HEALTH IT
STANDARDS TESTING INFRASTRUCTURE

Using NIST Tools to Advance Interoperability for Immunization Messaging Implementations

AIRA Conference April 2016, Seattle, Washington

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Agenda

- Overview (5m)
- NIST Resource Portal (5m)
- Immunization Test Suites – Web Applications (35m)
  - SOAP Testing
  - HL7 v2.5.1 Release 1.5 Testing
    - Context-free Testing
    - Context-based Testing
    - Data Quality Testing
- ONC 2015 Edition HIT Certification (10m)
- HL7 v2.5.1 Release 1.4 Testing (2m)
- Web Service Validation (10m)
- NIST Implementation Guide Authoring Tool (IGAMT) (10m)
- Future Work (5m)
- Questions

Collaboration is Key

National Institute of Standards and Technology

AIRA American Immunization Registry Association
Immunization Information Systems for a New Era

CDC

HHS/ONC

NIST Immunization Suites-Web Applications

- Immunization Test Suite: Released 2016
  - Web based application that supports End-to-End Conformance Testing
  - Testing of SOAP Envelope and SOAP Connectivity based on the CDC WSDL
  - Testing of HL7 v2.5.1 Immunization Implementation Guide (R1.5)
    - Support for all 8 profiles (including Query and Response)
    - Targeted Test Cases-ONC 2015 Edition Certification
    - Data Quality Assurance (DQA)
  - EHR-S and IIS Functional Requirements
- Immunization Test Suite: Released 2012
  - Testing of HL7 v2.5.1 Immunization Implementation Guide (R1.4)
    - Support the VXU profile
    - Targeted Test Cases-ONC 2014 Edition Certification

ONC 2015 Edition HIT Certification

- Review ONC 2015 Edition criterion for Immunization Messaging
- Understand the impact on the IIS community
- Learn how the NIST Immunization Test Suite is used to certify EHR systems
- Review NIST Test Cases used in certification

NIST HL7 v2.x Validation Web Service

- Web Service Application Programming Interface (API)
- Immunization Messaging Release 1.4 (VXU Only)
- Immunization Messaging Release 1.5 (All Profiles)
- Example Clients in Java and C#
- Validate production messages at IIS sites
- Use of validation reports to analyze data quality

NIST Implementation Guide Authoring Tool (IGAMT)

- Tool to create HL7 v2.x implementation guides
  - Profiling Tool
  - Create local implementation guides based on National Standard
- Produces artifacts for:
  - Input to Validation Tools (NIST or others)
  - Message Generation
  - Profile Viewing
  - Code Generation
- Update on Tool Progress
- Pilot Initiatives for Immunization
  - Immunization Message Implementation Guide R1.6
  - Local State of Connecticut Implementation Guide

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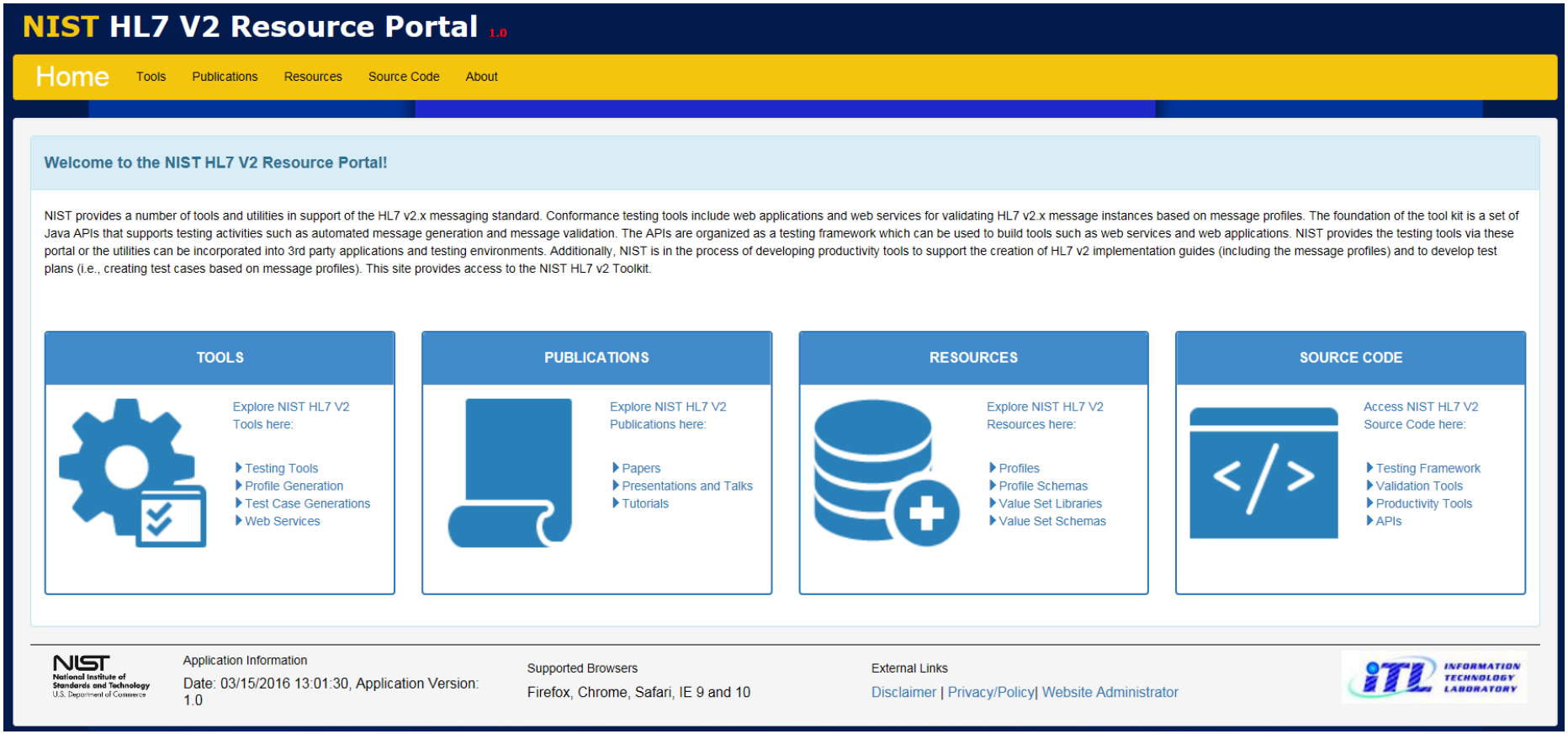
NIST Resource Portal

National Institute of Standards and Technology

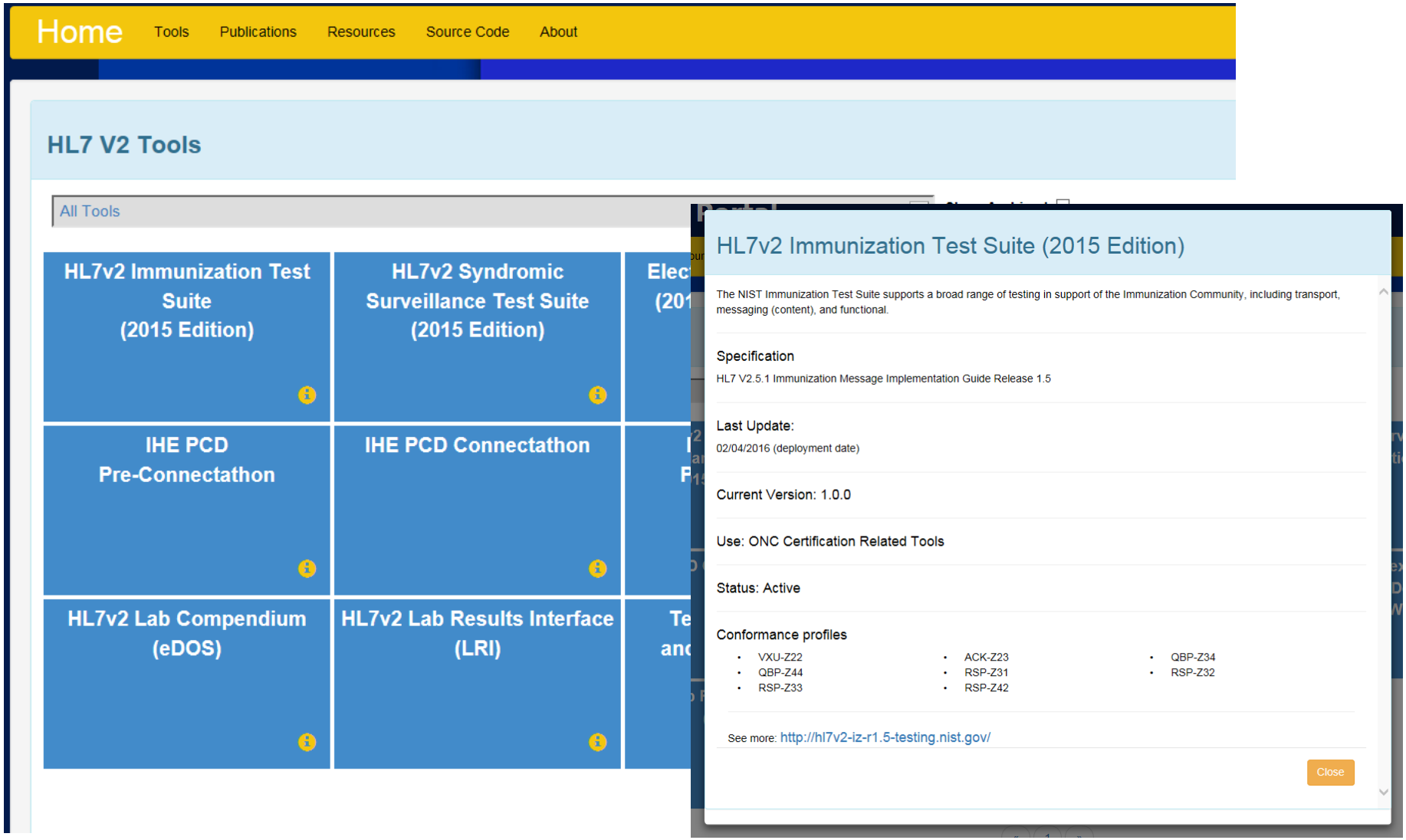
NIST Resource Portal

- Access point for all NIST HL7 v2.x Resources
  - Testing Tools
    - Validations Test Tools
  - Productivity Tools
    - IGAMT—Support for Implementation Guides
    - TCAMT—Support for Test Case Development (in progress)
  - Testing Artifacts
    - Profiles
    - Profile Schemas
    - Value Set Schemas
  - Informational Resources
    - Papers
    - Presentations
  - Source Code
- Web Based Application

NIST HL7 V2 Resource Portal



NIST HL7 V2 Resource Portal - Tools



NIST HL7 V2 Resource Portal - Publications

Home | Tools | Publications | Resources | Source Code | About

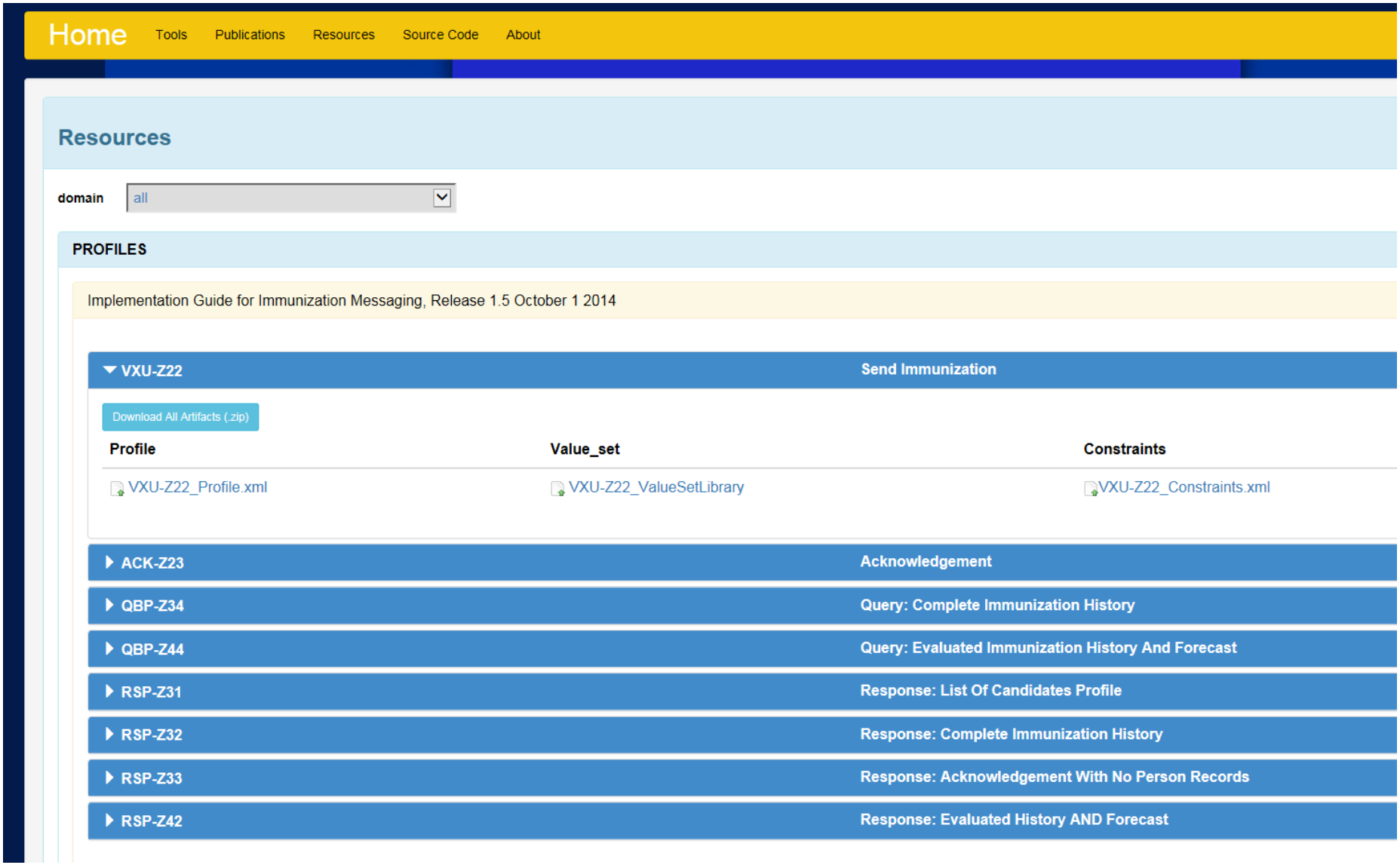
Publications

Papers

Title	Date	Authors	Publication	Slides
Conformance Testing of Healthcare Data Exage Standards for EHR Certification	July, 2015	R.Snelick	WORLDCOMP'15, HIMS	
An Interoperability Test Bed for Distributed Helthcare Applications	March, 2014	R.Snelick	Entreprise Interoperability VII Spring-Verlag, London	
Principles for Profiling Healthcare Data Communication Standards	July,2013	R.Snelick, F.Oeming	WORLDCOMP'13, SERP	
Understanding Meaningful Use with a Focus on Testing the HL7 V2 Messaging Standards	May, 2013	R.Snelick, S.Taylor	HL7 NewsLetter	
Testing Environments for Assessing Conformance and Interoperability	July, 2010	R.Snelick, L.Gebase	WORLDCOMP'10, SERP	
A Framework for Testing Distributed Helthcase Applications	July, 2009	R.Snelick, L.Gebase, G.O'Brien	WORLDCOMP'09, SERP	
Conformance Testing and Interoperability: A case Study in Helthcare Data Exchange	July, 2008	L.Gebase, R.Snelick, M.Skall	WORLDCOMP'08, SERP	
Towards Interoperable Helthcare Information Systems: The HL& Conformance Profile Approach	March, 2007	R.Snelick, P.Rontey, L.Gebase, L.Carnahan	Entreprise Interoperability II Spring-Verlag, London	
Selecting Effective Test Messages	June, 2006	L.Gebase, R.Snelick, R.Bertucat	WORLDCOMP'06, SERP	
Dynamically Generating Conformance Tests for Messging Systems	June, 2006	R.Snelick, L.Gebase, S.Henrard	WORLDCOMP'06, SERP	

Presentations

NIST HL7 V2 Resource Portal - Profiles



NIST HL7 V2 Resource Portal - Schemas

▶ ORU_R01	Unsolicited Observation Message (Report Result)
▶ ACK	ACK - Acknowledgement

SCHEMAS

▼ HL7 V2 Conformance Profile

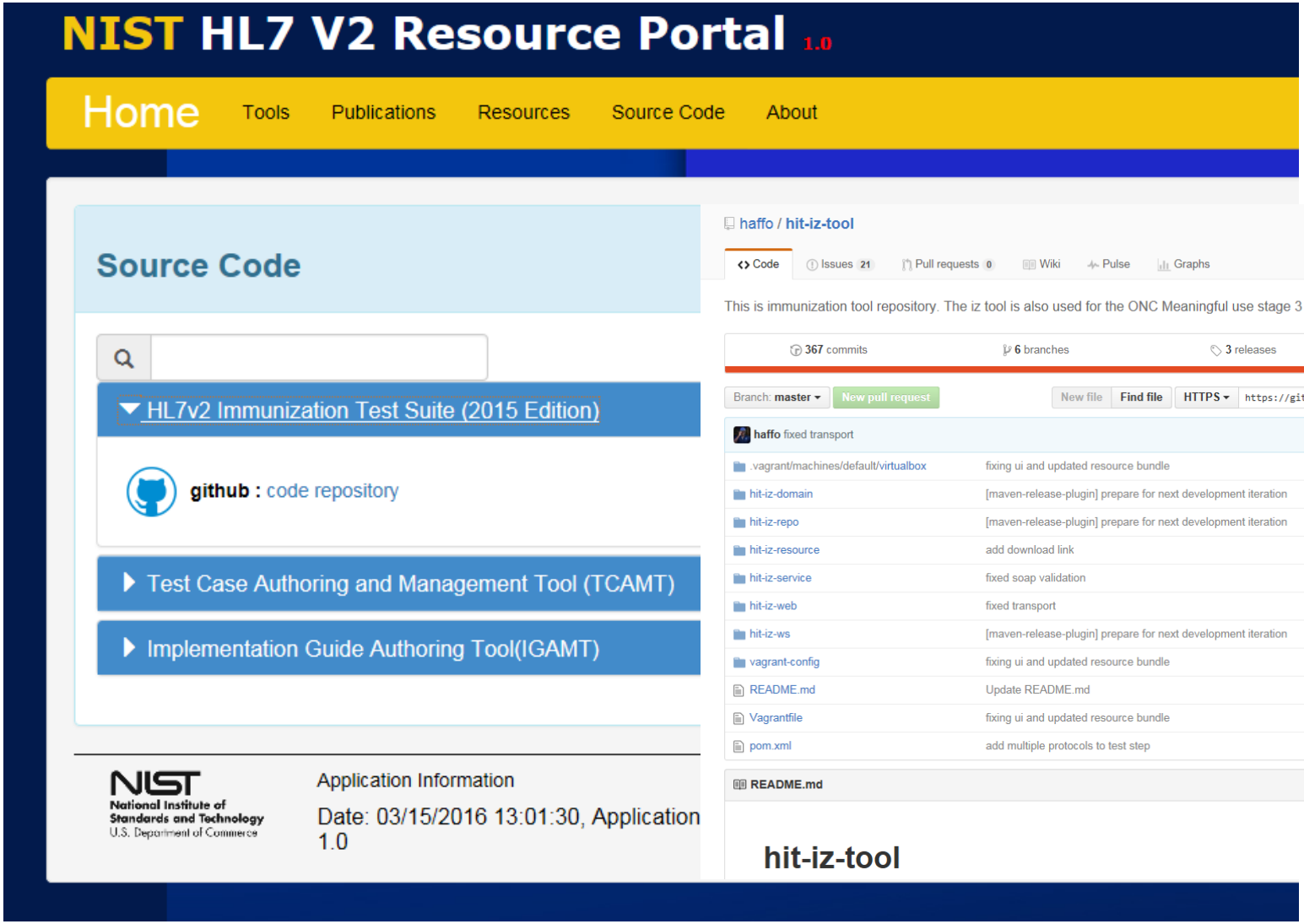
Name	Source
HL7 Conformance Profile V2.NIST-2	ProfileSchema_v29.xsd
HL7 Conformance Profile V2.NIST-1	ProfileSchema_v29.xsd
HL7 Conformance Profile V2.8	ProfileSchema_v28.xsd
HL7 Conformance Profile V2.7.1	ProfileSchema_v271.xsd
HL7 Conformance Profile V2.7	ProfileSchema_v27.xsd
HL7 Conformance Profile V2.5,v2.4,v2.31	ProfileValidationSchema_HL7v2.5.xsd

▶ Table Library or Value Set

▶ Validation Context

▶ HL7 V2 Web Service

NIST HL7 V2 Resource Portal – Source Code



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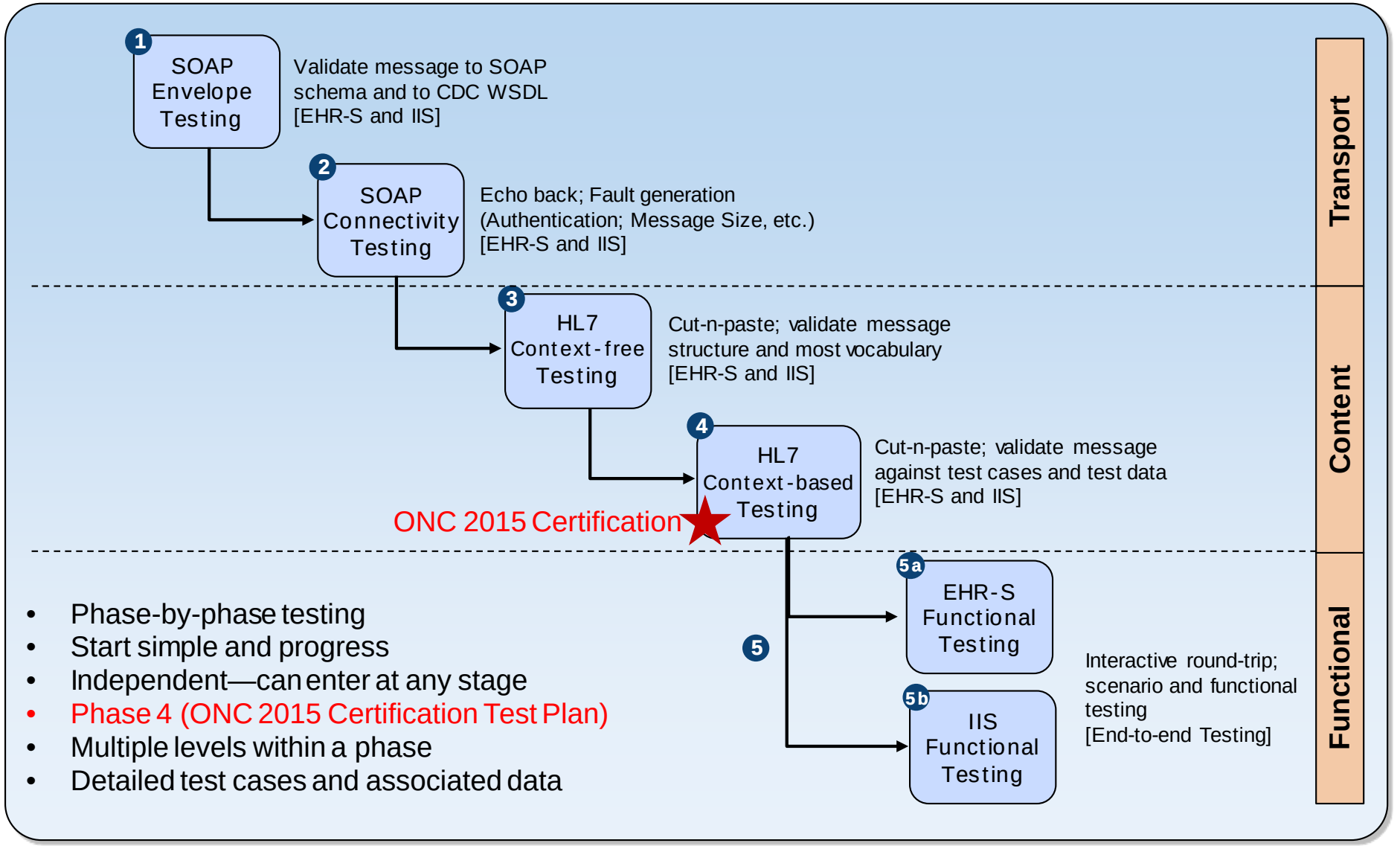
NIST Immunization Test Suite (2016)

Overview

National Institute of Standards and Technology

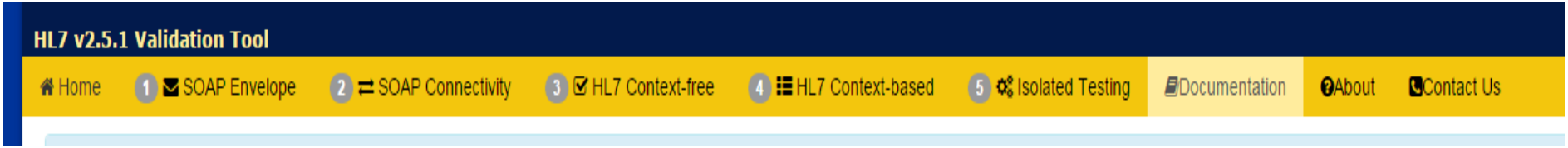
Immunization Test Suite: Overview and Capabilities



- Phase-by-phase testing
- Start simple and progress
- Independent—can enter at any stage
- Phase 4 (ONC 2015 Certification Test Plan)
- Multiple levels within a phase
- Detailed test cases and associated data

Immunization Validation Tool Overview

Tool Key Capabilities	
SOAP Envelope Testing	The SOAP Envelop Testing ensures SOAP envelopes are correctly formed, validating the conformance of the messages to the requirements in the SOAP and Transport specifications.
SOAP Connectivity Testing	The SOAP Connectivity Testing evaluates valid SOAP connectivity, the ability to send and receive SOAP messages, validating the conformance of the messages to the requirements in the SOAP and Transport specifications.
Context-Free Testing	Provides a simple and convenient method for testing immunization messages structure and most vocabulary. Validation is perform on messages with or without a SOAP wrapper.
Context-Based Testing	Context-based testing provides, in addition to HL7 Context-free validation, message validation associated with a given test script that includes data for a specific test scenario where the context is known by the validation tool. It also validate messages with a SOAP wrapper.
Isolated Testing	Isolated testing provides a simulated operational environment that allows validation at the functional level in addition to content and context-free testing, where Test Agents simulates the functions of IZ EHR-S or IIS.



Environment: NIST Immunization Test Suite is accessible as a web application.
Supported Browsers: Firefox, Chrome, Safari, and Internet Explorer (Version 10 and 11)
URL: http://hl7v2-iz-r1.5-testing.nist.gov
NOTE: The Test Tool (.war file) can also be downloaded and installed locally. See Documentation tab in Test Tool

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NIST Immunization Test Suite (2016)

SOAP Testing

National Institute of Standards and Technology

CDC Defined SOAP Web Service

- Message Transport
  - HL7 does not define how to send messages
- IIS support many different methods
  - FTP
  - Manual Upload (on web page)
  - HTTPS Post
  - Direct VPN Connection
  - SOAP Web Services
- CDC convened expert panel to recommend single standard
  - SOAP Web Service technology was chosen
  - Standard Web Service Description Language (WSDL) created
  - Encourage IIS to adopt in addition to or replacing current methods
  - Not intended to preclude use of other transport standards
  - Overall goal is to allow connecting systems to use one standard for all IIS

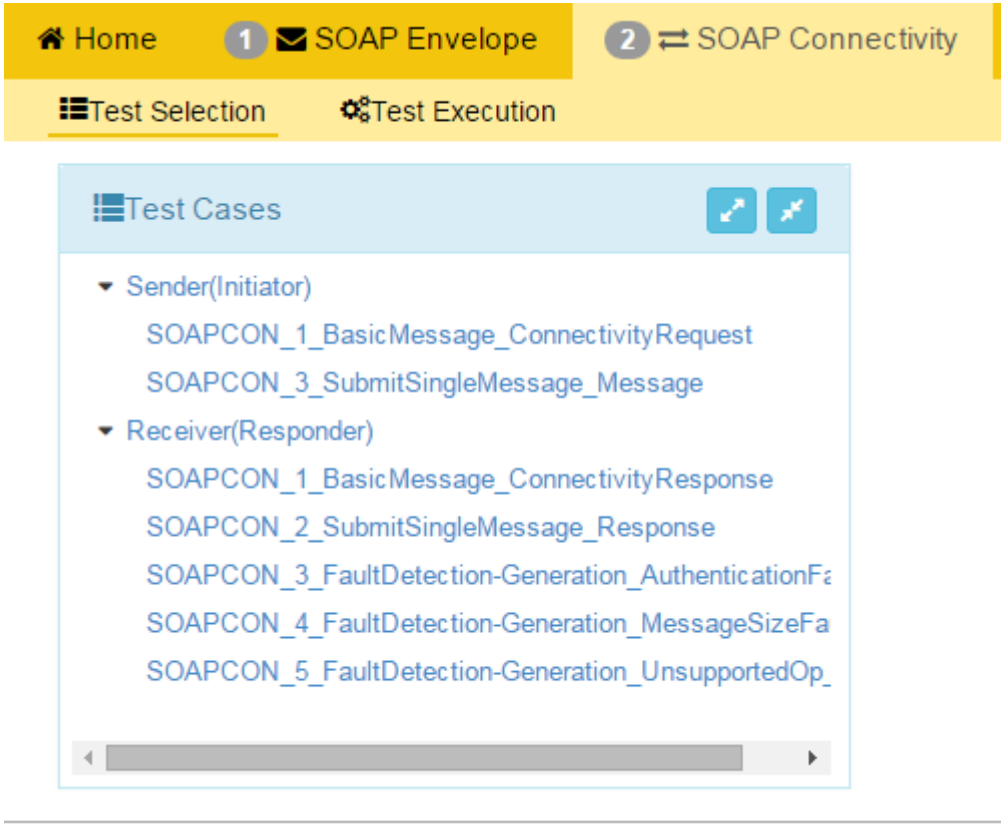
CDC Defined SOAP Web Service: Operations

- **connectivityTest**
  - Designed as a simple “Hello World” test.
  - Useful to test if an EHR sees your IIS without the need to worry about payload and business rules
- **submitSingleMessage**
  - 3 authentication parameters (user ID, password, facility ID)
  - Payload parameter (HL7 Message)
  - Supports both vaccine update and query/response
  - Common exceptions are defined

SOAP Envelope and Connectivity Testing Overview

- Purpose
  - To ensure SOAP envelopes are correctly formed according to the CDC specification and provide sample messages of each type.
  - To ensure valid SOAP connectivity (i.e., the ability to send and receive SOAP messages)
- Scope
  - SOAP Version 1.2 Part 1: Messaging Framework, W3C Recommendation 27 April 2007
  - Transport Layer Protocol Recommendation Formal Specification, version 1.0, August 25, 2011
- Tests
  - Validate against XML 1.1, SOAP 1.2, and CDC WSDL 1.0
  - Test cases for all message types defined by the CDC WSDL (including Fault messages)

Test Case List



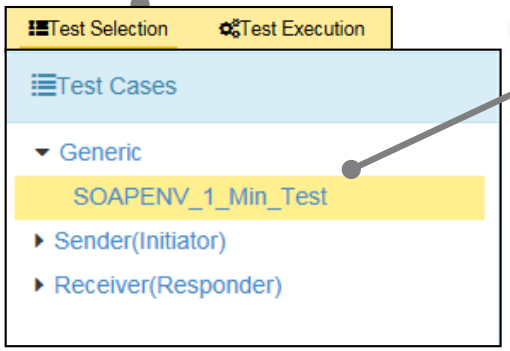
SOAP Envelope Testing Quick Guide

SOAP Envelope testing page

The SOAP Envelop Testing ensures SOAP envelopes are correctly formed, validating the conformance of the messages to the requirements in the SOAP and Transport specifications.

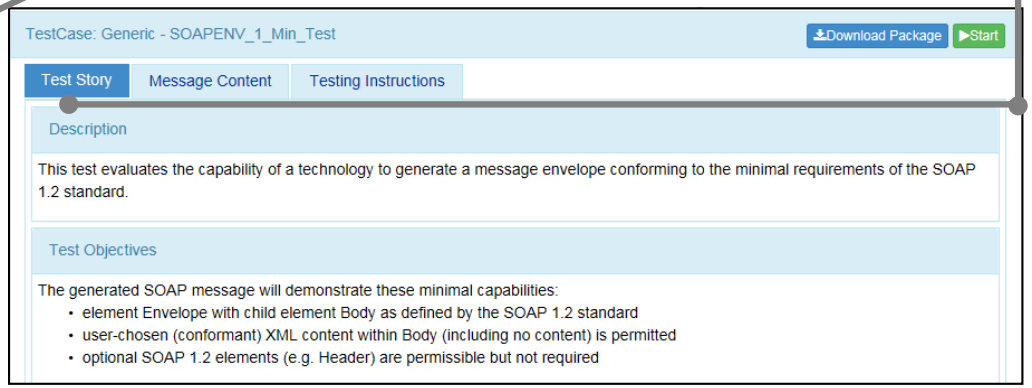
1. Open NIST Immunization Test Suite tool using link: http://hit-dev.nist.gov:8098/iztool/#home and clickon '**SOAP Envelope**' tab.

2. Under '**Test Selection**' Select a '**Test Case**'



3. Point arrow down to select a test step.

4. A '**Test Story**' will appear once a test step is selected.



6. Clickon '**Start** '

SOAP Envelope Testing: Other Utilities

SOAP Envelope Validation page

This page validates any Immunization message created by the EHR. It is disassociated from a test script, test case, or specific content (test data).

7 Clicking '**Start**' will generate the '**Test Execution**' tab.

Test Selection | Test Execution

8 Confirm '**Validation**' is highlighted.

Validation | Report

Tree Representation

- Envelope
  - Header
    - Action
      - http://tempuri.org/IServi
    - ActivityId
      - 43ffa660-a0c6-4249-bb
  - Body
    - MyOperation
      - MyValue

9 Insert a HL7 message by clicking '**Load Example**'.

Soap Envelope — Validate | Load Example | Browse | Download | Clear

```
<Envelope xmlns="http://www.w3.org/2003/05/soap-envelope">
  <Header>
    <Action xmlns="http://schemas.microsoft.com/ws/2005/05/addressing/none" mustUnderstand="1">
      http://tempuri.org/IService/MyOperation
    </Action>
    <ActivityId xmlns="http://schemas.microsoft.com/2004/09/ServiceModel/Diagnostics" CorrelationId="7224
      43ffa660-a0c6-4249-bb36-648b73a06213</ActivityId>
  </Header>
  <Body>
    <MyOperation xmlns="http://tempuri.org">
      <MyValue>Some Value</MyValue>
    </MyOperation>
  </Body>
</Envelope>
```

Soap Validation Result

0 Errors | 0 Warnings | 0 Alerts

Path	Description	Line

10 Clickon '**Report**' to generate a Message Validation Report.

Validation | Report

PDF | Word | Xml | Html

Message Validation Report — Date: 10 27 2015, 11:44:38.835-04:00

0
0
0
0
0

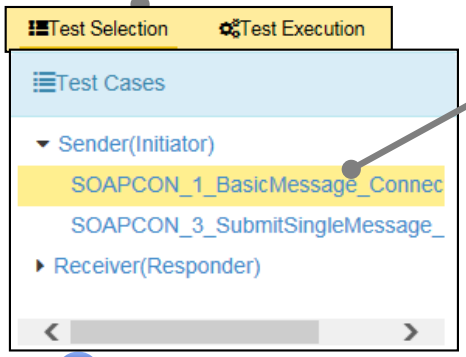
SOAP Connectivity Testing Quick Guide

SOAP Connectivity testing page

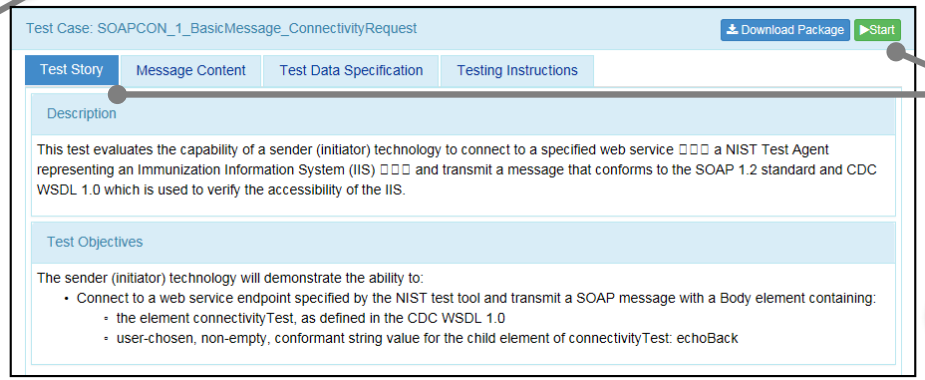
The SOAP Connectivity Testing evaluates valid SOAP connectivity, the ability to send and receive SOAP messages, validating the conformance of the messages to the requirements in the SOAP and Transport specifications.

1. Open NIST Immunization Test Suite tool using link: http://hit-dev.nist.gov:8098/iztool/#/home and click on '**SOAP Connectivity**' tab.

2. Under '**Test Selection**' Select a '**Test Case**'



3. Point arrow down to select a test step.



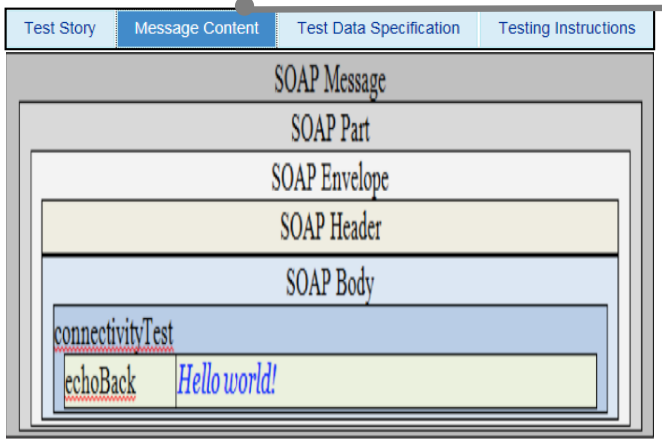
4. A '**Test Story**' will appear once a test step is selected.

