National Institute of Standards and Technology

IHE-PCD
ISO/IEEE 11073,
and
NIST

NIST Medical Device Connectivity Test Tooling

IHE-PCD/IEEE WG Meetings
(F2F @ Berkley, California)
May 4, 2010

Software and Systems Division

INFORMATION TECHNOLOGY LABORATORY

NIST Contacts

- John J. Garguilo
  301-975-4248
  john.garguilo@nist.gov
- Sandra Martinez
  301-975-3579
  sandra.martinez@nist.gov
- Maria Cherkaoui (Guest Researcher)
- Jing Gao (GR)

Project Web site:

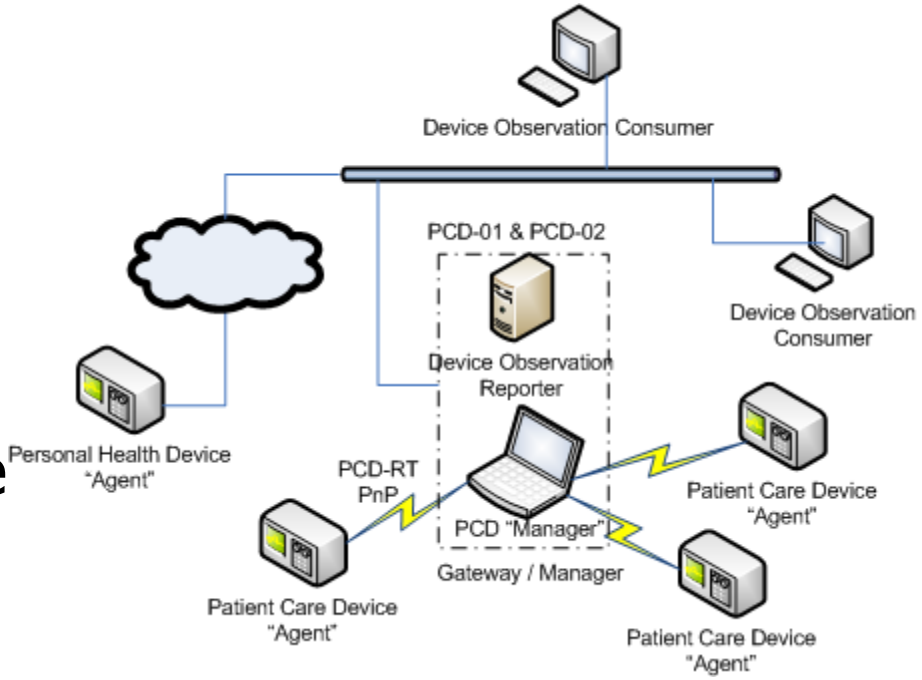
www.nist.gov/medicaldevices

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 cycle 4) & going forward…(2010-11 cycle 5)
- ISO/IEEE 11073 Tooling
  - RTMMS
  - ICSGenerator

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 plug-and-play interoperability



Medical Device Communication

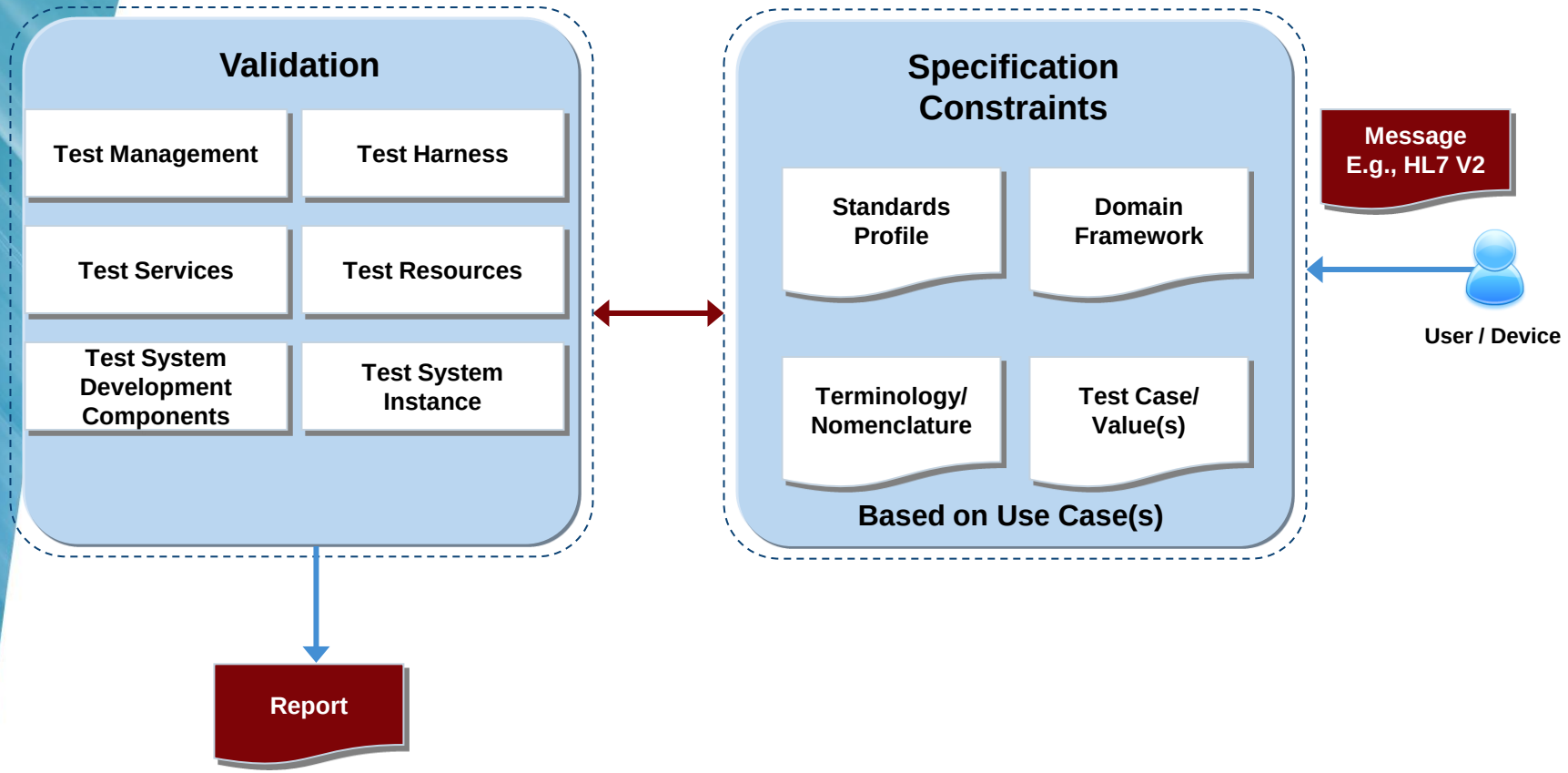
IHE-PCD Testing – Key Objectives

- 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
- 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

IHE-PCD Testing – Key Ingredients

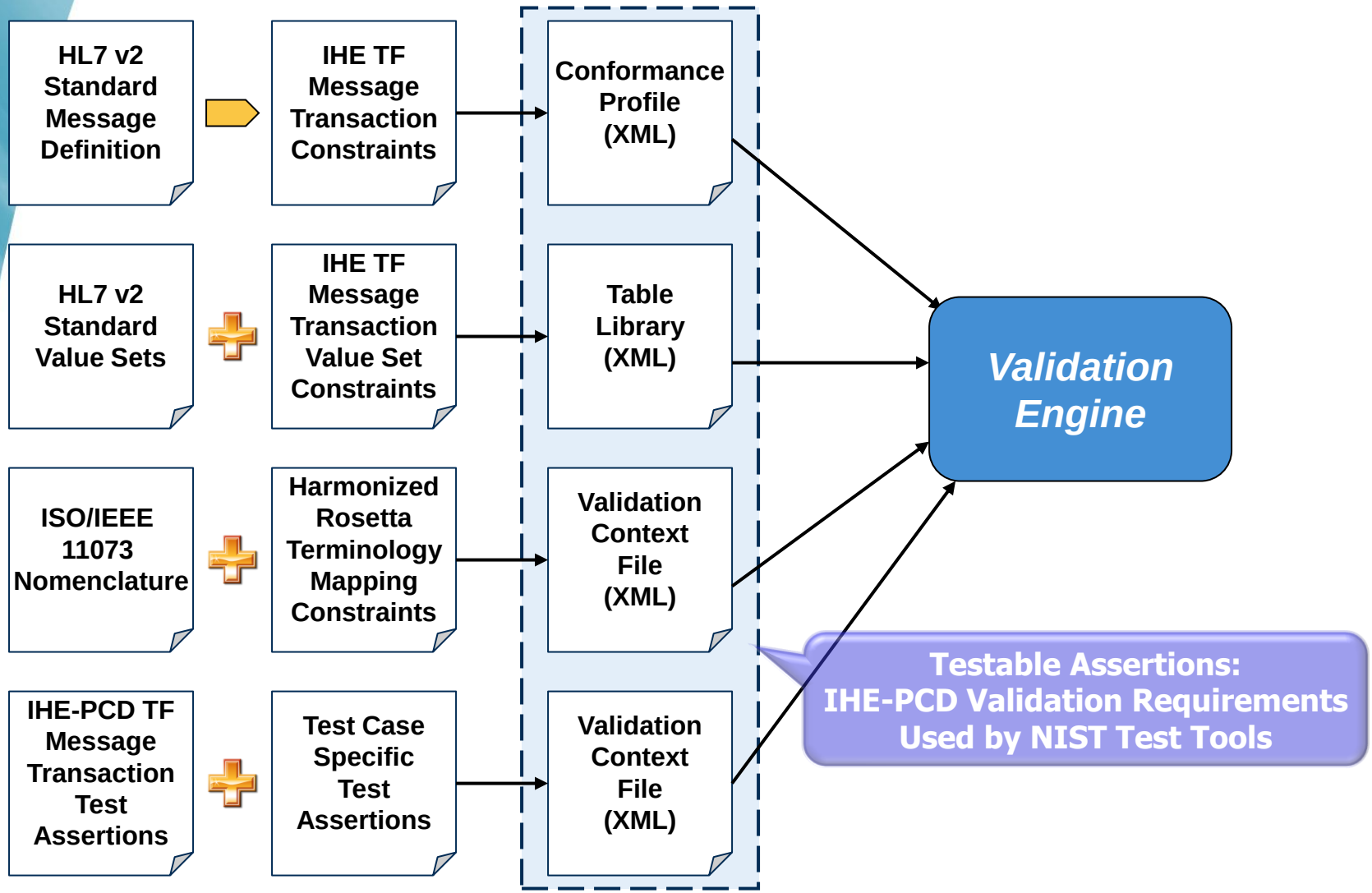
- Well Defined Integration Profiles
  - Technical Framework
  - Supplements
- Unambiguous Standards
- Test Guidelines
- Test Plans
  - Test Scenarios, Actors, Transactions, Validation Criteria
- Test Artifacts, including:
  - HL7 Profile(s) (*and eventually x73 Device Specializations?*)
  - Repositories
  - 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.

