NIST
National Institute of Standards and Technology

Software and Systems Division

HL7/Healthcare Devices WG
(Orlando, Florida)

NIST Tooling Activities

John Garguilo and Sandra Martinez

16-19 May, 2011

HL7/x73 and IHE-PCD Testing

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

HL7 / Healthcare Devices WG
(Orlando, Florida)

NIST Tooling: HL7 V2.6 Test Tool For Cycle 6 (2011-12)

17 May, 2011

Our Team and Project Web Sites…

Contacts

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Tools and Project Sites

- **NIST's IHE-PCD HL7 V2**
- **Pre-Connectathon**

  Coming in August…
- **Connectathon Web site:** http://xreg2.nist.gov:8080/PCD-HL7WebCon/
- **MDC Testing Web site:** www.nist.gov/medicaldevices

NIST Supported Test Tools Overview/Status Update

- HL7 V2 Validation (IHE-PCD)
  - Instance-type Environment (at message level)
  - http://xreg2.nist.gov:8080/PCD-HL7WebCon/
  - http://hit-testing.nist.gov:8080/HL7Web/
- Cycle 6 (2011-12)
  - Isolated-type Environment
  - Scenario based
  - Actor centric
  - One System Under Test (SUT)
- RTMMS – Rosetta Terminology Mapping Management System
  - No version available to public – yet…
- ICSGenerator (ICS = Implementation Conformance Statement)
  - ISO/IEEE 11073 device specialization/profile builder
    - Private Term implementation considerations being added to tool
- What's still needed
  - Envelope/Message wrappers (WS, SOAP, SAML?) validation
  - Web Services

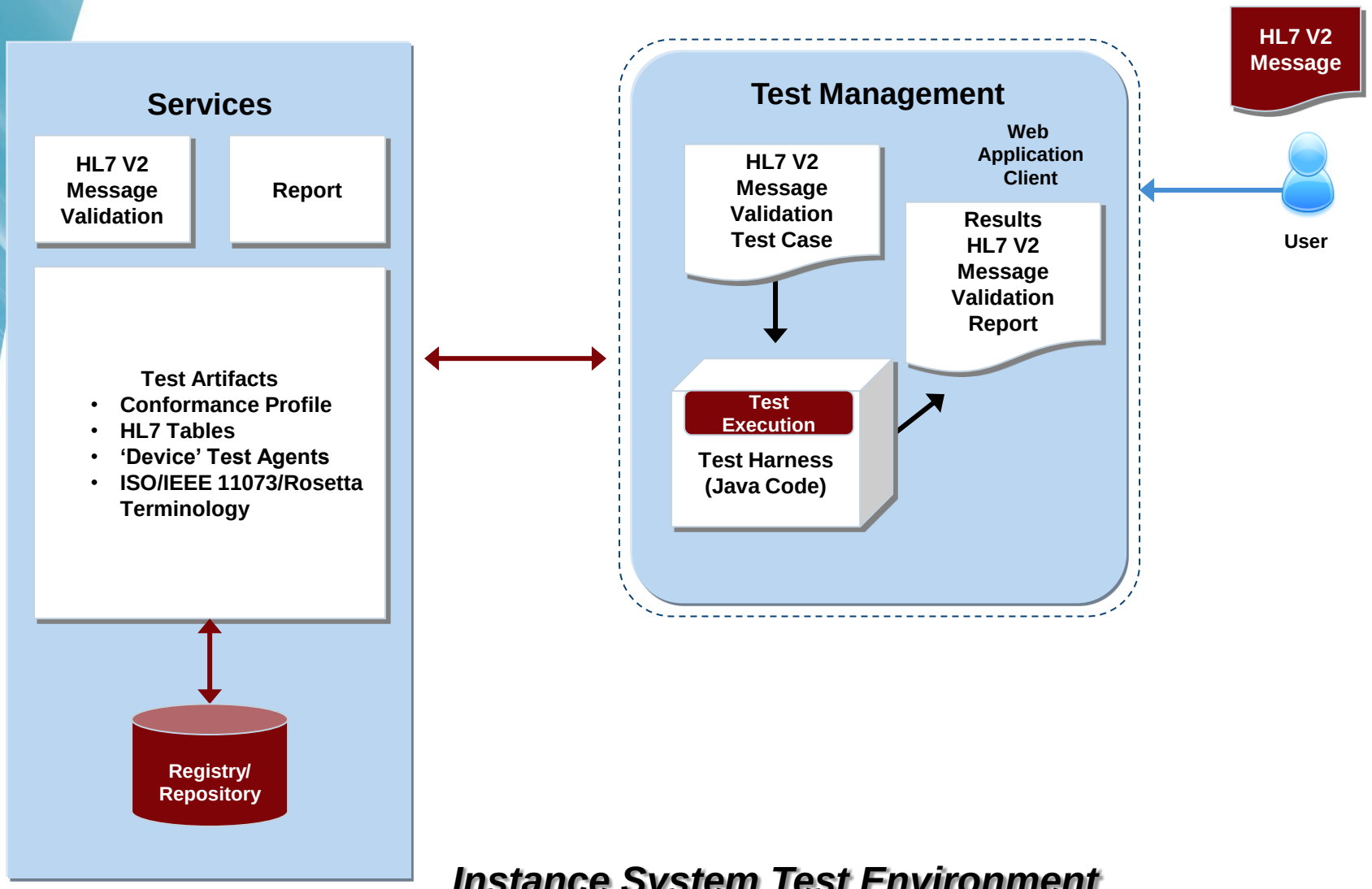
HL7 v2 Transaction Validation Process

- **HL7 v2 Syntax Validation**
  - Ensure the message structure is valid with respect to the HL7 v2 message definition and the HL7 v2 conformance profile
  - Ensure that the conformance requirements such as usage, cardinality, data type usage, etc. are valid with respect to the standard and the HL7 v2 conformance profile that constrains the message, in accordance with the IHE technical framework for a given transaction
- **Value Set Semantic Validation**
  - Ensure that elements that refer to a table are valid with respect to the value set it references. The value set is given by the HL7 v2 standard or as constrained by the IHE technical framework. An example includes confirming that the administrative sex element (PID.8) of the PID segment contains a value that is given in the HL7 v2 Administrative Sex table (HL70001).
  - Identify conformance violations of constraints implied by the IHE Integration Profile. These constraints are captured in a validation context file. An example of such a test includes an element that is fixed in the IHE integration profile (e.g., RCP.1 = I).
- **Terminology (and associated co-constraints) Semantic Validation (see RTM)**
- **Test Case Specific Validation**
  - Verify element content against a validation context file that captures test values as defined in the Pre-Connectathon test cases.
- **NEXT: HL7 v2 MLLP Validation**
  - Ensure the message is valid with respect to the HL7 v2 MLLP specification for wrapping and unwrapping HL7 v2 messages. This is an implied test.

