

This section defines what to change to address the change request, such as changes in software, hardware, manuals, labeling, GUI texts, help screens, illustrations etc.

2.1.3 Use Case Analysis

This section contains a use case analysis, used to help determine requirement impact and identification of test scenarios. The use case analysis describes the intended system behavior with the change implemented; but is not intended to the test case description.

Suggested content for each use case includes:

- *Name/Title – a descriptive name for the use case, should also indicate reason for the use case including whether the behavior is new or existing behavior*
- *Actors – the list of actors for the use case*
- *Preconditions – conditions in place when the sequence starts*
- *Sequence – description of stimuli to the system, including external and periodic elements as appropriate*
- *Variations – the different preconditions and sequences*
- *Expected Outcome – the expected outcome(s) for the use case*

2.1.4 HFE Assessment

For changes made to the product design (hardware, software, labeling, IFU, service script, etc.), requirements, user needs, intended use, product related processes, facilities, suppliers, etc., a Human Factors/Usability impact assessment will determine what parts of the HF/UE process and associated deliverables will be performed as a result of the change, if any. The HF assessment should discuss if the change has any impact on the intended user's interaction with the product, comprehension of action/information for safety, and whether the change could introduce any new use-related risk. If any HF/UE activities have been conducted before the change, the HF assessment should clarify if the results of previous activities or deliverables are impacted. If assessment results indicate there's an impact, further activities will be needed, which could include additional evaluations, HF studies, documentation remediation, etc., and traceable references need to be provided in the assessment.

In case the scope includes more than one change, as deemed appropriate by the HF SME, changes could be assessed individually or combined. The overall result should be summarized to clarify the following actions.

2.1.5 Risk Analysis

2.1.5.1 Risk Definition Analysis

The sections below should be reviewed for Risk Analysis Document (RAD) or Failue Mode and Effect Analysis (FMEA) impacts, including the proposed creation of new risks or the modification or reference to existing risks related to the change.

A summary of the relevant risks should be included.

Table 1 Related Risks

ID	Risk Text

Table 2 Modified Risks

ID	Original Text	Proposed Text

Table 3 Deleted Risks

ID	RCM Text

Table 4 New Risks

ID	Proposed Text

2.1.5.2 Risk Mitigation Analysis

This section should describe whether the suggested change mitigates or interferes with any existing risk control measures (RCMs). Add or delete tables as required.

Table 5 Related RCMs

ID	RCM Text	Risk ID

Table 6 Modified RCMs

ID	Original Text	Proposed Text	Risk ID

Table 7 Deleted RCMs

ID	RCM Text

2.1.5.3 New RCMs

This section should describe any new potential causes to hazardous situations and if any new risk control measures (RCMs) are required due to the change.

Table 8 New RCMs

ID	Proposed Text	Risk ID

2.1.6 Product Requirement Analysis

This section should contain, as applicable, modified, new and deleted TRS/CRS requirements for the device affected by the change. Add or delete tables as required.

Table 9 Related CRS

ID	Requirement Text

Table 10 Modified CRS

ID	Original Text	Proposed Text

Table 11 Deleted CRS

ID	Requirement Text

Table 12 New CRS

ID	Proposed Text

Table 13 Related TRS

ID	Requirement Text

Table 14 Modified TRS

ID	Original Text	Proposed Text

Table 15 New TRS

ID	Proposed Text

Table 16 Deleted TRS

ID	Requirement Text

2.1.7 System Requirement Analysis

This section should contain, as applicable, modified, new and deleted system (PRD) requirements for the device affected by the change. Add or delete tables as required.

Table 17 Related PRD

ID	Requirement Text	Allocating Requirement

Table 18 Modified PRD

ID	Original Text	Proposed Text	Allocating Requirement

Table 19 New PRD

ID	Proposed Text	Allocating Requirement

Table 20 Deleted PRD

ID	Requirement Text

2.2 Sub-System Requirements Analysis (CA2)

This section applies only if the proposed change affects project requirements. If this section does not affect project requirements, then complete this section with an explanation of why this phase does not apply.

This section should contain, as applicable, modified, new and deleted HRD/SRS/SDS/LRD requirements for the device affected by the change. Add or delete tables as appropriate.