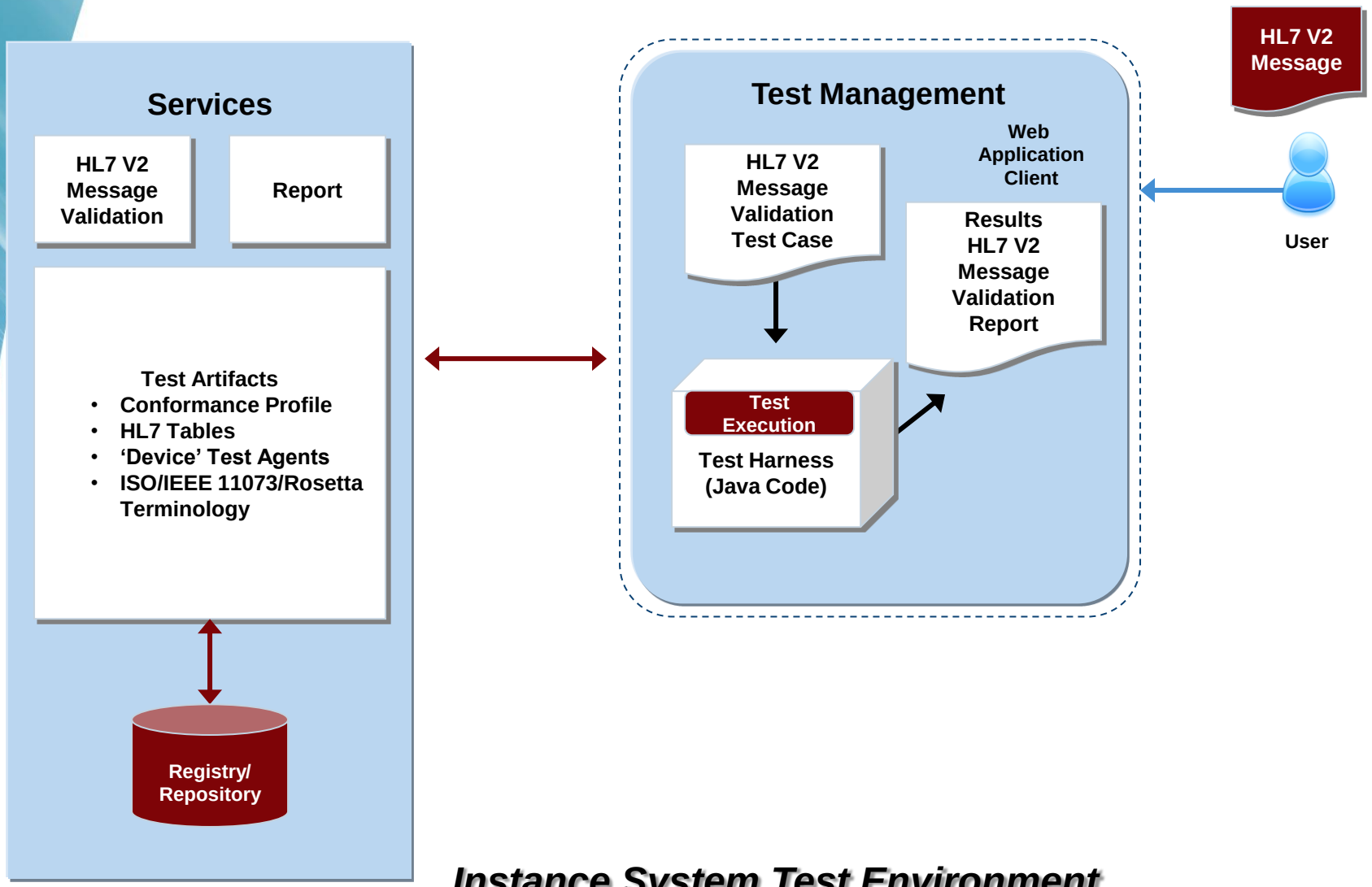
Test Environment Message Validation
NIST V2 Testing Tools: IHE-PCD

- 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)

