### HEALTH IT STANDARDS TESTING INFRASTRUCTURE

# NIST Medical Device Communication Testing

Semantic interoperability of Medical Devices

Test Tool Update
HL7 Healthcare Devices WG / IEEE x73 Upper Layers

John J. Garguilo
National Institute of Standards and Technology
22 January, 2015 – San Antonio, Texas

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#### **NIST MDC Testing Staff**

- John J. Garguilo
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   john.garguilo@nist.gov
- 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

## HEALTH IT STANDARDS TESTING INFRASTRUCTURE

# 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

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#### **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

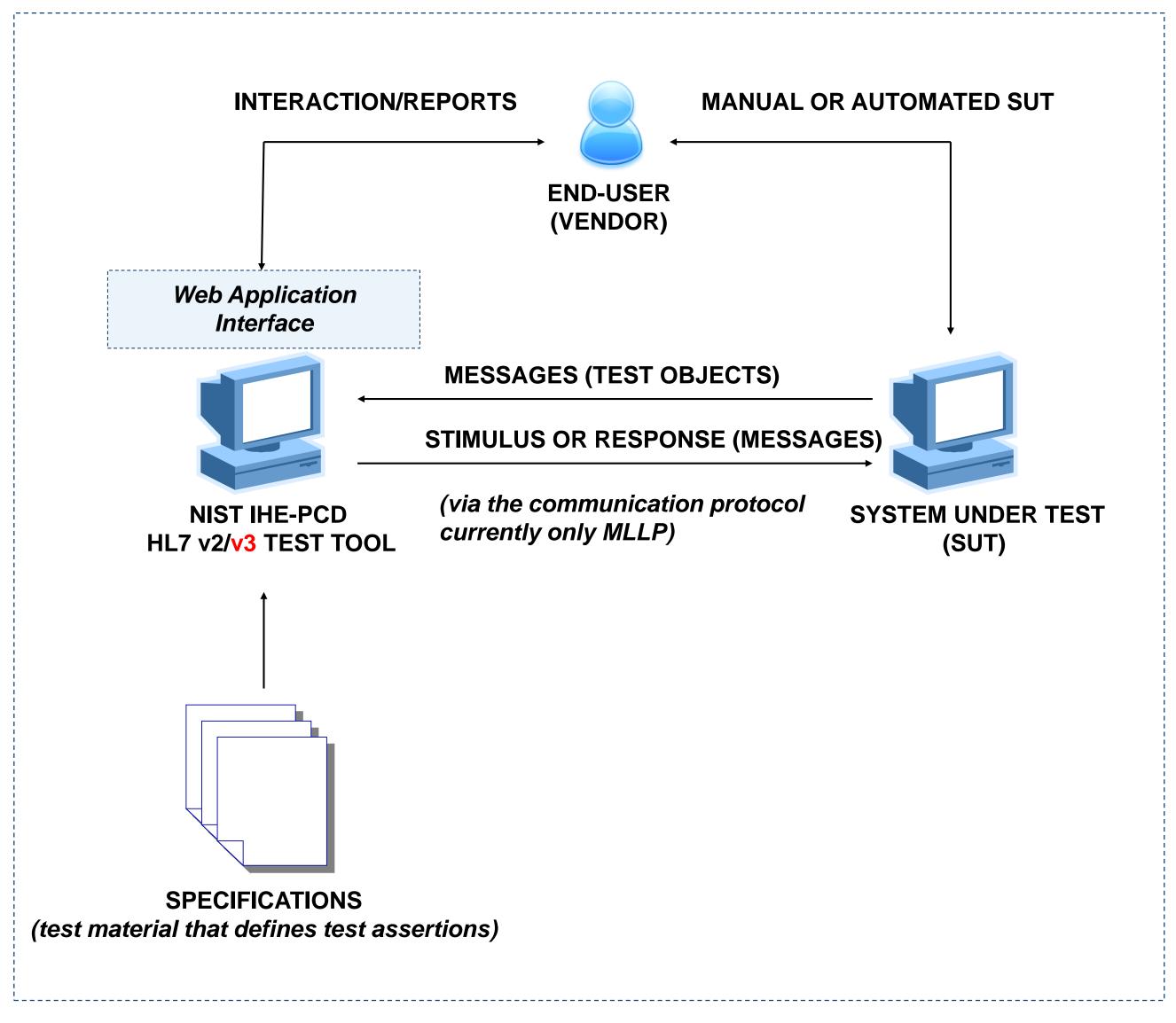
- Includes Isolated System Testing Activities
- Interoperability Testing
  - Testing complete application environment
  - May include interacting with Database, using Network Communications, or interacting with other hardware, applications, or systems if appropriate
  - IHE Model: ~Connectathon

