

HEALTH IT
STANDARDS TESTING INFRASTRUCTURE

NIST Medical Device Communication Testing

Semantic interoperability of Medical Devices

Test Tool Update

Joint IEEE / HL7 May WG Meeting @ San Diego, CA

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12 September 2017 – San Diego, California

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NIST MDC Testing Staff

- John J. Garguilo
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 - Nicolas Crouzier(Contractor-Dakota)
 - RTMMS – 11073-10101 MDC Nomenclature
 - HL7 V2 Tools
 - Michael Faughn, (Contractor - *Prometheus Computing, LLC* w/ Art Griesser)
 - 11073-10201 MDC Domain Information Model
 - DIM Modeling + “DIM Editor/Medical Device Profiler”
- ❖ Note: As part of US Federal Government, all NIST work products are freely and publically available

Key Discussion Topics

- Work Area & Status Updates
- HL7 V2 IHE-PCD Tooling Status & Updates
- DIM Editor work updates, tool review, discussion topics

Conformance Tooling Suite

- *HL7 V2 (2.6) IHE-PCD Validation Tools*
 - IHE-PCD Pre-Connectathon: <http://ihe-pcd-precon.nist.gov/>
 - IHE-PCD Connectathon, <http://ihe-pcd-con.nist.gov/>
- Rosetta Terminology Mapping Management System (*RTMMS*)
<https://rtmms.nist.gov>
- DIM Work - 'DIM Editor/Profiler' and ISO/IEEE 11073 UML Model
 - [Development Tool: dim.prometheuscomputing.com](http://dim.prometheuscomputing.com)
- NIST HL7 V2 Portal: <http://hl7v2tools.nist.gov/portal/#/tools>
 - IGAMT – Implementation Guide Authoring Management Tool
 - TCAMT – Test Case Authoring Management Tool

Conformance Tooling Portal: <http://hl7v2tools.nist.gov/portal/#/tools>

The screenshot shows the NIST HL7 V2 Resource Portal 1.0. The browser address bar displays hl7v2tools.nist.gov/portal/#/tools. The portal has a dark blue header with the title "NIST HL7 V2 Resource Portal 1.0" and a yellow navigation bar with links: Home, Tools, Publications, Resources, Source Code, Links, and About. Below the navigation bar is a light blue section titled "HL7 V2 Tools". A filter dropdown menu is set to "All Tools", and there is a "Show Archived:" checkbox. A search bar is located on the right. The main content area displays a grid of 18 tool cards, each with a title and a small information icon (i) in the bottom right corner.

HL7v2 Immunization Test Suite (2015 Edition)	HL7v2 Syndromic Surveillance Test Suite (2015 Edition)	Electronic Lab Reporting (2014 and 2015 Edition)	Immunization (2014 Edition)	Syndromic Surveillance (2014 Edition)	Laboratory Results Interface (2014 Edition)
IHE PCD Pre-Connectathon	IHE PCD Connectathon	IHE PIX and PDQ Pre-Connectathon	IHE PIX and PDQ Connectathon	RTMMS Rosetta Terminology Mapping Management System	HL7 Web Services
HL7v2 Lab Compendium (eDOS)	HL7v2 Lab Results Interface (LRI) Release 2 (2015)	Test Case Authoring and Management Tool (TCAMT)	Implementation Guide Authoring Tool (IGAMT)	NIST Vital Records (2016)	HL7v2 Context-free (Vital Records Death and Height and Weight)

Work Areas & Status Updates

HL7 V2 (2.6) IHE-PCD Validation Tools

- IHE-PCD Pre-Connectathon, “Isolated Environment”
<http://ihe-pcd-precon.nist.gov/>
- IHE-PCD Connectathon, “Instance Environment”
<http://ihe-pcd-con.nist.gov/>
- Enhancements to Pre-Connectathon, Connectathon Tools support IHE-PCD Cycle 12; mainly CPs
- *Key test events*
 - Supported IHE-Europe Connectathon (May 2017)
 - Supported IHE-Korea Connectathon (Aug 2017)
 - Upcoming: IHE-Japan Connectathon (Sept 2017)
 - Upcoming: IHE-North America Connectathon (Jan 2018)
 - (New) IHE Australia – targeted August 2017 (**NO PCD - cancelled**)
- IHE-PCD Cycle 12 underway - CP updates (as accepted) to be coded for 2017-18 (mainly from IHE-PCD; 1 April 2017 – 31 March 2018)