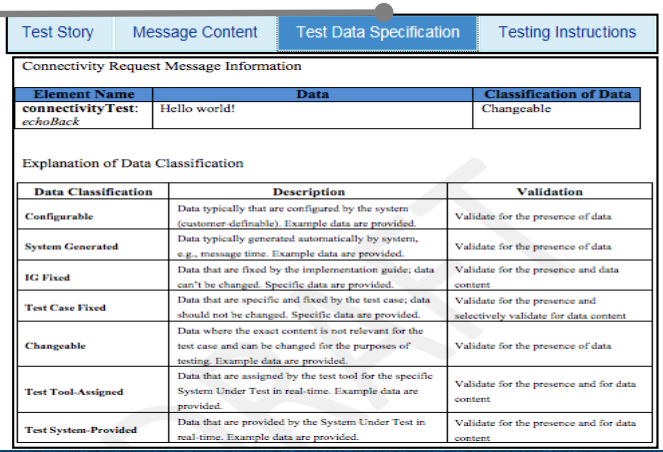
7. Click on '**Start** '

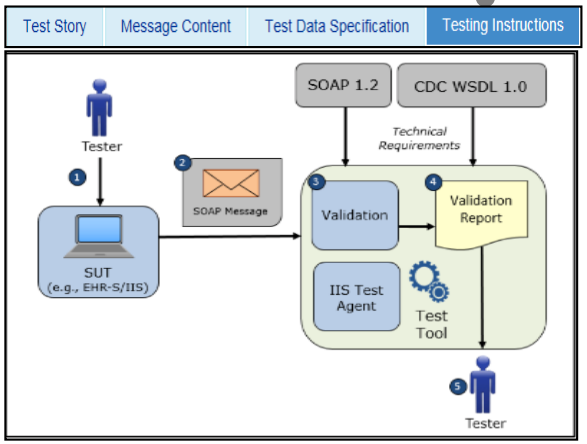
8. Please collect and validate your incoming/outgoing messages in the Stage 1: SOAP Envelope

5. Select "**Message Content**". Select "**Test Data Specification**".

6. Select "**Testing Instructions**".







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NIST Immunization Test Suite (2016)

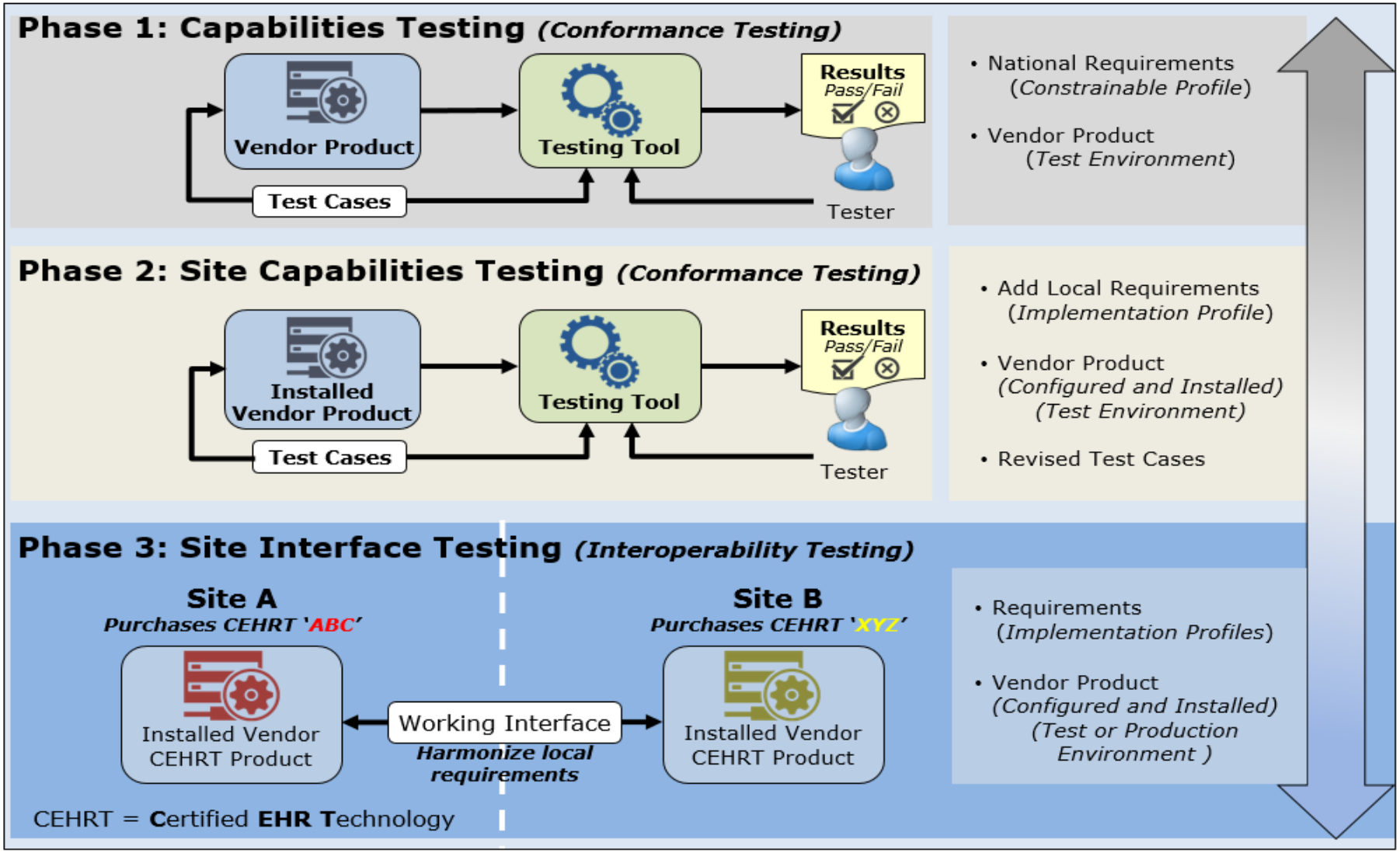
HL7 v2.5.1 Testing

NIST
National Institute of Standards and Technology

Messaging Standard – Supported Profiles

- HL7 2.5.1 Immunization Implementation Guide Release 1.5
- HL7 2.5.1 Immunization Implementation Guide Release 1.5, Addendum
- All 8 Profiles Supported
  - VXU^V04
    - Z22 - SEND UNSOLICITED IMMUNIZATION UPDATE USING A VXU
  - ACK
    - Z23 - RETURN AN ACKNOWLEDGEMENT
  - QBP^Q11
    - Z34 - REQUEST A COMPLETE IMMUNIZATION HISTORY
    - Z44 - REQUEST EVALUATED IMMUNIZATION HISTORY AND FORECAST QUERY PROFILE
  - RSP^K11
    - Z31 - RETURN A LIST OF CANDIDATES PROFILE
    - Z32 - RESPONSE PROFILE – RETURN COMPLETE IMMUNIZATION HISTORY
    - Z33 - RETURN AN ACKNOWLEDGEMENT WITH NO PERSON RECORDS
    - Z42 - RETURN EVALUATED HISTORY AND FORECAST

Testing Tiers

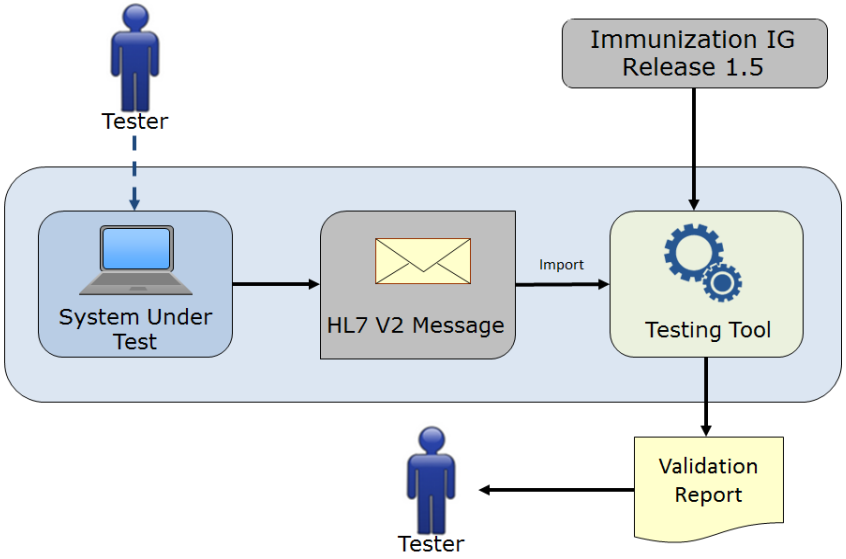


R. Snelick March 2015

HL7 Content Testing: Test Tool Operation Modes

- Testing the Sender (Message Creation)
  - Context-free Testing
    - Provides a simple and convenient method for testing message structure and most vocabulary
    - The context-free operational mode validates any message created by the EHR
    - It is disassociated from a test script, test case, or specific content (test data)
    - Good for site-testing
  - Context-based Testing (Use for Certification Testing)
    - Test Cases provided
    - Context (specific Test Scenario, etc.) is known to validation tool
    - Expands the scope of testing
    - Used in product certification testing
- Testing the Receiver (Incorporation)
  - Incorporation of message and associated functional requirements
  - Employs inspection testing (Juror Document)

Context-free Testing: HL7 Content



- No Test Cases provided
- Context (Test Scenario, etc.) is unknown to validation tool
- May be used to test any message created by an EHR
- Provides a simple and convenient method for testing message structure and most *vocabulary*
- Typically is not used for certifying EHR technologies for the ONC certification criteria, but may be used for certification testing in specific instances (the Tester must perform visual inspection to validate content of message)

Context-free Testing Quick Guide

Context-free Validation page

This page validates any Immunization message created by the EHR. It is disassociated from a test script, test case, or specific content (test data).

1. Open NIST Immunization Test Suite Tool using link: http://hl7v2-iz-r1.5-testing.nist.gov and click on '**HL7 Context-free**' tab.

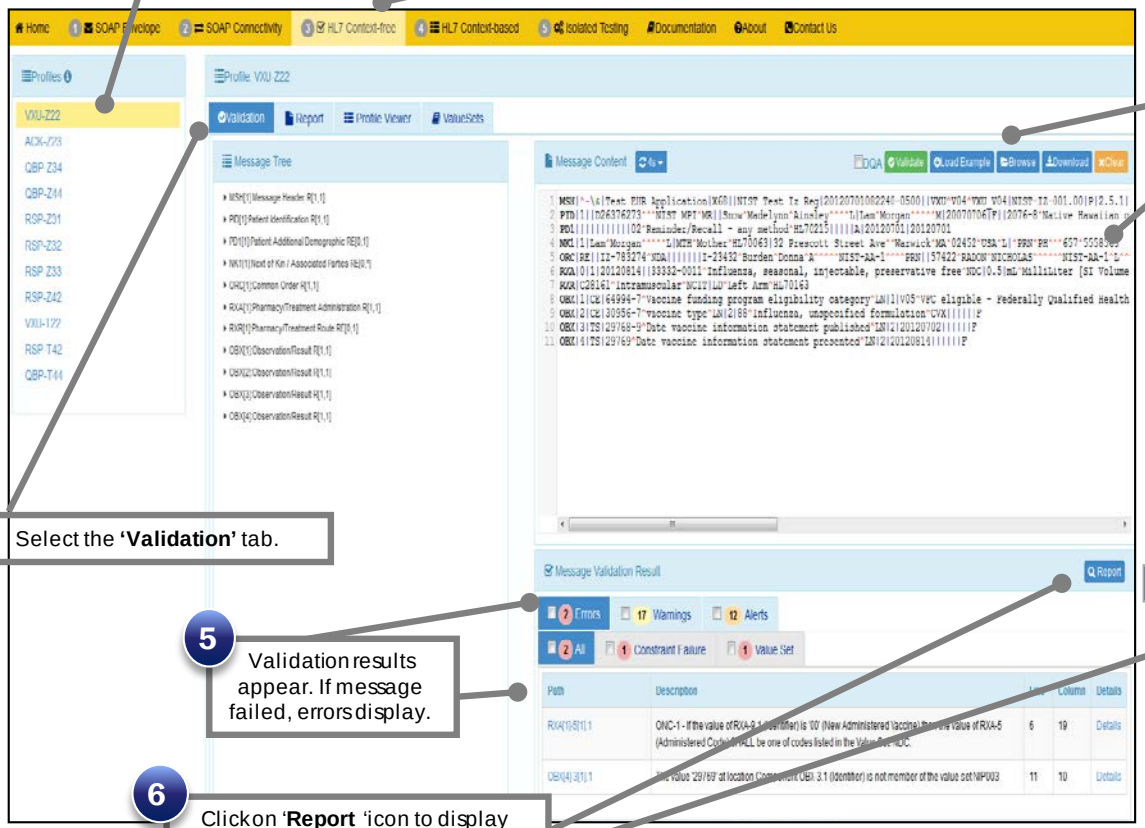
2. Select a '**Conformance Profile**' to test an HL7 message against.

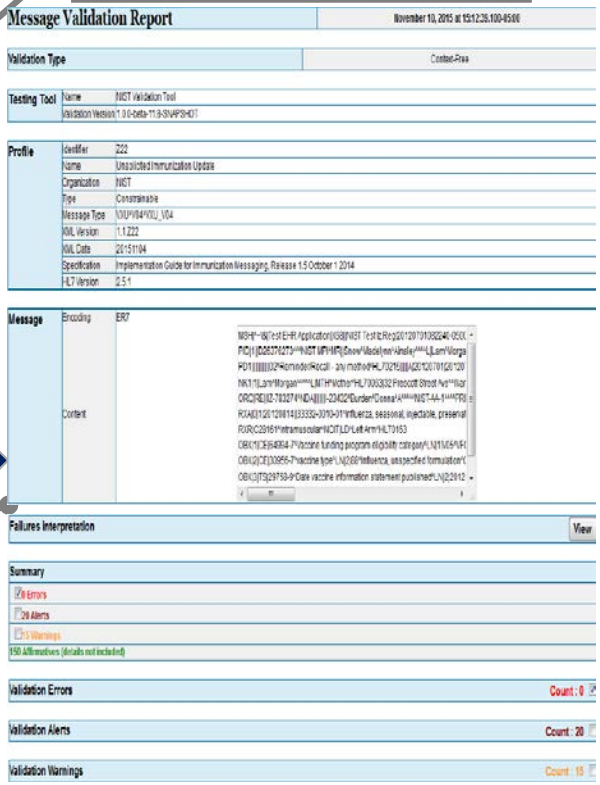
3. Select the **'Validation'** tab.

4. Copy/paste or click on Browse Message button to upload test message into Message Content window.

5. Validation results appear. If message failed, errors display.

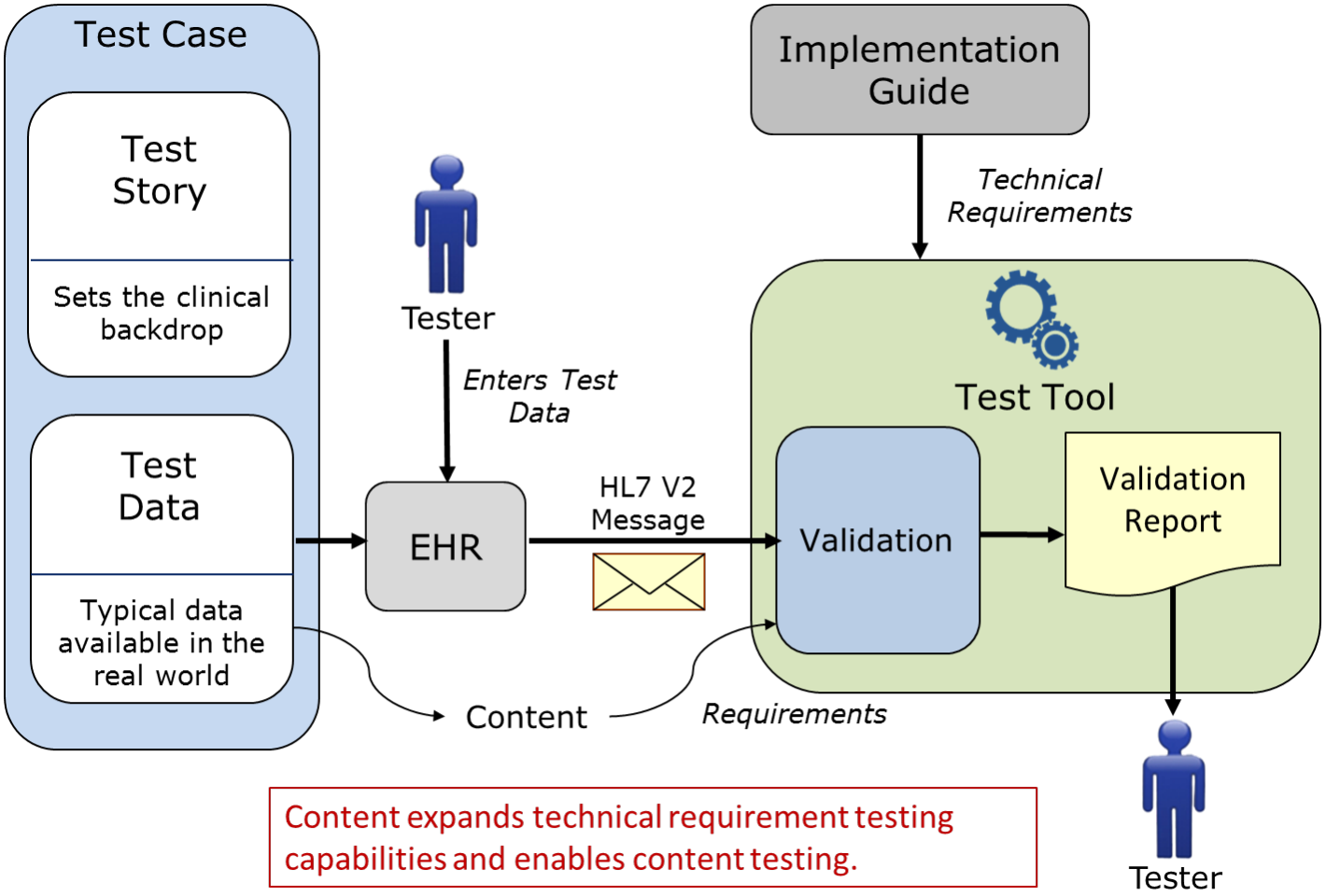
6. Click on '**Report** 'icon to display Message Validation Report.





Context-based Testing (Sending Application)

Used for ONC Certification



Note: EHR-S is the SUT in this Example

Context-based Testing

- The context-based operational mode validates messages associated with a given test script that includes data for a specific test scenario
  - The EHR creates a message that corresponds to the test data provided in the test script – Supports different use cases (Administered, Refusal, etc.)
  - Testing will include the technical requirements and content-specific requirements specified in the test case
- Context (specific Test Scenario, etc.) is known to validation tool
- Provides a method for testing/assessing a message for all conformance requirements of an Implementation Guide
- Is used for certifying EHR technologies for the ONC certification criteria
- **Significantly expands the scope of testing**
  - Usage: Required, but may be empty (RE), Conditionals (C)
  - Cardinality: Ranges
  - Length: Ranges
  - Vocabulary
- **Helps Interpretation and Use of the Standards**

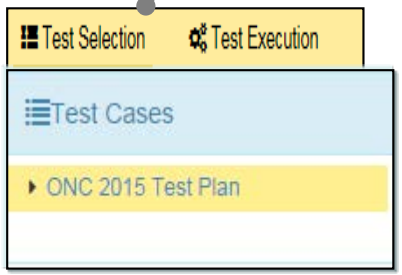
Context-based Testing Quick Guide

Context-based Testing page

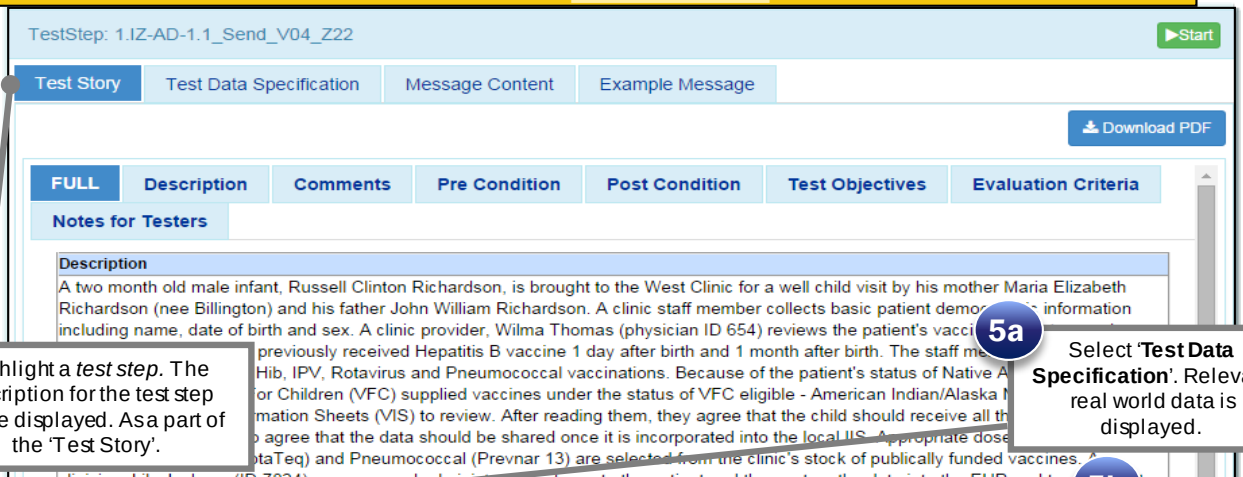
This page validates messages associated with a given test script that includes a specific Immunization test scenario. Testing will include the technical requirements and content-specific requirements specified in the Test Case.

2 Select 'Test Selection' to view or select a test case.

1 Open NIST Immunization Test Suite tool using link: http://hl7v2-iz-r1.5-testing.nist.gov and clickon '**HL7 Context-based'** tab.

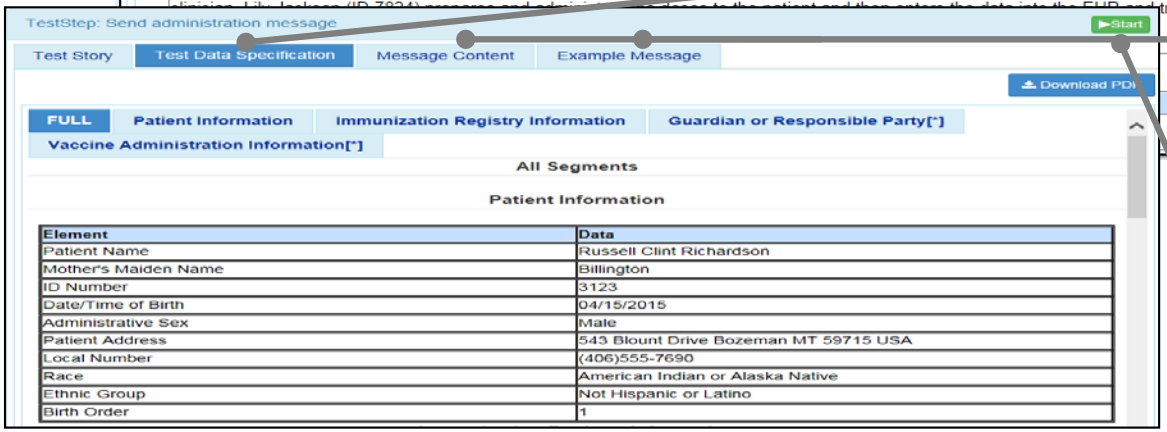


3 Arrow down '**Administration Group**' to choose a *test case* A description of the test case will be displayed.



4 Highlight a *test step.* The description for the test step will be displayed. As a part of the 'Test Story'.

5a Select '**Test Data Specification**'. Relevant real world data is displayed.



5b Create the test message with the EHR or IIS technology using the test data provided in the "Message Content." The **"Example Message"** tab also aidsin creating the test message.

6 Click '**Start**'

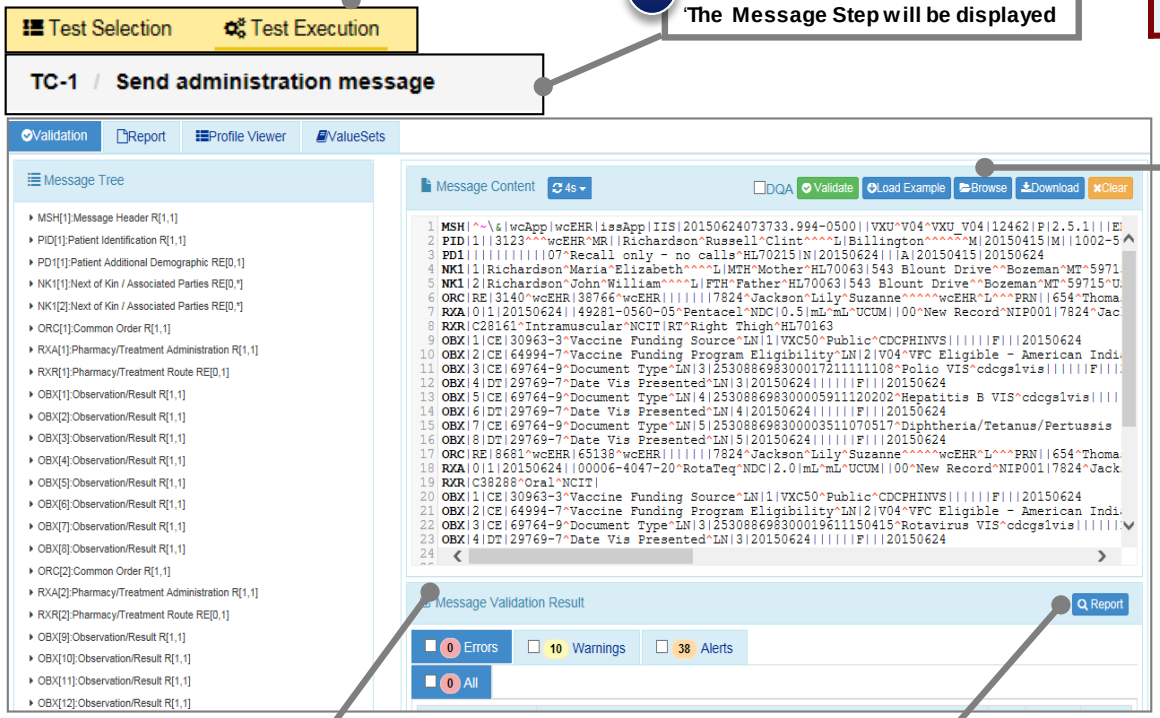
Context-based Testing Quick Guide

Context-based Validation page

This page validates any Immunization message created by the EHR. It is disassociated from a test script, test case, or specific content (test data).

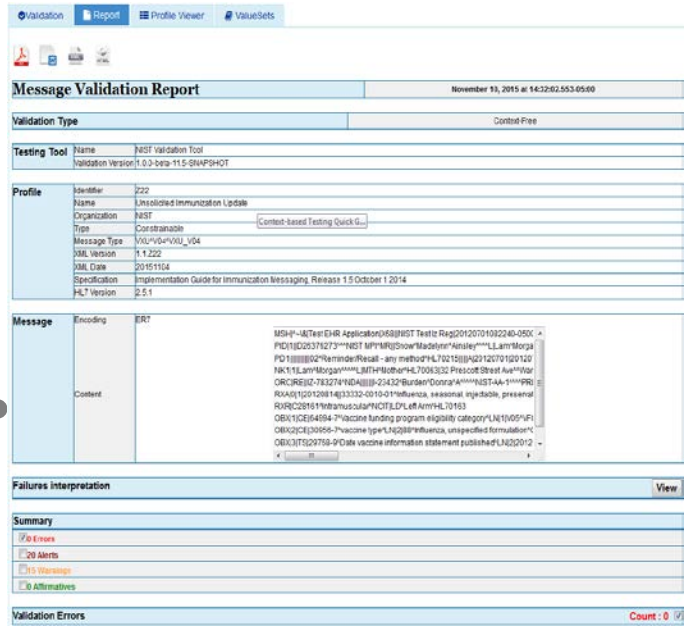
7 Selecting '**Start**' will load the test step and send you to the '**Test Execution**' tab.

8 '**The Message Step will be displayed**



9 Copy/paste or click Browse Message button to upload test message into the Message Content window.

10b The '**Report**' Tab can also be selected to generate a '**Message Validation Report**'



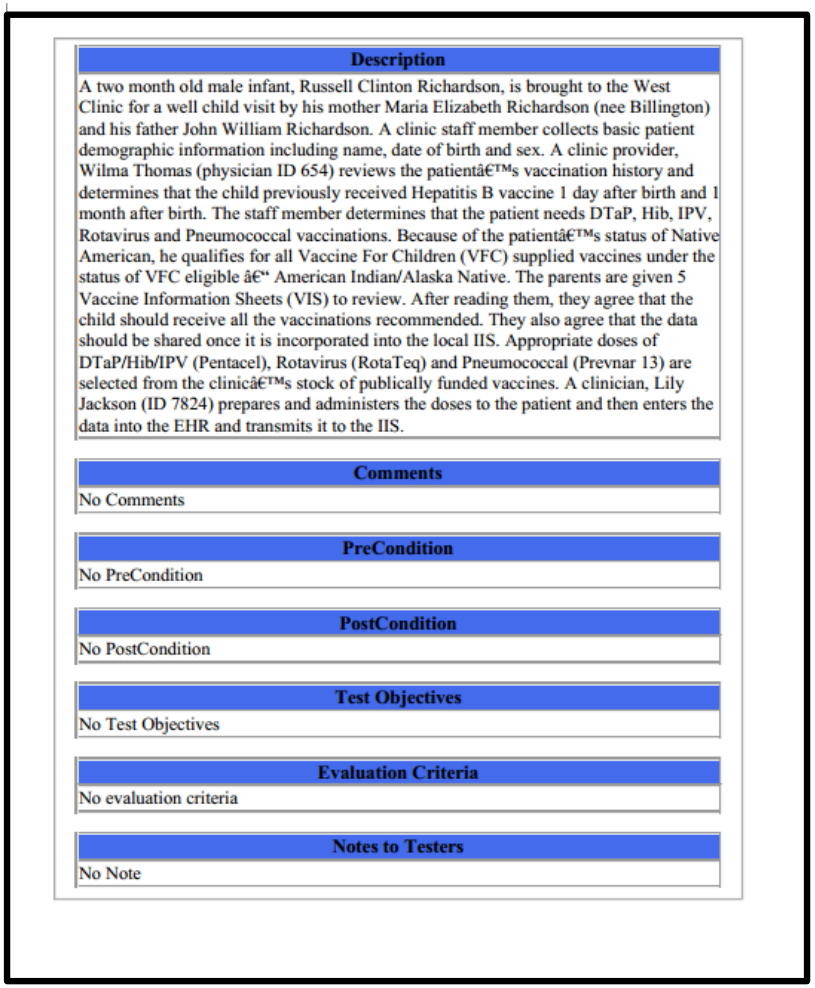
10a Validation results appear. If message failed, errors display.

11 Click on '**Report** 'icon to display Message Validation Report.

Test Case Overview

- Example use cases and messages
  - Provides realistic scenarios
  - Demonstrates desired interpretation and implementation of the standard—"brings it all together"
  - Implementers like to copy what they see—"we provide the example we want them to copy!"
- Test Plan
  - Scenario/Test Cases
  - Test Story
  - Test Data
  - Test Objectives
  - Pre-condition/Post Conditions
  - Evaluation Criteria and Notes to Testers
  - Poses questions to common real world scenarios and provides answers
- Dynamic "living" test cases on test site

Test Cases: Test Story



Description
A two month old male infant, Russell Clinton Richardson, is brought to the West Clinic for a well child visit by his mother Maria Elizabeth Richardson (nee Billington) and his father John William Richardson. A clinic staff member collects basic patient demographic information including name, date of birth and sex. A clinic provider, Wilma Thomas (physician ID 654) reviews the patientâ€™s vaccination history and determines that the child previously received Hepatitis B vaccine 1 day after birth and 1 month after birth. The staff member determines that the patient needs DTaP, Hib, IPV, Rotavirus and Pneumococcal vaccinations. Because of the patientâ€™s status of Native American, he qualifies for all Vaccine For Children (VFC) supplied vaccines under the status of VFC eligible â€“ American Indian/Alaska Native. The parents are given 5 Vaccine Information Sheets (VIS) to review. After reading them, they agree that the child should receive all the vaccinations recommended. They also agree that the data should be shared once it is incorporated into the local IIS. Appropriate doses of DTaP/Hib/IPV (Pentacel), Rotavirus (RotaTeq) and Pneumococcal (Prevnar 13) are selected from the clinicâ€™s stock of publically funded vaccines. A clinician, Lily Jackson (ID 7824) prepares and administers the doses to the patient and then enters the data into the EHR and transmits it to the IIS.

Comments
No Comments

PreCondition
No PreCondition

PostCondition
No PostCondition

Test Objectives
No Test Objectives

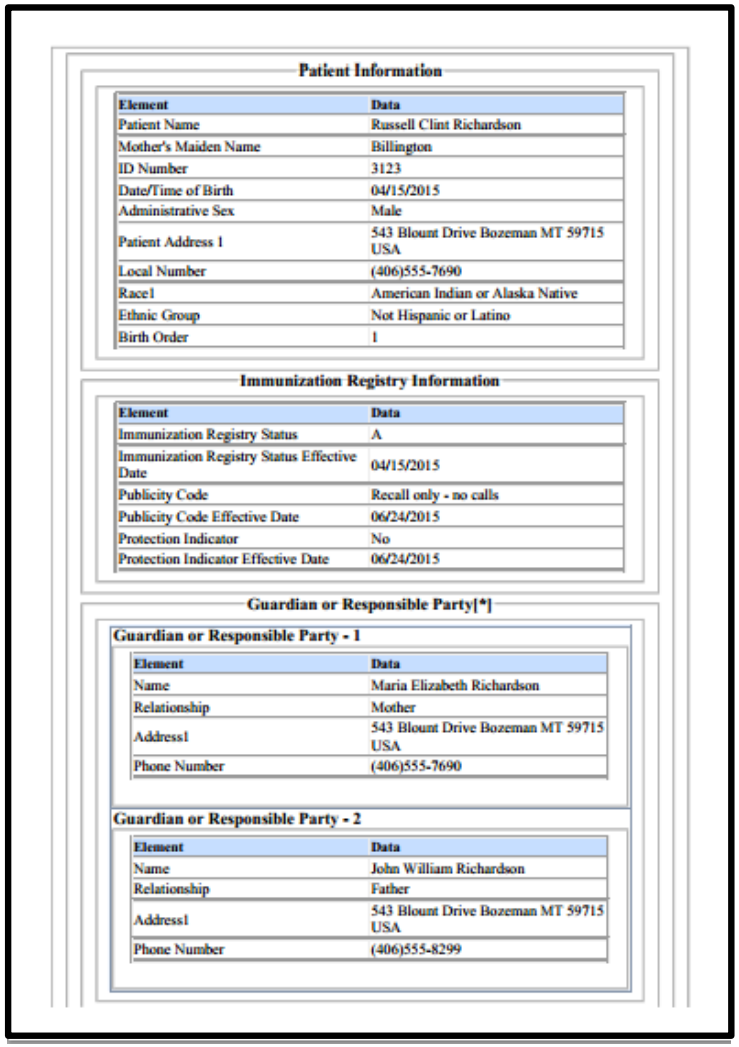
Evaluation Criteria
No evaluation criteria

Notes to Testers
No Note

Each Test Case includes a narrative Test Story that describes a real world situation and provides context for each Test Step

Example Test Data document: Test Case: IZ-AD-1_Admin_Child – 1.IZ-AD-1.1_Send_V04_Z22

Test Cases: Test Data Specification



Patient Information

Element	Data
Patient Name	Russell Clint Richardson
Mother's Maiden Name	Billington
ID Number	3123
Date/Time of Birth	04/15/2015
Administrative Sex	Male
Patient Address 1	543 Blount Drive Bozeman MT 59715 USA
Local Number	(406)555-7690
Race1	American Indian or Alaska Native
Ethnic Group	Not Hispanic or Latino
Birth Order	1

Immunization Registry Information

Element	Data
Immunization Registry Status	A
Immunization Registry Status Effective Date	04/15/2015
Publicity Code	Recall only - no calls
Publicity Code Effective Date	06/24/2015
Protection Indicator	No
Protection Indicator Effective Date	06/24/2015

Guardian or Responsible Party[*]

Guardian or Responsible Party - 1

Element	Data
Name	Maria Elizabeth Richardson
Relationship	Mother
Address1	543 Blount Drive Bozeman MT 59715 USA
Phone Number	(406)555-7690

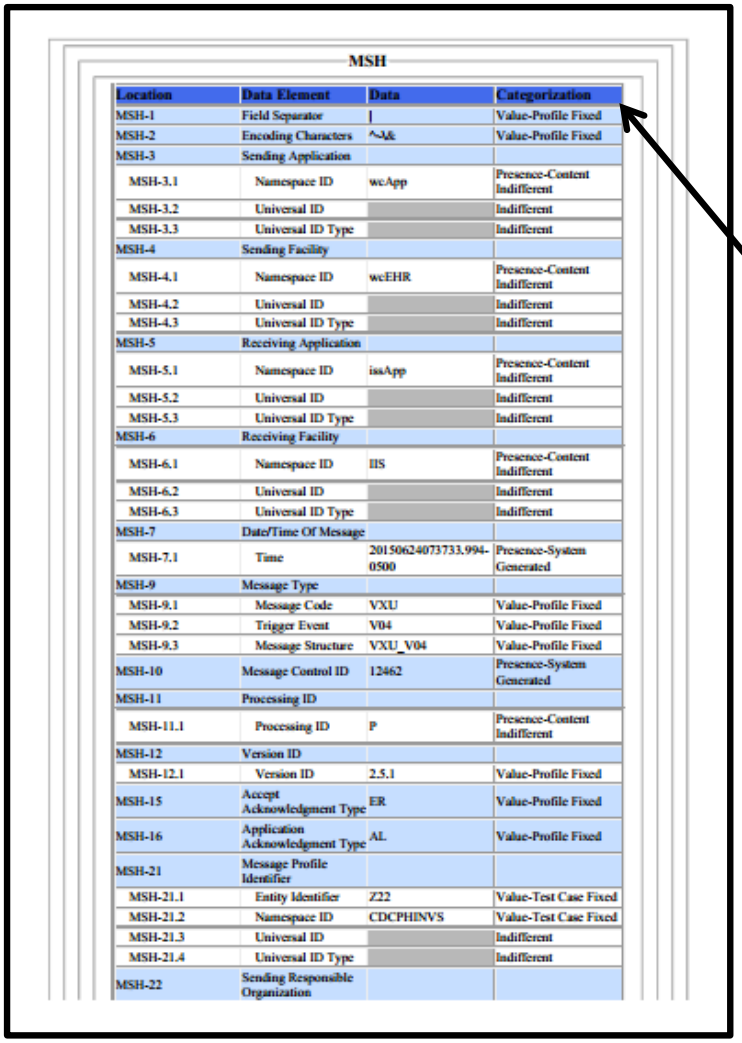
Guardian or Responsible Party - 2

Element	Data
Name	John William Richardson
Relationship	Father
Address1	543 Blount Drive Bozeman MT 59715 USA
Phone Number	(406)555-8299

