Test / Validation Plan

CMMS 2024 Bucket Change 1

**CMMS**

[CHGXXXXX](https://biogen.service-now.com/nav_to.do?uri=%2Fchange_request.do%3Fsys_id%3D5a812a241b900654fe4f75dcdc4bcb42%26sysparm_view%3D%26sysparm_view_forced%3Dtrue)

Document Approval

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Revision History

The revision history for this document is maintained in an electronic document management system, myCIMS.

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# Scope

## Scope Description:

This change (CHGXXXXX) plan outlines the validation process and deliverables required to execute the updates required per change control CHGXXXXX. The CR is noted as Level 1 as some of the updates are covered by item 1 in section 5.9.7 of PRCD-XXXXX (CMMS Application Management) - Creation/Modification of validated reports which require a level 1 change. The overall level of the CR will default to a level 1 as it includes these level 1 category changes.

This CR is to update the following items and includes all validation activities required to verify and document the proper function of the changes.

The following 9 changes are within the scope of this CR:

1. Audit Trail Report Logic Change:
   * Logic changes are made to the Audit trail reports. The reports will now have a note if the work order comment is greater than 3000 characters. This note prompts the reviewer to reference the work order tab itself rather than the report entry as the comment length is too long for the report field.
   * The following reports are affected by this change:
     1. audit trail review (WSJOBE) v1
     2. audit trail review (WSJOBW) v1
     3. audit trail review (WSJCRA) v1
     4. audit trail review (WSJACL) v1
2. Spelling fixes in Audit Trail
   * Edits to R5OBJECTS table to fix the following spelling:
     1. From “Dorment End Date” to “Dormant End Date”
     2. From “Reuse Dorment Date Range” to “Reuse Dormant Date Range”
   * Edits to R5PPMOBJECTS table to fix the following spelling:
     1. From “Doement End Date” to “Dormant End Date”
     2. From “Reuse Domant Date Range” to “Reuse Dormant Date Range”
3. Logic changes made to Work Order Report to change the pointed location at the Work Order and not at the object location
4. Add Lots to display on the Calibration Standards Tab
5. Add visible field to display last login of a user
6. Remove logic that automatically makes a new user have an active license
7. Change the View All Equip Update Requests screen
   * Hide “QA Review”
   * Hide “QA Reviewer (if req.)”
8. Hide the Administrative ECDB menus from users:
   * For SME, PLNSCH, and QA accounts disable Attribute Types, Phases, Revision Control Status, Revision Control Status Authorizations, and Revision Control eRecords Setup
   * For BUSADMIN accounts disable Revision Control Status, Revision Control Status Authorizations, and Revision Control eRecords Setup
   * For SME, PLNSCH, QA, and BUSADMIN users, provision access to the following ECDB reporting screens (reports validated in CHGXXXXX):
     1. Attributes on Equipment Report
     2. Bill of Equipment Revision Report
     3. Bill of Equipment Summary
     4. Equipment Change (IEL) Report
9. "Forgot Password” button
   * Removing the “Forgot Password” button located below the “LOGIN” button

After the successful completion of deliverables in section 12, combined Test/Validation Plan Report will be used to document that the fixes have been implemented successfully.

# Purpose

For the Computerized Maintenance Management System (CMMS) 2024 Bucket Change 1 (CHGXXXXX), this combined Test & Validation Plan describes the implementation strategy, including activities that will occur as part of the System Developmental Life Cycle (SDLC) updates.

This plan is required to provide documented evidence that the Computerized Maintenance Management System (CMMS) will perform accurately and reliably as intended. In addition, project roles and release for use criteria are also included in this document.

# Definitions, Acronyms, and Abbreviations

| **Term** | **Definition** |
| --- | --- |
| CMMS | Computerized Maintenance Management System (CMMS) |

## Risks and Assumptions

**Risk:** Affected requirements have been identified and are included in the functional/operational testing scope. See section 9.2 for details.

**Assumption**: Validation and Production environments are equivalent and current with respect to basic functionality and test data.

## Out of Scope

All other system changes other than those related to the functionality impacted in step 3.1.

# System Overview

## System Description

The Computerized Maintenance Management System (CMMS) is a GMP application that supports the Biogen maintenance and calibration processes. CMMS is an HTML5 compatible application accessed through a web browser for all users.