# IHE-PCD 2014/15 Pre-Connectathon + Connectathon **NIST Testing Support**

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**



V3 – Future Work

#### 2014-15 IHE-PCD

#### **Pre-Connectathon + Connectathon Status**

- 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
  - Dec. 2014 Jan. 2015 via on-line tool (ihe-pcd-precon.nist.gov)
- 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: <a href="http://wiki.ihe.net/index.php?title=PCD\_CP\_grid">http://wiki.ihe.net/index.php?title=PCD\_CP\_grid</a>
- Roadmap of activities updated... see PCD wiki

http://wiki.ihe.net/index.php?title=Patient\_Care\_Devices

<sup>\*</sup> To accommodate recent Alert terminology (to be included in 10101a release), e.g., "196616^MDC\_EVT\_ALARM^MDC "

# **2014-15 IHE-PCD Pre-Connectathon Tool: Cycle 9 Status,**Continued

- 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)
    - MEMDMC 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 <u>Pre-Connectathon Tool:</u> <u>Cycle 9 Status</u>, 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.
- ✓ Completed implementing PCD CPs (97-108 from) http://wiki.ihe.net/index.php?title=PCD CP grid)
- ✓ 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 & CON] Moved to faster server, new addresses: <a href="http://ihe-pcd-precon.nist.gov/">http://ihe-pcd-precon.nist.gov/</a> and <a href="http://ihe-pcd-con.nist.gov/">http://ihe-pcd-con.nist.gov/</a>
- ✓ [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, <u>RTMMS</u> – 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!



# Term Approval, Proposed cont. As of January 21, 2015 (Since September 2014)

Terms being vetted (by the numbers)

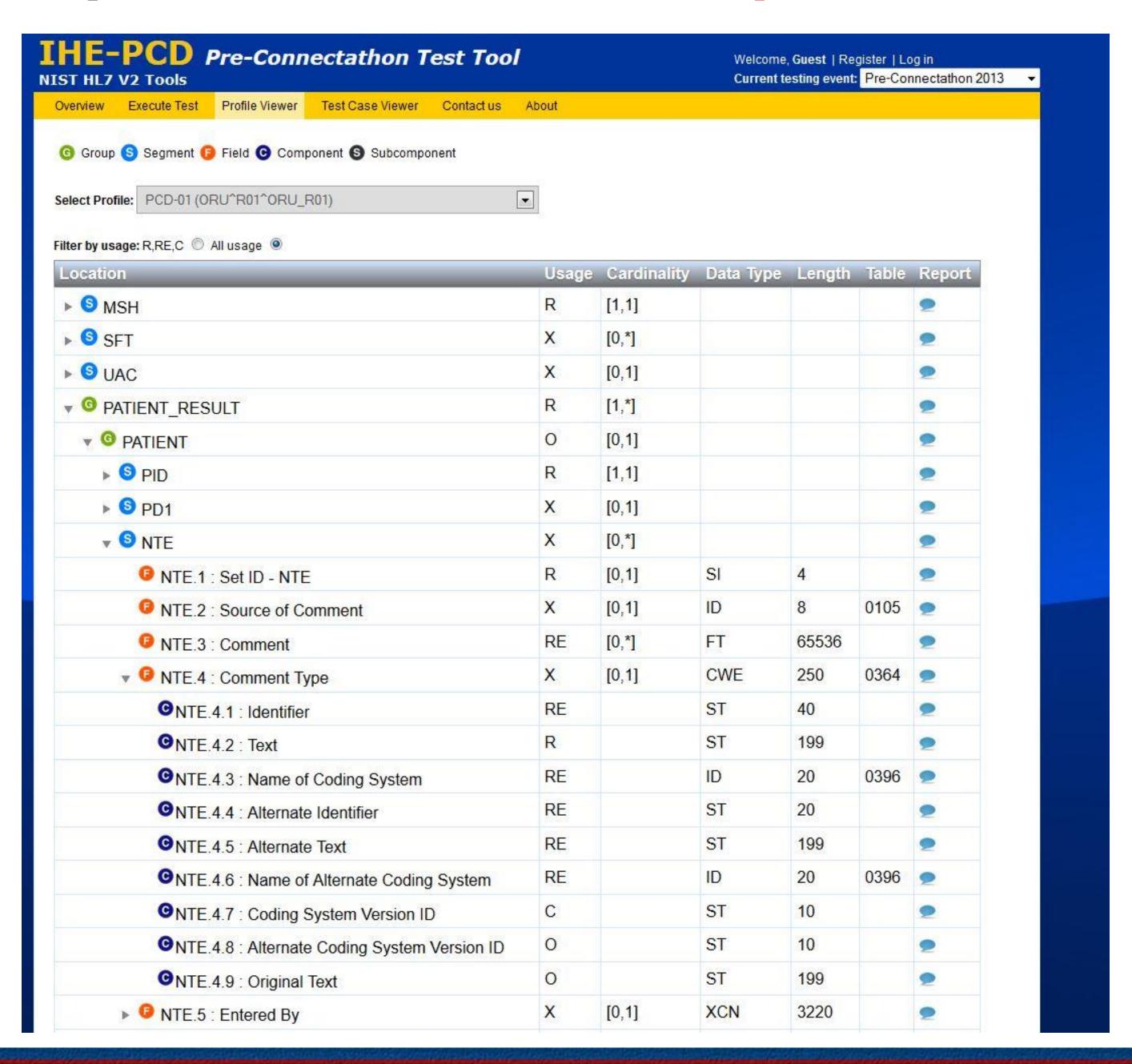
- "Proposed Terms": 192 rows (0)
- "Ready Terms Table": 282 rows (-4)
- "Mapped Terms": 33 rows (+6)
- "Proposed Units": 101 rows (0)
- "Proposed Enumerations": 133 rows (0)

