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# Purpose

The purpose of this Master Test Plan is to define the test strategy and identify the list of test cases that are going to be executed.

# Scope

*<Define the boundaries as to what is in and what is out of scope for this validation effort.>*

# References

*<List all the applicable documents/references used as guidance in creation of this document.>*

|  |  |
| --- | --- |
| **Document Number** | **Document Name** |
| *XXXX* |  |
| *XXXX* |  |

# Definitions

*<As Applicable, list definitions/acronyms/abbreviations that are used within this document.>*

|  |  |
| --- | --- |
| **Term** | **Definition** |
| IQ | Installation Qualification |
| OQ | Operational Qualification |
| PQ | Performance Qualification |
| *SQL* | *Structured Query Language* |

# Testing Approach

The following test strategy is used to scale the level of testing for <system name>’s components. This strategy follows company SOP XXX.

## Determine Test Rating

Test rating for each system component has been determined by using the table below:

|  |  |  |  |
| --- | --- | --- | --- |
| Patient / Product Quality Impact | Test Rating Method | | |
| Out of the Box | Configured | Custom |
| Direct | 3 | 4 | 5 |
| Indirect | 2 | 3 | 3 |
| None | 1 | 1 | 2 |

## Identify Testing Type

* The following table summarizes test ratings and the applicable test strategies based on guidance in Company SOP (Document # XXX):

|  |  |  |
| --- | --- | --- |
|  | TESTING STRATEGY | |
| Component / Functionality Name | Test Rating | Testing Types |
| <component 1> | 5 | Functionality validated through Scripted Testing with positive and negative conditions |
| <component 2> | 4 | Functionality validated through Unscripted Testing with positive and negative conditions |
| <component 3> | 3 | Functionality validated through Unscripted Testing with exploratory scenarios |
| <component 4> | 2 | Functionality validated through Functionality Certification |
| <component 5> | 1 | Relies on vendor audit and assurance based on market use of the tool |

Testing may be performed in more than one environment (Validation and Production). At the end of IQ/OQ qualification activities, a qualification report shall be generated and approved in the Validation environment.

*Include instructions for cutover/deployment strategies for:*

* *Setting up / Loading the Validation Environment*
* *Setting up / Loading the Production Environment*
* *Other Go-Live activities*

*This section of the Qualification Test Plan shall be used for planning out the sequence of the applicable cutover activities and any automated tools for managing different elements of the system during the cutover transition, such as managing:*

* *User Accounts,*
* *Test vs. Production Datasets,*
* *Interfaces/transactions with other systems,*
* *Impact on existing records,*

*These cutover activities may be documented in a variety of methods, depending on the system’s risk/complexity and the scope of the cutover effort. The methods for documenting the cutover activities include, but are not limited to:*

* *As part of the “Acceptance Criteria” section of this Qualification Test Plan*
* *Within the qualification protocol (i.e. as part of the pre-requisites and/or as part of pre-defined set-up steps in the Test Case.)*
* *Per the instructions in an existing or newly established procedure (i.e. per the User Administration procedure)*
* *Per the Data Migration Plan (i.e. data-scrubbing activities)*
* *Per the change control process for the impacted system(s)*
* *Per other pre-defined methods.*

*At the completion of all qualification activities (in both Validation and Production environment), a Validation Summary Report shall be generated and approved.*

***Note:***

* 1. ***Ensure all the work instructions or procedures for the system are either in draft or approved state prior to the execution of the protocols. All the draft procedures or work instructions must be approved prior to the closure of validation summary report for the system.***
  2. ***Ensure any test tools that are utilized during testing are validated prior to its use.***

# Validation Environment

## Installation Qualification

*<Installation Qualification (IQ) shall be conducted to ensure the Validation environment is installed and configured according to the specifications (Vendor, Design) for the system. The Installation Qualification tests shall be performed as listed in the table below.*

|  |  |  |
| --- | --- | --- |
| **Test Case ID** | **Test Case Title** | **Environment** |
| *X.1* | *Software Installation* | *Validation* |
| *X.2* | *Software Installation Verification* | *Validation* |
| *X.3* | *System, dataset, Specifications, and procedures Locations* | *Validation* |

## Qualification Report for Installation Qualification

*<Once the Qualification Report for the Installation Qualification is approved, Operational Qualification (OQ) shall commence.>*