The primary users of the CMMS are Facilities, Engineering, Manufacturing, Metrology, and Quality Assurance. The CMMS platform is accessible to all, but access is limited depending on the user group assigned. The CMMS platform is used to maintain equipment/instrument records, manage work and maintain spare parts. This includes all planned and unplanned work. The application is comprised of application servers, SQL databases, and Cognos advanced reporting servers.

## Environments

See section 8.7 for details.

# Validation Approach

## Overall Approach

This change is classified as a level 1 change per Administration and Management of the Computerized Maintenance Management System (CMMS) PRCD-XXXXX, and a Normal change per PRCD-XXXXX, Managing Changes to IT Systems.

The change will be validated according to the process defined in PRCD-XXXXX, Validating IT Computerized Systems v13.0. The change request will be managed according to PRCD-XXXXX. New testing has been developed and will be executed based on required configuration changes and required testing per PRCD-XXXXX, Computerized Systems Risk Management v8.0.

Testing activities will be outlined specifically in sections 7, 8, and 9 of this document.

Please see section 12 for a list of deliverables associated with this project.

## Vendor Documentation

N/A – No vendor documentation is being utilized for this change.

## Document Structure

CMMS SDLC documentation is controlled in MYCIMS and has the full suite of application SDLC documentation.

## Document Management

SDLC documents are managed in MyCIMS unless otherwise noted.

Testing and defects are managed in ALM unless otherwise noted.

All project related testing in ALM is located in the “POIT” domain with project name “CMMS”.

## Document Locations:

Department Controlled/ Information Technology/ IT Capital Projects/CMMS(Infor11)

## Data Migration

N/A - Data migration activities will not be conducted as part of this effort.

# Roles

The following roles have been identified for this project:

| **Role** |
| --- |
| System Owner |
| Testing Lead |
| IT Quality |
| Business Analyst |
| Business Process Owner (BPO) |
| Functional Lead |

The specific roles identified in the validation effort are not necessarily the final approvers of this plan.

# Testing Overview

## Testing Scope

This testing effort will include the following:

* Installation Qualification (IQ) – Installation and configuration will be performed
* Operational Qualification (OQ) – Functional verification of the updates
* User Acceptance Testing (UAT) – User verification of the updates

## Risks and Assumptions

**Risk:** Affected requirements have been identified and are to be included in the scope of the functional/operational testing

The change has been determined to be Medium Risk per PRCD-XXXXX, Computerized System Risk Assessment v8.0.

**Assumption**: Validation and Production environments are equivalent with respect to basic functionality.

## Out of Scope

1. n/a

# **Test Strategy**

## Test Outline

Testing shall be conducted using the electronic test management tool ALM VERA under the Domain: POIT and Project: CMMS. All test executions and any defects will be maintained in ALM VERA, per PRCD-XXXXX, IT Test Incident Reporting (TIR) v11.0.

Testers will use approved test scripts, governed by test instructions, and supported by customized data sets, to interact with the system and to record results.

1. IQ script will be executed in ALM for the Validation environment
2. Operational testing will be conducted in the Validation environment of the application.
3. User Acceptance testing will be conducted in the Validation environment of the application.
4. Production activities will be scheduled with the Change Request upon approval of all validation deliverables.

## Vendor Testing

N/A – vendor testing is not in scope

## Integration Testing

N/A – integration testing is not in scope

## Regression Testing

N/A - Operational Testing will confirm and verify system functionality. Separate regression testing is not required as the functional testing captures the full business process and the full scope of the configuration objects affected by IQ.

## Backup and Restore

N/A – Backup and restore testing is not in scope

## Data Migration Testing

N/A – Data Migration and testing is not in scope

## Environments

### Development (non-controlled):

Used for prototyping. Hardware and software in this environment are not maintained in a controlled state.

### Validation (controlled):

A Pre-Production environment used for formal testing. The hardware and software in this environment are maintained in a controlled state. Formal deployment of Operational Qualification testing for this change will occur in this environment.

### Production (controlled):

The Production environment is for operational use. The hardware and software in this environment are maintained in a controlled state.

# Testing

## Installation Qualification

### Purpose and Scope

IQ will be performed to add the required functional updates. IQ activities will be performed in the Validation environment and, following completion of successful testing, Production environment.

See section 15 for test script details.

**Domain**: POIT

**Project**: CMMS

### Dependencies

* Change Request (CR) for Test environment is approved in ServiceNow.
* Trace Matrix is updated with the appropriate Test IDs
* Combined Test & Val Plan is approved in myCIMS
* IQ Script is pre-approved in ALM.
* Environment is ready to perform the Installation Qualification.
* ALM VERA is up and running.

