National Institute of Standards and Technology

IHE-PCD , HL7 Dev WG, ISO/IEEE 11073, *and* NIST

NIST MDC Test Tooling

IHE-PCD/HL7/IEEE WG Meetings
(@ Phoenix, Az)
19 January 2010

Software and Systems Division

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Medical Device CommunicationTest Effort

NIST Contacts

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NIST Tool Sites

Pre-Connectathon Web site:
http://xreg2.nist.gov:8080/PCD-HL7Web/

Connectathon Web site:
http://xreg2.nist.gov:8080/PCD-HL7WebCon/

MDC Testing Web site: www.nist.gov/medicaldevices

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Topics

- HL7 Tooling Status (John)
  - NIST's HL7 V2 Tools
  - Supported IHE-PCD Cycle 4 Pre- & Virtual-Connectathons, and Connectathon
- ISO/IEEE 11073 Tooling Status (Sandra)
  - ICSGenerator Interface Update
  - Discussion (Cardinality)
- HIT Testing Infrastructure - Coordination with IHE "Gazelle Project" (Rob)
- Discussion – Testing Strategy

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IHE-PCD Testing – Key Objectives

- Increase test comprehensiveness & quality
- Support both conformance & interoperability testing
- Support for Pre- & Virtual- Connectathons, actual Connectathon & enable year round testing
- Remain in alignment with IHE-PCD integration profile development road map
- Establish single framework for PCD covering increasing complexity and technologies over next 5 years
- Coordinate with IHE "Gazelle Project"
- Generate work products that companies can use in their regulatory submissions

Test Environments

- Instance Testing
  - Conformance (e.g., against HL7 2.x or CDA)
    - Implementation conforms to Spec. on which it is based
    - IHE Model: *~Virtual and Pre-Connectathon*
- Isolated System Testing
  - Includes *Instance Testing* Activities
  - Protocol Conformance
  - Functional Behavior Conformance
    - Features and Operational behavior correspond to Specs.
    - IHE Model: *~Virtual and Pre-Connectathon*
- 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
    - IHE Model: *~Connectathon*

IHE-PCD Testing – Key Ingredients

- Well Defined Integration Profiles
  - Technical Framework
  - Supplements
- Test Guidelines
- Test Plans
  - Test Scenarios, Actors, Transactions, Validation Criteria
- Test Artifacts, including:
  - HL7 Profile(s) (*and eventually x73 Device Specializations?*)
  - Repositories
  - Nomenclature (e.g., RTM)
  - Value Tables (e.g., HL7, units, local, etc.), Default and Sample Values
- Test Cases

NIST IHE-PCD Test Guidelines (Cycle 4 '09-'10 Pre-connectathon)

- Quick, executive summary level view
- Defines testing requirements for those performing testing
  - HL7 Messaging version (e.g., V2.6)
  - HL7 profile
- Identifies test environment
  - See 'Test Environment' slides below…
- Identifies what types of testing shall occur
- Links *test artifact(s)* (needed) to validate specific test case(s)
- Syntax Validation
  - HL7 Syntax/structure – basic syntax via HL7 V2.6 standard
  - HL7 IHE-PCD Profile Validation – required fields, order, data types, cardinality via message profile
- Semantic Validation(via context validation file)
  - Integration Profile Validation – (semantic) via message profile file (XML)
  - Rosetta Validation – (semantic) terminology w/ co-constraints from RTM Integration Profile
  - Test case validation – (semantic) specific field values

NIST IHE-PCD Test Plans ('09-'10 Pre- and Virtual- Connectathon)

- Clear and concise documentation
- Mirror (point to) and/or include test cases
  - Already defined and new test cases as developed/introduced
- Necessary for rigorous HL7 profile and message validation
  - Defines "validation context" specifications used by tooling
- Recommended and used document template…
  - Used by IHE-PCD Integration Profile working groups to establish exactly what's to be tested
    - Communicates specific validation criteria to participating vendors
      - I.e., no surprises
    - …Supporting documentation for work products
      - …that perhaps companies can use in their regulatory submissions
    - Start w/ static messages and move into scenarios
  - Way to identify appropriate Rosetta Terminology according to IHE use case

IHE-PCD Cycle 4 Testing Documentation

Test Guideline Documents

- NIST DEC Pre-Connectathon Test Guidelines.docx
- NIST ACM Pre-Connectathon Test Guidelines.docx
- NIST IDCO Pre-Connectathon Test Guidelines.docx
- NIST PIV Pre-Connectathon Test Guidelines.docx

Test Plan Documents

- DEC_TEST PLAN.docx
- DEC_SPD_TEST PLAN.docx
- ACM_TEST PLAN.docx
- IDCO_TEST PLAN.docx
- PIV_TEST PLAN.docx