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



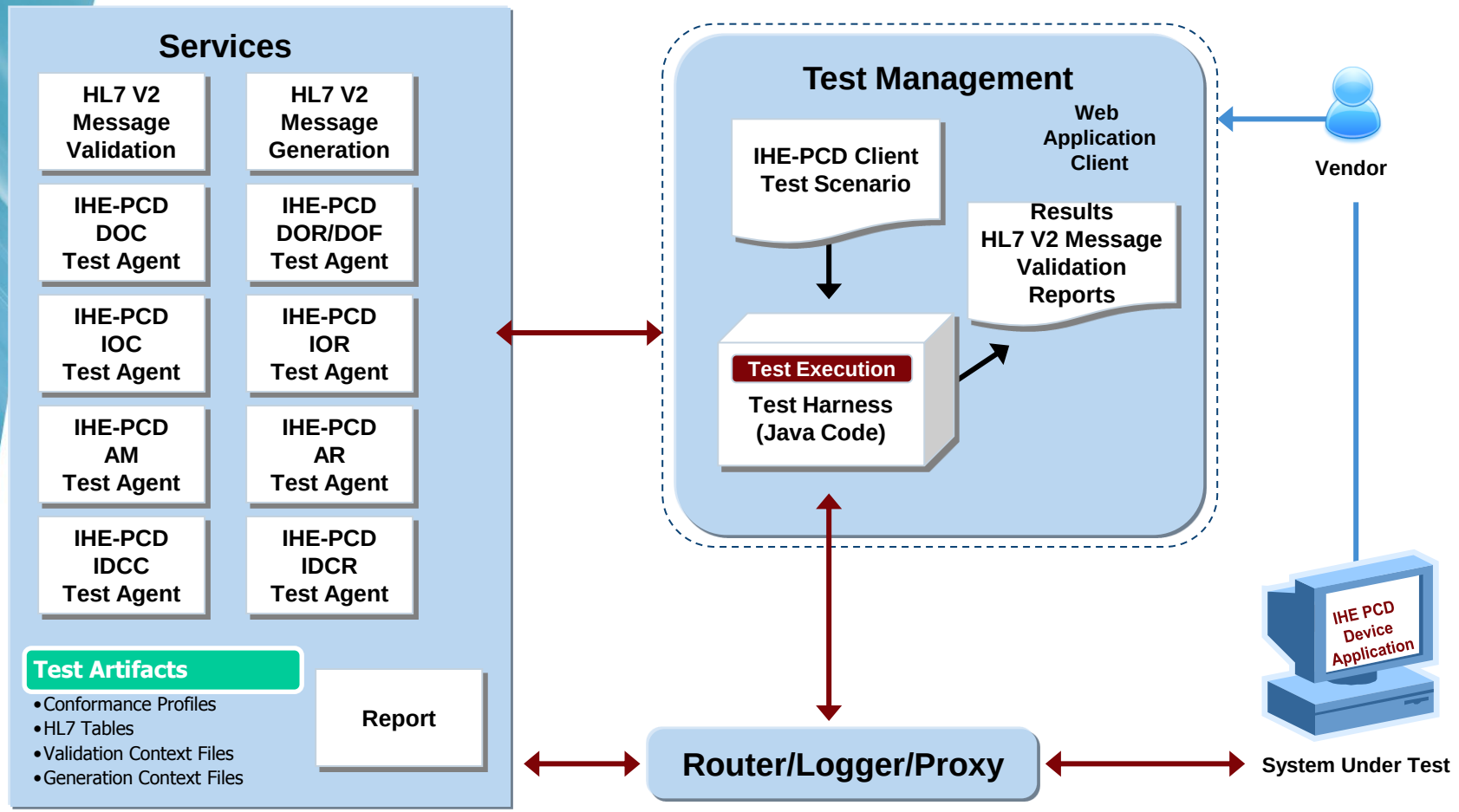
Instance System Test Environment

Software and Systems Division

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

IHE-PCD Testing using a Web Application Client



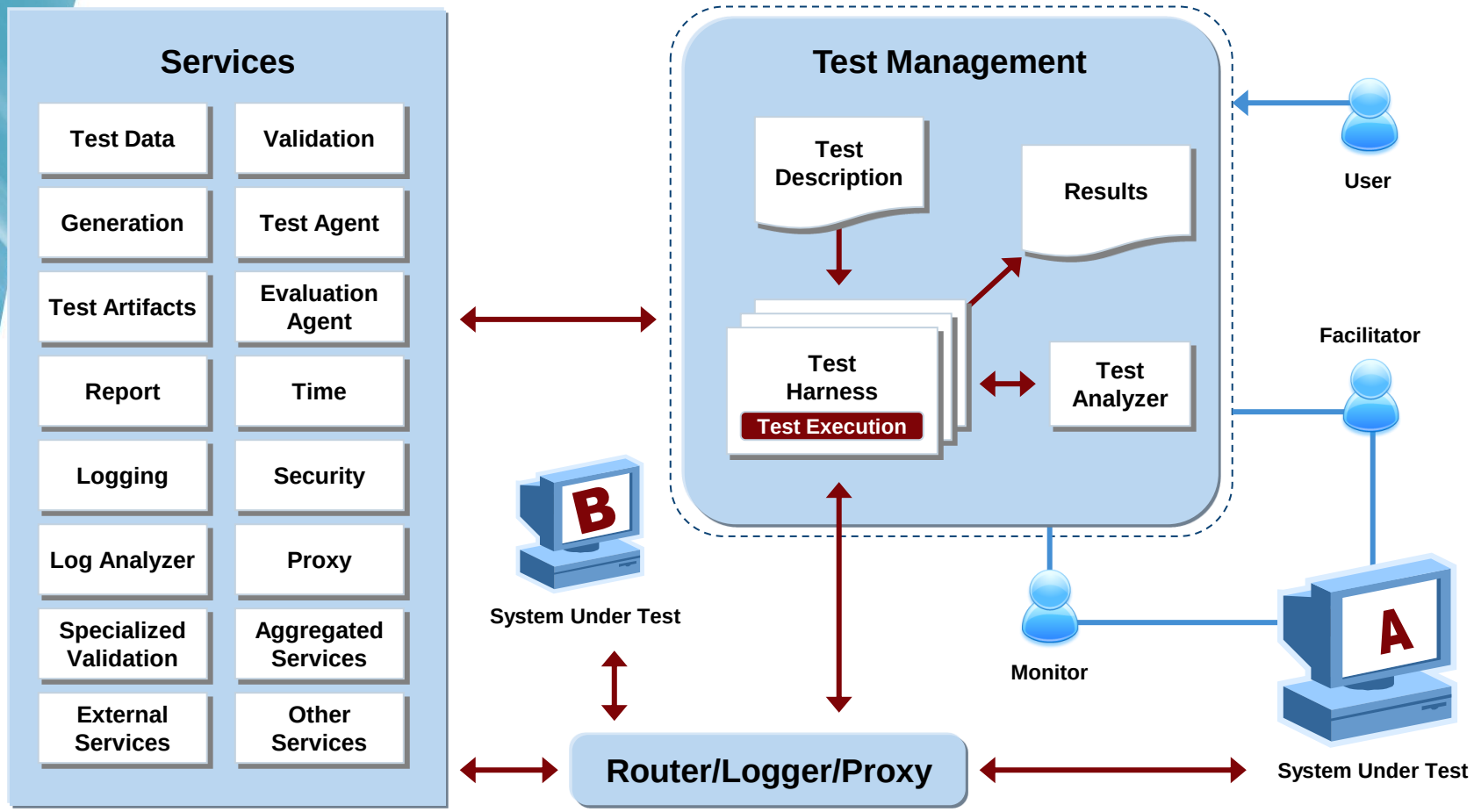
Isolated System Test Environment

Software and Systems Division

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

A Framework for Building Test Systems—an SOA Approach

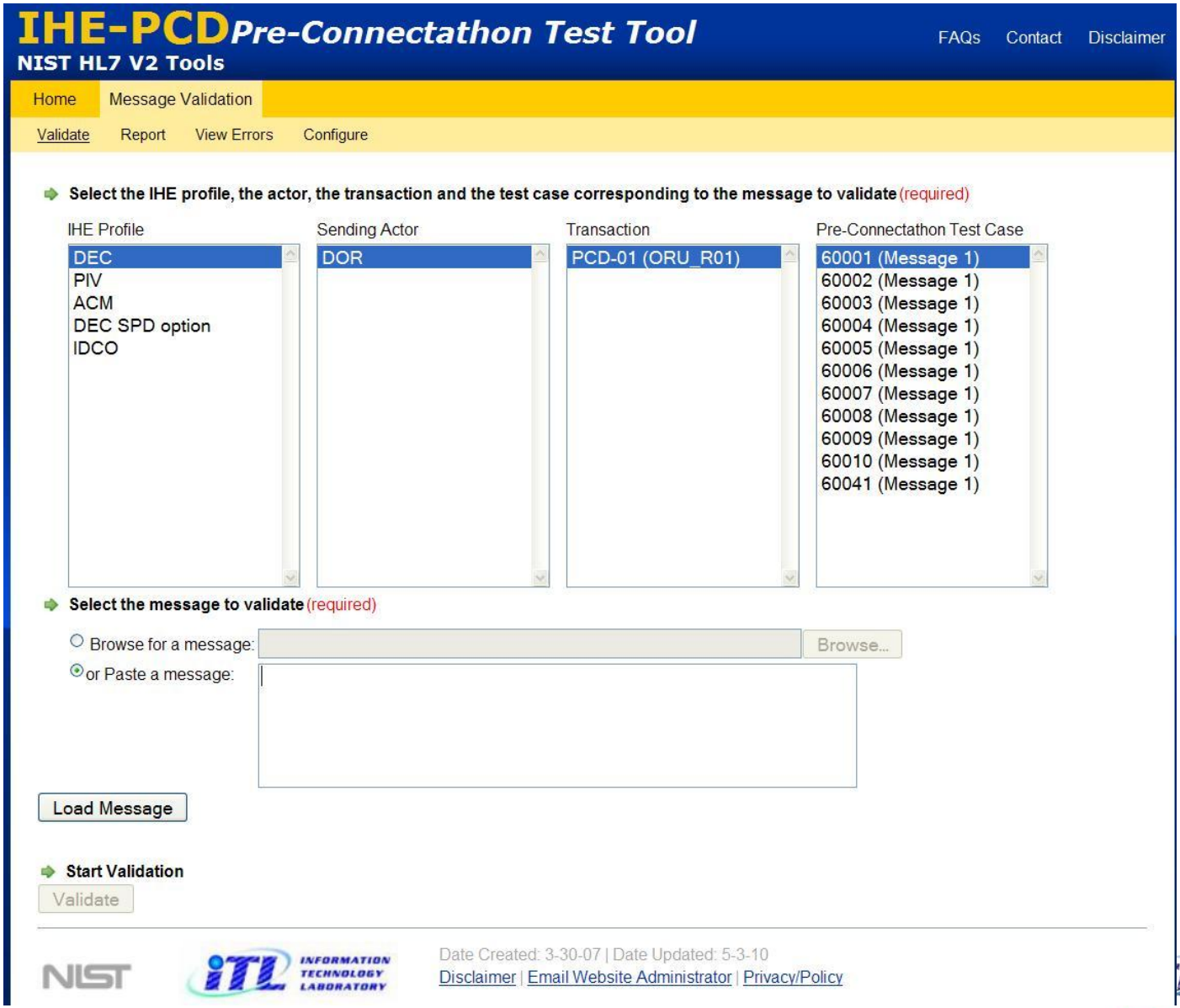


Peer-to-Peer Test Environment

NIST's IHE-PCD HL7 V2 Tools

IHE-PCD Pre-Connectathon Tool

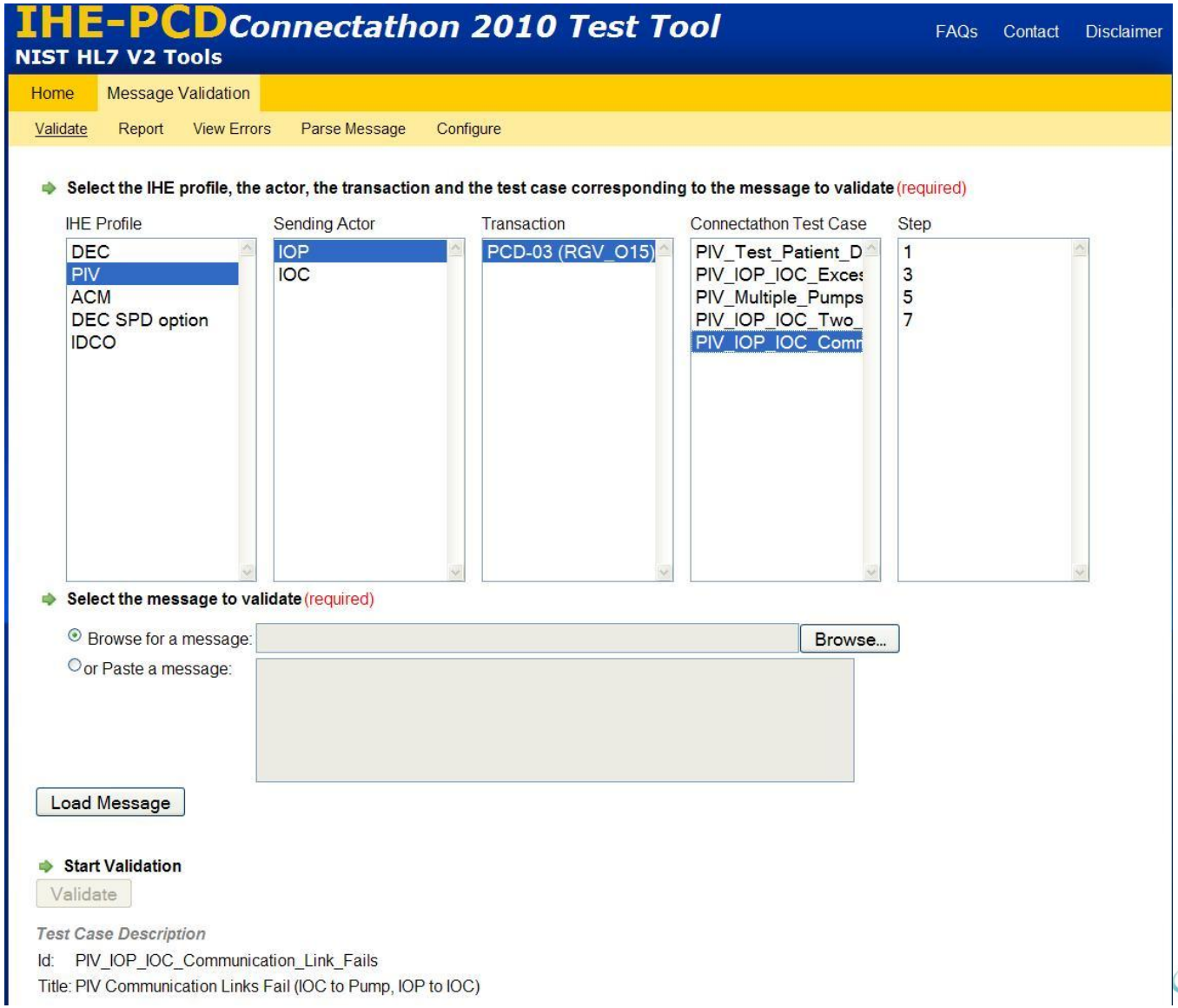
http://xreg2.nist.gov:8080/PCD-HL7Web/



NIST's IHE-PCD HL7 V2 Tools

IHE-PCD Connectathon Tool

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



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
  - 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)
  - 'Rosetta' Terminology Management System
    - Standardized terminology across MD manufacturers

National Institute of Standards and Technology

Software and Systems Division

Rosetta Terminology Mapping Management System (RTMMS)

National Institute of Standards and Technology (NIST)

MARIA CHERKAOUI, John Garguilo, Sandra Martinez

April 2010

INFORMATION TECHNOLOGY LABORATORY

NIST Tooling To Support RTM Process
(*Championed by Paul Schluter [GE Healthcare])

What is RTMMS?