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

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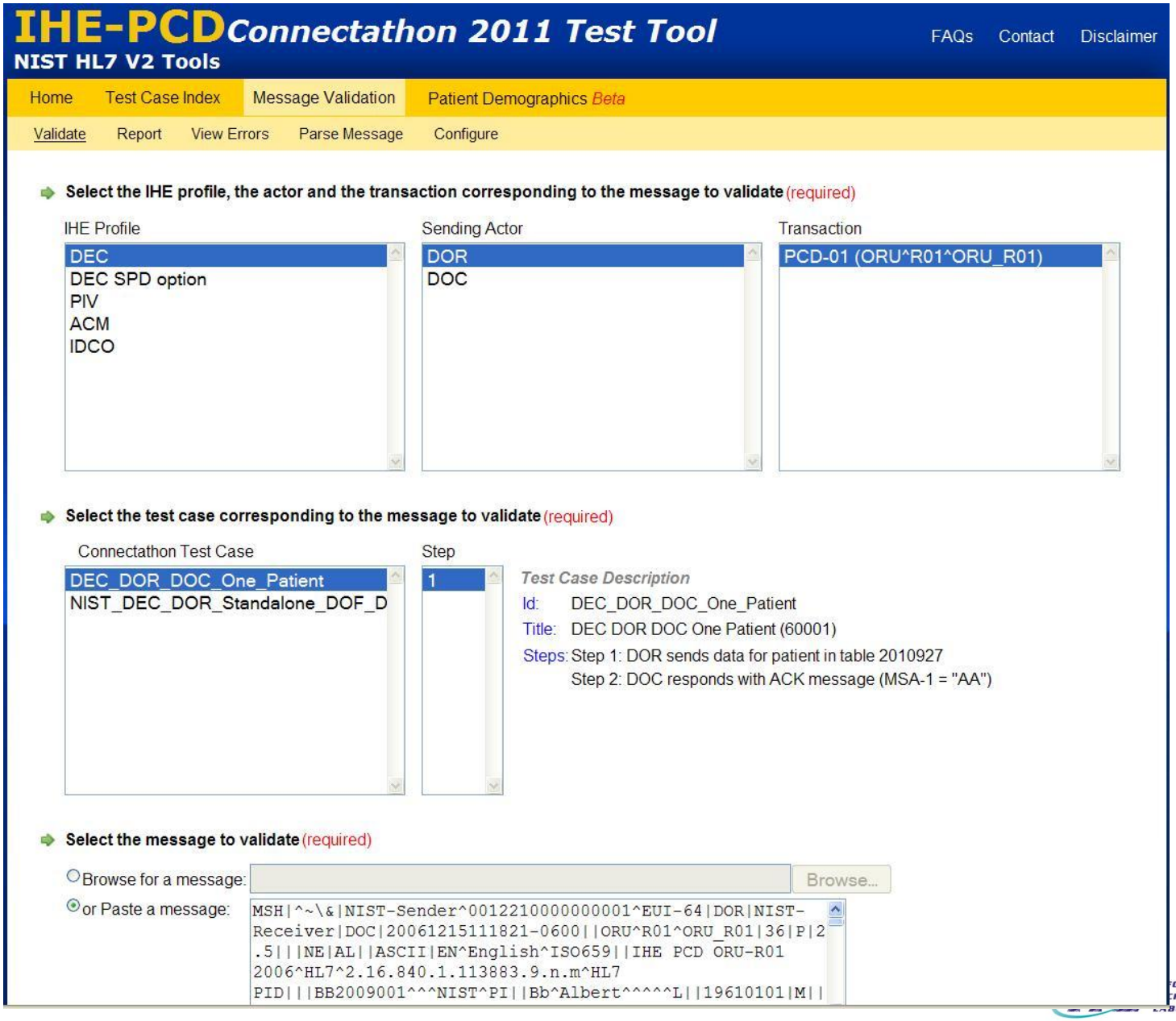
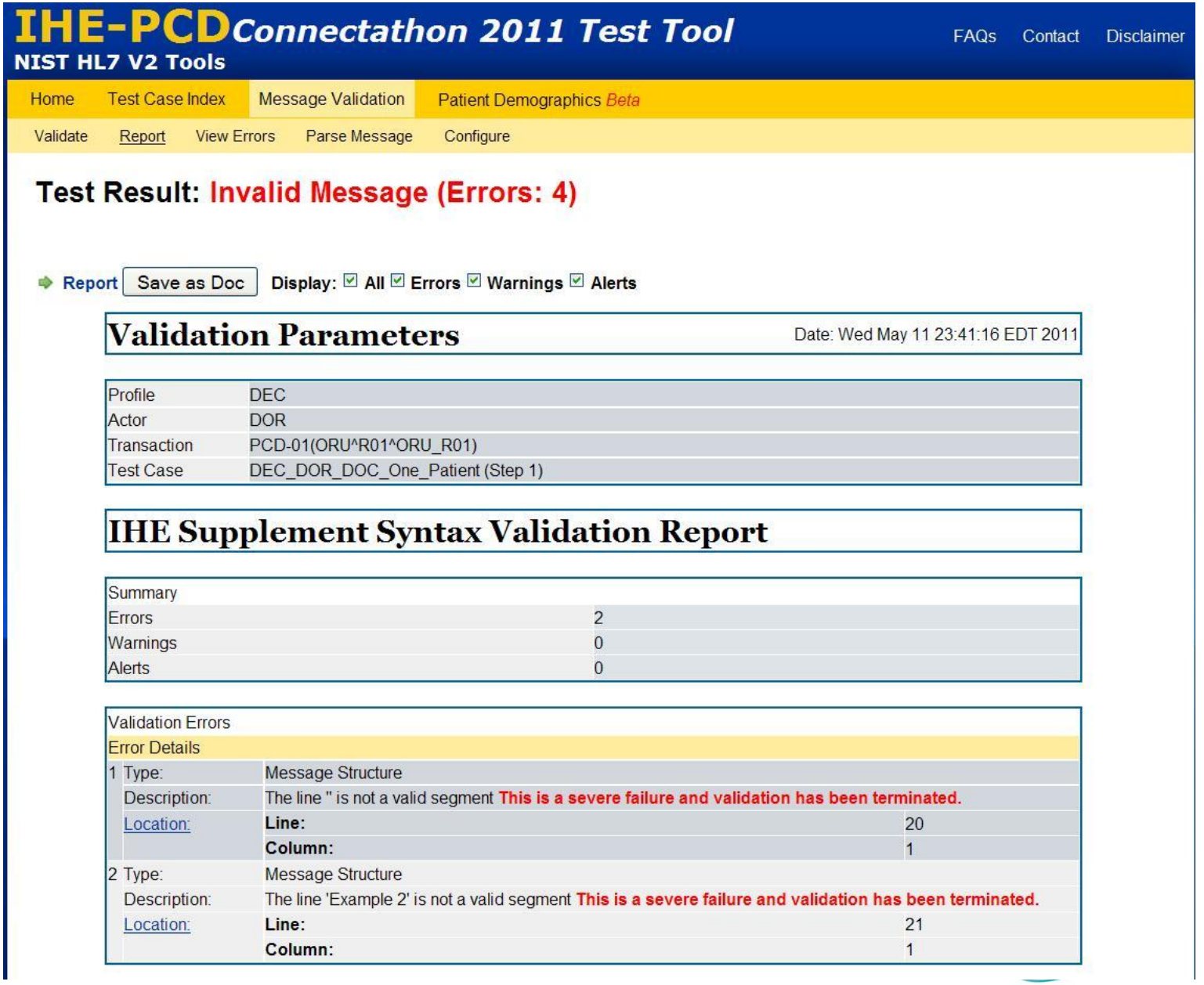
IHE-PCD Pre- and -Connectathon Tool

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



Validation Report (Example)



IHE-PCD Connectathon 2011 Test Tool
NIST HL7 V2 Tools

FAQs Contact Disclaimer

Home | Test Case Index | Message Validation | Patient Demographics *Beta*

Validate | Report | View Errors | Parse Message | Configure

Test Result: Invalid Message (Errors: 4)

Report | Save as Doc | Display: ☑ All ☑ Errors ☑ Warnings ☑ Alerts

Validation Parameters

Date: Wed May 11 23:41:16 EDT 2011

Profile	DEC
Actor	DOR
Transaction	PCD-01(ORU^R01^ORU_R01)
Test Case	DEC_DOR_DOC_One_Patient (Step 1)

IHE Supplement Syntax Validation Report

Summary	
Errors	2
Warnings	0
Alerts	0

Validation Errors

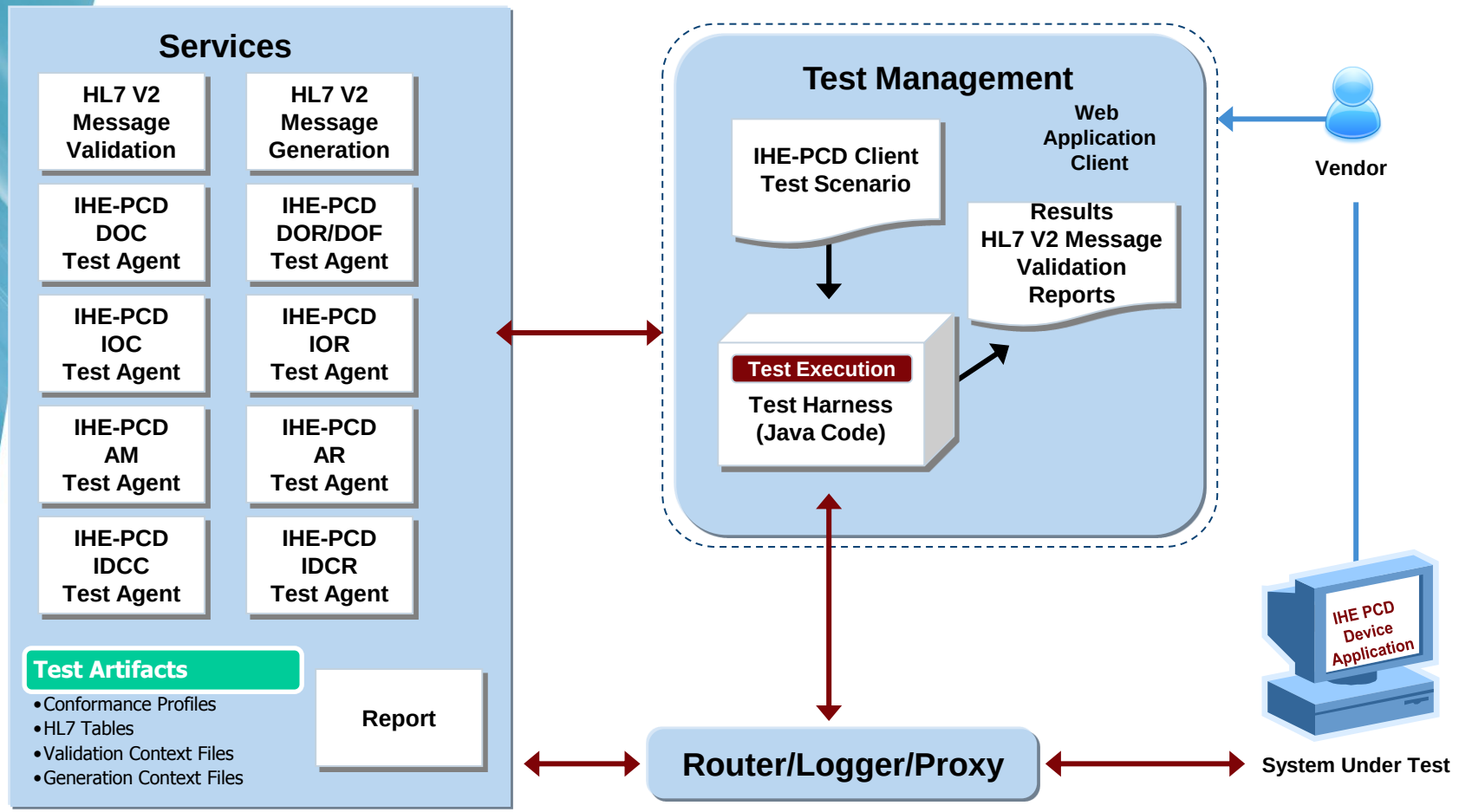
Error Details

1	Type:	Message Structure	
	Description:	The line '' is not a valid segment **This is a severe failure and validation has been terminated.**	
	Location:	**Line:**	20
		Column:	1
2	Type:	Message Structure	
	Description:	The line 'Example 2' is not a valid segment **This is a severe failure and validation has been terminated.**	
	Location:	**Line:**	21
		Column:	1

