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1 Purpose

1.1 The purpose of Stage 4 is to complete the design. Ensure production readiness, and make ready for sale.

2 Scope – *applies to where & when the procedure is used*

2.1 This process applies to all North American based R&D for MTS Test.

3 Definitions and Acronyms

3.1 BOM= Bill of Materials

4 Graphic (if needed)

Stage 4 Complete Design Rev F.pdf

5 Responsibilities

5.1 See graphic

6 Procedure

6.1 Approved Stage 4 Program Plan

The R&D council approves the development program for Stage 4 and notifies the Product Manager and Program Leader.

Output: Stage 4 Approval (Quality Record 7.1)

Template: None

6.2 Begin Product Compliance Process for Stage 4

The Program Leader works with Compliance Engineer to begin Product Compliance Process for Stage 4.

Output: None

Template: None

6.3 Create Saleable BOM Structure

The Product Manager defines the Bill of Material structure/hierarchy for production BOMs.

Output: Saleable BOM Structure (Quality Record 7.3)

Template: None

6.4 Create Production BOMs, Drawings, & Firmware

The Development Team creates and releases Production BOMs, Drawings, and Firmware under Alpha Revision control.

Output: None

Template: None

6.5 Complete EHS Analysis

The development team will complete the Environmental Health and Safety Analysis form.

Output: EHS Form (Quality Record 7.5)

Template: EHS Form Template

6.6 Create Spare Parts List

The Product Support Engineer, Product Manager and Development Team create and document a Spare Parts List.

Output: Spare Parts List (Quality Record 7.6)

Template: None

6.7 Define Packaging Requirements

The Development Team defines packaging requirements for how the components or system will be moved around the MTS facility for assembly and also for final shipment to customers.

Output: Packaging Requirements (Quality Record 7.7)

Template: Packaging Requirements Template

6.8 Update Material Fulfillment Plan

The Manufacturing Engineer updates the Material Fulfillment Plan.

Output: Material Fulfillment Plan (Quality Record 7.8)

Template: Material Fulfillment Plan Template

6.9 Create Component & Subassembly Test Specifications

The Development Team creates test specifications for components and subassemblies. The objective is to verify subsystem operation prior to system assembly and checkout.

Output: Component & Subassembly Test Specifications (Quality Record 7.9)

Template: Component & Subassembly Test Specifications Template

6.10 Create System Checkout Specifications

The Development Team creates System Checkout Specifications. The objective is to verify system operation at checkout.

Output: System Checkout Specifications (Quality Record 7.10)

Template: System Checkout Specifications Template

6.11 Acceptance Criteria

The Product Manager and Development Team define the Acceptance Criteria for the customer acceptance of the product upon installation.

Output: Acceptance Criteria (Quality Record 7.11)

Template: Acceptance Criteria Template

6.12 Define Manual Set

The Development Team identifies the set of manuals required for the product.

Output: Manual Checklist (Quality Record 7.12)

Template: Manual Checklist Template

6.13 Create Manual Set

The Technical Communications Team creates all required manuals per the Manual Checklist.

Output: Manual Set Part Number List (Quality Record 7.13)

Template: Manual Set Part Number List Template

6.14 Build 1st Article

The 1st Article should be built per the specified manufacturing process.

Output: None

Template: None

6.15 Create 1st Article Test Plan

A test plan should be constructed that consists of measuring the properties and geometry of the 1st Article.

Output: None

Template: None

6.16 Complete 1st Article Testing

The 1st Article should be tested per the specified Test Plan.

Output: None

Template: None

6.17 Review 1st Article Test Results

The Development Team will review the results from 1st article testing.

Output: None

Template: None

6.18 Do 1st Article Results Meet Plan Expectations?

If No, Determine Where to Re-Enter the Process (6.19).

If Yes, continue to Ensure Product Compliance Process is Complete for Stage 4 (6.20)

Output: None

Template: None

6.19 Determine Where to Re-Enter the Process

The Program Leader and Product Manager decide where to re-enter the process.

Output: None

Template: None

6.20 Ensure Product Compliance Process is Complete for Stage 4

The Program Leader ensures the Product Compliance Process is complete for Stage 4.

Output: None

Template: None

6.21 Create Declaration of Product Release

The Program Leader creates the Declaration of Product Release.

Output: Declaration of Product Release (Quality Record 7.21)

Template: Declaration of Product Release Template

6.22 Notify R&D Council that Program is Complete and FIOP Program

The Program Leader Notifies the R&D Council that Program is complete and FIOP Program.

Output: FIOP Confirmation Email (Quality Record 7.22)

Template: None

7 Associated Quality Records – as stated in the Quality Records List

	Required Record
7.1	Stage 4 Approval
7.3	Saleable BOM Structure
7.5	Spare Parts List
7.6	Packaging Requirements
7.7	Material Fulfillment Plan
7.8	Component & Subassembly Test Specifications
7.9	System Checkout Specifications
7.10	Acceptance Criteria
7.11	Manual Checklist
7.12	Manual Set Part Number List
7.20	Declaration of Product Release
7.21	FIOP Confirmation Email

8 Reference Forms / Templates / Documents

Form / Template / Document Title	Location

10 Current Revision's Training Requirements

Training requirements are determined by the document owner – either awareness or formal.

Select One (mark X)	Training Type	Training Definition
X (general)	Awareness	Awareness training is conducted by communication, which is sent/delivered by the approver/author/owner of the document to the affected employees/groups.
(Hardware Development) (Purchasing) (Manf. Eng.) (Tech. Writing) (Prod. Mang.)	Formal	Formal training requires the approver/author/owner to collect/store evidence that the affected employees/groups were trained.

Revision History & Approval

REVISION HISTORY			
Rev	**Description of Change**	**Author**	**Effective Date**
A	Created	S. Firman	2/27/2009
B	Moved to New Format and Removed CORRA File and Lessons Learned	S. Firman	6/7/2011
C	Updated to meet Rev. B of R&D Stage Gate and CE Process	S. Firman	8/27/2012
D	Updated stage 4 by adding Hardware Declaration of Release of Product Design	S. Firman	4-4-2013
E	Updated requirements training, and records location	S. Firman	5/17/13
F	Updated Process	S. Firman	11-20-2015

APPROVAL OF CURRENT REVISION		
Name / Function	**Signature**	**Date**
Scott Firman, Director of Solutions Engineering		