R.E.T.N.A Regulatory Addendum

Decision Governance, Auditability, and Compliance Alignment

Companion to: R.E.T.N.A Protocol Specification v0.1

Status: Regulatory Alignment Addendum

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Intended Audience: Regulators, auditors, compliance officers, standards bodies

Applies To: Systems implementing R.E.T.N.A-compliant decision governance

This document is a regulatory interpretation companion to the

R.E.T.N.A Protocol Specification v0.1 and should be read in

conjunction with the protocol specification.

Document Metadata

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This document provides **regulatory interpretation and alignment guidance** for the R.E.T.N.A Protocol.

It does not introduce new protocol requirements and should be interpreted as **informative regulatory mapping** rather than normative specification text.

Regulatory Notice

This document is provided for informational and architectural alignment purposes.

It does **not constitute legal advice** and does not replace consultation with qualified regulatory counsel.

Organizations remain responsible for compliance with all applicable laws, regulations, and guidance applicable to their systems.

The R.E.T.N.A Protocol provides technical governance mechanisms that may assist organizations in meeting regulatory expectations.

Table of Contents

1. Purpose and Scope of This Addendum

This addendum maps the governance mechanisms defined in the **R.E.T.N.A Protocol v0.1** to regulatory expectations across major oversight frameworks including:

- U.S. Food and Drug Administration (FDA)
- Federal Trade Commission (FTC)
- European Union Artificial Intelligence Act
- NIST Artificial Intelligence Risk Management Framework (AI RMF)

The purpose of this document is to:

- clarify the regulatory positioning of the protocol
- explain how R.E.T.N.A artifacts support inspection and audit
- provide regulator-safe characterization language
- reduce ambiguity during regulatory review or compliance evaluation

The document is intended to be used as:

- a regulatory briefing artifact
- an audit reference
- supporting documentation during regulatory consultation

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2. Regulatory Positioning Summary

R.E.T.N.A is **not an AI model, decision engine, or autonomous agent**.

It is a **decision governance protocol** that introduces a mandatory governance boundary between **decision construction** and **decision execution**.

The protocol provides:

- enforceable pre-execution policy controls
- standardized decision authorization artifacts (Decision Receipts)
- traceability across agents, models, and tools
- structured evidence for audits and investigations

R.E.T.N.A functions as **governance infrastructure that enables compliance** rather than replacing domain-specific regulation.

The protocol defines a canonical **Decision Receipt artifact** (see Section 8 of the R.E.T.N.A Protocol Specification v0.1) that records the authorization outcome, applied policies, and evidence associated with a governed decision.

3. FDA Alignment

Software as a Medical Device (SaMD) and AI-Enabled Systems

3.1 Regulatory Context

The U.S. FDA evaluates AI-enabled software using principles including:

- reasonable assurance of safety and effectiveness
- lifecycle risk management
- controlled model updates
- post-market monitoring

These concepts appear in guidance related to:

- Software as a Medical Device (SaMD)
- AI/ML-enabled medical devices
- Predetermined Change Control Plans (PCCP)

3.2 R.E.T.N.A Alignment With FDA Expectations

Governance as a Risk Control

R.E.T.N.A introduces a **governance boundary** that evaluates decisions before they are executed.

This boundary enables:

- enforcement of safety constraints
- escalation to human review
- prevention of unauthorized actions

The protocol therefore functions as a **technical risk control layer** that can complement device software safety mechanisms.

Controlled Iteration and Change Management

Decision Receipts record:

- model identifiers and versions
- policy bundle identifiers and versions
- decision context and constraints applied

These artifacts allow organizations to:

- trace system behavior across model updates
- compare outcomes before and after model change
- support PCCP-style controlled change evaluation.

Post-Market Surveillance Support

Decision Receipts enable structured analysis of system behavior.

Organizations can analyze:

- denied action
- escalated decisions
- degraded outcomes
- anomaly patterns

These artifacts can support post-market monitoring programs and CAPA workflows.