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

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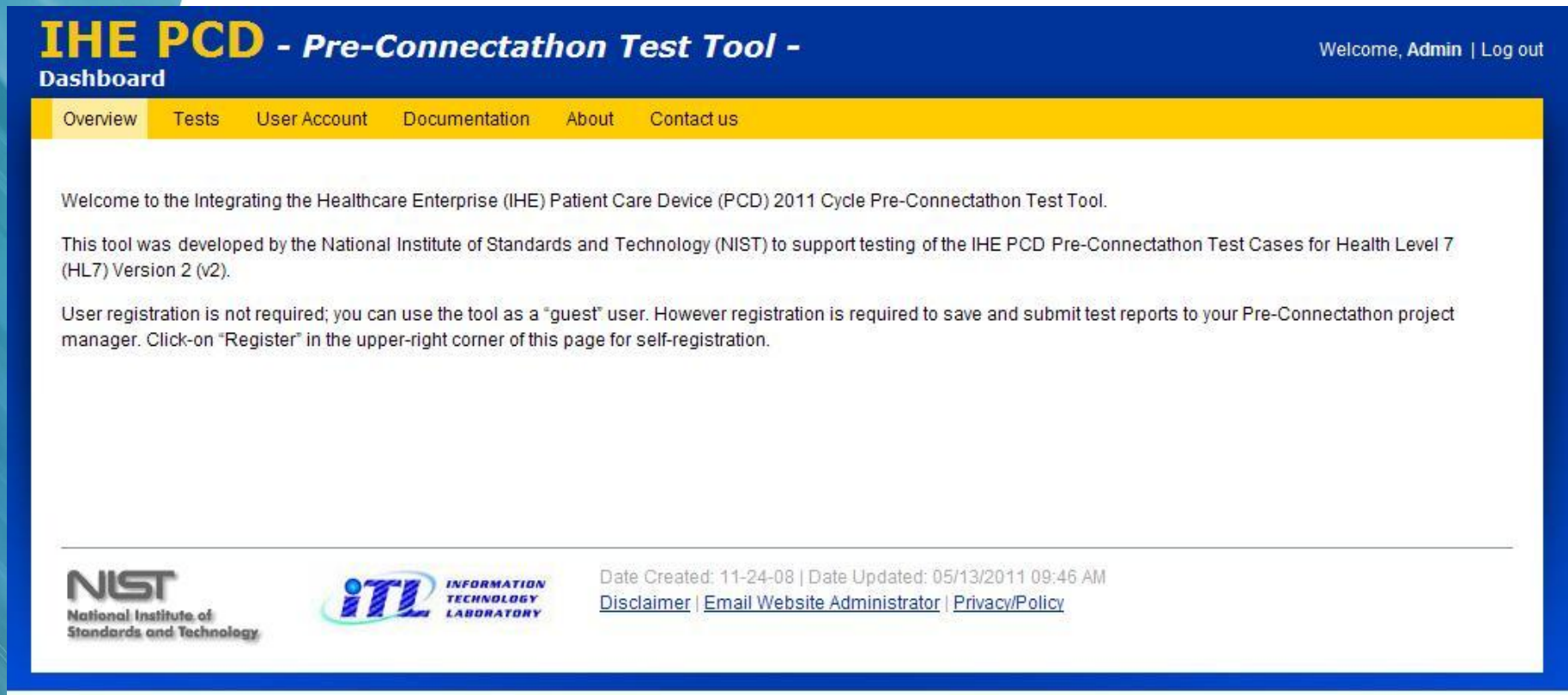
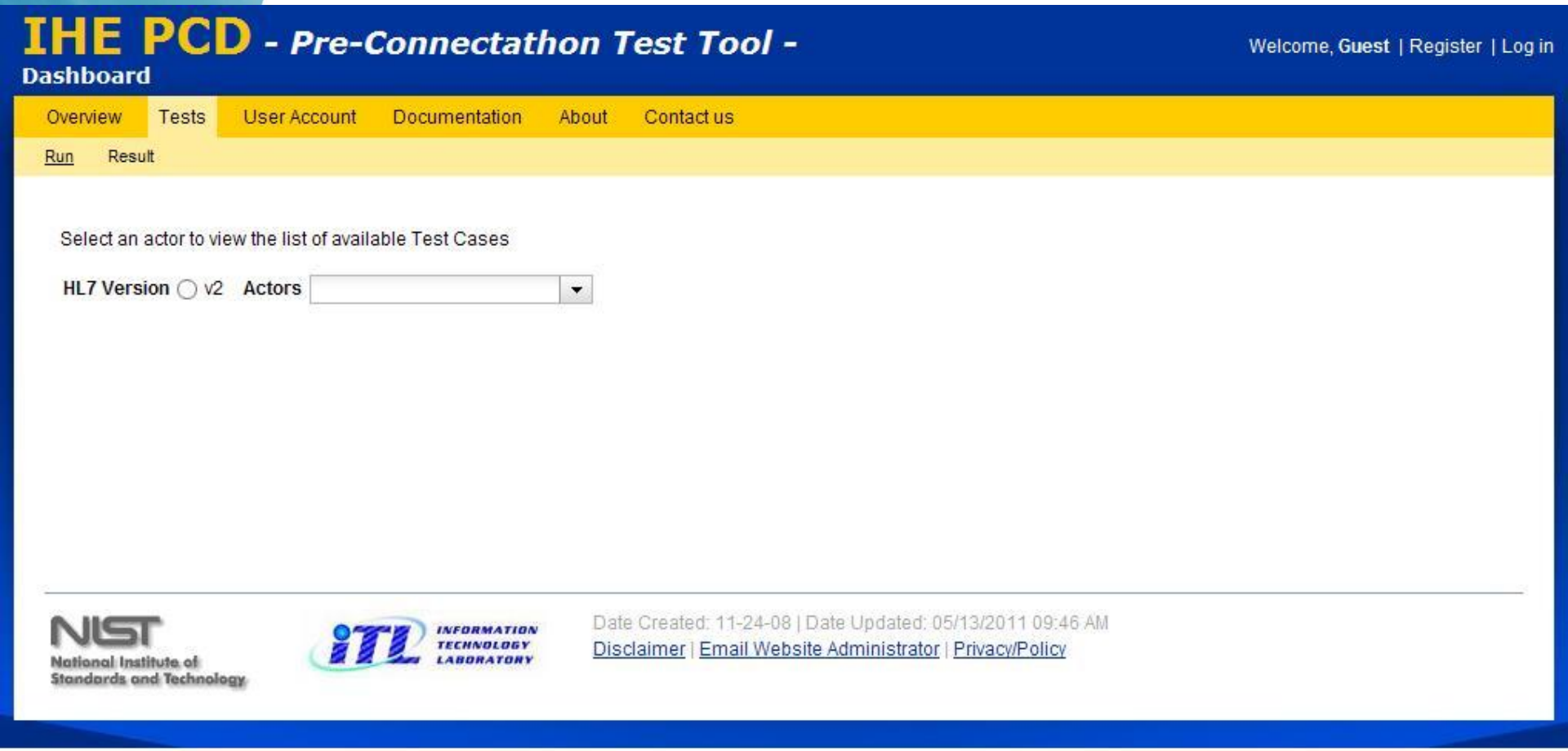
Isolated / Scenario Testing

