NIST Medical Device Communication Testing

Semantic interoperability of Medical Devices

Test Tool Update

HL7 Healthcare Devices WG / IEEE x73 Upper Layers

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22 January, 2015 – San Antonio, Texas

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NIST MDC Testing Staff

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- Nicolas Crouzier (GR)  
  - RTMMS,  
  - HL7 V2 Tools

- Michael Faughn (Contractor - Prometheus Computing, LLC w/ Art Griesser)  
  - DIM Modeling + “DIM Editor” + “MyDevice” (next gen ICSGenerator plus)
Key Discussion Topics

- Work Area & Status Updates
- DIM Editor work updates and tool review
- HL7 Tooling Status & Updates
Work Areas & Status Updates

- **HL7 V2 (2.6) IHE-PCD Validation Tools**
  - Enhancements to Pre-Connectathon, Connectathon Tools to support IHE-PCD Cycle 9
    “Pre-Connectathon 2014-15 (Cycle 9)” results in Pre-Con Tool
  - Cycle 9 - CP updates coded for 2014-15;
    → Fall/Winter Pre-Connectathon + Virtual Testing,
    → January/February 2015 Connectathon
  - IHE-PCD Pre-Connectathon, “Isolated Environment”
  - IHE-PCD Connectathon, “Instance Environment”

- **Rosetta Terminology Mapping Management System (RTMMS)** Overview + Update
  - RTMMS Deployment Update and service status
    - -10101a +
    - IEEE Agreement to make available the “Works” – ‘Common Term’ added
    - Latest numbers…
Work Areas & Status Updates, Continued

- IGAMT – Implementation Guide Authoring Management Tool
  - *Continue to develop PCD-01 (ORU^R01)* …
  - *Initial Goal: Develop first version of IG for PCD-01 (TF Vol. II)*
    • *Focus on IHE-PCD TF Vol. II/III*

- ISO/IEEE 11073 ‘*Domain Information Model Editor*’ -> “DIM Editor”
  - Progress/Update/Status (Michael Faughn)
  - UML Defined x73 DIM (-10201) basis for tooling
  - DIM Editor / ‘*MyDevice*’ pilot tool demo
  - Auto producing ISO/IEEE documentation (to meet SDO’s templates)
    • No major hurdles – from IEEE and w/ document generation
    • Michael provided a sample – Kathryn B. circulated w/in IEEE

  - Continue weekly TCons (Thursdays @ 11 am & 2 pm Eastern)

Work Areas, continued

- IHE North American Connectathon Under Way next week…
  - NIST Connectathon Tool being used for static validation
- John G., Nicolas C., and Sandra Martinez serving as test monitors
- John G. participating ("Staff") in IHE’s education series
  ("Connectathon 101") – presenting session on how PCD tests…
Royalty Free Agreement – Addendum (Sept. 2014)

- IEEE / NIST Royalty Free Agreement – December 2012

Definition of the “Works”

The following data items within the approved standards, existing and future versions, currently designated as:
1 - IEEE 11073-10xxx
2 - IEEE 11073-20xxx

Limited to the following data items within, currently designated as:
1 - Ref ID
2 - Code
3 - Description
4 - Systematic Name

Shall heretofore be designated as the “Works”

- September 2014

Add to the Definition of the “Works”
Data item
5 – Common Term
HL7 V2.6 Validation Tooling
IHE-PCD Pre-Connectathon Cycle 9

Semantic interoperability of Medical Devices

Test Tool Update
Joint HL7/IEEE 11073 Healthcare Devices Working Group

National Institute of Standards and Technology
22 January, 2015 – San Antonio, Texas
Contact: john.garguilo@nist.gov, 301-975-5248
Testing Environments

• Instance Testing
  – Conformance (e.g., against HL7 2.x or CDA)
    • Test object conforms to specification on which it is based
    • IHE Model: ~Virtual and Pre-Connectathon
    • NIST IHE-PCD v2 Message Validation Test Tool

• Isolated System Testing
  – Includes Instance Testing Activities
  – Protocol Conformance
  – Functional Behavior Conformance
    • Features and operational behavior correspond to specifications
    • IHE Model: ~Virtual and Pre-Connectathon
    • NIST IHE-PCD v2 Test Tool

• Peer-to-Peer System Testing
  – Includes Isolated System Testing Activities
  – Interoperability Testing
    • Testing complete application environment
    • May include interacting with Database, using Network Communications, or interacting with other hardware, applications, or systems if appropriate
    • IHE Model: ~Connectathon
The NIST V2 (2.6) Tools perform the following validation:

