Approval Cover Page

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Approval

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Rational CLM Operation and Maintenance

Approval Summary Table

Role	Approval Meaning	Approvers
Document Control	Agrees to the quality and readability of the content described and approves for distribution.	Hulda Hime Watson Health Compliance & Regulatory Document Control Signed electronically in QDMS as per Doc Control using QDMS for WH WI
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Contents

1 Purpose

This Standard Operating Procedure (SOP) defines the activities associated with the operation, maintenance and administration of Rational Collaborative Lifecycle Management (CLM), specifically focusing on the rollout of Rational Quality Manager (RQM). RQM is used to support test management. It stores test cases, records test execution and results, maps testing with requirements, and tracks defects in line with the Watson Health Quality Management system (WH QMS).

This SOP provides a description of how to manage RQM during routine use. This SOP outlines the daily administration tasks required to ensure the validated state of the system is maintained.

2 Background

Rational Collaborative Lifecycle Management is an application lifecycle management solution that includes IBM Rational Team Concert (RTC), Rational DOORS Next Generation (RDNG) and Rational Quality Manager (RQM) products. CLM is used by the WH team for requirement lifecycle management. This tool is also used in the verification and validation of WH offerings.

The inclusion and integrations of these products in one solution delivers requirements management, quality management, change and configuration management, and project planning and tracking capabilities on a single platform. This SOP focuses on the RQM component of Rational CLM.

WH QMS CLM deployment is hosted in the SoftLayer Green Zone. There is a DOU between WH and Watson IOT for this service. Watson IOT leverages a business partner called ClearObject to provide middleware support. ClearObject is a trusted vendor of Watson IOT that supports other regulated environments; they have significant expertise in supporting large enterprise Rational customers. The products that reside in the provided cloud solution includes:

- Rational CLM on Cloud/Practitioner
- Test Environment
- Development Environment

Both the production and test (Qualification) Environment will be qualified environments. The development environment is an uncontrolled environment for developers and it is outside the scope of this SOP. To learn about the CLM system architecture, see Figure 1. To learn about the deployment architecture, see Figure 2.

