

ISO/IEEE 11073, HL7 Medical Devices WG and NIST

NIST Medical Device Connectivity Test Tooling Semantic Interoperability of Medical Devices

HL7/IEEE WG Meetings (Healthcare Devices WG @ Cambridge, Mass) October 5, 2010





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- GRs: Jing Gao, Julien Deshayes, Isabelle Barclay

Project Web site:

www.nist.gov/medicaldevices





Topics

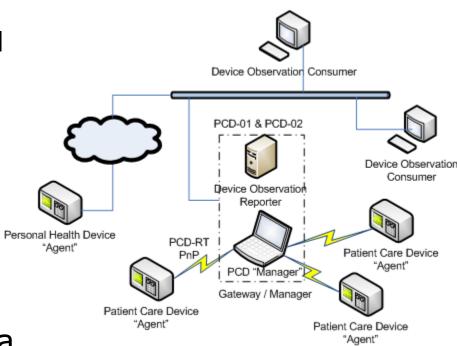
- Areas being addressed by Test Tooling Effort
- HIT Test Infrastructure
 - Conformance testing across various test environments
 - IHE-PCD HL7 Message Verification
 - Using Profiles (constraints → assertions)
- IHE-PCD Tooling (2010-11 cycle 5)
 & going forward...(2011-12 cycle 6)
- ISO/IEEE 11073 Tooling
 - ICSGenerator (Sandra)
 - RTMMS (Maria)





NIST Test Effort

- Medical Device Standards
 Work
 - Device and Enterprise-level
- Integrating Health Enterprise - Patient Care Devices (IHE-PCD)
 - Enterprise-level
 - Personal Health Devices
 - Personal Tele-health-level
- Facilitate the efficient exchange of medical device and vital signs data throughout the HC enterprise
 - Test Research Methods
 - Conformance →
 Interoperability (based on Standards)
 - Ultimately: Real-time plugand-play interoperability



Medical Device Communication



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 and underlying standards (e.g. HL7,x73)
- Establish single framework for PCD covering increasing complexity and technologies over next 5 years
- Coordinate with IHE "Gazelle Project" and NIST's HIT Test Infrastructure
- Generate work products that companies can use in their regulatory submissions or help in product evaluation



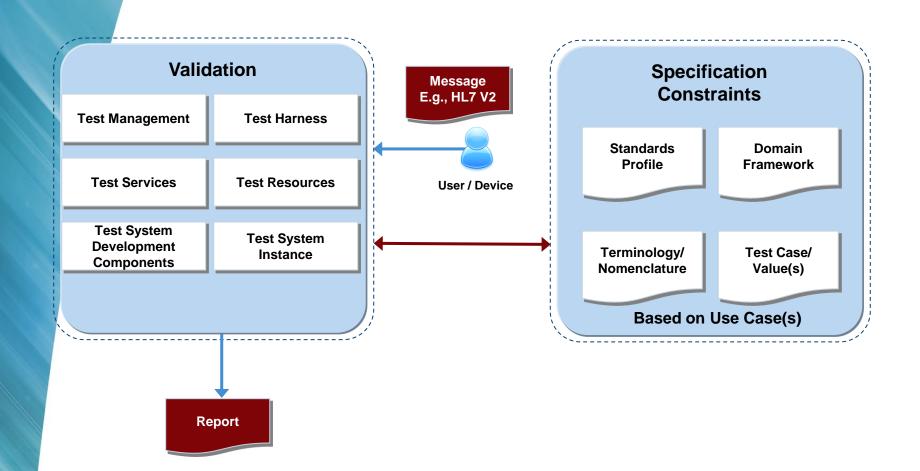
IHE-PCD Testing – Key Ingredients

- Well Defined Integration Profiles
 - Technical Framework
 - Supplements
- Unambiguous Standards
- Implementation Guides
- 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





Conformance Testing: Using 'Profiles' to Advance Rigorous Testing

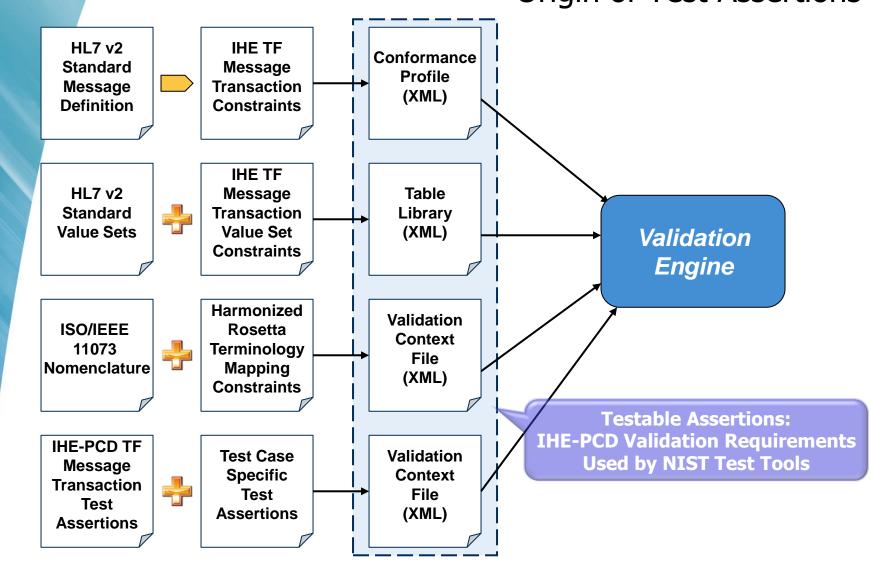


Patient Care Devices (PCD)





Validation Operational Process: Origin of Test Assertions



Patient Care Devices (PCD)





NIST V2 Testing Tools and Services 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 datatype 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.