#### **Tool Updates: Test Event Selection**

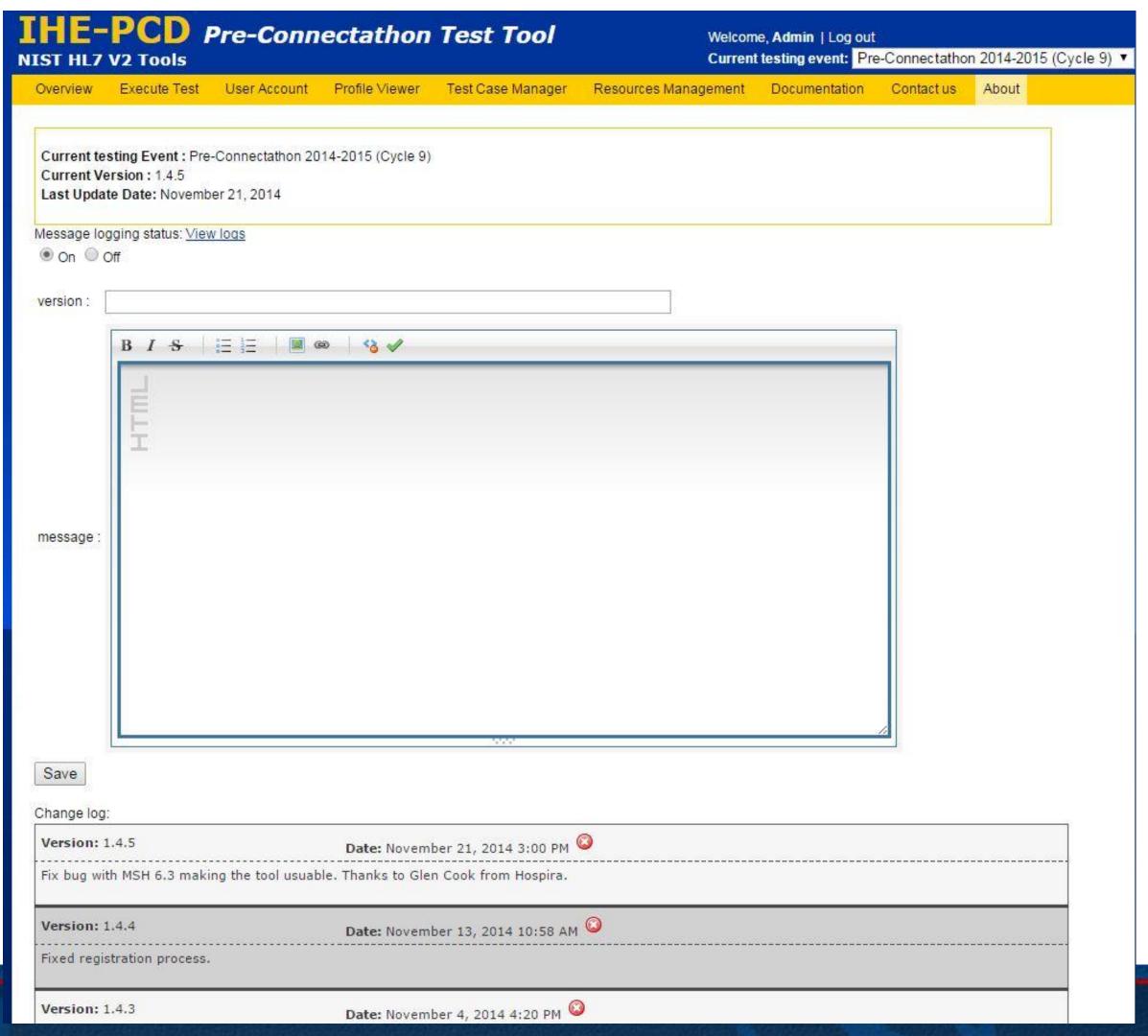


- Top Right Corner Cycle 9 Event to enable separation (historical) of test event results (for/by participants, current being Cycle 9 (Fall – Winter 2014-15)
