21 CFR Part 11 Assessment

January 2024

Contents

1 INTRODUCTION

The RealTime eDOCS system was designed to meet the 21 CFR Part 11 requirements for storing electronic documents with electronic signatures. User Requirements Specifications (URS) and underlying Functional Requirement Specifications (FRS) for the RealTime eDOCS system are often directly tied to the Part 11 Regulation.

The following assessment ties back RealTime eDOCS URS and FRS to Part 11. As the RealTime eDOCS system continues to develop, all new URS and FRS are evaluated for Part 11 compliance.

2 REQUIREMENTS

Requirement	Reg.	Y/N/NA	Evidence or Rationale
1. Is the system validated per FDA requirements?	11.10a	Yes	The system was evaluated by a 3rd party to check Part 11 requirements.
2. Does the validation documentation demonstrate the accuracy, reliability, and consistency of intended performance? And does the validation documentation demonstrate the ability to discern invalid or altered records?	11.10a	Yes	Validation documentation is stored as PDFs and is signed with Adobe Sign.
3. Have any testing tools used in system development been validated?	11.10a	No	Testing tools are utilized in support of the manual review of test success.
4. Has a vendor assessment been performed for any vendor whose tools or services have been employed in the development process?	11.10a	Yes	Vendor assessments are conducted based on SOP-QM10010 Vendor Management.
5. Can the system generate accurate and complete copies of electronic records suitable for inspection, review, and copying by the FDA?	11.10b	Yes	URS N*: System User Permissions* is tested and ensures Part 11 requirements are met.
6. Does the system protect records to enable their accurate and ready retrieval throughout the required record retention period?	11.10c	Yes	Documents are not able to be deleted from the RealTime eDOCS system once filed.
7. Does the system limit access to only authorized users?	11.10d	Yes	System access is controlled based on SOP-ENG20007 Access Management.
8. Does the system include a secure, computer generated, time stamped audit trail to independently record the date and time of operator entries and actions that create, modify, or delete electronic records?	11.10e	Yes	URS *A: Audit Trail* is tested and ensures Part 11 requirements are met.

Requirement	Reg.	Y/N/NA	Evidence or Rationale
9. Does the audit trail record change in a manner that prevents obscuring previously recorded information?	11.10e	Yes	URS *A: Audit Trail* is tested and ensures Part 11 requirements are met.
10. Does the system capture audit trail time to the second, handle daylight savings time changes, and is there a mechanism for converting that time to the local time of the original user?	11.10e	Yes	URS *A: Audit Trail* is tested and ensures Part 11 requirements are met.
11. Can the system generate audit trail records for FDA review and copying?	11.10e	Yes	URS *A: Audit Trail* is tested and ensures Part 11 requirements are met.
12. Does the system control the sequence of operator events to ensure the validity and accuracy of the electronic records?	11.10f	Yes	URS*: B Electronic Signatures* is tested and ensures Part 11 requirements are met.
13. Does the system control and check that only authorized individuals can use the system, electronically sign a record, access the computer system input, or output device, alter a record, or perform the operation at hand?	11.10g	Yes	System access is controlled based on SOP-ENG20007 Access Management.
14. Does the system limit certain functionality to a restricted set of equipment (e.g., desktops) to ensure the validity of data input or operational instructions?	11.10h	No	The system is available through the current version of browsers on Mobile and Desktop. *URS C: Input Validation* ensures the validity of data input.
15. Does the system lock a user's workstation after an extended period of inactivity?	11.10h	Yes	System access is controlled based on SOP-ENG20007 Access Management
16. Are there policies to ensure that all users of the system have the necessary education, training, and experience to perform their assigned tasks?	11.10i	Yes	SOP-CX30002 Configuration & Platform Roll-Out Training videos and materials are available within the System University.
17. Are there records to document that all persons who develop and maintain the electronic record/electronic signature system have the education, training, and experience to perform their assigned tasks?	11.10i	n/a	It is the responsibility of the customer to follow internal SOPs and/or processes for ensuring necessary education, training and experience is in place for each system user to perform assigned tasks.