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

- Validation of IHE-PCD message(s) and corresponding HL7 Profile(s)
- 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 Test Tool: Test Cases

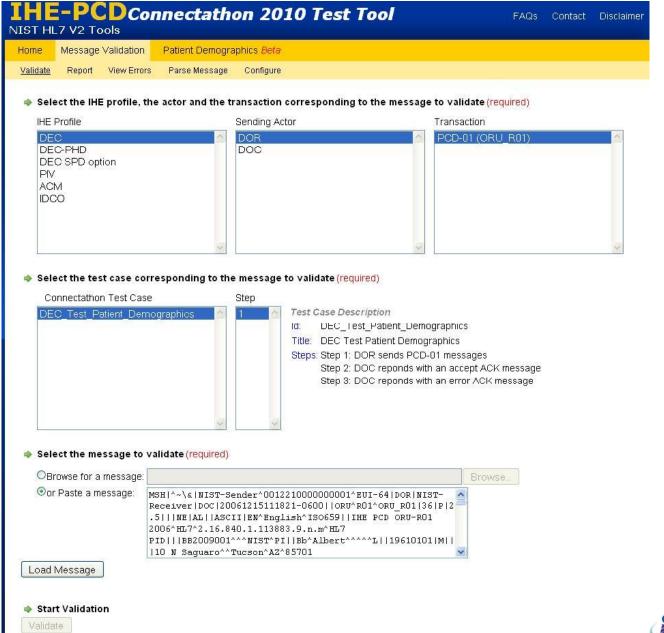
	IHE Profile	Test Case Title	Description		
1	DEC	NIST DEC DOR DOF DOC Patient Demographics Table2010927	Step 1	PCD-01 (ORU^R01^ORU_R01)	DOR sends data for patient in table 2010927
			Step 2	ACK (ACK^R01^ACK)	DOC responds with ACK message (MSA- 1 = "AA")
2	DEC	NIST DEC DOR DOF DOC One to One Communication	Step 1	PCD-01 (ORU^R01^ORU_R01)	DOR sends data for patient Albert Hon (MRN: HO2009001, DOB: Jan.1 1961, Location: HO Surgery, OR-1, Sex: M, Mother's Maiden Name: Adams). At least 4 parameters for each type of device are sent. Patient's data is not validated
			Step 2	ACK (ACK^R01^ACK)	DOC responds with ACK message (MSA- 1 = "AA")
			Step 3	PCD-01 (ORU^R01^ORU_R01)	DOR sends data for patient Charles Hon (MRN: HO2009002, DOB: Feb.1 1961, Location: HO Surgery, OR-2, Sex: M, Mother's Maiden Name: Brooks). At least 4 parameters for each type of device are sent. Patient's data is validated
			Step 4	ACK (ACK^R01^ACK)	DOC responds with ACK message (MSA- 1 = "AA")
3	DEC SPD Option	NIST DEC SPD By Location	Step 1	PCD-02 (QSB^Z02^QSB_Q16)	DOC sends subscription to DOF requesting patients in the ICU
			Step 2	ACK (ACK^Q16^ACK)	DOF sends ACK to DOC
			Step 3	PCD-01 (ORU^R01^ORU_R01)	DOR sends data for patient Amy Hon (MRN HO2009003) in ICU to DOF
			Step 4	ACK (ORU^R01^ORU_R01)	DOF sends ACK to DOR
			Step 5	PCD-01 (ORU^R01^ORU_R01)	DOF sends received data for patient Amy Hon to DOC
			Step 6	ACK (ORU^R01^ORU_R01)	DOC sends ACK to DOF
			Step 7	PCD-01 (ORU^R01^ORU_R01)	DOR sends data for patient Albert Hon (MRN HO2009001) in OR to DOF
			Step 8	ACK (ORU^R01^ORU_R01)	DOF sends ACK to DOR. DOF does not forward the message to DOC.





IHE-PCD Pre- and -Connectation Tool

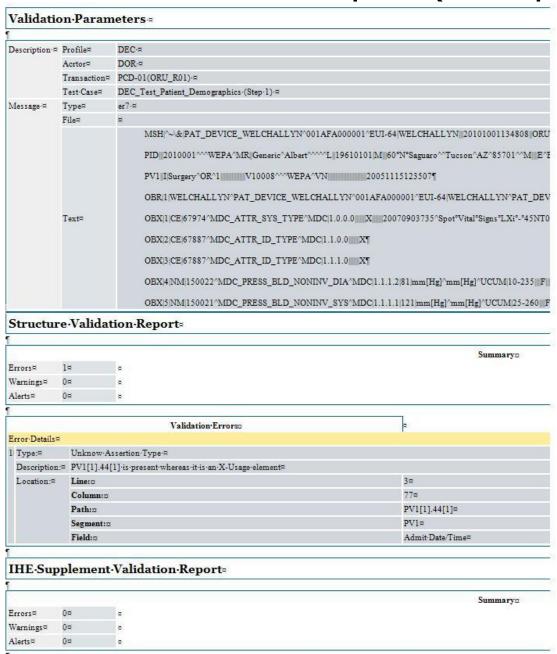
http://xreg2.nist.gov:8080/PCD-HL7WebCon/







Validation Report (Example)





