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 Garguilo National Institute of Standards and Technology 7 May, 2013 – Atlanta, GA

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NIST MDC Testing Staff

- John J. Garguilo
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- Julien Deshayes (Guest Researcher) HL7 V2 Tools
- Nicolas Crouzier(GR) RTMMS
- Jing Gao (GR) ICSGenerator
- Art Griesser + Michael Faughn (Contractor -Prometheus Computing, LLC) – DIM Modeling
- Sandra Martinez

 working on MU

Discussion Topics

- HL7 V2 (2.6) IHE-PCD Validation Tools
 - Cycle 7 2012-13; Fall/Winter Pre-Connectathon [completed] + Virtual Testing, January/February 2013 Connectathon, March 2013 HIMSS13
 - IHE-PCD Pre-Connectathon, "Isolated Environment"
 - IHE-PCD Connectathon, "Instance Environment
 - Cycle 8 Enhancements
- Rosetta Terminology Mapping Management System (RTMMS) Overview
 - RTMMS Deployment Update and service status
 - IEEE Agreement to make available the "Works" + latest numbers...
- ISO/IEEE 11073 'Domain Information Model Editor'
 - Progress Updates
 - UML Defined x73 DIM, Activity Diagram, Goals

HEALTH IT STANDARDS TESTING INFRASTRUCTURE

HL7 V2.6 Validation Tooling IHE-PCD Pre-Connectathon Cycle 7

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HL7 Healthcare Dev / IEEE WGs

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2012-13 IHE-PCD Pre-Connectathon Status

- IHE-PCD: NIST "Isolated Environment" Test Tools required
 - HL7 V2.6
 - Supports 6 Integration Profiles (number of test cases)
 - DEC Device Enterprise Communication (9)
 - SPD Filter (4)
 - POI Pulse Ox (3)
 - PIV Patient Infusion Verification (7)
 - IPEC Infusion Pump Event Communication (6)
 - IDCO Implantable Device Cardiac Observation (4)
 - ACM Alarm Communication Management (1)
 - RDQ Retrospective Data Query (1)
- 28 Test Cases
- 60+ existing User Accounts
 - In total since tool made available

2012-13 IHE-PCD

Pre-Connectathon + Connectathon Status, Continued

- Cycle 8 Test Cases being reviewed with IHE-PCD Tuesday calls
- IHE-PCD F2F week of April 15th in San Diego at WHI
 - Notable: Alarm Comm Mgmt → Alert Comm Mgmt
- CPs documented and submitted
- Roadmap of activities updated... see PCD wiki
- JG + JR addressing revisions to TF Vol II

IHE-PCD 2012/13 Pre-Connectathon + Connectathon **NIST Testing Support**

The NIST V2 (2.6) Tools perform the following validation:

- Syntax and Semantic Content Validation
 - Against IHE-PCD Technical Frameworks/Supplements (e.g., PCD-01, Communicate Device Data)
 - Against HL7 conformance profile
 - Against HL7 and/or user [local] 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)

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

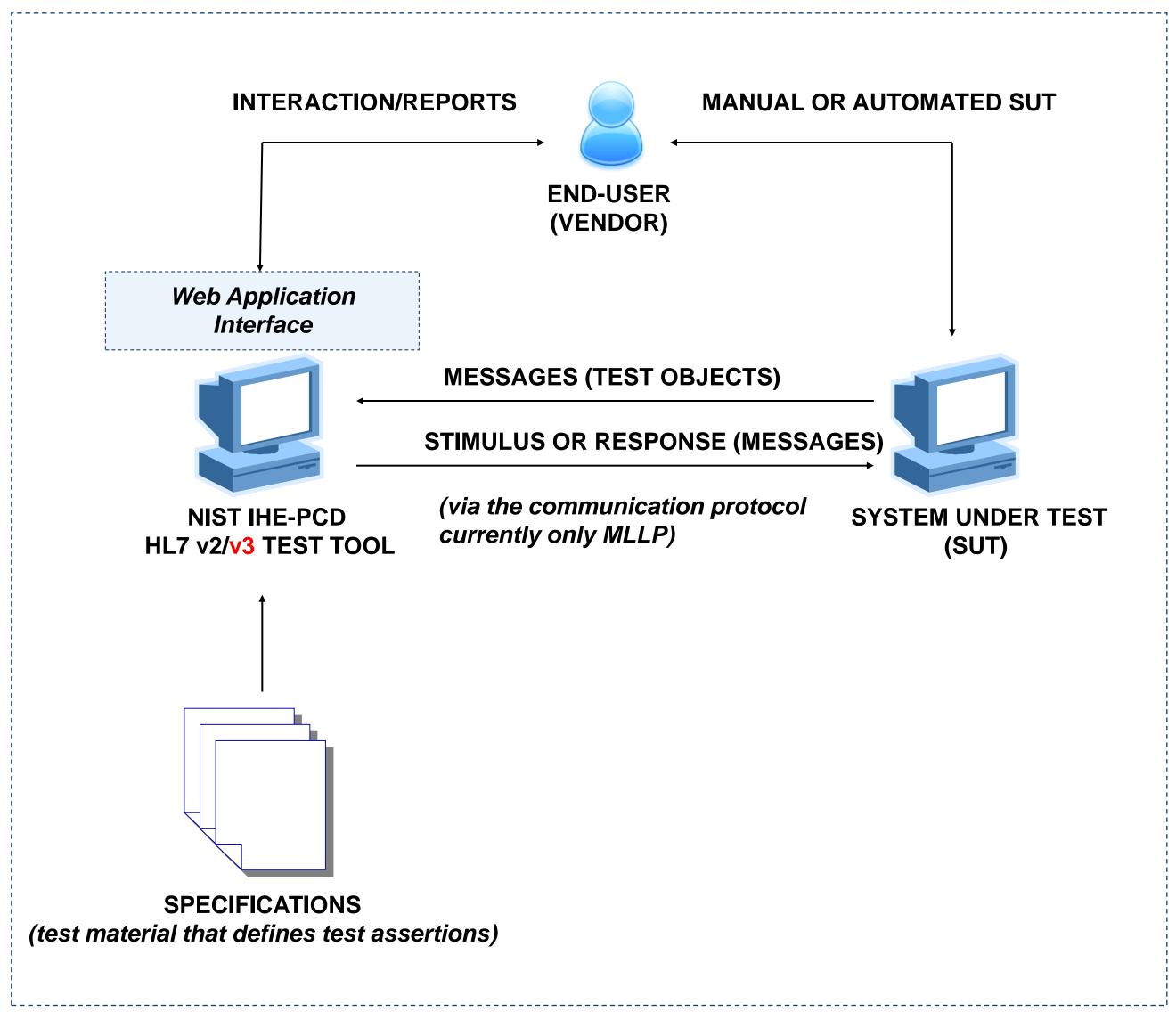
Isolated System Testing

- 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

NIST V2 HL7 IHE-PCD Test Tool: Operational Process



V3 – Future Work

IHE-PCD Cycle 7 2012-13 Pre-Connectathon Test Result Statistics – Organizations and Tests Executed