## Operational Qualification

*<The operational tests shall be performed as listed in the table below. Testing shall include limit testing for parameters with specified ranges >*

|  |  |  |
| --- | --- | --- |
| **Test Case ID** | **Test Case Title** | **Environment** |
| *X.1* | *Security Test* | *Validation* |
| *X.2* | *Navigation Test* | *Validation* |
| *X.3* | *Functional Test* | *Validation* |

## Qualification Report for Operational Qualification

*<Once the Qualification Report for the Operational Qualification is approved. If applicable, Performance Qualification (PQ) shall commence.>*

## Performance Qualification

*< PQ testing may be performed in the Validation environment. PQ testing shall comprise of execution of business processes defined for use of the system.>*

|  |  |  |
| --- | --- | --- |
| **Test Case ID** | **Test Case Title** | **Environment** |
| *X.1* | *Security Test* | *Validation* |
| *X.2* | *Navigation Test* | *Validation* |
| *X.3* | *Functional Test* | *Validation* |

## Qualification Report for Performance Qualification

*<Once the Qualification Report for the Performance Qualification is approved, then the cutover activities can be initiated in the Production environment.*

## Acceptance Criteria

*<All IQ/OQ/PQ protocols and cutover activities are executed successfully and corresponding reports are approved.>*

# Production Environment

## Installation Qualification

*<IQ of the Production environment shall be conducted to ensure the Production environment is installed and configured according to the specifications (Vendor, Design) for the system and that the Production environment is equivalent to the qualified Validation environment. The Installation Qualification tests shall be performed as listed in the table below.>*

|  |  |  |
| --- | --- | --- |
| **Test Case ID** | **Test Case Title** | **Environment** |
| *X.1* | *Software Installation* | *Production* |
| *X.2* | *Software Installation Verification* | *Production* |
| *X.3* | *System Location* | *Production* |
| *X.4* | *Evidence of equivalency between Validation and Production environment to help justify the omission of the OQ in Production environment* | *Production* |

*.*

## Qualification Report for Installation Qualification

*<Once the Qualification Report for the Installation Qualification is approved, Performance Qualification (PQ) shall commence.>*

## Performance Qualification

*<Once the report for the Installation Qualification is approved, Performance Qualification (PQ) shall commence. The tests shall be performed as listed in the table below.>*

*Note: If the PQ was performed in the Validation environment, additional Performance Qualification may NOT be required in Production environment.*

|  |  |  |
| --- | --- | --- |
| **Test Case ID** | **Test Case Title** | **Environment** |
| *X.1* | *Security Test* | *Production* |
| *X.2* | *Navigation Test* | *Production* |
| *X.3* | *“A-Day-in-Life” Test* | *Production* |

## Qualification Report for Performance Qualification

*<Once cutover activities are executed successfully and the Qualification Report for the Performance Qualification is approved, approval of the Validation Summary Report shall be initiated, and Performance Qualification Monitoring shall commence.>*

*Note: A Performance Qualification in the production environment is not always required, in such cases, completion of the cutover activities shall be captured in the Validation Summary Report.*

## Performance Qualification Monitoring

*<Immediately following the PQ in the Production environment the system shall transition to the monitoring period. The monitoring period shall continue for 5-business days to provide adequate time for users to challenge the system through normal business operating cycles.*

*During the PQ monitoring period, the records shall be updated to include any data values that could not be converted/copied from the existing <System Name, System Release> instance or any new values <System Name, System Release> that need inputs.*

*Extension of the monitoring period due to any issue that is unresolved at the conclusion of the established time frame shall be considered and an additional Qualification report shall be issued to authorize such an extension.>*

# Test Execution

## Actual Results

* + - The Actual Results column is used to document the results that were observed at the time of test case execution.
    - With the exception of prompting the tester to record specific information during execution, the actual results column shall not contain any pre-populated results prior to execution of the test.
    - If the tester notices any discrepancies OR if the Actual results **vary from** the Expected Results, record the actual results **observed** and mark the step as “*Failed*”.

## Defects

Defects module shall be used to document failures that occur during execution of the approved protocol.

If required, defects shall be used to document any change required to the approved protocol (modifying or adding instructional steps) prior to protocol execution.

## Acceptance Criteria

The test objective for each test case has been successfully met and all deviations encountered during protocol execution have been addressed.