- A web application that allows vendors and reviewers access, retrieval, and reporting of Rosetta Tables over the internet in conformance to RTM
- The tool provides the capability of saving the data in the XML format as defined by RTM
- Aid in The harmonization process by:
  - Identifying missing terms
  - Facilitate the proposal of new terms
  - Facilitate discussion of the proposed term
  - Automatic generation of the "Harmonized Rosetta Table"
- Database/XML Server initially prototyped and located at NIST
- A web service/tool used as part of SDO's ballot / approval process

"RTM Management System"

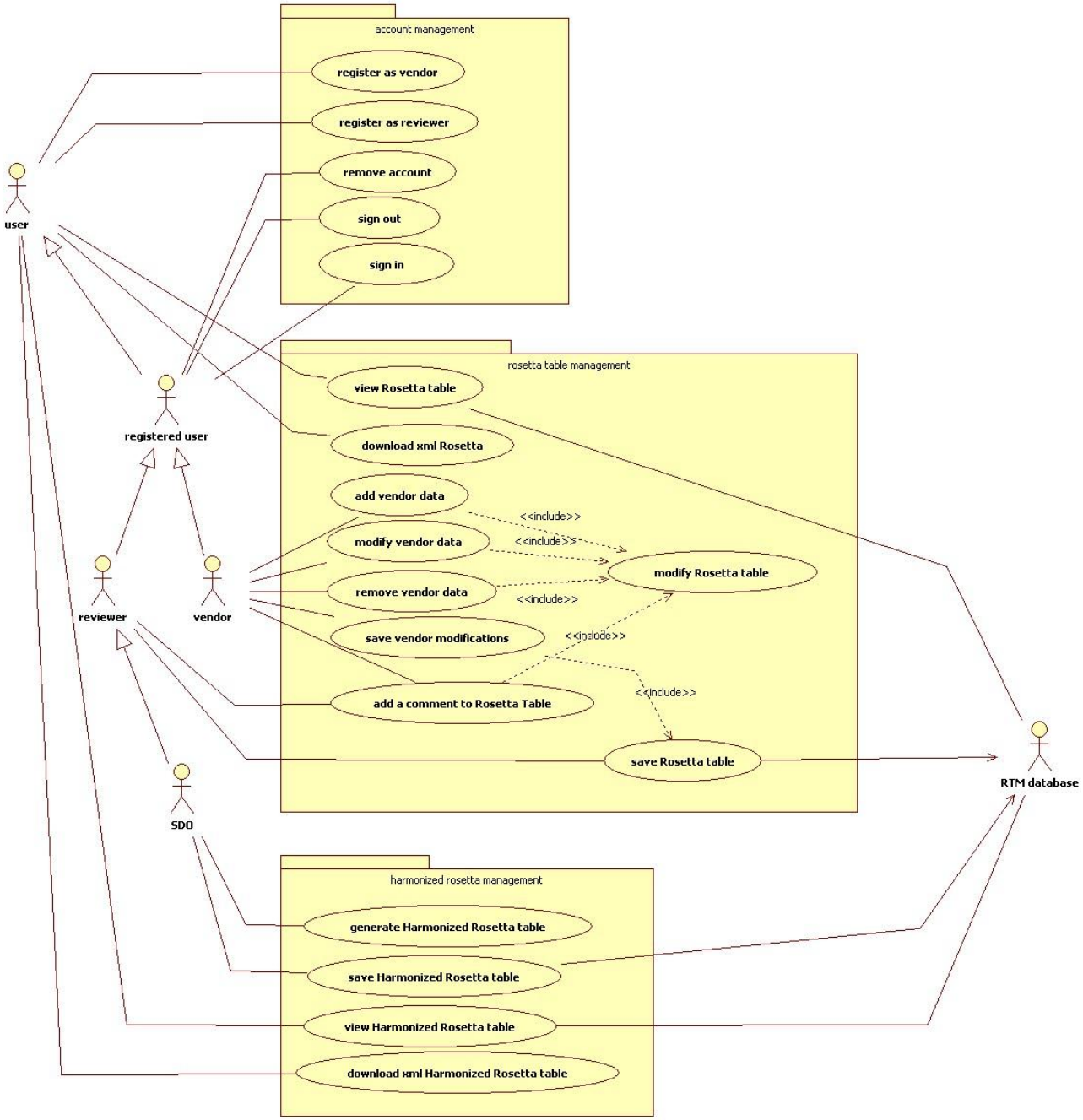
What is RTMMS? (Continued)

- Facilitate Conformance Tooling
  - Message verification and conformance
  - Leading to interoperability…

"RTM Management System"

RTMMS vs. RTM Excel process

- For Vendors
  - Facilitate input of entries by vendors
    - Tooltips providing supplementary information
    - Available Interface to lookup values from the database
    - Automatic completion of codes
    - Validation of required content
  - Reduce errors made by vendors while submitting entries
- For Reviewers and SDO
  - Facilitate the generation of the Harmonized Rosetta
  - Help the review process of Rosetta entries
    - Highlighting discussed entries
    - Highlighting proposed REFIDs
    - Adequate interface to view discussions and add comments
- For all users
  - Rosetta data available to everyone any time
  - Provide XML version of tables
    - All XSLT transformations can still be used


account management
register as vendor
register as reviewer
remove account
sign out
sign in
user
registered user
rosetta table management
view Rosetta table
download xml Rosetta
add vendor data
modify vendor data
remove vendor data
save vendor modifications
add a comment to Rosetta Table
save Rosetta table
modify Rosetta table
<<include>>
reviewer
vendor
SDO
RTM database
harmonized rosetta management
generate Harmonized Rosetta table
save Harmonized Rosetta table
view Harmonized Rosetta table
download xml Harmonized Rosetta table

RTMMS Roles

- "Non-registered User"
  - Able to download RTM (latest approved version)
- "Vendor" (Registered)
  - Able to view, edit and propose vendor terms (only for vendor they are registered with)
- "Reviewer" (Registered)
  - Able to view all vendor terms and make annotations (discussion points)
- "Expert Reviewer" (Registered and approved by SDO)
  - Technical expert (e.g., Jan Wittenber (Phillips) and Paul Schluter (GE)) who can view and comment on all vendor terms
  - Expert has the ability to generalize term to overall specification
- "SDO" (Standards Development Organization approved official)
  - Authority to approve/decline new or edited term proposed by vendor
  - Approval based on SDO ballet rules
  - Considers working group and especially 'Expert Reviewer' input
  - Usually chair/co-chair of standards body and or working group
- "Administrator" (Approved by 'SDO')
  - Provides administrative support to database
  - Generates and provides new user account information (user name and password), delete accounts, etc.

Database

- Models RTM data and relationships
- Uses x73 Nomenclature database
  - REFIDs
  - Term codes
  - Partition numbers
  - (New terms added as approved/normative additions to standard)
- Stores RTM data
  - Rosetta table
  - Units and Unit Groups
  - Enumerations and Enumeration Groups
  - hRTM table
  - (New terms proposed – may be missing from x73 Nomenclature Database)

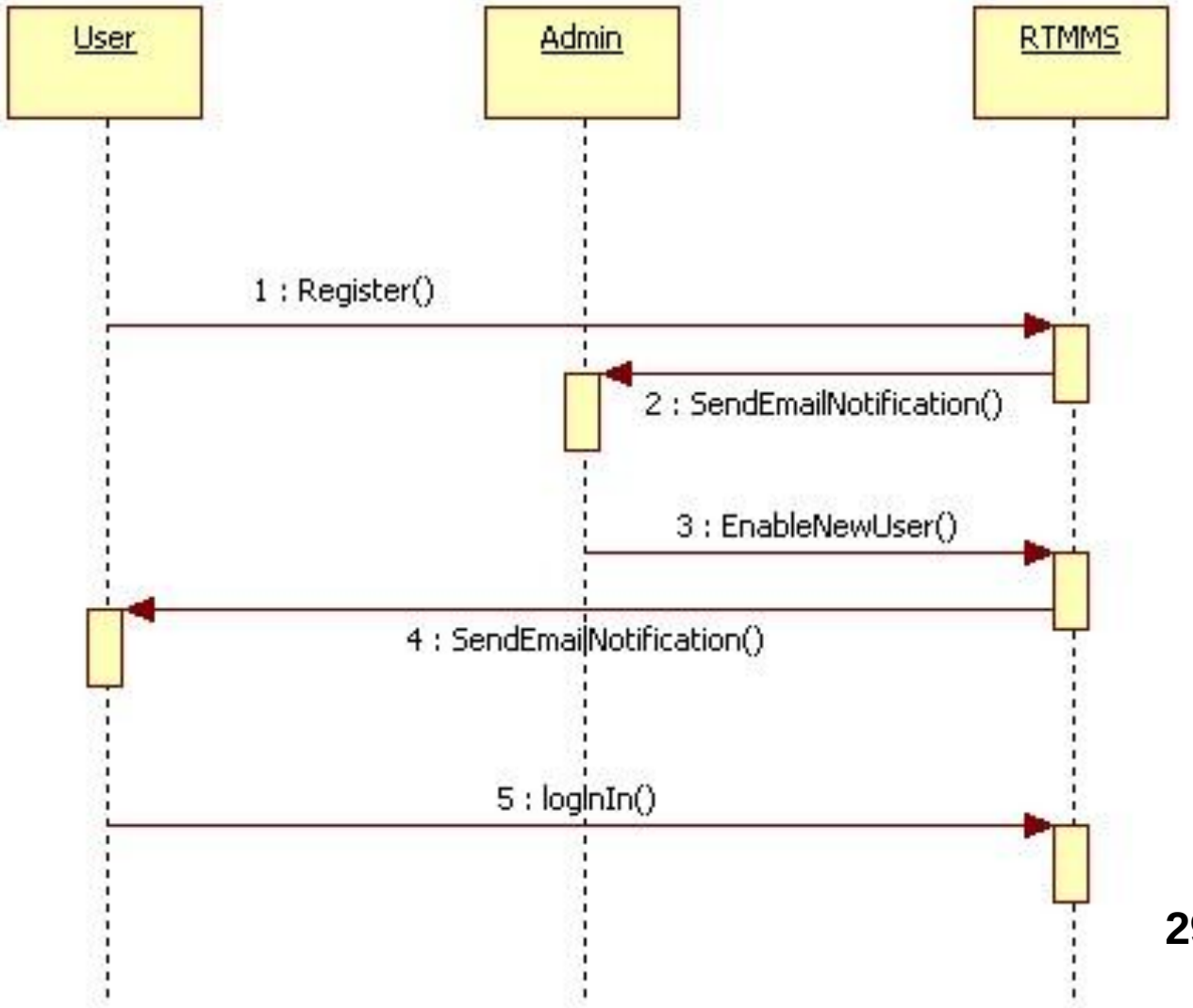
Available Features of RTMMS

- Features based on the Rosetta Supplement
  - Units table management
  - Unit groups management
  - Rosetta table management
  - Handling uncertain REFIDs
  - Automatic generation of the Harmonized Rosetta
    - Need additional requirements
  - XML Rosetta download
- User oriented features
  - User management module (Implemented user (roles) and privileges)
  - Columns filtering
  - REFIDs lookup in database
  - Group lookup in database
  - Units and Enumerations lookup in database
  - Term codes completion from database
  - Saving browsing history
  - User registration