- Total Organizations (by User Accounts): 19
- Total Organizations (by *unique Company Name): 12
 *Org No. followed by dash indicates more than one account from same organization in following slide

Registered (stored) at NIST site (over Pre-Con 2012-13 cycle)

- Total number of Tests Executed:82
 - Total Number of Tests Passed: 81
 - Total Number of Tests Failed: 1

Connectathon Test Monitors for IHE-PCD (North America @ Chicago, Jan 2013)

Garguilo, Martinez, Deshayes, Crouzier

IHE-PCD Cycle 7 2012-13 Pre-Connectathon Test Result Statistics – by Actor

(does not include supportive role participants – recorded /committed on NIST site)

Organization running DEC Reporter: 16

Organization running DEC Consumer: 1 (1 Test Case) – OZ Systems

Organization running DEC Filter: 1 (1 Test Case) – B Braun

Organization running PIV Programmer: 0

Organization running PIV Consumer: 5

Organization running ACM Reporter: 6

Organization running ACM Manager: 1 (1 Test Case) – Philips Medical

Organization running ACM Archiver: 0 (out of scope 2012-13)

Organization running IDCO Reporter: 0

Organization running IDCO Consumer: 0

Organization running IPEC Reporter: 4

Organization running IPEC Consumer: 0

Organization running RDQ Reporter: 0

Organization running RDQ Consumer: 0

Organizations running DEC Option POI: 1 (3 Test Cases) - Massimo

- Version / Release now shown on tool
 - Needs to be added (see example slide below)
- Maintain (test management) data from test events
 - E.g., 2012, 2013, etc.
 - Not an executable site (yet!) just results data + reports
- Documentation Tab (see coming slides)
 - Conformance Profile Tab
 - Patient Demographics
 - IDCO Patient Demographics
 - PIV Drugs
 - Other Drug Libraries tab?
 - Way to upload libraries + demographics (future) incorporated [automatically] into validation context files used by tooling

- Current Version / Release Notes
 - Needs to be added to be added soon…
 - Example shown from MU Lab Reporting Interface Tool

Release Notes

¢Release	≎Date	≎Notes	
1.3.0	04/26/2013	LRI_Release_Notes.1.3.0.docx	
1.2.0	03/22/2013	LRI_Release_Notes.1.2.0.docx	
1.1.0	02/15/2013	LRI_Release_Notes.1.1.0.docx	
1.0.0	12/15/2012	Initial Release	