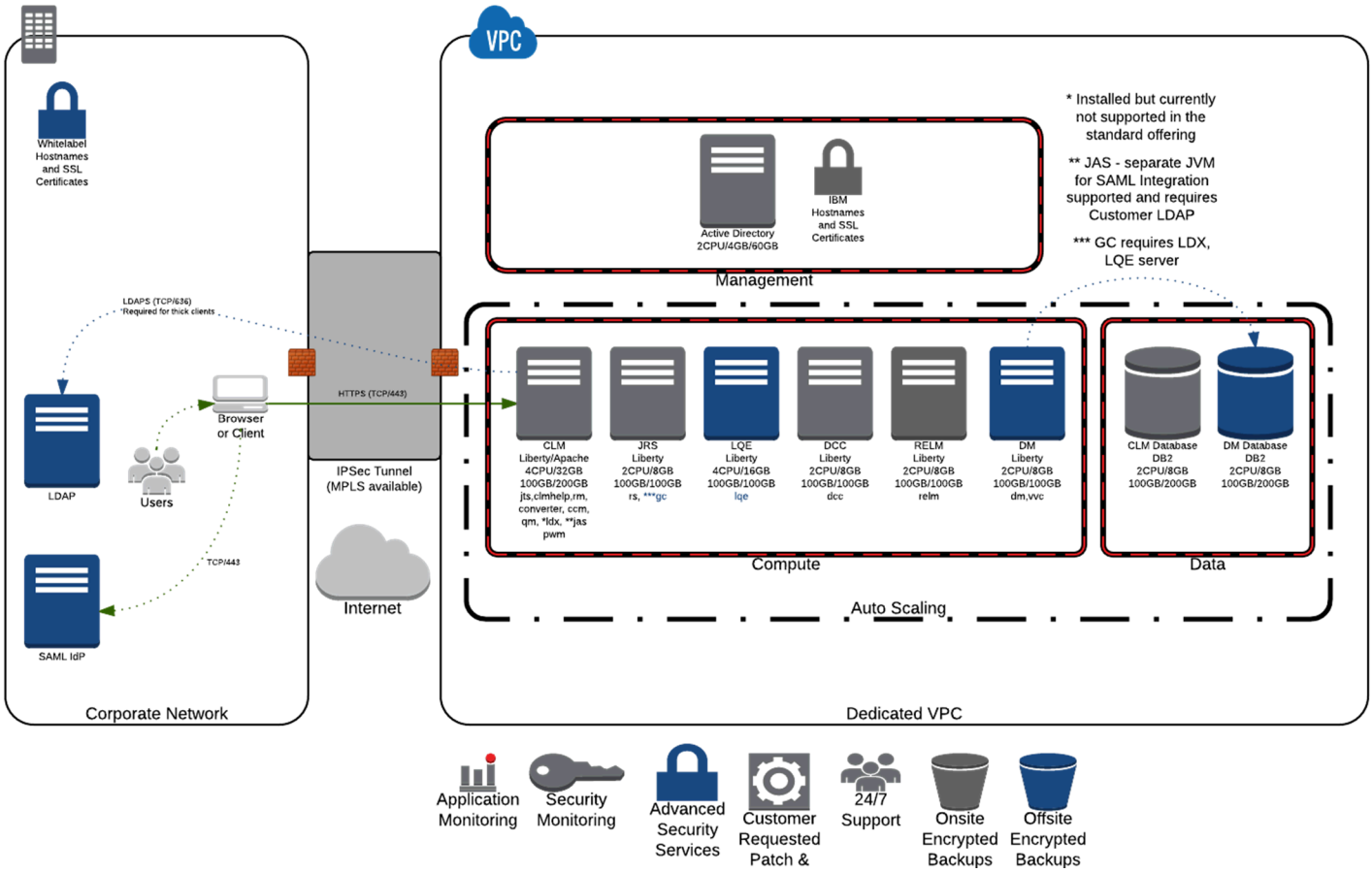

Figure 1. CLM system architecture diagram

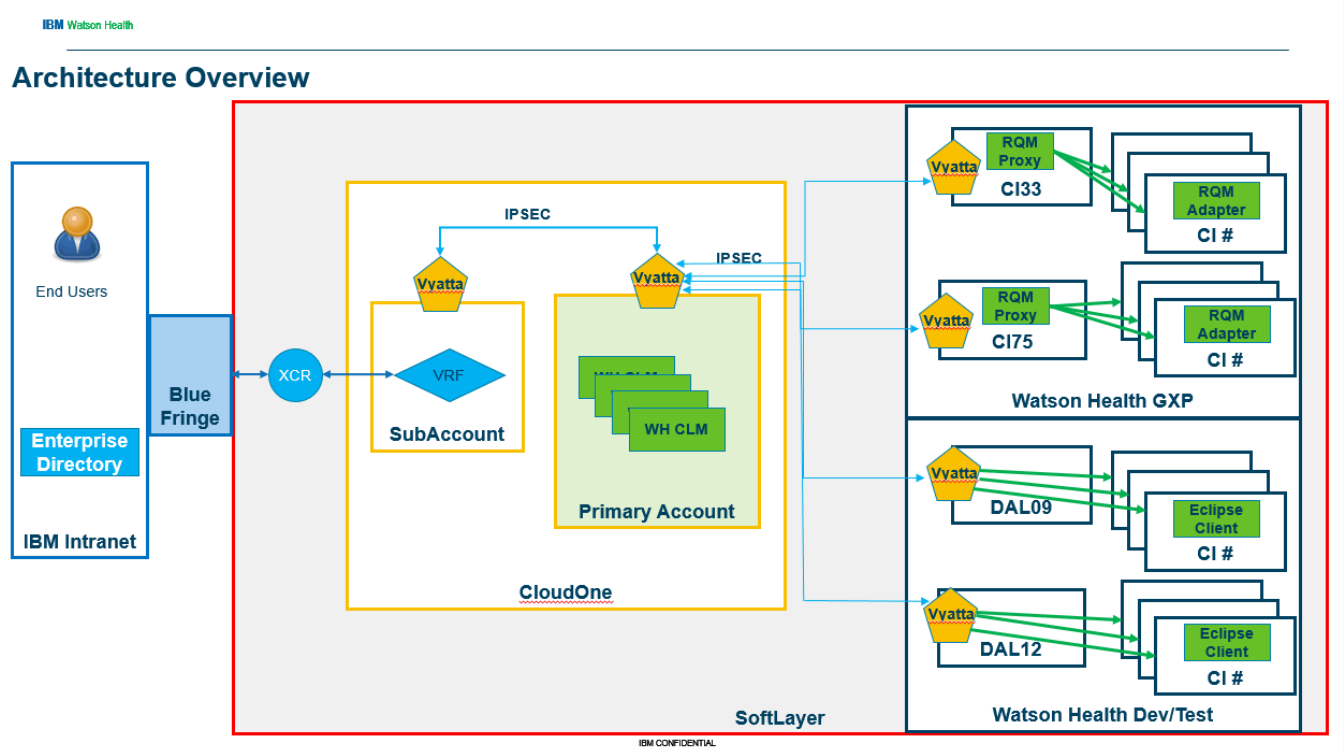

Figure 2. Deployment architecture diagram

3 Scope

This procedure is applicable to the RQM component of the overall Rational CLM system.