2017 IHE-PCD Pre-Connectathon Tool: Cycle 12 Status, continued

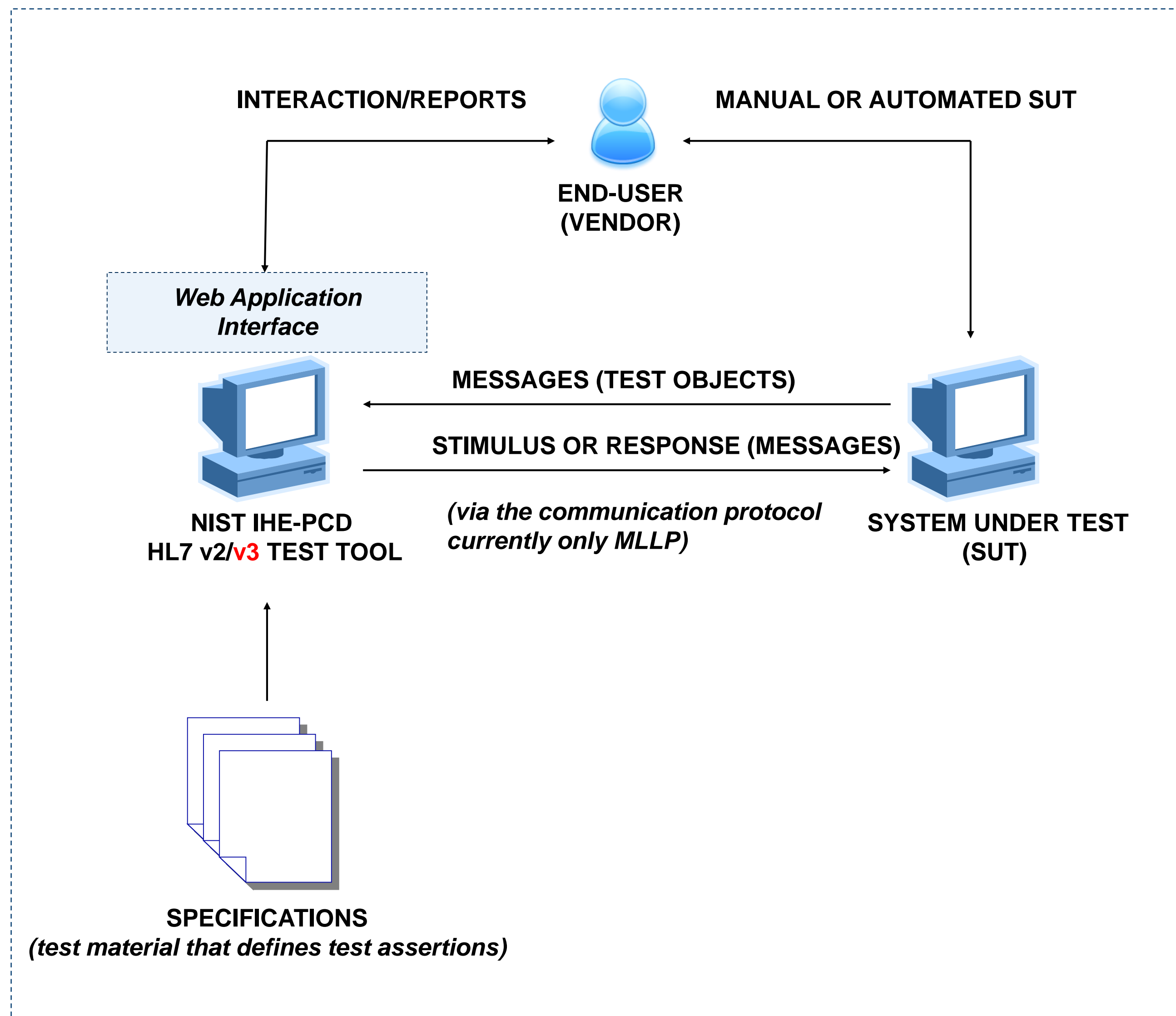
- 151 existing User Accounts (as of 12 Sept 2017)
 - Contributing Orgs, SDO (leads/Co-chairs), Reviewers
 - In total since tool made publically available (2011)