- Each Test Case includes a Test Data Specification for each Test Step for which test data are expected to be entered into the HIT Module
  - Lists data associated with the Test Story
  - Consists of typical information found in the clinical setting
  - Along with the Test Story, provides sufficient information to be entered into the HIT Module for the Test Step
- A test message is generated using these data and the HIT Module functions

Example Test Data document: Test Case: IZ-AD-1_Admin_Child – 1.IZ-AD-1.1_Send_V04_Z22

Test Cases: Message Content



MSH

Location	Data Element	Data	Categorization
MSH-1	Field Separator	|	Value-Profile Fixed
MSH-2	Encoding Characters	^~\&	Value-Profile Fixed
MSH-3	Sending Application		
MSH-3.1	Namespace ID	wcApp	Presence-Content Indifferent
MSH-3.2	Universal ID		Indifferent
MSH-3.3	Universal ID Type		Indifferent
MSH-4	Sending Facility		
MSH-4.1	Namespace ID	wcEHR	Presence-Content Indifferent
MSH-4.2	Universal ID		Indifferent
MSH-4.3	Universal ID Type		Indifferent
MSH-5	Receiving Application		
MSH-5.1	Namespace ID	issApp	Presence-Content Indifferent
MSH-5.2	Universal ID		Indifferent
MSH-5.3	Universal ID Type		Indifferent
MSH-6	Receiving Facility		
MSH-6.1	Namespace ID	IIS	Presence-Content Indifferent
MSH-6.2	Universal ID		Indifferent
MSH-6.3	Universal ID Type		Indifferent
MSH-7	Date/Time Of Message		
MSH-7.1	Time	20150624073733.994-0500	Presence-System Generated
MSH-9	Message Type		
MSH-9.1	Message Code	VXU	Value-Profile Fixed
MSH-9.2	Trigger Event	V04	Value-Profile Fixed
MSH-9.3	Message Structure	VXU_V04	Value-Profile Fixed
MSH-10	Message Control ID	12462	Presence-System Generated
MSH-11	Processing ID		
MSH-11.1	Processing ID	P	Presence-Content Indifferent
MSH-12	Version ID		
MSH-12.1	Version ID	2.5.1	Value-Profile Fixed
MSH-15	Accept Acknowledgment Type	ER	Value-Profile Fixed
MSH-16	Application Acknowledgment Type	AL	Value-Profile Fixed
MSH-21	Message Profile Identifier		
MSH-21.1	Entity Identifier	Z22	Value-Test Case Fixed
MSH-21.2	Namespace ID	CDCPHINVS	Value-Test Case Fixed
MSH-21.3	Universal ID		Indifferent
MSH-21.4	Universal ID Type		Indifferent
MSH-22	Sending Responsible Organization		

Each Test Case includes a Message Content Data Sheet that shows a conformant message instance for each Test Step

The Category of the test data is listed in the Categorization column for each Data Element Location

Example Test Data document: Test Case: IZ-AD-1_Admin_Child – 1.IZ-AD-1.1_Send_V04_Z22

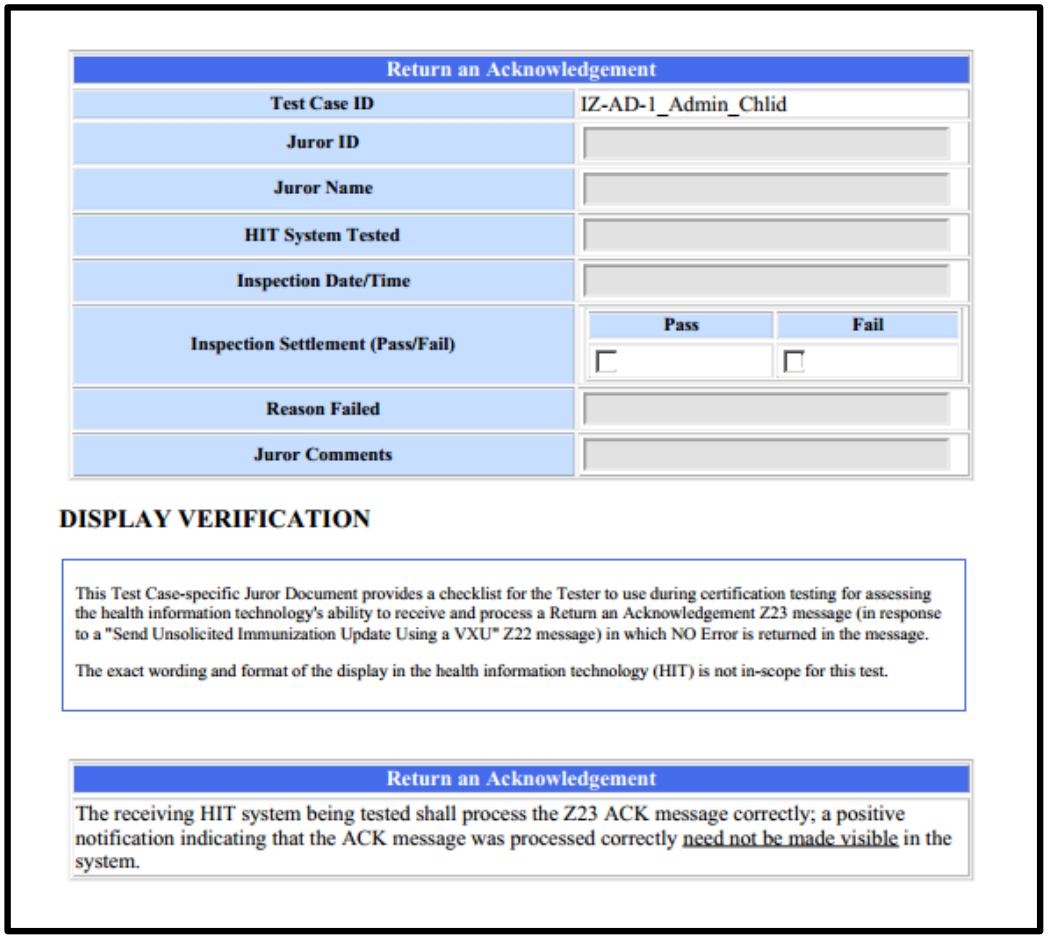
Test Data Categorization and Validation

- The Message Content Data Sheet shows the Categorization of the test data that are provided for each Location
- Each Test Data Category
  - Defines the criteria that are used by the test tool to assess the test data that populate each element in a message
  - Tells the Tester if the test data in a specific field can be changed, the source of the test data, and to what level of precision the validation tool will assess the data

Test Data Categorization	Description	Testing Implications	Comments
Indifferent	No test data are provided as part of the test case.	No additional validation.	The validation is indifferent to the presence of data or specific content in the message element. **Meaning: Value or don't value this data element.**
Presence	Test data are provided as part of the test case; content indifferent.	Validated for the presence of data.	The specific content is not pertinent to the test cases for the purpose of testing. The test data can be modified. **Meaning: Value this data element.**
Presence-Length	Test data are provided as part of the test case; minimum length of the content is expected.	Validate for the presence of data to a minimum length.	The specific content is not pertinent to the test cases for the purpose of testing, but the length of the content is. The test data can be modified as long as the minimum length of the test data is maintained. **Meaning: Value this data element to a minimum length.**
Value	Test data are provided as part of the test case; specific content is provided and expected.	Validate for the presence of data and for specific content.	The specific content (or choice of content) is provided and is expected to be present in the message. The test data can only be modified with data in the allowable data set. In some cases the set is a single constant. **Meaning: Value this data element with the test data options provided.**
Non-presence	No test data are provided as part of the test case and no content for this message element is expected.	Validate for the non-presence of data.	Content is not specified in the test case and is not expected to be present in the message. **Meaning: Don't value this data element.**

Important point—some data can be modified, e.g., "Presence"

Test Cases: Juror Document



Return an Acknowledgement	
Test Case ID	IZ-AD-1_Admin_Chlid
Juror ID	
Juror Name	
HIT System Tested	
Inspection Date/Time	
Inspection Settlement (Pass/Fail)	Pass ☐ Fail ☐
Reason Failed	
Juror Comments	

DISPLAY VERIFICATION

This Test Case-specific Juror Document provides a checklist for the Tester to use during certification testing for assessing the health information technology's ability to receive and process a Return an Acknowledgement Z23 message (in response to a "Send Unsolicited Immunization Update Using a VXU" Z22 message) in which NO Error is returned in the message.

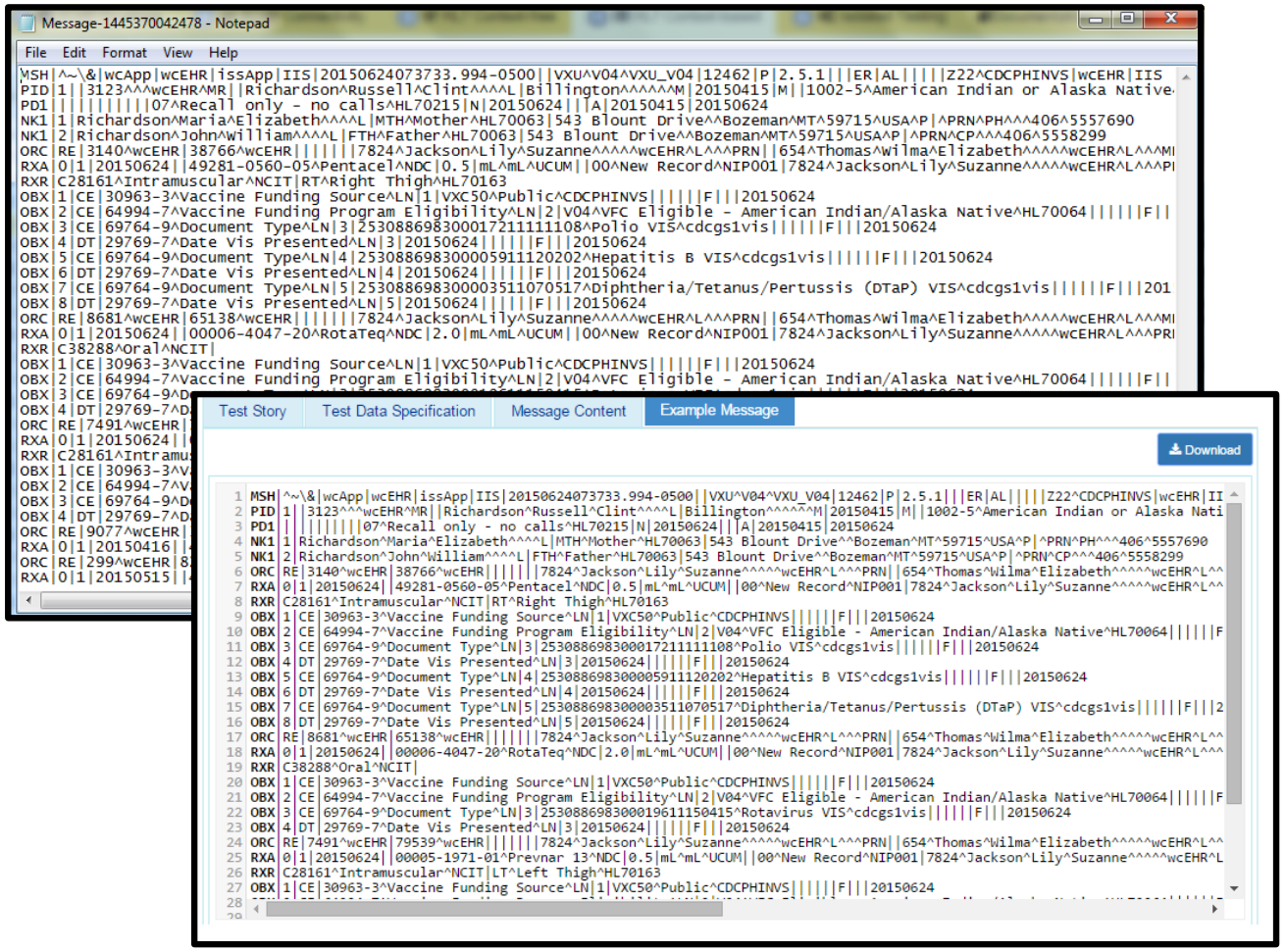
The exact wording and format of the display in the health information technology (HIT) is not in-scope for this test.

Return an Acknowledgement
The receiving HIT system being tested shall process the Z23 ACK message correctly; a positive notification indicating that the ACK message was processed correctly need not be made visible in the system.

Each Test Case includes a Juror Document for the Receive or Response Test Step

Example Test Data document: Test Case: IZ-AD-1_Admin_Child – 2.IZ-AD-1.2_Receive_ACK_Z23

Test Cases: Example Messages



- Each Test Case includes an Example Message instance for each Test Step
- These example messages demonstrate use and interpretation of the standards

Example Test Data document: Test Case: IZ-AD-1_Admin_Child – 1.IZ-AD-1.1_Send_V04_Z22

Profile Viewer and Vocabulary Viewer

Profile Viewer page

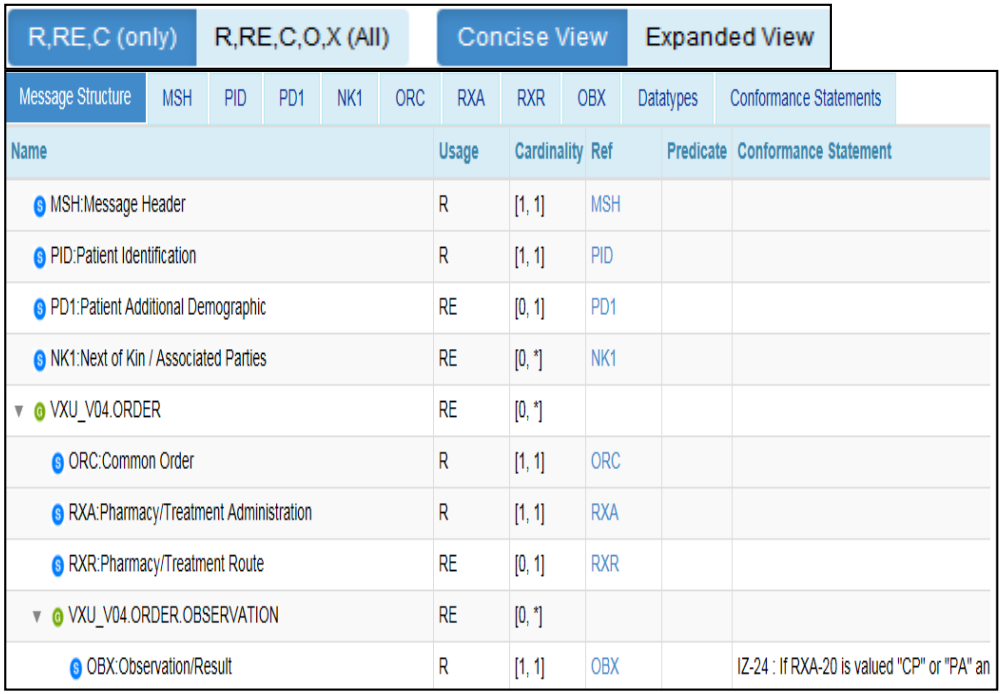
This page allows tester to view data element information including usage, cardinality, data type, length, table, condition predicate and conformance statements.

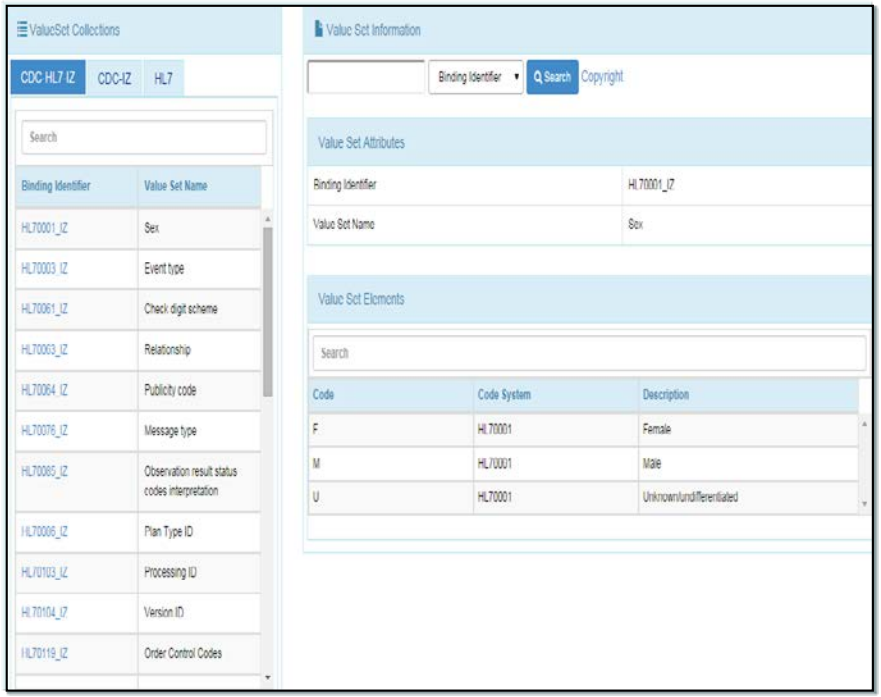
1. Select the '**Profile Viewer**' tab.

Value Sets page

This page provides the ability to browse the vocabulary requirements. Search capabilities are provided and include searching on value, table name, table ID and description.

2. Select the '**Value Sets**' tab.





HEALTH IT
STANDARDS TESTING INFRASTRUCTURE

NIST Immunization Test Suite (2016)

Understanding the Validation Results

National Institute of Standards and Technology

Classification of Validation Detections

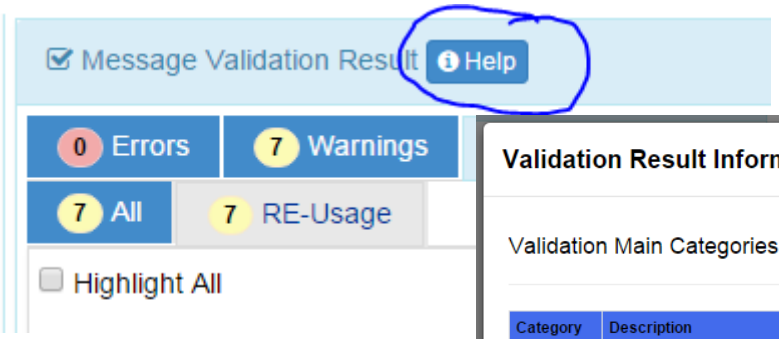
Classification	Description
Errors	➢ Indicates non-conformance to a requirement. ➢ Errors do constitute a failed validation ➢ An EHR Product will fail certification if any of the validation reports indicate an Error (unless the Error can be proved to be a false negative—NIST can be consulted to remediate)
Warnings	➢ Provides information about potential missing support for a requirement or recommendation. ➢ Warnings do not constitute a failed validation
Alerts	➢ Provides information about how the validation verifies or does not verify requirements. For example, the specification may provide a value set binding to an element but the value set is empty. Therefore, the user is alerted to the fact that no meaningful validation can be performed. ➢ Alerts do not constitute a failed validation
Affirmatives	➢ Provides an indication of a positive outcome to a validation assertion ➢ Affirmatives display only as user preference, not by default

Detection Categories

Structure Validation	Content Validation
R-Usage	Constraint Failure add content failure
X-Usage	Content (Based on Test Cases)
W-Usage	Predicate Failure – Usage determined by a Conditional
RE-Usage	Constraint Spec Error
Cardinality	Predicate Spec Err
Null-cardinality	**Value Set Validation**
Length	EVS
Format	PVS
Extra	Code Not Found
UnescapedSeparator	VS Not Found
Unexpected	Empty VS
InvalidContent	VS Error
	VS No Validation
	Coded Element

BLUE = Not relevant for ONC Certification

Validation Detections: Help



Validation Result Information

Close

Validation Main Categories

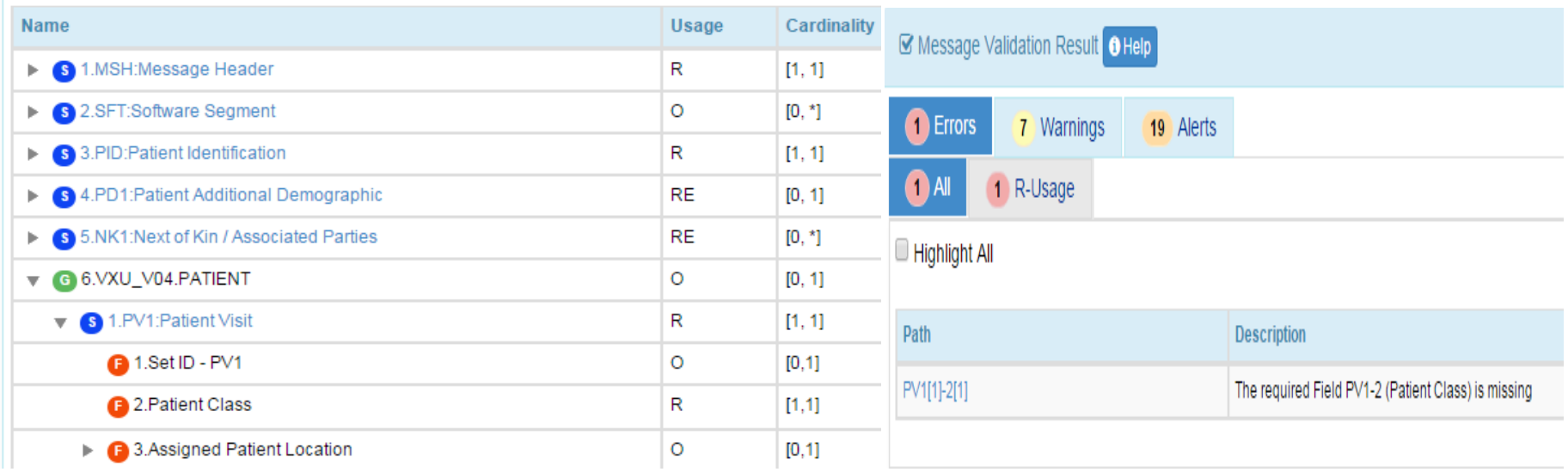
Category	Description
Errors	HL7 message elements that failed validation testing.
Alerts	HL7 message element information that may be useful for a Tester for profile conformance, but does not indicate a test fail nor non-profile conformant HL7 message element.
Warnings	HL7 message element information that may be useful for a Tester for profile conformance, but does not indicate a test fail nor non-profile conformant HL7 message element.
Affirmatives	Lists HL7 message validation successes and condition predicate satisfactions.

Structure Validation Categories

Category	Description
R-Usage	Issued when required element is missing.
X-Usage	Issued when a Not Supported element is present.
W-Usage	Issued when a HL7 withdrawn element is present.
RE-Usage	Issued when a "Required or Empty" element is missing.
Cardinality	Issued when either the minimal or the maximal cardinality is violated.
Null-cardinality	Issued when a null element has more than one occurrence.
Length	Issued when the specified data element length is violated.
Format	Issued when the data element format is violated. Format is derived from the data type.
Extra	Issued when a complex element has extra children.
UnescapedSeparator	Issued when a primitive element contains unescaped separators.
Unexpected	Issued for an unexpected segment at a specific position in the message.
InvalidContent	Issued for every line in the message instance which doesn't represent a valid segment definition.

Validation Policy for Optional Elements

- Primitive Elements with Optional Usage generates no detections
- Complex Elements with Optional Usage follows the base standard rules (if the element is present in the message instance). That is, if an implementer decides to support Optional Usage Elements, then they need to follow the base standard requirements for that Element.
- Example, if the PV1 segment is included, then PV1-2 SHALL be valued since it is Required.
- PV1|XXX||||| (will generate and error). This is a Certification Error.



Name	Usage	Cardinality
1.MSH:Message Header	R	[1, 1]
2.SFT:Software Segment	O	[0, *]
3.PID:Patient Identification	R	[1, 1]
4.PD1:Patient Additional Demographic	RE	[0, 1]
5.NK1:Next of Kin / Associated Parties	RE	[0, *]
6.VXU_V04.PATIENT	O	[0, 1]
1.PV1:Patient Visit	R	[1, 1]
1.Set ID - PV1	O	[0,1]
2.Patient Class	R	[1,1]
3.Assigned Patient Location	O	[0,1]

HEALTH IT
STANDARDS TESTING INFRASTRUCTURE

NIST Immunization Test Suite (2016)

Content Testing—Test Data Categories

National Institute of Standards and Technology

Test Data Categorization and Validation

- The Message Content Data Sheet shows the Categorization of the test data that are provided for each Location
- Each Test Data Category
  - Defines the criteria that are used by the test tool to assess the test data that populate each element in a message
  - Tells the Tester if the test data in a specific field can be changed, the source of the test data, and to what level of precision the validation tool will assess the data

Test Data Categorization	Description	Testing Implications	Comments
Indifferent	No test data are provided as part of the test case.	No additional validation.	The validation is indifferent to the presence of data or specific content in the message element. **Meaning: Value or don't value this data element.**
Presence	Test data are provided as part of the test case; content indifferent.	Validated for the presence of data.	The specific content is not pertinent to the test cases for the purpose of testing. The test data can be modified. **Meaning: Value this data element.**
Presence-Length	Test data are provided as part of the test case; minimum length of the content is expected.	Validate for the presence of data to a minimum length.	The specific content is not pertinent to the test cases for the purpose of testing, but the length of the content is. The test data can be modified as long as the minimum length of the test data is maintained. **Meaning: Value this data element to a minimum length.**
Value	Test data are provided as part of the test case; specific content is provided and expected.	Validate for the presence of data and for specific content.	The specific content (or choice of content) is provided and is expected to be present in the message. The test data can only be modified with data in the allowable data set. In some cases the set is a single constant. **Meaning: Value this data element with the test data options provided.**
Non-presence	No test data are provided as part of the test case and no content for this message element is expected.	Validate for the non-presence of data.	Content is not specified in the test case and is not expected to be present in the message. **Meaning: Don't value this data element.**

Important point—some data can be modified, e.g., "Presence"

Test Data Categorization and Validation (cont'd)

- **Qualifiers** enable refinement of the Test Data Category, providing additional information to the Tester about the source of the data and the expectations of the data element
- The Qualifier does not impact the validation of the data element

Test Data Categorization	Description	Qualifier	Description
Indifferent	No content is specified.	***None***	None
Presence	Example content is specified.	***Content Indifferent***	Content is expected to be present in the message, but not a specific value.
		Configuration	Content is expected to be present in the message, but not a specific value. The value is usually determined at installations.
		System Generated	Content is expected to be present in the message, but not a specific value. The value is system generated.
		Test Case Proper	Content is expected to be present in the message, but not a specific value. However, content is expected to be consistent with the clinical test story.
Presence-Length	Example content is specified to a minimum length.	***Same qualifiers as for Presence***	Content of a minimum length is expected to be present in the message, but not a specific value.
Value	Specific content is specified.	***Profile Fixed***	Content is defined as a constant in the conformance profile. The constant is specified in the test data.
		Profile Fixed - List	Content is defined as a set of allowable values in the conformance profile. One value from the allowable set is specified in the test data.
		Test Case Fixed	Content that is defined as a constant in the test case.
		Test Case Fixed - List	Content is defined as a set of allowable values in the test case. One value from the allowable set is specified in the test data.
Non-presence	No content is explicitly specified.	***None***	None

Test Category Assessment Table (Examples)

Element	Usage	Test Data	Test Category	Conformity Assessment	Data in Message	Validation Result
PID-5.3 (Middle Name)*	RE	Donna	Presence-Content-Indifferent	Required	<Empty>	Fail
PID-5.3 (Middle Name)	RE	Donna	Presence-Content-Indifferent	Required	Donna	Pass
PID-5.3 (Middle Name)	RE	Donna	Presence-Content-Indifferent	Required	Sue	Pass
PID-5.3 (Middle Name)	RE	Donna	Presence-Length-Content-Indifferent	Required Min Length = 5	Victoria	Pass
PID-5.3 (Middle Name)	RE	Donna	Presence-Length-Content-Indifferent	Required Min Length = 5	Sue	Fail
PID-5.3 (Middle Name)	RE	Donna	Value-Test Case Fixed	Required Value = Donna	Donna	Pass
PID-5.3 (Middle Name)	RE	Donna	Value-Test Case Fixed	Required Value = Donna	Sue	Fail
MSH-9.2 (Trigger Event)	R	V04	Value-Profile Fixed	Required Value = V04	V04	Pass

* Actual description is “Second and Further Given Names or Initials Thereof”

Coded Element Examples

Example Message Segment:

RXA|0|1|20150624||49281-0560-05^Pentacel^NDC|0.5|mL^mL^UCUM||00^New Record^NIP001|7824^Jackson^Lily^Suzanne^^^^^wcEHR^L^^^PRN|^^^wcEHR|||526434|20150722|SKB^GlaxoSmithKline^MVX|||CP|A

Element	Test Data	Test Category	Conformity Assessment
RXA.5.1	49281-0560-05	Value-Test Case Fixed	Content must be present and exactly "49281-0560-05"
RXA.5.2	Pentacel	Presence-Test Case Proper	Content must be present and indicate a value equivalent to Pentacel
RXA.5.3	NDC	Value-Test Case Fixed	Content must be present and exactly "NDC"

Example Message Segment:

RXR|C28161^Intramuscular^NCIT|RT^Right Thigh^HL70163

Element	Test Data	Test Category	Conformity Assessment
RXR-1.1	C28161	Presence-Content Indifferent	Content is expected to be present in the message, but not a specific value
RXR-1.2	Intramuscular	Presence-Test Case Proper	Content must be present and indicate a value equivalent to the code in RXR-1.1
RXR-1.3	NCIT	Value-Profile Fixed	Content is defined as a constant in the profile. The constant is specified in the test data; value must be present and exactly "NCIT"

HEALTH IT
STANDARDS TESTING INFRASTRUCTURE

NIST Immunization Test Suite (2016)

HL7 Context-free DQA Testing

National Institute of Standards and Technology

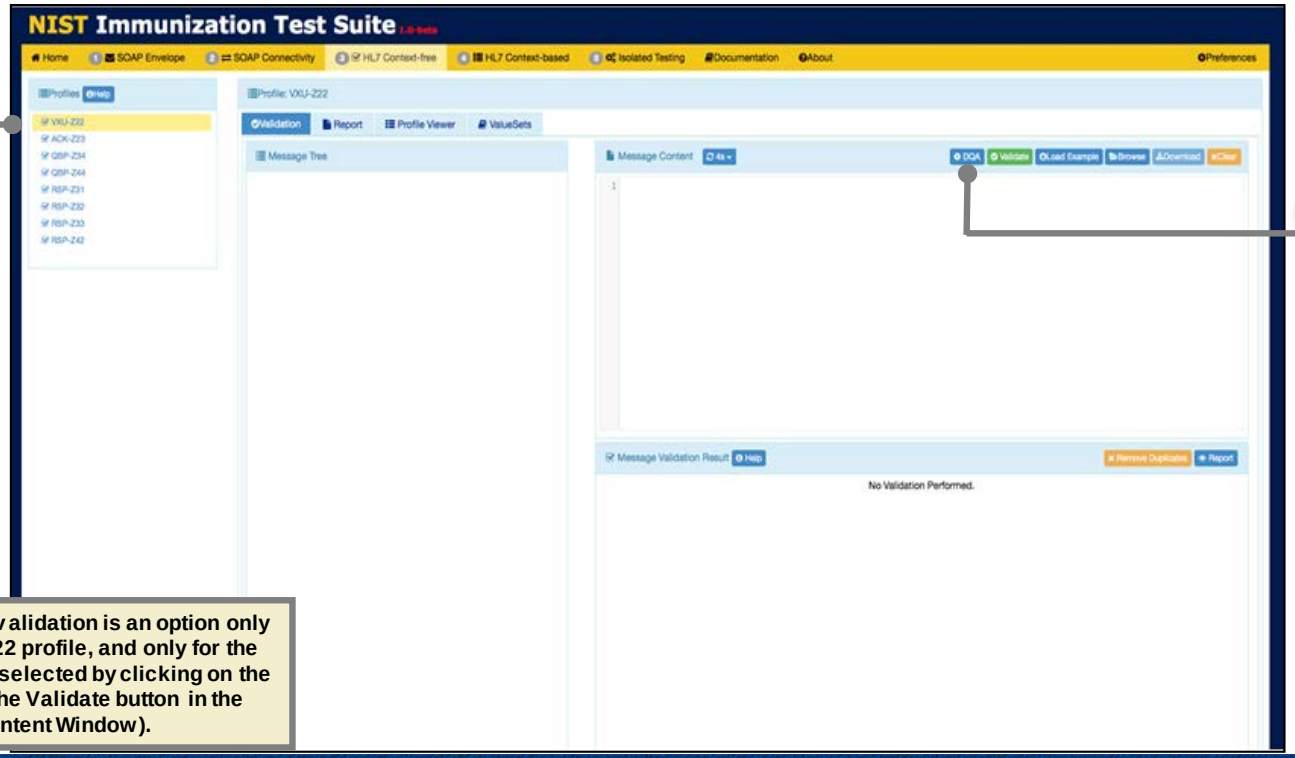
What is Data Quality Assurance (DQA)?

- DQA is an open source tool for detecting potential data quality issues in immunization messages, such as
  - Malformed, unlikely, or improbable components of name, address, phone, etc.
  - Internal inconsistencies (e.g. patient birthdate after vaccine admin date)
  - Code related issues (deprecation, conflicts with admin date, etc.)

- DQA detects approximately 500 issues, including data quality and HL7 message conformance issues
  - NIST uses the DQA **only** for detecting (~50) data quality related issues
  - HL7 conformance issues are already detected by NIST HL7 message validation
  - By default all data quality detections are turned off
  - Users can choose which data quality detections they want turned on
  - Detected quality issues reported along side of HL7 conformance issues after message validation

Data Quality Assurance (DQA)

Objectives	Informative Reference
• Select the *VXU-22* profile. • Locate '**DQA**' button • Obtain a data quality validation.	• In addition to HL7 message profile-based conformance validation, the user may also select "data quality validation" (using DQA) in order to produce additional report items related to any detected "quality issues" identified during validation. • DQA (Data Quality Assurance) is an open source tool for detecting quality problems in Immunization messages (refer to the slide "What is DQA" for more details)



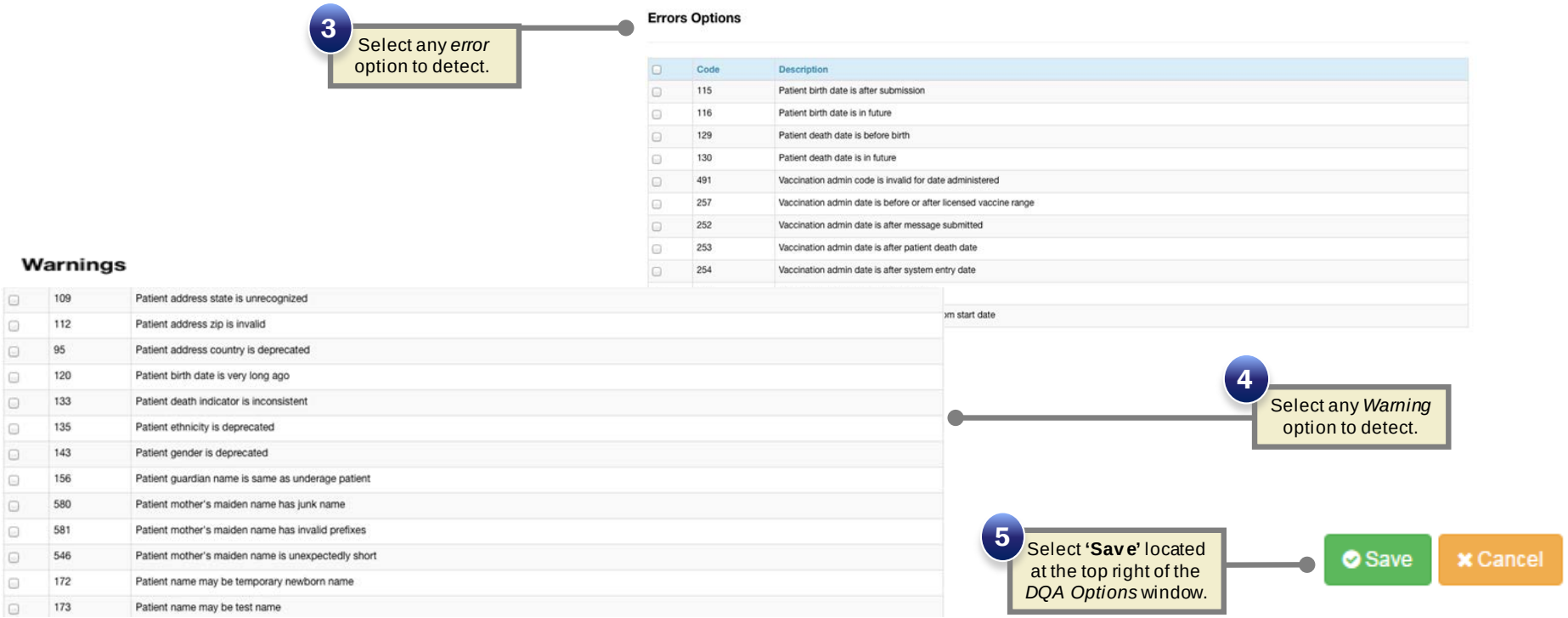
1 Select '**VXU-222**' Profile.