- Guidelines/Test Plans and Validation Context Files (XML) available at IHE Patient Care Devices' FTP site:
  - ftp://ftp.ihe.net/Patient_Care_Devices/Tools/NIST-Tools/NIST_HL7_V2_Tools/

NIST IHE-PCD HL7 Profiles (cycle 4)

- NIST_DEC_DOR_PCD-01_ORU^R01.xml
- NIST_SPD_DOC_PCD-02_QSB^Q16.xml
- NIST_PIV_IOP_PCD-03_RGV^O15.xml
- NIST_ACM_AR_PCD-04_ORU^R01.xml
- NIST_IDCO_IDCR_PCD-09_ORU^R01.xml

- Key: Msg_type^Event_type^ e.g., ORU^R01^…)

Message Validation Context
Technical Framework/Supplement Validation

- Naming Convention: w…w-yyy-nn-ValidationContext.xml
  - [*w…w*]: Integration Profile Group/Option (e.g., "PIV")
  - yyy-nn: IHE-PCD transaction-Number (e.g., "PCD-03")

- DEC-PCD-01-ValidationContext.xml
- SPD-PCD-02-ValidationContext.xml
- PIV-PCD-03-ValidationContext.xml
- ACM-PCD-04-ValidationContext.xml
- IDCO-PCD-09-ValidationContext.xml

Message Validation Context
hRTM Validation

- hRTM
  - Integrated via context validation files for this year's cycle
  - Future, likely a web service (call to repository)

- hDEC-PCD-01-ValidationContext.xml
- hPIV-PCD-03-ValidationContext.xml
- hACM-PCD-04-ValidationContext.xml
- hIDCO-PCD-09ValidationContext.xml

NIST Test Case

Message Validation Context ('09-'10 Pre-connectathon)

- NIST validation of specific values (derived from the test cases for each Integration Profile)
  - Based on Use Case
  - Instance of Use Case ultimately demonstrated at Showcase
- E.g., PIV(for PCD-03)
  - 60101-ValidationContext.xml
  - 60102-ValidationContext.xml
  - 60103-ValidationContext.xml
  - 60104-ValidationContext.xml
  - 60105-ValidationContext.xml
  - 60106-ValidationContext.xml
  - 60107-ValidationContext.xml
  - 60108-ValidationContext.xml
  - 60109-1-ValidationContext.xml
  - 60109-2-ValidationContext.xml
  - 60109-3-ValidationContext.xml
  - 60109-4-ValidationContext.xml
  - 60110-ValidationContext.xml

Test Environment Message Validation
NIST V2 Testing Tools: IHE-PCD

- Validation of IHE-PCD message(s) and corresponding HL7 *Profile(s)
  * Profiles developed by NIST to control testing – relieve vendors of burden
- Syntax and Semantic Content Validation
  - Against HL7 V2 message (e.g., PCD-01)
    - Message structure (e.g., MSH,PID,PV1,OBR,NTE,{{OBX},OBX,OBX,OBX,…})
  - Against HL7 profile
    - (Msg_type^Event_type^ e.g., ORU^R01^…)
  - Against HL7 and/or user provided tables
    - Example of user provided table is RTM for Ref_IDs, Units, etc.
  - Against 'validation context', including specific values
    - Defined in XML (e.g., specific test case values)

NIST IHE-PCD HL7 V2 Pre- & Connectathon Test Tool: Reports

- Resultant '*Validation Report*'
- Provides syntax and semantic results of checks against:
  - ✓ HL7 V2 Structure Validation
  - ✓ IHE-PCD Technical Framework/Supplements
  - ✓ Harmonized Rosetta (hRTM)
  - ✓ Test Case (specific value(s))

- Resultant Test reports may be saved (MS Doc)

NIST IHE-PCD HL7 V2 Pre-Connectathon Test Tool:
Testing Validation Types

- Validation against 'failure types':
  - **VERSION*:** The version in the message and in the profile should match.
  - **MESSAGE_STRUCTURE_ID*:** The message type (MSH.9 element) in the profile and in the message should match.
  - **MESSAGE_STRUCTURE:** The message should have a valid message structure (correct usage, correct cardinality, and correct element name).
  - **USAGE:** R elements should be present; X elements should not be present in the message.
  - **CARDINALITY:** Elements should be present at least the minimum times and at most the maximum times specified in the profile. It should also take into account the usage of the element (X element with a minimum of 4 should not be present in the message).
  - **LENGTH:** The value of the element should have a length equal or less than the value specified in the profile.
  - **DATATYPE:** For the data type NM, DT, DTM, SI and TM, the value of the element should match the regular expression defined in the standard.
  - **DATA:** The value of the element should match a constant specified in the profile, a value set specified in a table, a value or a regular expression specified in the message validation context.
  - **MESSAGE_VALIDATION_CONTEXT*:** This is a user input error when the location specified in the message validation context can't be found in the message.
  - **TABLE_NOT_FOUND*:** This is a user input when a table can't be found in the table files (TableProfileDocument).
  - **AMBIGUOUS_PROFILE*:** The profile should not be ambiguous.