Recorded or stored by NIST tool registered user

- Cycle 11: 14 Users Testing, 95 Tests Executed/Stored
 - 13 Unique Companies
- Cycle 10: 17 Users, 124 Tests Executed/Stored
- Cycle 9: 17 Users, 106 Tests Executed/Stored
 - 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*

NIST V2 HL7 IHE-PCD Test Tool: Operational Process



V3 – Future Work

Work Areas & Status Updates

2017 IHE-PCD Pre+Connectathon Tool: Cycle 12 Status

- IHE-PCD: NIST “Isolated Environment” Test Tools
 - 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 – Alert Communication Management (2), (*WTCP validation not supported*)
 - RDQ – Retrospective Data Query (1)
 - MEMDMC – Device Management Communication (1)
 - MEMLS – Location Services (1)
 - *OMS, RTLS/CMS, Security white papers/WGs*
- 64 Test Cases {31 Unique} (across all ‘Actors’)

Rosetta Terminology Mapping Management System (*RTMMS*) ISO/IEEE 11073-10101

- RTMMS Deployment Update and service status
 - -10101a added + harmonized co-constraints (e.g., units, enums, body sites):
590 LOINC mappings to MDC terms!
 - -10101b Work underway, 10101c (future TBD)
 - NIST-IEEE Royalty Free Agreement makes available the “Works” (5 key nomenclature attributes) – *perpetual agreement*
 - Latest numbers...
- Many thanks to lead Paul Schluter, retired Principal Engineer, GE Healthcare! 😊
- <https://rtmms.nist.gov>

RTMMS by the numbers; 11 September 2017

(@San Diego WG Mtgs)

	Oct 2015	Jan 2016	May 2016	Sept 2016	Jan 2017	May 2017	Sept 2017
11073-10101		10685	10685	10685	10685	10685	10713
Rosetta Terms	1642	1648	1731	1733	1763	1764	1765
hRTM (Harmonized)	693	804	879	880	911	911	911
Groups	226	317	323	323	337	337	337
Unit Groups	8	8	12	12	12	12	12
-Units (MDC)	515	524	547	551	552	552	552
-Units (UCUM)	520	526	540	545	548	548	548
Enumeration Groups	39	43	43	43	43	43	43
-Enumerations	317	317	403	403	436	436	436
Organizations Registered	61	65	70	71	78	91	91
Users							148

Term Approval in RTMMS

As of 11 September 2017

Terms being or to-be vetted
(“Term Approval” tab for ‘SDO’ user)

- “Proposed Terms”: 187
- “Ready Terms Table”: 79
- “Mapped Terms”: 79
- “Proposed Units”: 188
- “Proposed Enumerations”: 178

Work Areas & Status Updates, DIM Editor/Profiler

- ISO/IEEE 11073 ‘*Domain Information Model Editor*’ -> “DIM Editor”
 - Progress/Update/Status (Michael Faughn)
 - UML Defined 11073-10201 DIM basis for tooling
 - Issues list (actively/weekly addressing and resolving)
 - » Tool continues to improve performance and usability
 - ❖ DIM Editor tool – **Medical Device subject matter experts wanted!**
 - 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 and accepted
 - Continue weekly TCons (Thursdays @ 2 pm Eastern) – all welcome!