2 Select '**DQA**'

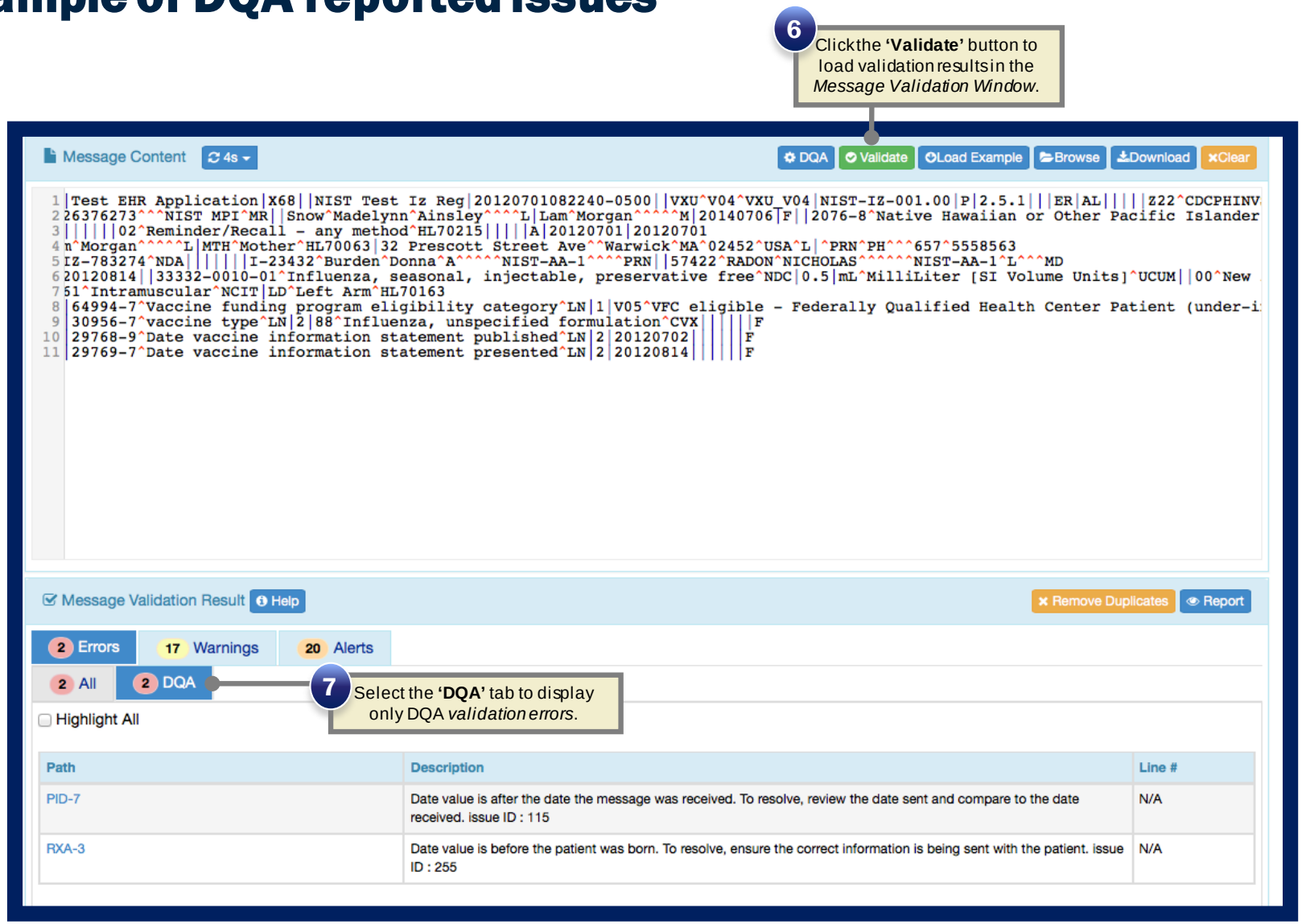
NOTE: The data quality validation is an option only for use with the VXU-Z22 profile, and only for the quality issues manually selected by clicking on the DQA button (next to the Validate button in the Message Content Window).

Data Quality Assurance (continued…)

Objectives	Informative Reference
• Review list of available data quality issues which can be detected • Use *Select All* or individually select *Errors/Warnings* to detect • Use the Save button to activate the selected data quality issues • Validate the message and view the Report	• After selecting the DQA button, a list of data quality issues will be displayed. The issues are grouped into two categories, Errors and Warnings, based on severity. The user may choose to detect all Errors and Warnings via the Select All option, or individually.



Example of DQA reported issues



DQA Message Validation Report

Message Validation Report	January 05, 2016 at 11:34:57.949-05:00

Validation Type	Context-Free

Testing Tool		
	Name	NIST Validation Tool
	Validation Version	1.0.0-beta-12.2-SNAPSHOT

Profile		
	Identifier	Z22
	Name	Unsolicited Immunization Update
	Organization	NIST
	Type	Constrainable
	Message Type	VXU^V04^VXU_V04
	XML Version	1.1.Z22
	XML Date	20151104
	Specification	Implementation Guide for Immunization Messaging, Release 1.5 October 1 2014
	HL7 Version	2.5.1

Message		
	Encoding	ER7
	Content	MSH|^~\&|Test EHR Application|X68||NIST Test Iz Reg|20120701082240-0500| PID|1||D26376273^^^NIST MPI^MR||Snow^Madelynn^Ainsley^^^^L|Lam^Mo PD1||||||||02^Reminder/Recall - any method^HL70215||||A|20120701|2012070 NK1|1|Lam^Morgan^^^^^L|MTH^Mother^HL70063|32 Prescott Street Ave^^ ORC|RE||IZ-783274^NDA||||||I-23432^Burden^Donna^A^^^^^NIST-AA-1^^^^ RXA|0|1|20120814||33332-0010-01^Influenza, seasonal, injectable, preservativ RXR|C28161^Intramuscular^NCIT|LD^Left Arm^HL70163 OBX|1|CE|64994-7^Vaccine funding program eligibility category^LN|1|V05^VF OBX|2|CE|30956-7^vaccine type^LN|2|88^Influenza, unspecified formulation^ OBX|3|TS|29768-9^Date vaccine information statement published^LN|2|20120 OBX|4|TS|29769-7^Date vaccine information statement presented^LN|2|20120

Failures interpretation	View

Summary

- ☑ 2 Errors
- ☐ 20 Alerts
- ☐ 17 Warnings

183 Affirmatives (details not included)

Validation Errors — Count : 2 ☑

DQA			Count : 2 ☑
1	Type :	DQA	
	Description:	Date value is after the date the message was received. To resolve, review the date sent and compare to the date received. issue ID : 115	
	Location:	**Path: PID-7**	
2	Type :	DQA	
	Description:	Date value is before the patient was born. To resolve, ensure the correct information is being sent with the patient. issue ID : 255	
	Location:	**Path: RXA-3**	

Validation Alerts — Count : 20 ☐

Validation Warnings — Count : 17 ☐

8 The Message Validation Report displays the Validation Errors produced while performing Data Quality Assurance.

HEALTH IT
STANDARDS TESTING INFRASTRUCTURE

NIST Immunization Test Suite (2016)

ONC 2015 Health IT Certification

NIST
National Institute of Standards and Technology

ONC Final Rule Criterion - Immunizations

§170.315(f)(1) Transmission to immunization registries

- Evaluates the capability for a Health IT Module to electronically *create* immunization information for electronic transmission using the Immunization Messaging Guide and associated Addendum, with CVX codes for *historical vaccines and* National Drug Code Directory codes *for administered vaccines*
- Evaluates the capability for a Health IT Module to enable a user to request, access, and display a patient's evaluated immunization history and forecast from an immunization registry with information from the Health IT Module, if applicable, using the Immunization Messaging Guide and associated Addendum
- Referenced Standards
  - §170.205 Content exchange and implementation specifications for exchanging electronic health information
    - (e)(4) Standard. HL7 2.5.1 Implementation specifications.
      - HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.5
      - HL7 Version 2.5.1 Implementation Guide for Immunization Messaging (Release 1.5)—Addendum, July 2015
  - §170.207 Vocabulary standards for representing electronic health information
    - (e)(2) Standard. HL7 Standard Code Set CVX -- Vaccines Administered, updates through August 17, 2015
    - (e)(4) Standard. National Drug Code Directory– Vaccine Codes, updates through August 17, 2015

Note: The ONC certification criterion does not specify use of a *transport* standard; therefore, testing for this criterion does not require Health IT Modules to be certified to any transport standards

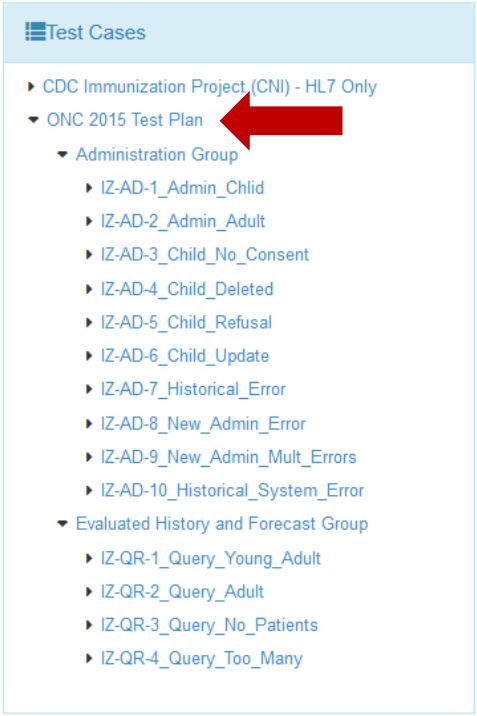
Messaging Standard – Supported Profiles

- HL7 2.5.1 Immunization Implementation Guide Release 1.5
- HL7 2.5.1 Immunization Implementation Guide Release 1.5, Addendum
- All 8 Profiles Supported
  - VXU^V04
    - Z22 - SEND UNSOLICITED IMMUNIZATION UPDATE USING A VXU
  - ACK
    - Z23 - RETURN AN ACKNOWLEDGEMENT
  - QBP^Q11
    - Z34 - REQUEST A COMPLETE IMMUNIZATION HISTORY
    - Z44 - REQUEST EVALUATED IMMUNIZATION HISTORY AND FORECAST QUERY PROFILE
  - RSP^K11
    - Z31 - RETURN A LIST OF CANDIDATES PROFILE
    - Z32 - RESPONSE PROFILE – RETURN COMPLETE IMMUNIZATION HISTORY
    - Z33 - RETURN AN ACKNOWLEDGEMENT WITH NO PERSON RECORDS
    - Z42 - RETURN EVALUATED HISTORY AND FORECAST

Test Plans and Associated Test Cases and Test Steps

ONC 2015 Certification Test Plan

- Designed for ONC 2015 Edition certification testing
- Consists of two Groups of Test Cases
  - 10 Administration Test Case
  - 4 Evaluated History and Forecast Test Cases
- Provides Test Steps containing the test data
- Includes five of the profiles defined in the Immunization Messaging Guide Release 1.5, which are paired for the certification testing



Profile Pair	Message Pair	Description
Z22/Z23	VXU^V04/ACK	Send Immunization/ACK
Z44/Z42	QBP^Q11/RSP^K11	Evaluated History & Forecast—Query/Respond OK (Found)
Z44/Z33	QBP^Q11/RSP^K11	Evaluated History & Forecast—Query/Respond NF (Not Found)
Z44/Z33	QBP^Q11/RSP^K11	Evaluated History & Forecast—Query/Respond TM (Too Many)

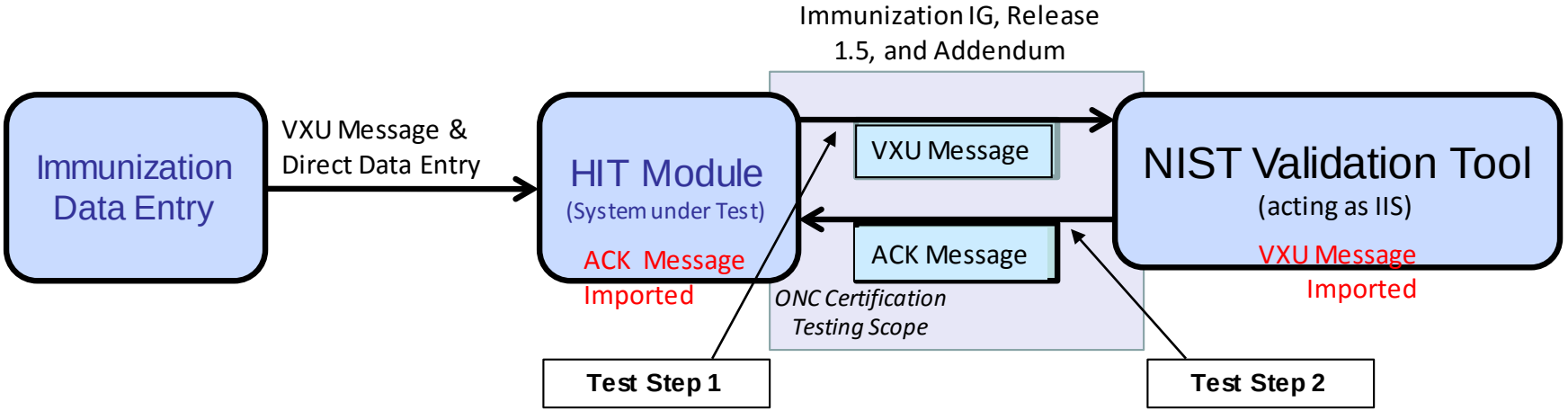
ONC 2015 Certification Test Plan

Test Cases	Message Created – Step 1	Message Returned – Step 2
Administration Group	**Send Administration Message**	**Consume ACK Message**
IZ-AD-1_Admin_Child	IZ-AD-1.1_Send_V04_Z22	IZ-AD-1.2_Receive_ACK_Z23
IZ-AD-2_Admin_Adult	IZ-AD-2.1_Send_V04_Z22	IZ-AD-2.2_Receive_ACK_Z23
IZ-AD-3_No_Consent	IZ-AD-3.1_Send_V04_Z22	IZ-AD-3.2_Receive_ACK_Z23
IZ-AD-4_Delete_Record	IZ-AD-4.1_Send_V04_Z22	IZ-AD-4.2_Receive_ACK_Z23
IZ-AD-5_Refusal	IZ-AD-5.1_Send_V04_Z22	IZ-AD-5.2_Recieve_ACK_Z23
IZ-AD-6_Update_Record	IZ-AD-6.1_Send_V04_Z22	IZ-AD-6.2_Receive_ACK_Z23
IZ-AD-7_Historical_IIS-Error	IZ-AD-7.1_Send_V04_Z22	IZ-AD-7.2_Receive_ACK_Z23
IZ-AD-8_Admin_IIS-Warning	IZ-AD-8.1_Send_V04_Z22	IZ-AD-8.2_Receive_ACK_Z23
IZ-AD-9_Admin_IIS-2Warnings	IZ-AD-9.1_Send_V04_Z22	IZ-AD-9.2_Receive_ACK_Z23
IZ-AD-10_Historical_IIS-SysError	IZ-AD-10.1_Send_V04_Z22	IZ-AD-10.2_Receive_ACK_Z23
Evaluated History & Forecast Group	**Send Query Message**	**Receive Response Message**
IZ-QR-1_Query_Child	IZ-QR-1.1_Query_Q11_Z44	IZ-QR-1.2_Response_K11_Z42
IZ-QR-2_Query_Adult	IZ-QR-2.1_Query_Q11_Z44	IZ-QR-2.2_Response_K11_Z42
IZ-QR-3_Query_No_Patients	IZ-QR-3.1_Query_Q11_Z44	IZ-QR-3.2_Response_NF_K11_Z33
IZ-QR-4_Query_Too_Many	IZ-QR-4.1_Query_Q11_Z44	IZ-QR-4.2_Response_TM_K11_Z33

Administrative Test Group Overview

Administrative Test Group	
➢ Tests the EHR-S capability of: ➢ (1) Creating immunization messages based on Immunization Messaging Standard (Z22 Profile) and specific Test Data, and ➢ (2) Receiving acknowledgment messages based on the Immunization Messaging Standard (Z23 Profile).	
➢ All 10 test cases consists of 2 test steps: ➢ (1) Create Immunization Message ➢ (2) Receive Acknowledgment	
(1) Create Immunization Message	Create immunization message test steps are designed to test a broad scope of the immunization messages including new and historical administrations, refusals, combination vaccines, patient consent and various observations including VIS, VFC.
(2) Receive ACK	Receive acknowledgement test steps are designed to test the EHR-S capability to correctly handle application accept, application error, and application warning acknowledgements. A juror document is provided for inspection.

Immunizations Administration Testing Process

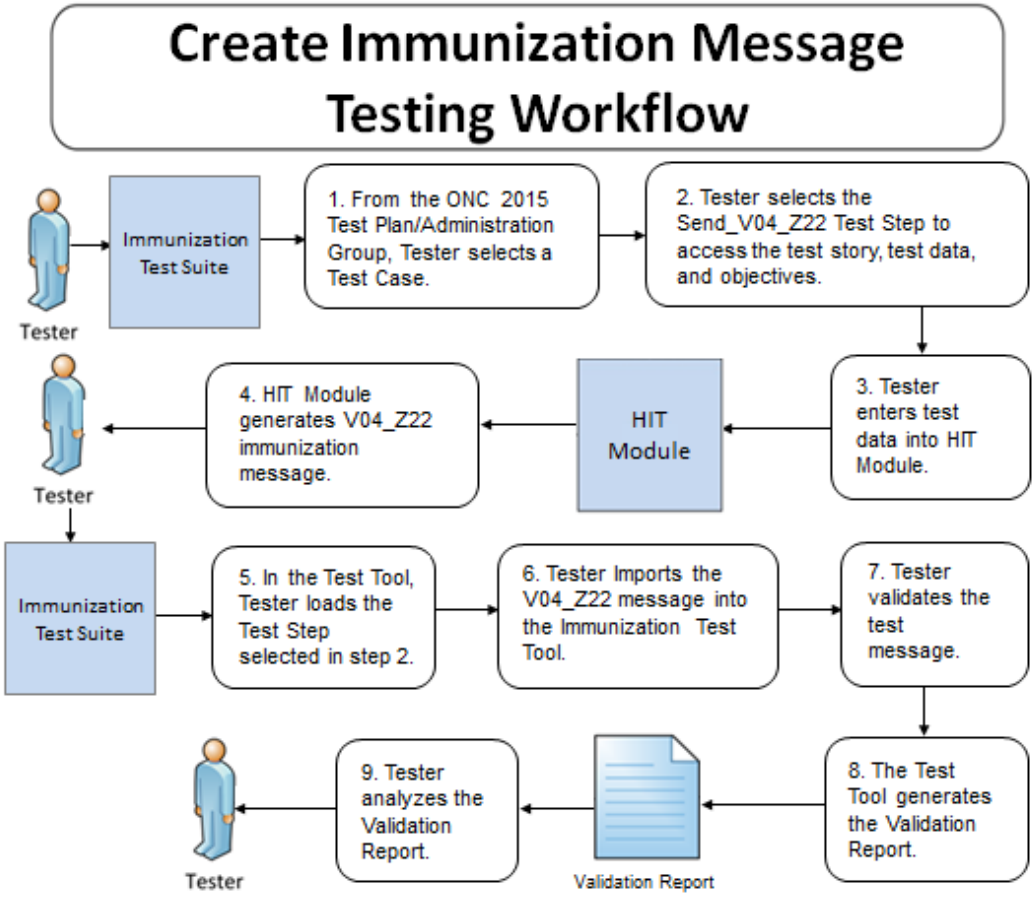


1. The HIT Module is the system being tested. The HIT Module is required to create VXU messages and consume ACK messages that conform to the referenced standards (see previous slides).
2. Test data can be entered into the HIT Module directly via the Module's user interface or can be imported via an incoming message.
3. The HIT Module is expected to process the test data to create a VXU message. This message is imported into the testing tool for validation (Test Step 1 – Z22 VXU). The HIT Module is expected to consume an ACK message. This message is imported from the testing tool into the HIT Module (Test Step 2 – Z23 ACK).
4. Test data are available through the Test Tool via the Test Steps in the Test Cases. Each Test Step includes a Test Story that provides the context, a Test Data Specification that lists the test data, a Message Content Data Sheet that shows the conformant message (in a table format), and a Juror Document (for ACK Test Steps).

Testing Workflow Diagram (Test Step 1 – Z22 VXU)

This diagram shows

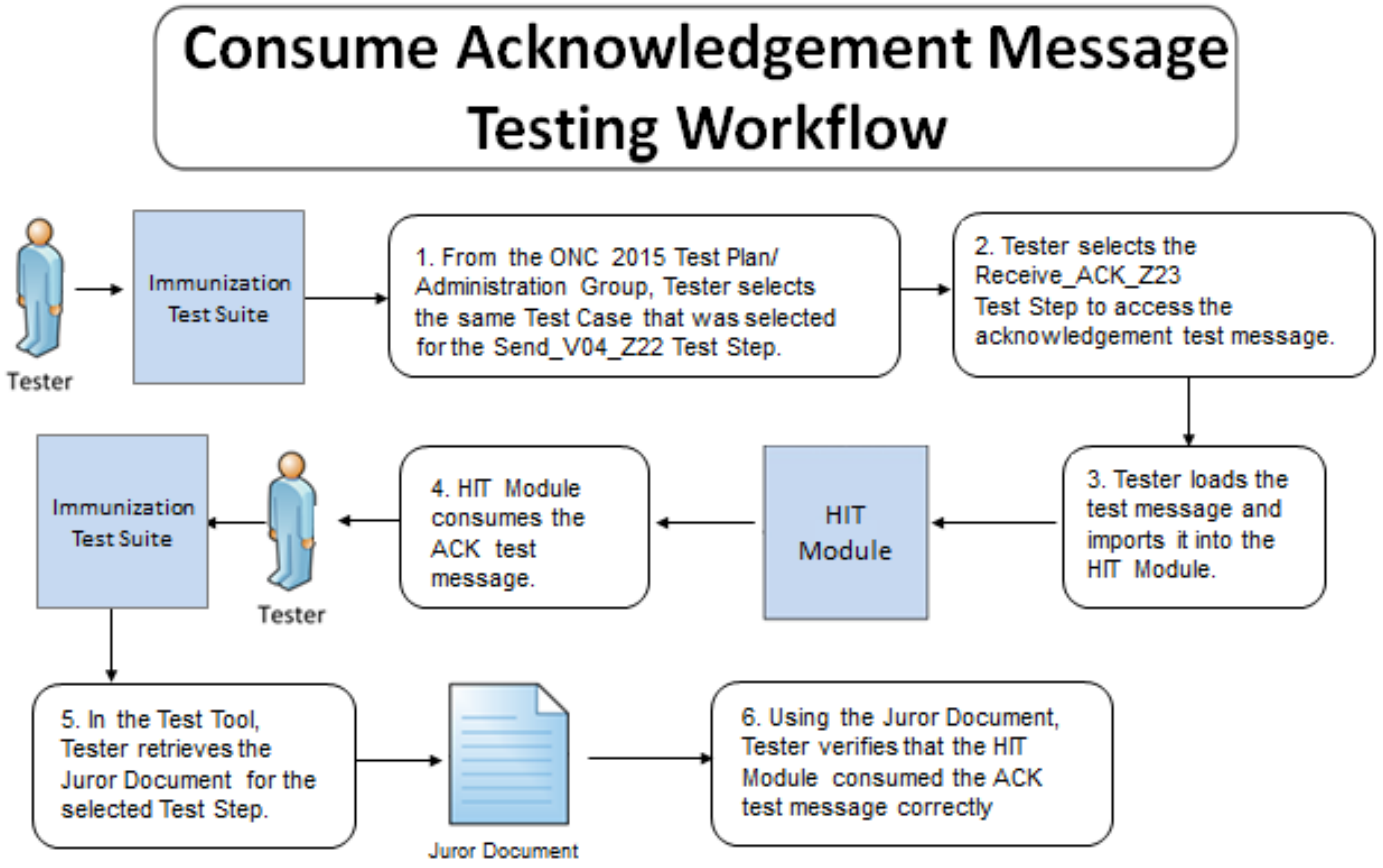
- How the major steps of the create VXU message test are sequenced
- When the Test Tool is to be used



Testing Workflow Diagram (Test Step 2 – Z23 ACK)

This diagram shows

- How the major steps of the consume ACK message test are sequenced
- When the Test Tool is to be used



Test Case 1: Immunization for Child

IZ-AD-1_Admin_Child	
Purpose	(1) Create administration message containing historical and new administrations for a child. (2) Receive an application accept acknowledgement
Steps	**High-level Test Objectives**

Step 1:
IZ-AD-1.1_Send_V04_Z22
Create Administration Message
	➢ Create record for a Child (Infant)
	➢ 3 New Administration Immunizations (use NDC)
	➢ 2 Historical Immunizations (use CVX)
	➢ Next of Kin (multiple instances)
	➢ Combination Vaccine
	➢ Observations including:
	  ➢ Patient Consent
	  ➢ VIS – Vaccination Information Statement
	  ➢ Funding Source
	  ➢ VFC Eligible – Vaccine Funding for Children

Step 2: **IZ-AD-1.2_Receive_ACK_Z23** Receive ACK	➢ Receive valid application accept acknowledgement without error and transparent to end user

Vaccine Codes Required for Immunization Messages

- 2015 ONC Certification Testing Only
  - Codes from the NDC Directory are required for vaccines in *new vaccine administered* records in
    - Z22 VXU (send unsolicited immunization update message)
  - CVX codes are required for vaccines in *vaccine historical* records in
    - Z22 VXU (send unsolicited immunization update message)
    - Z42 RSP (return evaluated history and forecast message)

Example Scenario

- A Z22 VXU message is transmitted from an EHR to an IIS with an NDC for a new vaccine administered
- A query for an Evaluated Immunization History and Forecast (Z44 QBP message) is performed via the EHR the next day
- The response for the Evaluated Immunization History and Forecast (Z42 RSP message) is transmitted from the IIS with a CVX code for the vaccine sent with an NDC in the Z22 VXU the day before, as this vaccine now exists as a historical record in the IIS

NDC Format

- NDC has various formats for representing a concept
  - Published NDC codes are 10 digits with dashes (can be groups of 4-5, 3-4, 1-2, digits but always 10 total)
  - CMS created 11 digit unformatted (padded without dashes, always with 5-4-2, groups of digits with one of the 1st, 2nd, or 3rd component padded with a 0)
    - The problem of the 10 digit format is that they don't often have the dashes and so can't reliably be determined to match a given vaccine. This motivated the "normalization" to 11 characters.
  - 11 digit format with dashes and padded. E.g., "CDC Vaccine Price List"
    - much of the vaccine used in the US is federally funded and ordering uses the 11 character with dash—this format was determine to be the most appropriate choice
    - The link in the ONC rule points to files that contain the 11 digit format with dashes and padded.
  - Bar codes are created that map to the NDC codes (Today's NDC bar codes are unique). Bar codes contain a prefix, 10 digit NDC (no dashes), and a check digit
  - There are crosswalk tables to keep all of this straight and to be able to go from one format to another (Implementers may need to do this to meet their implementation choices)
- Certification Requirements are to use the 11 digit format with dashes and padded
  - RXA-5.1 Example: 00006-4047-20^RotaTeq^NDC
  - Note 10 digit NDC code is 0006-4047-20 with the leading 0 added to the first component.
- No other formats are acceptable for certification
- If vendors wish to send an alternative code they may do so in the 2nd triplet of RXA-5
  - e.g., 00006-4047-20^RotaTeq^NDC^00006404720^RotaTeq^NDC
  - In this case the 11 digit padded without dashes format is used
  - First triplet must be NDC 11 padded with dashes
- Vendors can represent the NDC codes internally in their HIT system in any manner they choose

Testing Acknowledgements

- Test Cases 1-6 contain no Errors or Warnings
  - Nothing needs to be displayed or indicated by the EHR
  - It is invalid if an Error/Warning is indicated
  - ATLs should only be concerned if an error is raised
  - It is sufficient (at the discretion of the ATL) to only require 1 import of an acknowledgement containing no errors to warnings and confirm no that no Error or Warning is issued.
  - The EHR may indicate a valid incorporation but this is bad practice and highly unlikely.
- Test Cases 7-10 Contain an Errors and/or Warnings
  - Meaning the ACK message structure is valid but the content of the ACK message reports that the responding system (e.g., IIS) had trouble processing the incoming message (whether it is valid or not)
  - Each ACK message needs to be imported into the EHR
  - The ATLs are to confirm that the EHR displays some indication that the responding system had an issue with the incoming message

Test Case 2: Immunization for Adult

IZ-AD-2_Admin_Adult	
Purpose	(1) Create administration message containing historical and new administrations for an adult (2) Receive an application accept acknowledgement
Steps	**High-level Test Objectives**

Step 1:
IZ-AD-2.1_Send_V04_Z22
Create Administration Message
	➢ Create record for an Adult
	➢ 1 New Administration Immunization (use NDC)
	➢ 2 Historical Immunizations (use CVX)
	➢ Patient E-mail Address
	➢ Observations including:
	  ➢ Patient Consent
	  ➢ VIS – Vaccination Information Statement
	  ➢ Funding Source
	  ➢ Not VFC Eligible – Vaccine Funding for Children

Step 2: IZ-AD-2.2_Receive_ACK_Z23 Receive ACK	➢ Receive valid application accept acknowledgement without error and transparent to end user

Test Case 3: Immunization for Child but No Consent

IZ-AD-3_No_Consent	
Purpose	(1) Create administration message containing a new vaccine but consent is not given. (2) Receive an application accept acknowledgement
Steps	**High-level Test Objectives**

Step 1:
IZ-AD-3.1_Send_V04_Z22
Create Administration Message
	➢ Create record for a child
	➢ 1 New Administration Immunization (use NDC)
	➢ Patient Consent is not given (PD1-12 = Y)
	➢ Test support for full first and middle name (Length >= 9)
	➢ Observations including:
	  ➢ VIS – Vaccination Information Statement
	  ➢ Funding Source
	  ➢ VFC Eligible – Vaccine Funding for Children

Step 2: **IZ-AD-3.2_Receive_ACK_Z23** Receive ACK	➢ Receive valid application accept acknowledgement without error and transparent to end user

Test Case 4: Previous Vaccination Deleted

IZ-AD-4_Delete_Record	
Purpose	(1) Create administration message intended to delete a previously documented vaccination due to user error. (2) Receive an application accept acknowledgement
Steps	**High-level Test Objectives**
Step 1: **IZ-AD-4.1_Send_V04_Z22** Create Administration Message	➢ Complete information about a previously documented vaccination is requested ➢ Action Code is set to deleted (RXA-21 = D)
Step 2: **IZ-AD-4.2_Receive_ACK_Z23** Receive ACK	➢ Receive valid application accept acknowledgement without error and transparent to end user

Test Case 5: Refusal and Multiple Birth Indicator

IZ-AD-5_Refusal	
Purpose	(1) Create administration message that indicates a vaccine refusal for a twin. (2) Receive an application accept acknowledgement
Steps	**High-level Test Objectives**

Step 1:
IZ-AD-5.1_Send_V04_Z22
Create Administration Message
	➢ Create record for a child
	➢ 3 New Administration Immunizations (use NDC)
	➢ 1 Refused Immunization (use CVX, RXA-20 = RE, value RXA-18)
	➢ Child is a twin, set multiple birth indicator and order
	  ➢ Multiple Birth Indicator (PID-24 = Y)
	  ➢ Birth Order (PID-25 = 2)

Step 2: IZ-AD-5.2_Receive_ACK_Z23 Receive ACK	➢ Receive valid application accept acknowledgement without error and transparent to end user

Test Case 6: Previous Vaccination Updated

IZ-AD-4_Update_Record	
Purpose	(1) Create administration message intended to update a previously documented vaccination due to user error. (2) Receive an application accept acknowledgement
Steps	**High-level Test Objectives**
Step 1: **IZ-AD-6.1_Send_V04_Z22** Create Administration Message	➢ Complete information about a previously documented vaccination is requested ➢ Action Code is set to updated (RXA-21 = U) ➢ Lot Number (RXA-15) is changed
Step 2: **IZ-AD-6.2_Receive_ACK_Z23** Receive ACK	➢ Receive valid application accept acknowledgement without error and transparent to end user

Test Case 7: Historical Record with Error from IIS

IZ-AD-7-Historical_IIS-Error	
Purpose	(1) Create administration message containing a simple historical immunization (2) Receive an application accept acknowledgement with a error. The IIS rejected the message due to an internal error even though the message is valid.
Steps	**High-level Test Objectives**
Step 1: **IZ-AD-7.1_Send_V04_Z22** Create Administration Message	➢ Create record for an adult ➢ 1 Historical Immunization (use CVX) ➢ Organization ID used in MSH-22/23 using the Assigning Authority Namespace
Step 2: **IZ-AD-7.2_Receive_ACK_Z23** Receive ACK	➢ Receive application accept acknowledgement with error ➢ Make the error notification visible in the system

Test Case 8: New Vaccine with Warning from IIS

IZ-AD-8_Admin_IIS-Warning	
Purpose	(1) Create administration message containing a simple new administered immunization (2) Receive an application accept acknowledgement with a warning. The IIS issued a warning due to an internal warning even though the message is valid.
Steps	**High-level Test Objectives**
Step 1: **IZ-AD-8.1_Send_V04_Z22** Create Administration Message	➢ Record for infant ➢ 1 New Administration Immunization (use NDC) ➢ Test the use of OIDs throughout the message (e.g., MSH-3, assigning authority, etc.)
Step 2: **IZ-AD-8.2_Receive_ACK_Z23** Receive ACK	➢ Receive application accept acknowledgement with warning ➢ Make the warning notification visible in the system

Test Case 9: New Vaccine with Multiple Warnings

IZ-AD-9_Admin_IIS-2Warnings	
Purpose	(1) Create administration message containing 2 new administered immunizations (2) Receive an application accept acknowledgement with multiple warnings. The IIS issued warnings due to internal warnings even though the message is valid.
Steps	**High-level Test Objectives**
Step 1: **IZ-AD-9.1_Send_V04_Z22** Create Administration Message	➢ Create record for a child ➢ 2 New Administration Immunizations (use NDC) ➢ Guardian (as next of kin)
Step 2: **IZ-AD-9.2_Receive_ACK_Z23** Receive ACK	➢ Receive application accept acknowledgement with warnings ➢ Make the warning notifications visible in the system

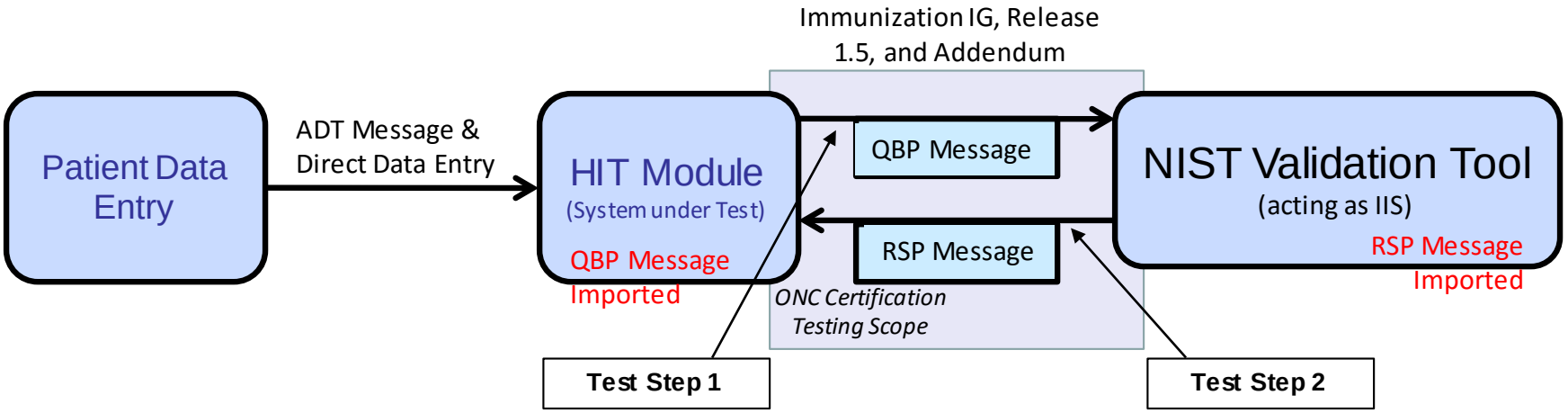
Test Case 10: Historical Record with System Error

IZ-AD-10-Historical_IIS-SysError	
Purpose	(1) Create administration message containing a simple historical immunization (2) Receive an application accept acknowledgement with a system error. The IIS rejected the message due to an internal error even though the message is valid (unrecognized version – MSH-12).
Steps	**High-level Test Objectives**
Step 1: IZ-AD-10.1_Send_V04_Z22 Create Administration Message	➢ Create record for an adult ➢ 1 Historical Immunization (use CVX)
Step 2: IZ-AD-10.2_Receive_ACK_Z23 Receive ACK	➢ Receive application accept acknowledgement with error ➢ Make the error notification visible in the system

Evaluated History and Forecast Test Group Overview

Evaluated History and Forecast Test Group	
➢ Test the EHR-S capability to: ➢ (1) create query messages based on Immunization Messaging Standard (Z44 Profile) and specific Test Data, and ➢ (2) receive (Z42 Profile) messages and display evaluated history and forecast OR receive (Z33 Profile) and display too many patients found or no patients found.	
➢ All 4 test cases consists of 2 test steps: ➢ (1) Create Query Message ➢ (2) Receive Response Message	
(1) Create Query Message	Create query message test steps are design to test typical query messages that include patient demographic information required by the implementation guide. Specific test data is provided.
(2) Receive Response Message	Receive response message based on query and display (1) evaluated history and forecast (2) too many patients found, or (3) no patients found. A juror document (inspection check list) is provided that indicates the content that is expected to be displayed.

