

$\epsilon \in \Gamma$ \wp $X^{\wedge} : \dot{q}$ $F A^{\wedge} \vee \wp$ $A^{\circ} B O \sim \& \tilde{a}^{\wedge} A$ $A G E D$ $E E G$

Template-04680 Major: Release Notes v1

Department: R&D

Process: Design Control

Effective Date: 2025-02-28

Doc no.: 07080

Version: 1

Author(s): Jacob Sjørøsløv

Reviewer(s): Jakov Božić; Crystal Jade
Valdez; Kim PanisalesApprover(s): Jacob Sjørøsløv; Kim
Panisales

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1. Introduction

1.1. Purpose of the Document

This document describes the differences between SimplerQMS 3.3 and SimplerQMS 3.4. It serves as a comprehensive reference to help users understand the changes and improvements introduced in the latest software update.

1.2. Objectives for SimplerQMS 3.4 based on customer feedback

SimplerQMS 3.4 is largely shaped by the invaluable feedback from our users. We have listened to and acted upon your input to make meaningful changes. Reference numbers (SQ numbers) are included to ensure transparency and keep you informed about how your feedback has directly influenced the enhancements and updates in this release.

The changes are divided into major and minor updates of existing functionality coming with SimplerQMS 3.4.

There are no prerequisites in SimplerQMS 3.4 to be met or managed by customers prior to roll-out.

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2. Summary of 3.4 release

2.1. Major New Features

Change Request Effectiveness Assessment

Mandatory effectiveness assessment can now be enabled for all change requests

A new feature for Change Request Effectiveness Assessment has been introduced, and it works very similarly to the CAPA Effectiveness Assessment that you are already familiar with. By default, this feature is disabled, but Metadata Administrators can enable it as needed. When enabled, all new Change Requests will require an Effectiveness Assessment to ensure proper evaluation and tracking. (SQ-511)

Project Permissions – Visibility Setting

New optional project documentation permission settings

A new Project Visibility metadata has been added on Projects, allowing projects to be set as Public or Private by the Metadata Administrator, Responsible Person, or their Delegate. Public Project documentation uses Site Permissions while Private Projects use Project Permissions. Changing visibility updates the document permissions accordingly.

Changes to document permissions are tracked in the Admin Log under the System Info section. Please note that depending on the amount of documentation on the project, permission changes may take more time. (SQ-334)

2.2. Major Improvements

Simplified Project Permission Management

Private project permissions moves from Person Object to Project Object

Private project permissions are now managed directly at the project level instead of through individual Person metadata cards. This allows Metadata Administrators and Human Resources user groups to control access. Users can also multi-select projects and assign permissions in bulk. Existing project permissions will remain unchanged. (SQ-644)

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2.3. Bug Corrections

- SQ-878:** Incorrect permissions when releasing a document in native format
Fix: Fixed an issue where some documents were assigned incorrect permissions when using the "Release in Native Format" functionality.
- SQ-879:** Empty Revision History Page on Change Requests
Fix: Fixed an issue where some change requests had an empty Revision History page on the released copy.
- SQ-891:** Retired templates creating new learning records
Fix: Fixed an issue where some retired templates triggered the creation of new learning records.
- SQ-898:** Approval and Review Groups not visible in the Approver(s)/Reviewer(s) Metadata
Fix: Fixed an issue where some Approval and Review Groups were not visible when attempting to assign them as Approver(s) or Reviewer(s).
- SQ-925:** Approval Dates Recalculated for CAPA Effectiveness Assessments
Fix: An earlier update for CAPA effectiveness records have updated the approval date of selected CAPA effectiveness records which is a mistake. Data integrity has not been impacted as the date of the approval signature is unchanged, which is also visible on the record itself. But an approval date property on the effectiveness assessment itself that is different than the signature date is confusing, which is why this is being corrected. This fix will re-enter the correct and original approval date.

