HEALTH IT
STANDARDS TESTING INFRASTRUCTURE

Helping the Cause of Medical Device Interoperability Through Standards-based Test Tools
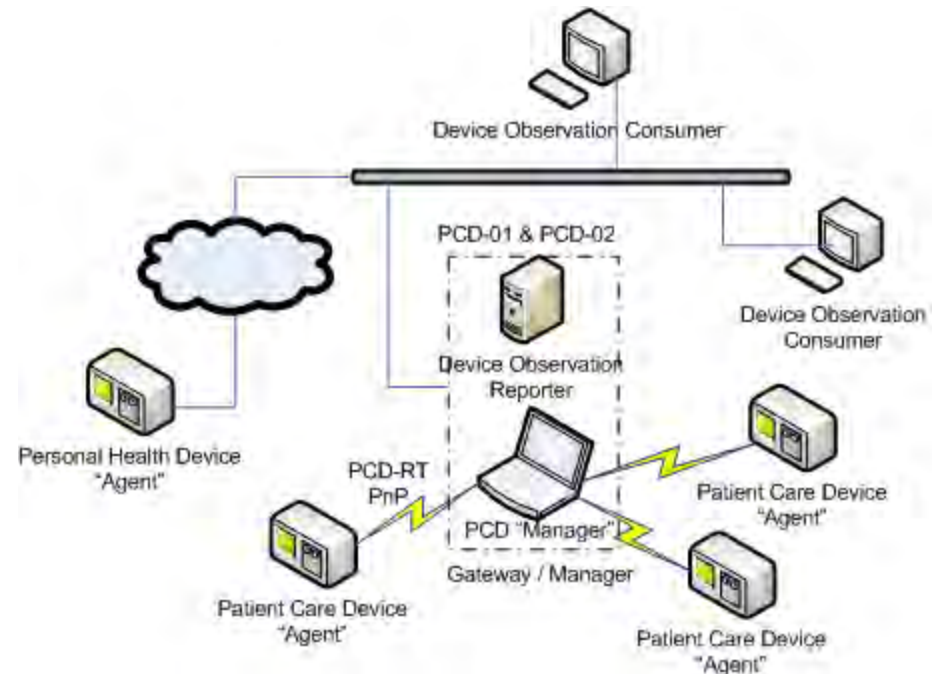
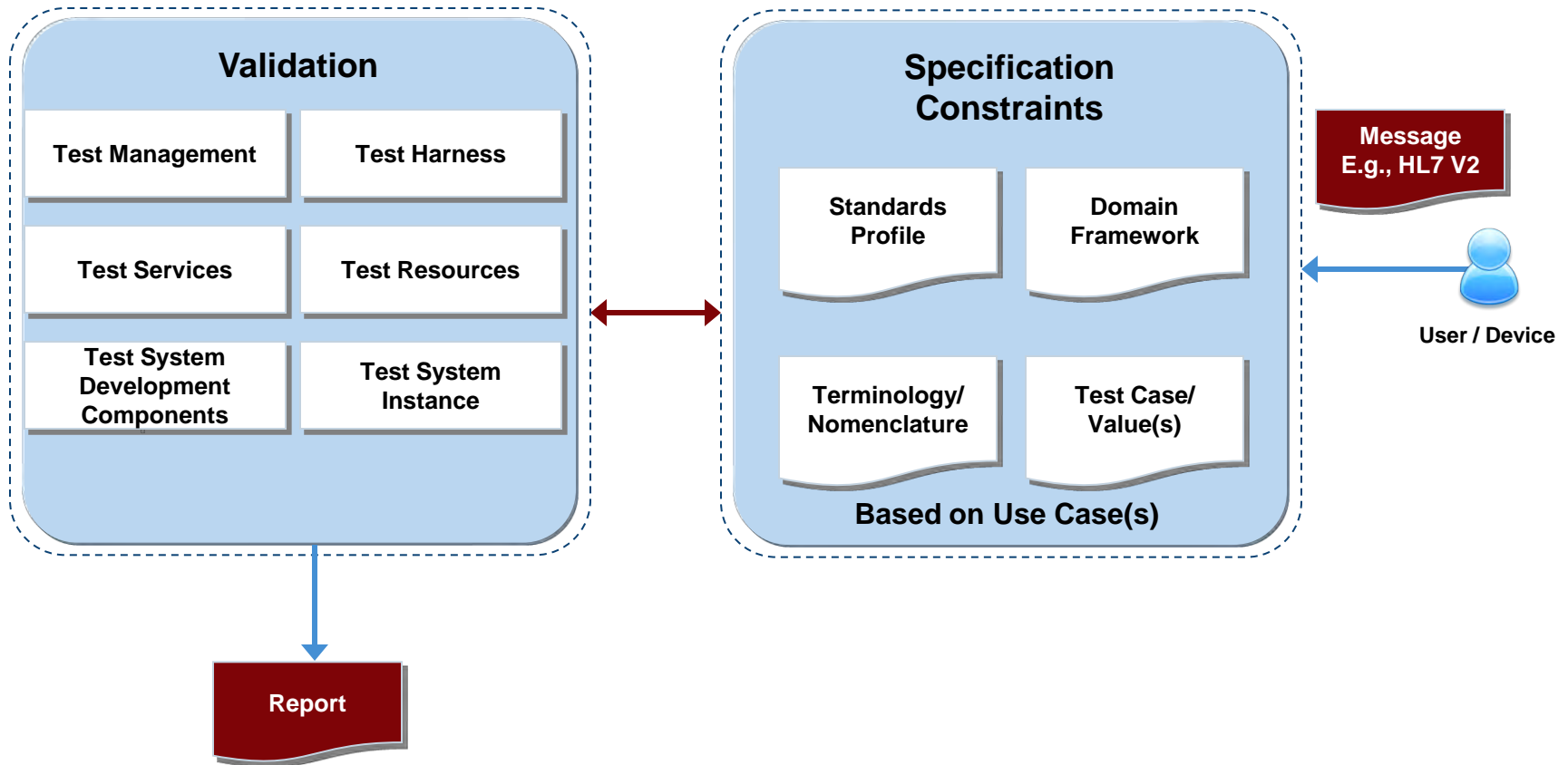**DoC/NIST**
