

User Requirements Specification (URS)

Document Title	User Requirements Specification (URS)
Document ID	URS-001
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System	Validated Document Control (VDC) – AWS Serverless (Demo)
Owner	William O'Connell
Approver	Approver 2, QA Approver

Controlled Record Notice: This document is part of a controlled CSV evidence set. Electronic approvals are captured via VDC workflow. All timestamps are UTC.

Version	Date	Author	Change Summary
1.0	(baseline)	William O'Connell	Initial baseline release (frozen in PROD).
1.1	31-Jan-2026	William O'Connell	Consolidates baseline and documents watermarking + audit trail updates implemented in PROD. No changes to approved SOPs/test reports (v1.0).

1. Purpose

Define user and compliance requirements for the Validated Document Control (VDC) demo system. Version 1.1 consolidates baseline (v1.0) requirements and documents watermarking and audit-trail enhancements implemented in PROD. Approved SOPs and test reports remain v1.0 and are not modified.

2. Scope

Applies to controlled document lifecycle, access control for named roles, audit trail, electronic signatures, integrity, and retention/backup controls.

3. Intended Use

- Provide a controlled document workflow with role separation (Submitter 1/2; Approver 1/2).
- Generate inspection-ready evidence via controlled copy identification (watermarking in system) and immutable audit trails.
- Protect approved records from modification/deletion and retain records per SOP-008.

4. Definitions & References

- **GxP**: Good Practice requirements (GMP/GLP/GCP).
- **CSV**: Computer System Validation; evidence that system meets intended use.
- **21 CFR Part 11**: FDA rule for electronic records and signatures.
- **ALCOA+**: Attributable, Legible, Contemporaneous, Original, Accurate (+ complete, consistent, enduring, available).
- **SOP-008**: Data Retention, Backup and Restore (governs retention and restore).
- **SOP-005**: Incident, Deviation and CAPA Management (governs deviations/CAPA).

5. Roles

- **Submitter 1 / Submitter 2**: Upload and submit documents; cannot approve/reject; cannot delete records.
- **Approver 1**: QA reviewer role for review activities.
- **Approver 2**: QA approver role for final approval/rejection and electronic signature.

6. Functional Requirements (FR)

Functional requirements describe what the system does. Requirements are verified via RTM-001 v1.1 using approved test reports and qualification evidence.

Req ID	Requirement (System SHALL...)	Rationale / Compliance	Verification
FR-001	Provide named user roles: Submitter 1, Submitter 2, Approver 1, Approver 2.	Defined roles required for segregation of duties and attributable actions (ALCOA+).	OQ
FR-002	Allow Submitter users to initiate uploads and capture required metadata (Document ID, Title, Type, Version, Owner).	Record creation and retrieval readiness (21 CFR 11.10(b)).	OQ
FR-003	Store documents as controlled versions (e.g., v1.0, v1.1) with unique identifiers per version.	Version control and traceability across lifecycle.	OQ
FR-004	Support lifecycle states: DRAFT, SUBMITTED, APPROVED, REJECTED.	Controlled workflow expected under CSV.	OQ
FR-005	Allow Submitter users to submit a DRAFT for review, transitioning state to SUBMITTED.	Controlled review entry point; auditability.	OQ
FR-006	Allow Approver 1/2 to review SUBMITTED records and record decisions (approve or reject).	Governed decision-making; attributable review.	OQ
FR-007	On approval, transition state to APPROVED and lock controlled content from modification.	Record protection; preserve approved state.	OQ
FR-008	On rejection, transition state to REJECTED and retain record and history.	Complete record; supports investigation/rework.	OQ
FR-009	Prevent end users from deleting documents through UI or standard API operations.	Record protection per 21 CFR 11.10(b).	OQ
FR-010	Prevent modification of approved document content; changes require creation of new version under change control.	Maintain integrity; controlled change process.	OQ
FR-011	Render a visible controlled-copy watermark in the document viewer for SUBMITTED/APPROVED/REJECTED states displaying Status, Actor, and Date/Time (UTC).	Prevents misuse of uncontrolled copies; supports inspection clarity.	OQ
FR-012	Populate watermark Actor and Date/Time from system-controlled status-change audit metadata, not user input.	Prevent falsification; attributable and contemporaneous.	OQ
FR-013	Generate a secure, computer-generated, time-stamped audit trail for all lifecycle events.	21 CFR 11.10(e) audit trail expectation.	OQ
FR-014	Audit trail events shall include at minimum: upload initiated, submitted for review, viewed/downloaded, approved, rejected.	Complete lifecycle traceability.	OQ
FR-015	Each audit event shall capture actor identity, action type, UTC timestamp, and document/version identifiers.	ALCOA+ attribution and traceability.	OQ
FR-016	Audit trail shall be immutable (append-only); standard users cannot alter or delete audit events.	Integrity and defensibility.	OQ
FR-017	Display full audit trail in the UI for a selected document version.	Ready retrieval for inspection and QA review.	OQ
FR-018	Capture electronic signature evidence for approval and rejection actions including signer, meaning (approve/reject), and UTC timestamp.	21 CFR Part 11 Subpart C signatures.	OQ
FR-019	Bind signature evidence to a specific document version.	Prevents ambiguity; ensures correct record association.	OQ
FR-020	Authenticate users via managed identity (Cognito) and enforce session controls.	Access control requirement.	OQ
FR-021	Support MFA (TOTP) for approver accounts used to approve/reject controlled records.	Elevated assurance for privileged actions.	OQ