2.4. Updated learning materials based on 3.4

The following work instructions have been changed due to the new version 3.4 and can be found via the shared customer folder link: [Work Instructions](#)

- WI-00034 Managing Masterdata
- WI-00035 Managing Change Request
- WI-07120 Assessing Effectiveness of Change Request
- WI-00341 Managing Project and Label
- WI-02349 User Roles and Permissions

SimplerQMS		Release Notes Major-07080 3.4 v1 [Effective]		
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- WI-01815 Workflows in SimplerQMS

There are also video recordings created to support the implementation of SimplerQMS 3.4 which can be found in the SimplerQMS knowledge base:

<https://simplerqms.com/knowledge-base/>

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3. Feature Deep Dive

3.1. Change Request Effectiveness Assessment

Assessments of the effectiveness of change requests have so far been a manual process where an action is created and remind the users of doing an effectiveness assessment before a certain deadline and capturing that it was done. New settings now allow you to make your own choice and either keep the current process or make effectiveness assessments of all new change request mandatory. The change request effectiveness assessment has some similarities with the CAPA effectiveness assessment workflow but also allows for a better scheduling function compared with the CAPA function.

Class *	SimplerQMS Setting
General Information	
Short Title *	SimplerQMS Setting - Change Request
Requires Effectiveness Assessment	Yes
CR Effectiveness	
Requires Effectiveness Assessment	Yes
Current Effectiveness Assessment	---
Effectiveness Assessment Result	---
Assessment Activation Date	---
Assessment Due Date	---

Class *	Assess Effectiveness
Periodic Task Info	
Version to Review *	CR-00284 Training 2025-01-20 v1 [Effective] 🔗
Controlled Working Copy	CR-00284 Training 2025-01-20 v1 🔗
Responsible Person(s)	Test3 🔗
Justification of Decision	---
Review Information	
Reviewer(s)	---
Your Review Conclusion	---
All Review Conclusions	---
Latest Review Close Date	---
Reviewer(s) - Remaining	---
Reviewer(s) - Completed	---
Group Member(s) Review	---
Processing Info	
Activation Date	2025-01-20
Date Approved	---
System Information	
🔒 View Only for All	🔄 CR Assess Effectiveness 📅 Scheduled

3.1.1. How it works

Metadata Administrator sets the system settings to either keep the current settings or make the assessment mandatory for all new change requests.

Responsible Person or Author defines the Activation Date and the Due date for the Change Request Assessment on the Change Request itself.

After the Change Request is Completed and any Controlled Items are Updated/Retired, an Effectiveness Assessment task is created and assigns to the responsible person when reaching the activation date and must be assessed before the defined due date.

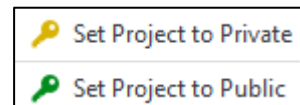
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3.2. Project Permissions

Introducing additional options for managing permissions for project documentation where project documentation can be released to give access to all site members.

3.2.1. Use case 1: Default access to project documentation for all site members

Projects are created and made public to all site members. All new documents are created giving access to all site members and there is no longer a need to maintain a list of project users that has access.



3.2.2. Use case 2: Maintain private project documentation and change access after to public for all site members

Project are created as private and only project members has access. These settings are maintained while the project is being executed and where access is controlled to a list of specific project members. Later when the project is closed and all documentation is completed, the project setting is changed so that all current and future site members now have access to the documentation.

Class*	
General Information	
Name or title*	Training 2025-01-20
Site(s)*	SimplerQMS A/S
Responsible Person(s)*	Test1
Project Visibility	Private
Parent Project	---
Child Project	---
Description*	Training 2025-01-20

3.2.3. How it works

New Property "Project Visibility" allows users to have permissions as today (private) or public for all site members.

Metadata Administrator, Responsible Person (on the project) and any Responsible Person Delegate can change Project Visibility to Private/Public using state transitions.

When set to Public/Private, all Project Documentation will be assigned the correct permissions (Private = Project Permissions, Public = Site/Department permissions).

The change of Project Visibility is logged on all project documents inside of the Admin Log property in System Info section.

Permission Rule	Project - Before Review
Created Formatted	08-11-2024
Admin Log	. Project Permissions changed to Private Project Permissions changed to Public Project Permissions changed to Private

$$\epsilon \in \Gamma \text{ or } \{\lambda^+ : \tilde{q}\} \cup \{A^+ \wedge \tilde{a} \wedge B \wedge A\} \cup \{A \wedge \tilde{a} \wedge B \wedge A\}$$

Signatures:


Controlled Document
Approved:

I hereby state that I have found no errors in the contents of this controlled quality document. The document is ready for release.

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Electronically Signed in  SimplerOMS

Timestamp


Controlled Document
Approved:

I hereby state that I have found no errors in the contents of this controlled quality document. The document is ready for release.

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