Deployment Information Browsers Supported

Version: 1.3.0

Update Date: 04/26/2013 IE 8, IE 9, Firefox 3.x, Chrome

Recommended Browsers: IE 9, Firefox, Chrome

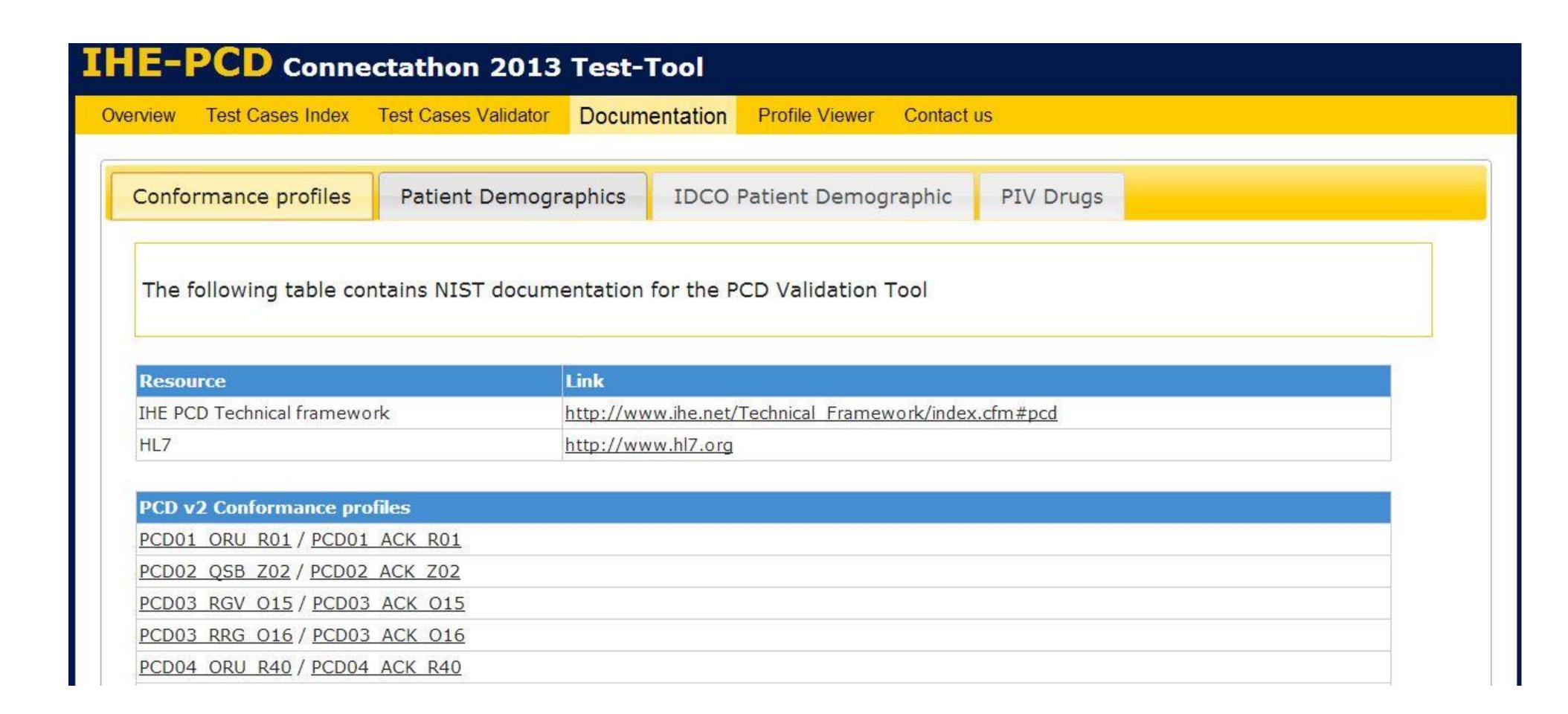
External Links

<u>Disclaimer</u>

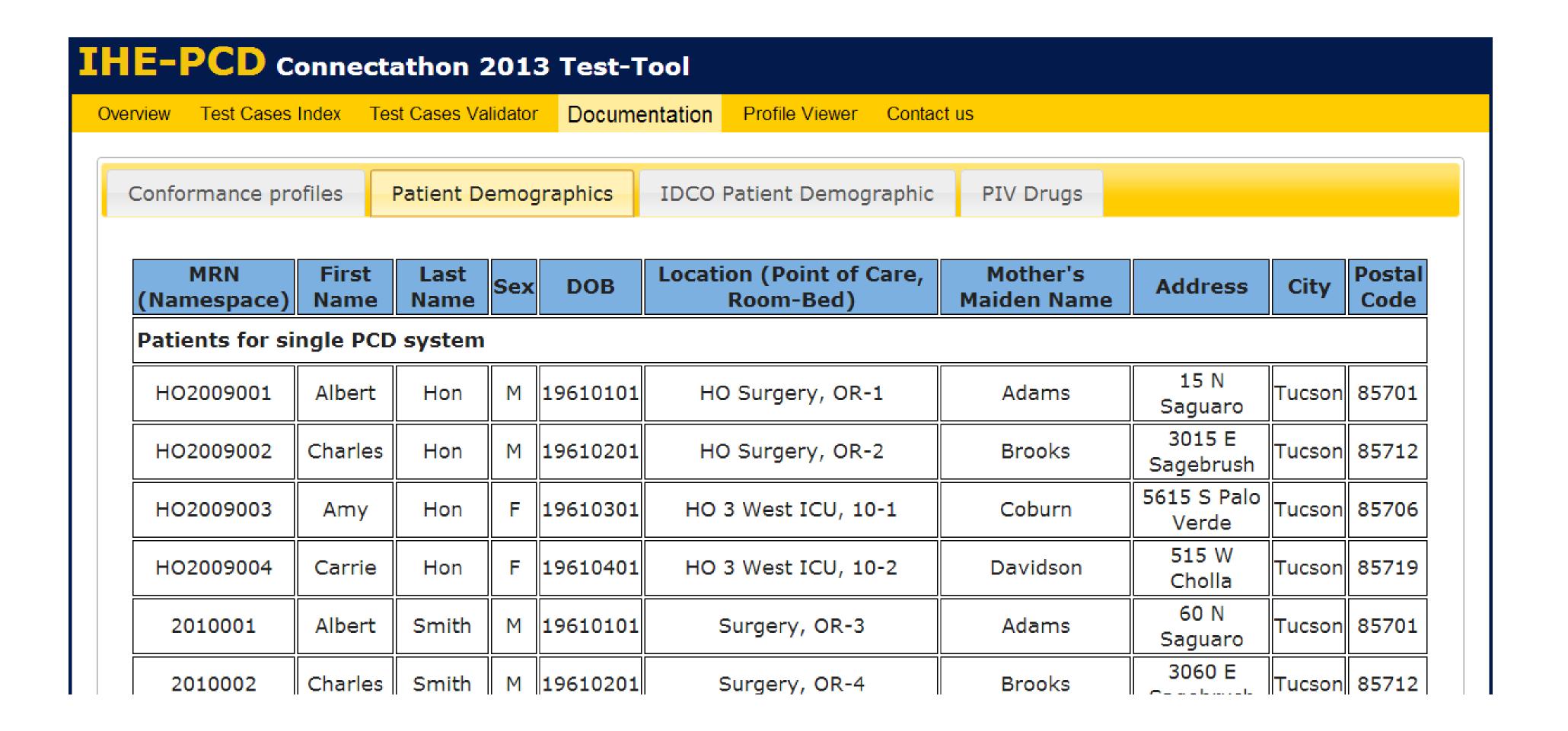
Privacy/Policy

Nebsite Administrator

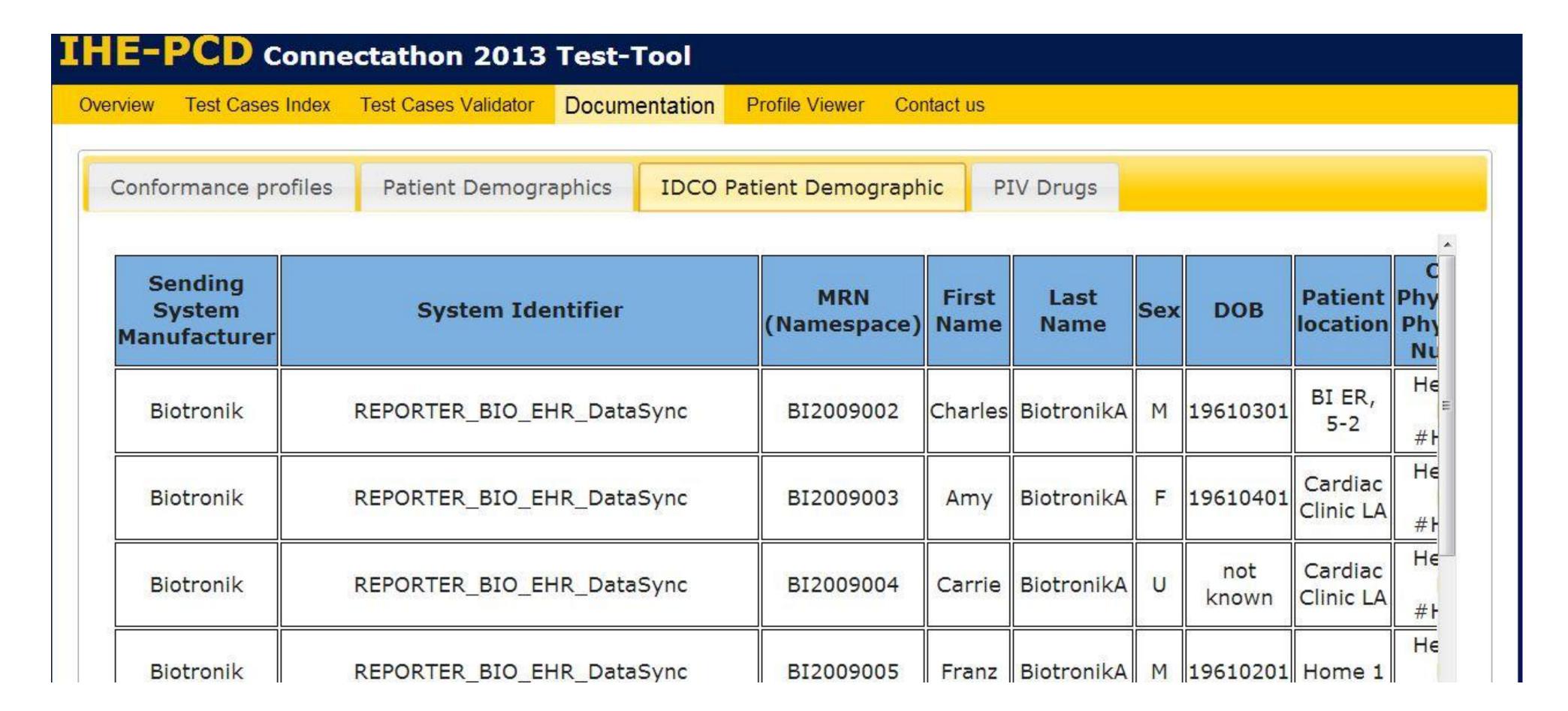
- Documentation Tab
 - Conformance Profiles