Evaluated Immunization History & Immunization Forecast Testing Process

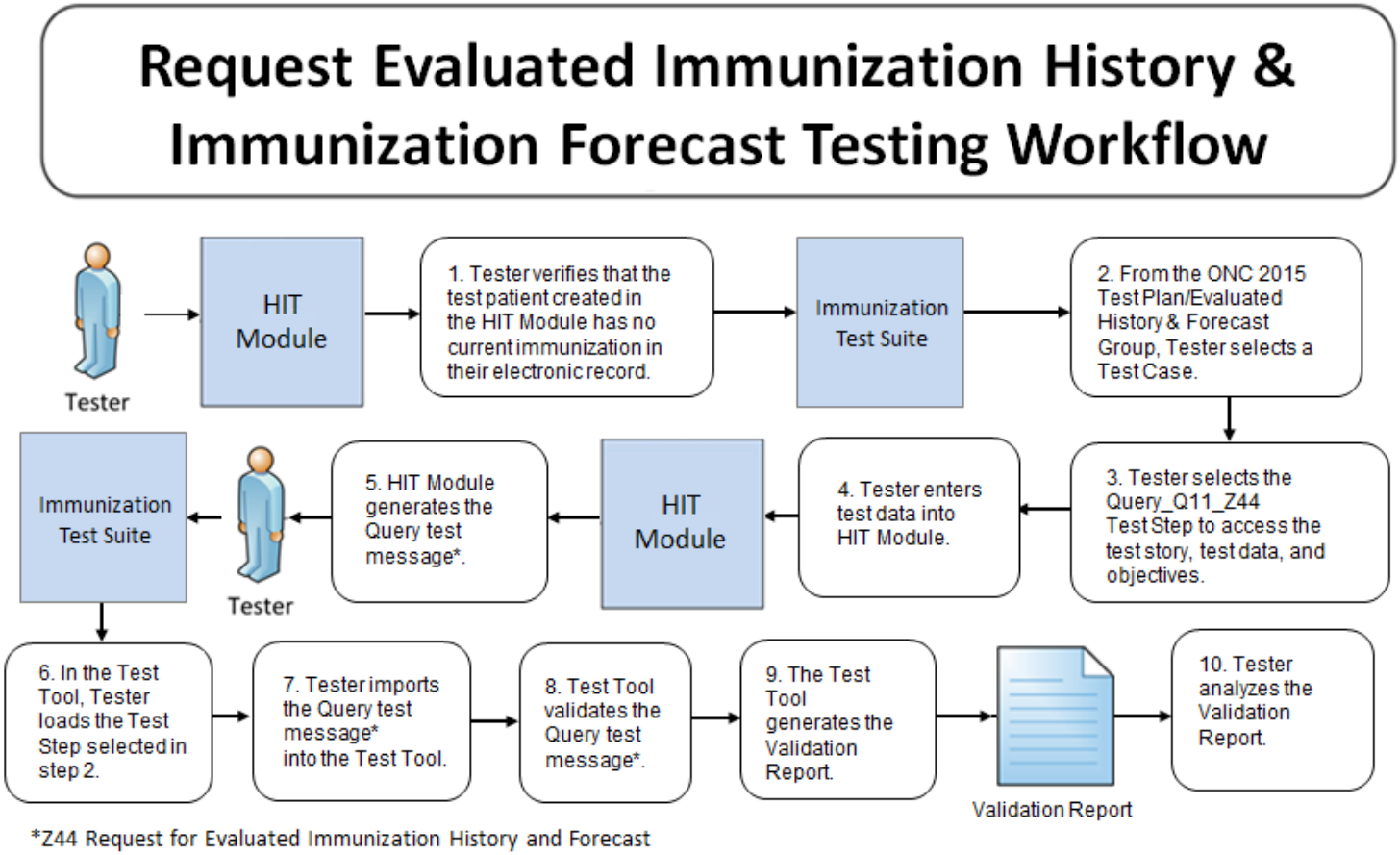


1. The HIT Module is the system being tested. The HIT Module is required to create QBP messages and consume RSP messages that conform to the referenced standards (see previous slides).
2. Test data can be entered into HIT Module directly via the Module's user interface or can be imported via an incoming message.
3. The HIT Module is expected to process the test data to create a QBP message. This message is imported into the testing tool for validation (Test Step 1 – Z44 QBP). The HIT Module is expected to process an RSP message and display the Evaluated Immunization History & Forecast if received. The RSP message is imported from the testing tool into the HIT Module (Tests Step 2 – Z42 or Z33 RSP).
4. Test data are available through the Test Tool via the Test Steps in the Test Cases. Each Test Step includes a Test Story that provides the context, a Test Data Specification that lists the test data, a Message Content Data Sheet that shows the conformant message (in a table format), and a Juror Document (for RSP Test Steps).

Testing Workflow Diagram (Test Step 1 – Z44 QBP)

This diagram shows

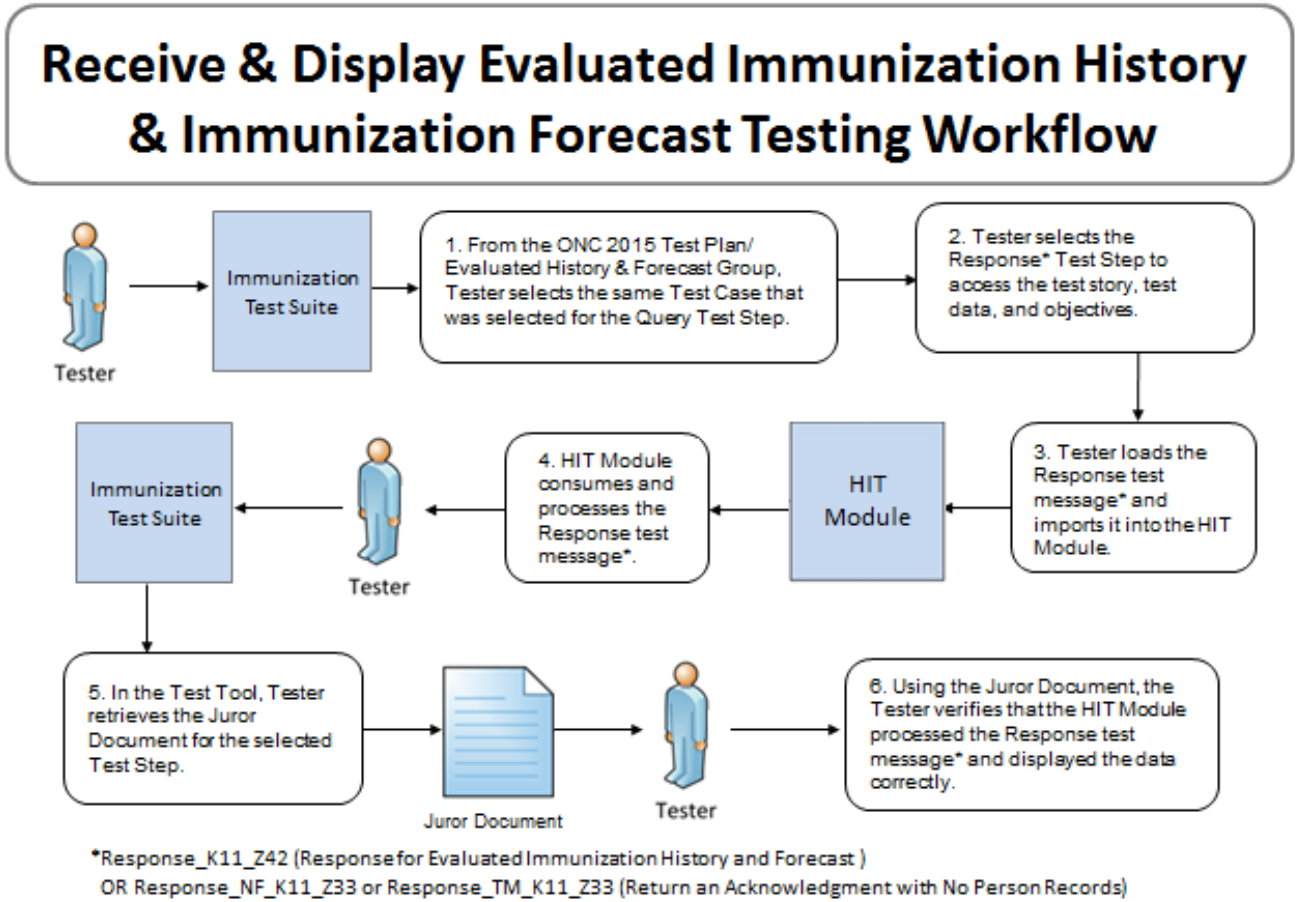
- How the major steps of the create QBP message test are sequenced
- When the Test Tool is to be used



Testing Workflow Diagram (Test Step 2 – Z42 or Z33 RSP)

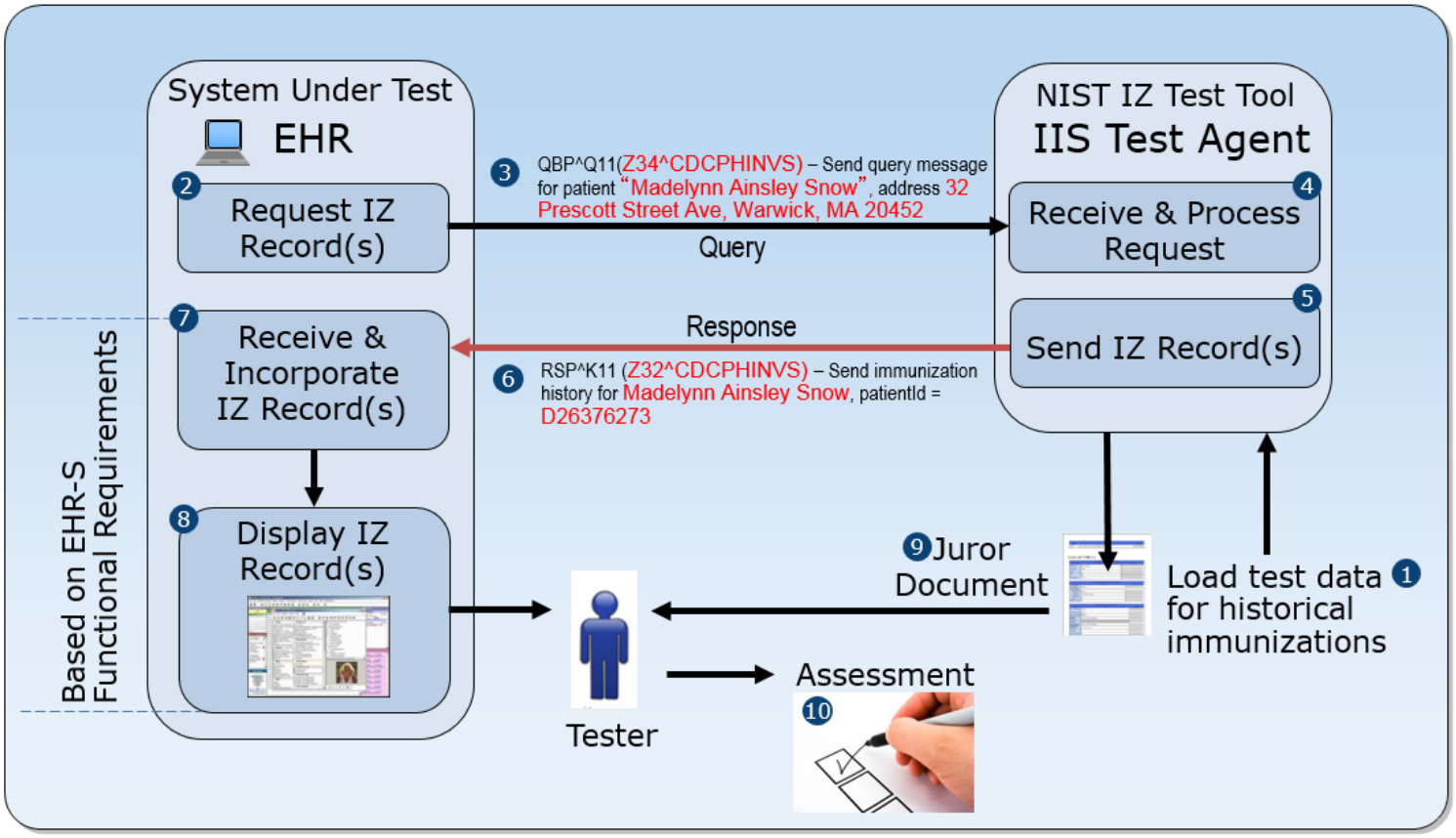
This diagram shows

- How the major steps of the process RSP message test are sequenced
- When the Test Tool is to be used



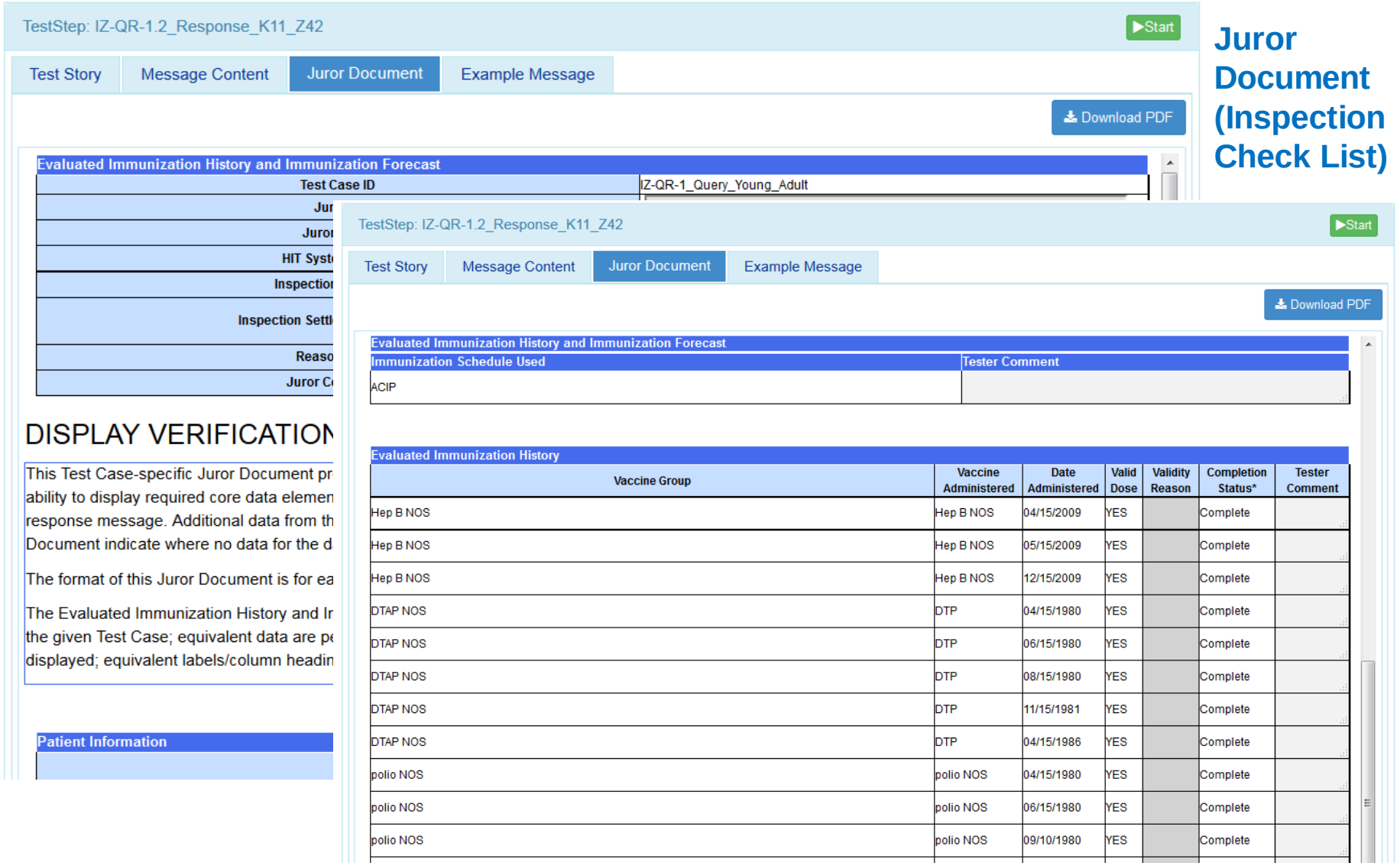
Query/Response Test Cases Work Flow

- Test the ability of an EHR-S to create a valid immunization history query message
- Receive and incorporate immunization history record(s) in the response message
- Display the immunization history record(s) according to the Juror Document provided



Note: It is important that the EHR system and hence the query message contains the data prescribed in the test case because the response message is tied to that data.

Display Evaluated History and Forecast



Juror Document (Inspection Check List)

Display of IIS Evaluated History and Forecast

- Work Flow and Pre-conditions
  - HIT Module has a test patient for the Test Case
  - Tester verifies that this patient has no current immunization administration information in their electronic record
  - Tester causes Module to create a Query for Evaluated History and Forecast
  - Module must display the Evaluated History and Forecast Response information returned by the IIS (IIS simulated by NIST Test Tool)
- Scope
  - ONC requirement is for the HIT Module to receive and display Evaluated History and Forecast from IIS
  - Test environment is set up so this information sent in the RSP message from the Test Tool is the only available immunization administration information in the patient's electronic record
  - This information must be displayed, and only display of this information for the Evaluated History and Forecast is valid for ONC certification testing—see next bullet (Exception: PID data can be from EHR)
  - HIT Modules can be designed to display the immunization Forecast based on data stored in the Module, but this capability is out-of-scope for ONC certification testing
  - Scope of ONC certification testing is focused on verifying that the HIT Module is able to display the Evaluated History and Forecast **from the IIS**
  - Substitution of a Forecast produced from patient immunization data stored in the HIT Module is not acceptable for the ONC certification testing; the Testers will check to make sure the electronic record for the test patient has no immunization information prior creation of the Evaluated History and Forecast Query (Some vendors may request a substitution—this is not acceptable)
  - The Juror Document used for assessing the Evaluated History and Forecast Response step indicates what information from the RSP message must be displayed, not how this information is to be displayed (Meaning that the entirely of the content must be displayed but the formatting is up to the vendor—e.g., e.g, the vendors may group certain data for screen efficiency if the data is the same and can be grouped—e.g., the date is the same for 5 immunizations, they could be group under the same date; the information is the same).

Test Case 1: Query for Child

IZ-QR-1_Query_Child	
Purpose	(1) Query for a child in which the patient record is found (2) Receive a response message containing the evaluated history and forecast; display history and forecast.
Steps	**High-level Test Objectives**
Step 1: **IZ-QR-1.1_Query_Q11_Z44** Create Query Message	➢ Create a query message for Young Adult ➢ Contains typical demographics data including: ➢ Patient Name ➢ Patient Identifier ➢ DOB ➢ Gender ➢ Address ➢ Phone
Step 2: **IZ-QR-1.2_Response_K11_Z42** Receive RSP	➢ Query was successful and returns an evaluated history and forecast for the patient ➢ EHR-S is to process and display the response message containing multiple immunization events and recommendations

Test Case 2: Query for Adult

IZ-QR-2_Query_Adult	
Purpose	(1) Query for an adult in which the patient record is found (2) Receive a response message containing the evaluated history and forecast; display history and forecast.
Steps	**High-level Test Objectives**
Step 1: **IZ-QR-2.1_Query_Q11_Z44** Create Query Message	➢ Create a query message for older Adult ➢ Contains typical demographics data including: ➢ Patient Name ➢ Patient Identifier ➢ DOB ➢ Gender ➢ Address ➢ Phone
Step 2: **IZ-QR-2.2_Response_K11_Z42** Receive RSP	➢ Query was successful and returns an evaluated history and forecast for the patient ➢ EHR-S is to process and display the response message containing a single immunization event and multiple recommendations

Test Case 3: Query where No Patients are Found

IZ-QR-3_Query_No Patients	
Purpose	(1) Query for a toddler in which the patient record is not found (2) Receive a response message indicating no person found
Steps	**High-level Test Objectives**
Step 1: **IZ-QR-3.1_Query_Q11_Z44** Create Query Message	➢ Create a query message ➢ Contains typical demographics data and additionally: ➢ Multiple Birth Indicator ➢ Birth Order ➢ Mother's Maiden Name ➢ Fully valued address ➢ Support of OIDs in the query message
Step 2: **IZ-QR-3.2_Response_K11_Z33** Receive RSP	➢ Query was successful but returned no high confidence matches ➢ EHR-S is to process the response message and display some indication to the end user that no matches were found

Test Case 4: Query where Too Many Patients Found

IZ-QR-4_Query_Too_Many	
Purpose	(1) Query for a child in which no patient record is returned because too many patients are found (2) Receive a response message and inform the end user
Steps	**High-level Test Objectives**
Step 1: IZ-QR-4.1_Query_Q11_Z44 Create Query Message	➢ Create a query message ➢ Contains typical demographics data including: ➢ Patient Name ➢ Patient Identifier ➢ DOB ➢ Gender ➢ Address ➢ Phone
Step 2: IZ-QR-4.2_Response_K11_Z33 Receive RSP	➢ Query was successful but returns an indication that too many matching patients were found ➢ EHR-S is to process the response message and display some indication to the end user that too many matches were found

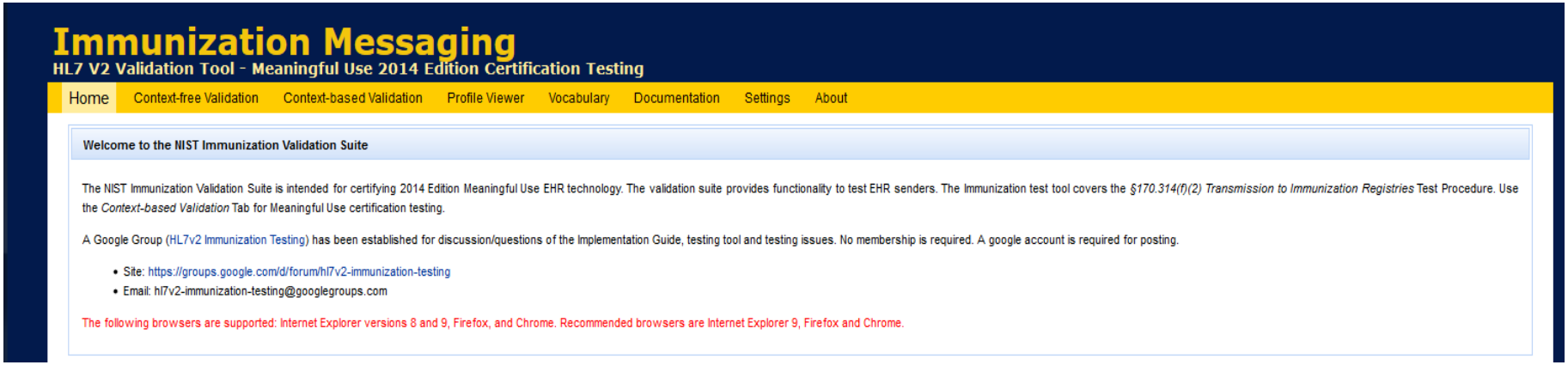
HEALTH IT
STANDARDS TESTING INFRASTRUCTURE

NIST Immunization Test Suite (2012)

National Institute of Standards and Technology

NIST Immunization Test Suite (2012)

- HL7 2.5.1 Immunization Implementation Guide Release 1.4
- HL7 2.5.1 Immunization Implementation Guide Release 1.4, Addendum
- Profiles Supported
  - VXU^V04
    - Z22 - SEND UNSOLICITED IMMUNIZATION UPDATE USING A VXU
- Used for 2014 Edition ONC Certification
- http://hl7v2-iz-testing.nist.gov



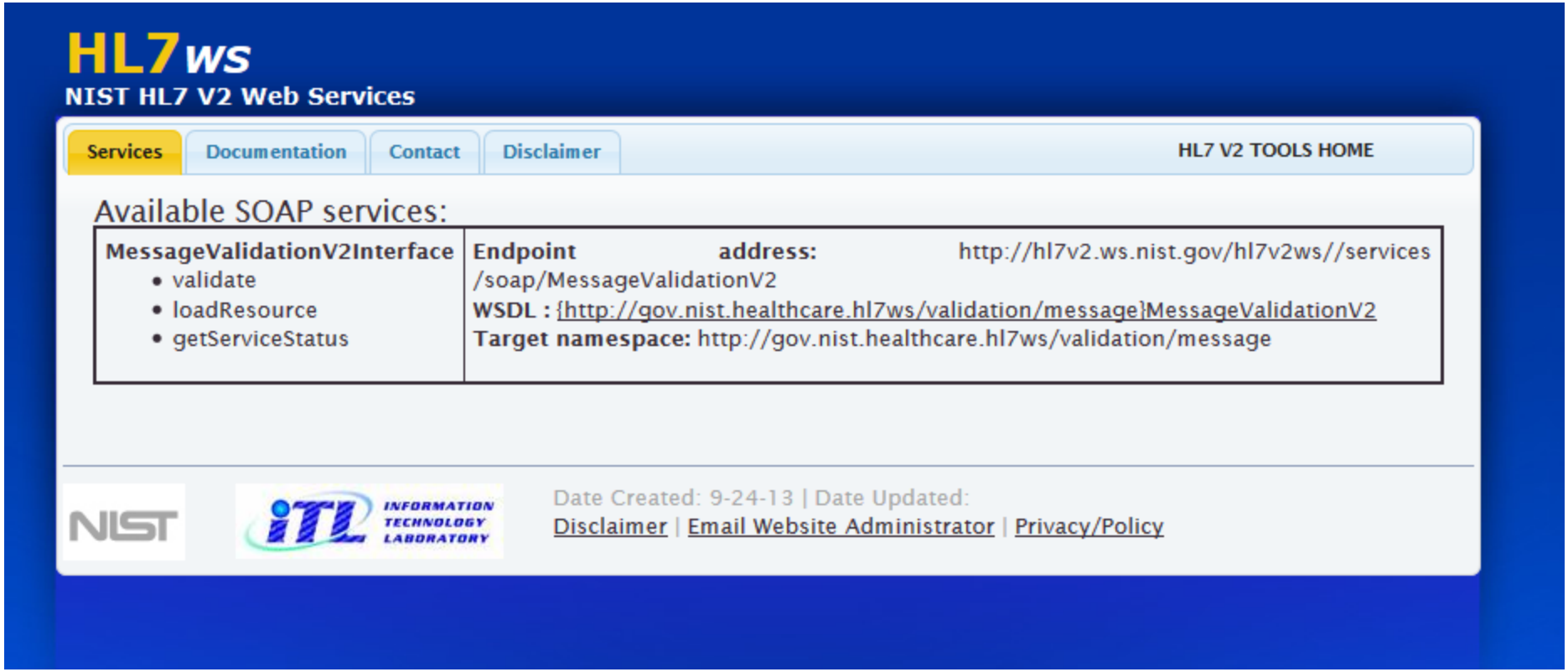
HEALTH IT
STANDARDS TESTING INFRASTRUCTURE

NIST Web Service Validation

API Access to Validation Services

National Institute of Standards and Technology

NIST Web Service Validation



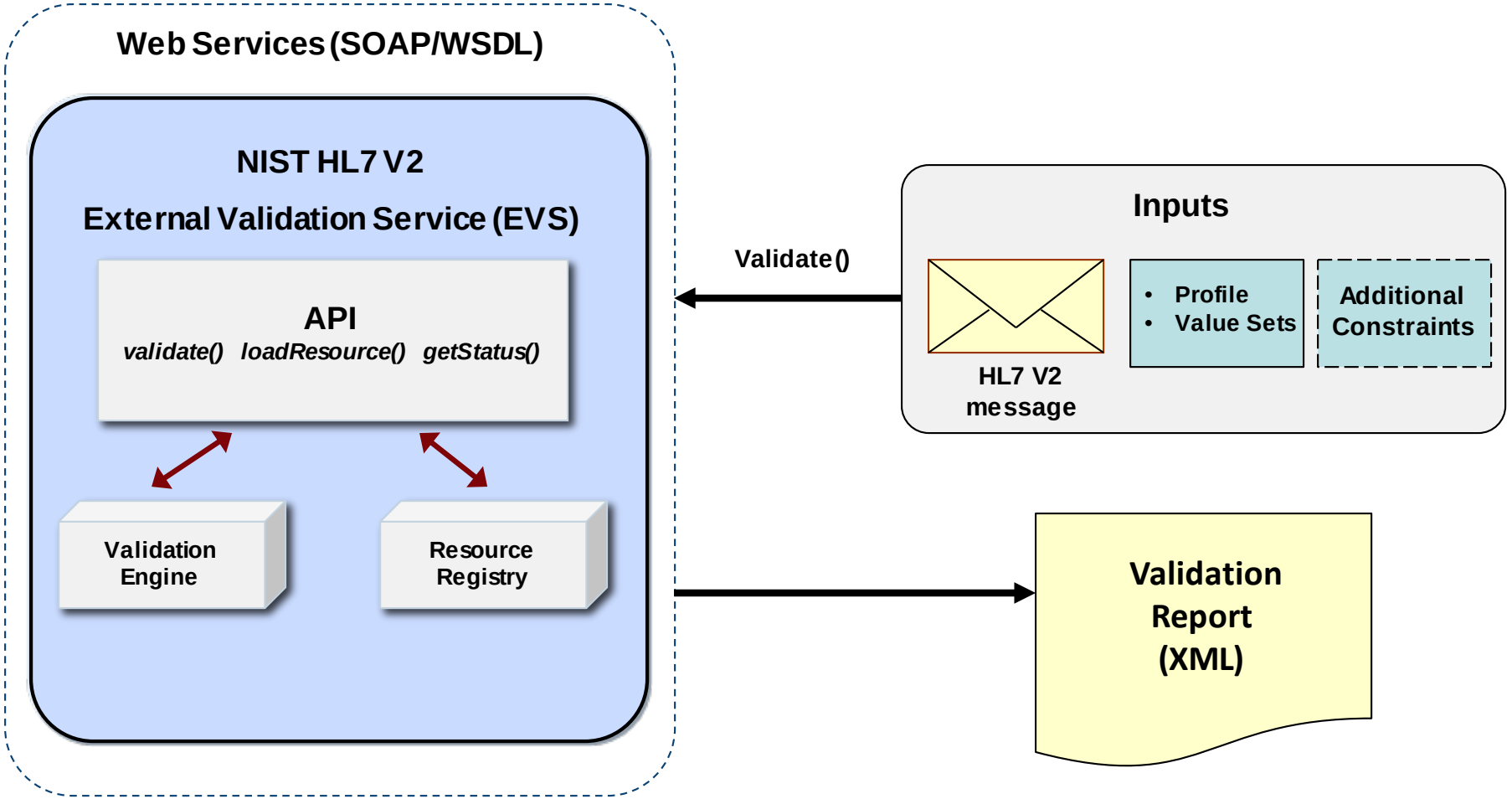
Web Page → hl7v2.ws.nist.gov/hl7v2ws

WSDL → hl7v2.ws.nist.gov/hl7v2ws/services/soap/MessageValidationV2?wsdl

Endpoint → hl7v2.ws.nist.gov/hl7v2ws/services/soap/MessageValidationV2

NIST Web Service Validation

Supports both the legacy validation engine and a new engine used by NIST Immunization Test Suites



WSDL

```
▼<wsdl:definitions xmlns:ns1="http://messagevalidation.hl7ws.healthcare.nist.gov/" xmlns:ns2="http://schemas.xmlsoap.org/soap/http"
 xmlns:soap12="http://schemas.xmlsoap.org/wsdl/soap12/" xmlns:tns="http://gov.nist.healthcare.hl7ws/validation/message" xmlns:wsdl="http://schemas.xmlsoap.org/wsdl/"
 xmlns:xsd="http://www.w3.org/2001/XMLSchema" name="MessageValidationV2" targetNamespace="http://gov.nist.healthcare.hl7ws/validation/message">
   <wsdl:import location="http://hl7v2.ws.nist.gov/hl7v2ws///services/soap/MessageValidationV2?wsdl=MessageValidationV2Interface.wsdl"
   namespace="http://messagevalidation.hl7ws.healthcare.nist.gov/"></wsdl:import>
 ▼<wsdl:binding name="MessageValidationV2SoapBinding" type="ns1:MessageValidationV2Interface">
    <soap12:binding style="document" transport="http://schemas.xmlsoap.org/soap/http"/>
  ▼<wsdl:operation name="validate">
     <soap12:operation soapAction="" style="document"/>
   ▼<wsdl:input name="validate">
      <soap12:body use="literal"/>
     </wsdl:input>
   ▼<wsdl:output name="validateResponse">
      <soap12:body use="literal"/>
     </wsdl:output>
    </wsdl:operation>
  ▼<wsdl:operation name="loadResource">
     <soap12:operation soapAction="" style="document"/>
   ▼<wsdl:input name="loadResource">
      <soap12:body use="literal"/>
     </wsdl:input>
   ▼<wsdl:output name="loadResourceResponse">
      <soap12:body use="literal"/>
     </wsdl:output>
    </wsdl:operation>
  ▼<wsdl:operation name="getServiceStatus">
     <soap12:operation soapAction="" style="document"/>
   ▼<wsdl:input name="getServiceStatus">
      <soap12:body use="literal"/>
     </wsdl:input>
   ▼<wsdl:output name="getServiceStatusResponse">
      <soap12:body use="literal"/>
     </wsdl:output>
    </wsdl:operation>
  </wsdl:binding>
 ▼<wsdl:service name="MessageValidationV2">
   ▼<wsdl:port binding="tns:MessageValidationV2SoapBinding" name="MessageValidationV2ServicePort">
     <soap12:address location="http://hl7v2.ws.nist.gov/hl7v2ws///services/soap/MessageValidationV2"/>
    </wsdl:port>
  </wsdl:service>
</wsdl:definitions>
```

NIST Web Service Validation API

Method Summary	
java.lang.String	**getServiceStatus**() The getServiceStatus() method returns a list of the profiles and tables currently supported by the validation service.
java.lang.String	**loadResource**(java.lang.String resource, java.lang.String oid, java.lang.String type) The loadResource() method is used to load an HL7 V2 conformance profile or table (resources) that can be used in a subsequence validate() invocation.
java.lang.String	**validate**(java.lang.String message, java.lang.String profileOID, java.lang.String tableOIDList, java.lang.String xmlValidationContext) Perform the message validation and return a report.

- The Web Service API consists of 3 methods
- The first 2 are for users who wish to load their own resources
- Most users will probably only use the validate() method
  - E.g.) for Immunization messages, all resources (e.g. profiles) are pre-loaded
- Javadoc is provided on the HL7V2WS Documentation tab

Validate

Method Detail

validate

```
java.lang.String validate(java.lang.String message,
                          java.lang.String profileOID,
                          java.lang.String tableOIDList,
                          java.lang.String xmlValidationContext)
```

Perform the message validation and return a report.

Message validation requires an HL7 v2 message encoded in ER7 or XML. The validation may also use a specification (i.e., an HL7 V2 conformance profile), a list of one or more HL7 table files, and a validation context. The validation context specifies specific content tests related to the message. The validation can be performed against a profile, a validation context, or both. One of these three options must be specified.

Parameters:

`message` - the HL7 V2 message that is being validated. The encoding of the message can be XML or ER7. The validation service determines the encoding type by examining the content of the message parameter.

`profileOID` - the profileOID is an OID that references the profile used in validation. The profileOID must reference a valid HL7 V2 conformance profile that is loaded on the server. The service requires that the profile is pre-loaded in the repository and validated. Profiles must conform to the appropriate **HL7 V2 Conformance Profile** schema.

If a profile is not specified in this parameter, then the validation is performed against the validation context only.

`tableOIDList` - the tableOIDList is a colon (":") separated list of OIDs which reference valid HL7 V2 table(s) loaded on the server. The service requires all tables are pre-loaded in the repository and validated before usage. Tables must conform to the NIST **Table Library** schema.

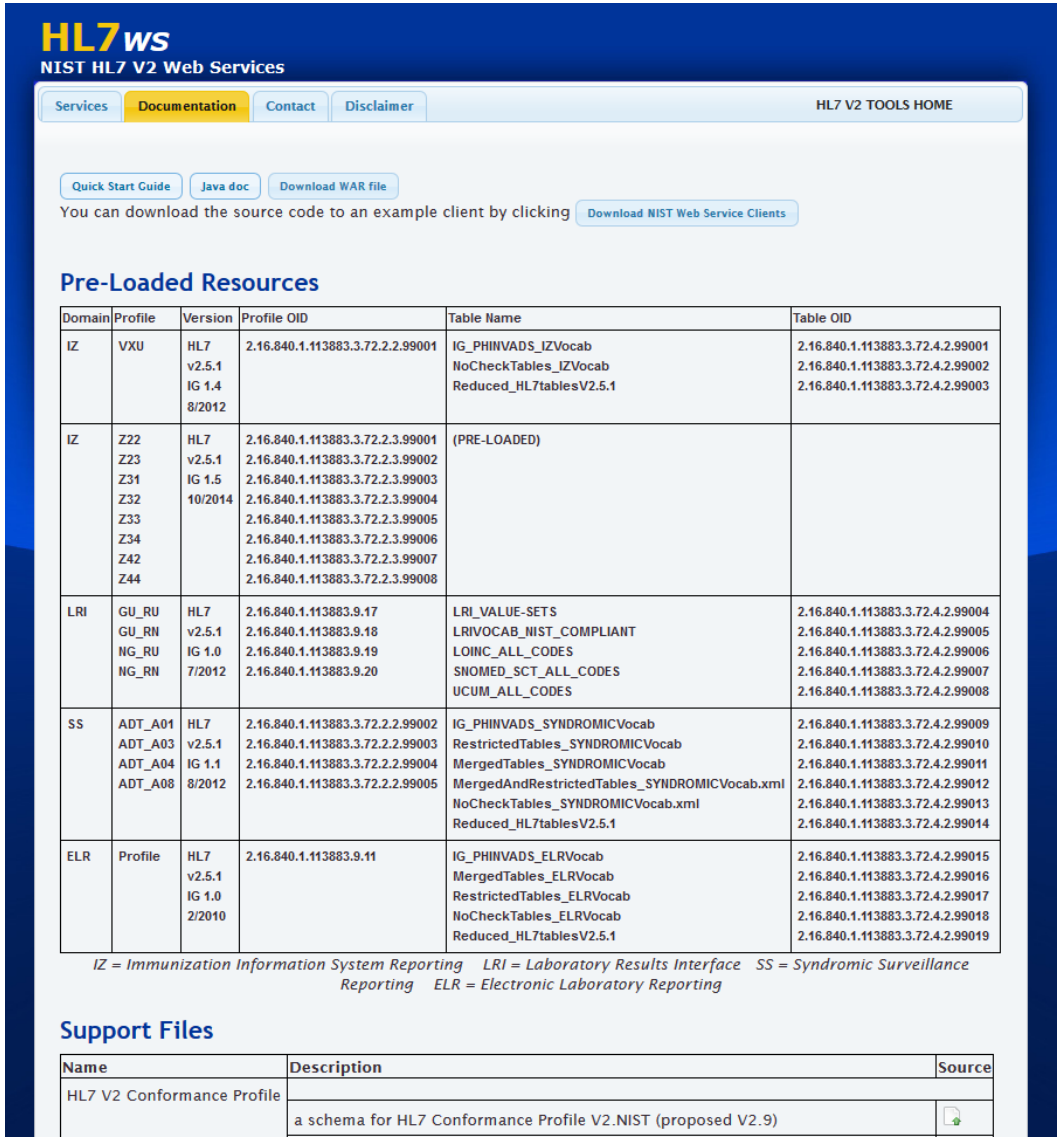
`xmlValidationContext` - describes specific data content tests associated with a specific HL7 V2 message. The validation context describes the location and values to be tested. The validation context information is used in scenario base testing. The validation context must adhere to the NIST **Validation Context** schema.

The xmlValidationContext can also set general validation configuration parameters that specify how certain failures are interpreted. For example, length failures may be detected by the validation service but ignored.

Returns:

xmlResults – an XML document for reporting the results of the HL7 V2 message validation. For details of the report see the NIST **xmlResults** schema. If the validation process couldn't be performed this is indicated along with the reason why in the results report.