3.3 FDA-Safe Characterization Language

The following phrasing is recommended when describing R.E.T.N.A in FDA-related contexts:

“R.E.T.N.A provides a governance and documentation layer that evaluates and records AI-enabled system decisions prior to execution. It does not generate clinical decisions or diagnoses.”

“The protocol supports traceability and controlled iteration by preserving versioned provenance of system behavior.”

4. FTC Alignment

Consumer Protection and Substantiation

4.1 Regulatory Context

The FTC enforces laws related to:

- deceptive practices
- unfair practices
- substantiation of claims

These principles apply equally to AI-enabled systems.

4.2 How R.E.T.N.A Supports FTC Objectives

Claim Substantiation

Decision Receipts allow organizations to produce evidence supporting claims such as:

- enforcement of spending limits
- confirmation requirements above thresholds
- policy-based authorization rules

Receipts allow these claims to be **demonstrated through artifacts rather than assertions**.

Dispute Resolution

Receipts provide structured evidence for:

- customer disputes
- internal investigations
- regulatory inquiries

Prevention of Deceptive Automation

The protocol enables:

- disclosure points when autonomous actions occur
- confirmation requirements for sensitive actions
- records of user acknowledgement where required.

4.3 FTC-Safe Language

Recommended phrasing:

"R.E.T.N.A enables organizations to substantiate operational claims about automated decision-making by producing standardized decision receipts."

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5. EU AI Act Alignment

Risk-Based Governance

5.1 Regulatory Context

The EU AI Act introduces requirements related to:

- risk management
- technical documentation
- human oversight
- transparency

5.2 R.E.T.N.A Alignment

Risk Management Systems

The protocol records:

- decision classifications
- constraint evaluation outcomes
- mitigation actions

These artifacts support continuous risk management.

Technical Documentation

Decision Receipts provide ongoing documentation of system behavior.

They record:

- inputs and evidence
- applied safeguards
- authorization outcomes.

Human Oversight

The protocol supports escalation and records human review actions where applicable.

Transparency

The governance boundary provides a standardized location where required disclosures can be enforced.

6. NIST AI RMF Mapping

AI RMF Function	R.E.T.N.A Alignment
GOVERN	policy bundles and governance boundary
MAP	decision classification and environment context
MEASURE	receipt metrics and anomaly detection
MANAGE	degrade/defer/escalate controls

These mappings illustrate how R.E.T.N.A operationalizes governance and risk management controls inside deployed AI-enabled systems.

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7. Audit Artifacts and Export Packages

R.E.T.N.A systems should support exportable audit artifacts.

Core Artifacts

- Decision Receipts
- policy bundle definitions
- constraint catalogs

Exception Reports

- all denied actions
- escalated actions
- degraded decisions
- human overrides

Change Impact Reports

- outcomes by model version
- outcomes by policy version
- pre/post change comparisons.

8. Non-Claims and Boundary Conditions

R.E.T.N.A does **not claim**:

- elimination of risk
- elimination of bias
- automatic regulatory compliance
- correctness of domain decisions.

R.E.T.N.A **does claim**:

- enforceable governance controls
- auditable decision artifacts
- traceability across system components.

9. Regulator-Facing Language

Approved phrasing for regulatory discussions:

"R.E.T.N.A introduces a governance boundary and decision receipt artifact that enables enforceable controls, traceability, and auditability for AI-enabled systems."

10. Adoption Guidance

Organizations adopting R.E.T.N.A should:

- integrate the protocol at decision execution boundaries
- maintain policy bundle versioning
- retain Decision Receipts for audit review.

Closing Statement

R.E.T.N.A establishes a standardized decision governance boundary and a portable Decision Receipt artifact that enables enforceable controls, traceability, and auditability for AI-enabled systems operating in real-world environments.

The protocol is designed to support—not replace—existing regulatory frameworks by introducing enforceable governance boundaries and auditable decision artifacts for AI-enabled systems operating in real-world environments.