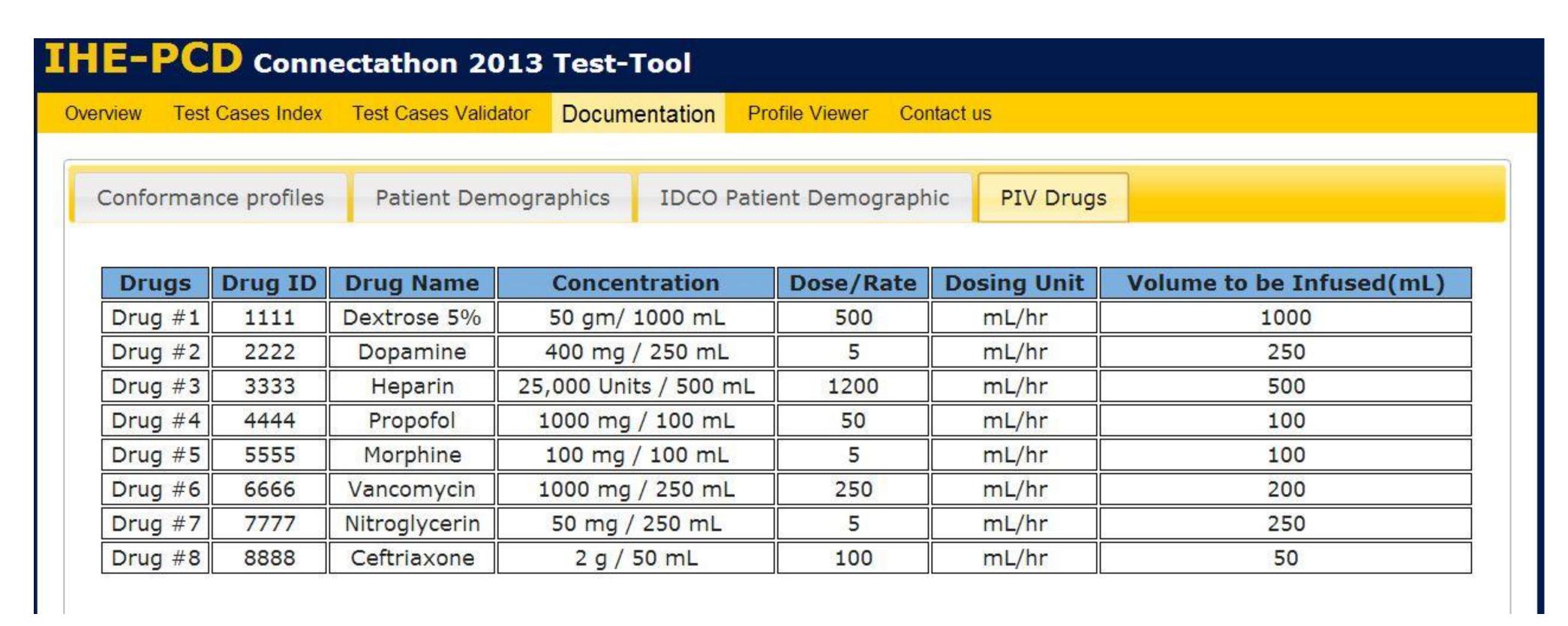
- Documentation Tab
 - Patient Demographics



- **Documentation Tab**
 - IDCO Patient Demographics



- Documentation Tab
 - PIV Drugs



HL7 V2 Tool Update, Continued

Profile Viewer



Need to review/update/synch w/ TF Vols. II + III

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 7 May, 2013 – Atlanta, GA

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

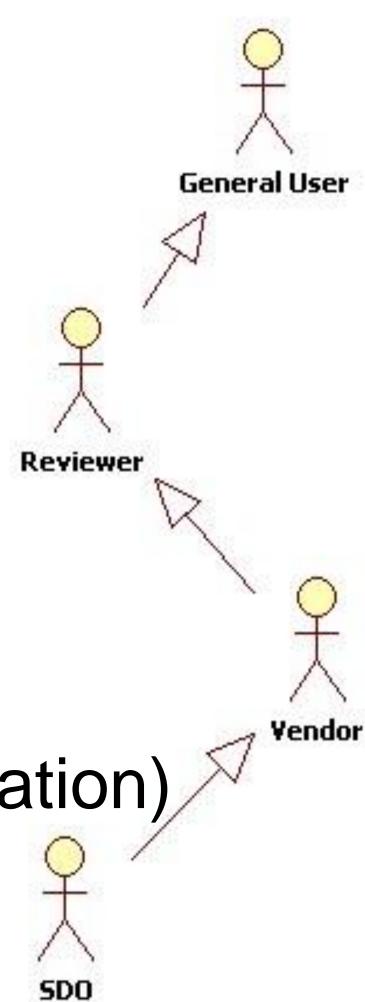
Security DB - Stores users information

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



RTMMS (as of 6 May 2013)

- 1587 Rosetta terms
- 644 hRTM terms
- 35 Contributing Organizations now Registered!

Edit contributing organization Add contributing organization Delete contributing organization Merge two contributing					
CO ID	Suffix	CO Name			
DocBox-Inc	DOCBOX	DocBox Inc			
Draeger		Draeger-Siemens			
Editorial-pss		Editorial additions (Paul Schluter)			
Editorial-RTMV					
Elbrys-Networks	ELBRYS	Elbrys Networks			
EPIC	EPIC	EPIC			
Eversolve	EVERSOLVE	Eversolve			
Fresenius	FRE	Fresenius			
GE_Aware	GE	GE (Aware Gateway)			
HL7-Hellas	HL7HELLAS	HL7 Hellas			
Hospira	HSP	Hospira			
IEEE	IEEE	ISO/IEEE 11073-10101 and its extensions			
IHE PCD Infusion Pump Wo	ork IHEPCDINF	IHE PCD Infusion Pump Work Group			
LiveData		LiveData			
Mindray	MR	Mindray			
Nuvon		Nuvon			
OSD_MIL	OSDMIL	OSD MIL			
Philips		Philips Healthcare			
Shoulders_Corporation	SCO	Shoulders Corporation			
Siemens	SI	Siemens			
Smiths Medical	SM	Smiths Medical			
Spacelabs		Spacelabs Healthcare			
STYK					
True Process Inc	TPI	True Process Inc.			
VA	VA	Veterans Affairs			
VIASYS		Cardinal VIASYS			
WelchAllyn		Welch Allyn			
West_Health	WH	West Health Institute			

RTMMS Primary Updates

- ✓ Agreement finalized between IEEE and NIST (Dec 2012)
 - 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]

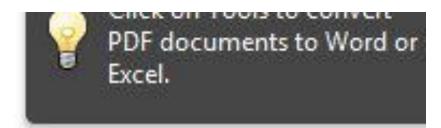
The following data items within the approved standards, existing and future versions, currently designated as:

- 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
- ✓ Revised "term approval" Functionality

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.