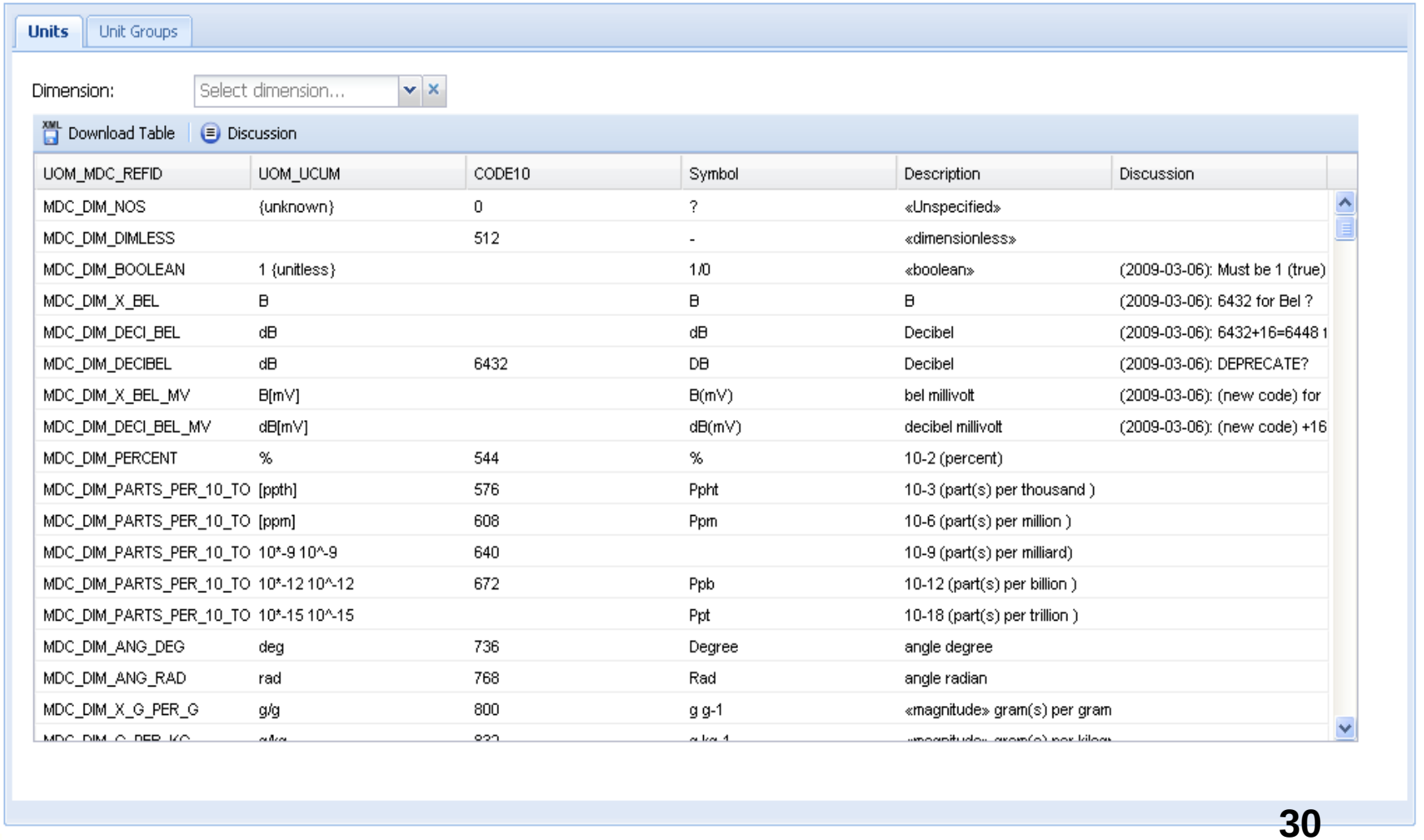
Features of RTMMS (continued)

- RTMMS Architecture improvements
- New Features (enhancements from May 2009 WG meetings)
  - New x73 Nomenclature
    - Terms in both annexes A and B.
    - IDC Nomenclature
  - Highlighted New Terms in Rosetta, Units and Enumerations Tables
  - Added Interface for selecting REFID from x73 Nomenclature database
  - Added Interface to propose New Terms
  - Added New Term View for SDO users
  - Implement Rosetta validation against H-Rosetta
  - Enhanced registration process.
    - Email confirmation, approval…
  - Added Admin Type of users to manage users and enable new users
  - XML Units Download
  - Added ranking capabilities to assess probability of valid terms in the Rosetta table
    - Scale from 1 to 10
  - Include column filtering based on regular expressions

User Registration



Units Table



Units | Unit Groups

Dimension: Select dimension...

Download Table | Discussion

UOM_MDC_REFID	UOM_UCUM	CODE10	Symbol	Description	Discussion
MDC_DIM_NOS	{unknown}	0	?	«Unspecified»	
MDC_DIM_DIMLESS		512	-	«dimensionless»	
MDC_DIM_BOOLEAN	1 {unitless}		1/0	«boolean»	(2009-03-06): Must be 1 (true)
MDC_DIM_X_BEL	B		B	B	(2009-03-06): 6432 for Bel ?
MDC_DIM_DECI_BEL	dB		dB	Decibel	(2009-03-06): 6432+16=6448 1
MDC_DIM_DECIBEL	dB	6432	DB	Decibel	(2009-03-06): DEPRECATE?
MDC_DIM_X_BEL_MV	B[mV]		B(mV)	bel millivolt	(2009-03-06): (new code) for
MDC_DIM_DECI_BEL_MV	dB[mV]		dB(mV)	decibel millivolt	(2009-03-06): (new code) +16
MDC_DIM_PERCENT	%	544	%	10-2 (percent)	
MDC_DIM_PARTS_PER_10_TO	[ppth]	576	Ppht	10-3 (part(s) per thousand)	
MDC_DIM_PARTS_PER_10_TO	[ppm]	608	Ppm	10-6 (part(s) per million)	
MDC_DIM_PARTS_PER_10_TO	10*-9 10^-9	640		10-9 (part(s) per milliard)	
MDC_DIM_PARTS_PER_10_TO	10*-12 10^-12	672	Ppb	10-12 (part(s) per billion)	
MDC_DIM_PARTS_PER_10_TO	10*-15 10^-15		Ppt	10-18 (part(s) per trillion)	
MDC_DIM_ANG_DEG	deg	736	Degree	angle degree	
MDC_DIM_ANG_RAD	rad	768	Rad	angle radian	
MDC_DIM_X_G_PER_G	g/g	800	g g-1	«magnitude» gram(s) per gram	

