Title:	CLUWE Web Tool Master Validation and Test Plan

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TITLE: CLINICAL USERS WORKING ENVIRONMENT (CLUWE) WEB TOOL MASTER VALIDATION AND TEST PLAN

REVIEWERS

Your electronic signature indicates that you have reviewed this document and that for your area of expertise, agree it is accurate and complete.

- ***Business Subject Matter Expert (BSME)***
- ***IT Subject Matter Expert (ITSME)***
- ***Quality Analyst (QA)***
- ***Test Lead (TL)***

APPROVERS

System Custodian

Your electronic signature attests that

- The appropriate persons involved in the validation process have reviewed the document to ensure that the plan is adequate to properly validate the computer system
- You understand your responsibility to provide the resources necessary to validate and the system as described in the plan
- You understand your responsibilities in the validation process.
- The plan meets the requirements of the Lilly Quality Practice LQP-302-18, Testing

System Owner

Your electronic signature attests that

- The appropriate persons involved in the validation process have reviewed the document to ensure that the plan is adequate to properly validate the computer system
- You understand your responsibility to provide the resources necessary to validate the system as described in the plan
- You understand your responsibilities in the validation process.

Computer System Quality Assurance Representative

Your electronic signature attests that this document complies with Corporate Computer Systems (CCS) Lilly Quality Standards and Practices.

TITLE: CLINICAL USERS WORKING ENVIRONMENT (CLUWE) WEB TOOL MASTER VALIDATION AND TEST PLAN

PURPOSE

The CLINICAL USERS WORKING ENVIRONMENT (CLUWE) WEB TOOL will be validated according to applicable Lilly Quality Standard (LQS) and Lilly Quality Practices (LQPs), IT Common (ITC) SOPs, and local procedures. The Validation Plan (this document) outlines the validation approach and provides the rationale for the extent of validation planned for the system.

This Master Validation and Test Plan serves as the overarching validation and test strategy for the CLUWE Web Tool that will be delivered in several releases each comprised of one or more sprints.

A change request will be created at the beginning of each release that will specify the planned validation activities and deliverables for that release.

This is a high-level document that will not have a corresponding overarching validation report. Major releases (new functionality) will have a release summary report that will document the actual deliverables and validation activities that were undertaken for that release. Minor releases (bug fixes, etc.) will document deliverables, validation activities, and system acceptance within the Change Control (CHG).

This document will be a living document that will be updated as needed over the life of the system.

SCOPE

See the System Description and Scope section for scope details.

ACRONYMS AND DEFINITIONS

The terms and acronyms in this document are defined at their first occurrence.

DOCUMENT REVISION HISTORY

Version	Revision Date	Reason for Revision (Include CR#, if Applicable)	Revised By, Title
2	12 Sep 2017	Updated the following sections per CHG1092912: • Global: Removed HP ALM version info, all places. Specified type of test/case/script, all places • Reviewers: removed BQA • 4.1.4, Deliverables: Updated reviewers, approvers • 5.1.1: Updated test levels column • 5.7: Updated Test Lead Responsibilities • 5.8.3, UAT Testing: updated all subsections • 5.9: Clarified documentation locations	Christopher Sheppard, Validation Lead
1	23 Sep 2016	CHG0988306: Updated purpose section to differentiate between major and minor releases. Updated 5.11 to include data only in CHG for minor releases.	Christopher Sheppard, Validation lead
0	1-Aug -2016	New document	Christopher Sheppard Validation Lead; Lalitha Pagala, Test Lead

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1. SYSTEM DESCRIPTION AND SCOPE

Area	Discussion
Description Of System To Be Validated	The system will initially perform the following functionalities: 1. Job Scheduling – off-line job/program execution including the ability to set execution time. 2. Versioning – version control of files within repository. 3. eSignature – CFR part 11 compliant Electronic Signature capabilities. 4. Admin features a. Re-Lock – re-locks files within specified folder(s) and within all sub-folders. New features will be added over time in subsequent iterations and added to this list.
Validation Scope and System Components	The CLUWE Web Tool will: • facilitate a business process around analysis and reporting of clinical data • be accessible globally with consistent performance The scope of validation will be to validate Job Scheduling, Versioning, eSignature, and Admin functionalities.
Purchased Components Included In System	Isilon Network Attached Storage by EMC.
Key Interfaces	Key interfaces with this system are: • Isilon • SAS Grid • Oracle • ActiveMQ
Out of Scope	• Validation of the EMC Isilon infrastructure • Validation of the SAS Grid infrastructure • Validation of the network and server infrastructure maintained by other support teams.