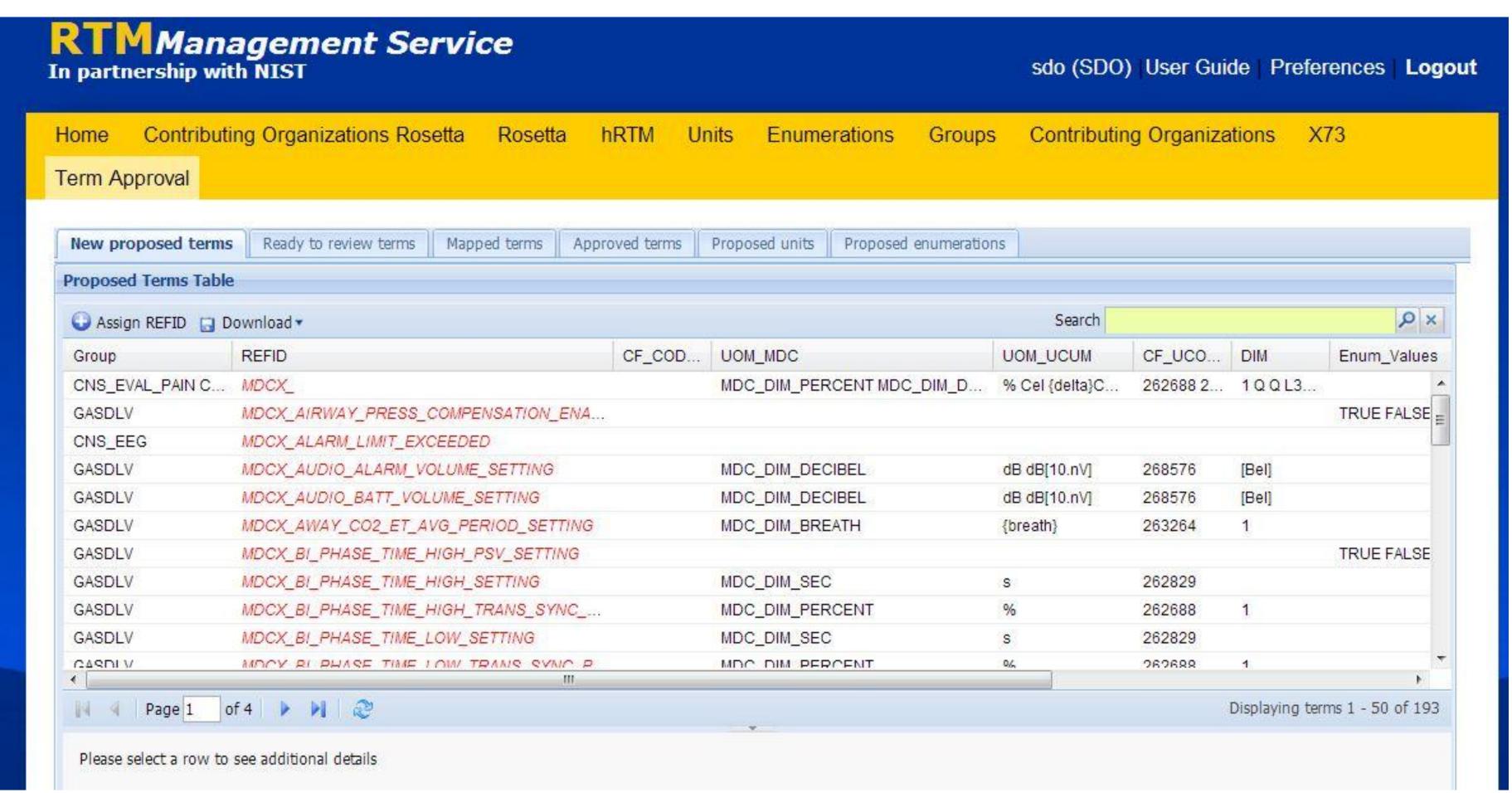
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Signature Signature	Signature Signature	
Konstantinos Kamarhalics Name	Ram D. Jvivaim	
Managing Director IEEE-SH Title	Pivision Chief Title	
Date Dec 2012	12 · 2 · 12 Date	

Term Approval

Revised "term approval" tables/tab

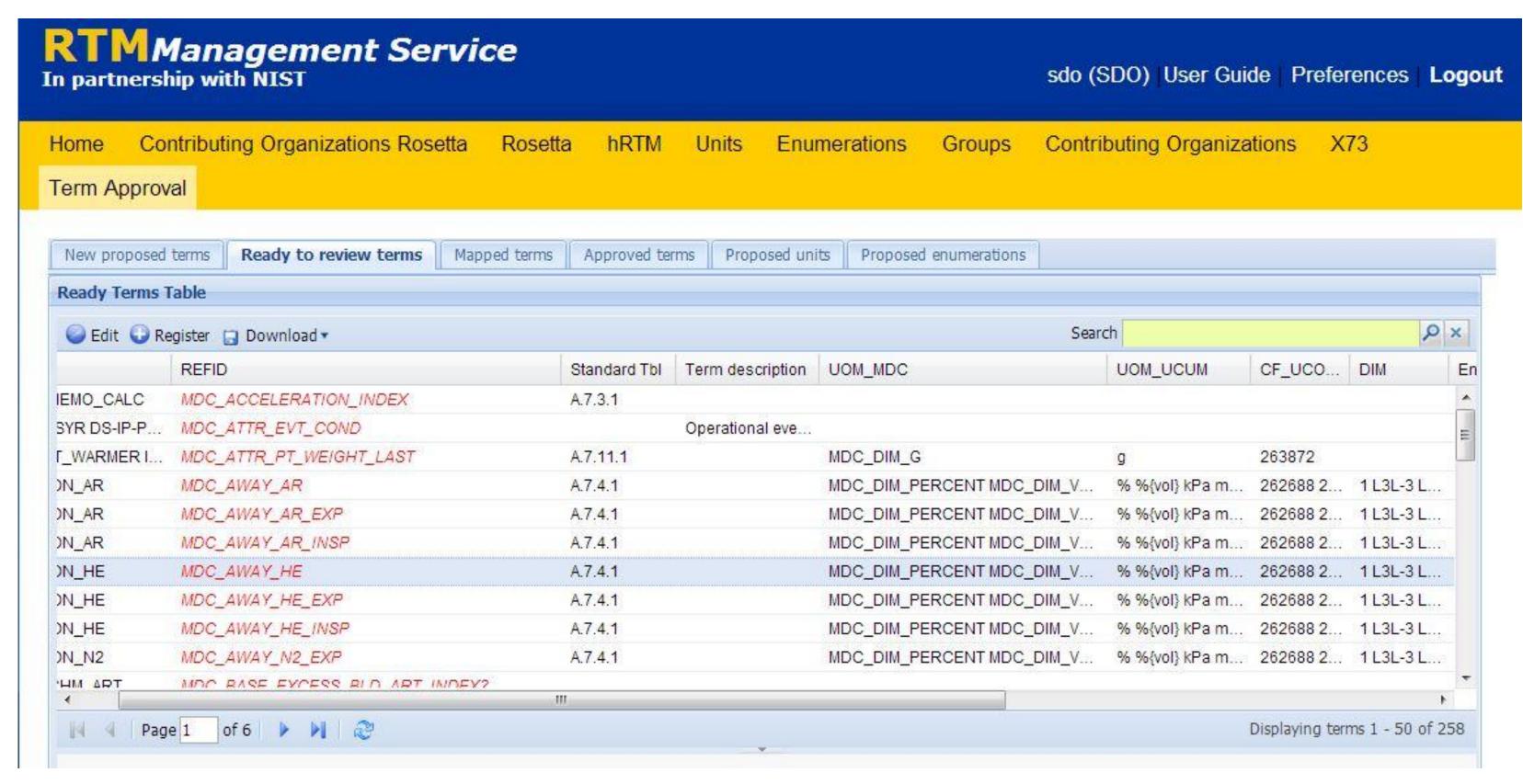
"New proposed terms" tab (192 rows)

Re-groups all the newly proposed terms with "MDCX" prefix The 'Assign REFID' button allows to change the REFID from an "MDCX" term to a "MDC term" (or anything else)



Term Approval, cont.

