Quality System Work Instruction
Test script validation

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1   Purpose

The purpose of the Test Script Validation Work Instruction is to describe and document all activities required for development, validation and release of automated Test Scripts.

2   Scope

This work instruction applies to automated Test Scripts that are created to support design verification activities as defined in the Design Verification Procedure 0312-01-P.

3   Responsibilities

Role	Responsibilities
Software engineer / Test Engineer	• Develop and Implement automated Test Script • Ensure execution of code review of Test Script by Test Script Reviewer and ensures that code review results are recorded • Determine Validation Level and if applicable request Test Script validation
Peer Software Engineer / Test Engineer	• Performs test script validation and documents the results in Test Script Validation Report

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Role	Responsibilities
Peer Software Engineer / Test Engineer	• Review Test Script with focus on whether the script o Properly addresses the applicable product or detailed requirement o Properly addresses the applicable test scenarios o Complies to relevant coding guidelines (as applicable)
Verification Lead / Manager	• Has overall responsibility for the Test Script validation activities • Responsible for the quality of the Validation deliverables • Review and Approve Test Script Validation Report • Responsible for Test Script release and maintenance

4 Definitions and Acronyms

4.1 Definitions

Term	Definition
None	None

4.2 Acronyms

Short	Long
PRS	Product Requirement Specifications

5 Work Instruction

5.1 Test Script Development

Test Scripts are developed to automate design verification of identified product requirements and detailed requirements, if applicable. Development of the automated Test Scripts shall adhere to the relevant Coding standards/ scripting guidelines, as applicable.

Test Scripts are managed according to the 0337-01-P Configuration Management Procedure.

The Test Scripts shall be uniquely labelled and shall be traceable to the product requirements/ detailed requirements as applicable. Release identification strategy shall be defined for the Test Scripts.The organization shall decide on the Test Script labelling and identification strategy.

5.2 Test Script Validation

Validation of an automated Test Script consists of execution of an automated test scripts that explains how a Test Script covers a requirement and gathering evidence that the automated Test Script meets its intended purpose.

The amount of validation for automated Test Script depends on the risk that the automated Test Script poses on product safety, security and effectiveness of a product. The level of risk is determined using the Validation Level decision tree below, resulting in a Validation Level of Scenario 1, Scenario 2 or Review only.

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Test Script shall be successfully validated before they are used for performing Design Verification activities as per 0312-01-P and the results of these Test Scripts can be used as objective evidence of verification activities.

Test Script validation decision tree below shall be used to determine the level of validation and identify the next steps.

Test Script validation level decision tree

1a	Does the automated Test Script verify a product/detailed requirement associated with safety/security risk or performance of the product?	☐Yes ....**go to 1b** ☐No..........**REVIEW ->go to 'Review** Test Script'
1b	Can the automated Test Script have a manual counterpart? i.e. Can the product / detailed requirement related to safety, security or performance be verified using Manual Test cases? E.g. API related requirements cannot be verified using manual test cases.	☐Yes ....**Scenario 1 ->go to 'Scenario1** Test Script validation' ☐No..........**Scenario 2 ->go to 'Scenario2** Test Script validation'

5.2.1 Scenario1 Test Script Validation

In case of Scenario1 Test Script validation, validation comprises of 2 steps:

- All Test Scripts shall be subjected to code review by a Test Script Reviewer. Evidence of code reviews shall be recorded. Execute review of Test Script with focus on:

  o Whether the Test Script is complete and adequate to verify the applicable product requirement / detailed requirement

  o Whether the Test Script adheres to relevant coding guidelines (as applicable)

- Additionally, to check if the Test Script is in line with the product / detailed requirement, the automated Test Script shall be compared against its manual counterpart. The following steps shall be executed:

  o Identify the product code revision on which the validation will be performed.

  o If Automated test scripts are created based on existing Manual test cases, then Manual counterpart test cases shall be available, reviewed and approved. If not, then Manual test cases may be created stand-alone or be created as part of automated Test Script using logs.

  o Gather test results/logs by execution of the automated Test Script on the product code revision.

  o Gather manual test results by executing manual test cases on the product code revision.

  o Compare automated test results/logs against the actual results of the manual test

  o Conclude on validation status per test step OR on the overall test case level that results of automated execution and manual execution are the same.

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- o Defects reported upon validation failure shall be fixed and Test Scripts shall be revalidated.

- o Test Script Validation Report shall be created, reviewed and approved. Test Script Validation Report [0312-01-T8] may be used to create the report. Alternatively, tools may be used to generate and record Test results.

- o Where tools are used to record test results, a report will be extracted from the tool and will be reviewed and approved as per General Document Control Procedure [0730-02-P]. This report shall contain:

    - ▪ Evidence or reference to the results of automated test execution.