2. RISK EVALUATION AND REGULATORY STATUS

This validation will be right-sized based on business processes and system risks. Decisions made during discussions where these risks are assessed will be documented throughout the validation package in the applicable validation deliverable, and validation activities will be planned and implemented based on managing and controlling these known risks.

The initial risk assessment for this system provided the following information:

Risk Factor	Discussion
Regulatory Status	The system is designated as GCP and Quality Critical.
Potential Impact	This system has a direct impact to Privacy and Information Classification as the interface to file system and can manipulate file name, properties, and security.
Type of System	The system is custom developed and will be used globally.
System Complexity	This system has high complexity due to the integration with Isilon and SAS-Grid.
Supplier Involvement	There is no vendor involved in the system.

3. ROLES AND RESPONSIBILITIES

Following is the roles and responsibilities of individuals performing validation activities for this system.

ROLE	RESPONSIBILITIES
Business Quality Assurance (BQA)	• Participate in completion of PIC assessment. • Provide product quality support and consultancy • Review/Approve deliverables as stated within this document
Business SME	• Represents Business in interaction with IT Product Owner • Review/Approve deliverables as stated within this document
Computer Systems Quality Assurance (CSQA)	• Leads Potential Impact Criticality(PIC) discussion • Provide Computer System Quality support and consultation • Review/Approve deliverables as stated within this document
IT Data Privacy SME	• Review and approve PIC form with respect to Privacy detailed section • Review deliverables as appropriate
Product Owner	• Author requirements/Acceptance criteria • Manages product backlog items (user stories) • Manages product backlog priority • Manages releases • Serves as a bridge between business and IT
Quality Analyst (QA)	• Define the validation process/strategy • Create and update the Master Validation Plan • Create the Release Summary Report • Create/Review deliverables • Provide ad-hoc consultancy • Drive the Risk Assessments
Scrum Master	• Helps the team, organization, and process • Removes team impediments
System Owner(SO)	• Review/Approve deliverables as stated within this document
System Custodian(SC)	• Define the Support Model for the application • Review/Approve deliverables as stated within this document
Technical SME/IT SME	• Configure the application in a way that is aligned with Lilly Standards • Deliver technical documentation • Perform Unit testing • Fix bugs and deploy further changes to the configuration of the application • Review/Approve deliverables as stated within this document • Approve the test cases/scripts

ROLE	RESPONSIBILITIES
Test Lead	• Create Test Plan • Manages System Testing • Review/Approve deliverables as stated within this document

4. VALIDATION PLANNING

The following table includes more validation planning information/activities.

Area	Discussion
System Development Process	Systems development will follow the Lilly Systems Engineering Framework (LSEF) as it applies to an AGILE methodology.
Software Tools	The following software tools are used in the development and testing of the system. Unless otherwise noted, the tools are compliant with the Enterprise Architecture, supported by infrastructure teams, and appropriately validated based on risk to the system. • Jenkins – Continuous Integration system responsible for code builds and automated testing. • Eclipse Java IDE – Development environment used by the developers. • HP ALM– Used for Testing the system and to store requirements, test scripts and code reviews.
Requirements Management Plan (RMP)	Requirements will be documented as Acceptance Criteria within each User Story and from here on will be referred to as User Stories. These User stories will be stored and managed in HP ALM. From here on HP ALM will be referred to as Quality Center.
Pre-Implementation Change Control Strategy (Configuration Management)	• Approved validation deliverables are version controlled and stored in Regulus. Once a document is approved, proposed changes must be approved by the roles responsible for reviewing and approving the document. • User Stories are managed and controlled using Quality Center. Once User Stories are approved, proposed changes are analyzed to determine the impact and agreed upon by System Owner and System Custodian before the changes can be implemented. • Code is managed and controlled using Apache Subversion (SVN) for day to day activity. Once the code is ready for QA and PRD it is checked into TFS. TFS is the final source for all code that is formally tested.
Supplier Management	There is no vendor involved in the development of this system
Document Storage	All CLUWE WEB TOOL validation documents will be managed electronically and stored within Regulus and Quality Center. Please refer to the section on Validation Documentation for location.
Applicable Standard and Practices	The validation of this system will follow the current Corporate Computer System (CCS) Lilly Quality Standard (LQS) and Lilly Quality Practices (LQP) requirements for computer system validation.