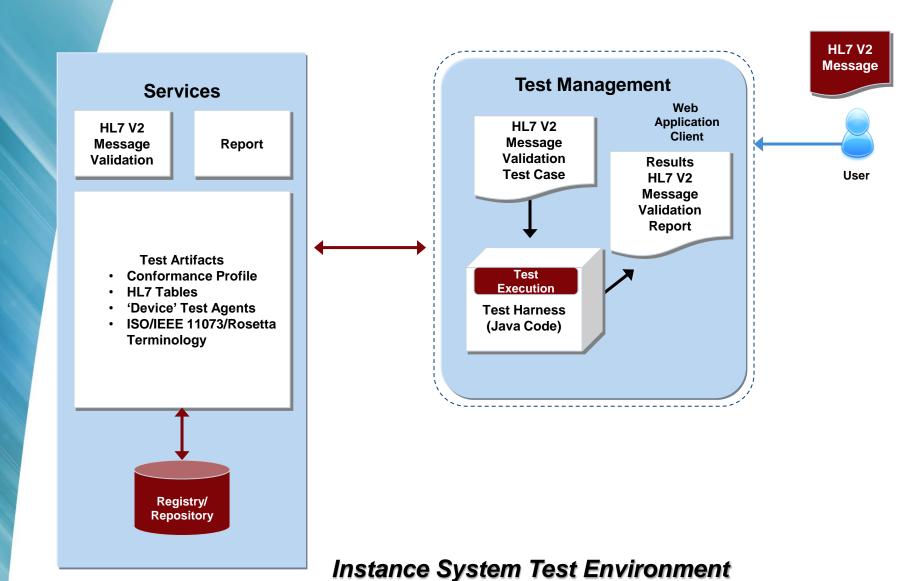
Test Environments

- Instance Testing
 - Conformance (e.g., against HL7 V2.x or CDA)
 - Implementation conforms to Spec. on which it is based
- Isolated System Testing
 - Includes *Instance Testing* Activities
 - Protocol Conformance
 - Functional Behavior Conformance
 - Features and Operational behavior correspond to Specs.
- 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





Conformance Testing of an HL7 V2 Message







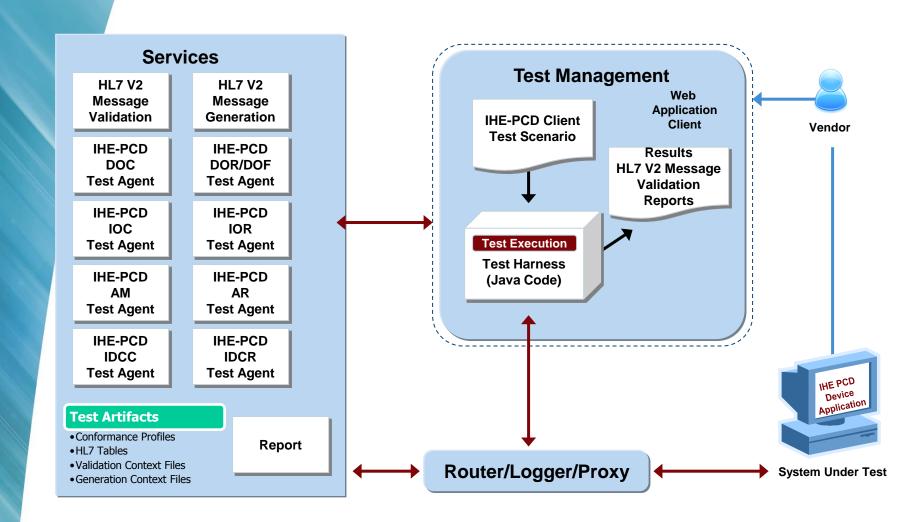
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IHE-PCD Testing using a Web Application Client







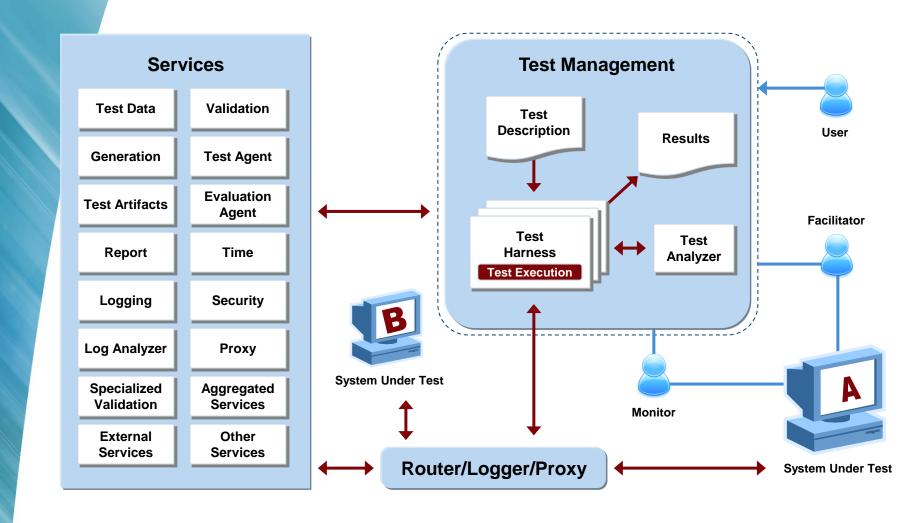


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A Framework for Building Test Systems—an SOA Approach



Peer-to-Peer Test Environment





ISO/IEEE 11073 – How Are We Involved?