Requirement	Reg.	Y/N/NA	Evidence or Rationale
18. Are there written policies that hold individuals accountable and responsible for actions initiated under electronic signatures?	11.10j	n/a	These are the responsibility of the customer.
19. Are there controls in place for distribution and access to system operation and maintenance documentation?	11.10k	Yes	SOP-ENG20004 Change Control.
20. Is system documentation maintained under proper change control procedures that include an audit trail of documentation development and modification?	11.10k	Yes	SOP-QM10001 Controlled Document Management & Identification.
21. If this is an open system, are document encryption and appropriate digital signature standards in place to ensure record authenticity, integrity, and confidentiality?	11.30	n/a	RealTime eDOCS is not an open system.
22. Do all electronic signatures include the name of the signer, date, time of signing, and the meaning of the signature?	11.50a	Yes	URS*: B Electronic Signatures*
23. Is the electronic signature included in human-readable form as part of each signed record whenever it is displayed or printed?	11.50b	Yes	URS*: B Electronic Signatures*
24. Are electronic signatures linked to their respective electronic records in a way that they cannot by ordinary means be removed, copied, or transferred to falsify the signature?	11.70	Yes	The electronic document is stored on the record and is not able to be edited.
25. Are electronic signatures unique to each individual and not reused by or reassigned to anyone else?	11.100a	Yes	Because each electronic signature is unique to a username (and usernames are unique), the signature cannot be reassigned.
26. Is there a process to verify the identity of everyone who is given a means to electronically sign a document in the system?	11.100b	Yes	URS*: B Electronic Signatures*
27. Has the organization certified to the FDA that electronic signatures are being used in the organization and are intended to be the legally binding equivalent of traditional handwritten signatures?	11.100c	No	We do help our customers to submit this request. RealTime eDOCS as an organization is not storing signatures on Clinical Trial information.
28. Do non-biometric signatures employ at least two distinct identification components (such as user id and password)?	11.200a1	Yes	All signatures require a user id and a password.
29. Does the system require entry of both signature components for initial or independent signing and at least the secret component of the signature for subsequent sequential signings in a continuous session?	11.200a1	Yes	URS*: B Electronic Signatures*

Requirement	Reg.	Y/N/NA	Evidence or Rationale
30. Are there clear processes employed to ensure that non-biometric signatures can only be used by their genuine owner?	11.200a2	Yes	The password is required to apply an electronic signature. URS*: B Electronic Signatures*
31. Are there controls that ensure that the attempted use of an individual's electronic signature by anyone other than its genuine owner requires collaboration of two or more individuals?	11.200a3	Yes	We do not allow the use of an individual's electronic signature by anyone other than its genuine owner.
32. Are biometric signatures designed so that they cannot be used by anyone other than their genuine owner?	11.200b	Yes	URS*: B Electronic Signatures.*
33. Is there a process to ensure that no two-user id/password combinations are identical?	11.300a	Yes	SOP-ENG20007 Access Management
34. Does the system require that administrator issued passwords are changed upon first use?	11.300b	Yes	SOMS-F System Access
35. Does the system require that passwords be changed periodically, at least every 120 days?	11.300b	Yes	SOMS-F System Access
36. Is there a process in place which deactivates id and password access when an authorized user is no longer authorized to use the system?	11.300b	Yes	SOP-ENG20007 Access Management
37. Is there a process to rapidly deauthorize access for lost, stolen, missing, or otherwise compromised tokens, cards, or other devices that bear or generate password information?	11.300c	Yes	SOP-QM10004 Employee and Contractor Offboarding.
38. Can the system detect attempts to make unauthorized access using passwords and codes and report in an immediate and urgent manner such attempts to system security?	11.300d	Yes	The system automatically locks out an account after a set number of failed login attempts. All login attempts are logged.
39. Does the system provide a report of failed login attempts?	11.300d	Yes	This information is stored in system logs.
40. Are there processes for periodic testing of devices that bear or generate identification codes to ensure that they are still functioning properly?	11.300e	Yes	SOP-ENG20003 Computer System Validation requires testing.