FR-022	Enforce role-based authorization so Submitters cannot approve/reject and Approvers cannot impersonate Submitters.	Segregation of duties; reduces fraud risk.	OQ
FR-023	Log and audit all downloads/views of controlled copies.	Inspection expectation; supports investigation.	OQ
FR-024	Store integrity evidence per document version (e.g., SHA-256 hash and/or storage version identifier).	Detect tampering; ALCOA+ integrity.	OQ
FR-025	Retain documents and audit data per SOP-008 Data Retention, Backup and Restore.	Retention and availability per quality system.	SOP/IQ
FR-026	Support backup and restore procedures per SOP-008 (evidence of restore capability).	Record availability and disaster recovery readiness.	SOP/IQ
FR-027	Handle incidents, deviations, and CAPA per SOP-005 Incident, Deviation and CAPA Management.	Quality management alignment.	SOP

7. Non-Functional Requirements (NFR)

Non-functional requirements describe constraints and quality attributes (security, integrity, availability, performance).

Req ID	Requirement (System SHALL...)	Rationale / Compliance	Verification
NFR-001	All timestamps stored and displayed shall be UTC.	Consistency across geographies; audit defensibility.	OQ
NFR-002	Records shall be readily retrievable for the full retention period.	21 CFR 11.10(b) ready retrieval.	SOP/IQ
NFR-003	System shall protect records against unauthorized alteration or deletion via least-privilege access controls.	Security and integrity.	OQ
NFR-004	System shall use encryption in transit (HTTPS) for all user interactions.	Confidentiality and integrity in transit.	OQ
NFR-005	System shall use encryption at rest for stored document objects and metadata.	Confidentiality and integrity at rest.	OQ
NFR-006	System shall maintain an audit trail that is tamper-evident and operationally immutable for standard users.	Audit reliability.	OQ
NFR-007	System shall provide reasonable performance for typical actions (list, open document, view audit) under demo load.	Usability; operational expectation.	PQ
NFR-008	System shall maintain availability suitable for demonstration and review activities.	Operational expectation.	PQ

8. Acceptance Criteria

- All FR and NFR are traced to verification evidence in RTM-001 v1.1.
- Existing approved test reports (Users/RBAC, MFA, Document Deletion) remain valid for v1.1 with no modification.
- Watermarking and audit-trail enhancements are verified through controlled OQ walkthrough evidence (observational verification) and documented in OQ-001 v1.1.

9. Related Controlled Documents

- FS-001 v1.1 Functional Specification
- RTM-001 v1.1 Traceability Matrix
- IQ-001 v1.1, OQ-001 v1.1, PQ-001 v1.1 Qualification Summaries
- SOP-005 v1.0; SOP-008 v1.0; Approved Test Reports (v1.0)

Approvals

Prepared/Reviewed/Approved electronically in VDC; this PDF represents the controlled copy for the evidence package.

Role	Name / Title	Date (UTC)
Prepared By	William O'Connell, System Owner / Tester	31-Jan-2026
Reviewed By	Approver 1, QA Reviewer	31-Jan-2026
Approved By	Approver 2, QA Approver	31-Jan-2026