- MDC Standards development
 - ISO/IEEE 11073 Point-of-care Medical Device Communication
 - Co-chair new normative chapter addition provides NIST developed electronic information model
 - Assist development of more complete and correct specifications prior to balloting
 - Work with SDOs (testing perspective), clinicians, clinical engineers
- Device Communication Test Tooling
 - XML Schema of the ISO/IEEE 11073 Domain Information Model
 - ICSGenerator Tool
 - Produces standard-compliant device profiles and specializations
 - Generates Implementation Conformance Statements
 - 'Rosetta' Terminology Management System
 - Standardized terminology across MD manufacturers
 - ValidatePDU Tool
 - Provides message syntax and semantic validation
 - Java Class Library (of standard's syntax notation)
 - Implementable-code of abstract types defined in standard
 - Coder (encodes and decodes APDUs/messages)





NIST Test Tool: "ICSGenerator"

National Institute of Standards and Technology (NIST)

SANDRA MARTINEZ, John Garguilo

5 October 2010





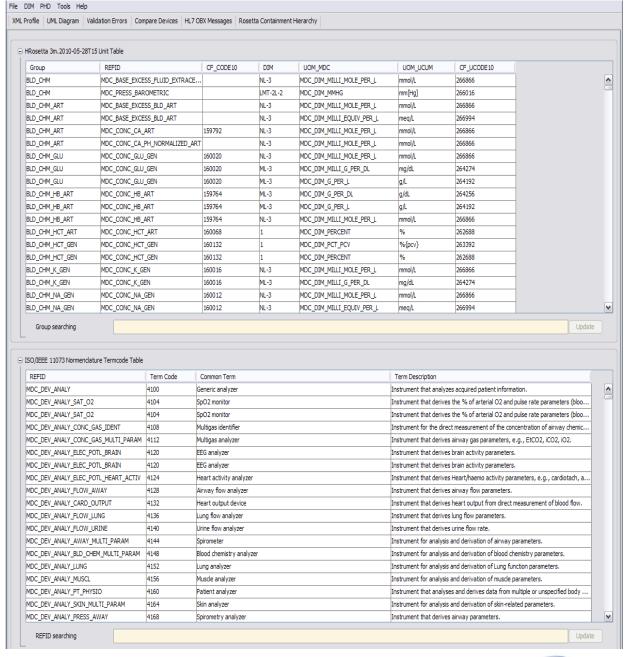
ICSGenerator: Status Update (since last meeting)

- Incorporated hRTM Database (latest version 3M)
 - unit code
- Enhanced hRTM and x73 Nomenclature database display with group and keyword searching
- Added a profile unit display table
- Added ability to change parameter cardinality
- Improve application interface to increase usability.
 - Private attribute now available from the attribute table display.
 - Ability to edit and remove attributes from the attribute table display.
 - Added drop down menu for unit code on a Nu-obs-Value.
 - Profile specific from the profile unit table.
 - Enhanced object Type Id drop down menu providing RefId search capability with term code and term code description.
- Reviewed and enhanced the ANS.1 library.
- Develop ventilator setting profile in support of "ICE-PAC Rapid Device Configuration" project.





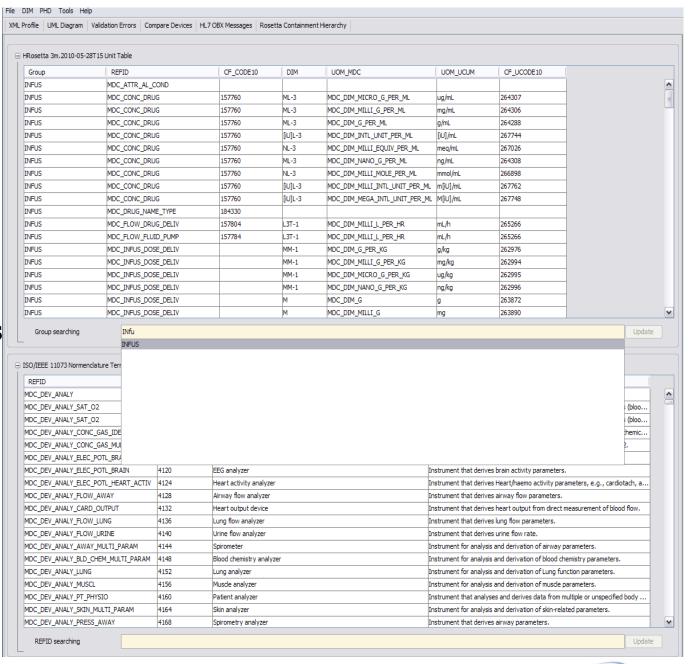
hRTM and x73
Nomenclature
database display
with keyword
searching.







