# Table of Contents

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

# Purpose

## The purpose of the Stage 3C – Validation is to plan and perform a validation of the new resulting product.

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

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

# Definitions and Acronyms

# Graphic (if needed)



# Responsibilities

##  See graphic

# Procedure

## **Create Validation Plan**

The Development Team creates a Validation Plan. The plan should include tests to confirm that Market Requirements are met.

Output: Validation Plan (Quality Record 7.2)

Template: Validation Plan Template

## **Validation Plan Review Meeting**

The Development Team reviews the Validation Plan.

Output: Validation Plan Review Notes (Quality Record 7.3)

Template: None

## **Will Validation Plan Validate Market Requirements?**

If No, return to Create Validation Plan (6.2).

If Yes, continue to Execute Validation Plan (6.5).

Output: None

Template: None

## **Execute Validation Plan**

The Development Team executes the Validation Plan.

Output: Validation Results (Quality Record 7.5)

Template: None

## **Validation Results Review Meeting**

The Development Team presents the Validation Results for review and feedback. Possible attendees include: subject matter experts, development managers, application engineers, staff engineers, etc.

Output: Validation Results Review Meeting Notes (Quality Record 7.6)

Template: None

## **Do Validation Results Show Market Requirements Were Met?**

If No, Determine Where to Re-enter the Process (6.8).

If Yes, continue to Is Stage 3B Complete? (6.9).

Output: None

Template: None

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

The Development Team and Product Manager determine where to re-enter the process.

Output: None

Template: None

## **Is Stage 3B Complete?**

If No, Complete Stage 3B.

If Yes, continue to Stage 3D.

Output: None

Template: None

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

|  |  |
| --- | --- |
|  | **Required Record** |
| 7.2 | Validation Plan |
| 7.3 | Validation Plan Review Notes |
| 7.5 | Validation Results |
| 7.6 | Validation Results Review Notes |

# Reference Forms / Templates / Documents

|  |  |
| --- | --- |
| **Form / Template / Document Title** | **Location** |
| Validation Plan Review Notes | QMS – Product Development – Hardware Development |

# 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 Team | 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 | Initial release | S. Firman | 2/27/2009 |
| B | Release Into New Format | 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 procedure owner, training requirements, and record location | S. Firman | 5/17/13 |
| F | Updated process to better fit SPD group objectives. | S. Firman | 11-20-2015 |

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