HL7 V2 Tools: Next Steps

- Re-visit Lessons Learned from Pre-Connectathon and Connectathon
- Update NIST HL7 tools/documentation accordingly
- Test Case revision/composition
- Start addressing Isolated (Scenario) and Peer-to-Peer type testing for IHE-PCD cycle 5
- Integrate ICS XML resultant files w/ IHE-PCD
  - Volume III/IV – Device-level profiles?

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Tooling Status: *ICSGenerator*

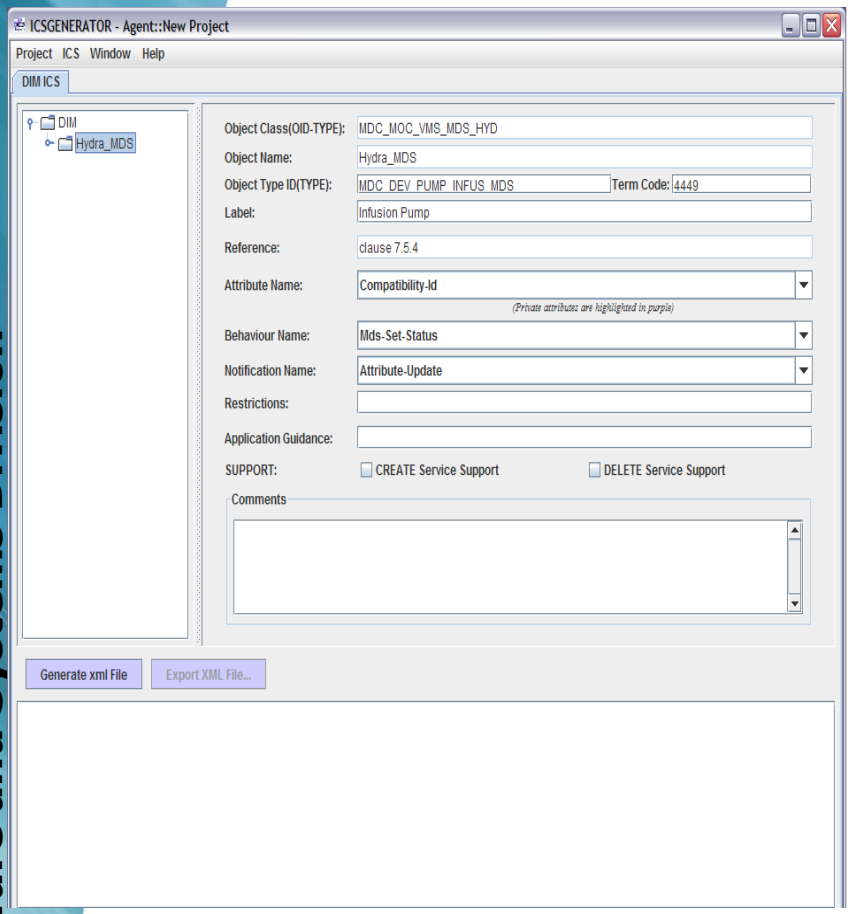
- Interface update:
  - Modified attribute list display for selected MOC in the right pane.
    - ❖ The value and unit are not included in this enhancement, but will be included when Rosetta dbase is incorporated.
  - Added status bar to show the nature of medical device profile (e.g. Application Profile Type).
  - Added tool bar to directly access Tool's functionality.
  - Added a tree panel tool bar to aid in managing and operating ICSGenerator modeling capabilities (also available when right clicking the objects in the tree).
- Incorporated the x73 Nomenclature Dbase
  - Added drop down menu for any text box where data is derived from the database.
    - Infrastructure terms (e.g., object & attribute names)
    - Object Type ID
    - Object Class
  - Term codes auto-filled.
  - The drop down includes auto completion and keyword searching.
  - ICSGenerator does not depend on dbase installation; data accessed via an XML file that contains the x73 Nomenclature Dbase.