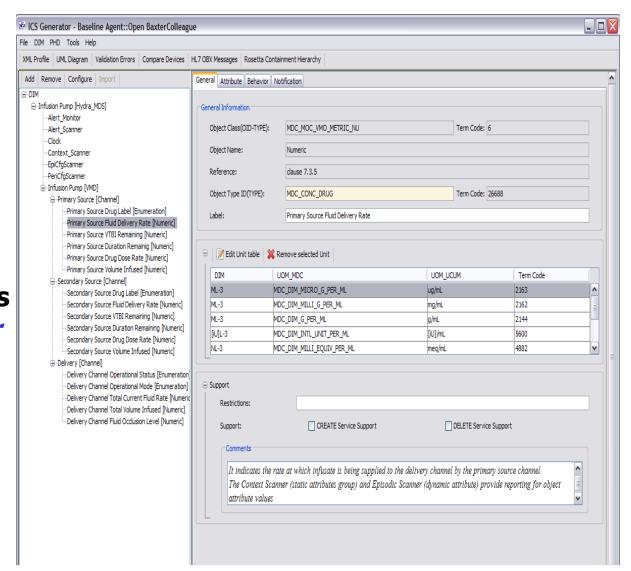
hRTM group searching







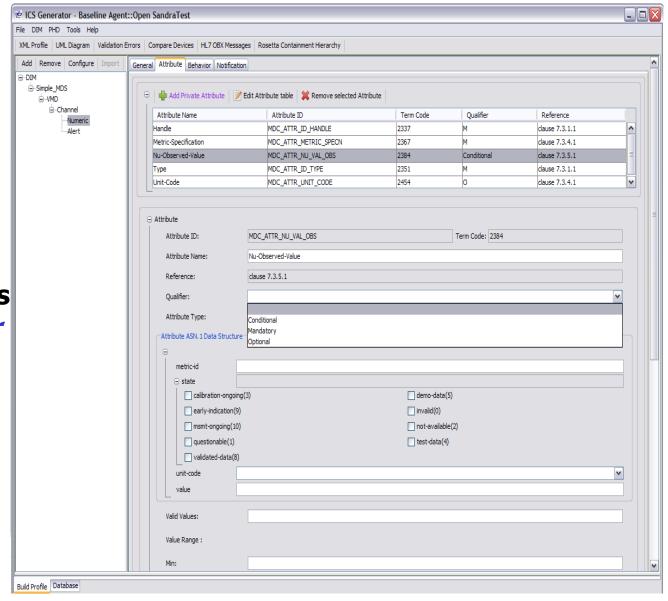
 Unit code drop down from hRTM Database







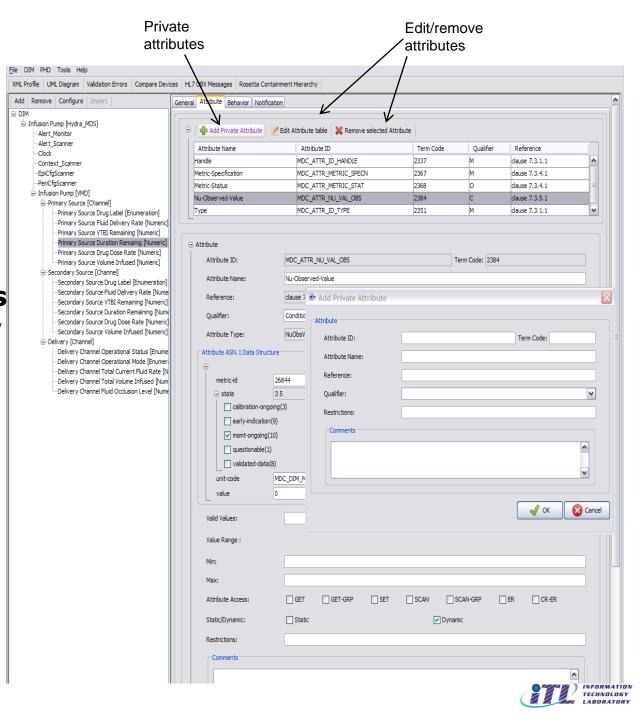
Changing parameter cardinality





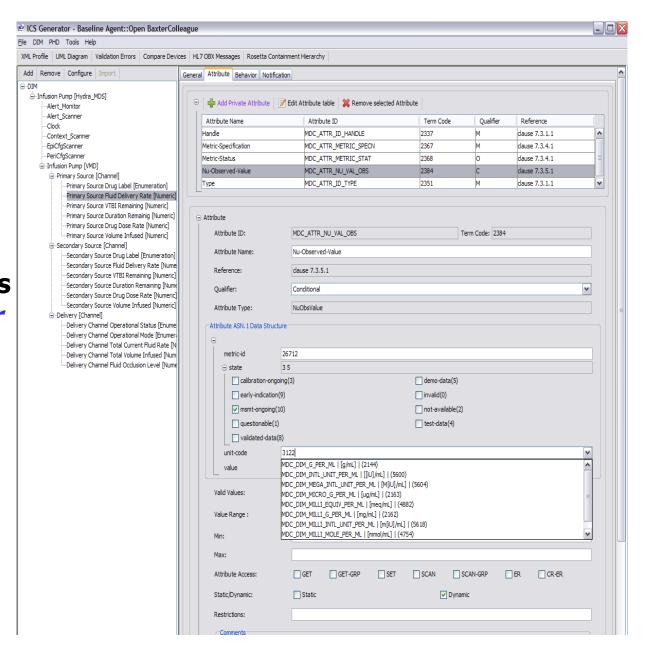


 Private attribute available from the attribute table display.





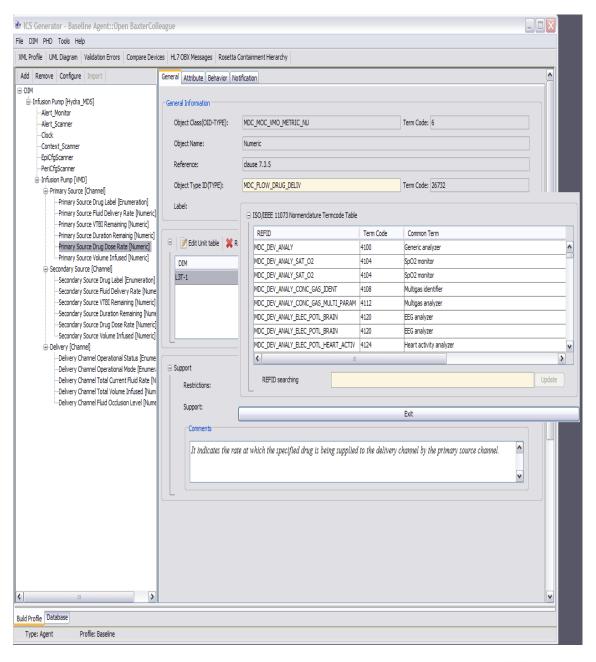
 Drop down menu for unit code on a Nu-obs-Value







 Object Type Id drop down menu and RefId search capability including term code and term code description.







ICSGenerator: Next Steps

- Add hRTM database update capability
- Add Enumeration values from hRTM
- Work on profile template capability
- Add capability to select ASN.1 types for private attributes.
- Add the capability of customize and save a profile unit table
- Finalize implementation of RCH, (expecting guidance...)
 - Implementing OBXV and derived OBX-4
- Update PHD DIM and specialization profiles
- Working on delivering an ICSGenerator web application
- Developing an ICSGenerator launching program to:
 - Synchronize/update required packages automatically
 - E.g., the hRTM database
- Continue code improvement and enhancement.