    - ▪ Evidence or reference to the results of manual test execution.

    - ▪ Review id or the Change set number, which captures the code review evidence.

5.2.2   Scenario2 Test Script Validation

In case of Scenario2 Test Script validation, validation comprises of 3 steps:

- All Test Scripts shall be subjected to code review by a Test Script Reviewer. Evidence of code reviews shall be recorded. Execute review of Test Script with focus on:

    - o Whether the Test Script is complete and adequate to verify the applicable product requirement / detailed requirement

    - o Whether the Test Script adheres to relevant coding guidelines (as applicable)

- Additionally, for cases where automated tests cannot have a manual counterpart, the test results should ensure that all applicable preconditions/criteria associated with test automation are met to ensure test completeness and accuracy against the detail requirement.

    Following are the preconditions/criteria that may be considered to measure completeness and accuracy of test automation. These are the examples and can vary product to product.

    - o Measuring at different user load conditions

    - o Measuring at different server load conditions

    - o Executing for a considerable duration

    - o Test client at minimum specifications mentioned in PRS

    - o One of the infrastructure specifications mentioned in PRS

    - o Executing tests for multiple times

    - o Querying data multiple times to check consistency in results

    - o Testing in different data sets

- The following steps shall be executed:

    - o Identify the product code revision on which the validation will be performed.

    - o Appropriate preconditions/criteria are assessed and identified for test automation design

    - o Gather test results/logs by execution of the automated Test Script on the product code.

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- o Conclude on validation status per assessed acceptance criteria and requirements

- o Defects reported upon validation failure shall be fixed and Test Scripts shall be revalidated.

- o Test Script Validation Report shall be created, reviewed and approved. Test Script Validation Report [0312-01-T8] may be used to create the report. Alternatively, tools may be used to generate and record Test results.

- o Where tools are used to record test results, a report will be extracted from the tool and will be reviewed and approved as per General Document Control Procedure [0730-02-P]. This report shall contain:

  - ▪ Evidence or reference to the results of automated test execution.
  - ▪ Review id or the Change set number, which captures the code review evidence.

5.2.3 REVIEW Test Script

All Test Scripts shall be subjected to code review by a Test Script Reviewer. Evidence of code reviews shall be recorded. Execute review of Test Script with focus on:

- Whether the Test Script is complete and adequate to verify the applicable product requirement / detailed requirement

- Whether the Test Script adheres to relevant coding guidelines (as applicable)

Test Script Validation Report [0312-01-T8] may be used to record the evidence for code reviews. Alternatively, tools may be used to record the evidence for code reviews.

Where tools are used to record code review evidence, a report will be extracted from the tool and will be reviewed and approved as per General Document Control Procedure [0730-02-P]. This report shall refer to the Review id or the change set number, which captures the code review evidence.

5.3 Test Script Release and Maintenance

Test Scripts shall be released for use in Design Verification activities after successful completion of validation. Release Record which contains Test Script identification, including version shall be maintained by the organization.

Changes to Test Script post validation and release shall be controlled by the organization. When changes are required, the impact of the change to the Test Script shall be assessed to determine the need for revalidation and the impact assessment outcome shall be documented. Revalidation shall be planned based on the Validation Level decision tree provided in section 5.2.

6 Records

Record Name	Description
0312-01-T8	Test Script Validation Report

7 References

Reference Number	Description
0312-01-P	Design Verification Procedure
0730-02-P	General Document Control Procedure

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Reference Number	Description
0337-01-P	Configuration Management Procedure

8   Document History

Revision	Description of changes
1.0	Initial Release created to align with HI Test script validation Work instruction (HISS-W-030010.01, Rev A)
2.0	• Section 5.2.1 (Scenario1 Test Script Validation) was updated to remove the requirement to have Validation Protocol reviewed and approved as the test script itself serve as a validation protocol and no separate protocol document needs to be generated. • Section 5.2.2 (Scenario2 Test Script Validation) was updated requirements for the automated tests that does not have manual counterpart • Corrected the record name from "0312-01-T7" to "0312-01-T8" • Renamed the "test script protocol and validation report" to "Test Script Validation Report"
3.0	Below are the updates made per CR#601 • Section 5.2.1 (Scenario1 Test Script Validation) was updated that if no Manual test cases are available test script logs can be used instead. • Made template 0312-01-T8 optional if tools are used to create Test Script Validation Report

9   Document Control

Process	Owner(s)
Approval	Manager Q&R, Process Owner
Review	Test Manager, Quality Engineer's
Author	Vinay K
Approval date	See eDMS
Effective date plan	Standard

End of Document

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