From a user perspective, the scope of this SOP applies to the End User, the System Owner and the Rational Administration team.

4 Definitions, Abbreviations, Acronyms

Terms listed here are found within the content of this document.

Term	Definition	Abbrev./ Acronym
Artifacts	General term for a specific element that is part of the project. An artifact can be a specific requirement, or it can be supplemental information, such as a heading, a picture, a use case diagram. In the context of RQM, the central artifacts are test plans and test cases.	N/A
Change Management	The process of identifying, assessing, communicating, approving, documenting, and implementing changes with the appropriate level of control throughout the System Life Cycle.	N/A
Computer System Validation	The process of establishing documented evidence which provides a high degree of assurance that a computer system will consistently perform per its intended use.	CSV
Configuration Management	The process of identifying and defining the configuration items in a system, controlling the release and change of these items throughout the system lifecycle, recording and reporting the status of configuration items and change requests, and verifying the completeness and correctness of configuration items.	N/A
Defect	A condition in a software product which does not meet a requirement or end user expectations.	N/A

Term	Definition	Abbrev./ Acronym
Federal Drug Administration	The Food and Drug Administration is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices.	FDA
Good x (Clinical, Manufacturing, Laboratory) Practices	Good “anything” Practices per Watson Health QMS specific to food, drug, biologics or devices	GxP Also (GCP, GMP, GLP)
Incident Management	An incident is any unplanned occurrence which prevents (or may prevent) or delays users, the system, an operation, or a service from proceeding with an assigned task.	N/A
Lifecycle	The span of time that a system is in existence, beginning at the time of early concept definition to when it is ultimately retired from use/support.	N/A
Periodic Review	A documented assessment of the documentation, procedures, records, and performance of a computer system to determine whether it is still in a validated state and what actions, if any, are necessary to maintain its validated state.	N/A
Quality Management System	A collection of processes focused on achieving quality policy and quality objectives to meet Client and regulatory requirements (includes organizational structure, policies, procedures, and resources).	QMS

Term	Definition	Abbrev./ Acronym
Rational Collaborative Lifecycle Management	Rational Collaborative Lifecycle Management combines IBM Rational Team Concert, IBM Rational DOORS Next Generation and IBM Rational Quality Manager. It delivers requirements management, quality management, change and configuration management and project planning and tracking. These integrated capabilities foster greater communication, collaboration and visibility to accelerate delivery, improve quality and support better development decisions.	CLM
Rational Quality Manager	An IBM Rational test management tool. It stores test plan, test cases, test scripts, test execution records and results which maps testing into requirements and tracks defects.	RQM
Standard Operating Procedure	Established or prescribed methods to be followed for the performance of designated operations or in designated situations.	SOP
System Requirement	When a system is removed from production use, no longer sold, updated, or supported.	N/A
Test Environment	A test artifact used to set up of software and hardware in which the testing team will perform the testing of the software product.	N/A
Watson Health	IBM Healthcare unit.	WH

5 Roles/Responsibilities

Roles and their associated responsibilities listed below are involved in the execution of this procedure or process.

Role	Responsibility
Rational System Owner	• Verifies and documents the justification for creating or altering a Rational user account. • Verifies the end user has appropriate training for the associated role within the system. • Provides oversight on system operation and maintenance. • Endorses system changes. • Raises system defects as per QMS requirements. • Ensures periodic system reviews are completed.
Administrator	• Verifies and documents the justification for creating or altering a Rational user account. • Verifies that end users have the appropriate role-based training for the system. • Manages user account privileges and access levels. • Manages the process for granting, amending and revoking access. • Implements system changes as requested. • Ensures that the correct process for making changes is followed. • Ensures system incidents are reported and documented as per the requirements of this SOP. • Raises system defects as per QMS requirements. • Ensures the Rational CLM backup and restore processes are applied correctly. • Ensures that the Rational CLM backup and restore processes meets the system availability requirements of the business. • Provides comprehensive system monitoring and performance with service provider.