### Acceptance Criteria

* Executed IQ Test script must be approved in ALM.
* Defects (if any) are approved in ALM.

## *Operational Testing*

Operational Testing (OQ) will be performed in accordance with risk class of User Requirements relevant to this change as per ITPD-XXXXX (CMMS Risk Assessment).

OQ testing is conducted on a complete, integrated, system to evaluate the conformance of system functionality with the User Requirements Specification, Functional Specification, and Design Specifications.

Functional testing (**positive** testing only) will be performed to validate the following **Medium** **and low** risk functional requirements:

1. Prevent New Users from Taking Active License. New users are assigned 'Requestor' by default and must submit a separate request to gain active status. Ensures user access control and compliance with role-based security policies.:
   * BR 9.2 (FR 6.8.3) (Low)
2. Calibration Standards Tab Update. Enhancing the Calibration Standards tab by displaying Lot locations for calibration records in the Standards Used section of Work Orders, ensuring compliance with calibration data storage requirements, including instrument categories, calibration limits, and standard tracking.
   * BR 4.3 (FR 6.4.10) (Low)
3. View All Equip Update Requests Screen Updates. Adjusting visibility settings in the Equipment Update Requests module by restricting access to the QA Review field, enforcing data access controls per system permissions.
   * BR 3.1 (FR 6.3.1) (Low)
4. Audit Trail Report:
   * BR 4.50 (FR 6.4.65) (Low)
5. Work Order Report Location Update:
   * BR 7.2 (FR 6.1.7) (Low)
   * New DS
6. Forgot Password Button:
   * BR 10.1 (FR 6.1.9) (Low)
   * New DS

Functional testing (**positive and negative, where applicable)** will be performed to validate the following **High** risk functional requirements:

1. Audit Trail Spelling Fixes:
   * UR-REG-36 (FS-REG-36) (High)
2. See Last Login of User:
   * BR 8.1 (FR 6.7.9) (High)
   * New FR
   * New DS
3. ECDB Menu Modifications:
   * BR 8.1 (FR 6.7.2) (High)

See section 16 for IQ and OQ test script details.

### Purpose and Scope

Operational Testing provides documented assurance that the system performs as intended and without issue.

* Verification of correct installation will be performed for all changes involved.
* Functional Testing in the positive case will occur around the Medium and Low Risk User Requirement Specification impacted by this update.
* Functional Testing in both the positive and negative case will occur around the High Risk User Requirement Specification impacted by this update.

### Dependencies

* Executed IQ Scripts approved, and defects (if any) are closed. (i.e. fixed, deferred, or rejected) as defined in PRCD-XXXXX, IT Test Incident Reporting (TIR) v11.0.
* Test Data setup: The Validation and Production environments are identical in terms of application functionality and configurations.

### Acceptance Criteria

* Executed OQ must be approved in ALM
* Defects (if any) are approved in ALM

## *User Acceptance Testing*

User Acceptance Testing will be performed in accordance with the high-level User Requirements relevant to this change. For detailed test information see Appendix C.6.3.1

### Purpose and Scope

The UAT provides documented assurance that the system performs as intended and without issue from an end-user business perspective

### Dependencies

* UAT testing can commence in the Validation environment once the OQ has been completed successfully, all executed OQ Test Scripts are approved, and OQ defects are resolved.
* UAT test scripts are pre-approved in ALM 15.
* UAT test scripts can complete execution in any sequence.

### Acceptance Criteria

* Executed UAT must be approved in ALM
* Defects (if any) are approved in ALM

# Test Data

All required test data (i.e. documents of a particular type for validation of document workflows) are outlined in prerequisites on respective test scripts referenced in Section 11, *Appendices A, B, & C* of this document, and will be readily available in the Validation environment or are able to be generated by the tester.

# Defect Management

Defects identified during testing activities shall be reported and managed in ALM VERA in accordance with PRCD-XXXXX, IT Test Incident Reporting (TIR) v11.0.

# Deliverables

The following deliverables are for the project as specified in PRCD-XXXXX, Validating IT Computerized Systems v13.0. For specific requirements for each deliverable, including approvers refer to PRCD-XXXXX.