- Syntax and Semantic Content Validation
  - Against HL7 conformance profile
  - Against IHE-PCD Technical Frameworks/Supplements constraints (e.g., PCD-01: ORU^R01, Communicate Device Data)
  - Against HL7 and/or user [local] provided tables
    - Example of user provided table is RTM for Ref_IDs, Units, body sites, etc.
  - Against ‘validation context’, including specific values
    - Defined in XML (e.g., specific test case values)
NIST V2 HL7 IHE-PCD Test Tool: Operational Process

INTERACTION/REPORTS | MANUAL OR AUTOMATED SUT
---|---
END-USER (VENDOR)

Web Application Interface

MESSAGES (TEST OBJECTS)

NIST IHE-PCD HL7 v2/v3 TEST TOOL

(via the communication protocol currently only MLLP)

STIMULUS OR RESPONSE (MESSAGES)

SYSTEM UNDER TEST (SUT)

SPECIFICATIONS
(test material that defines test assertions)

V3 – Future Work
• Cycle 9 - Test Cases/demographics reviewed – used as basis for tooling at 2015 NA Connectathon

• IHE-PCD Fall F2F
  – Oct 20-24, 2014 @ Philips in Boca Raton, Fl.

• IHE-PCD Cycle 9 Pre-Connectathon

• CPs documented and submitted (see PCD wiki)
  – Note: Agreement on two CPs* (prior to “official” ballot to accommodate cycle 9 testing)
  – 11 CPs received and processed: http://wiki.ihe.net/index.php?title=PCD_CP_grid

• Roadmap of activities updated… see PCD wiki

* To accommodate recent Alert terminology (to be included in 10101a release), e.g., “196616^MDC_EVT_ALARM^MDC “
IHE-PCD: NIST “Isolated Environment” Test Tools required

- HL7 V2.6
- Supports 8 Integration Profiles (number of test cases, some duplicated amongst actors)
  - DEC – Device Enterprise Communication (10)
    - SPD – Filter (4)
    - POI – Pulse Ox (3)
  - PIV – Patient Infusion Verification (9)
  - IPEC – Infusion Pump Event Communication (6)
  - IDCO – Implantable Device Cardiac Observation (4)
  - ACM – Alarm Communication Management (2)
  - RDQ – Retrospective Data Query (1)
  - MEMDMD – Device Management Communication (1)
  - MEMLS – Location Services (1)
  - OMS, RTLS/CMS, Security white papers/WGs

- 30+ Unique Test Cases (across ‘Actors’)
2014-15 IHE-PCD Pre-Connectathon Tool: Cycle 9 Status, continued

- 60+ existing User Accounts
  - Contributing Orgs, SDO (leads/Co-chairs), Reviewers
  - In total since tool made publically available (2011)
- 17 Users – cycle 9
- 106 Test Cases – executed in Cycle 9
  - Recorded or stored by NIST tool registered user

- **Cycle 8**: 22 Users, 115 Tests Executed/Stored
- **Cycle 1-7**: 42 Users, 99 Tests Executed/Stored*
  
  *Cycles 1-7 not all test were stored in tool – 99 tests are primarily from cycle 7
HL7 V2 Tool Updates – New/In Progress

- Various test cases corrections (messages examples, validation contexts…) – Update to reflect updated TF
- IPEC containment tree validation tested; now integrated into tooling for Cycle 9 (as of summer 2014)
- Pre-Connectathon tool, fixed test case scenarios and validation files for DOC-DOR-DOF test cases.
- Limit of 999 for HD-2 length error on MSH-3
  - Should be 199 with total length of 277 for combined length of components
  - Updated TF-2 table (page 140, table C.6-1, second component (999) to 199)
- Updated tool to fix error on OB X-3 validation
  69986^MDC_DEV_PUMP_INFUS_VMD^MDC
HL7 V2 Tool Updates, New for Cycle 9, continued

PRE and Connectathon tools:


✓ [PRE] Re-engineered overall the way tests are represented and processed in the system. This makes testing more stable and faster, allows the potential for dynamic testing (i.e. testing against values vendors enter at launch of test).

✓ [PRE] Every validation artifact is now stored in a database thus allowing faster updates.

✓ [PRE] ‘Admin’ User type can create test case “live”, in future similar functionality could be added (fully or partially) for all users.