Enumeration Groups Table

Enumerations | **Enumeration Groups**

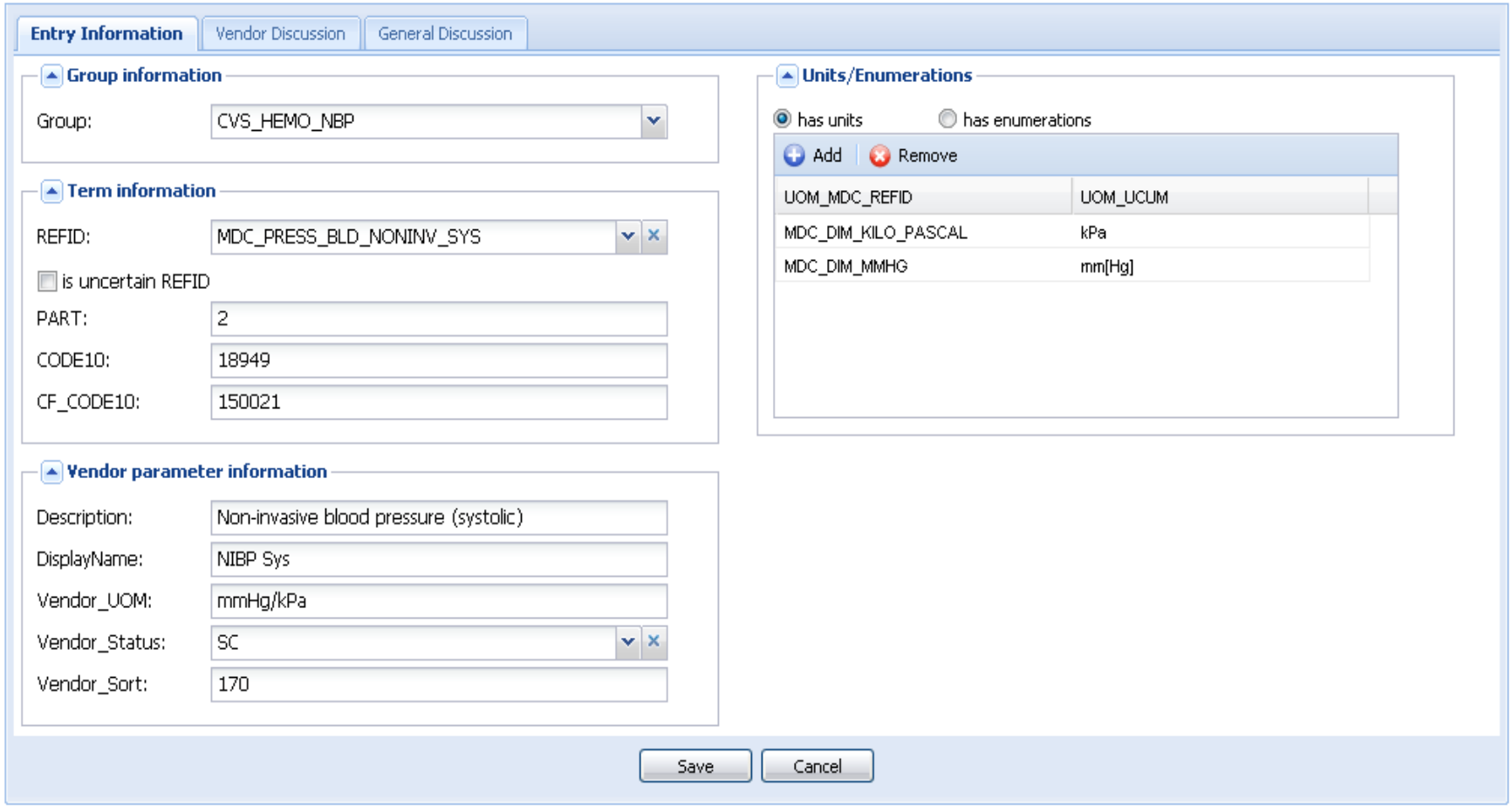
Enumeration groups

_ENUM_GROUP	GroupDescription
_MDC_ATTR_AL_COND	Alarm Condition
_MDC_PUMP_MODE	Operational Mode
_MDC_PUMP_STAT	Operational Status
_BODY_SITE_NBP_BP	Body Site - BP
_BODY_SITE_HR	Body Site - HR
_BODY_SITE_TEMP	Body Site - Temperature
_BODY_SITE_SPO2	Body Site - SpO2
_BODY_SITE_EEG_EX	Body Site - EEG
_BODY_SITE_EEG	Body Site - EEG
_MDC_BREATH_PHASE	See MDCX_BREATH_ANNOTATIONS

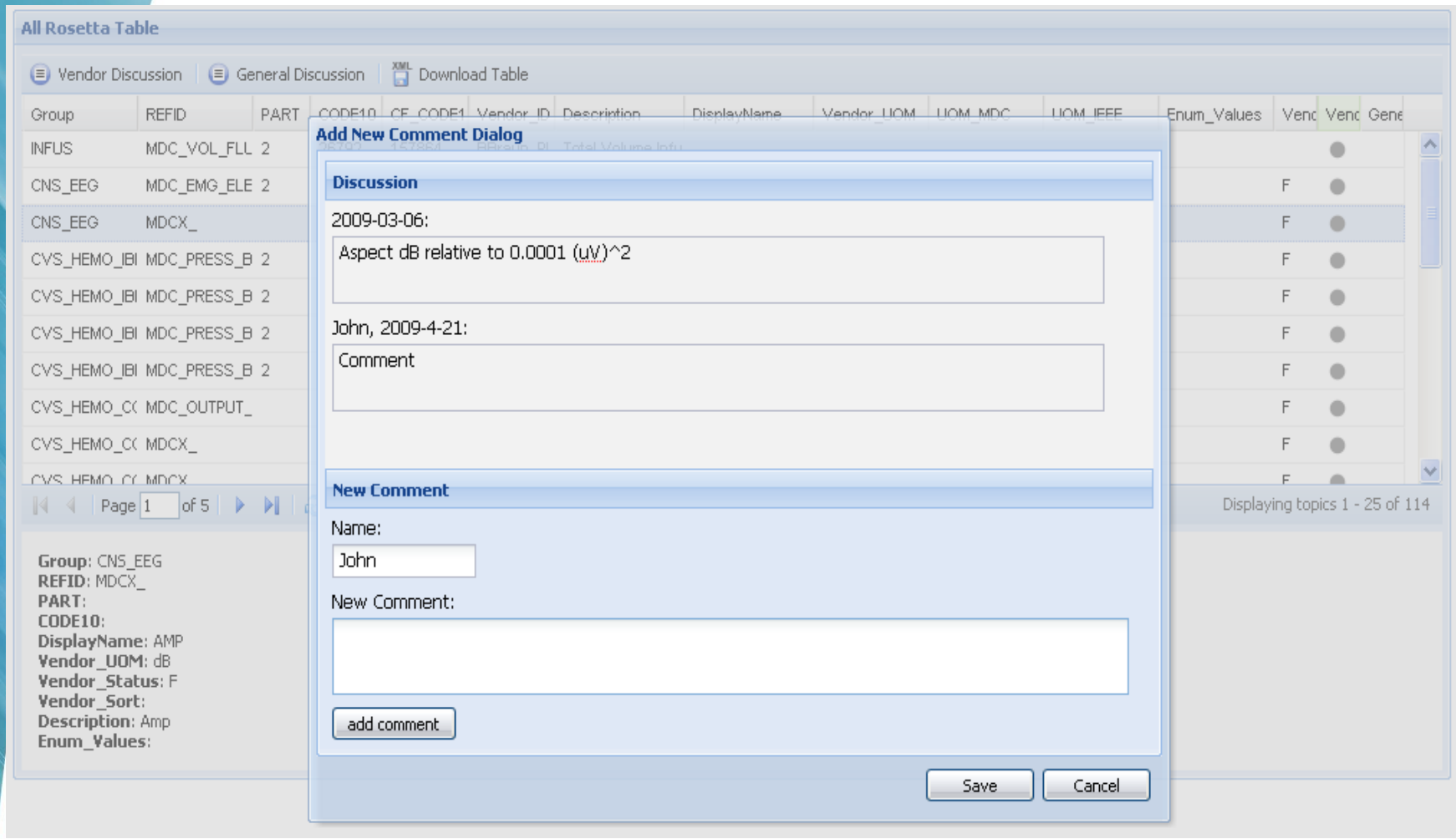
Contained enums

ENUM_VALUE_TOKEN	ENUM_VALUE_REFID	PART	CODE10	VendorDescription	Discussion
	MDC_UPEXT_ARM_UPPER_L			Left Upper Arm	
	MDC_UPEXT_ARM_UPPER_R			Right Upper Arm	
	MDC_LOEXT_LEG_L			Left Leg	
	MDC_LOEXT_LEG_R			Right Leg	

