**System Name**

***Trace Matrix***



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**Contents**

[1 Introduction 4](#_Toc201125918)

[1.1 Purpose 4](#_Toc201125919)

[1.2 Scope 4](#_Toc201125920)

[1.3 Definitions, Acronyms and Abbreviations 4](#_Toc201125921)

[2 Trace Matrix <Example Contents> 5](#_Toc201125922)

[3 Revision History 6](#_Toc201125923)

[4 Approvals 7](#_Toc201125924)

# Introduction

## Purpose

The purpose of this Trace Matrix is to confirm the completeness of testing by providing a map that demonstrates design and testing coverage between the:

* User Requirements Specification
* Functional Requirements Specification
* Validation Protocols

## Scope

Describe the scope of the testing covered by this Trace Matrix. Identify any portion(s) of the system that are not within scope.

## Definitions, Acronyms and Abbreviations

| **Term** | **Definition** |
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# Trace Matrix

Cross-reference the system’s user requirements to the systems functional requirements. Then ID the validation document (e.g., OQ or PQ) within with each user requirement and functional requirement is tested. Use the “Function” column to group related requirements and provide a visual index for the users of the Trace Matrix.

Two examples of trace matrices are provided. The first example identifies the testing of each requirement to the specific test case and step ID. The second example identifies only the protocol ID and name.

**Example 1:** Trace from User Requirement to Functional Requirement to Protocol Test Steps

| **Function** | **User Requirement** | **Functional Requirement** | **Validation Protocol(s)** |
| --- | --- | --- | --- |
| Student Curriculum Creation | 3.2.1  The systems shall provide the ability to create a training curriculum for each student | 3.2.1.1 | OQ-001 “Student Set Up and Maintenance”, Test Case #1, Step 1.2 and 1.4  PQ-003 “Training Coordinator Student Maintenance”, Test Case 5, Steps 5.1 and 5.2 |
| 3.2.1.1.1 | OQ-001 “Student Set Up and Maintenance”, Test Case #1, Step 1.3 |
| 3.2.1.2 | OQ-001 “Student Set Up and Maintenance”, Test Case #1, Step 1.6 and 1.7  PQ-003 “Training Coordinator Student Maintenance”, Test Case 7, Steps 7.23 and 7.25 |
| 3.2.1.3 | OQ-001 “Student Set Up and Maintenance”, Test Case #1, Step 1.4  PQ-003 “Training Coordinator Student Maintenance”, Test Case 7, Steps 7.1 through 7.22 |
| 3.2.1.3.1 | OQ-001 “Student Set Up and Maintenance”, Test Case #1, Steps 1.8 through 1.11 |

**Example 2:** Trace from User Requirement to Functional Requirement to Protocol

| **Function** | **User Requirement** | **Functional Requirement** | **Validation Protocol(s)** |
| --- | --- | --- | --- |
| Initiating a Workflow | 3.2.1 | 3.2.1 | OQ-001 Workflow Initiation  PQ-001 Document Management  PQ-010 End to End Process Verification |
| Entering Monitoring Report Approval Information | 3.2.2 | 3.2.2.1 | OQ-001 Workflow Initiation  PQ-001 Document Management |
| 3.2.2.2 |
| 3.2.2.3 | OQ-002 Workflow Processing  PQ-001 Document Management |
| 3.2.2.4 | OQ-002 Workflow Processing  PQ-001 Document Management |
| Adding Comments to a Workflow | 3.2.3 | 3.2.3.1 |
| Attaching a Document to the Workflow | 3.2.4 | 3.2.4.1 | OQ-002 Workflow Processing  PQ-001 Document Management  PQ-010 End to End Process Verification |
| 3.2.4.2 | OQ-002 Workflow Processing  PQ-001 Document Management |
| 3.2.5 | 3.2.5.1 | OQ-002 Workflow Processing  PQ-001 Document Management |
| 3.2.5.2 | OQ-002 Workflow Processing  PQ-001 Document Management |
| Referencing Supporting Documentation | 3.2.6 | 3.2.6.1 | OQ-002 Workflow Processing  OQ-003 Specialist Processing  PQ-001 Document Management  PQ-010 End to End Process Verification |
| 3.2.6.2 |
| Submitting Workflow to Reviewer | 3.2.7 | 3.2.7.1 |
| Viewing Workflow Information | 3.2.8 | 3.2.8.1 | OQ-008 Workflow Viewing  PQ-002 Document Process Viewing  PQ-011 21 CFR Part 11 Compliance |
| 3.2.8.2 |
| Viewing Attached Documents | 3.2.9 | 3.2.9.1 |
| Viewing and Adding Comments to Workflow | 3.2.10 | 3.2.10.1 |
| Approving or Rejecting a Workflow | 3.2.11 | 3.2.11.1 |
| Notification of Workflow Rejection | 3.2.12 | 3.2.12.1 | OQ-004 Workflow Processing Part II  PQ-001 Document Management  PQ-011 21 CFR Part 11 Compliance |
| Adding Comments and Modifying the Document | 3.2.13 | 3.2.13.1 |
| 3.2.14 | 3.2.14.1 |
| Resubmitting the Workflow | 3.2.15 | 3.2.15.1 |
| Notification of Required Signature | 3.2.16 | 3.2.16.1 | OQ-005 Workflow Processing Part III  PQ-001 Document Management  PQ-011 21 CFR Part 11 Compliance |
| Adding Comments to Workflow | 3.2.17 | 3.2.17 |
| Signing or Rejecting the Workflow | 3.2.18 | 3.2.18.1 |
| 3.2.18.2 |

# Revision History

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| --- | --- | --- | --- |
| **Document Version Number** | **Document Revision Date** | **Revisions Made By:** | **Revision Summary**  *(Reference section[s] changed)* |
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# Approvals

Signature(s) below indicate agreement with the contents of this Trace Matrix document as an accurate representation of the alignment of system functions, requirements, and validation protocols.

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| --- | --- | --- | --- |
| Document Prepared by: | | | |
| Function | Name | Signature | Date |
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Signatures below additionally signify approval of this Trace Matrix document.

| Document Approvals: | | | |
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| Function | Name | Signature | Date |
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