- Demonstration of DOC and DOR Test Agents

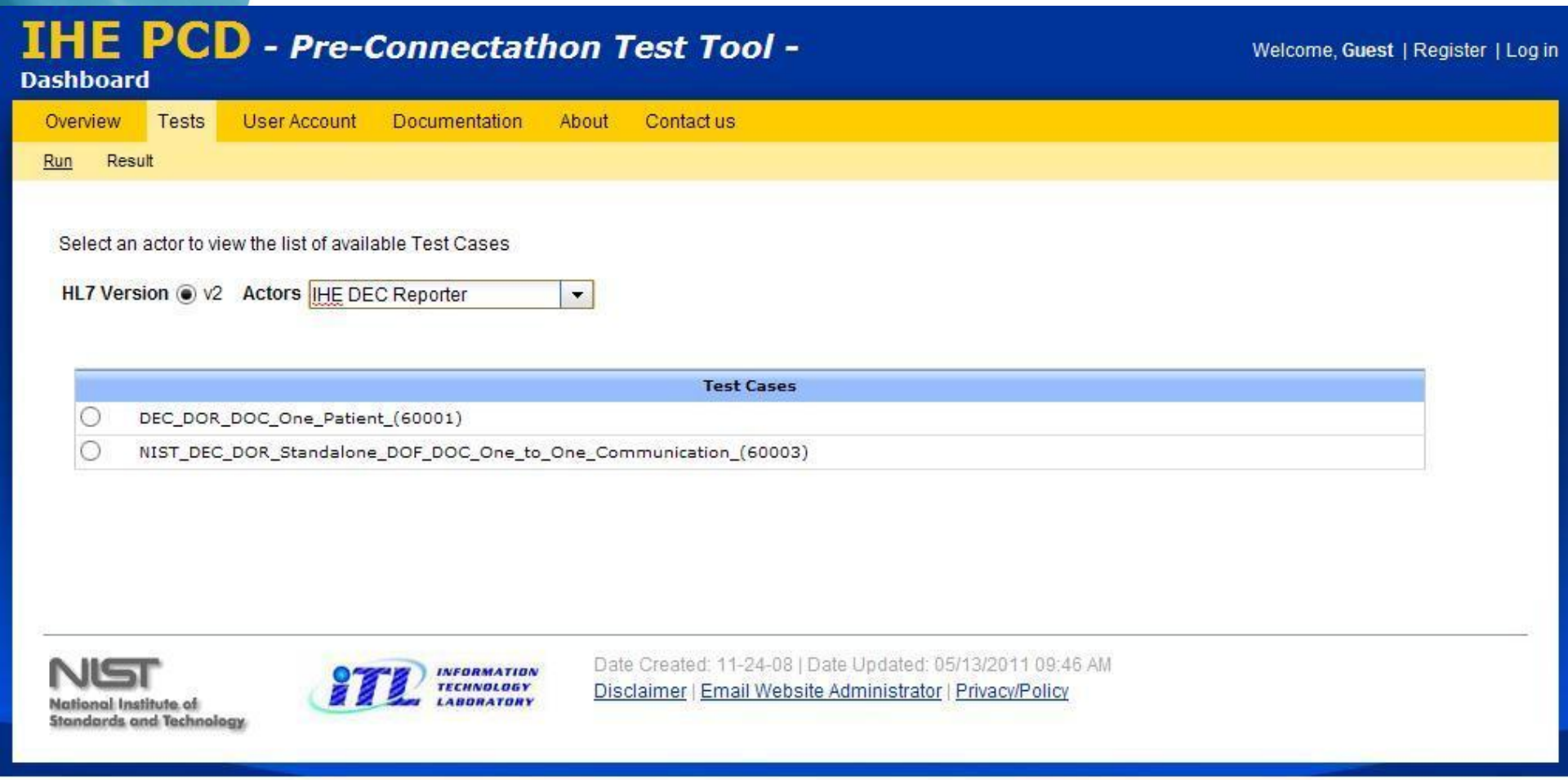
IHE-PCD HL7 V2 Isolated Test Tool



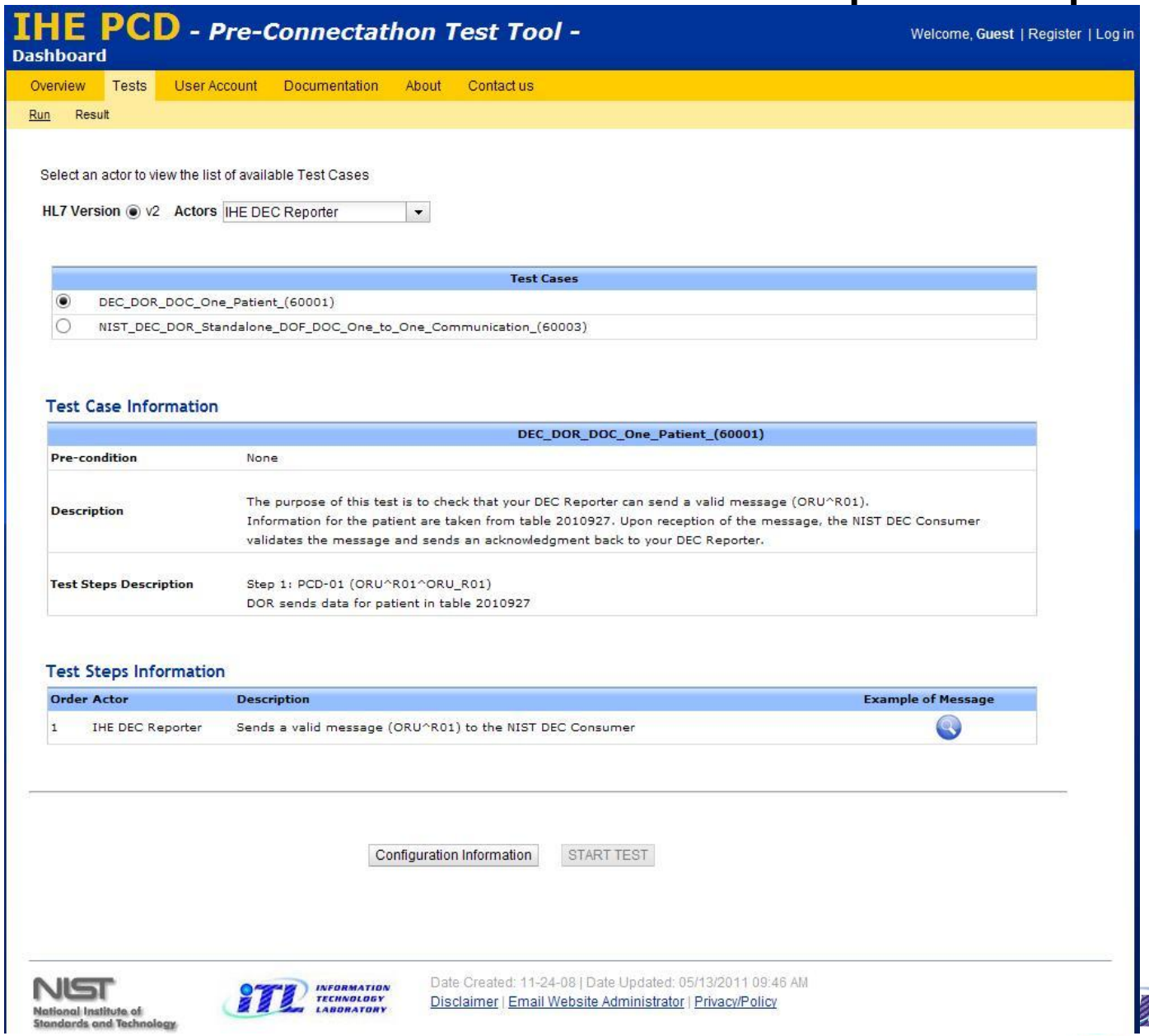
IHE-PCD HL7 V2 Isolated Test Tool
Select Version and Actor



IHE-PCD HL7 V2 Isolated Test Tool DOR – select test case



IHE-PCD HL7 V2 Isolated Test Tool Test Case and Step Descriptions



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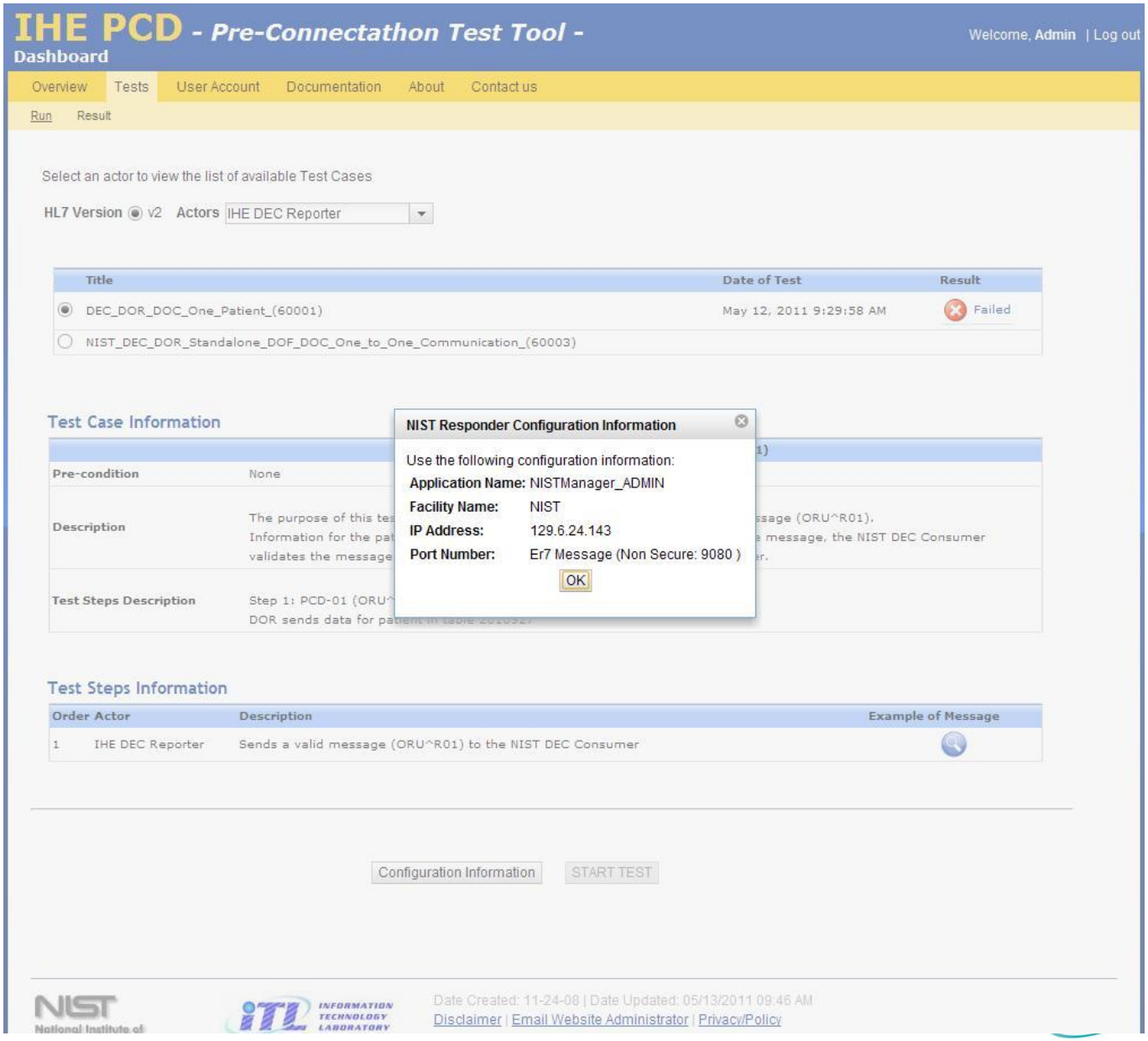
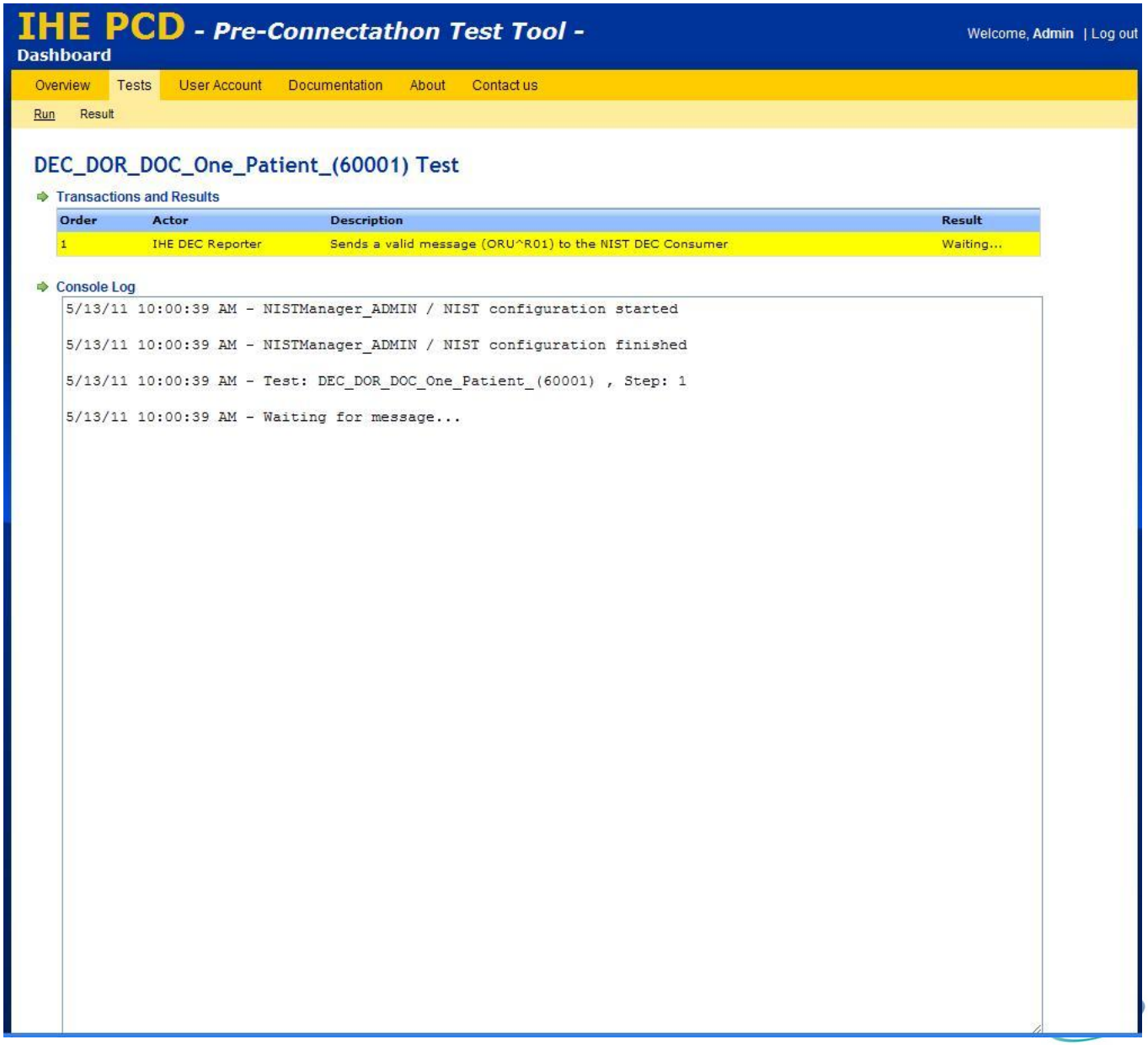
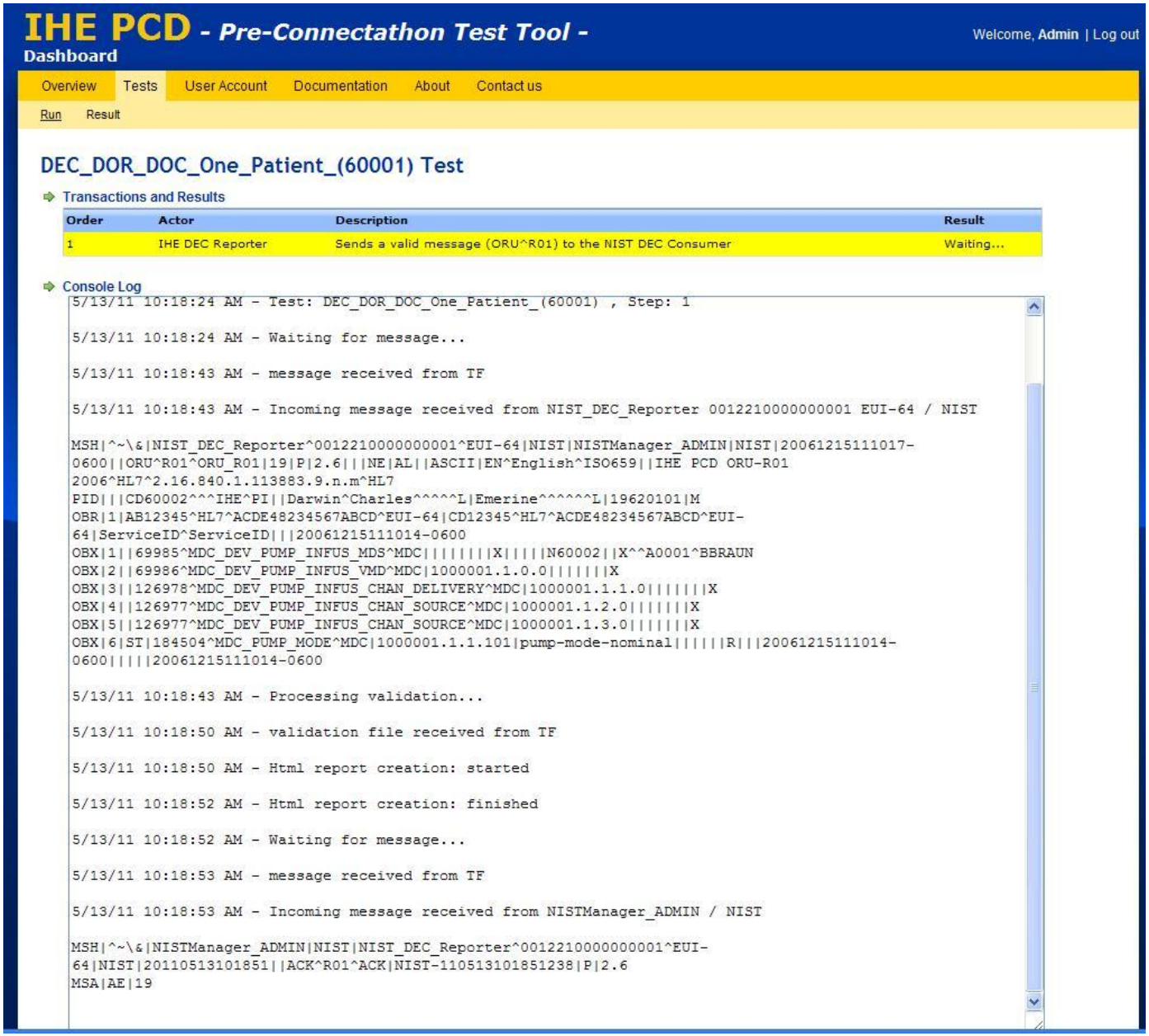
IHE-PCD HL7 V2 Isolated Test Tool Configuration



