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Operational Governance and Traceable Change Control for Clinical Software in Virology and Immunology Research

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Abstract

Modern virology and immunology research laboratories rely heavily on automated diagnostic instrumentation (such as PCR thermocyclers, immunoassay analysers) and high-throughput digital microscopy setups. While these systems streamline data ingestion, they lack pre-execution validation mechanisms to enforce protocol-level boundaries before data is committed to primary clinical registries [1]. This paper presents a high-level conceptual framework for on-node, inline compliance gating middleware. We define design patterns for integrating black-box validation filters within PACS/DICOM networks and laboratory information systems (LIS). By validating data payloads at the collection boundary, this architecture mitigates upstream diagnostic drift, prevents out-of-bounds metrics from propagating into clinical profiles, and generates immutable, tamper-evident logs for clinical validation and regulatory reporting.

Keywords: Modern Virology; Immunology; Traceable Change Control; Immunoassay Analysers

Introduction

Modern clinical research labs process high-throughput assays and multi-spectral digital pathology images at a scale that exceeds manual verification capacity. In typical clinical workflows, laboratory information systems (LIS) and digital imaging archives (PACS/DICOM) ingest data directly from lab devices.

Traditional safety systems rely on post-hoc logging (checking system state after data has already been recorded) or cloud-hosted checks that add latency and data exposure risks [1]. If a device malfunctions, calibration drifts, or a diagnostic pipeline experiences transcription errors, bad data enters the registry, creating significant downstream safety and scientific integrity risks.

We propose a shift to inline, on-node compliance gating. Under this model, transactional writes and diagnostic payloads are intercepted, evaluated against local policy parameters, and committed only if they pass strict validation bounds.

Architectural Design Patterns for Gating

The middleware operates as a black-box verification filter placed directly at the boundary of data entry points. It contains three main components:

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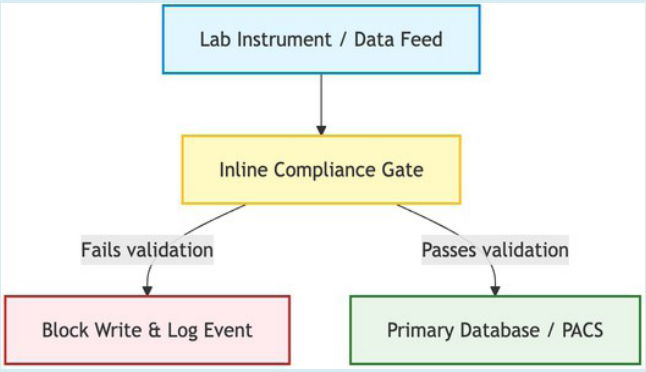

Figure: Conceptual workflow of the proposed inline compliance gate for laboratory data validation.

Clinical Lab Automation Gating

For immunoassay analysers and PCR pipelines, the middleware acts as an inline database gating agent. It intercepts incoming assay telemetry and evaluates it against expected laboratory thresholds (e.g., control limits, valid assay coefficients) before writing the records to the LIS database [2,3].

Immunodiagnostic Assay Gating

In flow cytometry and ELISA data output engines, policy-gated layers check specific target criteria. For example, if a flow cytometry report records cell counts that indicate a system failure or extreme out-of-bounds anomaly, the transaction is gated and logged for investigator review rather than being automatically accepted [4].

Medical Imaging and Digital Pathology Plugins

For digital pathology slide databases, the gate acts as a DICOM validator. It reads metadata headers and verifies structural conformance (e.g., patient identity constraints, image format parameters) before permitting the image data to commit to the imaging database [5,6].

Core Outcomes of Gating Implementation

By utilising this black-box verification architecture, three distinct operational outcomes are achieved:

1. Input and Data Integrity at Point of Collection: Restricting corrupted, malformed, or out-of-bounds diagnostics from entering primary clinical databases.
2. Pre-Execution Audit Controls: Transitioning systems from passive logging to active, deterministic runtime validation.
3. Immutable Compliance Verification: Generating a cryptographic, tamper-evident trail of all validation events, policy parameters, and authorised overrides to serve as regulatory compliance evidence.

Fail-Safe and Fault Tolerance Mechanisms: To prevent system locks during unexpected hardware or software crashes, the middleware features a dual-path routing loop. If a middleware node failure occurs, the validator triggers an automated fail-safe state, logging the system event to a secondary local cache and passing primary control signals to a bypass route without halting critical laboratory diagnostic device streams.

Exception Handling Workflows for Rejected Payloads: When incoming telemetry or a diagnostic payload violates compliance bounds (e.g., calibration values outside expected coefficients), the gate rejects the write attempt. The rejected data is immediately routed to a local quarantine file and registered as a validation anomaly. This triggers a visual alert on the LIS console, requiring an authorised laboratory investigator override before the data can be cleared or re-ingested.

Discussion and Future Work

Establishing standardised design blueprints for inline database gating allows laboratories to achieve high-assurance data integrity. To support formal integration into clinical laboratories, this framework aligns with major regulatory standards, including FDA 21 CFR Part 11 for electronic record traceability, HIPAA for patient health data security, and ISO 15189 for medical laboratory quality assurance. Our upcoming research focuses on benchmarking performance metrics and transaction latency overhead under simulation workloads, preparing the framework for formal clinical testing and regulatory validation.

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