Tooling Status: *ICSGenerator (continued)*

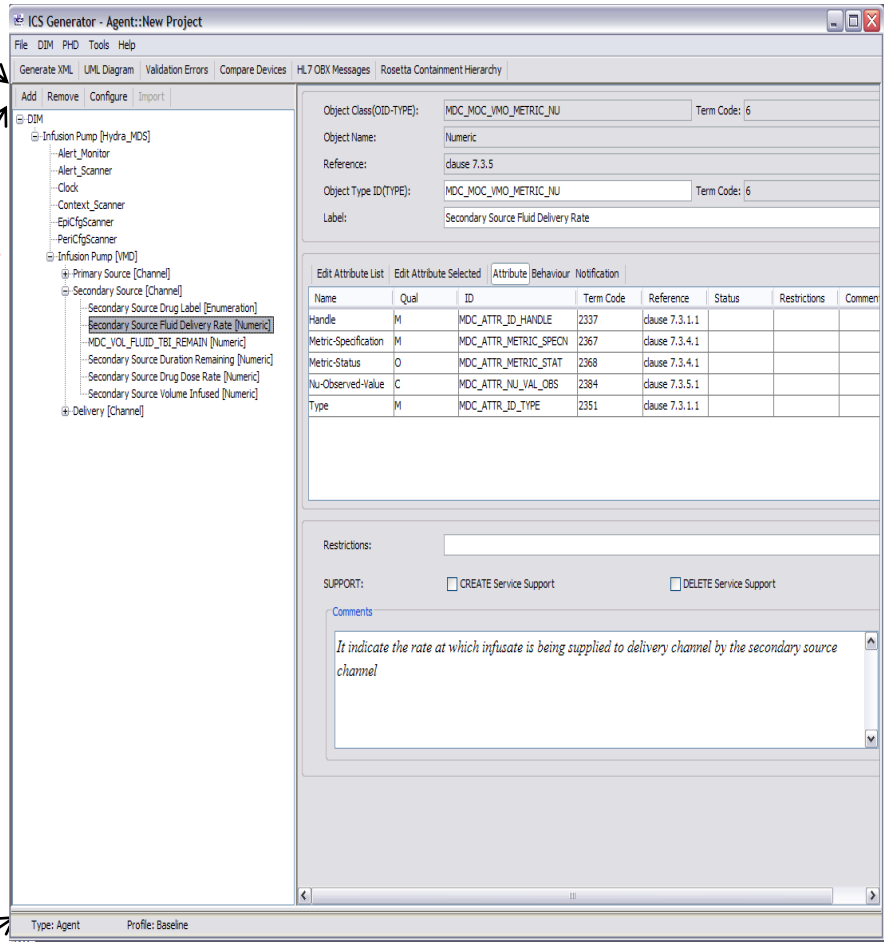
- Added capability for device specialization to constrain attribute status - when the status is not "mandatory".
- Added a transformation capability to generate "proposed" Rosetta Containment Hierarchy (RCH).
  - ICSGenerator supports the generation of:
    - a device specific observation and general attribute observation hierarchy.
    - OBXV visibility (user supplied)
    - OBX-4 representation based on visibility and containment.
    - The ability to save RCH in xml format.
  - ❖ ICSGenerator must be enhanced to support device specialization cardinality constraints.
- Code restructured; Improves:
  - maintainability, expandability, and performance.
- Issues/bugs Fixed
  - Label now fully displayed on Jtree.
  - Attribute update panel no longer hangs when removing attributes and/or adding the changes.

Tooling Status: *ICSGenerator*

Old Interface:



New Interface:



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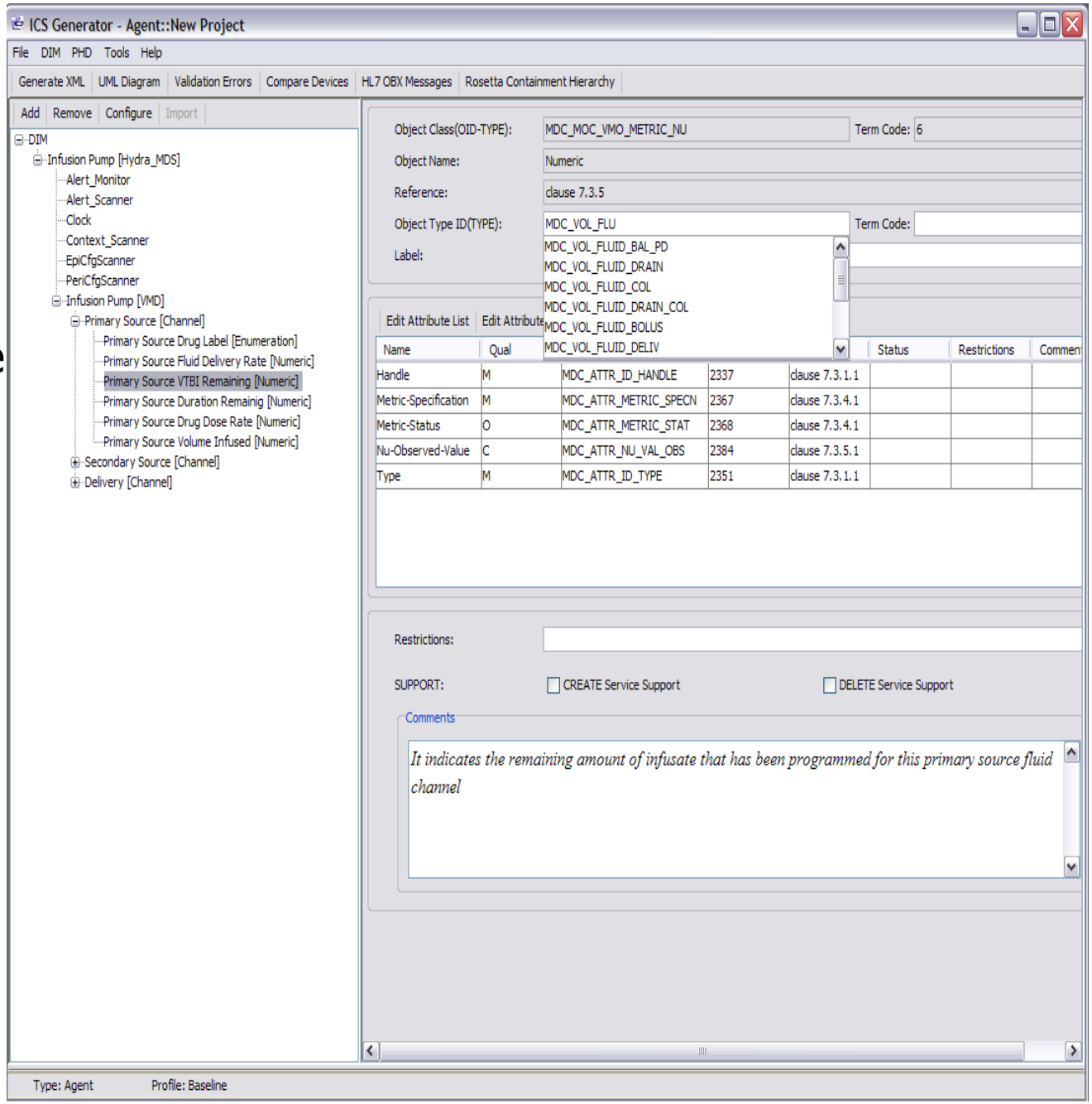
ICSGenerator
Tooling Status

Drop down menu RefIds derived from the x73 Nomenclature database.



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ICSGenerator
Tooling Status

Rosetta Containment Hierarchy Report.

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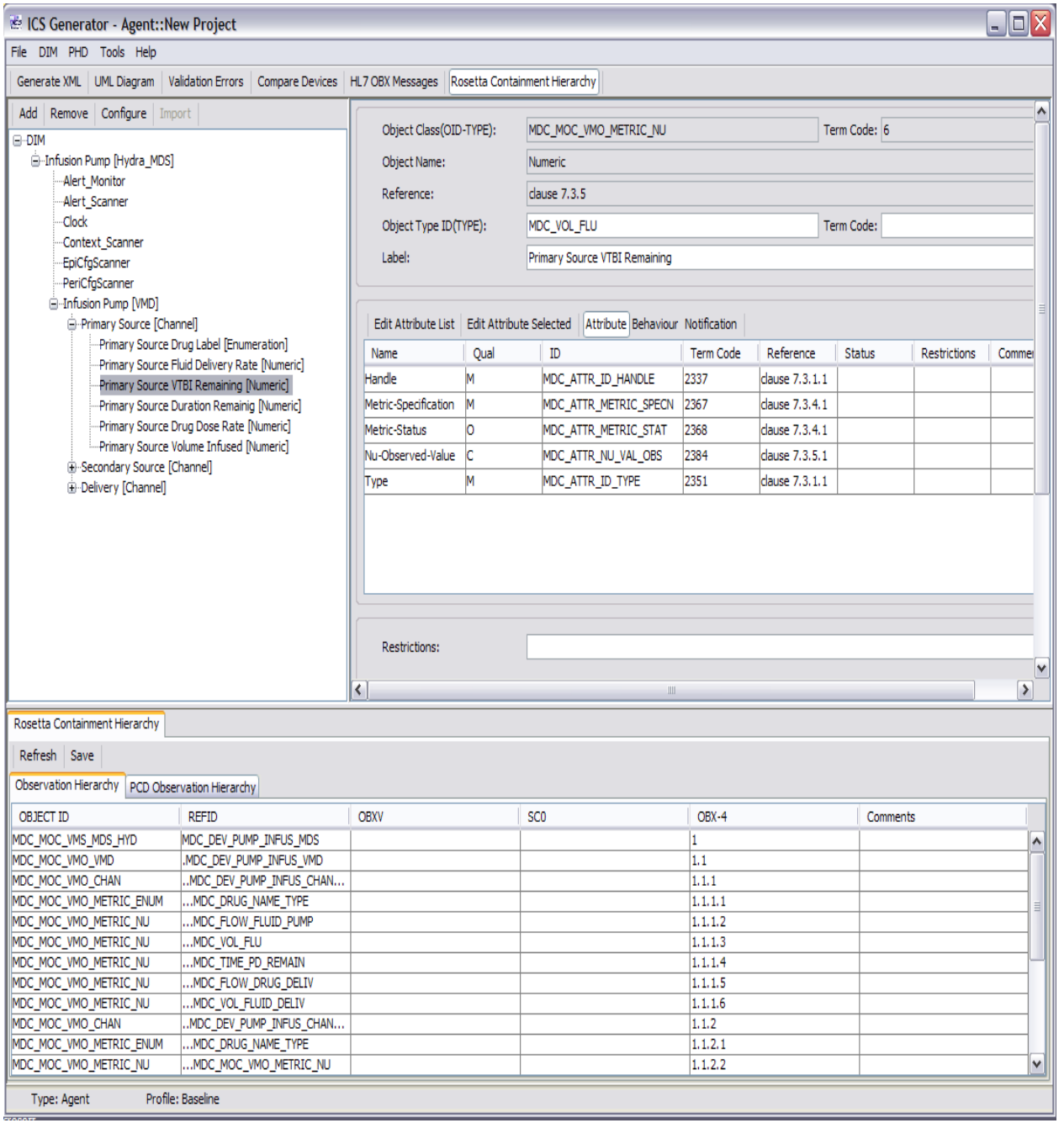