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NIST
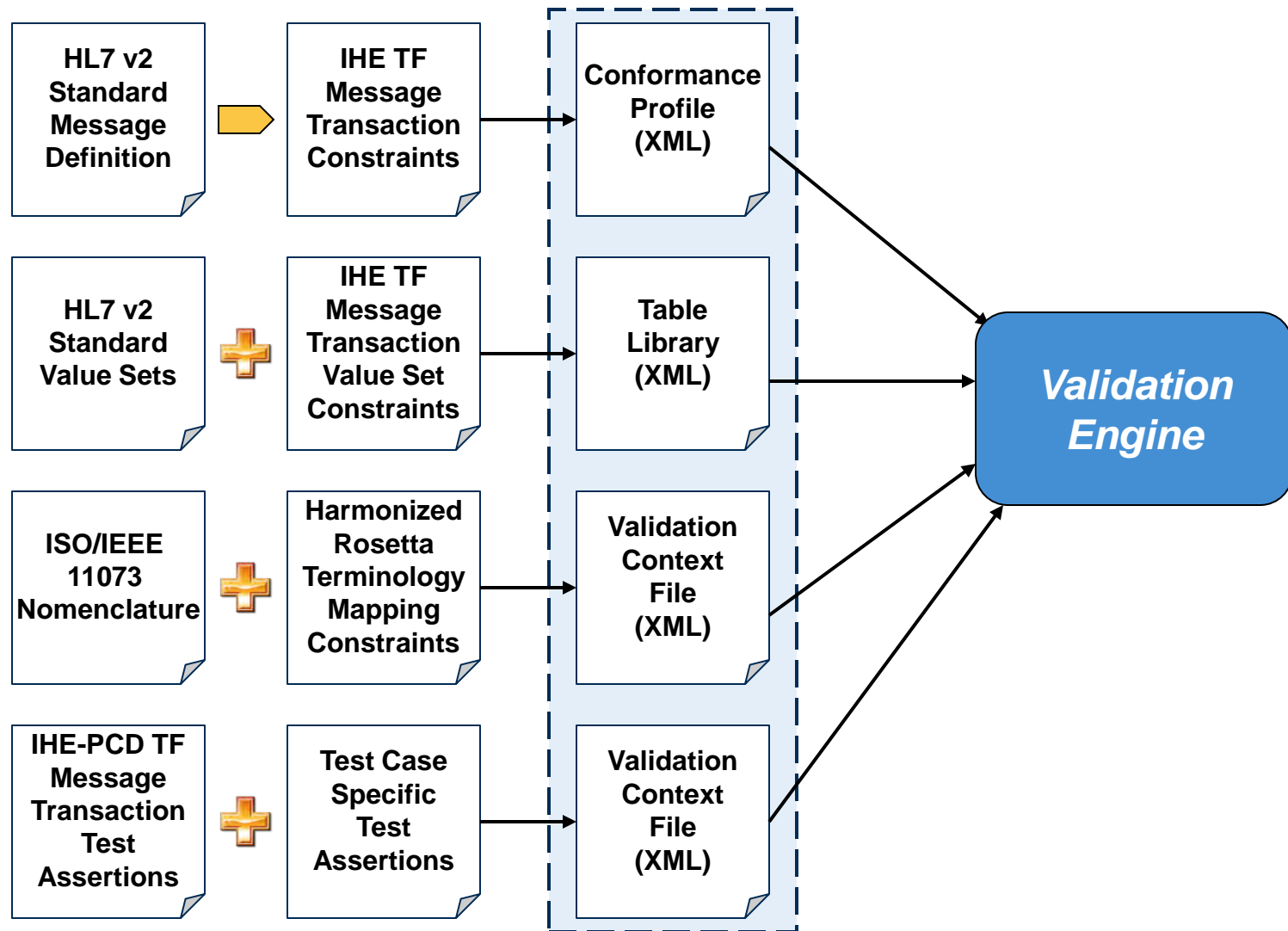National Institute of Standards and Technology