4.1 Validation Documentation

4.1.1 Validation Deliverable Roles

The roles involved in reviewing and approving validation deliverables include:

Role Key	
Role Acronym	**Definition**
BQA	Business Quality Assurance
BSME	Business Subject Matter Expert
CSQA	Computer Systems Quality Assurance
IT SME	IT Subject Matter Expert
QA	Quality Analyst
SC	System Custodian
SO	System Owner
TL	Test Lead

4.1.2 Validation Deliverables to be produced

The following table provides a list and summary of the validation deliverables to be produced at the start of this effort:

Validation Product	Description/Discussion	Reviewer(s)	Approver(s)	Deliverable Location (Regulus, QC etc)
Validation Planning				
Master Validation and Test Plan	This document will serve as the overarching validation and testing strategy for CLUWE.	• BSME • IT SME • QA • TL	• SC • SO • CSQ	Regulus

4.1.3 Validation Deliverables to Be Produced for each Release

The following table provides list and summary of the validation deliverables which will be produced for each release of this effort:

Validation Product	Description/Discussion	Reviewer(s)	Approver(s)	Deliverable Location (Regulus, QC etc)
Validation Planning				
Release Summary Report	A Release Summary Report will state the validation status for each release. Approval of a Release Summary Report indicates acceptance or non-acceptance of that release. These Release Summary Reports will summarize the completion of all validation activities, resulting deliverables, and supporting documentation that provide documented evidence of the validation status of each release. The Release Summary Report will include a test summary to document the execution of testing as well as document problem reports encountered during testing.	• BSME • IT SME • QA • TL • BQA	• SC • SO • CSQA	Regulus
Source Code Review	Source Code Reviews (SCRs) will be conducted in accordance with the LQP *Application Source Code Review* (LQP302-3). A summary of the SCR results will be included in the Validation Release Summary Report for each release.	• N/A	• IT SME	Quality Center
Traceability Matrix	The Traceability Matrix will be updated with each release to document the traceability of requirements to design to testing.	• N/A	• IT SME	Quality Center

4.1.4 Validation Deliverables to be Created or Updated

The following is a list of deliverables that will be created and updated during the course of this validation effort:

Validation Product	Description/Discussion	Reviewer(s)	Approver(s)	Deliverable Location (Regulus, QC etc)
Validation Planning				
Requirements	The Requirements Definition will define what the system capabilities should be. This will include functional, security, and Electronic Records/ Electronic Signature (ER/ES) requirements for the system. This will be represented as User Stories.	• IT SME • BSME	• SC • SO • CSQA • BQA	Quality Center
System Overview	The System Overview document will be updated as needed to provide high-level information about the system.	• IT SME • QA • BQA	• SC • SO • CSQA	Regulus
System Configuration Specifications	The System Configuration Specification document will be updated as needed to address the requirements defined in the Lilly Quality Practice: *Requirements and Design* (LQP302-16).	• IT SME • QA	• SC	Regulus
Design Specifications	The Design Specifications will be updated to address the requirements defined in the Lilly Quality Practice: *Requirements and Design (LQP302-16).*	• IT SME	• IT SME	Quality Center
Testing				
Test Cases/Scripts	Test cases and scripts will be updated and new test cases created as needed to test requirements and specifications.	• IT SME	• IT SME	Quality Center

Validation Product	Description/Discussion	Reviewer(s)	Approver(s)	Deliverable Location (Regulus, QC etc)
Installation and Verification Instructions (IVI)	The IVI will be updated as needed to verify that the system has been installed and configured properly.	• N/A	• IT SME	Quality Center
Supporting Documentation				
Security Plan	The Security Plan will be updated as needed to describe the physical and logical security controls for the system.	• IT SME • QA • BQA	• SC • SO • CSQA	Regulus
Security Administration SOP	The Security Administration SOP will be updated as needed to describe how physical and logical security will be administered.	• IT SME • QA	• SC • SO • CSQA	Regulus
Disaster Recovery Plan	The Disaster Recovery Plan (DRP) will be updated as needed to describe the process that will be followed to recover the system in the event of a disaster.	• IT SME • QA	• SC	Regulus
Business Continuity Plan	The Business Continuity Plan (BCP) will be updated as needed to describe the process that will be followed to continue operations in the event the system becomes unavailable.	• BSME • QA	• SC • SO • BQA	Regulus
System Administration and Support SOP	The System Administration and Support SOP will be updated as needed to detail changes to policies, procedures, and practices applicable to system administration and support activities.	• IT SME • QA	• ITSME	Regulus