- Simply choose other Event (from pull-down) to see past results stored for (by user account/Log-in)

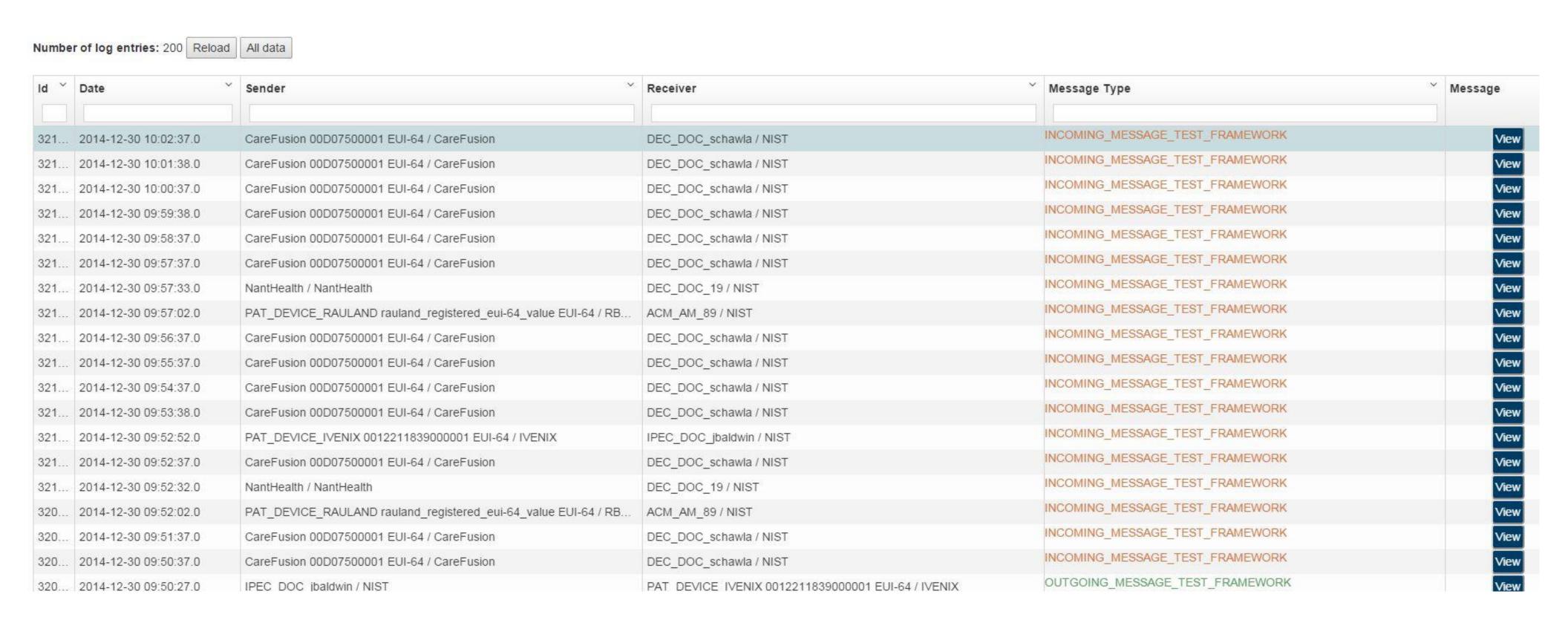
#### **Tool updates – Profile Viewer – updated to reflect CPs**