- ## Medical Device Standards Work
  - Device and Enterprise-level
- ## Integrating Health Enterprise - Patient Care Devices (IHE-PCD)
  - Enterprise-level
- ## Personal Health Devices
  - Personal Tele-health-level
- ## Facilitate the efficient exchange of medical device and vital signs data throughout the HC enterprise
  - Test Research Methods
  - Conformance → Interoperability (based on Standards)
  - Ultimately: Real-time plug-and-play interoperability

Conformance Testing:
Using 'Profiles' to Advance Rigorous Testing

Validation

Test Management	Test Harness
Test Services	Test Resources
Test System Development Components	Test System Instance

Specification Constraints

Standards Profile	Domain Framework
Terminology/ Nomenclature	Test Case/ Value(s)

Based on Use Case(s)

Message
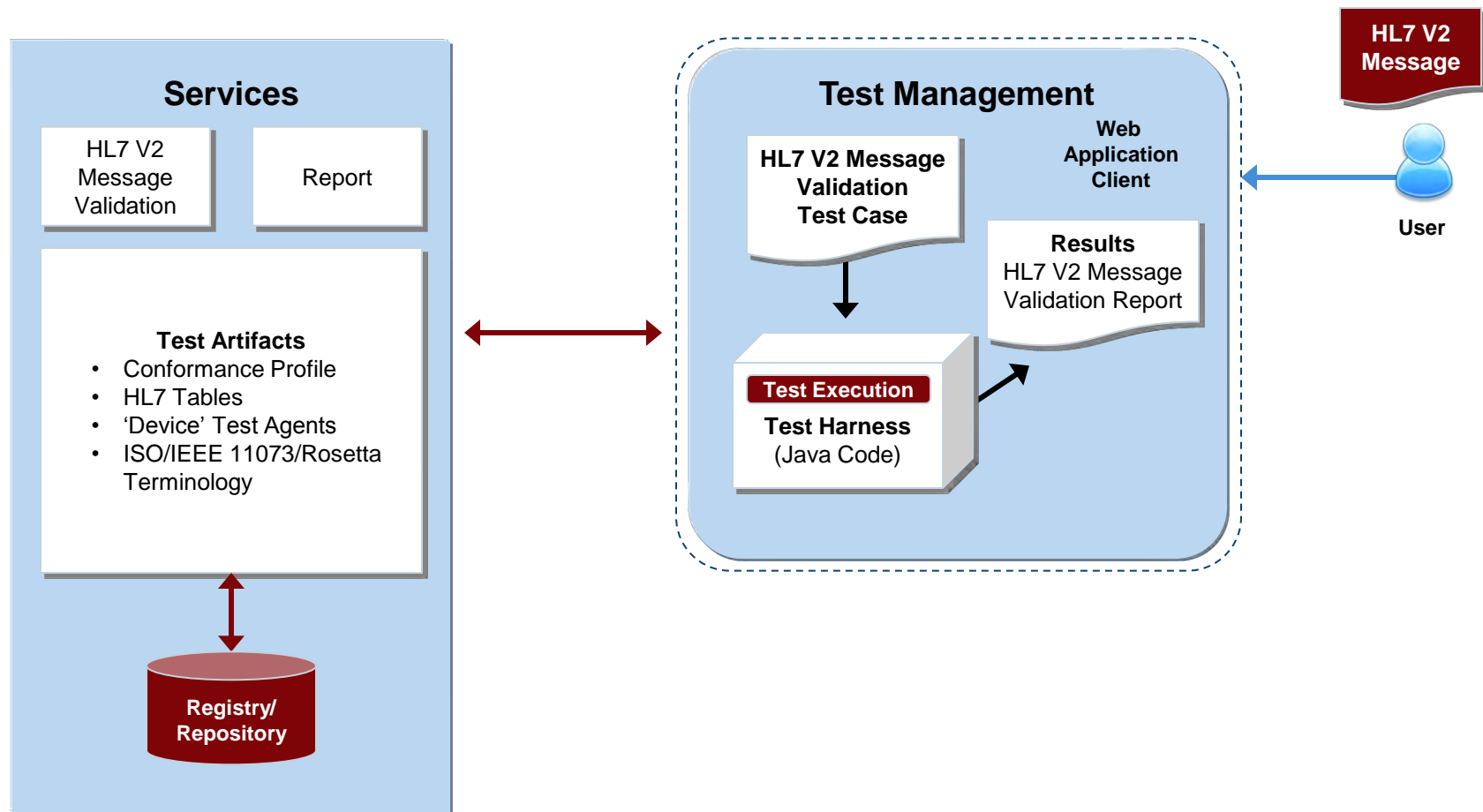E.g., HL7 V2

User / Device

Report

Validation Operational Process: Origin of Test Assertions

- **Instance Testing**
  - Conformance (e.g., against HL7 V2.x or CDA)
    - Implementation conforms to Spec. on which it is based

- **Isolated System Testing**
  - Includes *Instance Testing* Activities
  - Protocol Conformance
  - Functional Behavior Conformance
    - Features and Operational behavior correspond to Specs.