ICSGenerator: Issues

Discussion Points

- Valid values and value range...
- Object template capability...
- Profile Template use case...

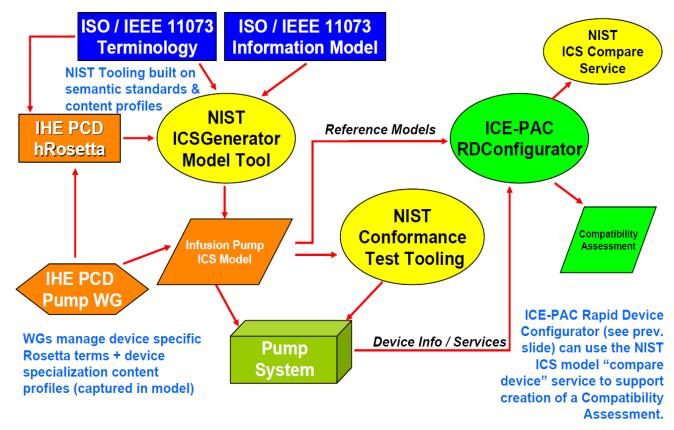




ICSGenerator: Leveraging the Tool

- To support IHE-PCD device specializations (e.g., MEM, DPI)
- In support of ICE-PAC Rapid Device Configuration
 - For the generation of compatibility assessments.

RDC Device Models – Leveraging NIST ICSGenerator Tooling







NIST Tool:

"Rosetta Terminology Mapping
Management System"

(RTMMS)

(*Championed by Paul Schluter [GE Healthcare])

National Institute of Standards and Technology (NIST)

MARIA CHERKAOUI,
John Garguilo, Sandra Martinez
5 October 2010





IHE PCD Profile: RTM

Rosetta Terminology Mapping

- Identifies the core set of semantics appropriate for medical devices
- Maps vendors terminology to standard terminology
- Maps numeric parameters to their associated unitsof-measure and enumerated values
- ftp://ftp.ihe.net/Patient_Care_Devices/TechnicalFra meworkforTrialImplementation/IHE_PCD_TF_Suppl ement_Rosetta_Terminology_Mapping_RTM_TI_20 08-08-22.pdf





IHE PCD Profile: RTM

Goals:

- Identify terms that are missing from the standard nomenclature
- Ensure correct and consistent use of units-ofmeasure
- Ensure correct and consistent use of enumerated values





IHE PCD Profile: RTM

- 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





RTMMS Overview

- A web application that allows vendors and reviewers:
 - access, retrieval, and reporting of Rosetta Tables over the internet in conformance to IHE RTM Profile.
 - saving the data in the xml format as defined by RTM Profile.
- Aids in The harmonization process by:
 - Identifying missing terms.
 - Automatic generation of the "Harmonized Rosetta Table"
 - Viewing and downloading latest hRTM table.
- Facilitates the proposal of New Terms to x73 Nomenclature





Features Added Since Last Meeting

- Enhanced NIST x73 Nomenclature database
 - Included Terms in both annexes A and B.
 - Included IDC Nomenclature
- Highlighted Proposed Terms in Rosetta, Units and Enumerations Tables
- Implemented Interface to:
 - lookup REFID from x73 Nomenclature database
 - propose New Terms to the standard
- Implemented "Proposed Terms" management features for SDO users
- Enhanced registration process
 - Email confirmation, approval...
- Added Admin Type of users





Features Added (continued)

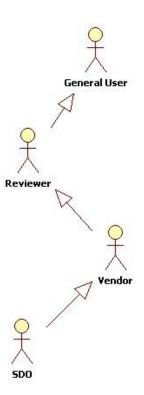
- Added ranking capabilities to assess probability of valid terms in the Rosetta table
 - Scale from 1 to 10
- Included column filtering based on regular expressions
- Implemented Rosetta validation against hRTM
- Added XML Units and Enumerations Download
- Added "Enumerations" management capabilities
 - Edit/Add Enumeration
 - Deprecate Enumeration
 - Edit/Add Enumeration Group
 - Deprecate Enumeration Group





RTMMS Users

- General user
 - Views Rosetta Tables
- Reviewer
 - Participates in discussions
- Vendor
 - Modifies Vendor Rosetta Table
 - Suggests new terms
- SDO
 - Modifies Units and Enumerations Table
 - Register new terms
- Admin
 - Manages User Accounts







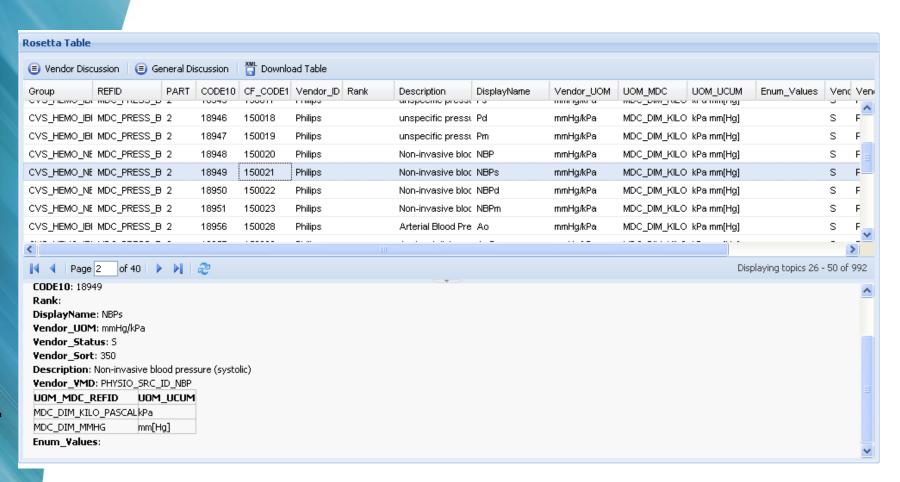
'General' Type User Capabilities

- View/Download Rosetta Table
- View/Download Units Table
- View/Download Enumerations Table