- Current Version / Release Notes new text entry feature (only for 'Admin' user role)
  - 'About' Tab (yellow ribbon)



Admin view of log entries (i.e., messages by SUT)

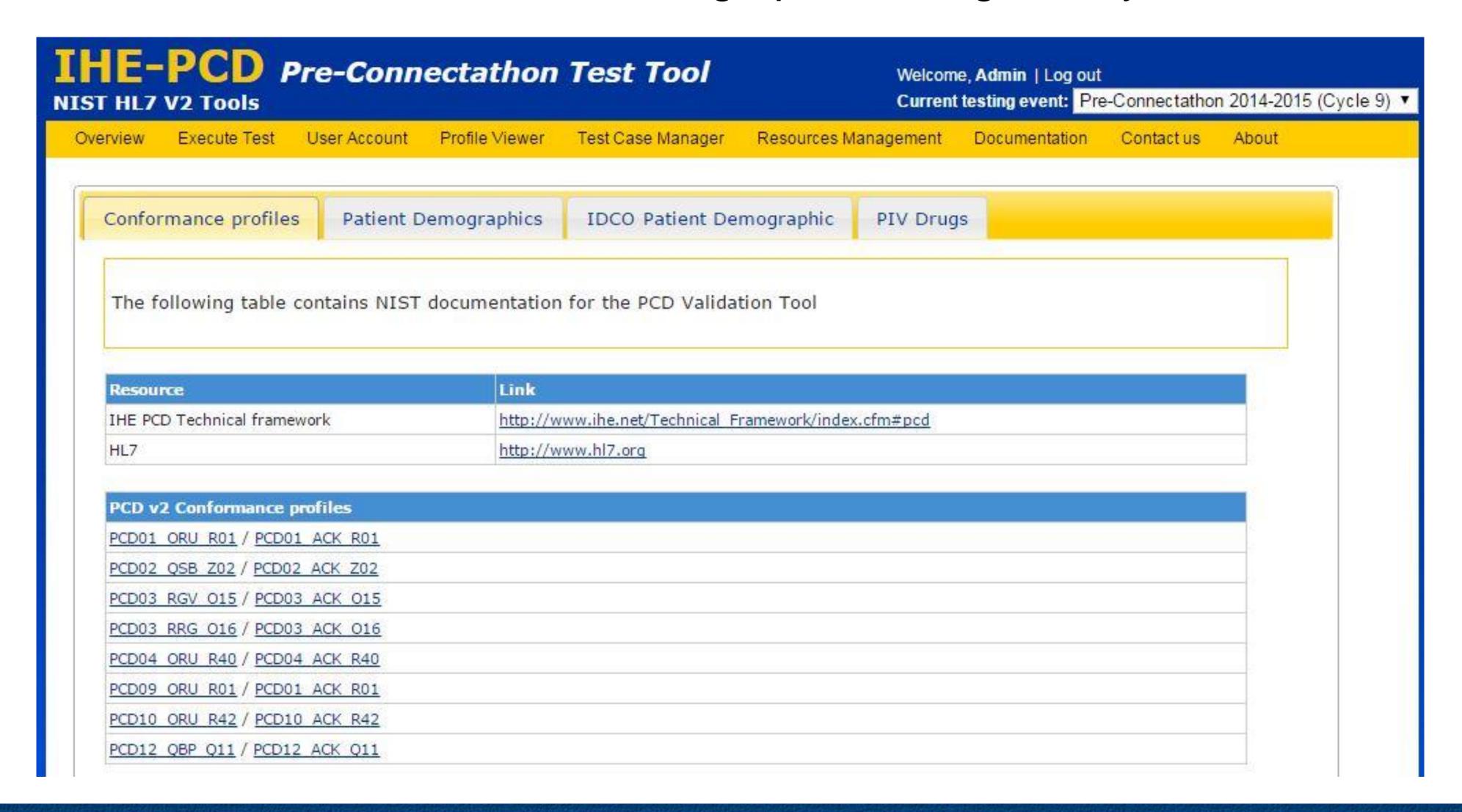


 Admin view of exchanged HL7 V2 message (being validated) after selection prior slide's "View" button