✓ [PRE] Accept ‘Ack’ now generated and sent as appropriate (Previously, some ‘Acks’ were not sent at all when certain errors occurred in the inbound message)
HL7 V2 Tool Updates, New for Cycle 9, continued

✓ Better and faster profile viewer
✓ Added MEMLS and MEMDMC profiles and basic test recently for Cycle 9 (1 test case each)
✓ Nomenclature update for ACM
✓ Updated POI tests and profiles
✓ Updated DOC-DOF tests
✓ Better log system for admin to help with user issues
✓ Some fixes in user interface for browser compatibility and logging issues
HL7 V2 Tool Updates, RTMMS – New for Cycle 9

✓ Moved to secure server, new address: https://rtmms.nist.gov
✓ Added timestamp to terms for latest update
✓ Added term standard table field (i.e., table in x73 Standard) and populated values for available terms
✓ Added API for ‘My Device’
✓ Updated some terms and corresponding co-constraints that were missing
✓ Fixes in UI and a small performance tweak
HL7 V2 Tool Updates, continued – To Do

• Cycle 10: Looking into capability to upload libraries + demographics
  • incorporated [automatically] into validation context files used by tooling
RTMMS by the numbers (as of 21 January 2015) – (since September 2014)

- 1619 (0) Rosetta terms
- 667 (-4) hRTM terms
- 224 (0) Groups
- 8 (0) Unit Groups
  - 445 (0) Units (MDC)
  - 444 (+14) Units (UCUM)
- 28 (0) Enumeration Groups
  - 273 (0) Enumerations
- 57 (+8) Contributing Organizations now Registered!
Terms being vetted (by the numbers)

- “Proposed Terms”: 192 rows (0)
- “Ready Terms Table”: 282 rows (-4)
- “Mapped Terms”: 33 rows (+6)
- “Proposed Units”: 101 rows (0)
- “Proposed Enumerations”: 133 rows (0)

As of January 21, 2015 (Since September 2014)
Tool Updates: Test Event Selection

- Top Right Corner – Cycle 9 Event - to enable separation (historical) of test event results (for/by participants, current being Cycle 9 (Fall – Winter 2014-15)
- Simply choose other Event (from pull-down) to see past results stored for (by user account/Log-in)
Tool updates – Profile Viewer – updated to reflect CPs
HL7 V2 Tool Updates

- Current Version / Release Notes – new text entry feature (only for ‘Admin’ user role)
  - ‘About’ Tab (yellow ribbon)
HL7 V2 Tool Updates

- Admin view of log entries (i.e., messages by SUT)
HL7 V2 Tool Updates

- Admin view of exchanged HL7 V2 message (being validated) after selection prior slide’s “View” button
**HL7 V2 Tool Updates**

- Updated Documentation Tab for Cycle 9 testing
  - Conformance Profiles, Demographics, Drug Library

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**IHE-PCD Pre-Connectathon Test Tool**

Welcome, Admin | Log out
Current testing event: Pre-Connectathon 2014-2015 (Cycle 9)

Overview | Execute Test | User Account | Profile Viewer | Test Case Manager | Resources Management | Documentation | Contact us | About

- **Conformance profiles**
- **Patient Demographics**
- **IDCO Patient Demographic**
- **PIV Drugs**

The following table contains NIST documentation for the PCD Validation Tool

<table>
<thead>
<tr>
<th>Resource</th>
<th>Link</th>
</tr>
</thead>
<tbody>
<tr>
<td>HL7</td>
<td><a href="http://www.hl7.org">http://www.hl7.org</a></td>
</tr>
</tbody>
</table>

**PCD v2 Conformance profiles**

- PCD01 ORU R01 / PCD01 ACK R01
- PCD02 QSB Z02 / PCD02 ACK Z02
- PCD03 RGV O15 / PCD03 ACK O15
- PCD03 RRG O16 / PCD03 ACK O16
- PCD04 ORU R40 / PCD04 ACK R40
- PCD09 ORU R01 / PCD01 ACK R01
- PCD10 ORU R42 / PCD10 ACK R42
- PCD12 QBP O11 / PCD12 ACK O11
Rosetta Terminology Mapping Management System - RTMMS

Semantic interoperability of Medical Devices

Test Tool Update
Joint HL7/IEEE 11073 Healthcare Devices Working Group

National Institute of Standards and Technology
21 January, 2014 – San Antonio, TX
Contact: john.garguilo@nist.gov, 301-975-5248
RTMMS Overview