Web Service – Resources



HL7ws
NIST HL7 V2 Web Services

Services | Documentation | Contact | Disclaimer | HL7 V2 TOOLS HOME

Quick Start Guide | Java doc | Download WAR file

You can download the source code to an example client by clicking Download NIST Web Service Clients

Pre-Loaded Resources

Domain	Profile	Version	Profile OID	Table Name	Table OID
IZ	VXU	HL7 v2.5.1 IG 1.4 8/2012	2.16.840.1.113883.3.72.2.2.99001	IG_PHINVADS_IZVocab NoCheckTables_IZVocab Reduced_HL7tablesV2.5.1	2.16.840.1.113883.3.72.4.2.99001 2.16.840.1.113883.3.72.4.2.99002 2.16.840.1.113883.3.72.4.2.99003
IZ	Z22 Z23 Z31 Z32 Z33 Z34 Z42 Z44	HL7 v2.5.1 IG 1.5 10/2014	2.16.840.1.113883.3.72.2.3.99001 2.16.840.1.113883.3.72.2.3.99002 2.16.840.1.113883.3.72.2.3.99003 2.16.840.1.113883.3.72.2.3.99004 2.16.840.1.113883.3.72.2.3.99005 2.16.840.1.113883.3.72.2.3.99006 2.16.840.1.113883.3.72.2.3.99007 2.16.840.1.113883.3.72.2.3.99008	(PRE-LOADED)	
LRI	GU_RU GU_RN NG_RU NG_RN	HL7 v2.5.1 IG 1.0 7/2012	2.16.840.1.113883.9.17 2.16.840.1.113883.9.18 2.16.840.1.113883.9.19 2.16.840.1.113883.9.20	LRI_VALUE-SETS LRIVOCAB_NIST_COMPLIANT LOINC_ALL_CODES SNOMED_SCT_ALL_CODES UCUM_ALL_CODES	2.16.840.1.113883.3.72.4.2.99004 2.16.840.1.113883.3.72.4.2.99005 2.16.840.1.113883.3.72.4.2.99006 2.16.840.1.113883.3.72.4.2.99007 2.16.840.1.113883.3.72.4.2.99008
SS	ADT_A01 ADT_A03 ADT_A04 ADT_A08	HL7 v2.5.1 IG 1.1 8/2012	2.16.840.1.113883.3.72.2.2.99002 2.16.840.1.113883.3.72.2.2.99003 2.16.840.1.113883.3.72.2.2.99004 2.16.840.1.113883.3.72.2.2.99005	IG_PHINVADS_SYNDROMICVocab RestrictedTables_SYNDROMICVocab MergedTables_SYNDROMICVocab MergedAndRestrictedTables_SYNDROMICVocab.xml NoCheckTables_SYNDROMICVocab.xml Reduced_HL7tablesV2.5.1	2.16.840.1.113883.3.72.4.2.99009 2.16.840.1.113883.3.72.4.2.99010 2.16.840.1.113883.3.72.4.2.99011 2.16.840.1.113883.3.72.4.2.99012 2.16.840.1.113883.3.72.4.2.99013 2.16.840.1.113883.3.72.4.2.99014
ELR	Profile	HL7 v2.5.1 IG 1.0 2/2010	2.16.840.1.113883.9.11	IG_PHINVADS_ELRVocab MergedTables_ELRVocab RestrictedTables_ELRVocab NoCheckTables_ELRVocab Reduced_HL7tablesV2.5.1	2.16.840.1.113883.3.72.4.2.99015 2.16.840.1.113883.3.72.4.2.99016 2.16.840.1.113883.3.72.4.2.99017 2.16.840.1.113883.3.72.4.2.99018 2.16.840.1.113883.3.72.4.2.99019

IZ = Immunization Information System Reporting LRI = Laboratory Results Interface SS = Syndromic Surveillance Reporting ELR = Electronic Laboratory Reporting

Support Files

Name	Description	Source
HL7 V2 Conformance Profile	a schema for HL7 Conformance Profile V2.NIST (proposed V2.9)	

- Pre-loaded Profiles
- IZ IG Release 1.4 VXU (Z22)
- IZ IG Release 1.5 (All Profiles)
- Value Sets
- Profile Schemas
- Also supports ELR and Syndromic Surveilance

NIST Web Service Validation

Message Validation from Java

```
MessageValidationV2SoapClient client =
        new MessageValidationV2SoapClient(http://hl7v2.ws.nist.gov/hl7v2ws/services//soap/MessageValidationV2/);
iz_profile_oid="2.16.840.1.113883.3.72.2.3.99001";
String iz_msg_fn=dataFilePath+"VXU_Messages/Admin_Child_Message.txt";
String iz_msg=IOUtils.toString(new FileReader(new File(iz_msg_fn)));
res = client.validate(iz_msg,iz_profile_oid, null , null);
System.out.println("Received: " + res.replaceAll("\r","\n") + "\n\n\n");
```

- Example WS client code using Apache CXF/JAX-WS
- Instantiates ‘client’ object and calls validate() method
  - Parameters: OID of VXU profile (listed on Documentation tab) and VXU message
- XML report is returned
  - NIST can provide style sheets to render as HTML

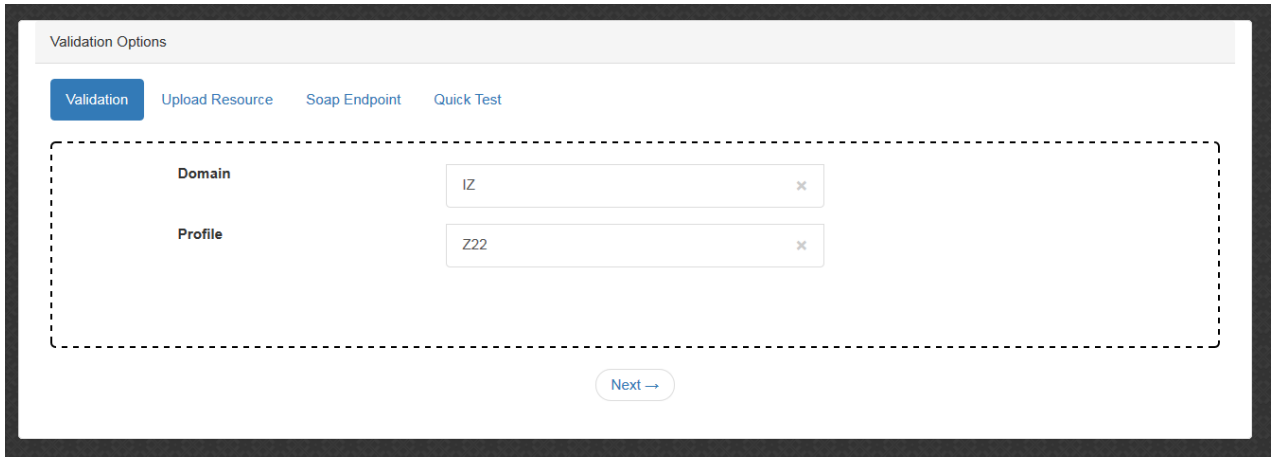
WS_Tester: Example HL7V2WS Client (Web App)

- WS_Tester is a web application which provides a client interface to the NIST HL7 V2 Validation Web Service
- Single or multiple messages may be validated via HL7V2WS (via cut-n-paste, or uploading message files)
- WS_Tester validates messages using pre-loaded or user provided Profiles & Tables
- Context free or Context based validations may be performed
- Reports are formatted for HTML and can also be downloaded in their original XML

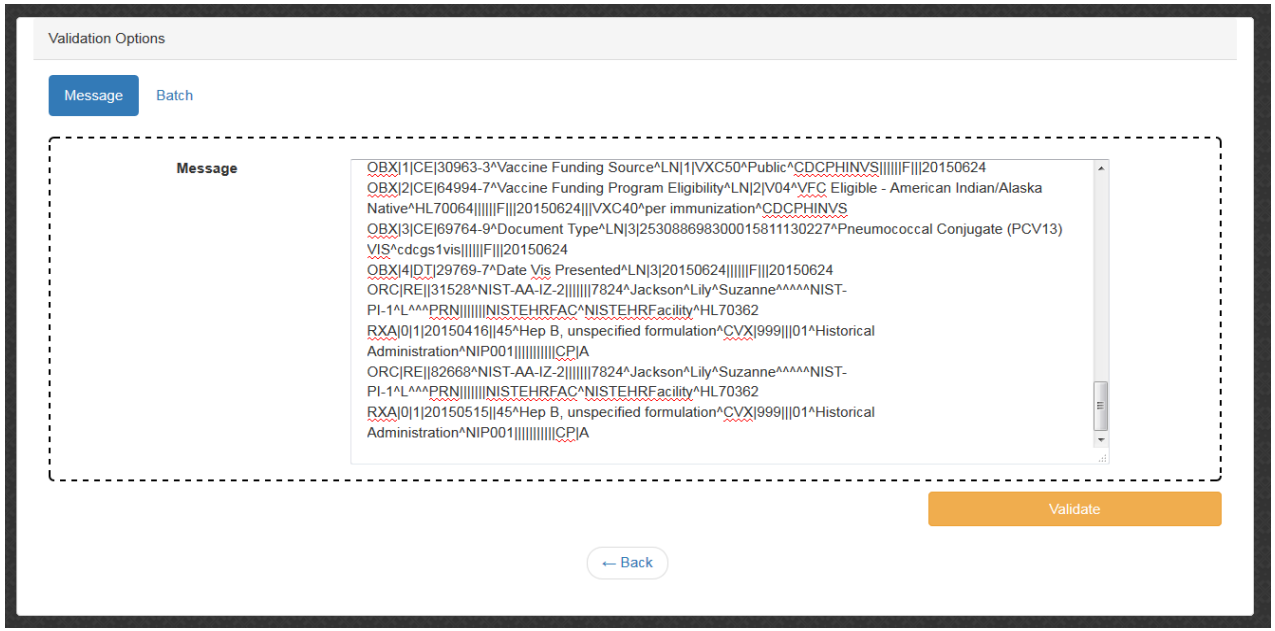
- http://hit-testing2.nist.gov:8090/WS_tester

Web Service Example Client

1) Select Profile



2) Load Message and Validate



Web Service Example – Validation Report

Summary
☑ 2 Errors
☐ 55 Alerts
☐ 10 Warnings
☐ 596 Affirmatives

Validation Errors		Count : 2 ☑
VALUE_SET		Count : 2 ☑
1	Type :	VALUE_SET
	Description:	The value 'X' at location Field PID-8 (Administrative Sex) is not member of the value set HL70001_IZ
	Location:	**Line: 2**
		Column: 87
		Path: PID[1]-8[1]
2	Type :	VALUE_SET
	Description:	The value '102-5' at location Component PID-10.1 (Identifier) is not member of the value set CDCREC_R_IZ
	Location:	**Line: 2**
		Column: 90
		Path: PID[1]-10[1].1

Validation Alerts	Count : 55 ☐

Validation Warnings	Count : 10 ☐

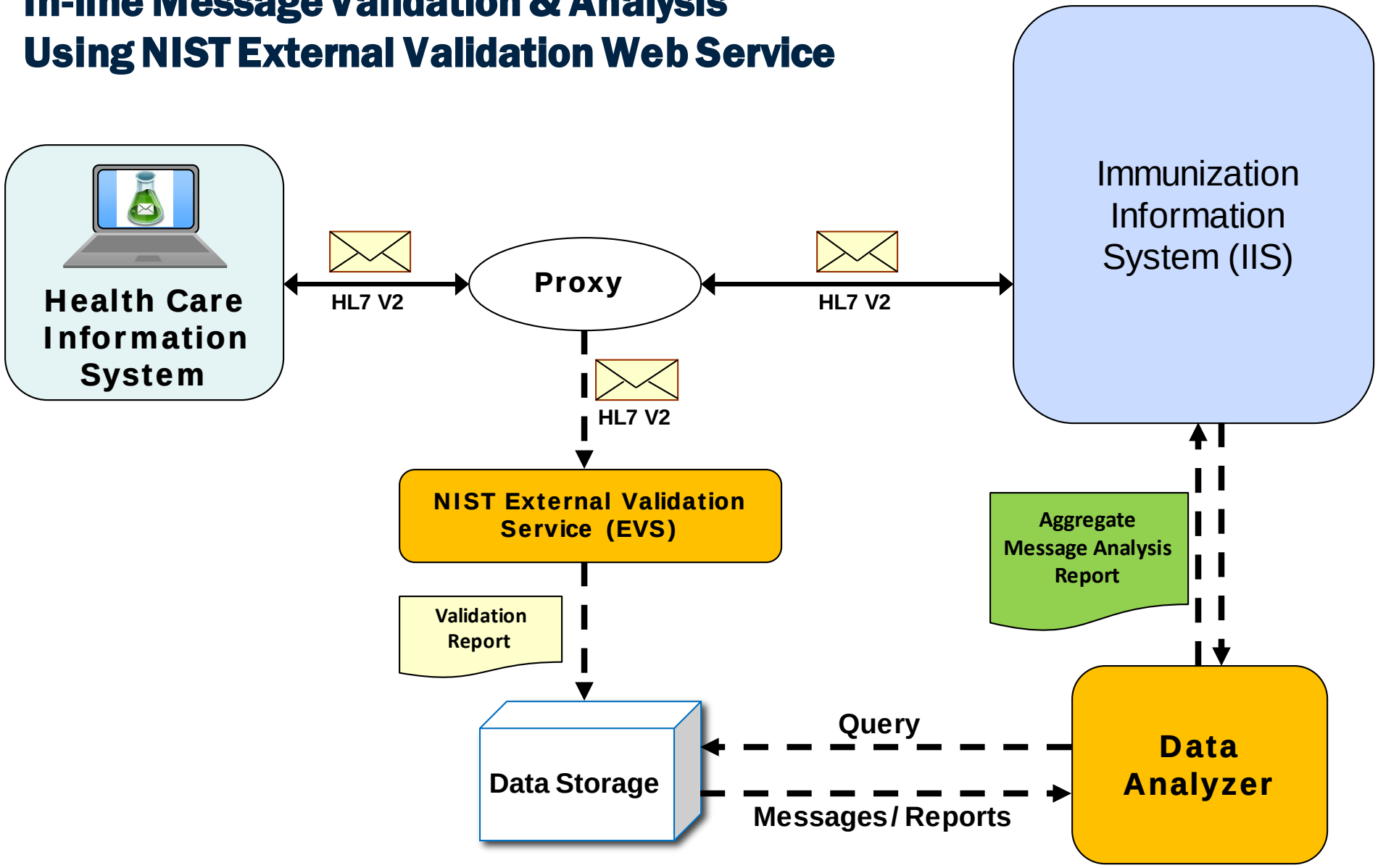
Validation Affirmatives	Count : 596 ☐

New Validation

Web Service Example – Validation Report (XML)


```
    </ns6:Location>
  − <ns6:Description>
      The value set HL70362_IZ has been excluded from the validation
    </ns6:Description>
  </ns6:Assertion>
− <ns6:Assertion Type="VALUE_SET" Result="error">
  − <ns6:Location>
      <ns6:Line>2</ns6:Line>
      <ns6:Column>87</ns6:Column>
      <ns6:Path>PID[1]-8[1]</ns6:Path>
    </ns6:Location>
  − <ns6:Description>
      The value 'X' at location Field PID-8 (Administrative Sex) is not member of the value set HL70001_IZ
    </ns6:Description>
  − <ns6:MetaData>
    − <ValueSet>
        <BindingStrength>R</BindingStrength>
        <Id>HL70001_IZ</Id>
      </ValueSet>
    </ns6:MetaData>
  </ns6:Assertion>
− <ns6:Assertion Type="VALUE_SET" Result="error">
  − <ns6:Location>
      <ns6:Line>2</ns6:Line>
      <ns6:Column>90</ns6:Column>
      <ns6:Path>PID[1]-10[1].1</ns6:Path>
    </ns6:Location>
  − <ns6:Description>
      The value '102-5' at location Component PID-10.1 (Identifier) is not member of the value set CDCREC_R_IZ
    </ns6:Description>
  − <ns6:MetaData>
    − <ValueSet>
        <BindingLocation>Position(1)</BindingLocation>
        <BindingStrength>R</BindingStrength>
        <Id>CDCREC_R_IZ</Id>
      </ValueSet>
    </ns6:MetaData>
  </ns6:Assertion>
− <ns6:Assertion Type="RE_USAGE" Result="warning">
  − <ns6:Location>
      <ns6:Line>19</ns6:Line>
      <ns6:Column>1</ns6:Column>
      <ns6:Path>RXR[2]-2[1]</ns6:Path>
```

In-line Message Validation & Analysis Using NIST External Validation Web Service



REST API Access to Web Application

- An alternative to using the Web Service is to access the validation via a REST API of the Web Application
- A REST API of the tool accessible remotely from any HTTP client such as curl or a browser, bypassing the web interface/UI.
  - **curl** is a command line http client. For more information https://curl.haxx.se/
- The API documentation can be found at:
  - http://hl7v2-iz-r1.5-testing.nist.gov/iztool/#/api-docs

HEALTH IT
STANDARDS TESTING INFRASTRUCTURE

Implementation Guide Authoring and Management Tool (IGAMT)

National Institute of Standards and Technology

IGAMT-Create Implementation Guides and Profiles

Input Requirements

1) Select base HL7 v2.x Message Types

2) Define Requirements

3) Add Use Case

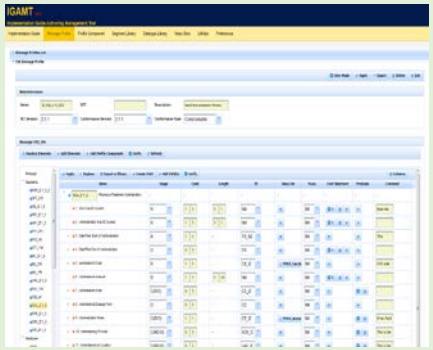
4) Profile Data Types, Segments, Messages, and Value Sets

5) Add Examples

6) Add Guidance

7) Etc.

IGAMT

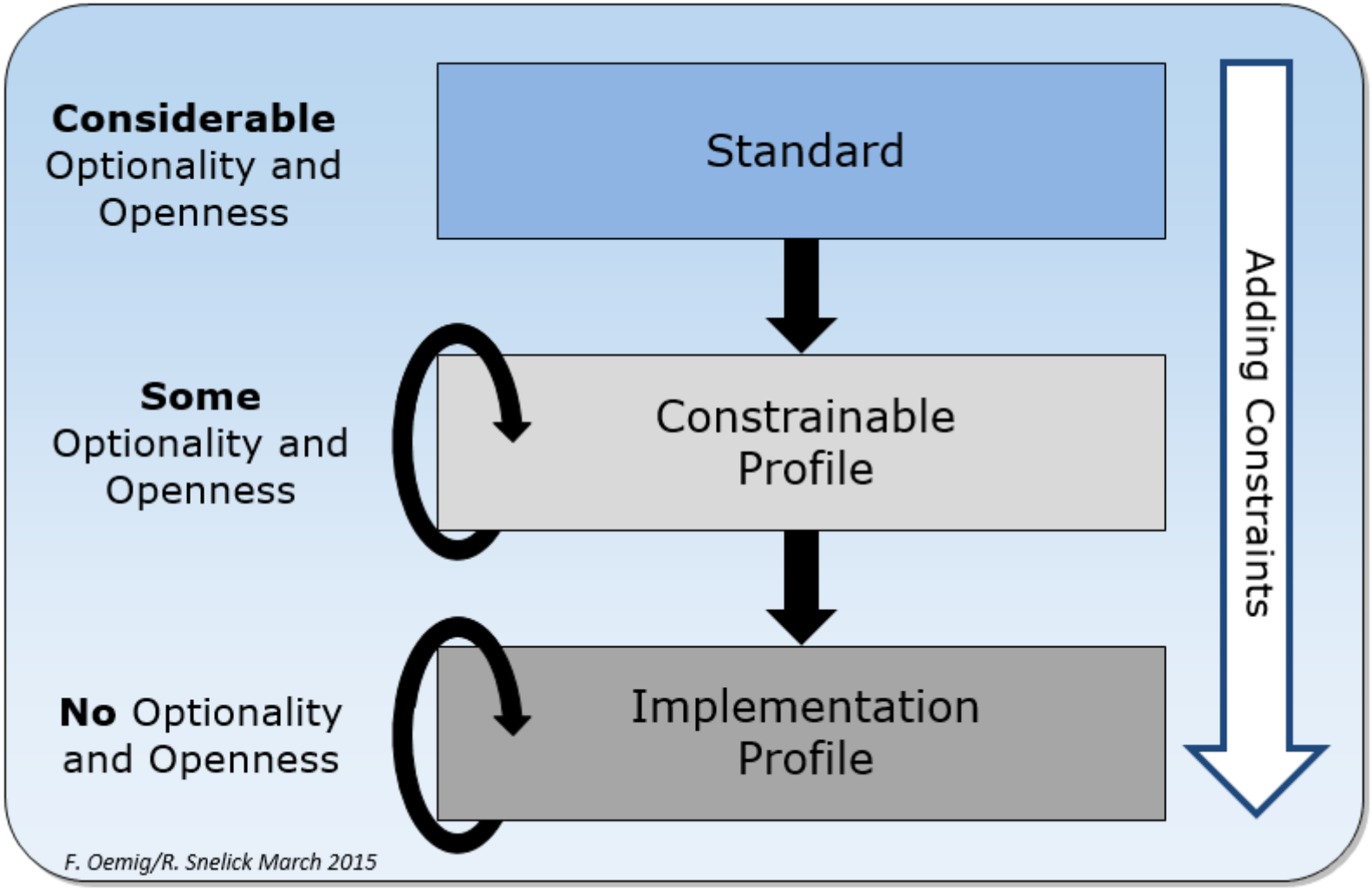


Output Artifacts

- Conformance Profile (XML, JSON, PDF, Word)
- Vocabulary Library (XML, JSON, PDF, Word)
- Data type Library (XML, JSON, PDF, Word)
- Segment Library (XML, JSON, PDF, Word)
- Implementation Guide (JSON, PDF English, Word-English, HTML)

- Publish Guide
- Message Validation
- Message Generation
- Code Generation
- Etc.

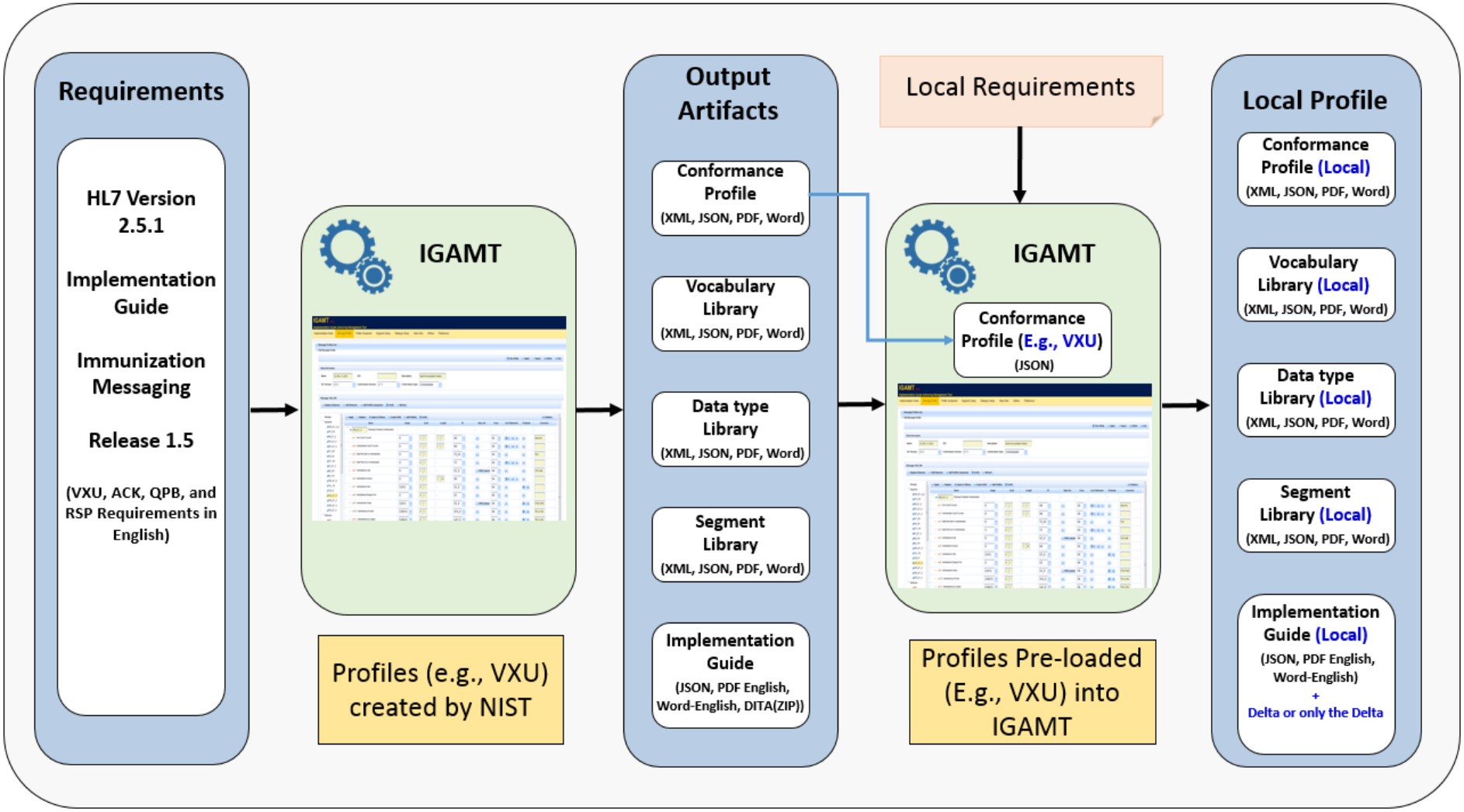
HL7 V2.x Profiling and Profile Hierarchy



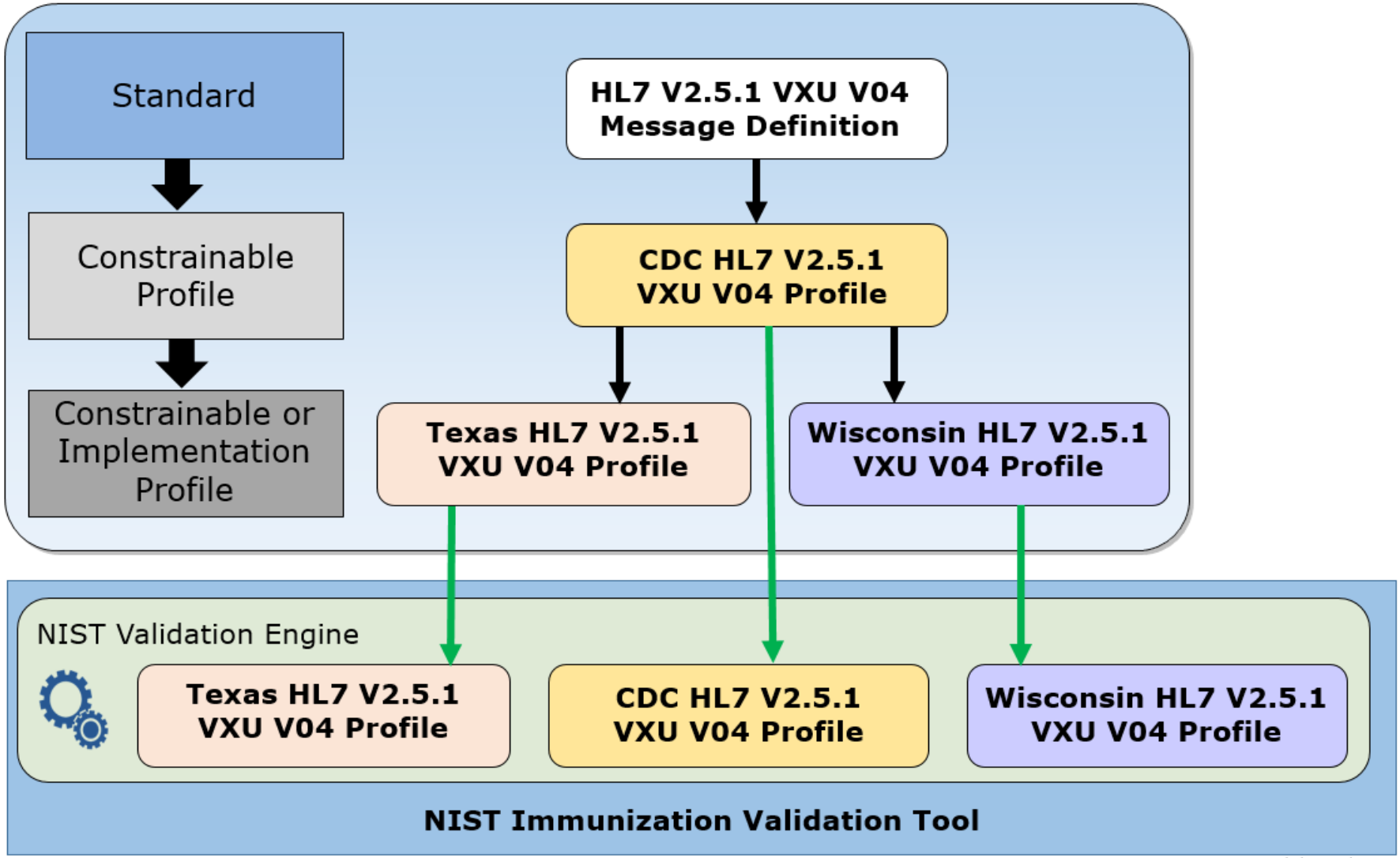
Applying Constraints

<table>
<tr><th>Constraint Type</th><th>Description</th><th>Examples</th></tr>
<tr><td>Usage</td><td>Indicates requirements for the presence (appearance) of an element. Also referred to as Appearance or Optionality indicator.</td><td>Constraint optional to required
O → R</td></tr>
<tr><td>Cardinality</td><td>Indicates the number of occurrences for an element by specifying the minimum and maximum bounds.</td><td>Constrain the minimum cardinality from 0 (may be sent) to 1 (required to be sent)
[0..1] → [1..1]</td></tr>
<tr><td>Data Type</td><td>Defines the data element structure and, at the primitive level, the type of data it may contain. Constraints include type substitution and specialization (when combined with other constraint types).</td><td>
<table>
<tr><th>DT</th><th>Usage</th><th>Cardinality</th></tr>
<tr><td>Element 1</td><td>R</td><td>1..1</td></tr>
<tr><td>Element 2</td><td>O</td><td>0..*</td></tr>
<tr><td>Element 3</td><td>O</td><td>0..1</td></tr>
<tr><td>Element 4</td><td>O</td><td>0..*</td></tr>
</table>
→
<table>
<tr><th>DT_IZ</th><th>Usage</th><th>Cardinality</th></tr>
<tr><td>Element 1</td><td>R</td><td>1..1</td></tr>
<tr><td>Element 2</td><td>RE</td><td>0..5</td></tr>
<tr><td>Element 3</td><td>X</td><td>0..0</td></tr>
<tr><td>Element 4</td><td>O</td><td>0..*</td></tr>
</table>
</td></tr>
<tr><td>Value</td><td>Defines the allowable values for a coded element (i.e., a list of values).</td><td>[M, F, U, O, A] → [M, F, U]</td></tr>
<tr><td>Length</td><td>Defines a constraint on the number of characters that may be present in one occurrence of an element. Can specify a maximum or the minimum and maximum bounds.</td><td>80
Element may have at most 80 characters.
[2..4]
Element may have at minimum 2 and at most 4 characters.</td></tr>
<tr><td>Predicate
(Conformance Statement)</td><td>Provides an explicit normative statement expressed in text or a testable expression that defines a constraint. Also referred to as a “conformance statement”.</td><td>PID.6.7 (Mother’s Maiden Name – Name Type Code) SHALL be valued “M”.</td></tr>
</table>

IGAMT-Create Local Implementation Guides

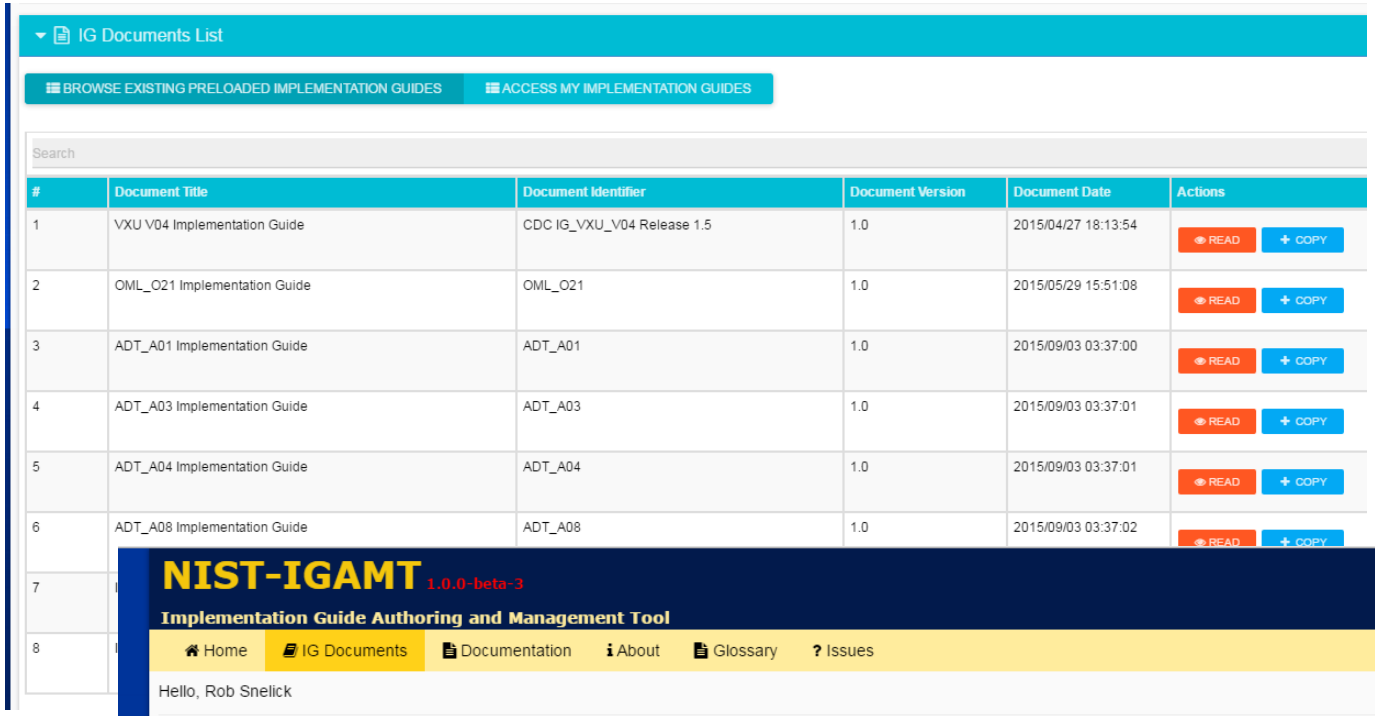


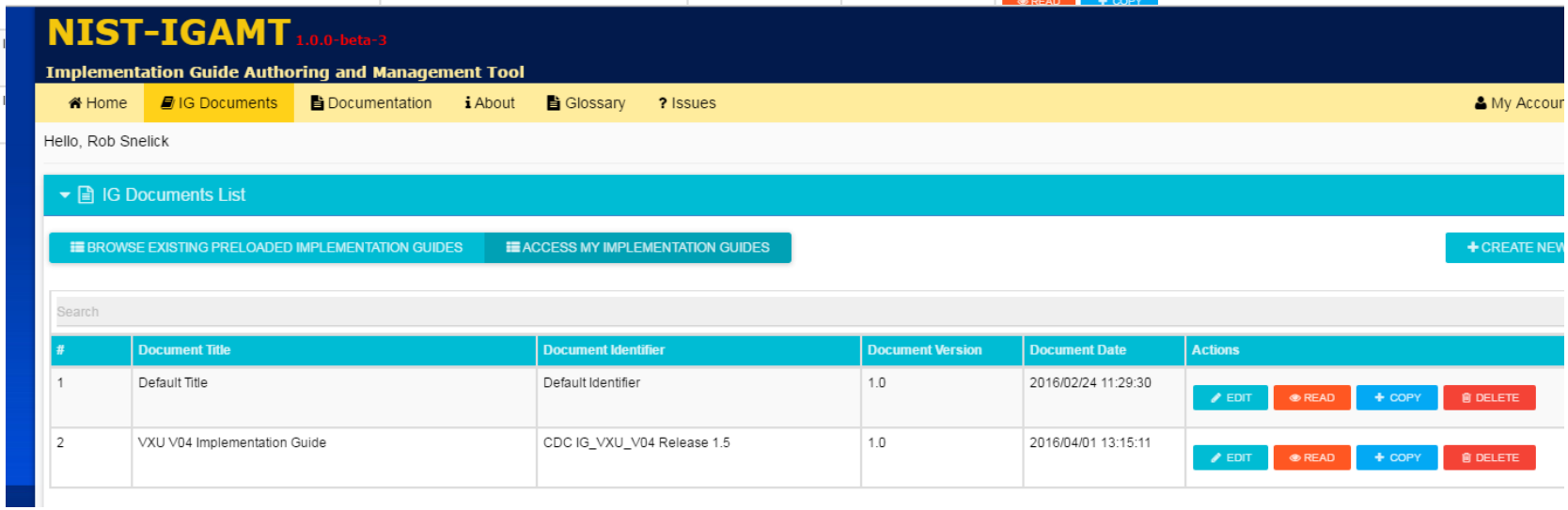
Conformance Testing of Local Profiles



R. Snelick March 2015

IGAMT Implementation Guides





Pre-loaded IGs and user IGs

IGAMT – Navigation Bar (Use Case)

Edit IG Document

IG Document: VXU V04 Implementation Guide Saved

SAVE | EXPORT | CLOSE | DELETE

version: 1.0

Table of Contents

- Metadata
- Introduction
  - Purpose
  - Audience
  - Organization of this guide
  - Referenced profiles - antecedents
  - Scope
    - In Scope
    - Out of Scope
  - Key technical decisions [conventions]
- Use Case
  - Actors
  - Use case assumptions
    - Pre Conditions
    - Post Condition
    - Functional Requirements
  - User story
  - Sequence diagram
    - Acknowledgement
    - Error Handling
- Message Infrastructure
  - Metadata
  - Conformance Profiles
    - VXU_V04 - Unsolicited vaccination recor
  - Segments and Field Descriptions
    - GT1_154 - Guarantor
    - IN1_IZ 1_5 - Insurance
    - IN2_218 - Insurance Additional Informatio
    - IN3_179 - Insurance Additional Informatio
    - MSH_IZ 1_5_Z22 - Message Header
    - NK1_IZ 1_5 - Next of Kin / Associated Par
    - NTE_IZ 1_5 - Notes and Comments
    - OBX_IZ 1_5 - Observation/Result

Edit Area

Send Immunization -->

Contents

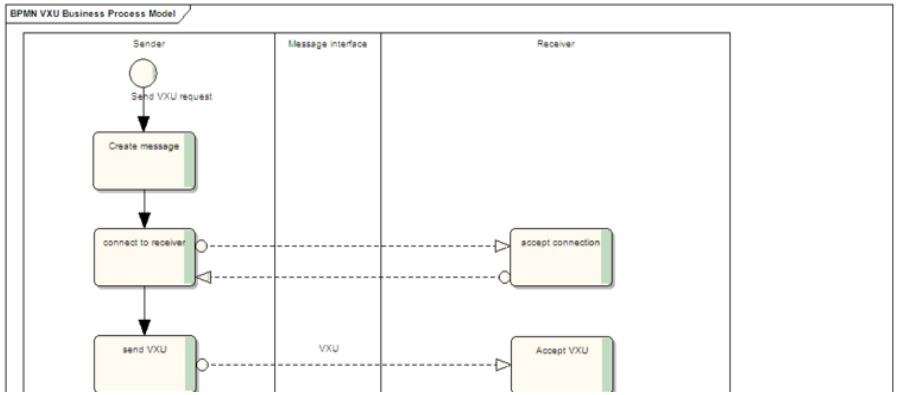
Use Case 1—Send Immunization History

Goal: To send an immunization history for an individual client from one system to another. In addition to EHR-S and IIS, other systems such as vital records systems or billing systems could use this message to send immunization histories. This goal includes receiving the immunization history.