Message info for CareFusion 00D07500001 EUI-64 / CareFusion to DEC\_DOC\_schawla / NIST on the 2014-12-30 10:02:37.0 MSH|^~\&|CareFusion^00D07500001^EUI-64|CareFusion|DEC\_DOC\_schawla|NIST|20141230070238-0800||ORU^R01^ORU\_R01|1412300702385349|P|2.6|||AL|NE|||||IHE\_PCD\_ORU\_ OBX[1][69985^MDC\_DEV\_PUMP\_INFUS\_MDS^MDC[1.0.0.0][][][X][20141230070233-0800][]M8015S12460079^Alaris^00D075BA9DDD8F2F^EUI-64[20141230070233-0800] OBX|2||70050^MDC\_DEV\_PUMP\_INFUS\_LVP\_VMD^MDC|1.1.0.0||||||X|||20141230070233-0800|||M8100S12656404^Alaris^00D075BC98844314^EUI-64|20141230070233-0800 OBX|3||70067^MDC\_DEV\_PUMP\_INFUS\_CHAN\_DELIVERY^MDC|1.1.1.0||||||X|||20141230070233-0800|||||20141230070233-0800 OBX|4|CWE|184512^MDC\_PUMP\_MODE\_CURRENT^MDC|1.1.1.50||||||R|||20141230070233-0800|||2^AMEAS||20141230070233-0800 OBX|5|CWE|184508^MDC\_PUMP\_STAT^MDC|1.1.1.51|^pump-status-not-infusing^MDC|||||R|||20141230070233-0800|||2^AMEAS||20141230070233-0800| OBX|6|CWE|184513^MDC\_PUMP\_NOT\_INFUSING\_REASON^MDC|1.1.1.55|^pump-stopped-standby^MDC|||||R|||20141230070233-0800|||2^AMEAS||20141230070233-0800|



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



## HEALTH IT STANDARDS TESTING INFRASTRUCTURE

# 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)

#### RTMMS Key Tables

#### 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

Linked to RTMMS

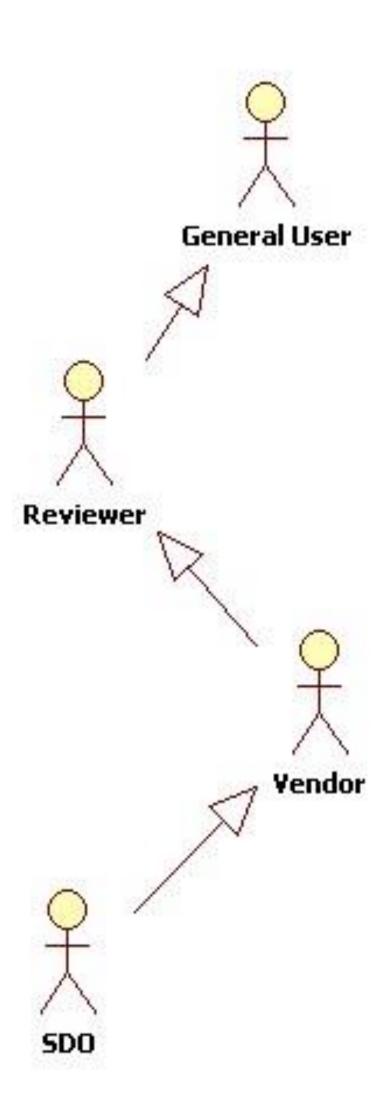
Security DB - Stores users information

#### **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'

#### **RTMMS Users**

- 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



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#### RTMMS Terminology Access and Views

- ✓ 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]

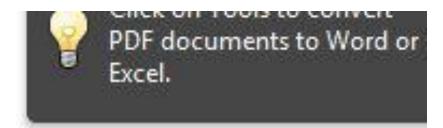
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Limited to the following data items within, currently designated as:

- 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



For IEEE:

Konstantinos Karachalios Managing Director, IEEE-SA The Institute of Electrical and Electronic Engineers, Inc. 445 Hoes Lane, Piscataway, NJ 08854

For NIST: Ram Sriram Chief - Systems and Software Division Information Technology Laboratory National Institute of Standards & Technology 100 Bureau Drive, Gaithersburg, MD 20899

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.

Licensor	Licensee	
Signature Konstantinos Kanachalics Name	Signature  Ram D. Svivaim  Name	
Managiny Director I ECE-SH Title	Title	
Date Dec 2012	12 · 2 0 - 12 Date	

#### **NIST MDC Testing Project**

- Project Web site: www.nist.gov/medicaldevices Web Sites
- 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

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# Domain Information Model UML / DIM Editor, Progress Update

Semantic interoperability of Medical Devices

Test Tool Update – Michael Faughn
Prometheus Computing
Joint HL7/IEEE 11073 Healthcare Devices Working Group

National Institute of Standards and Technology 22 January 2015 – San Antonio, Texas