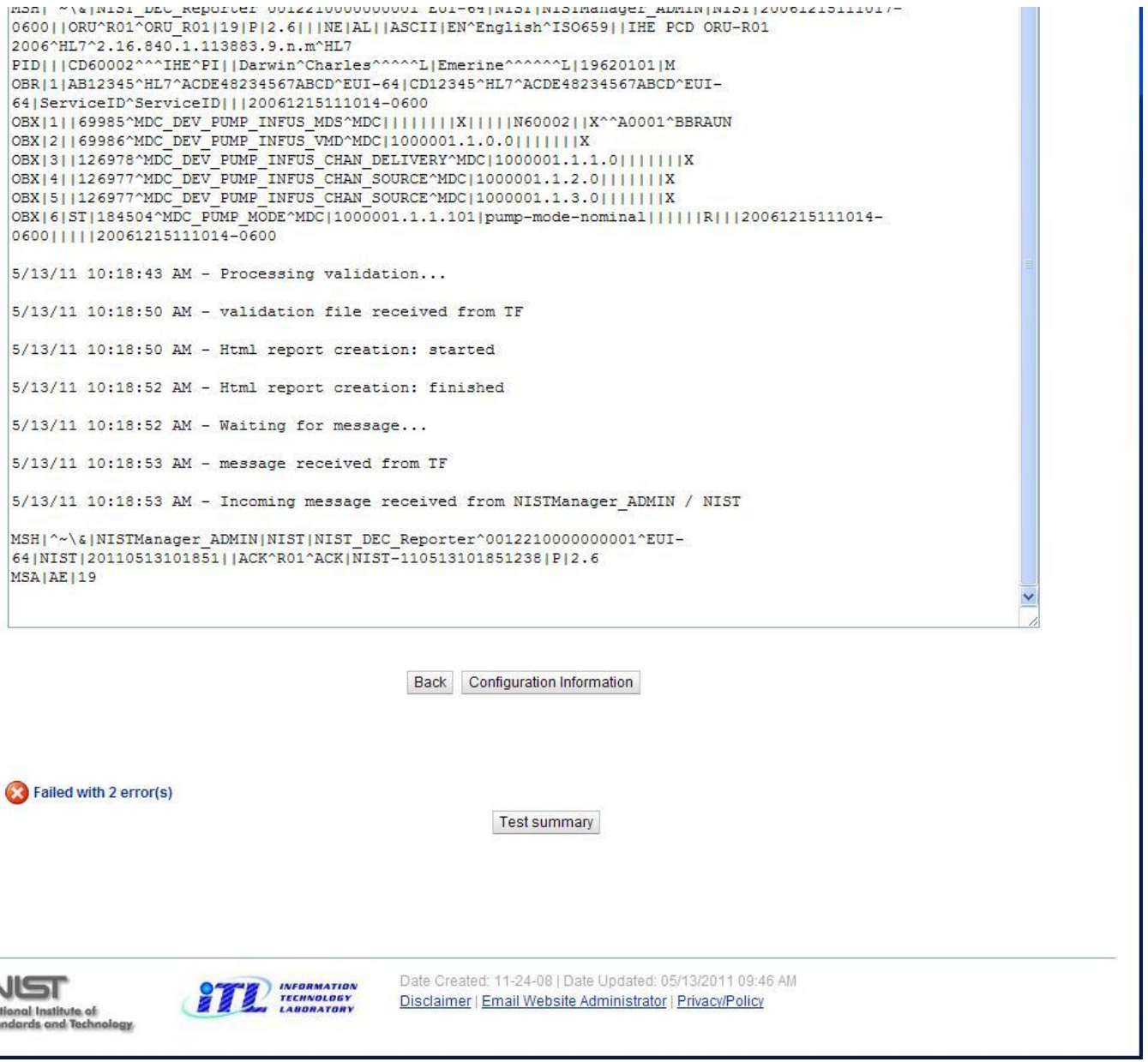
IHE-PCD HL7 V2 Isolated Test Tool Waiting for DOR/SUT…