Role	Responsibility
Platform Support Team (SoftLayer)	• Performs the backup and restore process. • Reports all backup and restore process issues. • Resolves all backup and restore issues.
End User	• Requests the creation, modification, or deactivation of an account. • Follows the content of relevant user instructions. • Ensures all training is complete prior to applying of system access.
Quality Assurance	• Reviews and approves this SOP. • Ensures the content of this SOP is followed. • Approves system changes which impacts GxP. • Approves non-conformance which impacts GxP.

6 Procedure / Requirements

6.1 User access and administration

Rational Collaborative Lifecycle Management (CLM) contains two types of permissions:

- repository group permissions, and
- role-based permissions.

Within a project area, you assign role-based permissions for performing operations to individual roles. When you add a user as a member of a project area or team area, you assign one or more roles to the user.

Access to repositories and role based permissions shall be granted after the end user has:

- completed training commensurate with their job function or role within CLM, and
- documented verification of their completion of the training.

The Rational System Owner, Rational System Administrator or designee will ensure that initial account setup and the associated password for the account are consistent with the appropriate IBM security policy and standards.

The RQM Account and Project Area Administration Work Instruction WH_QMS_SOP_0042 provides for further information on Security and Administration for RQM. This work instruction outlines the process for completing system training as well as requesting and granting access to RQM repositories and project areas.

6.2 Training requirements

The End User must be trained commensurate with their job function or role within RQM and have documented verification of their completion of the training. Training requirements for role based access are outlined in the RQM Account and Project Area Administration Work Instruction WH_QMS_SOP_0042.

6.3 Change and configuration management

Change and configuration management applies to the Rational CLM tools once validation testing has commenced. Change and configuration management will continue to be applicable during routine operation of the system and up to the point of system retirement. This will ensure that the validated state of the CLM tools is maintained throughout the validation lifecycle.

Change management as per Change Management SOP WH_QMS_SOP_0004 will be applied to elements of the system which have been deemed critical to the Watson Health QMS or have the potential to impact the validated state of the system. Those changes cover the following types:

6.3.1 Infrastructure changes

Any changes to the production or test environment must be assessed by the Rational System Owner and Administrator to ensure there is no impact to GxP. Changes include, but are not limited to the following types of changes:

- VM setting controls
- Operating system versions and applications
- Patching
- Data flows
- Disaster recovery
- Backup
- Service level agreement support
- Any changes which are deemed to impact GxP must be raised as per WH_QMS_SOP_0004.

6.3.2 Application changes

Any changes to the application such as system upgrades, patches, and so on must be assessed as per Change Management SOP WH_QMS_SOP_0004.

6.3.3 Configuration management for RQM

In RQM, the system configuration is made up of many system processes. These processes are the collections of roles, practices, rules, and guidelines that are used to organize and control the flow of work. User roles and permissions have been customized for performing operations within the tool. Some examples of customization that have been created defines how to change the state of a work item, describes the rules of process behavior through preconditions and follow-up actions for various operations.

6.3.3.1 Validated GxP configuration

Any system configuration changes which impact the baseline specification document, RQM System Design/Configuration Specification (SDS), WH_QMS_RQM_SDCS _1.0, 1.1, 1.2, 1.3, 1.4 and 1.5 must follow formal change management as defined in Change Management WH_QMS_SOP_0004). Following this SOP ensures any changes do not impact the validated state of the system and ensure the configuration change has been documented in the correct manner.

Within the WH QMS RQM Process Template, there are three main areas that should never be modified or deleted: Project Area Configuration, Project Area Properties, and Project Area Artifact Templates. Where changes to the above configurations are required a change request as per the requirements of WH_SOP_QMS_SOP_0004 must be raised. Rational Quality Manager: Refer to Project Area and Configuration Management Work Instruction. WH_QMS_SOP_0036 for further details.

It is the responsibility of the Rational System Owner (or designee) to ensure that any changes to baseline configuration follow WH_QMS_SOP_0004.

6.3.3.2 Project-specific configuration changes

In RQM, administering and customizing quality management project areas may be required for specific end user needs outside the scope of the defined configuration as outlined in the RQM System Design/Configuration Specification (SDS), WH_QMS_RQM_SDCS _1.0, 1.1, 1.2, 1.3, 1.4 and 1.5. Additions to project specific configuration is acceptable on the basis that it does not impact or change the validated state of the defined baseline configuration.