Work Areas & Status Updates

Implementation Guide and Test Case Tools

<http://hl7v2tools.nist.gov/portal/#/tools>

- IGAMT – Implementation Guide Authoring Management Tool
- TCAMT – Test Case Authoring Management Tool
- Underlying ‘Framework’: HL7 profile→IGAMT→TCAMT→Tool
 - Tool to create Implementation Guides and conformance profiles
 - Tool to create test plans, test cases, and associated test data
 - Testing Infrastructure and test framework to build testing tools
- Rethink “normal” approach
 - Requirements are captured with tools that internalize the requirements as computable artifacts
(not as typically done – using natural language and subsequently interpreting the requirements to create test plans and test assertions)...
- Approach entry in tools (IGAMT + TCAMT) from a ‘Quality’ perspective by SME

Work Areas & Status Updates

Implementation Guide and Test Case Tools

<http://hl7v2tools.nist.gov/portal/#/tools>

- IGAMT – Implementation Guide Authoring Management Tool
- TCAMT – Test Case Authoring Management Tool
 - *Currently being used for MU/ONC + CDC domains (e.g., within Lab, Immunization, Syndromic Surveillance, eRX)...*
 - *Development work underway on IHE-PCD HL7 V2 Messages:*
 - *PCD-01 (ORU^R01) + PCD-03 (RGV^R015)...*
 - *Initial Goal: Develop first version of IG for PCD-01 (TF Vol. II)*
 - *Focus on IHE-PCD TF Vol. II/III (+ IHE-PCD test cases in TCAMT)*
 - *Base device profiles*
 - *(?? On hold; pending next release) Contributing to CAsC ‘Virtual Machine’ (conformity Assessment ISO 17025)*
 - *TCAMT focus on relatively small number of CAsC Identified Test Cases (presently from IHE-PCD, cycles 11+12)*
 - *Begin producing IGs for device baseline profiles/specializations*

- Underlying ‘Framework’ (continued):
HL7 profile→IGAMT→TCAMT→Tool
 - “**Resource Bundle**” generated to automatically produce (and update) tool instance
 - *Concept investigated by developing initial version of PCD-01 (ORU^R01, ACK^R01) and PCD-03 (RGV^O15, ACK^O15)... additional constructs (e.g., support of “conditionals” such as OBX-2 [Value Type] and OBX-5 [Observation Value] in development)*
 - *However, existing IHE-PCD V2 tools need to be upgraded to new NIST framework – which may be accomplished via IGAMT + TCAMT*
 - *Initial Goal: Develop first version of IG for PCD-01 (TF Vol. II)*
 - *Focus on IHE-PCD TF Vol. II/III*
 - *Continue to grow IGs for Volume IIIs (Device Specializations)*

Meetings + Activities: past, on-going and future

- Joint HL7 HCD / IEEE 11073 WG Mtgs., San Diego, CA (Sept. 2017)
- Weekly “DPI” Meetings on Thursdays @ 2pm (w/ Jan Wittenber)
- ✓ Joint HL7 HCD / IEEE 11073 WG Mtgs., San Antonio, TX (Jan 2017)
- ✓ Joint HL7 HCD / IEEE 11073 WG Mtgs., Madrid, Spain (May 2017)
- ✓ IHE-PCD F2F: Spring 2017 (San Diego @ Qualcomm)
 - Past Fall F2F, Boca Raton (Oct 2016)
- ✓ HIMSS’17 – Orlando (Feb.2017)
- ✓ IHE North American Connectathon, Cleveland (23-27 Jan 2017)
 - NIST Connectathon Tool used for static validation
 - John G., Nicolas C., Ismail M., and Sandra Martinez serving as test monitors
 - John G. to participated (“Staff”) in IHE’s education series (“Connectathon 101”)
 - presented session on how PCD tests...
 - NIST’s IHE-PCD V2 Tool Tutorial
 - (recorded fall 2015 for cycle 10 – on IHE wiki)
- ~~NIST supporting IHE CaSC effort by providing PCD tooling~~
 - ~~Validation tooling to be part of CaSC “Virtual Machine”~~

- IHE-PCD Cycle 12 (2017-18)
 - New HL7 V2 Tooling framework (same functionality and execution)
 - Generate tooling from resource bundle (files output from IGAMT and TCAMT)
 - Test Cases/demographics reviewed – used as basis for tooling 2017-18
 - CPs as introduced + requirements added into tooling
(see PCD wiki: http://wiki.ihe.net/index.php?title=PCD_CP_grid)
 - Consider ACM WCTP validation service (from TF Vol 2)
 - Continue to support IHE (Inter-)National Test Events
 - N. America, Europe, Korea, Japan, Australia(tbd)
 - Roadmap of activities updated... see PCD wiki
http://wiki.ihe.net/index.php?title=Patient_Care_Devices

Terminology Additions Continuing...