- "Ready to review terms" tab: 259 rows:
 - Terms with MDC_ prefix and null or 0 term code
 - The 'Register' button allows to register a term
 (define a Block, partition, code, systematic name etc...) to the x73 database



✓ These processed terms would become / be added to the harmonized Rosetta terms (hRTM) upon approval by SDO user and balloting

RTMMS Updates, cont.

- User can now download an HTML version of:
- "hRTM"
- "New proposed terms"
- "New proposed terms" table,
- Note: hope is users find this version to be easier to work with when working outside the tool
- "Standard Table"
- A new column "Standard table" is now present in all Rosetta, hRTM and review tables
- Provides association of the term with corresponding table in the base standard
- Only the terms given by Jan W. (275) REFIDs are currently linked
- NIST can add more if community provides the/additional mapped terms.

HEALTH IT STANDARDS TESTING INFRASTRUCTURE

Domain Information Model UML / DIM Editor, Progress Update

Semantic interoperability of Medical Devices

Test Tool Update – Art Griesser

Joint HL7/IEEE 11073 Healthcare Devices Working Group

National Institute of Standards and Technology 7 May, 2013 – Atlanta, GA

Contact: Arthur Griesser, Ph. D. a.griesser@prometheuscomputing.com, Prometheus Computing, LLC



Progress I

- Made UML model from DIM standard
- Made XML Schema from UML model of DIM
- Made web-based editor for DIM data
- Added to DIM UML and web app:
 - RTMMS data
 - Conformance statements
 - Meta-information
- Demonstrated an example (non-DIM) standard derived from a model

Progress II

- Created interface for DIM section 8
- Finished testing framework document
- Injected additional meta information into UML
 - Encoding values, clause numbers & titles, name binding, registered as, description, update type, attribute id
- Discussed semantics of DIM groups
- Discussed ASN.1 representation of inheritance
- Generated JSON and YAML files of meta-info

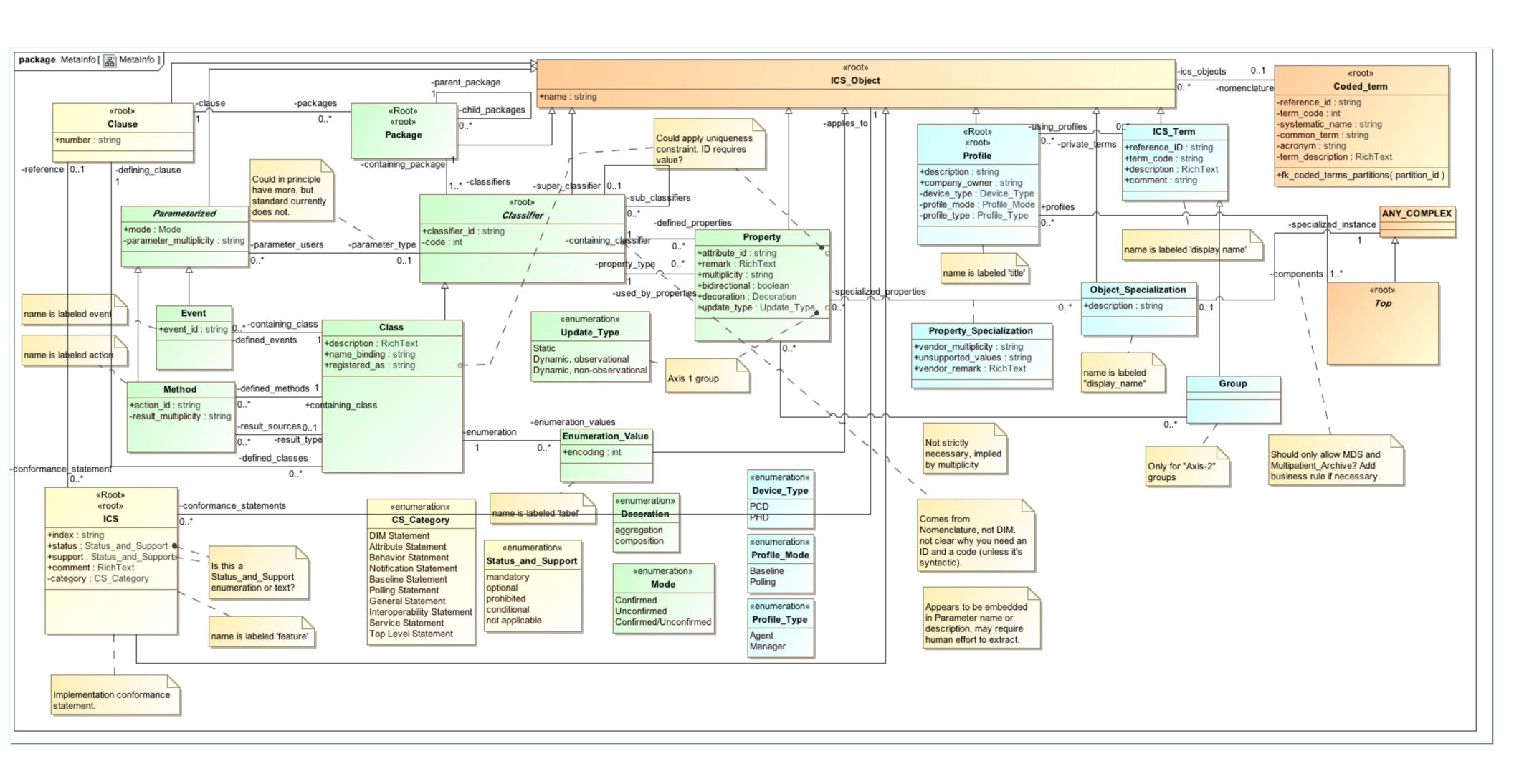
Progress III

- Created Java code to parse JSON meta-info
- Derived complete ASN.1 schema from UML
- NIST Face-to-Face meeting
 - Created model of goals (next slide)
 - Resolved some questions about UML mappings
- Added tree view of containment to MyDevice
- Reverse engineered UML of NIST XML Schema
- Finished first draft of DIM gap analysis