Ensure that all deliverables listed in the table below are addressed including rationale for any exclusion in the notes section below. If no comments are required, please enter “N/A”.

| **Activities** | **Applicable?**  (*check ü if Yes*) |
| --- | --- |
| **NOTES: n/a** | |
| **Activities (New or Updated)** | **Applicable** |
| System Assessment (SA) | ☐ |
| Vendor Audit/Assessment | ☐ |
| Data Process Map | ☐ |
| User Requirements Specification (URS) | ☐ |
| Architecture Document (AD) | ☐ |
| Functional Specification | ☑ |
| Design Specification | ☑ |
| Risk Assessment (ALM) | ☐ |
| Combined Validation & Test Plan (this document) | ☑ |
| Test Scripts | ☑ |
| Installation Qualification – Pre-Production (VAL) | ☑ |
| Operation Qualification – Pre-Production (VAL) | ☑ |
| User Acceptance Test | ☑ |
| Traceability Matrix | ☑ |
| Test/Validation Plan Report | ☑ |
| Installation Qualification - Production | ☑ |
| Application Management SOP updates | ☐ |
| **Considerations** | **Applicable** |
| Service Level Agreement(s) | ☐ |
| Knowledge Base Article(s) | ☐ |
| Maintenance Manual(s) | ☐ |
| Quality Agreement(s) | ☐ |

# Acceptance criteria

Upon completion of the following, the system will be deemed validated and therefore released for production use:

* Completion/approval of all deliverables listed in the previous section of this document.
* Approval of the project Change Request (CR).

# References

| **Document ID**  **Include the Version** | **Title** |
| --- | --- |
| GLBL-XXXXX | Computerized Systems |
| PRCD-XXXXX | Validating Computerized Systems |
| PRCD-XXXXX | Using ALM with VERA for Lifecycle Management of IT Computerized Systems |
| PRCD-XXXXX | IT Test Incident Reporting (TIR) |
| PRCD-XXXXX | Managing Changes to IT Systems |
| PRCD-XXXXX | Planning and Executing of GxP Software Vendor Audit Program |
| PRCD-XXXXX | Performing System Assessments |
| PRCD-XXXXX | Computerized System Risk Assessment |
| PRCD-XXXXX | Managing Testing of Computerized Systems |
| PRCD-XXXXX | Developing a System Administration / Management Procedure for IT Computerized Systems |
| PRCD-XXXXX | Implementing Elements to IT Computerized Systems |
| ITPD-XXXXX | CMMS User Requirements Specifications |
| ITPD-XXXXX | CMMS Design Specification |
| ITPD-XXXXX | CMMS Functional Specification |
| ITPD-XXXXX | CMMS Traceability Matrix |

# Appendix A: IQ Test Scripts

## Installation Qualification (IQ)

**Domain:** POIT

**Project:** CMMS

**IQ Path:** Subject\2024 CRs\CHGXXXXX - Bug Enhancements\IQ

|  |  |
| --- | --- |
| **Test ID** | **IQ TEST SCRIPTS** |
| 260 | CHGXXXXX - Bug Enhancements IQ - Audit Trail Report |
| 262 | CHGXXXXX - Bug Enhancements IQ - Audit Trail Spelling |
| 264 | CHGXXXXX - Bug Enhancements IQ - Calibration Standards Tab |
| 265 | CHGXXXXX - Bug Enhancements IQ - Disable Active License for New Users |
| 268 | CHGXXXXX - Bug Enhancements IQ - ECDB Menu User Access |
| 267 | CHGXXXXX - Bug Enhancements IQ - Equipment Update Request Screen Update |
| 266 | CHGXXXXX - Bug Enhancements IQ - Last Login of User |
| 263 | CHGXXXXX - Bug Enhancements IQ - Workorder Report |
| 269 | CHGXXXXX - Bug Enhancements IQ - Forgot Password Button |

# Appendix B: OQ Test Scripts

## Operational Qualification (OQ)

**Domain:** POIT

**Project:** CMMS

**OQ Path:** Subject\2024 CRs\CHGXXXXX - Bug Enhancements\OQ

|  |  |
| --- | --- |
| **Test ID** | **OQ TEST SCRIPTS** |
| 261 | CHGXXXXX - Bug Enhancements OQ |

# Appendix C: UAT Test Scripts

## User Acceptance Testing (UAT)

**Domain:** POIT

**Project:** CMMS

**OQ Path:** Subject\2024 CRs\CHGXXXXX - Bug Enhancements\UAT

|  |  |
| --- | --- |
| **Test ID** | **OQ TEST SCRIPTS** |
| 275 | CHGXXXXX - Bug Enhancements UAT |