- 10101a (~240 terms) + co-constraints; 10101b near completion...

Informational Update

- MDC / LOINC mappings view (i.e., tab in interface)
 - 590...
 - Thanks to Dr. Swapna Abhyankar (Regenstrief)

RTMMS Technology Update

(On hold - coming soon (??) – Early '18)

- Updating tool (interface and dBase)
- 'AngularJS' for the front end (user interface).
- 'Node.js' for the backend and MongoDB for the NoSQL database.

- DIM Editor/Profiler 11073-10201
 - Generate camera ready IEEE standard in MS Word
 - Redesign application for reusable profiles
 - Resolve critical issues on “Revisions & Comments”
- Finished implementation of r/w permissions in web application
- Improved integration with RTMMS
- Comprehensive audit of updated DIM model / application with respect to 11073:10201© 2004
- Easier access to metadata and information from the DIM standard for device profile users
- Deploy to NIST server (from Prometheus Computing)
- Release Device Profiling app for general use
- Conformance statements from the profile editor
- Work with Open SDC (11073 Web Services) on similar tool

Key Goal:

- Build library of template ‘Device Specializations’

❖ *See Michael Faughn’s slides*

- Devices on FHIR
- DoF Validation Service
 - Evaluating and researching FHIR validation services
 - Key goal: develop framework (similar to HL7 V2)
- Use RTMMS as nomenclature/mapping repository
 - Continue to build alliance around RTMMS being medical device terminology “single source of truth”...
 - Continue work with PHD – PCH/A/Continua + PoCD - IHE-PCD/IEEE Upper Layers WG

Conformance Tooling Suite

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Thank You or your attention 😊

- Questions
- Discussion

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HL7 V2.6 Validation Tooling IHE-PCD Pre-Connectathon Cycle 12

Semantic interoperability of Medical Devices

Test Tool Update

Joint HL7/IEEE 11073 Healthcare Devices Working Group

National Institute of Standards and Technology

12 September, 2017 – San Diego, CA

Contact: john.garguilo@nist.gov, 301-975-5248

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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*