4.1.5 Validation Deliverables Not Produced

The following is a list of deliverables that will not be produced, along with the rationale:

- Backup and Restoration Plan (backup and recovery services are provided by Global Infrastructure Center of Excellence [GICOE])
- Platform Qualification - The system is supported by Global Infrastructure Center of Excellence (GICOE). GICOE supports the hardware and software platforms where the system resides and provides resources to perform those platform support services.
- Installation Qualification/Operational Qualification (IQ/OQ) document – This will not be covered as IVIs have been created to ensure installation success.
- Data Migration Plan/Report – Data Migration Plan/Report will not be created because no changes will be made to the data structures in the repositories. The CLUWE Web Tool does not migrate data.

5. TEST PLANNING

5.1 Test Strategy and Approach

CLUWE Web Tool has been classified as Quality Critical and GCP system. To ensure adherence to requirements and policies, testing will include:

- Unit Testing
- System Testing
- User Acceptance Testing (UAT)
- Regression Testing

The test strategy outlined in this Master Validation and Test Plan will be delivered in one or more releases and is based on Agile methodology as it applies to Lilly System Engineering Framework (LSEF) Test Management Process and Lilly Quality Practice (LQP)-302-18, Testing. The scope of testing will ensure that the system meets its intended use by testing specific User Stories. Testing will be performed using a specific set of test cases to ensure the coverage and implementation of these User Stories.

The Change request generated for each release will document the specific features developed for the release and list the test scripts to be executed for each level of testing.

The following strategy will be used to test each release of the CLUWE system.

1. A Master Validation and Test Plan will be approved for all the releases. Each release may have one or more sprints, which is an iterative development cycle.
2. A Release Summary Report (RSR) will be drafted and approved for each release. The RSR will be created at the end of each release and approved at the completion of testing.
3. User stories will be created to describe business use cases for the system.
4. User Stories will be documented in Quality Center and mapped to Test Scripts.
5. System test cases will be created to verify the functionality and uses defined in the User Stories. System test cases will be documented in Quality Center.
6. User stories and system test cases will be defined at the beginning of each release. System test cases will be executed informally at the end of each sprint and formally prior to each production release.
7. Defects identified in the Formal Testing will be moved to the next sprint/Release.

The following sections provide additional detail regarding test tools and processes.

5.1.1 Test Risks

Risk	Test Level (Test level the risk associated with)	Probability of Risk (Low, Medium, High)	Impact of Risk (Low, Medium, High)	Mitigation Strategy
Insufficient Testing Performed	Formal System	Low	High	Test Scripts should handle all types of scenarios including negative, functional and exception handling and should be reviewed by IT SME before formal testing begins.
Environments become unavailable	Formal System/UAT	Low/Medium	High	Work with internal group to regain functionalities.
Testing cannot be completed in scheduled timeline	Formal System	Medium	High	Use additional testers if priority necessitates.
Security – Unauthorized users may gain access to the system	Formal System	Low	High	Security will be tested during System Testing.
Testers using the same environment and deleting test data	Formal System/UAT	Low	High	Identify which test data would impact the execution prior to execution of the test and ensure using different data to perform the test in same environment.
Formal Test environment not setup to match the Production instance	Formal System/UAT	Low/Medium	High	IT SME should ensure that the design for QA and production instance should be similar.
Testers using accounts with higher permissions which might cause the applications to function differently	Formal System	Low	Medium	System test scripts to capture which account levels to be used to test the particular test case. Tool Admin should provide the necessary security roles to the testers.

5.2 Test Data

The test data will be specified in the Test Setup section of the system test scripts, or will be included in the steps of the script itself.

Directory Structure and folder security of CLUWE Web Tool will be setup as is in production.