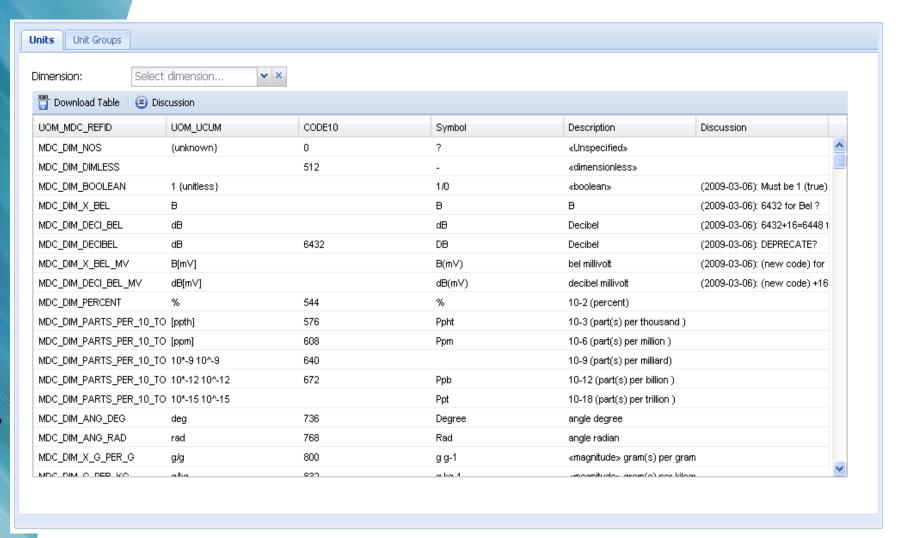
Rosetta Table







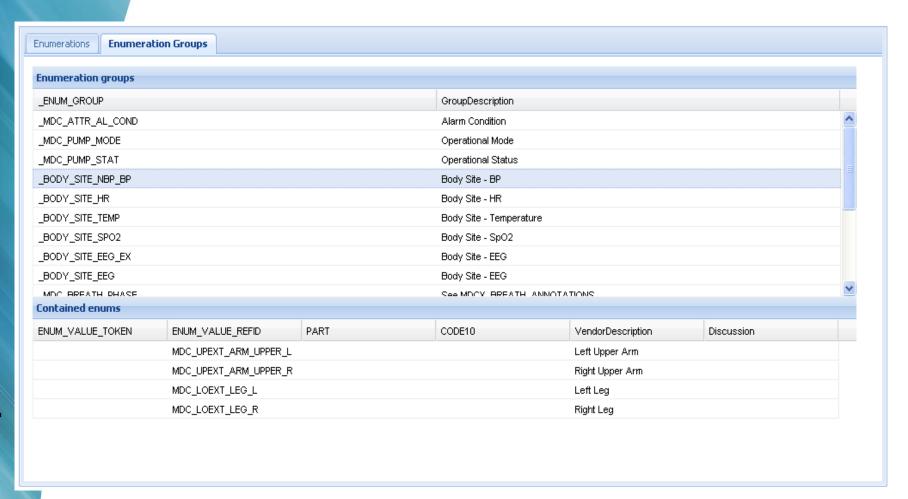
Units Table







Enumeration Group Table







'Reviewer' Type User Capabilities

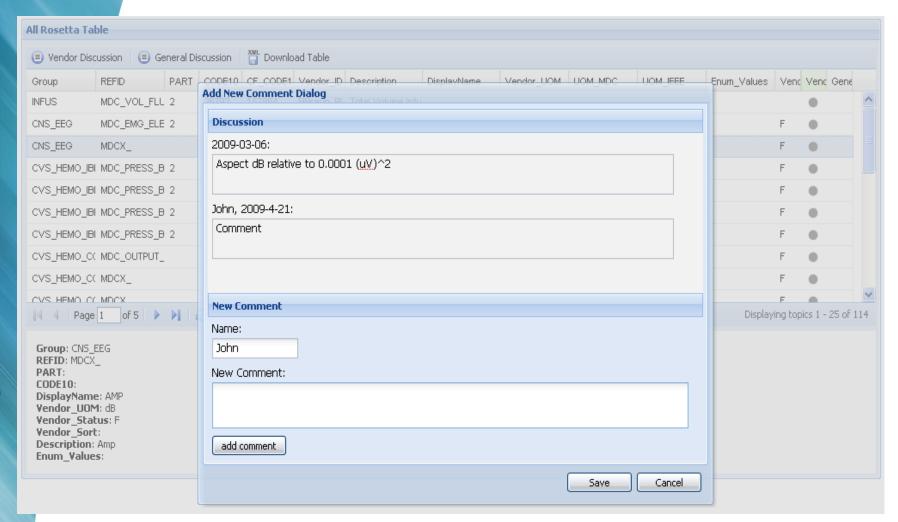
- Filter Rosetta Table
 - By Vendor ID (Philips)...
 - Using Regular Expressions (MDCX_.*)
 - Viewing Discussed Entries
- Contribute to Discussions
 - Adding Comments