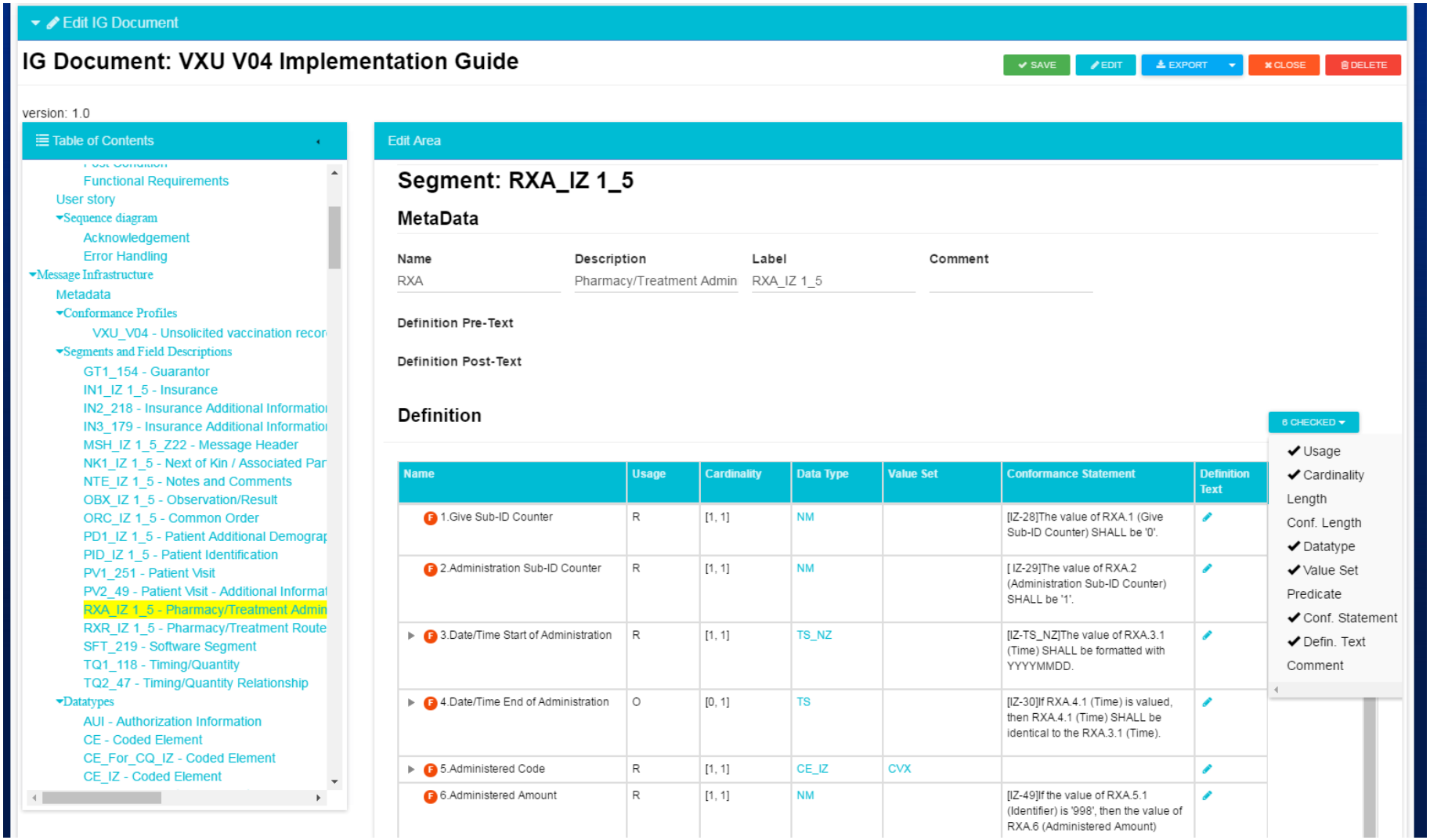
Supporting HL7 version 2.5.1 Message Type: VXU – Profile Z22

Precondition:A user or other actor requests that the sending system send an immunization history.

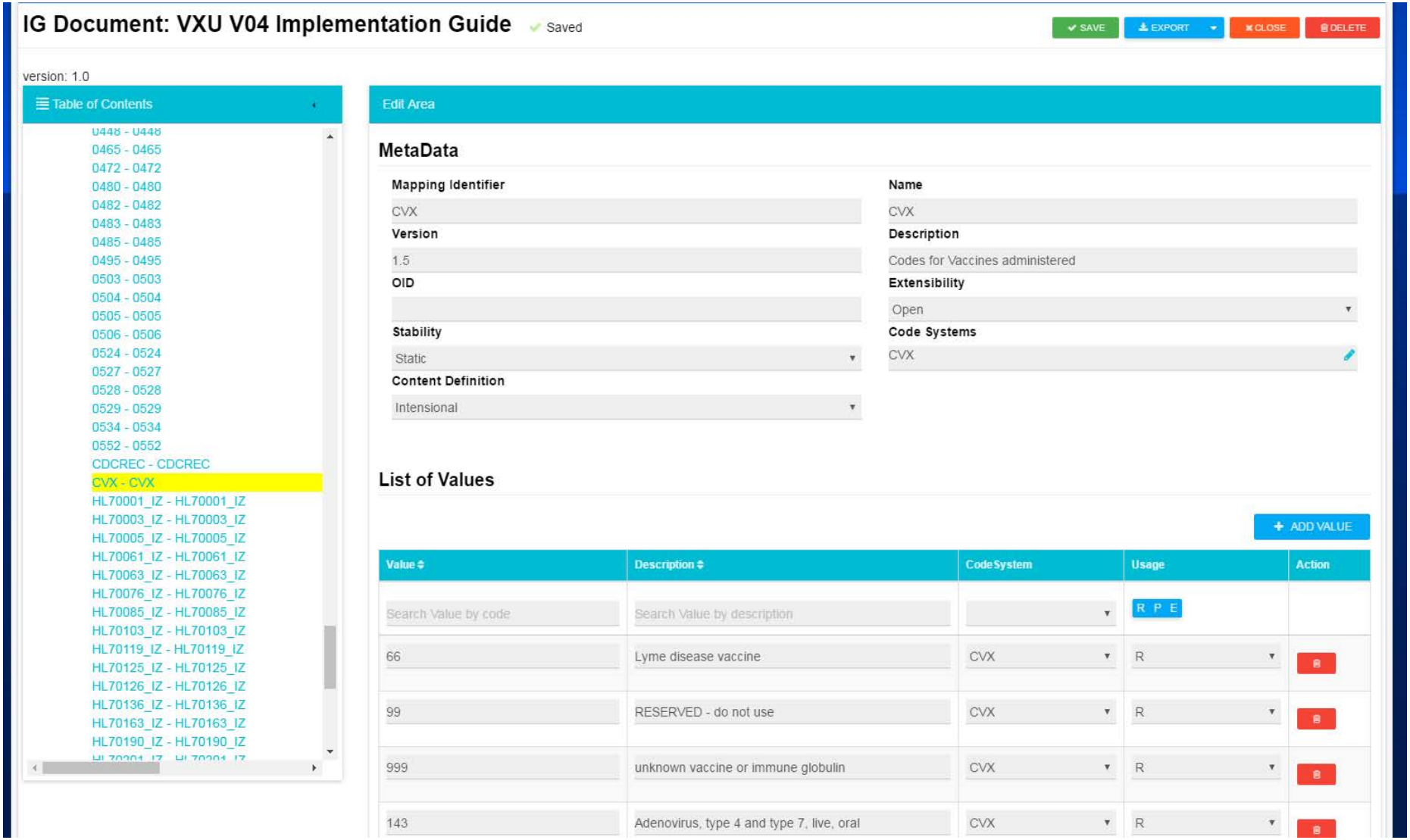
Post-condition: The receiving system has accepted the immunization history.



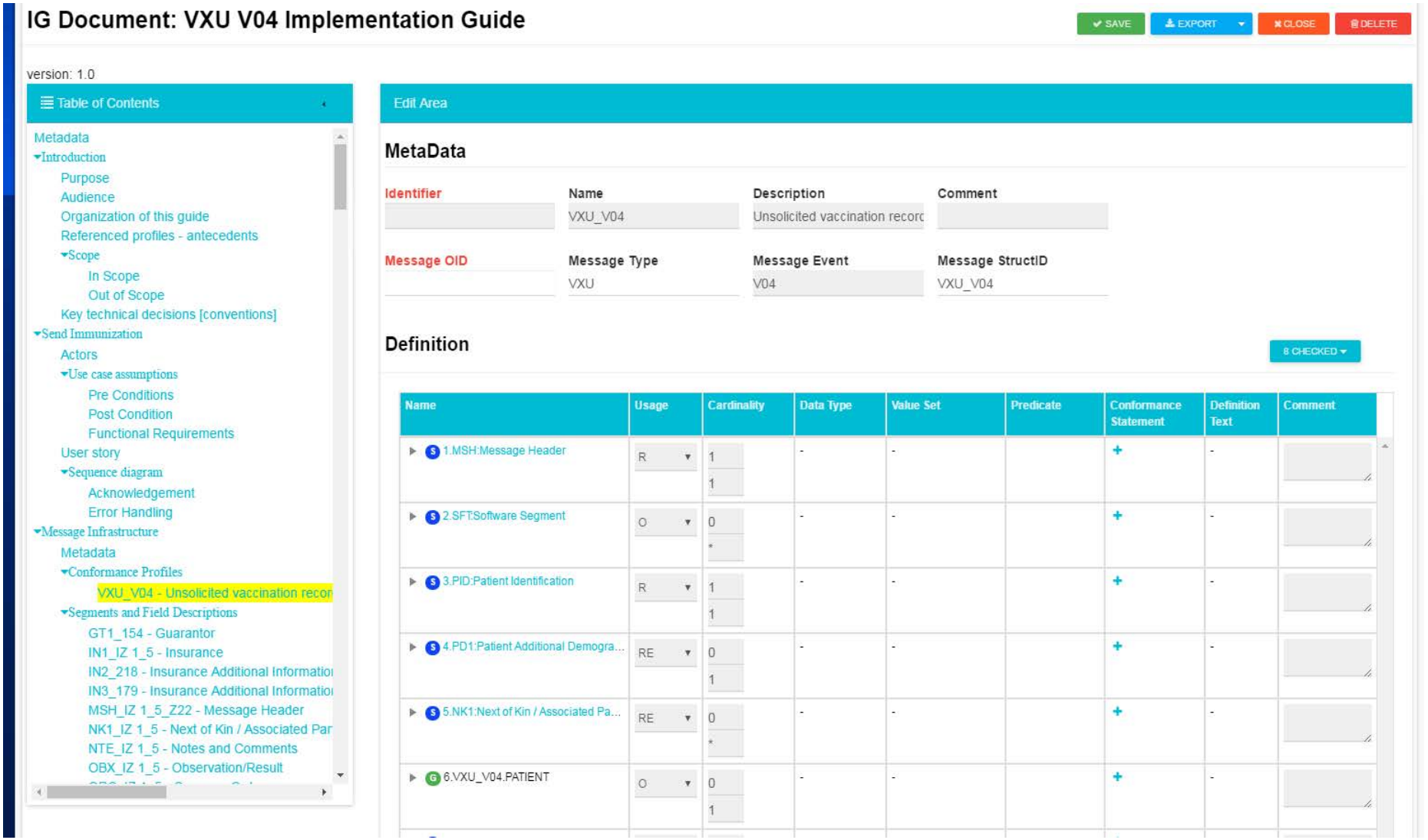
IGAMT – Navigation Bar (Segments)



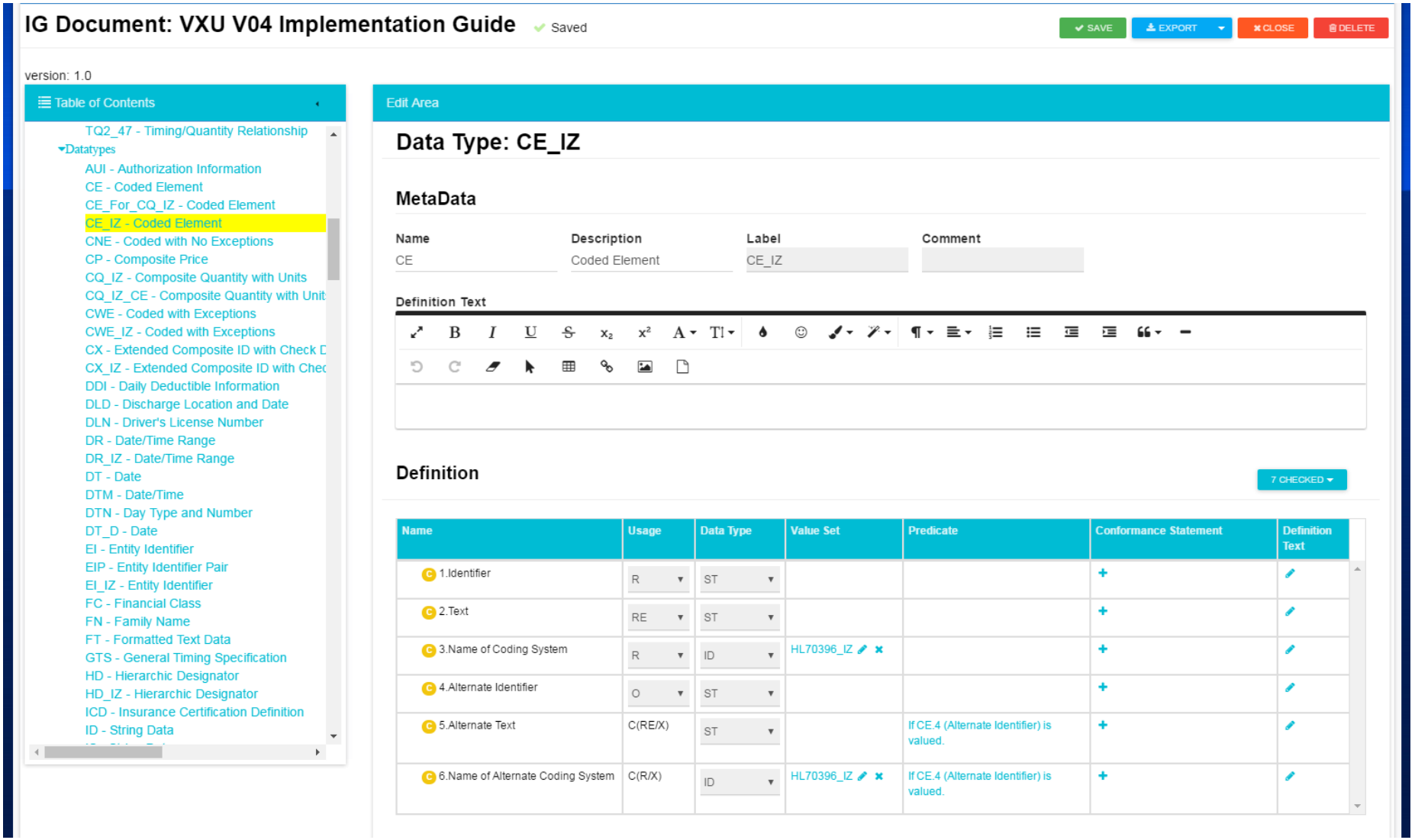
IGAMT – Navigation Bar (Value Sets)



IGAMT – Profiling (Message Level)



IGAMT – Profiling (Data Types)



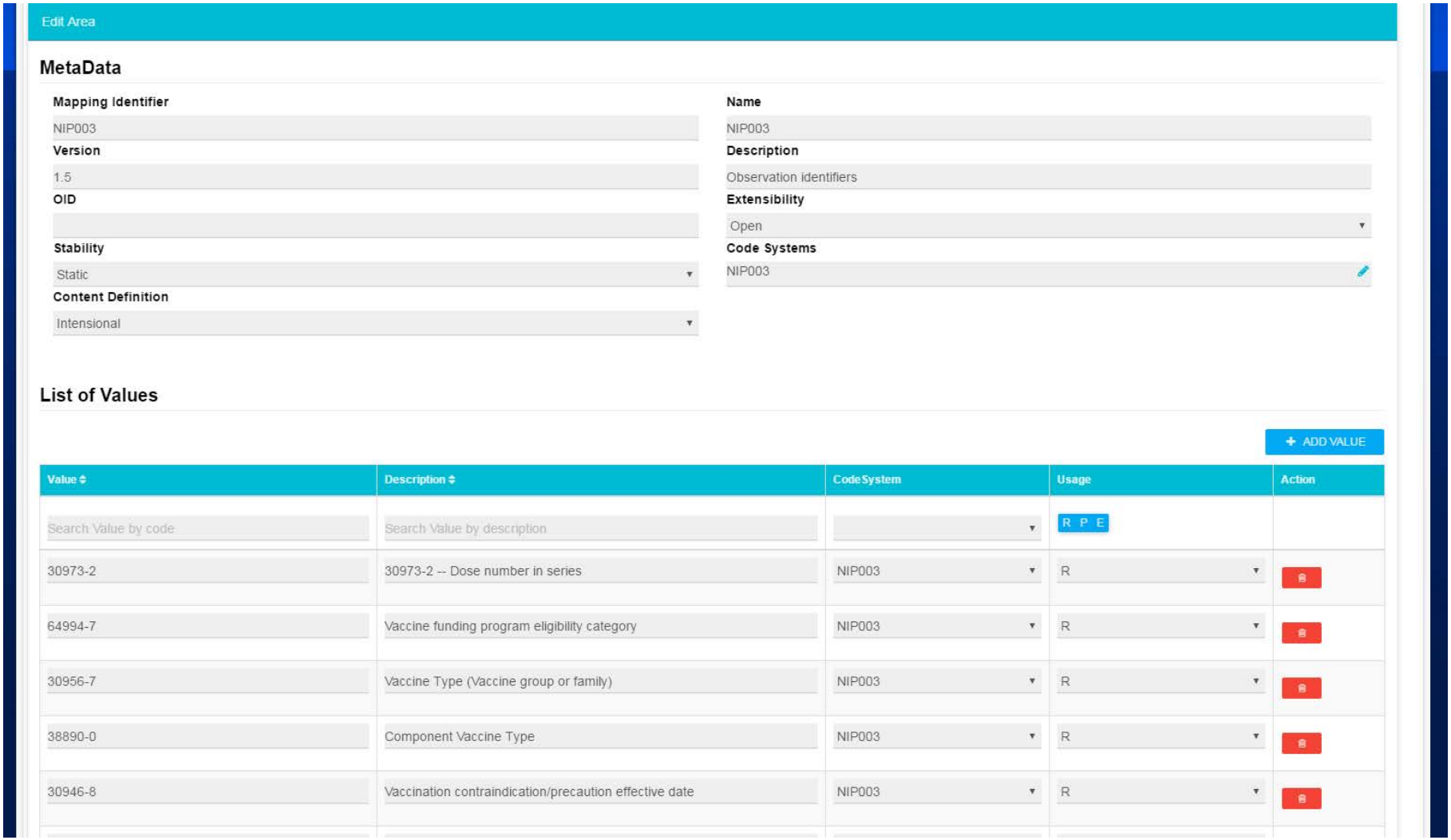
IGAMT – Profiling (Segments)

Definition

8 CHECKED

Name	Usage	Cardinality	Data Type	Value Set	Predicate	Conformance Statement	Definition Text	Comment
F 1.Give Sub-ID Counter	R	1..1	NM			[IZ-28]The value of RXA.1 (Give Sub-ID Counter) SHALL be '0'.		
F 2.Administration Sub-ID Counter	R	1..1	NM			[IZ-29]The value of RXA.2 (Administration Sub-ID Counter) SHALL be '1'.		
▶ F 3.Date/Time Start of Administration	R	1..1	TS_NZ	+		[IZ-TS_NZ]The value of RXA.3.1 (Time) SHALL be formatted with YYYYMMDD.		
▶ F 4.Date/Time End of Administration	O	0..1	TS	+		[IZ-30]If RXA.4.1 (Time) is valued, then RXA.4.1 (Time) SHALL be identical to the RXA.3.1 (Time).		
▼ F 5.Administered Code	R	1..1	CE_IZ	CVX		+		
C 1.Identifier	R	-	ST					
C 2.Text	RE	-	ST					
C 3.Name of Coding System	R	-	ID	HL70396_IZ				
C 4.Alternate Identifier	O	-	ST					
C 5.Alternate Text	C(RE/X)	-	ST		If CE.4 (Alternate Identifier) is valued.			
C 6.Name of Alternate Coding Sy...	C(R/X)	-	ID	HL70396_IZ	If CE.4 (Alternate Identifier) is valued.			
F 6.Administered Amount	R	1..1	NM			[IZ-49]If the value of RXA.5.1 (Identifier) is '998', then the value of RXA.6 (Administered Amount) SHALL be '999'. [IZ-48]If RXA.20 (Completion Status) is valued and the value of RXA.20 (Completion Status) is 'RE' then the value of RXA.6 (Administered Amount) SHALL be '999'. [IZ-50]If RXA.9[1].1 (Identifier) is not valued or the value of RXA.9[1].1		

IGAMT – Profiling (Value Sets)



HEALTH IT
STANDARDS TESTING INFRASTRUCTURE

Future Work

In-progress and Planned

National Institute of Standards and Technology

NIST Future Work

- Test Plan for IIS Functional Requirements
- Test Plan and Reference Implementation for Acknowledgements
- Test Case Authoring and Management Tool
- Test Plan for Clinical Decision Support (CDI)
- Further integration of DQA into Web Services and Acknowledgement Testing
- Continue improvement of the Test Suite
- Continue improvements of IGAMT

HEALTH IT
STANDARDS TESTING INFRASTRUCTURE

Thank You!

Questions?

HEALTH IT
STANDARDS TESTING INFRASTRUCTURE

NIST Immunization Test Suite Tutorial

Robert Snelick

National Institute of Standards and Technology
April 1st, 2016

Contact: rsnelick@nist.gov

NIST Immunization Test Suite Tool Overview

Tool Key Capabilities	
SOAP Envelope Testing	The SOAP Envelop Testing ensures SOAP envelopes are correctly formed, validating the conformance of the messages to the requirements in the SOAP and Transport specifications. *This is not used for ONC certification testing.*
SOAP Connectivity Testing	The SOAP Connectivity Testing evaluates valid SOAP connectivity, the ability to send and receive SOAP messages, validating the conformance of the messages to the requirements in the SOAP and Transport specifications. *This is not used for ONC certification testing.*
Context-Free Testing	Provides a simple and convenient method for testing immunization messages structure and most vocabulary. Validation is perform on messages with or without a SOAP wrapper.
Context-Based Testing **2015 ONC Certified**	Context-based testing provides in addition to HL7 Context-free validation, message validation associated with a given test script that includes data for a specific test scenario where the context is known by the validation tool. It also validate messages with a SOAP wrapper.
Isolated Testing	Isolated testing provides a simulated operational environment that allows validation at the functional level in addition to content and context-free testing, where Test Agents simulates the functions of IZ EHR-S or IIS.

Version: v1.0-beta

Environment: The NIST IZ Test Suite is currently only accessible as a web application.

Supported Browsers: Firefox, Chrome and Safari

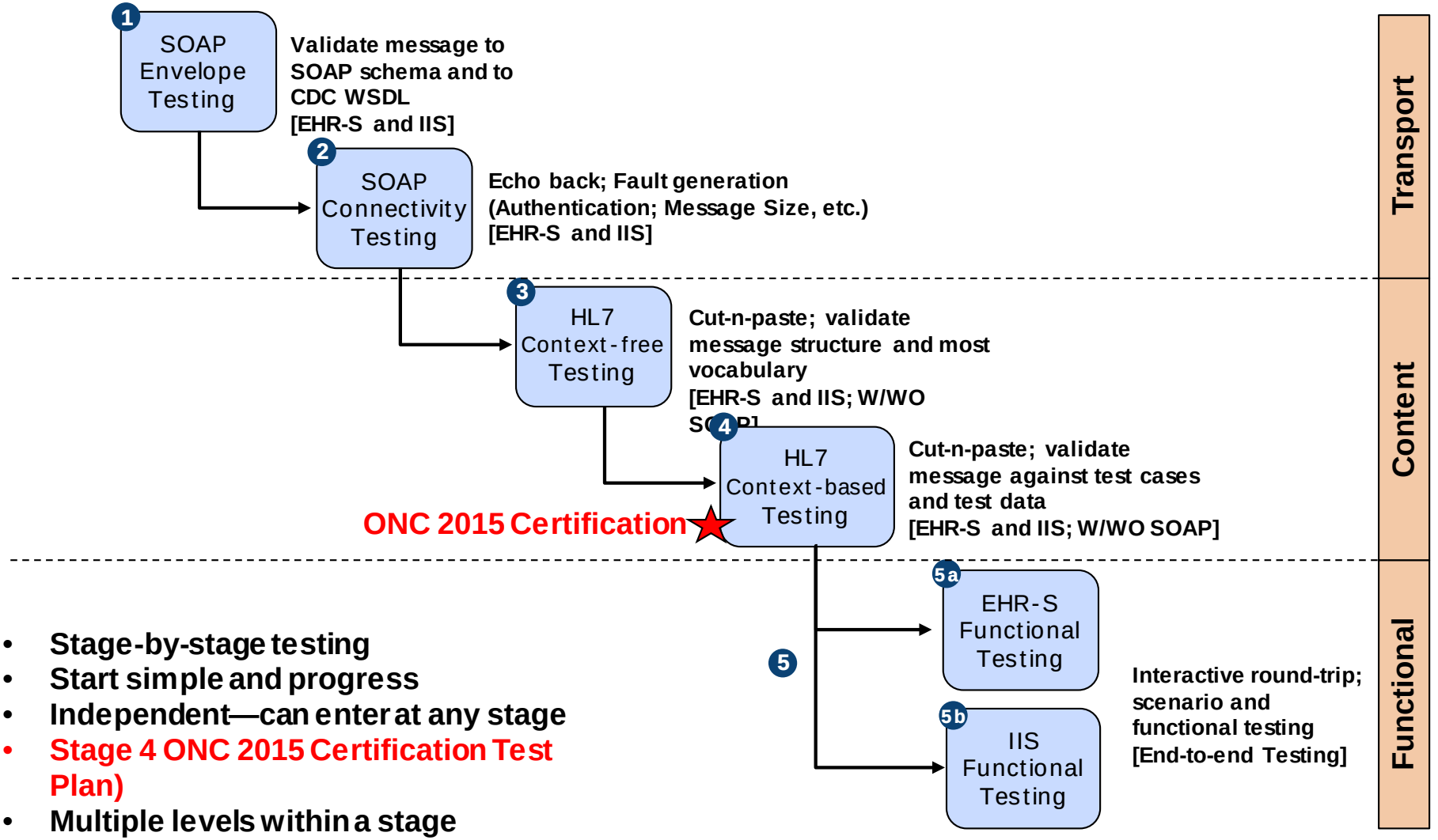
URL: http://hl7v2-iz-r1.5-testing.nist.gov

HEALTH IT
STANDARDS TESTING INFRASTRUCTURE

HL7 Context-free Testing Walk Through Tool Demonstration

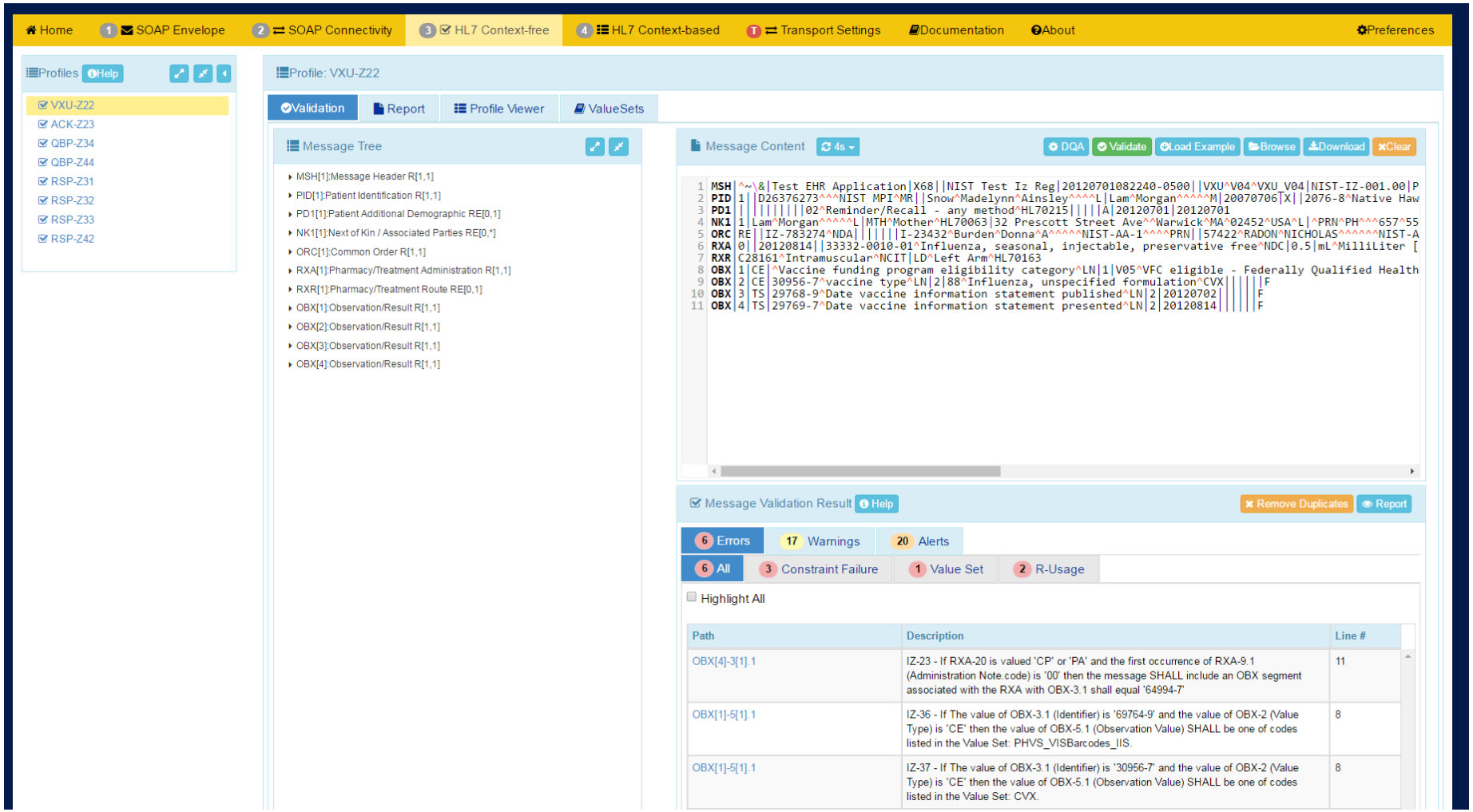
National Institute of Standards and Technology

Immunization Test Suite: Overview and Capabilities



- Stage-by-stage testing
- Start simple and progress
- Independent—can enter at any stage
- Stage 4 ONC 2015 Certification Test Plan)
- Multiple levels within a stage
- Detailed test cases and associated data

Context-Free Testing



Context-Free Testing

Context-Free Testing

Message Validation Result | Help | Remove Duplicates | Report

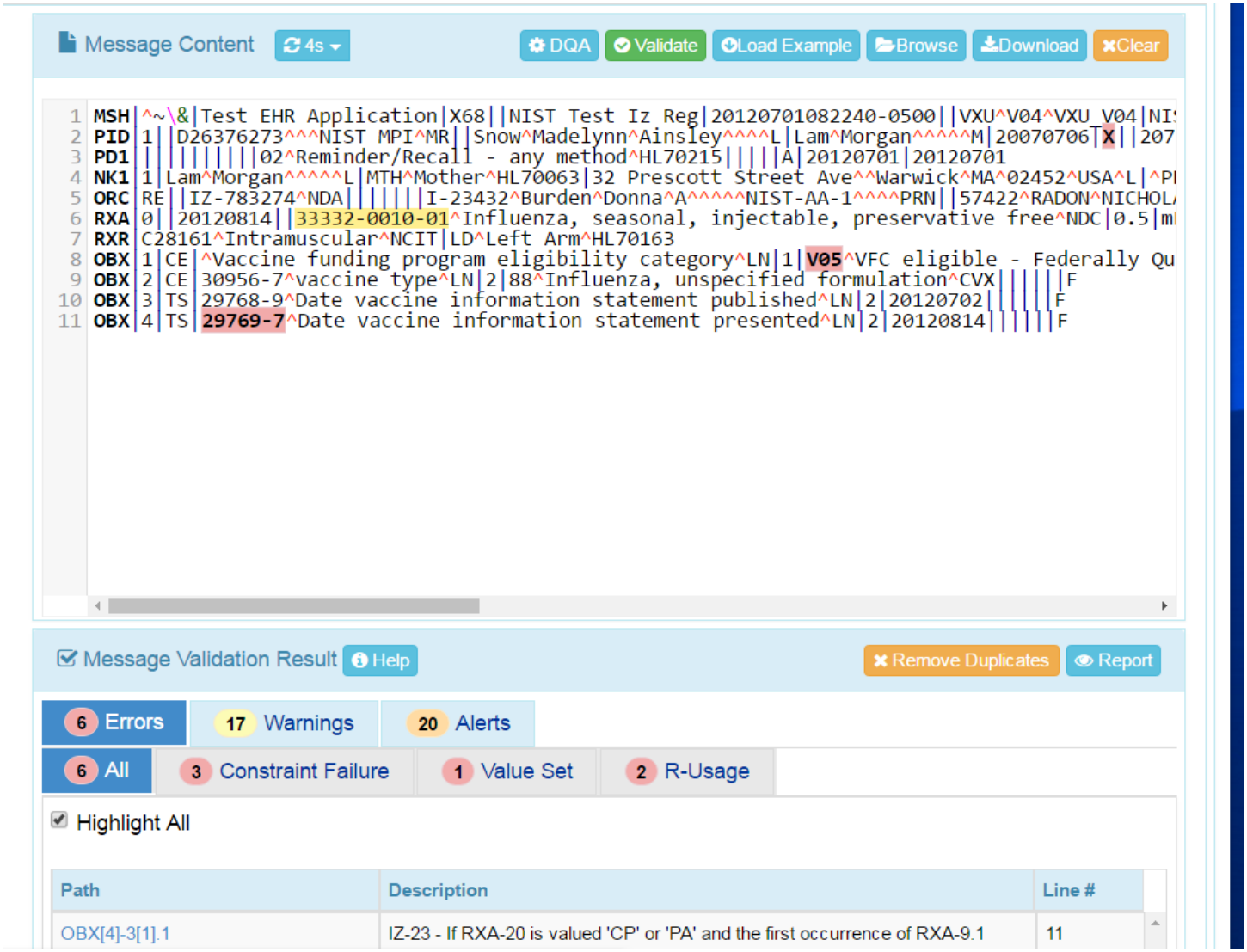
6 Errors | 17 Warnings | 20 Alerts

6 All | 3 Constraint Failure | 1 Value Set | 2 R-Usage

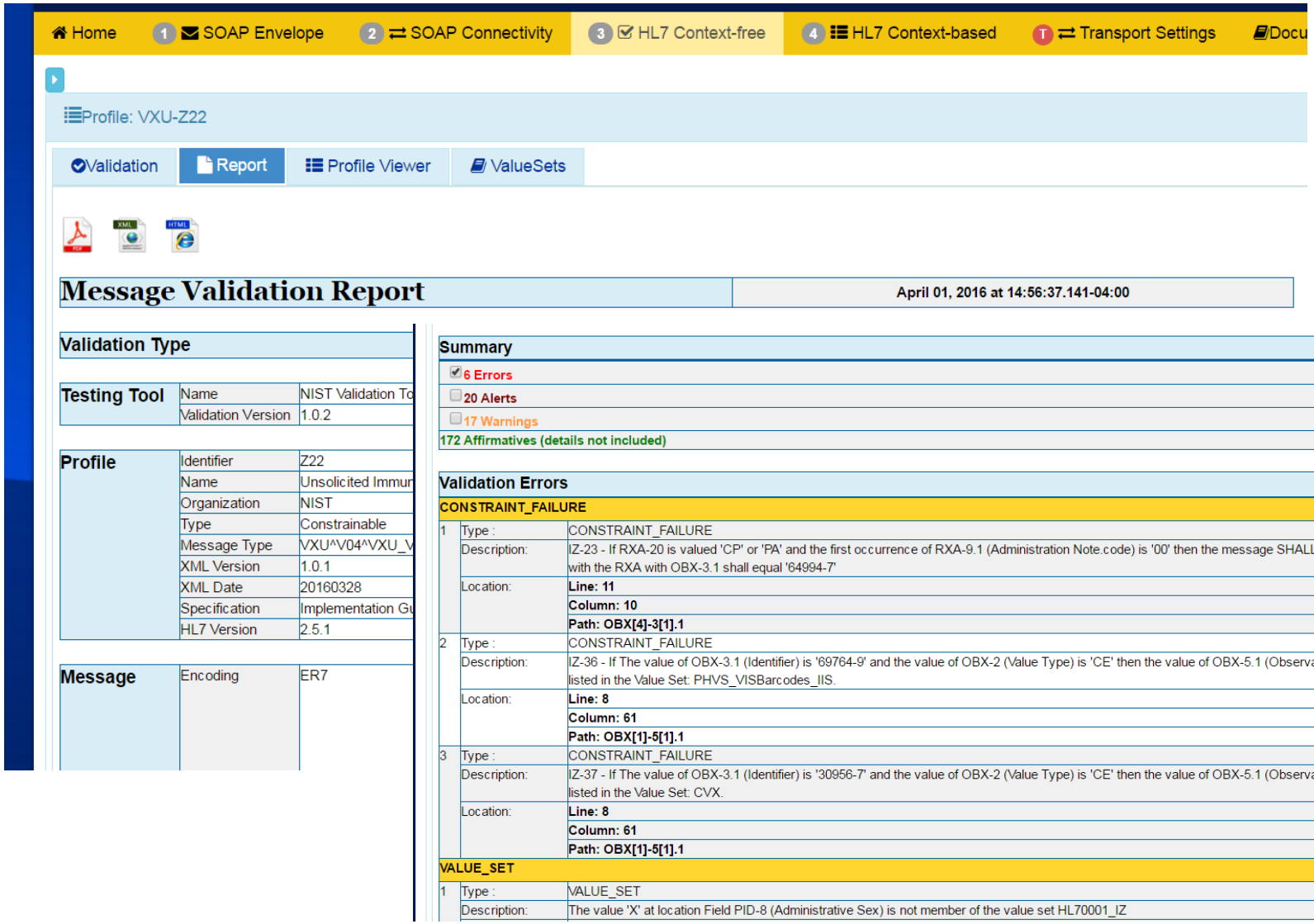
Highlight All

Path	Description	Line #
OBX[4]-3[1].1	IZ-23 - If RXA-20 is valued 'CP' or 'PA' and the first occurrence of RXA-9.1 (Administration Note.code) is '00' then the message SHALL include an OBX segment associated with the RXA with OBX-3.1 shall equal '64994-7'	11
OBX[1]-5[1].1	IZ-36 - If The value of OBX-3.1 (Identifier) is '69764-9' and the value of OBX-2 (Value Type) is 'CE' then the value of OBX-5.1 (Observation Value) SHALL be one of codes listed in the Value Set: PHVS_VISBarcodes_IIS.	8
OBX[1]-5[1].1	IZ-37 - If The value of OBX-3.1 (Identifier) is '30956-7' and the value of OBX-2 (Value Type) is 'CE' then the value of OBX-5.1 (Observation Value) SHALL be one of codes listed in the Value Set: CVX.	8
PID[1]-8[1]	The value 'X' at location Field PID-8 (Administrative Sex) is not member of the value set HL70001_IZ	2
OBX[1]-3[1].1	The required Component OBX-3.1 (Identifier) is missing	8
RXA[1]-2[1]	The required Field RXA-2 (Administration Sub-ID Counter) is missing	6