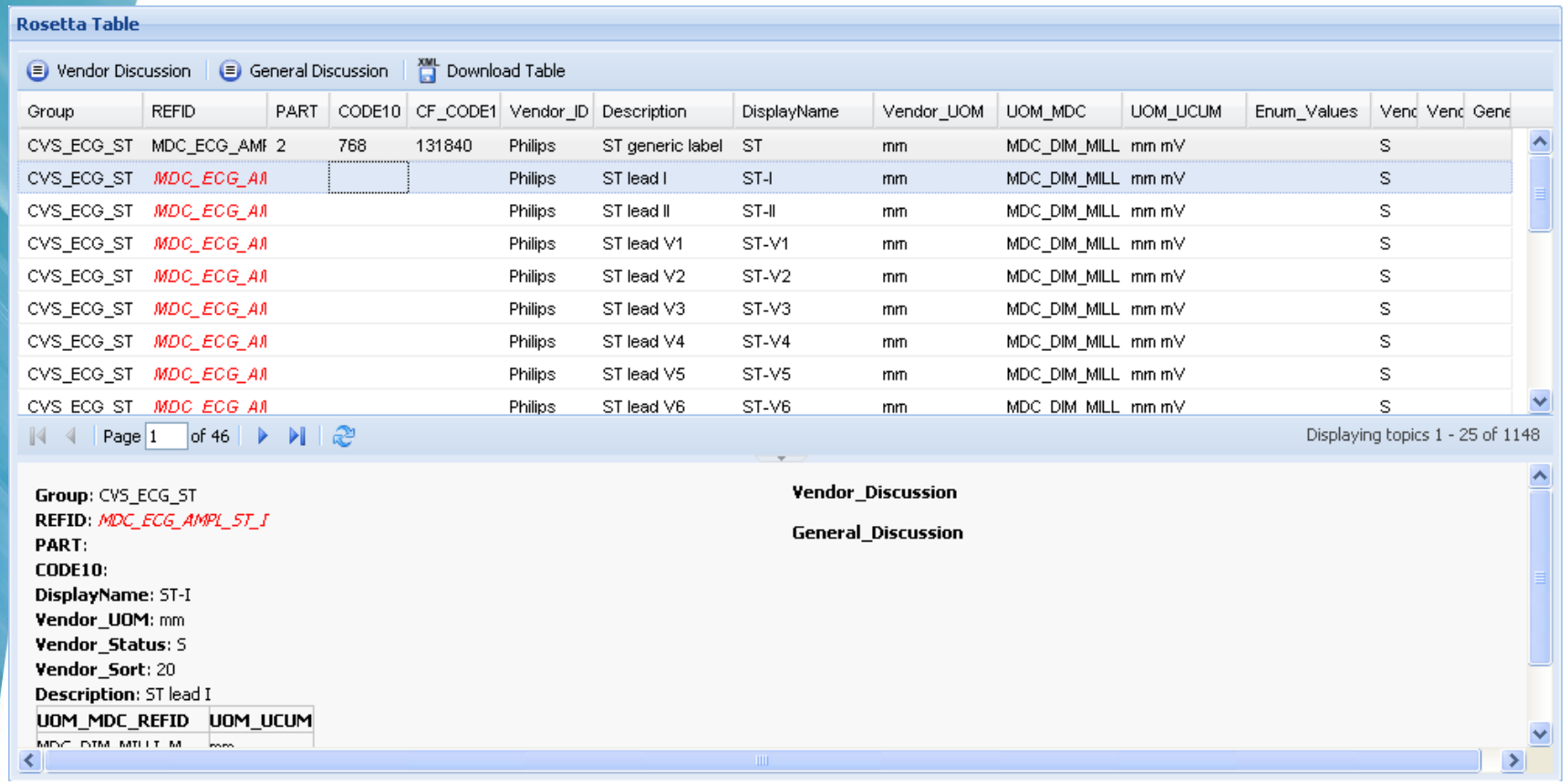
Edit Entry Form



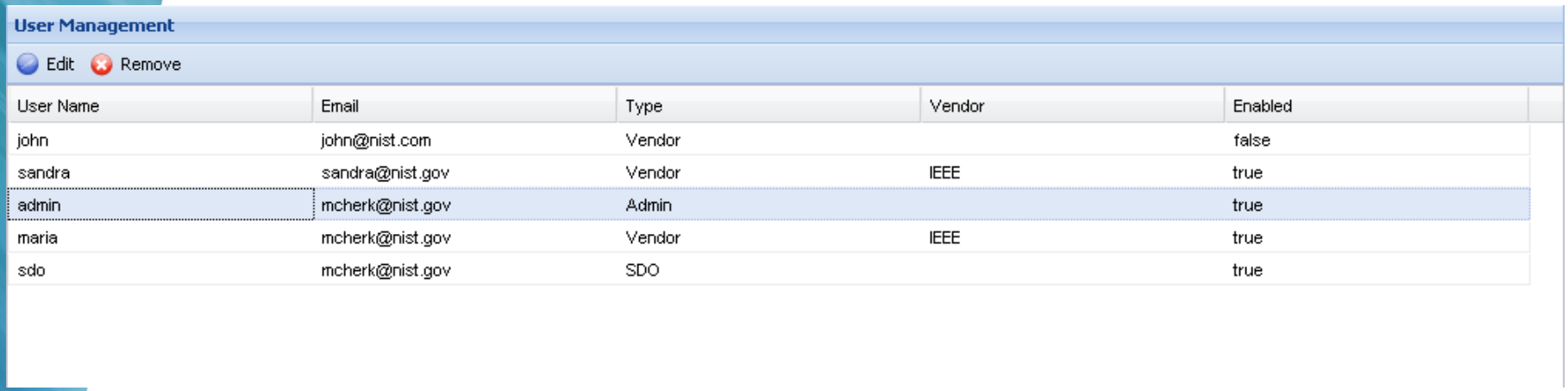
Add Comment Dialog



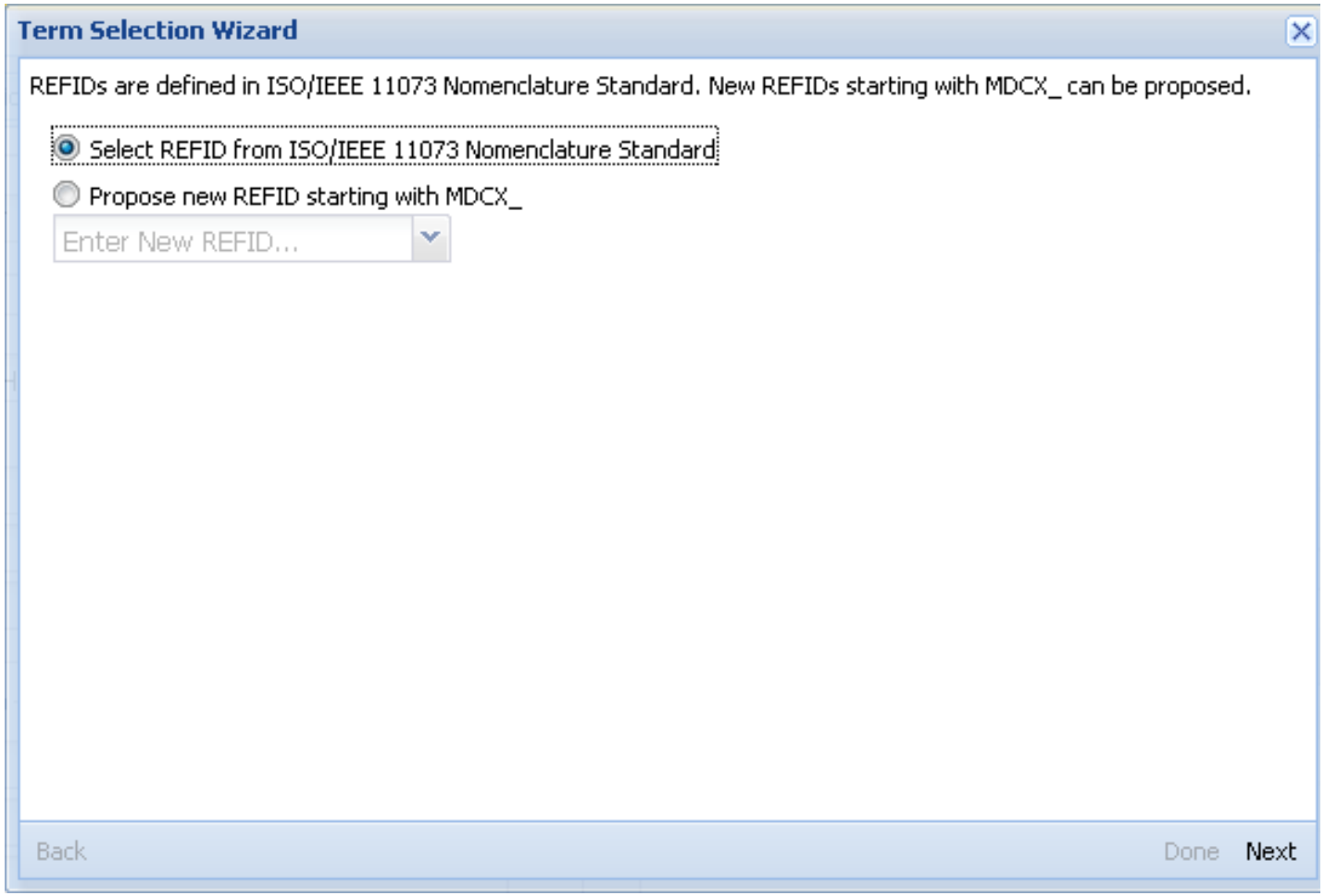
Rosetta Table



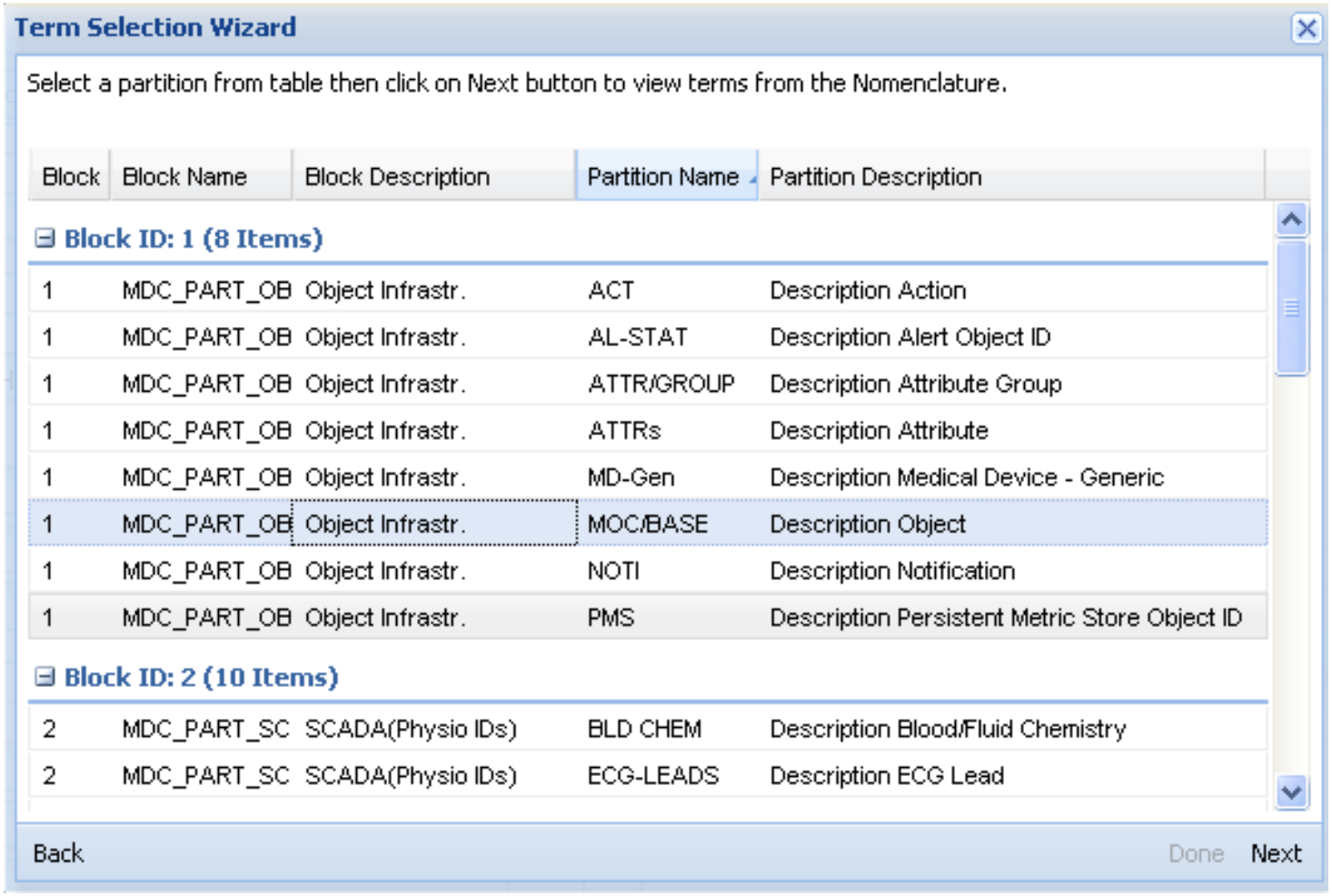
User Management Table



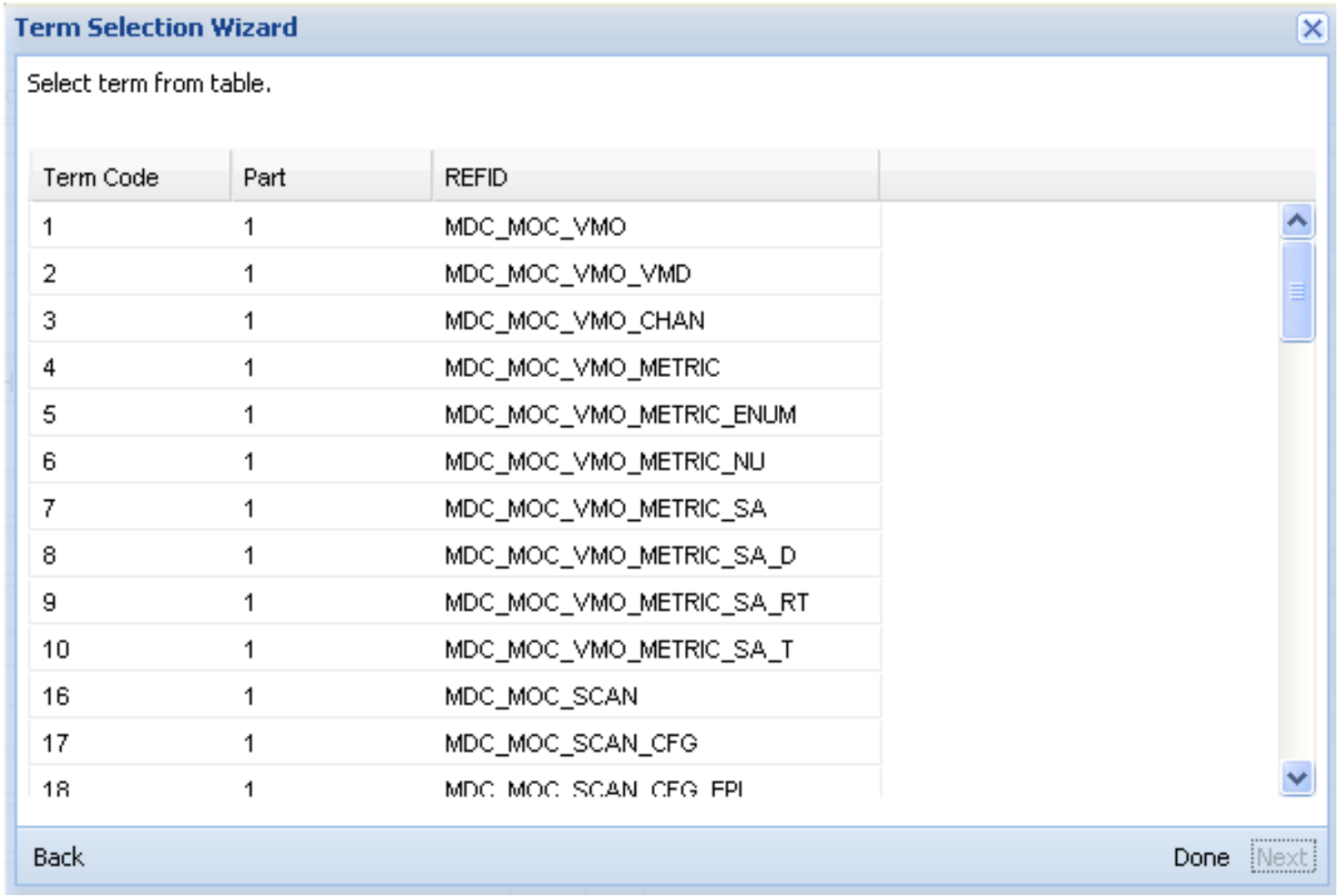
REFID Selection Dialog (1/3)



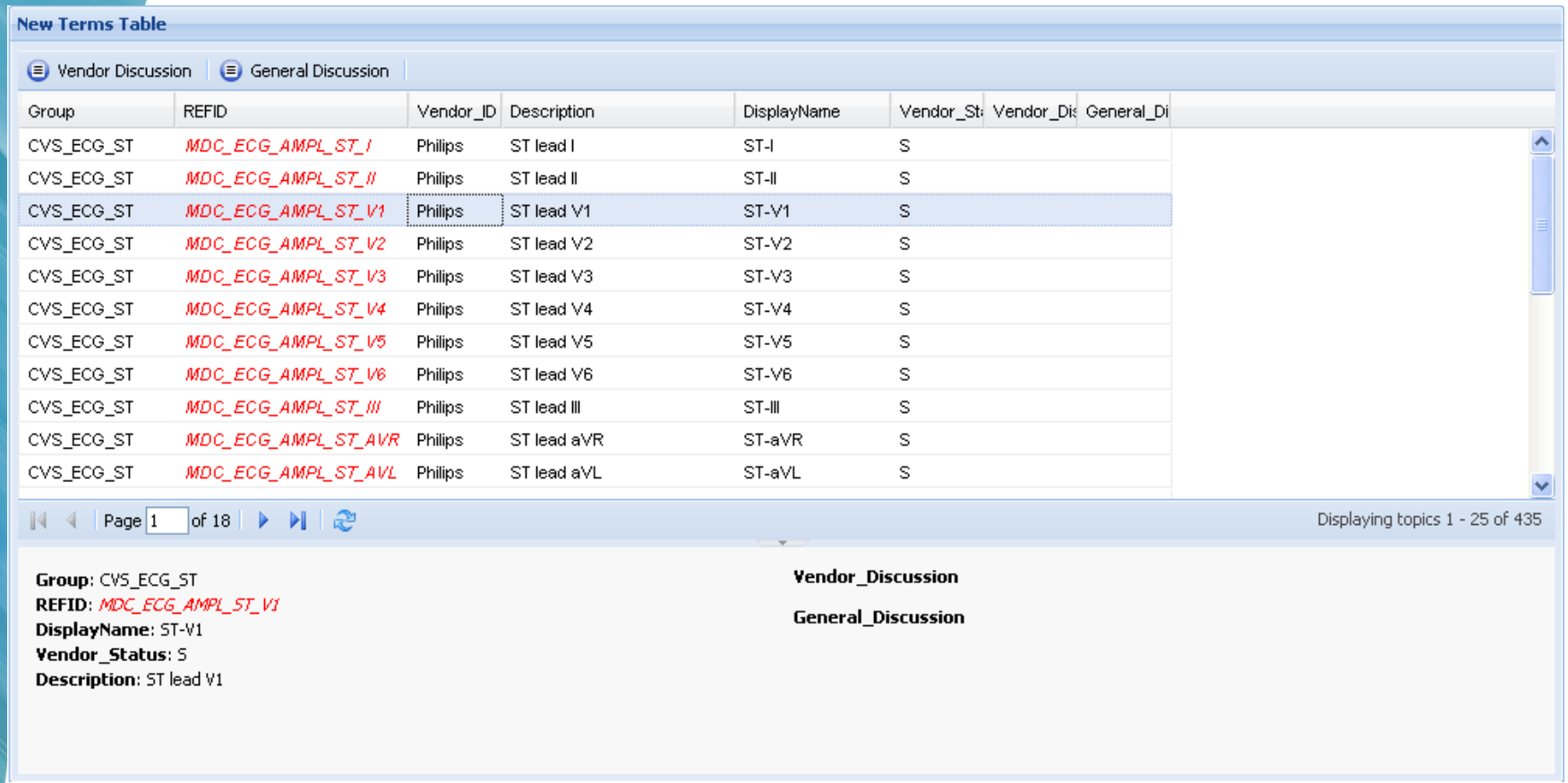
REFID Selection Dialog (2/3)



REFID Selection Dialog (3/3)



New Terms Table



Next Steps

- Features based on the Rosetta Supplement
  - Incorporate "Enumerations" management capabilities
  - Add "containedBy", "contains" and "External_Sites" to the interface
  - Ability to edit Harmonized Rosetta table and save changes
- User oriented features
  - Implement "change trailing" capabilities
    - To identify occurred changes, time they were made, users who made them…
  - Incorporate enhanced X73 Nomenclature database
    - Includes Systematic name, description…
  - Automate generation of the "Harmonized Rosetta Table"
  - Adding new user role "Expert (or Technical) Reviewer"
- Continue discussion of approving and adding normalized terminology to IEEE x73
  - Build on April 23 Discussion (w/ Jan, Paul, Melvin, Todd, John R, others?)

ICSGenerator Capabilities

- Generates Implementation Conformance Statements (ICSs)
  - Required in conformance section (10) of DIM x73 document
  - Ensures common format for ICS generation
- Builds Device Profile (XML)
  - Generates an electronic (XML) version of device data model based strictly on the IEEE x73 DIM
  - Includes private or manufacturer-specific extensions
- Provides validation against DIM Schema
  - A device data model generated using this tool can be validated against an updated version of the DIM XSchema
- Provides high level semantic interoperability
  - Ensures correct containment relationship and terminology at the object class and related attribute, notification, and behavior level
  - Compare Device ICSs
    - Device ICSs comparison capability aids in identifying *potential interoperability issues*
- Generates HL7 OBX Segments
- Generates Device UML Diagram

Tooling Status
ICSGenerator

- Interface update:
  - Make list of attributes visible for selected MOC in the right pane.