- For System level testing, business will provide de-identified data to IT to use as test data
- For UAT, business will use de-identified data as test data

5.3 Test Tools

Tool	Use
Hewlett Packard (HP) Application Lifecycle Management (ALM) Domain: GMR Project: GSS_eSig	This tool will be used for system testing to create a release tree and to manage releases. Listed below are the uses of HP ALM: • Create, review and approve User Stories as Requirements. • Create, review and approve the Requirement Traceability Matrix (RTM) • Create, review, and approve system test cases • Approve system test results • Provide a repository for tracking the system test problem reports or tracking bugs and fixes.

5.4 Test Sequence and Dependencies

Test Phase	Tool to be used	Dependency
Unit Testing	None	Code is developed and available in Development environment.
System Testing	HP ALM	1. User Stories are formally Approved. 2. Formal System Testing scripts pre-approved. 3. QA available for testing.
User Acceptance Testing	Regulus	1. System level Testing is complete for one or more test scripts within HP ALM. 2. User Stories are approved. 3. QA is available for testing. 4. Business testers are available during the planned UAT timeline.
Regression Testing	HP ALM	1. System Requirements (pre-agile) and User Stories (agile) Approved. 2. Formal System Testing scripts pre-approved. 3. QA available for testing For Formal Regression. 4. Dev Available for testing for Informal Regression.

5.5 Test Documentation

The system test scripts will be developed in HP ALM. All the system test scripts will be named uniquely based on the functionality being tested. The corresponding User Stories will be mapped to the system test scripts. System Test execution details and approved test results will be retained in HP ALM.

5.5.1 Format of the Test Documents

Each system test document (i.e. test script) will be identified with a unique number.

The system test document will detail the exact steps required to complete the test for a requirement. Each test step will identify any setup, precursor documents or data requirements required to execute that particular test step. During system test document creation, each step in the test document will consist of the following fields as depicted in the HP ALM:

Field Name	Description
Step Name	Unique test step identifier, which references the unique requirement number.
Description	Describes the actions to perform when testing a particular facet of a requirement.
Expected	Documents what the tester should expect to see as a result of the actions described in the "Description" column.

While executing the document, the Tester will be required to fill in the details for the following additional fields:

Field Name	Description
Actual	Examples to be documented in the "Actual Results" column include, but are not limited to, • Noting a data item • Obtaining a screen shot • Printing a report or entering the actual results In addition, if a step is purely navigational, it may be appropriate to allow the tester to enter a simple PASS or FAIL to document the outcome of an executed step. NOTE: Although it may be appropriate to have individual steps confirmed with a simple pass or fail (i.e., navigational steps), it may not be appropriate for all the steps of a particular document be documented with a pass or fail answer, unless some other form of evidence is provided, such as an attached screen print. Ensure that any step that supports a requirement has documented evidence that it passed.
Overall Execution Status	Reflects the outcome of the test step based on the status selected by the test executor.

5.6 Test Environment

CLUWE Web Tool will be hosted on QA (non-production) environment for testing purposes. The QA (non-production) environment will mirror the intended production environment.

5.7 Test Roles and Responsibilities

Test Role	Responsibilities
Business QA	• Approves Requirements in HP ALM • Reviews Master Validation and Test Plan and Release Summary Report
Business SME	• Reviews User requirements/User Stories to ensure approval readiness • Performs UAT • Reviews Master Validation and Test Plan, UAT Scripts, and Release Summary Report • Approves UAT test results uploaded into Regulus. This approval is for Post approval of the UAT testing results

Test Role	Responsibilities
CSQA	• Approves Requirements/User Stories in HP ALM • Approves Master Validation and Test Plan and Release Summary Report
Development Lead	• Ensures proper development practices are followed during the sprints • Ensures all the defects detected in System and UAT phase are resolved or deferred.
ITSME	• Reviews system requirements/User Stories to ensure approval readiness • Reviews and approves RTM, Design Elements • Participates in system testing and UAT • Reviews Master Validation and Test Plan, Test Scripts, and Release Summary Report • Approves System Test scripts prior to Formal Test Execution • Approves Formal System Test Runs after Formal Test Execution
QA	• Reviews Master Validation and Test Plan and Release Summary Report • Verify the testing deliverables adhered to LQPs and Lilly Quality Standards (LQSs)
System Custodian	• Approves Requirements/User Stories in HP ALM • Approves Master Validation and Test Plan • Approves Release Summary Report
System Owner	• Approves Requirements/User Stories in HP ALM • Approves Master Validation and Test Plan • Approves Release Summary Report
Test Analyst	• Upload Requirements/ User Stories into HP ALM (not authoring) • Write and Maintain System test scripts in HP ALM • Obtains test script(s) pre-approval and post-approval • System Test Script Execution • System Testing Defects Logging and Tracking in HP ALM • Creation of Requirements/ User Stories Traceability Matrix • Involve in creation of Release Summary Report