- **Peer-to-Peer System Testing**
  - Includes *Isolated System Testing* Activities
  - Interoperability Testing
    - Testing complete application environment
    - May include interacting w/ Database, using Network Communications, or interacting w/ other hardware, apps, or systems if appropriate
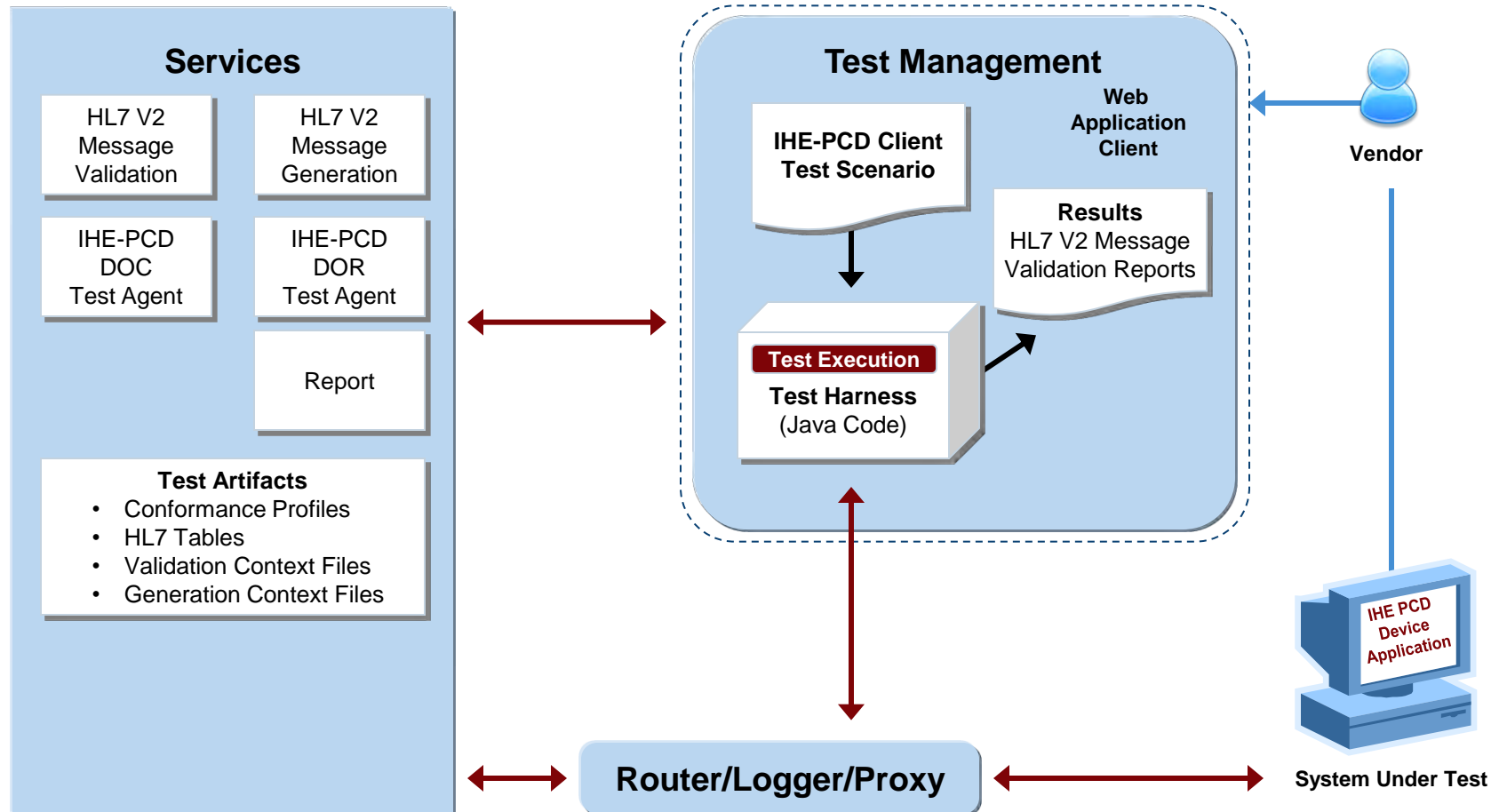
Instance Test Environment
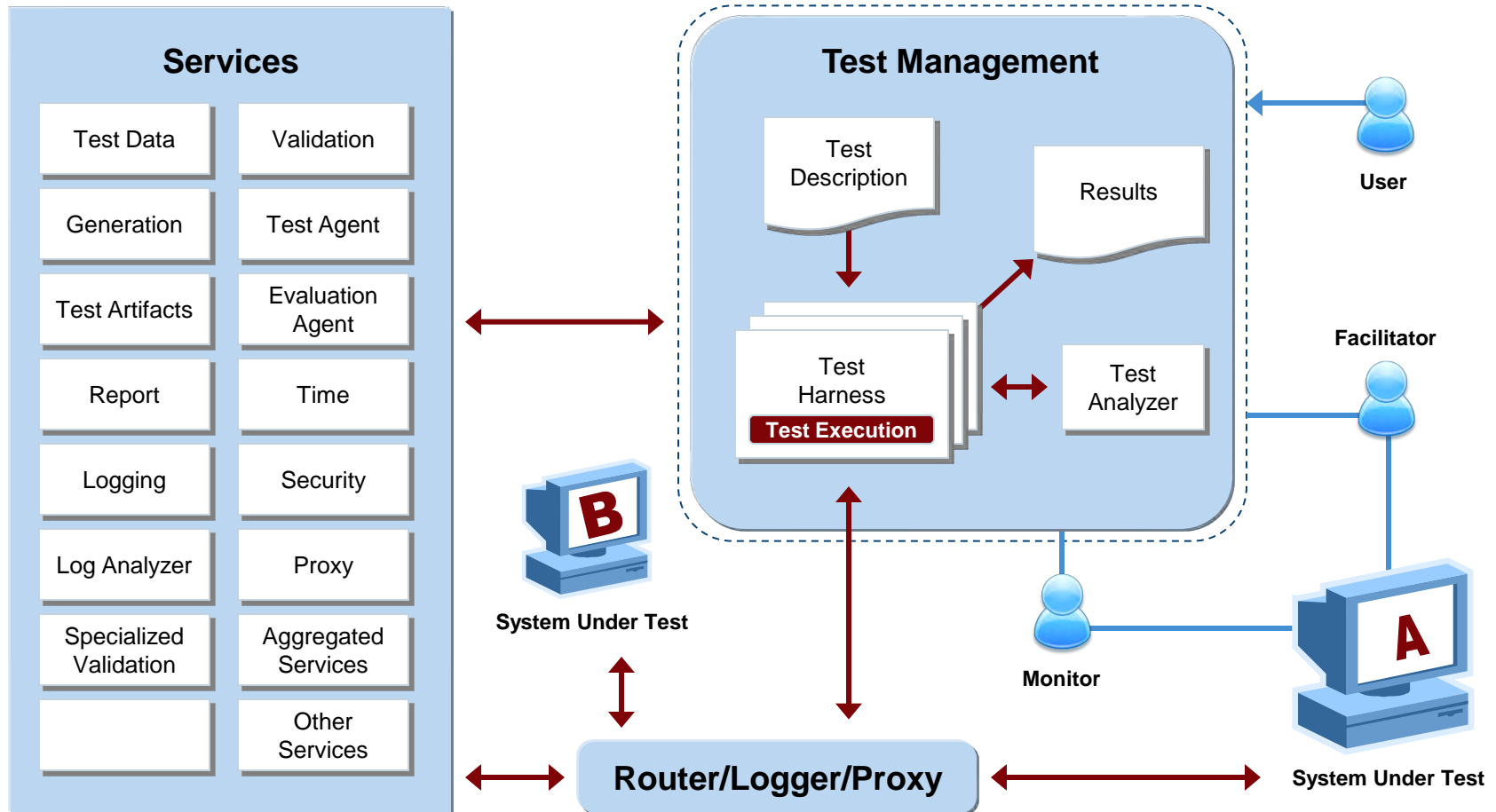## E.g., *Conformance Testing of an HL7 V2 Message*

Isolated System Test Environment
E.g., *IHE-PCD Testing using a Web Application Client*

Services

- HL7 V2 Message Validation
- HL7 V2 Message Generation
- IHE-PCD DOC Test Agent
- IHE-PCD DOR Test Agent
- Report

Test Artifacts
- Conformance Profiles
- HL7 Tables
- Validation Context Files
- Generation Context Files

Test Management

Web Application Client

IHE-PCD Client Test Scenario

Results HL7 V2 Message Validation Reports

Test Execution
Test Harness (Java Code)

Vendor

IHE PCD Device Application

Router/Logger/Proxy

System Under Test

NIST HIT Testing Infrastructure Design
A Framework for Building Test Systems—an SOA Approach

Thank YOU!

- Discussion/Questions/Comments
- **Visit us at the NIST Tool Sites:**
  - ➢ **MDC Testing Web site: www.nist.gov/medicaldevices**
  - ➢ **IHE-PCD Pre-Connectathon Web site: http://xreg2.nist.gov:8080/PCD-HL7Web/**
  - ➢ **IHE-PCD Connectathon Web site: http://xreg2.nist.gov:8080/PCD-HL7WebCon/**