    - The value and unit are not included in this enhancement, but will be included when Rosetta dbase is incorporated.
  - Added status bar to show the nature of medical device profile.
  - Added a direct tooling accessibility tool bar.
  - Added a tree panel tool bar to aid in managing and operating ICSGenerator modeling capabilities. (also available when right clicking the objects in the tree)
- Incorporated the x73 Nomenclature Dbase
  - Added drop down menu for any text box where the data could be extracted from the database.
    - Infrastructure terms (e.g., object & attribute names)
    - Object Type ID (if not in hRTM)
    - Object Class
  - Term code auto-filled when object type is available from dbase.
  - The drop down include auto completion and keyword searching, no case sensitive.
  - ICSGenerator does not depend on dbase installation, it access the data from and XML file that contains the data from the x73 Nomenclature Dbase.

Tooling Status
ICSGenerator

- Status (cont.)
  - Added a drop down to allow user to change the attribute status when the status is not "mandatory".
  - Initial implementation of RCH (Rosetta Containment Hierarchy).
  - Code restructuring to improve maintainability, expandability and performance.
  - Fixed bugs
    - Label not fully displayed on Jtree.
    - Attribute update panel hanging when removing attributes and adding the changes.

Tooling Status/Next Steps

ICSGenerator

- Incorporate Rosetta Dbase.
  - Object Type, unit code, metric id (?)- in Nu-Observed-Value value type
- Finalize implementation of RCH.
  - Implementing OBXV and derived OBX-4
- Value display enhancement
- Add information description to tabs
- Provide initial guidance on the right panel when stating ICSGenerator
- Update PHD specialization profiles

Summary / Discussion

- Develop "Conformance Test" WG for this cycle
  - Bi-weekly, meet w/ individual Integration Profile Groups
  - Update test cases
  - Update/Continue work on Test Plans / Conformance Guide
- Develop 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 April 23 Discussion (w/ Jan, Paul, Melvin, Todd, John R, others?)
  - Add two columns to support mapping to ITSDO work (w/ Jan)
- 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!