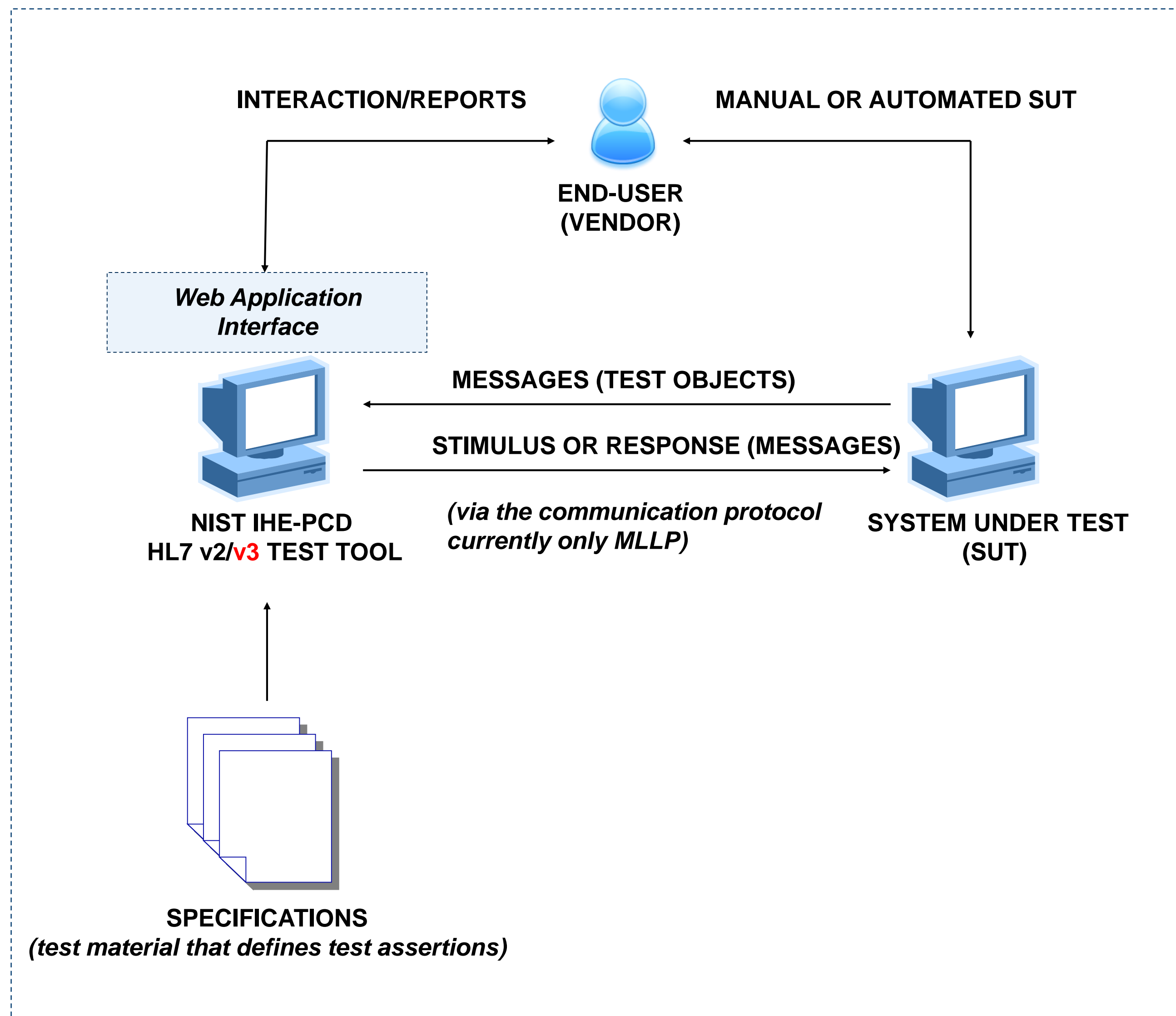
IHE-PCD 2014/15 Pre-Connectathon + Connectathon

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

HEALTH IT
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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

9 May, 2017 – Madrid, Spain, Madrid

Contact: john.garguilo@nist.gov, 301-975-5248

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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

