

Functional Specification (FS)

Document Title	Functional Specification (FS)
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System	Validated Document Control (VDC) – AWS Serverless (Demo)
Owner	William O'Connell
Approver	Approver 2, QA Approver

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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

Describe the functional design and controls implementing URS requirements for the VDC system. This document defines how the system enforces workflow, audit trail immutability, access control, integrity, and controlled copy identification (watermarking in-system).

2. System Overview (High Level)

- Frontend web UI provides role-based pages for submitters and approvers.
- Authentication via Amazon Cognito; MFA enabled for approver accounts.
- API Gateway exposes allowed operations; Lambda performs workflow actions.
- DynamoDB stores metadata and append-only audit events; S3 stores document objects.

3. Key Design Controls (URS Coverage)

The table below maps major design controls to URS requirements.

Design ID	Design / Control	URS Coverage	Verification
FS-ARCH-001	Authentication handled by Cognito with distinct user accounts (Submitter 1/2; Approver 1/2).	Meets FR-001/20/21/22.	Design review
FS-ARCH-002	Document objects stored in S3; metadata stored in DynamoDB; workflow executed via Lambda behind API Gateway.	Meets FR-002/03/04/05/06.	Design review
FS-CTRL-001	No standard delete routes exposed; IAM denies deletion operations for standard roles.	Meets FR-009 and NFR-003.	Approved Test + OQ
FS-WM-001	Viewer renders controlled-copy watermark (Status, Actor, Date/Time UTC) for non-draft states; fields derived from status change audit event.	Meets FR-011/12.	OQ walkthrough
FS-AUD-001	Audit events written append-only to DynamoDB; events include action, actor, timestamp UTC, doc/version; display in UI.	Meets FR-13..17 and NFR-6.	OQ walkthrough
FS-ESIG-001	Approve/Reject writes signature evidence (meaning, signer, UTC time) into audit record.	Meets FR-18/19.	OQ walkthrough
FS-INTEG-001	Integrity evidence recorded per version (hash and/or storage version id).	Meets FR-24.	OQ walkthrough
FS-RET-001	Retention/backup/restore governed by SOP-008; incidents governed by SOP-005.	Meets FR-25..27.	SOP reference

4. Watermarking Control (Implemented in System)

- Watermark fields required: Status, Actor, Date and Time (UTC).
- Displayed for SUBMITTED / APPROVED / REJECTED controlled views.
- Watermark populated from system-controlled status metadata and latest status-change audit event.
- Watermark is not user-editable; visually identifies controlled copy state.

5. Audit Trail Control

- Audit events are computer-generated and time-stamped in UTC.
- Audit store is append-only; standard users cannot update or delete events.
- UI displays complete audit trail and technical context needed for inspection/readiness.

6. Security & Access Control

- Role-based authorization: submitters cannot approve/reject; approvers cannot submit as submitter.
- MFA used for approver accounts.
- Least privilege IAM protects records from deletion/alteration.

7. Data Integrity & Retention

- Integrity evidence stored per document version (hash/version id).
- Retention/backup/restore per SOP-008; incidents per SOP-005.
- Approved record protection aligns to 21 CFR 11.10(b) ready retrieval and record protection.

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