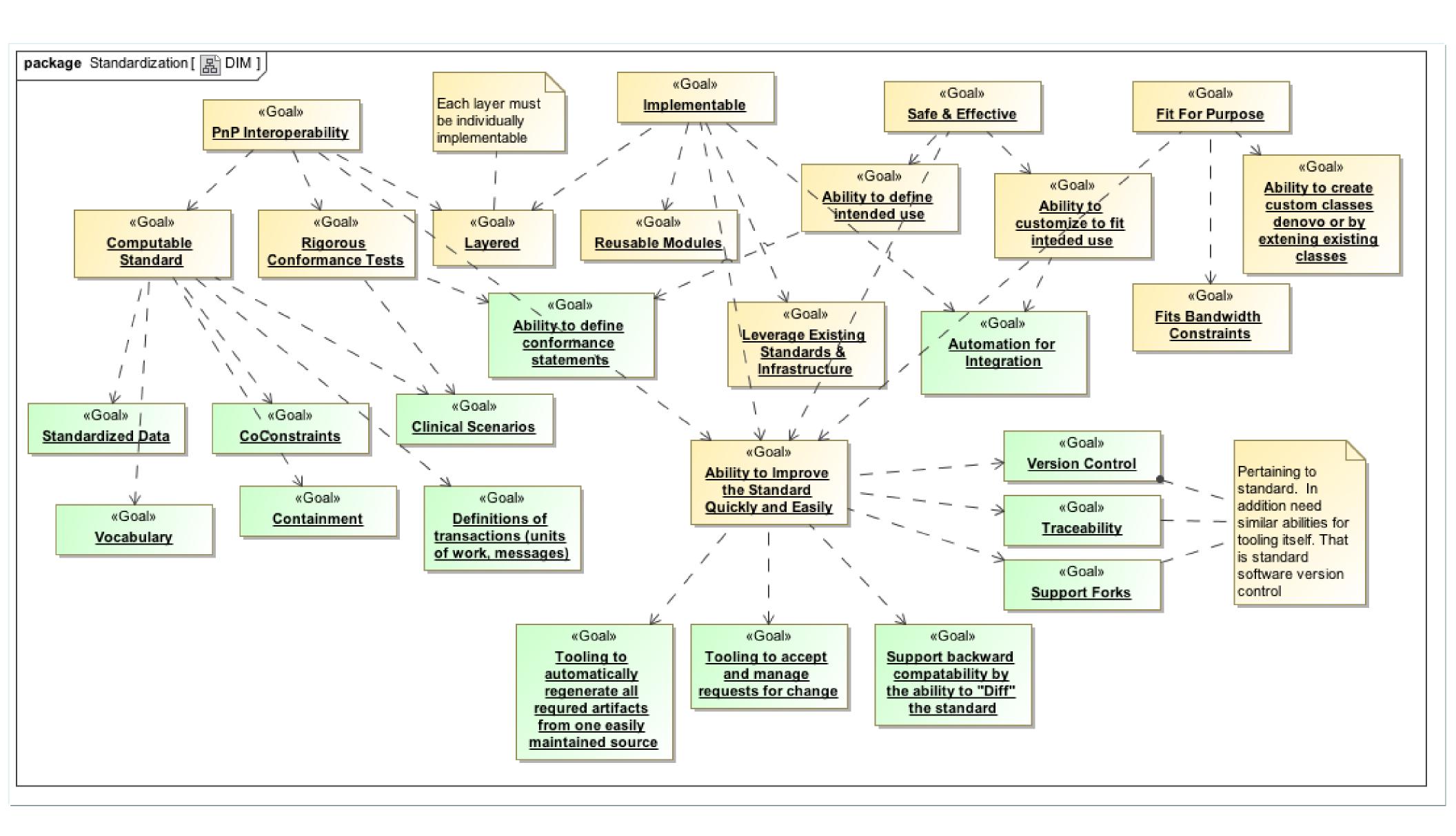
Progress III

- Determine "Golden Repository"
 - See Meta Information Management Model
 - Further progress documentation (from Jan Wittenber) in coordination with 11073 work... [discussed earlier @ Spring F2F in April]
- 2-Day F2F Summit at NIST (26-27 March)
 - Project Plan de/revised for DIM work
 - Aimed at scoping logical (and doable tasks based on priorities identified
 - Summit Outcome Goals
 - DIM Activity Diagram
- Integrating ICSGenerator into new tooling...
 - Via Cucumber tool / use cases

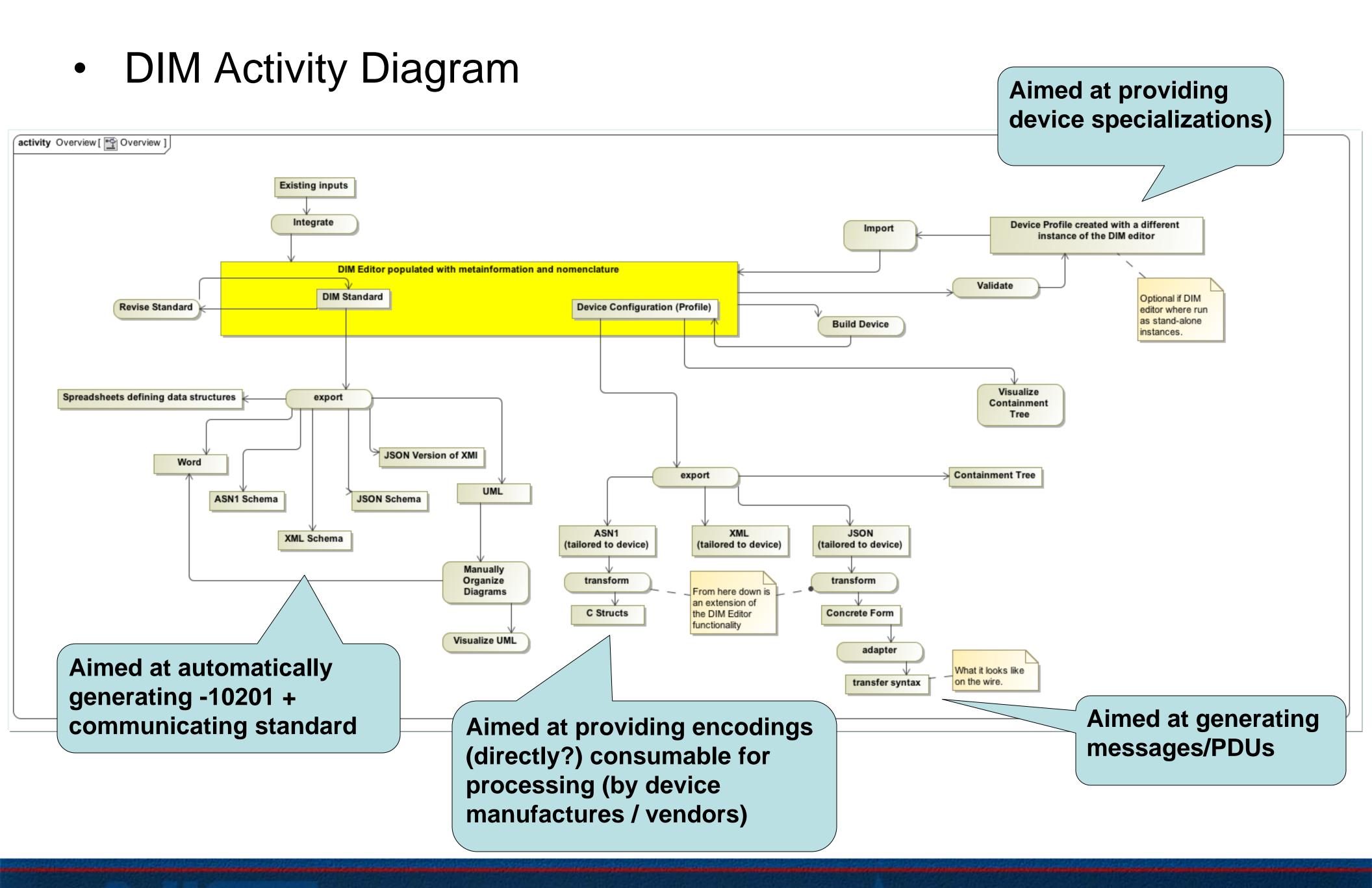
Proposed x73 DIM UML (from Art Greisser)