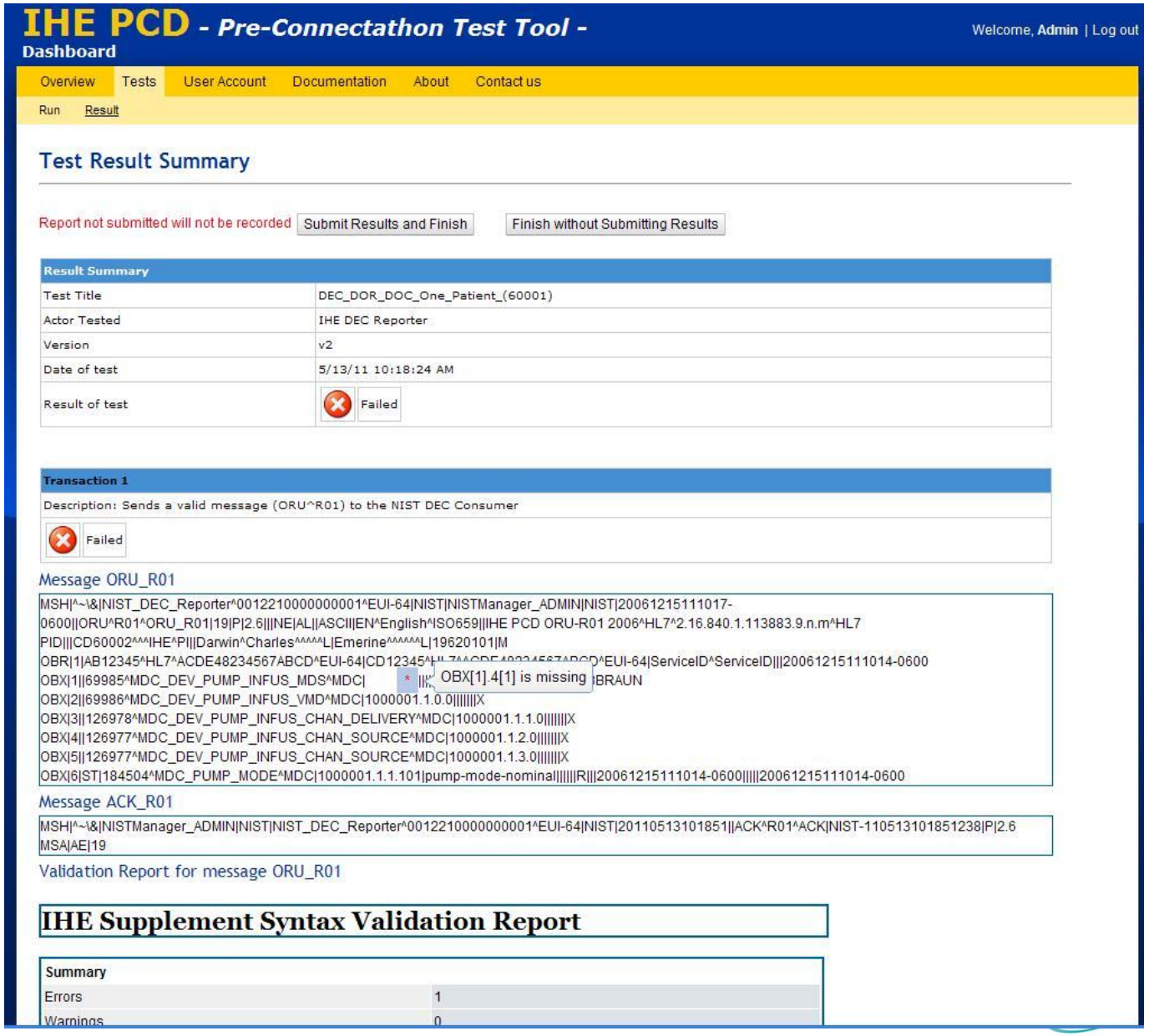
IHE-PCD HL7 V2 Isolated Test Tool
Parse ORU^R01; Send ACK^R01



IHE-PCD HL7 V2 Isolated Test Tool Transaction Processing, with result



IHE-PCD HL7 V2 Isolated Test Tool Test Result Summary



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IHE-PCD HL7 V2 Isolated Test Tool Validation Report

IHE Supplement Syntax Validation Report

Summary	
Errors	1
Warnings	0
Alerts	0

Validation Errors			
Error Details			
1	Type:	Usage	
	Description:	OBX[1].4[1] is missing	
	Location:	**Line:**	4
		Column:	41
		Path:	OBX[1].4[1]
		Segment:	OBX
		Field:	Observation Sub-ID

IHE Supplement Semantic Validation Report

Summary	
Errors	0
Warnings	0
Alerts	0

hRTM Validation Report

Summary	
Errors	0
Warnings	0
Alerts	1

Validation Alert			
Alert Details			
1	Type:	Message Validation Context	
	Description:	The specified message element match location does not map to a message element. The data value at the specified match location can't be evaluated. Refine the message element match location. The provided path expression is 'OBX[6].5[1].2'.	
	Location:	**Path:**	OBX[6].5[1].2
	Assertion Declaration:	OBX[6].5[1].2 = pump-mode-nominal; pump-mode-drug-dosing; pump-mode-ramp-taper; pump-mode-multi-step; pump-mode-multi-dosing; pump-mode-bolus; pump-mode-loading-dose; pump-mode-multi-channel; pump-mode-pca; pump-mode-continuous; pump-mode-pca-and-continuous; pump-mode-piggyback; pump-mode-concurrent	

IHE-PCD HL7 V2 Isolated Test Tool Validation Report, Continued

Alerts	0

hRTM Validation Report

Summary	
Errors	0
Warnings	0
Alerts	1

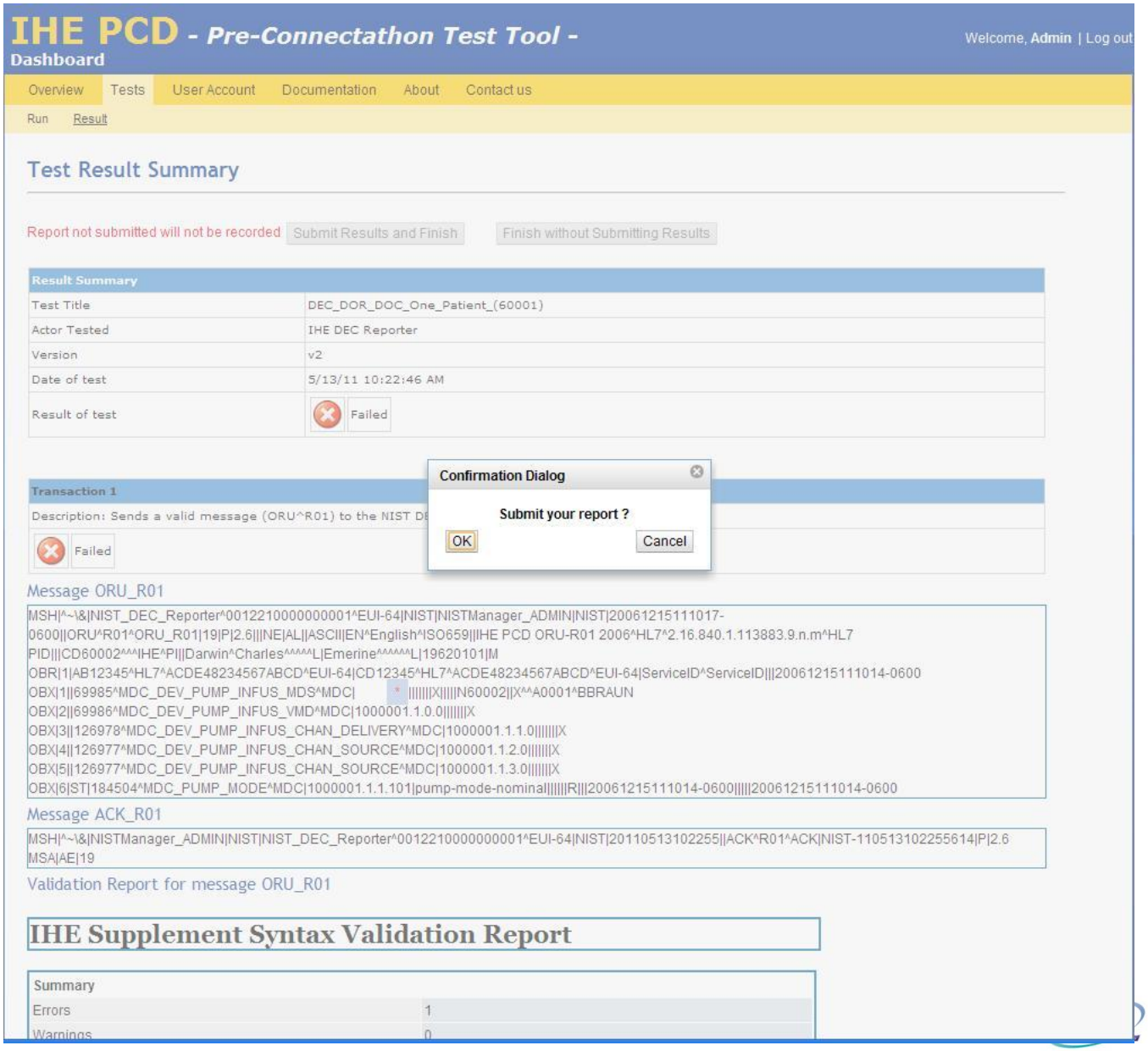
Validation Alert			
Alert Details			
1	Type:	Message Validation Context	
	Description:	The specified message element match location does not map to a message element. The data value at the specified match location can't be evaluated. Refine the message element match location. The provided path expression is 'OBX[6].5[1].2'.	
	Location:	**Path:**	OBX[6].5[1].2
	Assertion Declaration:	OBX[6].5[1].2 = pump-mode-nominal; pump-mode-drug-dosing; pump-mode-ramp-taper; pump-mode-multi-step; pump-mode-multi-dosing; pump-mode-bolus; pump-mode-loading-dose; pump-mode-multi-channel; pump-mode-pca; pump-mode-continuous; pump-mode-pca-and-continuous; pump-mode-piggyback; pump-mode-concurrent	

Test Case Specific Validation Report

Summary	
Errors	1
Warnings	0
Alerts	0

Validation Errors		
Error Details		
1	Type:	Data
	Description:	'HO2009001; HO2009002; HO2009003; HO2009004; 2010001; 2010002; 2010003; 2010004; HO2010001; HO2010002; HO2010003; HO2010004; 2011001; 2011001; 2011001; 2011001; HO2011001; HO2011002; HO2011003; HO2011004; 2012001; 2012001; 2012001; 2012001; HO2012001; HO2012002; HO2012003; HO2012004; 2013001; 2013001; 2013001; 2013001' has not been found in the message at the location 'PID[*].3[1].1'