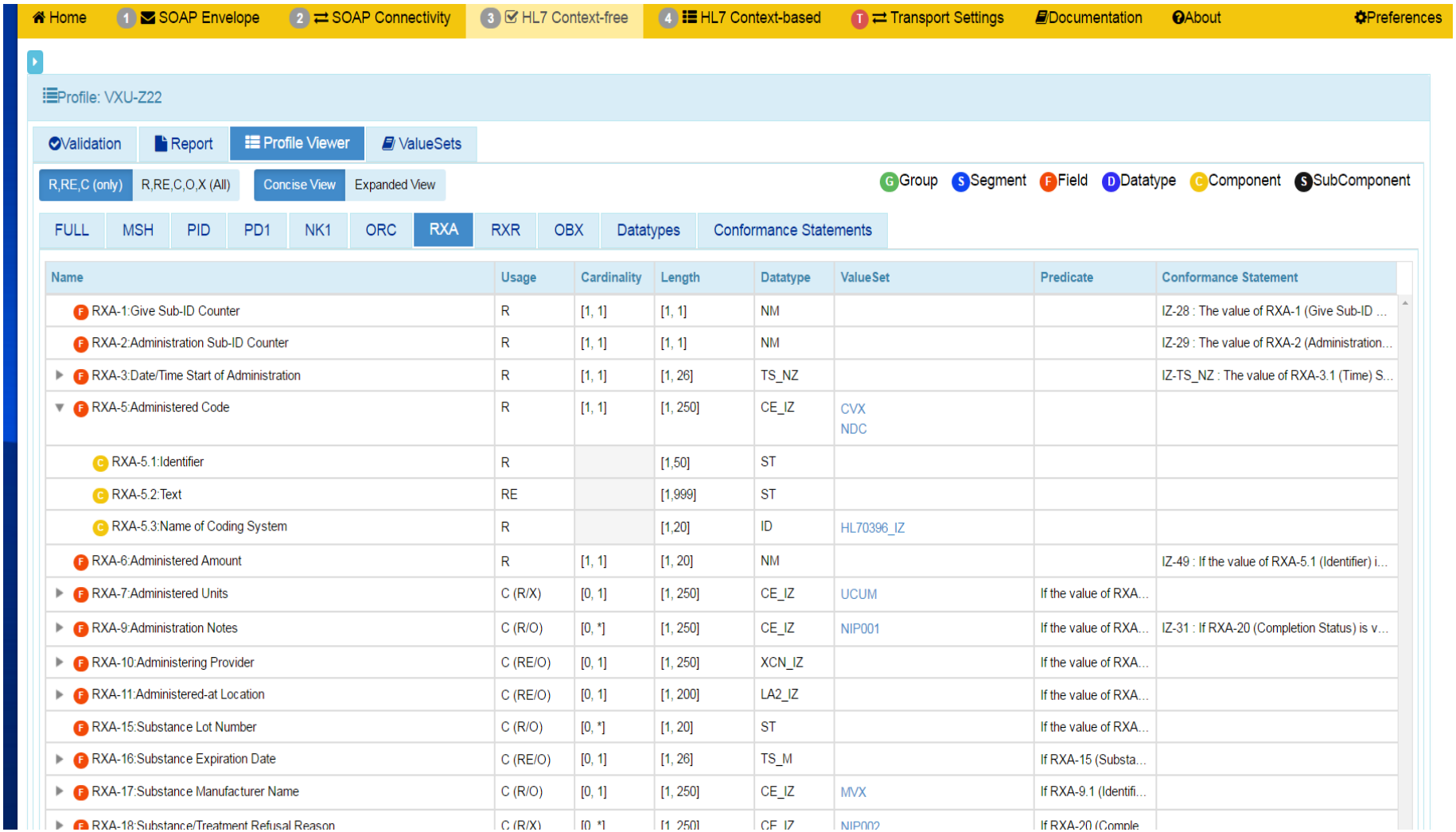
Context-Free Testing



Context-Free Testing

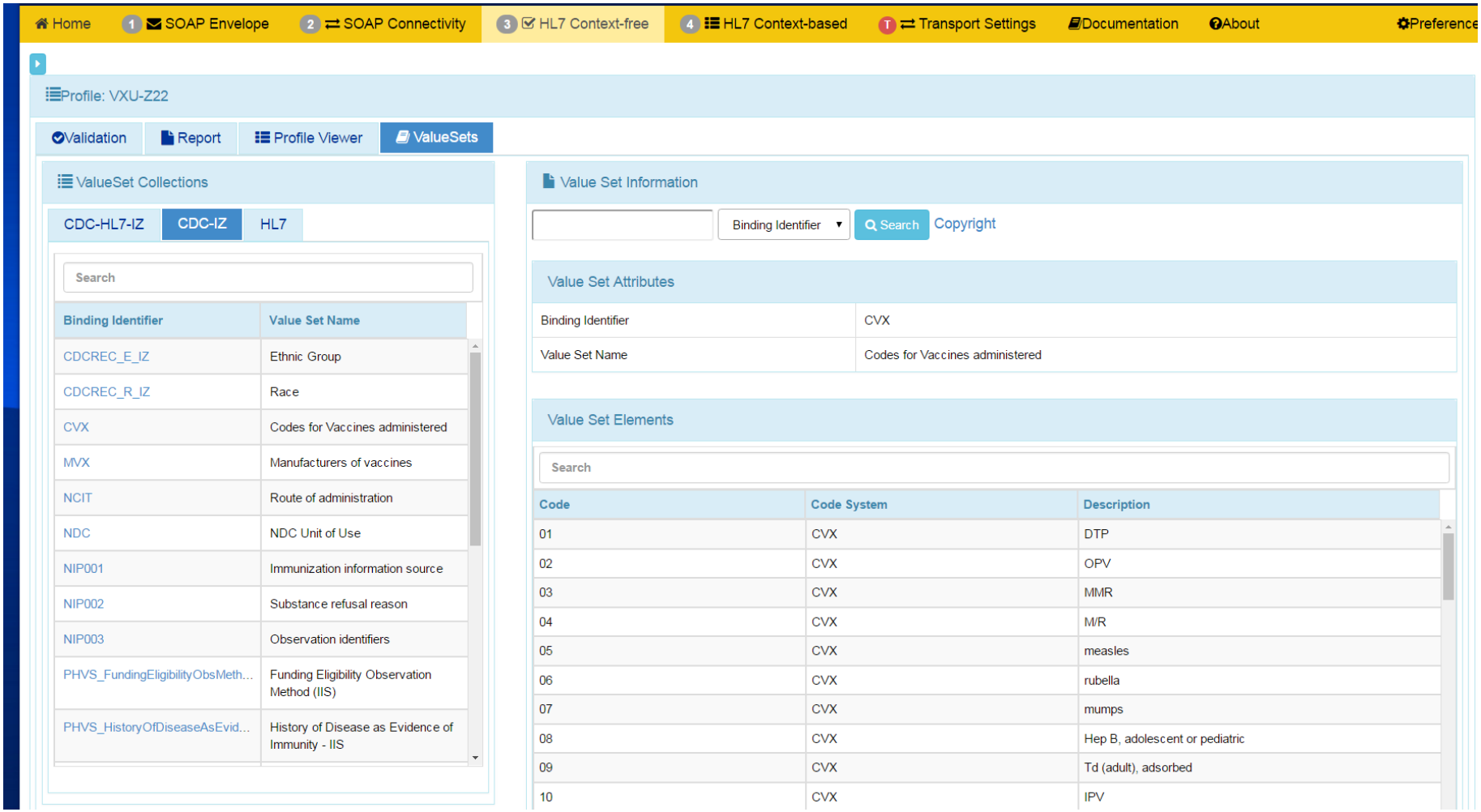


Profile Viewer



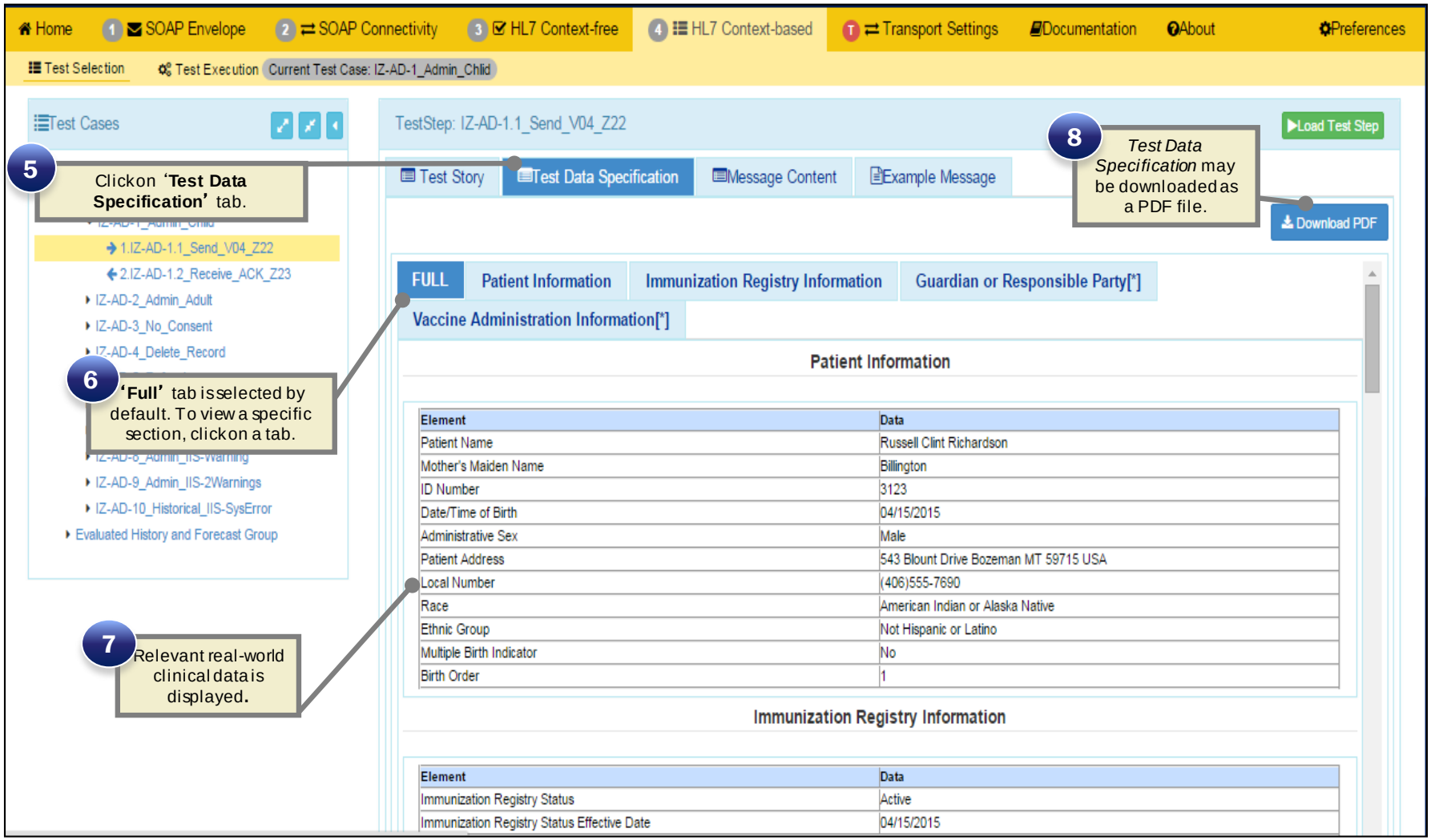
Name	Usage	Cardinality	Length	Datatype	ValueSet	Predicate	Conformance Statement
F RXA-1:Give Sub-ID Counter	R	[1, 1]	[1, 1]	NM			IZ-28 : The value of RXA-1 (Give Sub-ID ...
F RXA-2:Administration Sub-ID Counter	R	[1, 1]	[1, 1]	NM			IZ-29 : The value of RXA-2 (Administration...
▶ F RXA-3:Date/Time Start of Administration	R	[1, 1]	[1, 26]	TS_NZ			IZ-TS_NZ : The value of RXA-3.1 (Time) S...
▼ F RXA-5:Administered Code	R	[1, 1]	[1, 250]	CE_IZ	CVX NDC		
C RXA-5.1:Identifier	R		[1,50]	ST			
C RXA-5.2:Text	RE		[1,999]	ST			
C RXA-5.3:Name of Coding System	R		[1,20]	ID	HL70396_IZ		
F RXA-6:Administered Amount	R	[1, 1]	[1, 20]	NM			IZ-49 : If the value of RXA-5.1 (Identifier) i...
▶ F RXA-7:Administered Units	C (R/X)	[0, 1]	[1, 250]	CE_IZ	UCUM	If the value of RXA...	
▶ F RXA-9:Administration Notes	C (R/O)	[0, *]	[1, 250]	CE_IZ	NIP001	If the value of RXA...	IZ-31 : If RXA-20 (Completion Status) is v...
▶ F RXA-10:Administering Provider	C (RE/O)	[0, 1]	[1, 250]	XCN_IZ		If the value of RXA...	
▶ F RXA-11:Administered-at Location	C (RE/O)	[0, 1]	[1, 200]	LA2_IZ		If the value of RXA...	
F RXA-15:Substance Lot Number	C (R/O)	[0, *]	[1, 20]	ST		If the value of RXA...	
▶ F RXA-16:Substance Expiration Date	C (RE/O)	[0, 1]	[1, 26]	TS_M		If RXA-15 (Substa...	
▶ F RXA-17:Substance Manufacturer Name	C (R/O)	[0, 1]	[1, 250]	CE_IZ	MVX	If RXA-9.1 (Identifi...	
▶ F RXA-18:Substance/Treatment Refusal Reason	C (R/X)	[0, *]	[1, 250]	CE_IZ	NIP002	If RXA-20 (Comple	

Profile Viewer

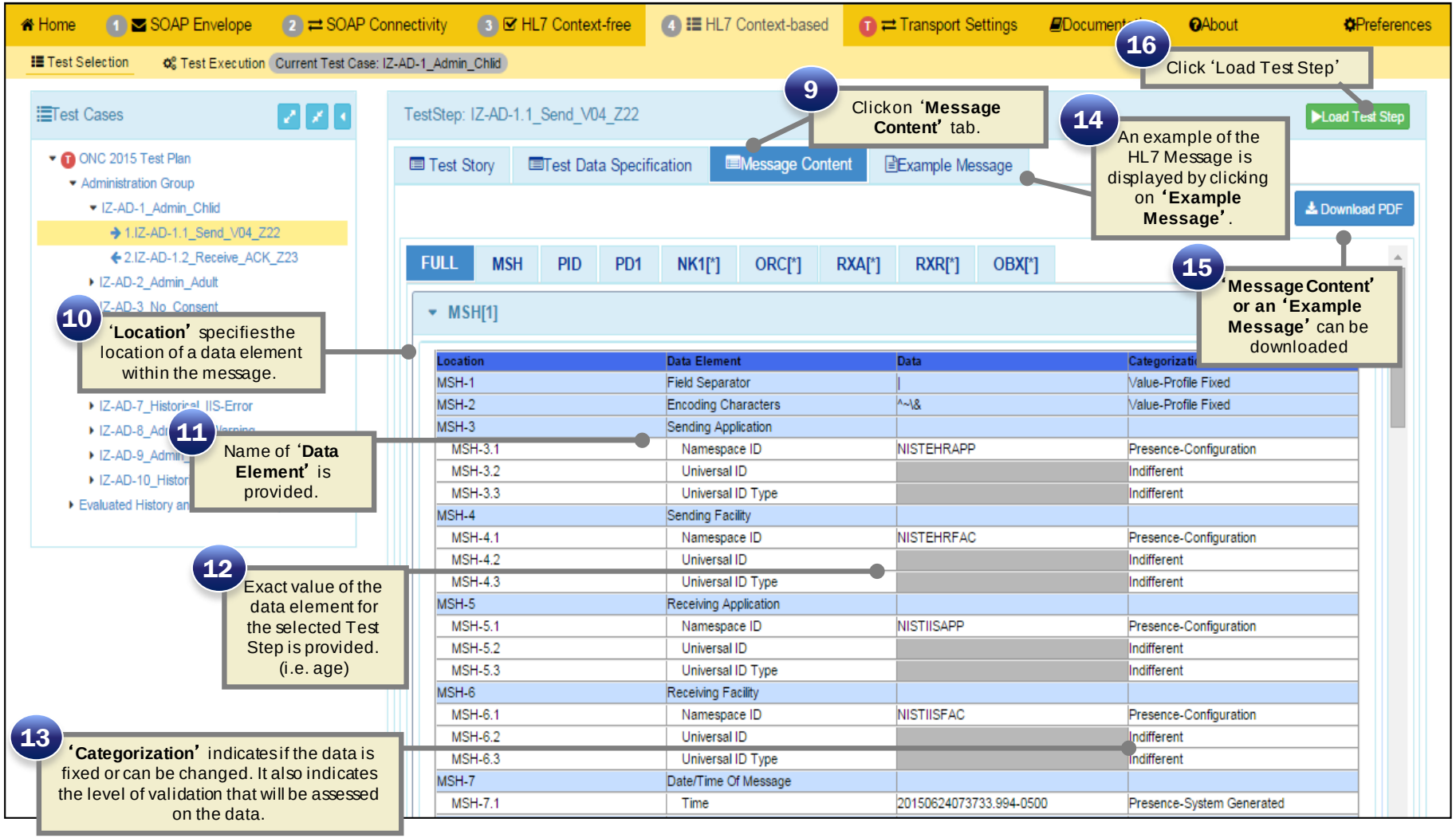


Context-based Message Validation (via Test Step)

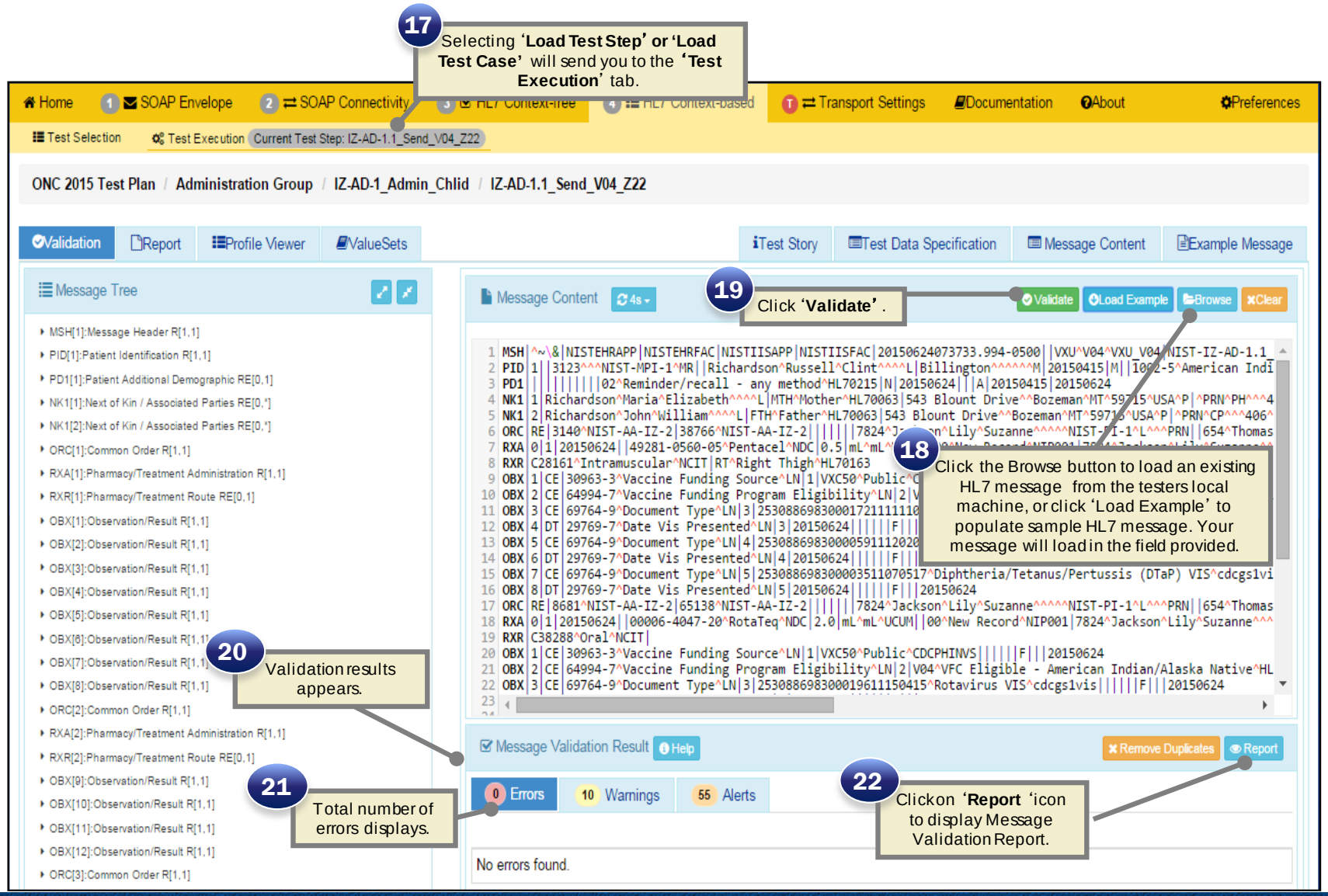
Context-based Message Validation (continued…)



Context-based Message (additional utilities)

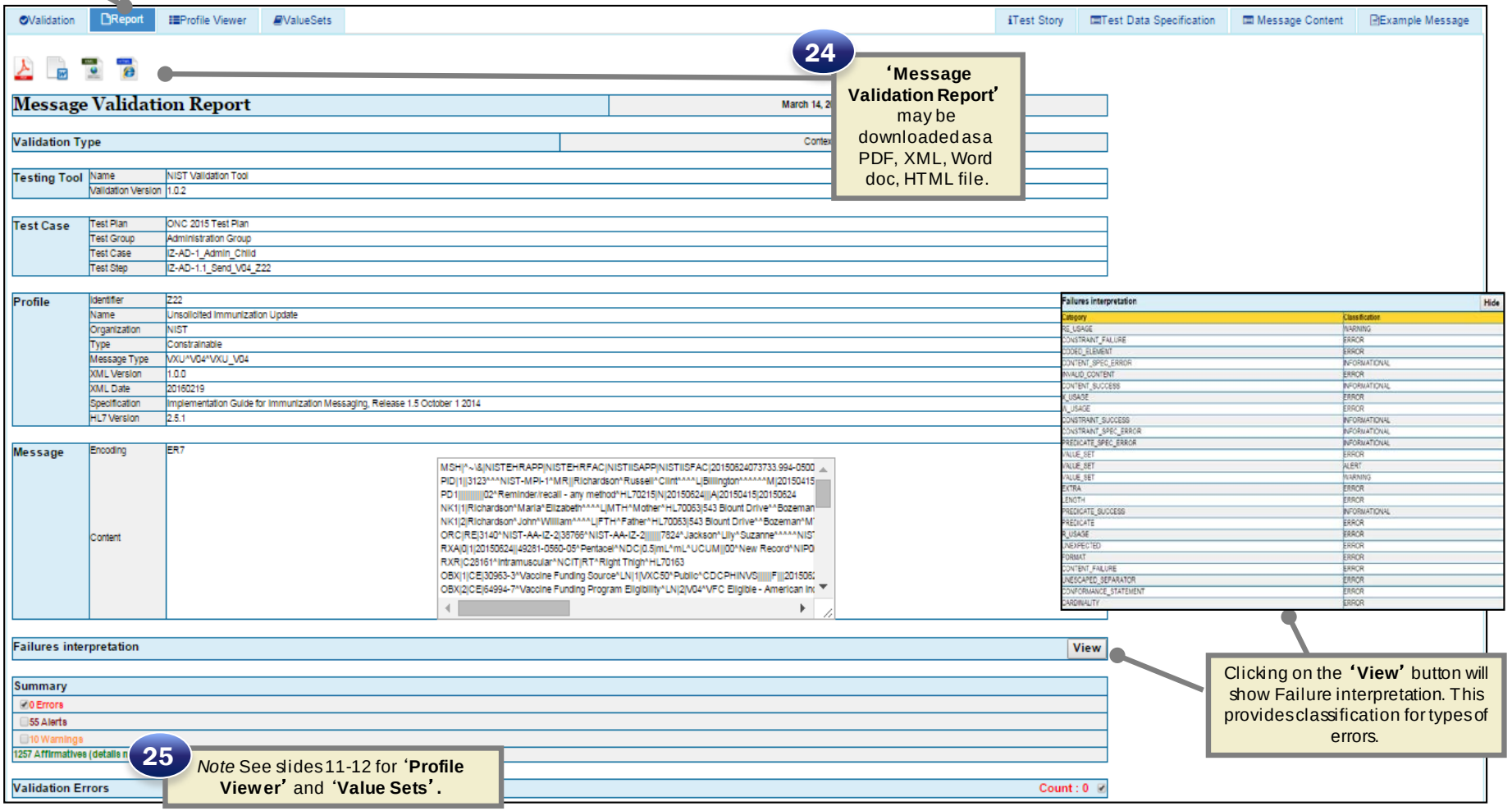


Context-based Testing Message Validation Report



Context-based Testing Message Validation Report (continued…)

23 After clicking **'Report'**, the Message Validation Report will appear.

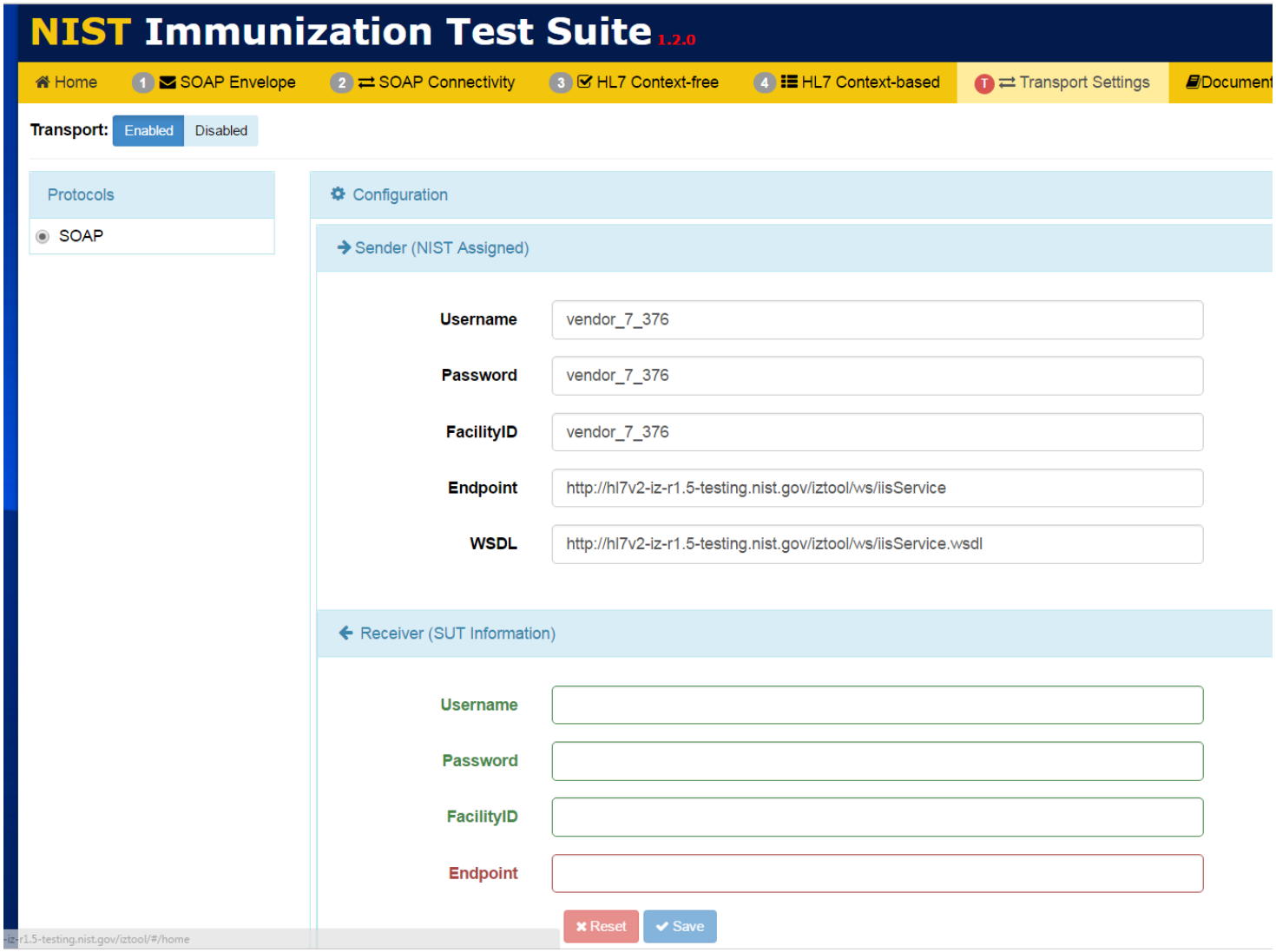


24 **'Message Validation Report'** may be downloaded as a PDF, XML, Word doc, HTML file.

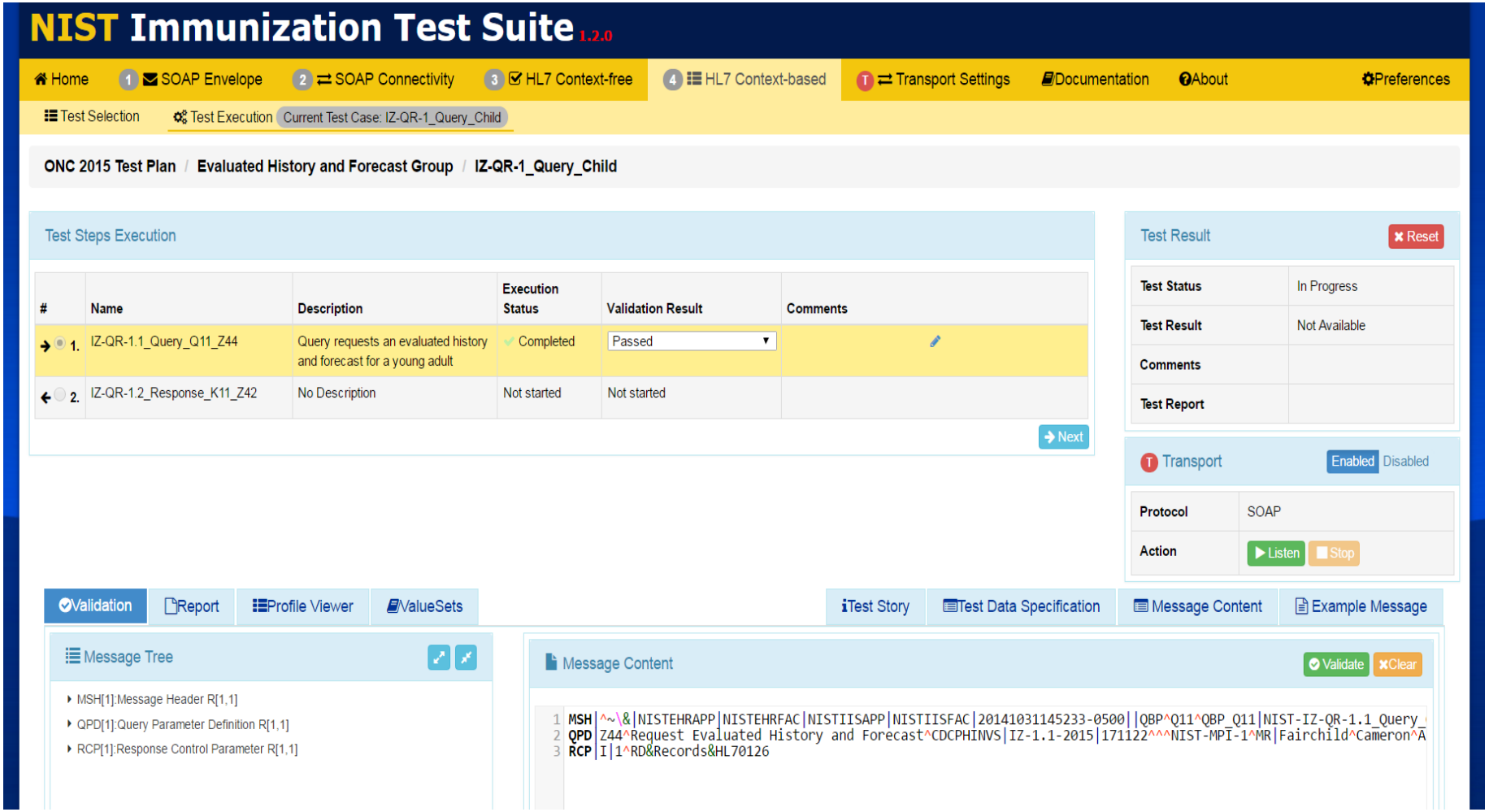
Clicking on the **'View'** button will show Failure interpretation. This provides classification for types of errors.

25 *Note* See slides 11-12 for **'Profile Viewer'** and **'Value Sets'**.

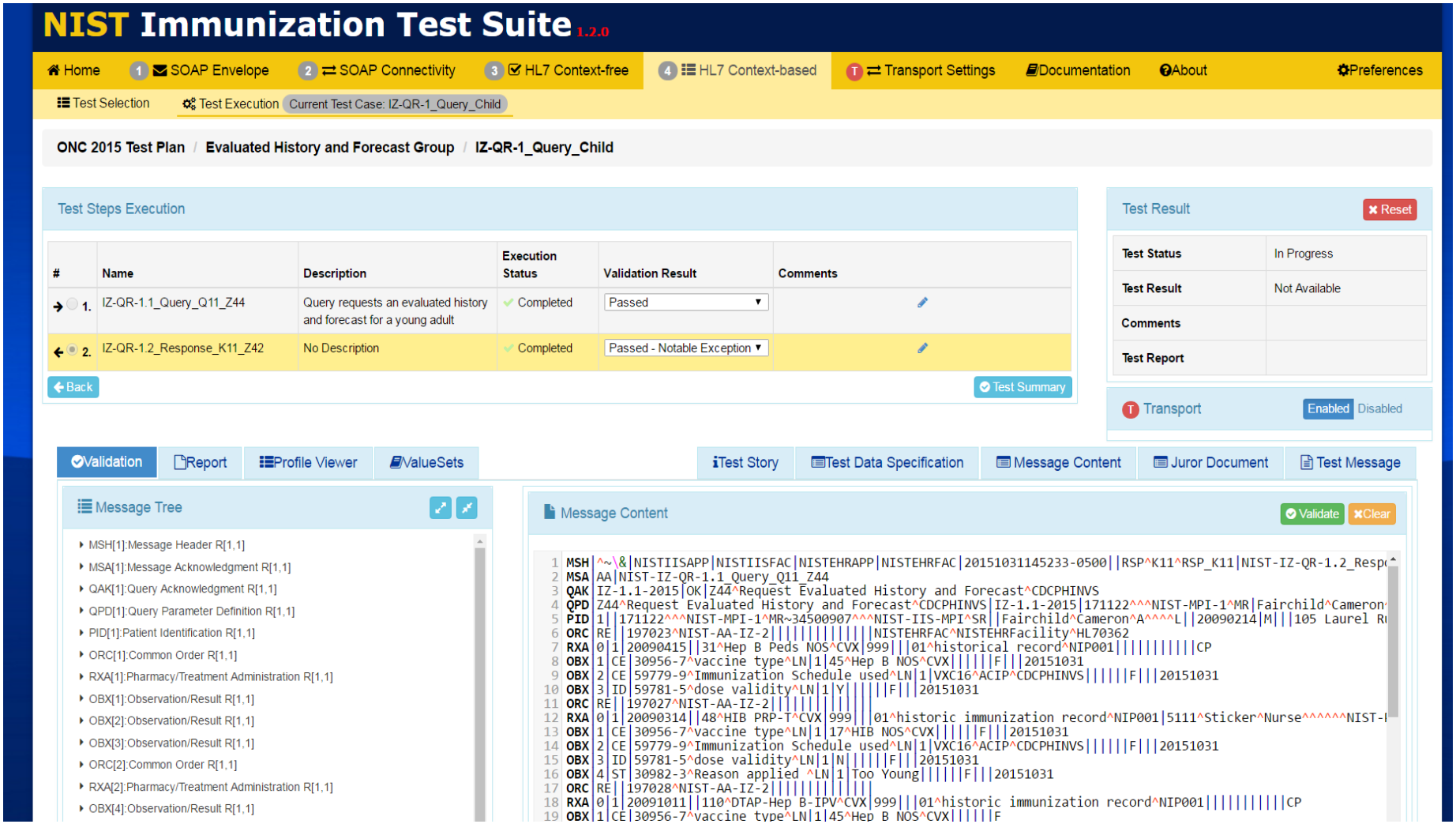
Testing with Direct Communication via SOAP



Testing with Direct Communication via SOAP



Testing with Direct Communication via SOAP



Documentation