C20: Regulatory Scope and Negative Applicability Statement

Proof-of-Unchanged Methodology (Electronic Records & Audit Infrastructure)

Audience: CRO Quality Assurance, Regulatory Affairs, Inspection Readiness, Independent Evaluators
Applies to: Proof-of-Unchanged methodology; AuditLog.AI execution evidence; QMS Auditor outputs
Scope Type: Methodology positioning and negative regulatory applicability
Anchoring Software: AuditLog.AI **Auditing Software:** QMS Auditor **Version:** v5
Mode: Zero-Custody | Hash-Only | Human-Verified | Machine-Deterministic | Time-Anchored
Protocol Originator: Dr. Fernando Telles
Date: 06 February 2026
AI_used: true
LLM_used: LLM1<>LLM4
Human_verified: true (HV_FT)
Classification: Public methodology-level positioning (non-authoritative; non-binding)
Primary references:
- C12 AuditLog.AI Global Compliance Matrix (Ordinal 12; DOI: 10.5281/zenodo.17462383)
- C17 Proof-of-Unchanged Global Application Matrix (Ordinal 16; DOI: 10.5281/zenodo.18501507)

> **One-sentence summary:** This document clarifies the regulatory scope boundaries of the Proof-of-Unchanged methodology as documented in publicly anchored materials and explicitly identifies frameworks to which it does not apply.

Purpose of this page

This page clarifies the **regulatory scope boundaries** of the AuditLog.AI Proof-of-Unchanged methodology, as documented in publicly available, cryptographically anchored materials.

It is intended to help CRO QA and Regulatory Affairs teams: - understand **what regulatory frameworks this methodology is positioned under**, - understand **what it is explicitly not**, and - avoid misclassification (e.g., as clinical decision support or medical device software).

This page does **not** assert regulatory approval, clearance, or endorsement.
Formal regulator engagement (e.g., FDA Q-Submission, EMA Scientific Advice, TGA Excluded Software Determination) is planned but has **not yet occurred**. No regulatory authority has reviewed, classified, or endorsed this methodology.

High-level positioning (methodology, not approval)

Based on the published evidence and mappings in **C12: AuditLog.AI Global Compliance Matrix**, the Proof-of-Unchanged methodology is positioned as:

> **Audit-trail and electronic-records verification infrastructure**, operating at custody boundaries, under electronic records, data integrity, and audit documentation frameworks.

This positioning reflects **how the methodology is designed and documented**, not a determination by any regulatory authority.

What this methodology does (intended use)

As documented in **C17: Proof-of-Unchanged (Global Application Matrix)**, the intended use of the methodology is to:

- Verify whether **exported digital evidence has remained byte-unchanged** since a prior, verifiable checkpoint.
- Operates **post-export, pre-archive**, or at other custody boundaries.
- Uses **hash-only, zero-custody verification** with optional decentralized time attestation and public anchoring.
- Produces **deterministic outcomes**:
    - **PASS (proof-of-unchanged)**, or
    - **divergence enumeration** (informational deltas to bound human review).

The methodology **detects change**; it does not prevent, judge, or interpret it.

What this methodology does not do (negative scope)

Based on its documented design and published evidence, the Proof-of-Unchanged methodology:

- **Does not provide clinical recommendations** regarding diagnosis, treatment, prevention, or patient care.
- **Does not analyze patient-specific medical information** for clinical decision-making.
- **Does not generate compliance determinations**, audit opinions, or regulatory judgments.
- **Does not infer intent, misconduct, or error** when divergence is detected.
- **Does not operate inside source systems** (EDC, eTMF, CTMS, LIMS, cloud platforms).
- **Does not require system integration** or modification of operational workflows.
- **Does not perform real-time monitoring or control**.

Divergence outcomes are **informational signals**, intended solely to **direct proportional human effort** under applicable SOPs.