- Linked to RTMMS

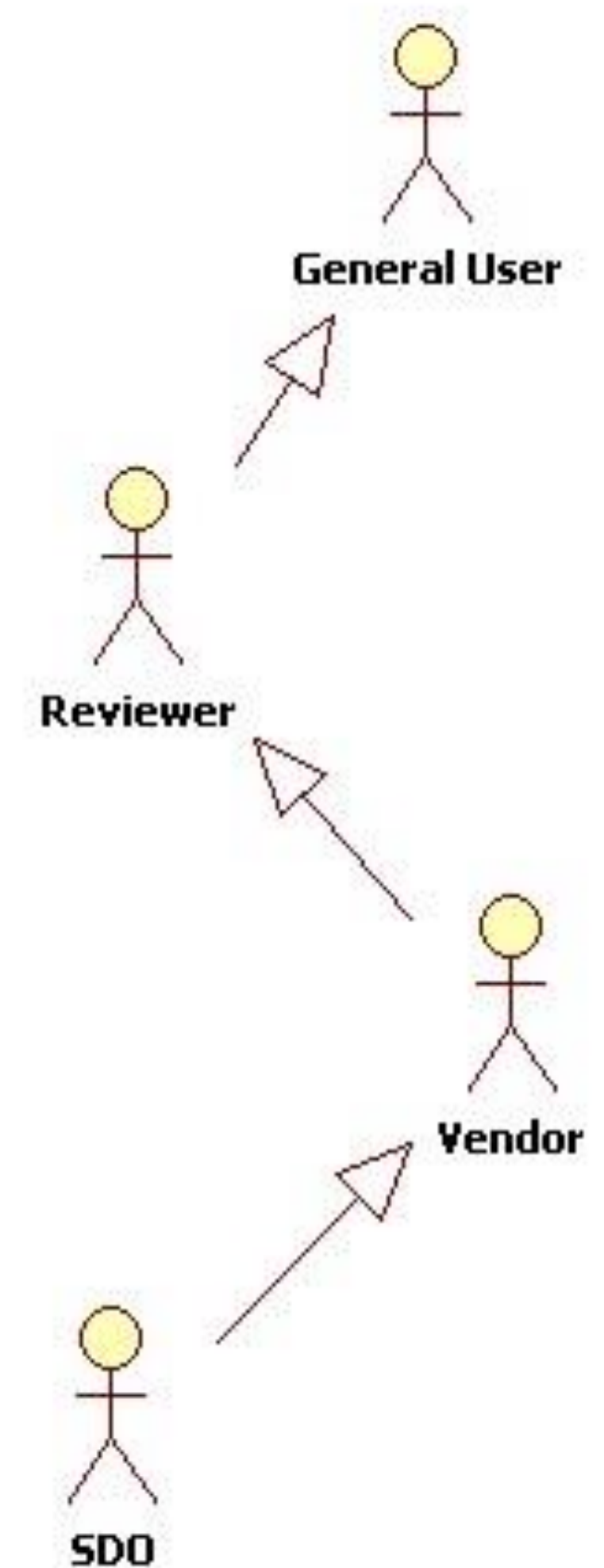
Security DB - Stores users information

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/Contributor ‘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



HL7 V2 Tool Updates, RTMMS

- ✓ 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

RTMMS by the numbers; 9 May 2017 (@Madrid WG Mtgs)

	Oct 2015	Jan 2016	May 2016	Sept 2016	Jan 2017	May 2017
Rosetta Terms	1642	1648	1731	1733	1763	1764
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Enumerations	317	317	403	403	436	436
Organizations Registered	61	65	70	71	78	91

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]

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

5 – Common Term – added to agreement in Sept. 2014 (worked w/ Kathryn Bennett/IEEE to amend)

- Banner page updated on tool

Royalty Free Agreement – Addendum (Sept. 2014)

- IEEE / NIST Royalty Free Agreement – December 2012

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Shall heretofore be designated as the “Works”

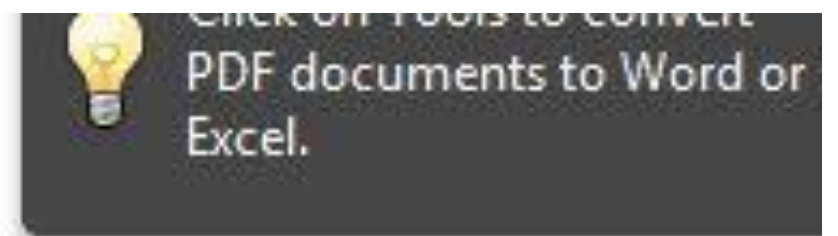
- September 2014

Add to the Definition of the “Works”

Data item

5 – Common Term

RTMMS Primary Updates – Signed Agreement 12/20/12



For IEEE:

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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.

Licensors


Signature

Konstantinos Karachalios
Name

Managing Director IEEE-SA
Title

20 Dec 2012
Date

Licensee


Signature

Ram D. Sriram
Name

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:
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- NIST Medical Device Terminology Service:
 - Rosetta Terminology Mapping Management System (*RTMMS*):
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- DIM Work - 'DIM Editor' and UML Model
 - [Development Tool: dim3.prometheuscomputing.com](http://dim3.prometheuscomputing.com)
- NIST Implementation Conformance Statement Generator (*ICSGenerator*): (no longer supported)
 - http://hit-testing.nist.gov/medicaldevices/ICSGenerator/ics_download.html

Thank You or your attention 😊

- Questions
- Discussion

Domain Information Model UML / DIM Editor, Progress Update

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- See Michael Faughn's slide set...