Project specific configuration additions and changes must be documented by the end user requesting the change and assessed by the Rational Project Administrator (or designee) to ensure there is oversight on any project area changes. This oversight will ensure that any potential impact to the WH processes or validated state of RQM has been properly assessed and have the correct level of regulatory supervision.

The process for documenting, assessing and implementing additions to project areas, changes to project area templates (outside scope of the RQM configuration specification WH_QMS_RQM_SDCS _1.0, 1.1, 1.2, 1.3, 1.4 and 1.5) is defined in the following RQM Work Instruction: Project Area and Configuration Management, WH_QMS_SOP_0036. This work instruction must be followed for making project specific additions to project area templates.

The System Owner is responsible for oversight of all changes made to the CLM system. All changes must be evaluated to ensure the changes does not impact the validated state of the system.

Personnel competent to review the change request (for example, personnel in the System Administrator and System Owner roles) should assess the change request to establish the nature and scope of the change. The System Administrator and System Owner roles are also responsible for determining if the change should proceed; they also determine the urgency or priority of the change request.

Where appropriate, the technical impact of the change should be assessed to inform any subsequent change review and approval process. It is the responsibility of the System Administrator and trained users with the appropriate level of system access to execute changes within the system.

6.4 Data backup and restore

Backup is the operational process of copying records, data, and software to protect against loss of integrity or availability of the original. Restore is the subsequent restoration of records, data, or software to their original configuration when required.

The backup and restore of the following items related to the Rational CLM system are routinely backed up and restoration must be periodically checked. In RQM, data collected as during routine use is deemed regulated data as per the requirements of 21 CFR Part 11.

The RQM repository includes auditable item types; each item type maintains a history of creation and subsequent modifications for audit purposes. The audit trail includes a record of past states of the item, the user who saved the item, and the time of the change. For item types that do not require audit history, the repository retains only the latest state of the item.

6.4.1 Backup, snapshot, and restore

Incremental backups of the environment are performed nightly; complete backups are performed weekly. Each environment includes a minimum of 5 recovery points with 1 recovery point daily as outlined in the Watson Health QMS CLM Document of Understanding (DOU).

All changes to the Backup Configuration must be documented in compliance with the WH/ IBM IOT DOU and are executed under Change Management WH_QMS_SOP_0004.

6.4.2 Verification of the ability to restore backups

The Rational CLM System Administrator ensures that at least once a year, all data as defined above can be restored from the backups.

For Rational CLM Application components (for example, challenging server backups), such a restore should happen once a year.

If no restore request was initiated during routine operation by a Rational CLM User, the System Administrator must formally initiate a restore request and verify that the restore works correctly.

6.4.3 Requesting a restore

Any active user is entitled to request a restore.

The restore request of document metadata or documents must be approved by the System Owner or System Administrator.

The restore request of Rational CLM application components must be approved by the System Owner or designee.

Any unplanned restore which is as a result of deviating performance of the backup and restore tasks will by managed in accordance to Process Deviation Management WH_QMS_SOP_0014.

6.5 Business continuity and disaster recovery

Business continuity and disaster recovery encompasses the steps required to restore critical business processes following a disruption, while continuing to provide product or services to the process owner.

A disaster is an unplanned event that has the potential to impact process and data integrity or restrict access to or performance of the system for a prolonged duration.

As defined in the DOU between Watson IOT and Watson Health, designated users are supported for the IBM Rational Virtual Private Cloud Environment including the following areas:

- Workstation access and performance
- External network
- Server software
- Service management (patches, uptime, outage scheduling, upgrades)
- Operations (backup and disaster recovery)
- Scalable hardware assets
- Secured facilities

Support is available 24 hours a day, 5 days a week globally for non-severity 1 issues and 24 hours a day, 7 days a week globally for severity 1 issues.

The target application availability level is 99.9% in any calendar year period calculated on an annual basis. The applications availability level is defined as the number of hours during a particular period that the applications were available, excluding planned downtime events.

In the event of a disaster, a process deviation as per Process Deviation Management SOP WH_QMS_SOP_0014 should be raised to assess the impact to the GxP status of the system, its validated state and impact to any GxP data.

6.6 Periodic review

Periodic reviews are performed to verify that a computer system:

- remains in a validated state
- remains compliant with regulatory requirements

- aligns with intended use
- satisfies applicable IBM policies and procedures.