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Tooling Status/Next Steps

ICSGenerator

- Incorporate Rosetta Dbase.
  - Object Type, unit code, metric id (?)- in Nu-Observed-Value value type.
- Add the capability for specializations to constrain object cardinality.
- Value display enhancement.
- Continue improving application interface to increase usability.
- Provide initial guidance (on the right panel) when starting ICSGenerator.
- Finalize implementation of RCH (based on standards-body approval).
  - Implementing OBXV and derived OBX-4
- Update PHD specialization profiles as approved by ISO/IEEE

RTMMS and x73-10201 Status

- RTMMS
  - No update, updates forthcoming as more Rosetta terms identified
  - Management and Hosting Discussion – later in day (Q2/Q3)
- X73-P10201 Electronic DIM (XML Schema)
  - No update

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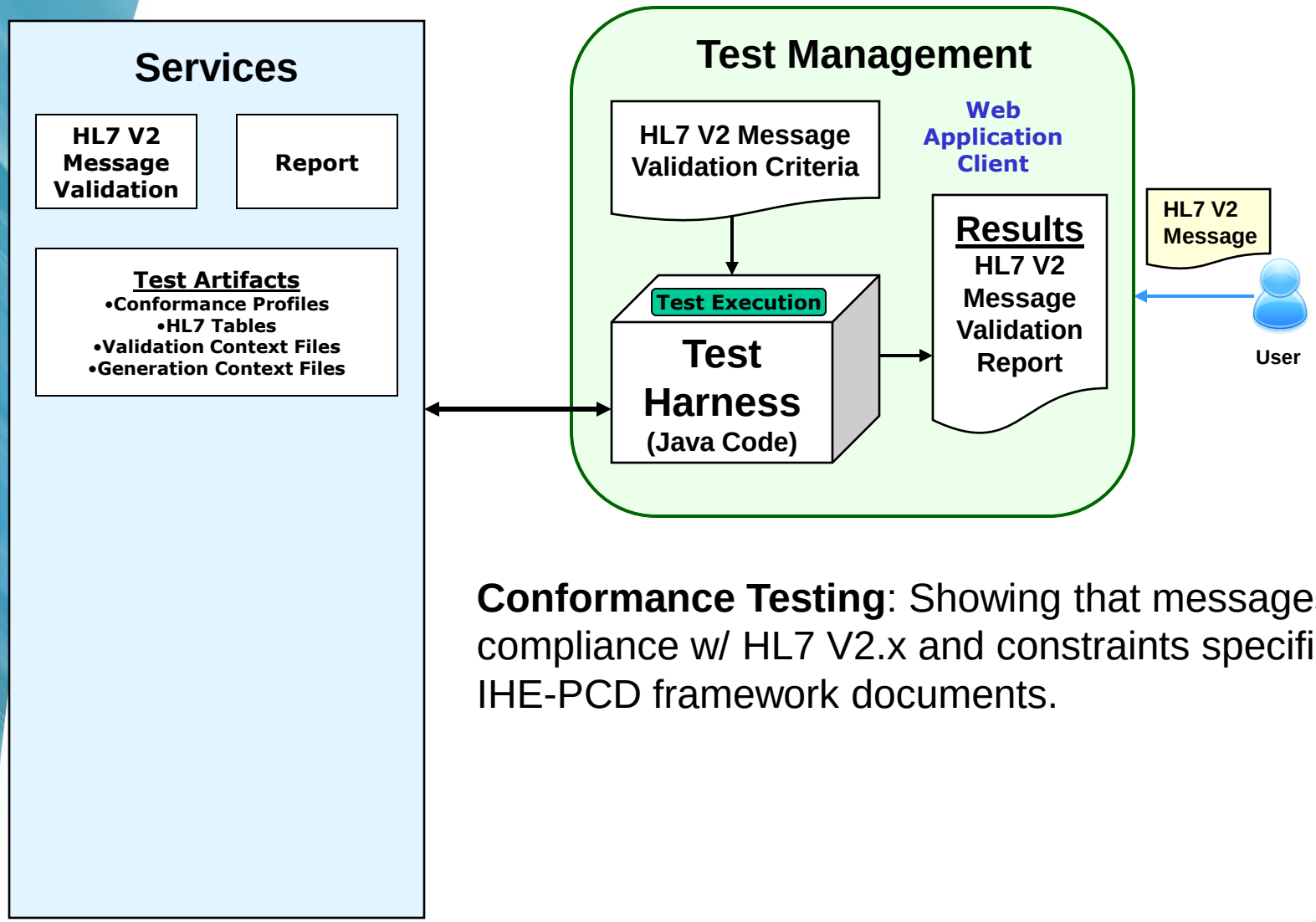
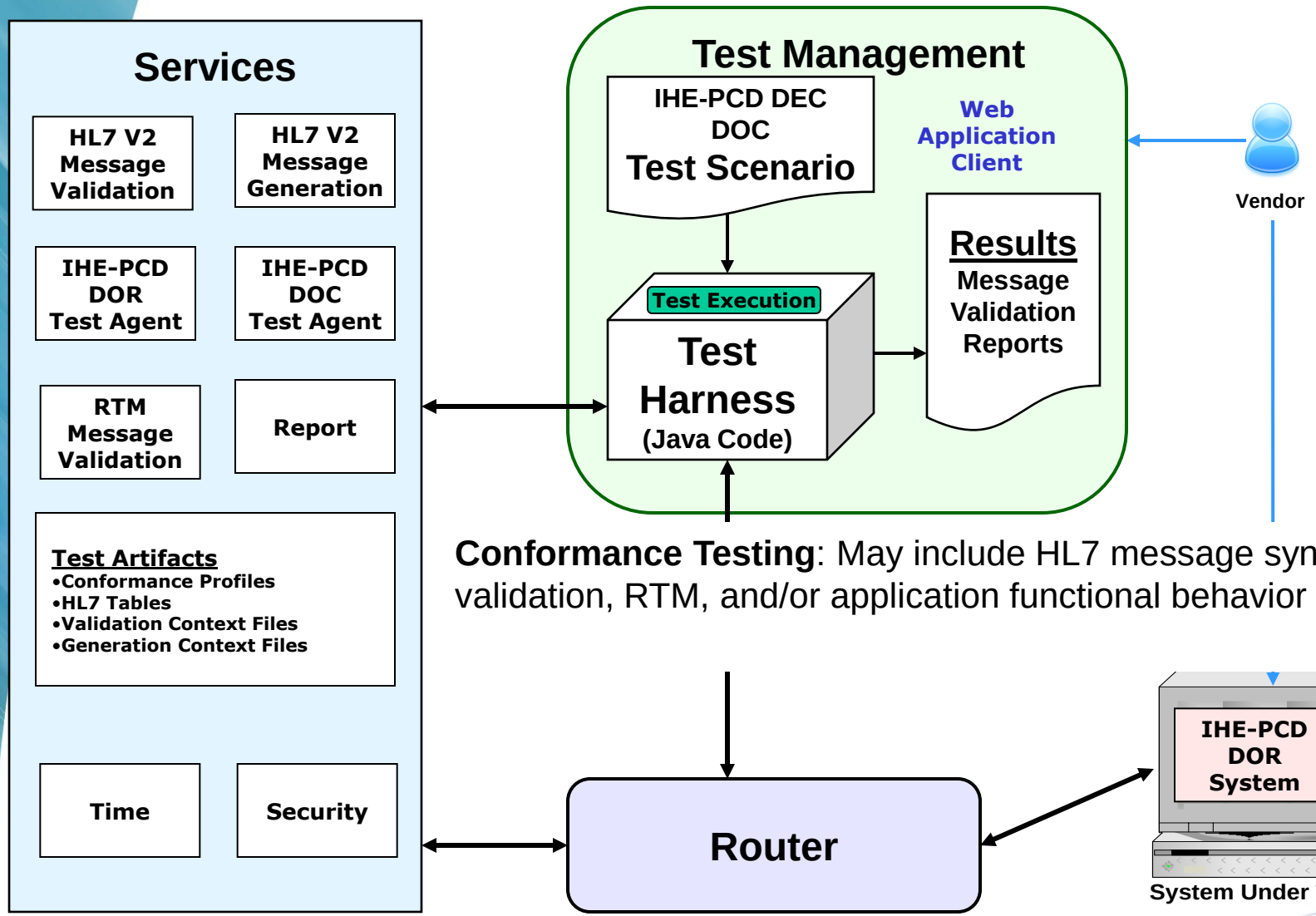
Instance Testing
HL7 V2 *Message Validation*



Conformance Testing: Showing that messages are in compliance w/ HL7 V2.x and constraints specified in IHE-PCD framework documents.