IHE-PCD HL7 V2 Isolated Test Tool Submit Report (to Test Management)



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IHE-PCD HL7 V2 Isolated Test Tool
Test Management – Vendor Summary

IHE PCD - *Pre-Connectathon Test Tool* -
Dashboard

Welcome, **Admin** | Log out

Overview | Tests | User Account | Documentation | About | Contact us

Account | Reports | History

Please select a Vendor, an Actor and a HL7 Version (v2 or v3) to view the vendor list of Test Cases

Vendors Summary

	Last name	First name	Organization name	V2 results	V3 results	Last test date
◉ 1.	Admin	Admin	NIST	2 (Passed: 1, Failed: 1)	0	Today May 13, 2011 10:23:49 AM

Actors Tested: IHE DEC Reporter — HL7 Version: ◉ v2 ○ v3

Tests List

	Title	Date of Test	Result
◉	DEC_DOR_DOC_One_Patient_(60001)	May 13, 2011 10:23:49 AM	Failed

XML Result | HTML Result

Result Summary	
Test Title	DEC_DOR_DOC_One_Patient_(60001)
Actor Tested	IHE DEC Reporter
Version	v2
Vendor Name	Admin Admin
Vendor Organization Name	NIST
Date of test	May 13, 2011 10:23:49 AM
Result of test	Failed

Transaction 1
Description: Sends a valid message (ORU^R01) to the NIST DEC Consumer
Result: FAILED

Message ORU_R01

```
MSH|^~\&|NIST_DEC_Reporter^0012210000000001^EUI-64|NIST|NISTManager_ADMIN|NIST|20061215111017-
0600||ORU^R01^ORU_R01|19|P|2.6|||NE|AL||ASCII|EN^English^ISO659|||IHE PCD ORU-R01 2006^HL7^2.16.840.1.113883.9.n.m^HL7
PID|||CD60002^^^IHE^PI||Darwin^Charles^^^^^L|Emerine^^^^^^L|19620101|M OBR|1|AB12345^HL7^ACDE48234567ABCD^EUI-
64|CD12345^HL7^ACDE48234567ABCD^EUI-64|ServiceID^ServiceID|||20061215111014-0600
OBX|1||69985^MDC_DEV_PUMP_INFUS_MDS^MDC|||||X|||||N60002||X^^A0001^BBRAUN OBX|2||69986^MDC_DEV_PUMP_INFUS_VMD^MDC|1000001.1.0.0||||||X
OBX|3||126978^MDC_DEV_PUMP_INFUS_CHAN_DELIVERY^MDC|1000001.1.1.0||||||X
OBX|4||126977^MDC_DEV_PUMP_INFUS_CHAN_SOURCE^MDC|1000001.1.2.0||||||X
```

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IHE-PCD HL7 V2 Isolated Test Tool
Test Management – Vendor Dashboard

IHE-PCD HL7 V2 Isolated Test Tool Validation Report

Validation Report for message ORU_R01

IHE Supplement Syntax Validation Report

Summary	
Errors	1
Warnings	0
Alerts	0

Validation Errors			
Error Details			
1	Type:	Usage	
	Description:	OBX[1].4[1] is missing	
	Location:	**Line:**	4
		Column:	41
		Path:	OBX[1].4[1]
		Segment:	OBX
		Field:	Observation Sub-ID

IHE Supplement Semantic Validation Report

Summary	
Errors	0
Warnings	0
Alerts	0

hRTM Validation Report

Summary	
Errors	0
Warnings	0
Alerts	1

Validation Alert			
Alert Details			
1	Type:	Message Validation Context	
	Description:	The specified message element match location does not map to a message element. The data value at the specified match location can"t be evaluated. Refine the message element match location. The provided path expression is "OBX[6].5[1].2".	
	Location:	**Path:**	OBX[6].5[1].2
	Assertion Declaration:	OBX[6].5[1].2 = pump-mode-nominal; pump-mode-drug-dosing; pump-mode-ramp-taper; pump-mode-multi-step; pump-mode-multi-dosing; pump-mode-bolus; pump-mode-loading-dose; pump-mode-multi-channel; pump-mode-pca; pump-mode-continuous; pump-mode-pca-and-continuous; pump-mode-piggyback; pump-mode-concurrent	

IHE-PCD HL7 V2 Isolated Test Tool Validation Report, Cont

hRTM Validation Report

Summary	
Errors	0
Warnings	0
Alerts	1

Validation Alert		
Alert Details		
1	Type:	Message Validation Context
	Description:	The specified message element match location does not map to a message element. The data value at the specified match location can"t be evaluated. Refine the message element match location. The provided path expression is "OBX[6].5[1].2".
	Location:	**Path:** OBX[6].5[1].2
	Assertion Declaration:	OBX[6].5[1].2 = pump-mode-nominal; pump-mode-drug-dosing; pump-mode-ramp-taper; pump-mode-multi-step; pump-mode-multi-dosing; pump-mode-bolus; pump-mode-loading-dose; pump-mode-multi-channel; pump-mode-pca; pump-mode-continuous; pump-mode-pca-and-continuous; pump-mode-piggyback; pump-mode-concurrent

Test Case Specific Validation Report

Summary	
Errors	1
Warnings	0
Alerts	0

Validation Errors		
Error Details		
1	Type:	Data
	Description:	"HO2009001; HO2009002; HO2009003; HO2009004; 2010001; 2010002; 2010003; 2010004; HO2010001; HO2010002; HO2010003; HO2010004; 2011001; 2011001; 2011001; 2011001; HO2011001; HO2011002; HO2011003; HO2011004; 2012001; 2012001; 2012001; 2012001; HO2012001; HO2012002; HO2012003; HO2012004; 2013001; 2013001; 2013001; 2013001" has not been found in the message at the location "PID[*].3[1].1"

IHE-PCD Face-to-Face
(Boca Raton, Florida)

"Rosetta Terminology Mapping Management System"
(RTMMS)

National Institute of
Standards and Technology
U.S. Department of Commerce

12 May, 2011

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- Isabelle P. Barclay(Guest Researcher)

Project Web site:

www.nist.gov/medicaldevices

Discussion Topics

- Rosetta Terminology Mapping (RTM) Overview
- Rosetta Terminology Mapping Management System (RTMMS) Overview
- RTMMS DEMO
- Issues
  - IEEE copyright issues
    - Against NIST Policy to maintain proprietary data
  - Integration of LOINC Terms
    - We have no documentation on LOINC.
    - Mapping must be provided
  - PHD added new refIds under x73 Alert partition. The term codes assigned to these events are not in within the range specified in the alert block

IHE PCD Profile: RTM Overview

- RTM is an IHE PCD Profile that addresses the problem of medical device semantic interoperability by proposing a mapping to a standard nomenclature.
  - Identifies the core set of semantics appropriate for medical devices
  - Maps vendors terminology to standard terminology
  - Maps numeric parameters to their associated units-of-measure and enumerated values

- ftp://ftp.ihe.net/Patient_Care_Devices/TechnicalFrameworkforTrialImplementation/IHE_PCD_TF_Supplement_Rosetta_Terminology_Mapping_RTM_TI_2008-08-22.pdf

RTMMS Tables

- 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

RTMMS was developed to support the IHE-PCD Rosetta Terminology Mapping (RTM)

- 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/Appendix.

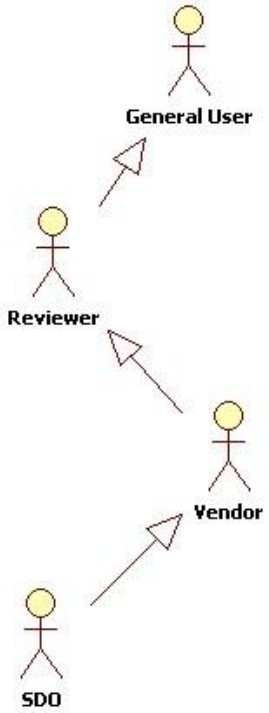
- Aids in The harmonization process by:
  - Identifying missing terms.
  - Automatic generation of the "Harmonized Rosetta Table"
  - Viewing and downloading latest hRTM table.

- Facilitates the proposal of New Terms to x73 Nomenclature

RTMMS Users

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

- Potential IEEE-Member User



RTMMS Features

- Access to NIST IEEE 11073 Nomenclature database
  - Appendix A terms
  - Appendix B terms
  - IDCO terms
  - PHD terms
- Access to RTM database
- Ability to proposed terms in Rosetta
- hRTM, units and enumeration download in XML format
- User registration
  - Email confirmation, approval…
- Filtering based on regular expressions
- Rosetta validation against hRTM
- Management capabilities for SDO users

RTMMS Updates (since last F2F in January)

- Integrated PHD nomenclature into the IEEE 11073-10101 NIST Nomenclature database
  - Provided by UL Chair (Jan W.) in January 2011 F2F.
  - PHD nomenclature includes; terms under new PHD partitions, terms already in the nomenclature and new terms under existing x73 nomenclature partitions.
    - New terms under PHD partitions were added to the IEEE 11073-10101 Nomenclature dbase:
      - MDC_PART_PHD_AI (aging independently)
      - MDC_PART_PHD_DM (disease management)
      - MDC_PART_PHD_HF (health and fitness)
    - Terms already in the existing X73 nomenclature partitions
      - Association done using the block and partition id
    - New terms (PHD) under existing X73 nomenclature partitions.
      - These terms are not captured yet we need some clarifications.
  - No association between specialization and terms – RTM dbase and X73 dbase does not handle these associations.