The frequency, depth, rigor and level of documentation of the review process should be based on the system impact on patient safety, system complexity, controls in place on the system, accumulated changes for the system and the nature of the event that triggered the review (if applicable).

The periodic review process includes a Periodic Review Report, which summaries the review results. Any corrective actions that cannot be implemented prior to the approval of the report should be tracked.

Periodic review frequencies will be determined as per the requirements of GxP Computer System Validation SOP WH_QMS_SOP_0011. Similarly the process for execution and documenting the periodic review for the Rational CLM system will follow the requirements of the WH QMS.

6.7 Computer system operation

All the operational tasks for hosting and running WH QMS CLM deployment is hosted in the SoftLayer Green Zone. There is a DOU between WH and Watson IOT for this service.

A DOU has been established between the system owner and Watson IOT/Softlayer to ensure the support needs are identified and to maintain the system in a state of compliance. The DOU describes the IT service, documents service level targets and specifies the responsibilities of the IT service provider and System Owner.

This DOU provides IBM Watson Health cloud managed services solutions in a managed virtual private cloud instance. This instance currently entails the CLM SAAS offering provided by IBM Watson IOT.

The configured VPC (Virtual Private Cloud) environment built to support Rational QMS CLM complies with the following Information Security (ISEC) requirements:

- Access is supported in the IBM Green Zone.
- Environment must meet IBM SaaS Security Requirements.
- Environment must meet ITCS security standards.

6.8 Incident management

An incident is any unplanned occurrence which prevents (or may prevent) or delays users, the system, an operation, or a service from proceeding with an assigned task.

The process aims to categorize incidents to direct them to the most appropriate resource or complementary process to achieve a timely resolution. In some cases, where there it has been deemed there is potential for GxP impact or impact to the validated state of the system, incidents will need to be escalated to formal investigation and CAPA where applicable. Therefore, a relationship between the incident management deviation process and CAPA processes exist. Process deviations and CAPAs which impact either GxP data the validated state of a system are initiated as per Process Deviation Management SOP WH_QMS_SOP_0014 and Corrective and Preventive Action (CAPA) SOP WH_QMS_SOP_0008 respectively.

7 Records Management

The document of record is stored by the Document Controller or designee in a secure, controlled document repository. Documents will be retained per the Records Management SOP WH_QMS_SOP_0013.

8 References

8.1 Prerequisites

8.1.1 Quality Manual WH_QMS_QM_0001

8.2 Dependencies

8.2.1 Document Log Form WH_QMS_FRM_0002

8.2.2 GxP Computer System Validation WH_QMS_SOP_0011

8.2.3 Records Management WH_QMS_SOP_0013

8.2.4 Document Log Form WH_QMS_FRM_0002

8.2.5 Change Management WH_QMS_SOP_0004

8.2.6 Corrective and Preventative Action WH_QMS_SOP_0008

8.2.7 GxP Computer System Validation WH_QMS_SOP_0011

8.2.8 RQM Account and Project Area Administration Work Instruction WH_QMS_SOP_0042

8.2.9 Project Area and Configuration Management, WH_QMS_SOP_0036

8.2.10 Process Deviation Management WH_QMS_SOP_0014

8.2.11 WH_QMS_RQM_SDCS _1.0 – RQM System Design Configuration Specification

8.2.12 WH_QMS_RQM_SDCS _1.1, WH RQM Template configuration

8.2.13 WH_QMS_RQM_SDCS _1.2, WH RQM Template permissions

8.2.14 WH_QMS_RQM_SDCS _1.3, Project properties

8.2.15 WH_QMS_RQM_SDCS _1.4 RQM Project Configuration and Setup

8.2.16 WH_QMS_RQM_SDCS _1.5 – WH RQM Template Work Items

8.2.17 2017 Document of understanding IBM Watson IOT & IBM Watson Health-Watson Health QMS CLM Version 06-FEB-2017

8.3 Regulations / Guidance / Standards

Refer to WH_QMS_SOP_0001 for regulations, guidance and standards related to this SOP.

9 Version History

Version	Change	Revised By	Date (dd-MMM-yyyy)
1.0	Original	Chad Beery	QDMS Approval Date
2.0	Updated the document header by removing the governing SOP per CR CR-PROC-2017-101. Updated the document title to Rational CLM Operation and Maintenance.	Chad Beery	QDMS Approval Date