Future: Isolated System Testing

IHE-PCD *Application Functional Behavior Testing*



Conformance Testing: May include HL7 message syntax validation, RTM, and/or application functional behavior testing

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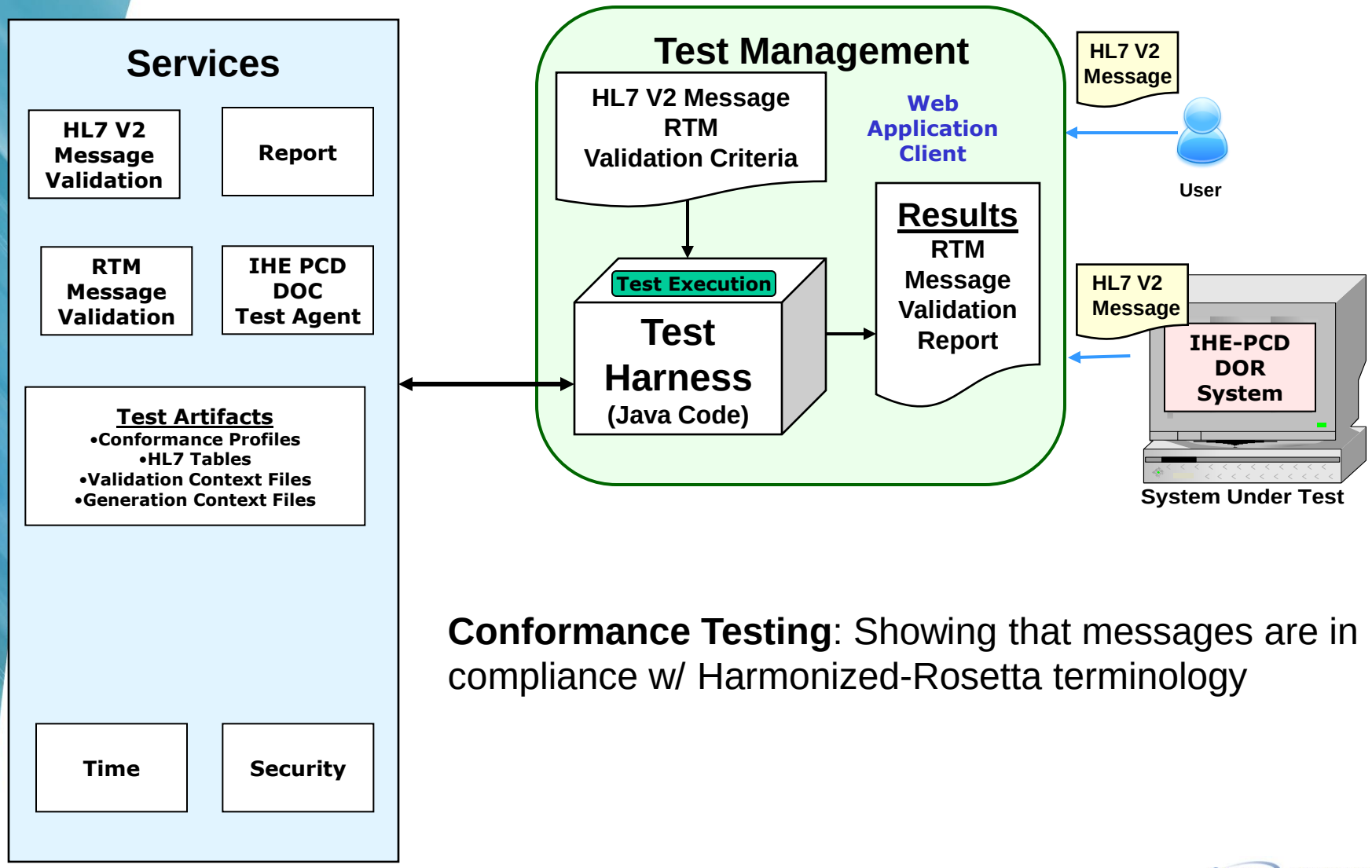
Future: Isolated System Testing
IHE-PCD *RTM Validation*



Conformance Testing: Showing that messages are in compliance w/ Harmonized-Rosetta terminology

Future: Peer-to-Peer System Testing

IHE-PCD *Application Functional Behavior Testing*