• A web application* that allows vendors and reviewers access, retrieval, and reporting of Rosetta Tables over the internet in conformance to IHE-PCD RTM Profile
• An electronic resource/tool providing the capability of saving data in xml format (as defined by RTM Profile)
• Aids the harmonization process by:
  – Identifying missing terms
  – Automatic generation of the “Harmonized Rosetta Table”
  – Providing latest up-to-date view of hRTM table
• Facilitates the proposal of New Terms to IEEE 11073 Nomenclature standard
• Facilitates Conformance Tooling
  – Message verification and conformance (syntax and semantics)
  – Leading to interoperability…
  – *developed by and currently hosted at NIST
  – Integrated with ICSGenerator Tool (hRTM also imported into DIM Editor)
Rosetta Terminology Mapping Data Base

- **Rosetta Table**
  - Maps vendor supported observations, units and enumerations to ISO/IEEE x73 nomenclature

- **Units Table**
  - Defines allowed units-of-measure
  - Defines groups of related units-of-measure

- **Enumerations Table**
  - Defines groups of enumerated values

- **hRTM Table**
  - Generated from the original Rosetta X73 Nomenclature DB

**RTMMS Key Tables**

- Linked to RTMMS Security DB - Stores users information
RTMMS Key Features

- Access to NIST IEEE 11073 Nomenclature database
  - Appendix A terms (from ISO/IEEE 11073 10101: Nomenclature)
  - Appendix B terms (from ISO/IEEE 11073 10101: Nomenclature)
  - IDCO terms (ISO/IEEE 11073-10301 – implantable device cardiac)
  - aECG (annotated Electrocardiography)
  - PHD terms (personal health domain)

- Access to RTM database

- Ability to propose terms in Rosetta

- hRTM, units, and enumeration download-able in XML format

- User registration
  - Email confirmation, approval process… controlled through ‘admin’

- Filtering based on regular expressions

- Rosetta validation against hRTM

- Management capabilities for SDO users

  ❖ Integrated w/ ICSGenerator / exported to ‘DIM Editor’
- General user
  - Views Rosetta Tables
- Reviewer
  - Participates in discussions
- Contributing Organizations
  - Vendor/Contributer ‘sandbox’
  - Modifies Vendor Rosetta Table
  - Suggests new terms
  - Modifies Units and Enumerations Table
- SDO (Standard Development Organization)
  - Modifies Units and Enumerations Table
  - Register new terms
- Admin
  - Manages User Accounts
RTMMS by the numbers (as of 21 September 2014) – (since September 2014)

- 1619 (0) Rosetta terms
- 667 (-4) hRTM terms
- 224 (0) Groups
- 8 (0) Unit Groups
  – 445 (0) Units (MDC)
  – 444 (+14) Units (UCUM)
- 28 (0) Enumeration Group
  – 273 (0) Enumerations
- 57 (+8) Contributing Organizations now Registered!
Agreement finalized between IEEE and NIST (Dec 2012, Sep. 2014)
• Allows users free and public access of terminology attributes that were formally ‘pay-for’ via the NIST tool
• The “Works”

Definition of the “Works” [from IEEE/NIST Agreement]
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Limited to the following data items within, currently designated as:
1 – Ref ID
2 – Code
3 – Description
4 – Systematic Name
5 – Common Term – added to agreement in Sept. 2014 (worked w/ Kathryn Bennett/IEEE to amend)
RTMMS Primary Updates – Signed Agreement 12/20/12

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WHEREFOR, the signatories below, having signed this License Agreement, attest as to having the authority to enter into this Agreement and, agree to comply with all of the terms and conditions, covenants and obligations contained herein.

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Division Chief
Title

12. 20. 12
Date
• Project Web site: www.nist.gov/medicaldevices

• NIST HL7 V2 Test Tooling Web sites:
  ➢ IHE-PCD Pre-Connectathon:
    http://ihe-pcd-precon.nist.gov/
  ➢ IHE-PCD Connectathon:
    http://ihe-pcd-con.nist.gov/

• NIST Medical Device Terminology Service:
  ➢ Rosetta Terminology Mapping Management System (RTMMS):
    http://rtmms.nist.gov/

• NIST Implementation Conformance Statement Generator (ICSGenerator): (no longer supported)
  – http://hit-testing.nist.gov/medicaldevices/ICSGenerator/ics_download.html

• DIM Work
  – http://mdcx73-working.wikispaces.com/_NIST-ArtG
Domain Information Model
UML / DIM Editor, Progress Update

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Test Tool Update – Michael Faughn
Prometheus Computing

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