3 SUMMARY

Based on the details of the Part 11 regulations, the RealTime eDOCS system does meet the 21 CFR Part 11 requirements.

4 REVISION HISTORY

Document Version Number	Document Revision Date	Revisions Made By:	Revision Summary *(Reference section[s] changed)*
1	31-Aug-2023	Evelyn Jackson	First Version
2	14-Dec-2023	Camielle Pinto	Changed name of file from eDOCS_21 CFR Part 11 Assessment_v4.10.0 to eDOCS_21 CFR Part 11 Assessment_v4.11.0 Page 1. Updated date from August 2023 to January 2024 Page 6. Removed the page break between the Summary and Revision History changing the document from 8 pages to 7. Page 5. Requirement 40 Evidence or Rationale – correcting spelling of Validation from Valdation to Validation Page 7. Updated the Document Prepared By: System Owner from Michele Corvino VP of Product to Camielle Pinto eDOCS Product Manager Page 7. Updated the Document Approvals: Engineering Manager Jeff King's title from Software Engineering Architect and Manager to Sr. Director of Software Engineering Page 7. Updated the Document Approvals: System Owner from Michele Corvino VP or Product to Camielle Pinto eDOCS Product Manager

5 APPROVALS

Signature(s) below indicates agreement with the contents of this 21 CFR Part 11 Assessment document as an accurate representation of the system and supporting processes.

Document Prepared by:			
Role	**Name - Title**	**Signature**	**Date**
System Owner	Camielle Pinto eDOCS Product Manager	Camielle Pinto	Dec 14, 2023

Signatures below additionally signify approval of this 21 CFR Part 11 Assessment document.

Document Approvals:			
Role	**Name - Title**	**Signature**	**Date**
Engineering Manager	Jeff King – Sr. Director of Software Engineering	Jeff King Jeff King (Dec 14, 2023 16:01 EST)	Dec 14, 2023
Quality Assurance	Nathan Levens – VP of Product Strategy, Head of Quality Management	Nathan Levens (Dec 14, 2023 15:14 CST)	Dec 14, 2023
System Owner	Camielle Pinto eDOCS Product Manager	Camielle Pinto	Dec 14, 2023

eDOCS_21 CFR Part 11 Assessment_v4.11.0

Final Audit Report 2023-12-14

Created:	2023-12-14
By:	daniel diaz (ddiaz@realtime-ctms.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAE3hX4rn8UP5PVb1__9HgDDCYgOTv8Gvh

"eDOCS_21 CFR Part 11 Assessment_v4.11.0" History

Document created by daniel diaz (ddiaz@realtime-ctms.com)
2023-12-14 - 8:23:11 PM GMT

Document emailed to jking@realtime-ctms.com for signature
2023-12-14 - 8:24:35 PM GMT

Email viewed by jking@realtime-ctms.com
2023-12-14 - 9:01:41 PM GMT

Signer jking@realtime-ctms.com entered name at signing as Jeff King
2023-12-14 - 9:01:55 PM GMT

Document e-signed by Jeff King (jking@realtime-ctms.com)
Signature Date: 2023-12-14 - 9:01:57 PM GMT - Time Source: server

Document emailed to Nathan Levens (nlevens@realtime-ctms.com) for signature
2023-12-14 - 9:01:58 PM GMT

Email viewed by Nathan Levens (nlevens@realtime-ctms.com)
2023-12-14 - 9:14:04 PM GMT

Document e-signed by Nathan Levens (nlevens@realtime-ctms.com)
Signature Date: 2023-12-14 - 9:14:11 PM GMT - Time Source: server

Document emailed to Camielle Pinto (cpinto@realtime-ctms.com) for signature
2023-12-14 - 9:14:12 PM GMT

Email viewed by Camielle Pinto (cpinto@realtime-ctms.com)
2023-12-14 - 9:41:43 PM GMT

Document e-signed by Camielle Pinto (cpinto@realtime-ctms.com)
Signature Date: 2023-12-14 - 9:42:17 PM GMT - Time Source: server

Agreement completed.

2023-12-14 - 9:42:17 PM GMT