Test Role	Responsibilities
Test Lead	• HP ALM Setup • HP ALM Admin role to manage HP ALM related activities • Manages the overall testing lifecycle and scope • Ensures that all testing activities are occurring in accordance to this Master Validation and Test Plan • Creates the Testing portion of Master Validation and Test Plan, RTM and Testing Portion Release Summary Report • Ensures that the requirements/User Stories in HP ALM are reviewed and approved • Ensures that the Test Scripts and Test Runs are approved • Manages folders in test plan module, manage folders and test sets in Test Lab module, add tests to test set in Test Lab • Assigns the test scripts to the testers • Manages Test Execution Reporting • Manages resolution of defects reported in HP ALM, ensuring appropriate defect status is assigned to all defects for a testing effort • Coordinates the creation of the test environments • Ensure test analysts are trained on tool usage and procedures • Responsible for acquiring testing resources • Communicates testing status at daily and/or weekly team meetings

5.8 Test Levels

5.8.1 Unit Level Testing

The development team is responsible for Unit testing and no formal documentation is required. Unit testing will occur continuously throughout system development, and issues or defects encountered during this period will not be tracked in HP ALM.

5.8.2 System Level Testing

5.8.2.1 Approach

Formal System testing will be executed in the qualified Quality Assurance (non-production) environment. This testing will cover the complete set of requirements in scope for the release. Integration testing will be performed as part of System level testing. Associated documentation will be stored in HP ALM.

5.8.2.2 Objectives

The objective for System testing is to demonstrate that the computer system meets its intended use. Refer to Testing, LQP 302-18 for additional information on System testing.

5.8.2.3 Entry Criteria

- Code is locked and moved to QA environment

- All requirements for the release have been Unit tested
- Testers have read the Test Plan and have access with right security setup to the qualified Environment
- Test data is created
- Requirement / User Stories and design documentation are formally approved in quality center
- Test cases or scripts are approved
- RTM is approved

5.8.2.4 Exit Criteria

- All System test scripts have been completely executed
- All problems identified during testing have been fixed, closed, or accepted and deferred by the System Owner
- Test Runs are approved
- Results and defects are documented in the Release Summary Report

5.8.3 User Acceptance Testing

User Acceptance Testing may be performed if any additional testing is required after System Testing. UAT will be defined and executed by the business and/or representatives of the business. The UAT is in addition to the system level testing and provides for business knowledge to be applied in exercising the various CLUWE functions. UAT has concluded when the business is satisfied the system is fit for use and all system testing defects have an appropriate disposition.

5.8.3.1 Approach

- Once the system testing is completed, User Acceptance Testing will be done outside HP ALM in QA environment by BSME.
- UAT scripts will be shared with IT team for their review, to ensure all the Business scenarios are covered in system testing.
- Any issues identified during UAT will be communicated back to the Testing team. The Test team will verify the defect via System testing and log defects in HP ALM and within the Test Summary Report.
- Only final pass runs of UAT results will be uploaded into Regulus and approved by the BSME. Failed runs of UAT will not be retained.

5.8.3.2 Objectives

The objective of UAT is to ensure that the completed system is ready for business use.

5.8.3.3 Entry Criteria

- All exit criteria specified for the system level/ integration testing have been successfully completed.

5.8.3.4 Exit Criteria

- All issues identified have been resolved and retested as a part of system testing.
- The BMSE agrees that the system meets the expectations.
- The final run of UAT results are uploaded into Regulus and approved by the BSME.

5.8.4 Regression Testing

5.8.4.1 Approach

Regression Testing is needed to make sure the User Stories implemented in previous releases are not affected by subsequent releases. To ensure this, Regression Testing needs to be in conjunction with Unit Testing in the subsequent releases once the first release is implemented. The Test cases written for the previous releases can be re-used for this testing.