RTMMS Updates (since last F2F in January)

- Integrated PHD nomenclature into the IEEE 11073 Nomenclature database (Cont.)
  - Need clarification:
    - PHD added new refIds under x73 Alert partition. The term codes assigned to these events are not in within the range specified in the alert block :

      MDC_PART_EVT MDC_EVT_PEF_MED 21106

Description	Current
Alerts/Events[a]	0000–6600
Device events	0000–0596
Pattern events	3072–3294
Status events	6144–6730
Private	61440–65535

Ongoing Work

- Implementing Backup cycle
- Developing XML2DB Module
  - Adding Import XML Rosetta Data feature
- Implementing synonym terms
  - Support synonyms in Nomenclature Database
  - Support synonyms in RTM Database
- Adding new data to hRTM table
  - Support Vendor_VMD, and Vendor Description in hRTM

Next Steps

- Update RTMMS database access/update mechanism.
- Add aECG into X73 Nomenclature Dbase.
- Edit hRTM Table
  - Add new entry
  - Edit an entry
  - Deprecate an entry
  - Support multiple versions
  - Ability to set current version to use for validation
- Implement versioning system
- Add logging history capabilities
  - To identify occurred changes, time they were made, users who made them…

Issues

- IEEE copyright issues
  - Against NIST Policy to maintain proprietary data
- Integration of LOINC Terms
  - We have no documentation on LOINC.
  - Mapping must be provided.

National Institute of Standards and Technology

Software and Systems Division

IHE-PCD Face-to-Face
(Boca Raton, Florida)

"*ICSGenerator*"
(Implementation Conformance Generator)

12 May, 2011

INFORMATION TECHNOLOGY LABORATORY

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ICSGenerator Overview

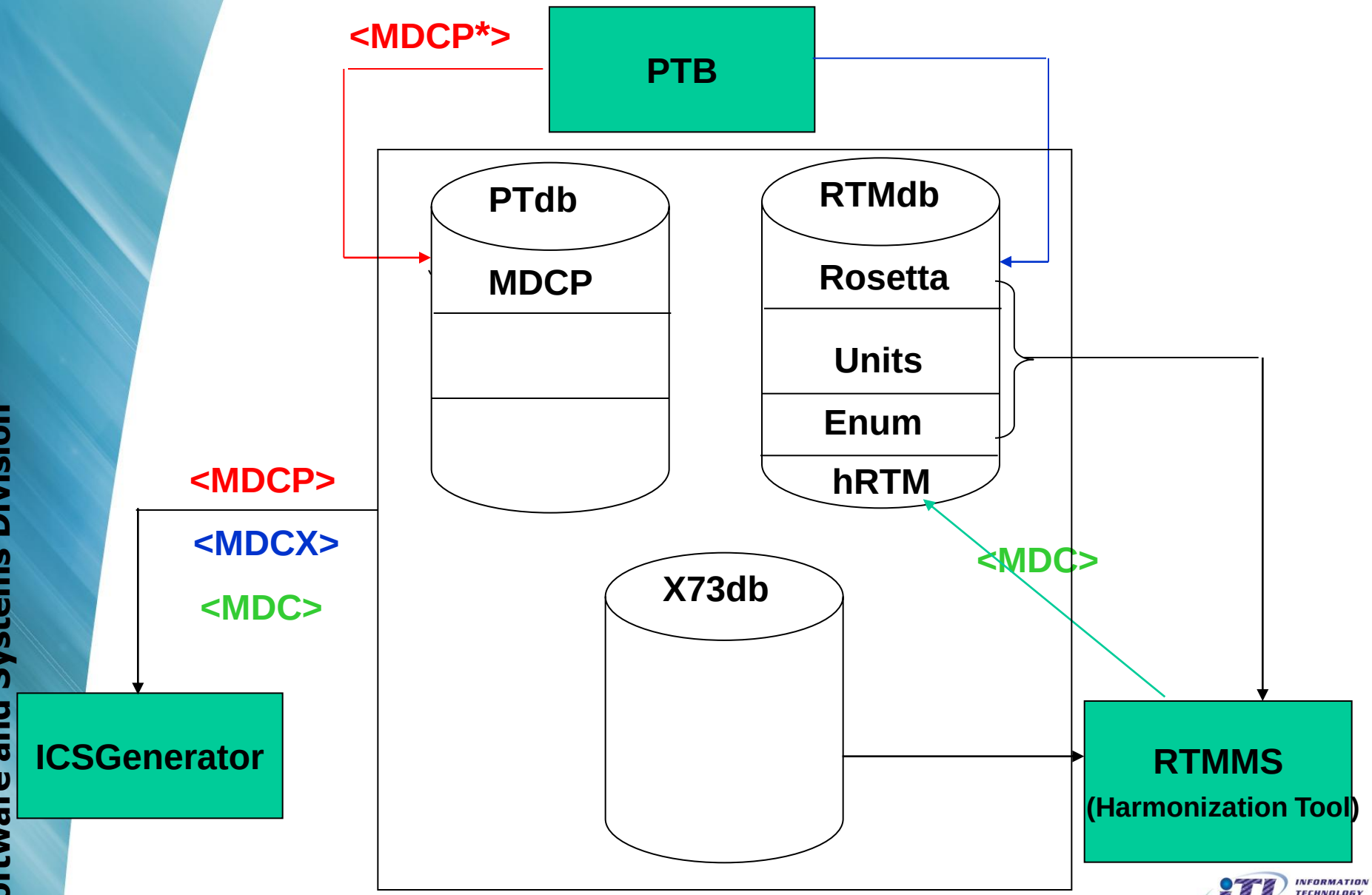
ICSGenerator was developed to:

- Support IEEE 11073 Conformance Testing.
  - Generate Implementation Conformance Statements (ICSs)
  - Build Device Profile (XML)
  - Provide validation against DIM Schema
  - Provide high level semantic interoperability
    - Ensures correct containment relationship and terminology at the object class and related attribute, notification, and behavior level
    - Provides access to Rosetta Dbase and X73 dbase

ICSGenerator Next Steps

- Working on the following enhancements:
  - Update ICSGenerator to have access to the latest X73 Nomenclature dbase version (containing IDC, PHD and Appendix B.)
  - Support PHD standards
    - Update specializations with published versions
  - Private Terms support

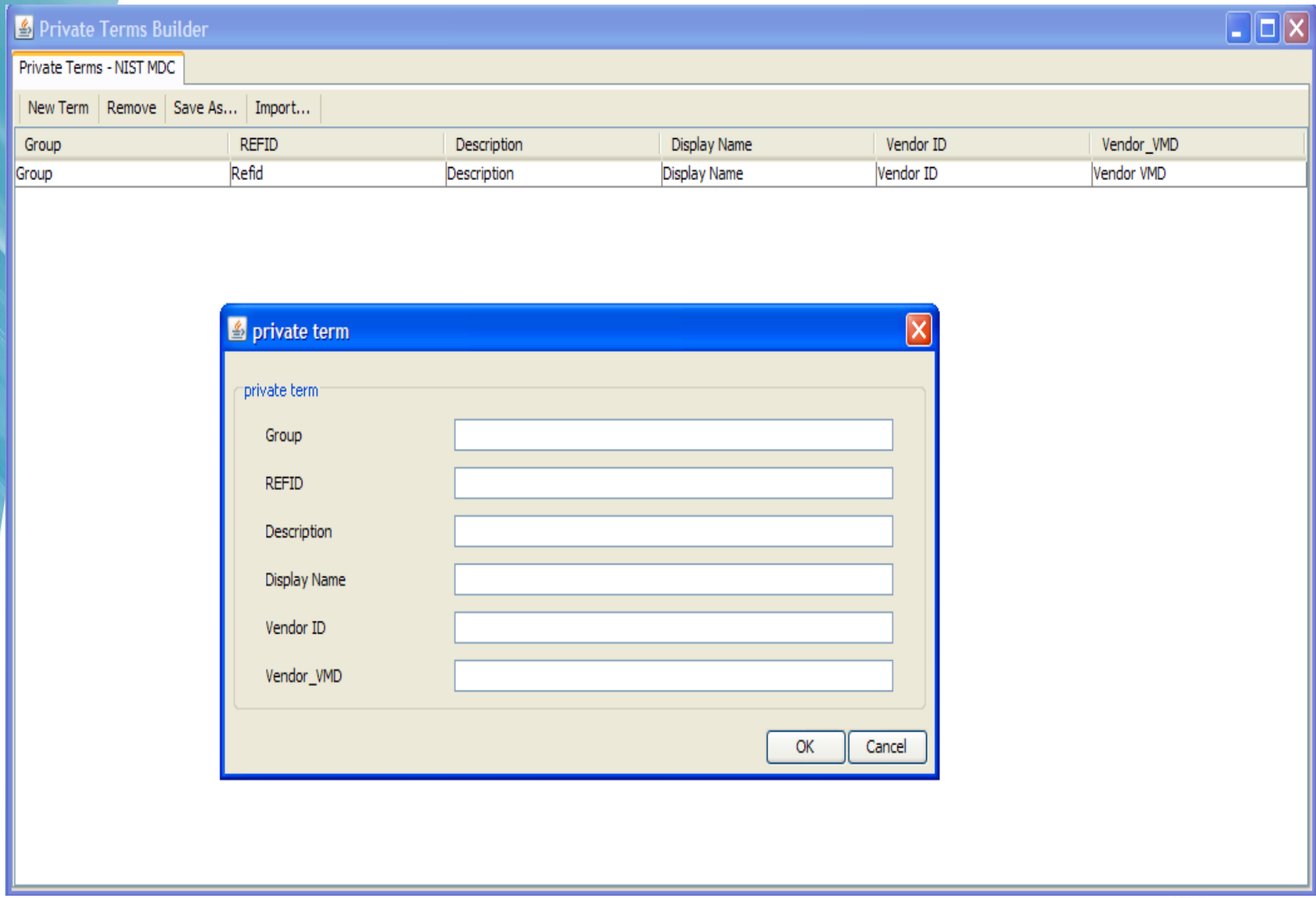
Private Term Support (Private Term Builder)



Private Term Builder Status

- Developed an initial **"Private Term Builder"** application (PTB) with the following goals:
  - Capture vendor private terms
  - Associate a private term to an x73 object – facilitating integration to the modeling tool (ICSGenerator)

- Initial PTB application includes the following features:
  - Imbedded database for private term storage.
  - Import/export capabilities in RTM xml formats.
  - Ability to enter vendor ref ids – not in compliance with x73 nomenclature
  - Ability to enter vendor term code – if available, nothing to do with x73 private space.
  - Ability to enter a common name (display name) – vendor name
  - Ability to enter a description for the term

Note: This is a private vendor application, vendor chooses to share terms for harmonization.

Private Term Builder Status