Goals for DIM – outcome from 2-day Summit @ NIST (March '13)

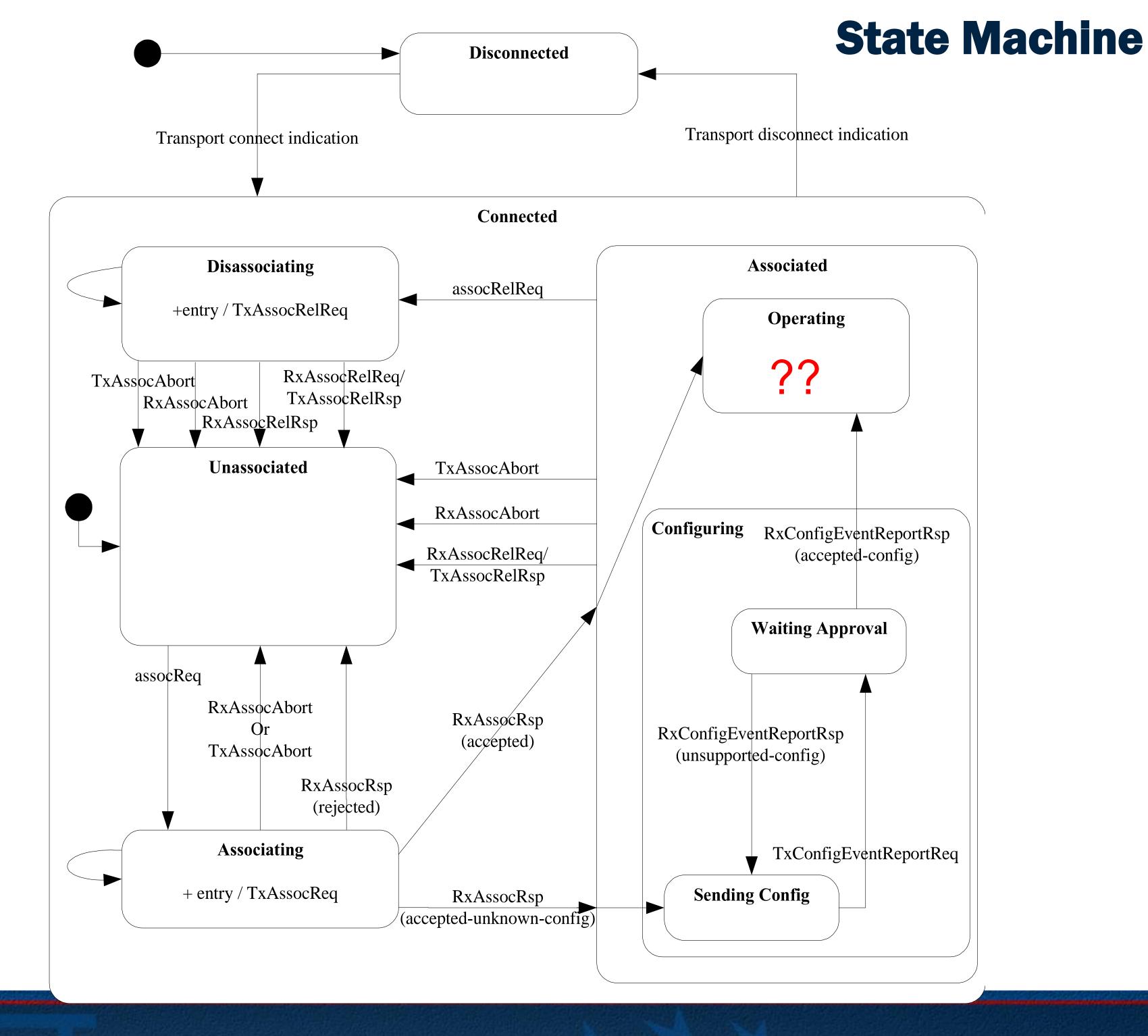


Outcomes from 2-day Summit @ NIST (March '13)



Current Foci

- Create executable use cases for ICSGenerator
 - Use them to prove MyDevice has all functionality
- Normative text
 - Extract from DIM standard
 - Inject into UML
 - Use to generate next version standard from UML
- Possibility of describing operational state



Open Questions (from Action item list of January 2013)

From Monday, May 6, 2013:

- Art --> what's the status of DIM UML --> generation of standard 10202?
 - Inject into Word Doc (Todd has example)
 - Tied to IEEE new publications formats as identified
- 10202 (electronic version of DIM): Equivalent XML (withdrawn)
 - New Par: UML + Companion Standards for syntactic representations (e.g., XML, JSON) + automated tooling(?)
 - Jan noted current "open window" w/in IEEE publication (e.g., repository IEEE is looking at to facilitate this kind of publication process...)
- Tiger Team
 - Art work w/ IEEE (Kathryn + Dom Messina(?))
 - Get Todd's example (word doc infusion)

NIST MDC Testing Project Web Sites

- Project Web site: www.nist.gov/medicaldevices
- NIST HL7 V2 Test Tooling Web sites:
 - ➤ IHE-PCD Pre-Connectathon:
 http://hit-testing.nist.gov:13100/PCD-HL7WebPreCon/
 - ➤ IHE-PCD Connectathon:

 http://hit-testing.nist.gov:13100/PCD-HL7WebCon/
- NIST Medical Device Terminology Service:
 - Rosetta Terminology Mapping Management System (RTMMS): http://hit-testing.nist.gov:13110/rtmms/
- NIST Implementation Conformance Statement Generator (ICSGenerator):
 - http://hit-testing.nist.gov/medicaldevices/ICSGenerator/ics_download.html