5.9 Process for Documenting Test Execution in HP ALM

Every run of a particular Formal System Testing document will be executed in HP ALM. User Acceptance Testing (UAT) will be documented separately and not within HP ALM. Each system test document represents a complete test of a single requirement or a set of requirements; therefore, any single test document must be executed in its entirety unless otherwise documented in the Release Summary Report. When executing any system test document, all testers will follow good documentation practices as follows,

- Each test document is composed of one or more steps. The specifics of what is included in a test document can be found in the section titled Format of Test Documents of this document. If the actual results for any test step do not match the expected results, the Tester will indicate the actual results in the appropriate column, mark the step as 'Fail' and the problem will be documented as a defect
- If a step in a test document requires the Tester to produce some sort of hardcopy printout, the printout will be scanned and imported into HP ALM attached to the appropriate test step
- If the Tester encounters a spelling or grammatical error during testing, the Tester may pass the test document with Execution status as "Pass Script Error" and raise a defect in HP ALM. For all other errors, including non-obvious typographical errors, the test step should be failed and tester should log a defect in HP ALM
- Once the test document has been completely executed, the Tester will route it for review within HP ALM 11. If the test document failed, the tester will log a defect in HP ALM
- After the Tester has completed the test document, a reviewer will review the test document to ensure that it has been executed appropriately. The IT SME will then indicate their acceptance or rejection of the results of the test document, note any appropriate comments (if required), and electronically sign the test document
- If required, the Test Lead may generate graphs and reports from HP ALM

5.10 Test Problem Management

5.10.1 Scripting Errors

In case of navigational error during execution of any script, a decision will be taken by Test Lead to restart or rerun the failed script. Rationale to partially run a script will be documented in the Release Summary Report.

System script changes that will be made to resolve script errors will be documented in the '*Actions Taken to Fix*' column of the defect in HP ALM.

5.10.2 Problem Identification

Testing's primary goal is to identify defects in the system (i.e. not meeting requirements) for resolution or acceptance prior to global roll out to users. Any system defects from informal testing will be recorded on the system's project development collaboration site. A review of these defects will be done by BSMEs and IT SMEs to verify their status as a system defect. The Project Execution Lead or Lead BSME will report the defects to the developers for correction. Any formally, executed test documents will be re-executed once known issues from informal testing has been resolved. Any new issues identified during formal system testing will be recorded in HP ALM.

5.10.3 Problem Resolution

Defects, Script Errors, and suggestions for enhancements identified during the testing process will be recorded on the system's project development collaboration site from informal testing, and HP ALM during formal testing. The project execution lead and System Owner will review the issues to identify if they are defect (i.e. not meeting requirements), script error, or suggestion. All defects will be directed to the developers for correction followed by re-execution of the test document. Although the goal is to resolve all defects before release into production, the System Owner has the option to accept the system with a known defect. Acceptable known defects will be minor in nature such as spelling, labeling, help text, navigational etc. with no impact to the System Functionality.

5.11 Release Summary Report

After all of the system test documents have been executed, reviewed, and electronically signed by the reviewer in HP ALM, the appropriate test execution data will be generated from HP ALM for inclusion in the Release Summary Report for major versions. At a minimum, the Release Summary Report must include the following information:

- Summary of changes made
- Validation deliverables approved
- Code modules modified
- Outstanding issues
- Validation status
- Departures from the master validation and test plan
- Overall test results
- Test levels executed and summary of the results of each test level executed
- List of all system test cases and scripts executed
- List of all test problem reports and the problem statuses and justification for any problem not fixed
- Documentation of system configuration used for system and acceptance (if executed) level testing
- Departure from the planned testing contained in the CHG to include description and justification of departure

All executed test documents must be listed in the Release Summary Report including all failed runs. For minor versions, all executed test documents and validation activities designated above for a Release Summary Report must be listed in the CHG.

6. REFERENCES

A current list of system-specific documents stored in Regulus can be generated using Regulus. The documents are stored in the IT Library Regulus repository at IT_Library > LRL IT > Systems C to D > CLUWE Web Tool and in IT_Library > LRL IT Secure> Systems C to D > CLUWE Web Tool.