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1 Purpose

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

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

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

3 Definitions and Acronyms

4 Graphic (if needed)

Stage 3C Validation Rev F.pdf

5 Responsibilities

5.1 See graphic

6 Procedure

6.2 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

6.3 Validation Plan Review Meeting

The Development Team reviews the Validation Plan.

Output: Validation Plan Review Notes (Quality Record 7.3)

Template: None

6.4 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

6.5 Execute Validation Plan

The Development Team executes the Validation Plan.

Output: Validation Results (Quality Record 7.5)

Template: None

6.6 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

6.7 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

6.8 Determine Where to Re-Enter the Process

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

Output: None

Template: None

6.9 Is Stage 3B Complete?

If No, Complete Stage 3B.

If Yes, continue to Stage 3D.

Output: None

Template: None

7 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

8 Reference Forms / Templates / Documents

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

9 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.

10 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		