Comment Dialog







'Vendor' Type User Capabilities

- Add a new Rosetta entry
 - REFIDs lookup from x73 Nomenclature
 - Group lookup from RTM tables
 - Units/Unit Groups and Enumerations/Enumeration Groups lookup from RTM tables
 - Term codes completion from x73 Nomenclature
 - Suggesting new terms to the standard
 - Validating Required fields
- Edit a Rosetta entry
- Deprecate a Rosetta entry
- Validate Rosetta Entries against current hRTM Table







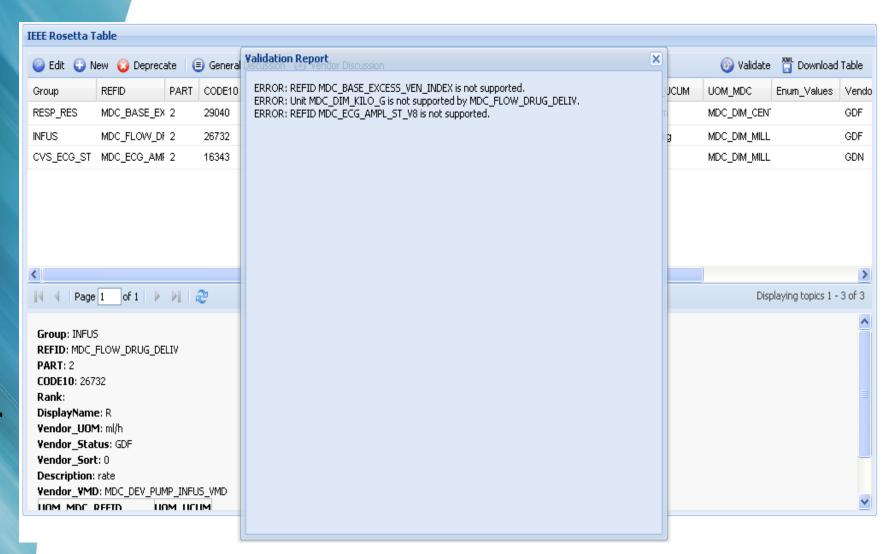
Edit Entry

— 🔼 Group informa	ation ————		— ■ Units/Enumerations —		
Group:	CVS_HEMO_NBP	•	has units	nerations	
− ▲ Term informa	tion —		UOM_MDC_REFID	UOM_UCUM	
REFID:	MDC_PRESS_BLD_NONINV_SYS	v X	MDC_DIM_KILO_PASCAL	kPa	
🔳 is uncertain RE	FID		MDC_DIM_MMHG	mm[Hg]	
PART:	2				
CODE10:	18949				
CF_CODE10:	150021				
Vendor param	Non-invasive blood pressure (systolic)				
	NIBP Sys				
DisplayName:					
DisplayName: Vendor_UOM:	mmHg/kPa				
	mmHg/kPa	v x			





Validation Report







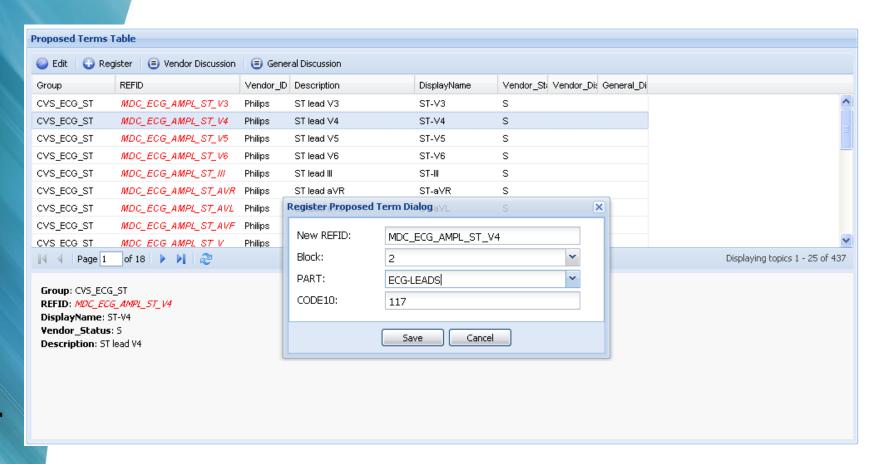
SDO' Type User Capabilities

- Review Proposed Terms
- Register a Proposed Term
 - Assigning term code
 - Automatically updating Vendor tables





Register Proposed Term







Next Steps

- Import XML Rosetta Data
- Implement Containment Hierarchy
- Edit hRTM Table
- Implement Backup cycle
- Implement versioning system
- Add logging history capabilities
 - To identify occurred changes, time they were made, users who made them...
- Automatic generation of hRTM

- RTMMS Release scheduled for May 2011
 - NIST Suggested/estimated time frame





Issues

- Should Vendors see other Vendors information?
- IEEE copyright issues
 - Against NIST Policy to maintain proprietary data
- Integration of SNOMED CT Terms
- Requirements needed for:
 - hRTM Automatic Generation
 - Currently all done by (and only by) Paul Schluter (GE)
 - Containment Hierarchy





Summary / Discussion

- Update/Continue work on Test Plans / Conformance Guide
- Developing Test Agents across Integration Profile Actors
 - Continue work on TF and Supplements
 - Further define 'scenarios' (message transaction sequences)
- RTMMS
 - Continue discussion of approving and adding normalized terminology to IEEE x73
 - Build on Today's Discussion (w/ Jan, Paul, Melvin, Todd, John R, others?)
 - Add two columns to support mapping to ITSDO work (w/ Jan) or others (perhaps Clem McDonald?) for SNOMED CD; LOINC?
- ICSGenerator
 - Start developing IHE-PCD Device 'specializations' for devices across various IHE-PCD Integration Profiles
- Explore OHT work (w/ Ioana, David Carlson)
 - http://mdht.projects.openhealthtools.org
- Questions? / Discussion...
- Thank-you!

