# Table of Contents

|  |  |
| --- | --- |
| **Section** | **Page** |
| 1 Purpose | 1 |
| 2 Scope | 1 |
| 3 Definitions | 1 |
| 4 Graphic | 1 |
| 5 Responsibilities by Function | 1 |
| 6 Procedure | 2-4 |
| 7 Associated Quality Records | 5 |
| 8 Forms / Templates | 5 |
| 9 Revision Training Requirements | 5 |
| 10 Revision History & Approval | 6 |

# Purpose

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

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

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

# Definitions and Acronyms

## BOM= Bill of Materials

# Graphic (if needed)



# Responsibilities

## See graphic

# Procedure

## **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

## **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

## **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

## **Create Production BOMs, Drawings, & Firmware**

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

Output: None

Template: None

## **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

## **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

## **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

## **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

## **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

## **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

## **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

## **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

## **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

## **Build 1st Article**

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

Output: None

Template: None

## **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

## **Complete 1st Article Testing**

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

Output: None

Template: None

## **Review 1st Article Test Results**

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

Output: None

Template: None

## **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

## **Determine Where to Re-Enter the Process**

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

Output: None

Template: None

## **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

## **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

## **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

# 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 |

# Reference Forms / Templates / Documents

|  |  |
| --- | --- |
| **Form / Template / Document Title** | **Location** |
|  |  |

# 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 |  |  |