2.2.1 Hardware Requirement Analysis

Table 21 Related HRD

ID	Requirement Text	Allocating PRD Requirement

Table 22 Modified HRD

ID	Original Text	Proposed Text	Allocating PRD Requirement

Table 23 New HRD

ID	Proposed Text	Allocating PRD Requirement

Table 24 Deleted HRD

ID	Requirement Text

2.2.2 Software Requirement Analysis

Table 25 Related SRS

ID	Requirement Text

Table 26 Modified SRS

ID	Original Text	Proposed Text	Allocating PRD Requirement

Table 27 New SRS

ID	Proposed Text	Allocating PRD Requirement

Table 28 Deleted SRS

ID	Requirement Text

Table 29 Related SDS

ID	Requirement Text

Table 30 Modified SDS

ID	Original Text	Proposed Text	Allocating SRS Requirement

Table 31 New SDS

ID	Proposed Text	Allocating SRS Requirement

Table 32 Deleted SDS

ID	Requirement Text

2.2.3 Labeling Requirement Analysis

Table 33 Related LRD

ID	Requirement Text

Table 34 Modified LRD

ID	Original Text	Proposed Text	Allocating PRD Requirement

Table 35 New LRD

ID	Proposed Text	Allocating PRD Requirement

Table 36 Deleted LRD

ID	Requirement Text

3 CHANGE DESCRIPTION (CD)

This section should describe the design changes necessary for the proposed change. The design changes originate from the requirement changes described in the CA section of this document, if applicable..

3.1 Design Description

This section provides additional/modifications to the system design documents, such as: ADD, SAD, HDD, drawings, specifications, etc. It should contain both high-level design material as well as a description of the implementation, and should include the rationale for design decisions and important design features.

If appropriate, it can be separated into subsections that cover individual change elements.

3.2 Change List

List the files/part numbers that have changed including revision information as part of this CADV.

3.3 Labeling Update

This section should describe all labelling changes to the user interface, both strings and graphics.

The table below defines all string changes.

Table 37 String Updates

String ID	Type of Change			Content
	Added	Modified	Deleted	

The table below lists all of the user interface screen changes. Instead of reproducing the figures here, use cross-references to the actual figures.

Table 38 Screen Updates

Screen Name	Screen Number	Type of Change			Reference
		Added	Modified	Deleted	

3.4 Reviews

Provide a list of all design/implementation reviews performed. Note that formal reports (ERs) should appear in the list of references.

Note that for software changes, when code reviews are being performed on the final version of code before merging to the trunk, those code reviews should be listed here. When code reviews are performed on incremental changes to developmental branches, then the individual code reviews do not need to be listed.

4 CHANGE VERIFICATION (CV)

This section should reference test cases necessary to be executed to verify a correct implementation of the change, or reference a separate document in which it is contained. This section should also reference the verification report where the actual result of the test execution of the listed test cases is presented.

4.1 Verification Testing

For the changes covered by this CADV, this section should identify and describe the tests that will verify that each change was implemented correctly. The supplied test description should identify what the test does, but does not need to be a detailed procedure.

If desired, this section can be broken into multiple sub-sections to cover different test types.

Table 39 Verification Test Descriptions

Test ID	Test Description

4.2 Regression Testing

This section defines the testing that is performed to ensure that there are no unintended consequences introduced by the changes implemented by this CADV.

4.2.1 Regression Analysis

This section should include the analysis used to determine potential impacts to the system and identify testing to perform to ensure that there are no unexpected changes to the system.

If desired, this section can be broken into multiple sub-sections to cover different analyses.

4.2.2 Regression Test Descriptions

This section defines the tests used to verify that there were no unexpected changes, as identified though the regression analysis.

If desired, this section can be broken into multiple sub-sections to cover different test types

Table 40 Regression Test Identification

Test ID	Test Description

4.3 Test Execution

This section should list the results of all tests that are executed to verify that the change has been implemented correctly. For any test with a failed result, a rationale must be provided for acceptance of a failed result before the CADV can be closed. The configuration tested must be included as well – either directly or implicitly as part of the test run documentation.

The following note should be included in all CADVs.

Note: The results of the test runs indicated in this CADV represent the test run results obtained upon executing the test runs following the CADV development process. The test run results do not represent the current test run results documented in HP-ALM because the process of handling the test run execution and failures in HP-ALM are independent of the CADV development process.

Table 41 Test Results

Test ID	Pass/Fail Status	Run ID

If desired, the Test Results can be reported in multiple tables based upon test type.