HEALTH IT
STANDARDS TESTING INFRASTRUCTURE

Customizing and Testing State and Local Immunization HL7 v2 Implementation Guides

Using NIST IGAMT-lite and Immunization Test Suite

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April 21st, 2015

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AIRA AMERICAN IMMUNIZATION REGISTRY ASSOCIATION
Immunization Information Systems for a New Era

CDC

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Workshop Goals

- Create a local immunization VXU implementation Guide
- Gain a better understanding of HL7 v2.x Conformance Profiles and how to add constraints
- Gain an understanding of NIST Conformance Testing
  - Understand context-free testing
  - Learn to use test suite to validate messages against the CDC national guide and customized (local) guide
- Gain an understanding of how to leverage the NIST tools to improve your On-boarding process

Agenda

- Presentation (20 minutes)
  - Overview
  - HL7 v2.x Conformance Profiles and Profile Hierarchy
  - Applying Constraints to the National Standard
  - Conformance Profiles and Relationship to Conformance Testing

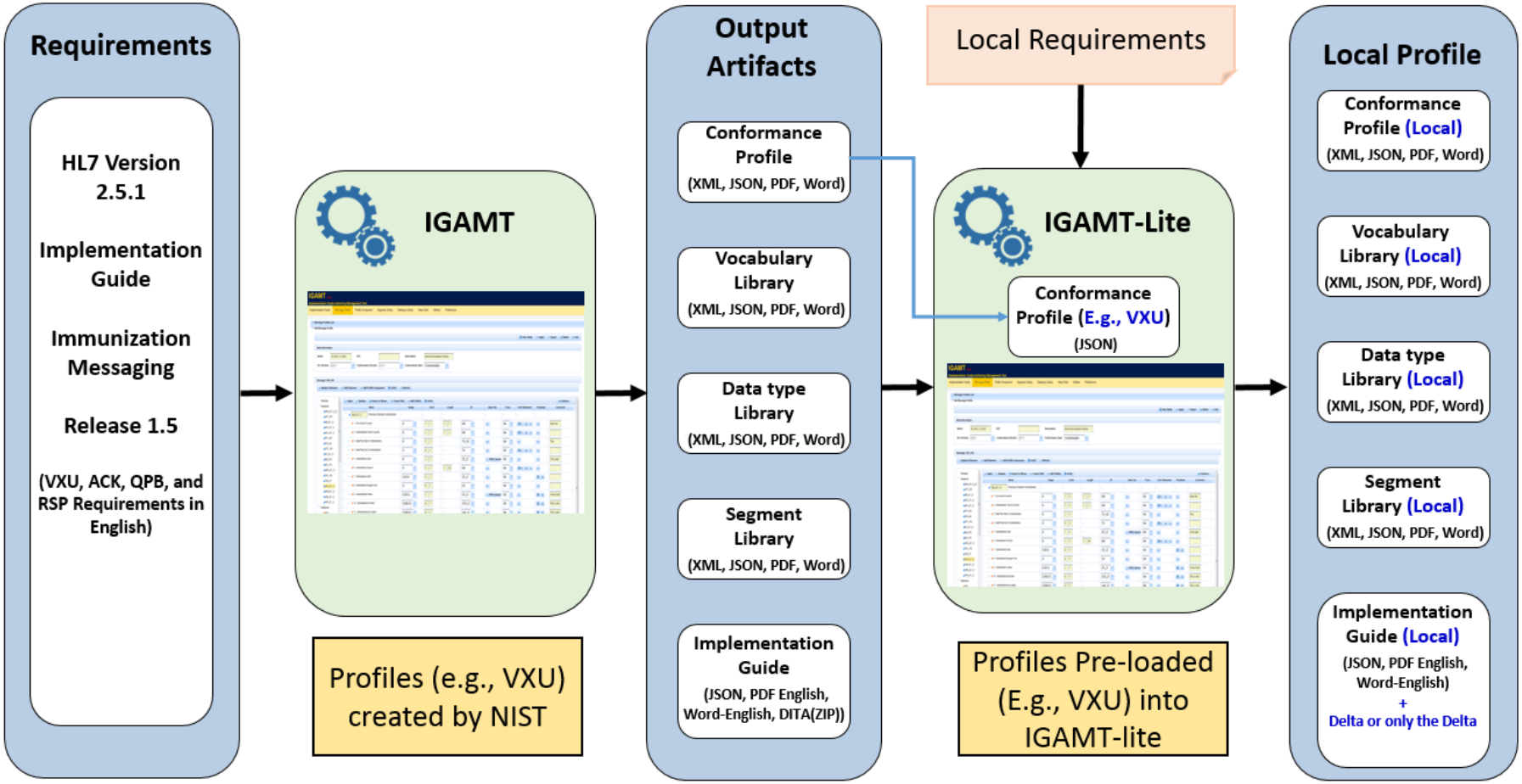
- Tutorial (20 minutes)
  - Case Study: California Immunization Registry (CAIR) Implementation Guide
  - Review of the local implementation guide template
  - Using IGAMT-lite
    - User Registration
    - Creating an Implementation Guide
    - Adding Constraints and additional text to further document local constraints
    - Exporting the Implementation Guide (human and machine readable)
  - Context-free Validation

- Hands-on (20 minutes)
  - Using IGAMT-lite to modify national profile for local requirements

Benefits of Using IGAMT-lite

- Provides a way to manage and publish your local requirements
  - Enforces compliance with national guide
    - Beneficial for local implementations
  - Creates and manages HL7 V2 requirements
    - Message Definition
    - Segment Tables
    - Data Type Tables
    - Value Sets
    - Conformance Statements
  - **Better Specification of Requirements**
- Provides a machine processable (XML) profile
  - Can be used for many purposes:
    - Validating messages
      - NIST Framework or Local (NIST could host local validation—future consideration)
      - Web Application or Web Service
    - Part of testing EHR-S and IIS functional requirements
    - Documenting and Comparing interfaces and implementations
    - Generating messages
    - Generating code

Overview of Profile Customization using IGAMT-lite



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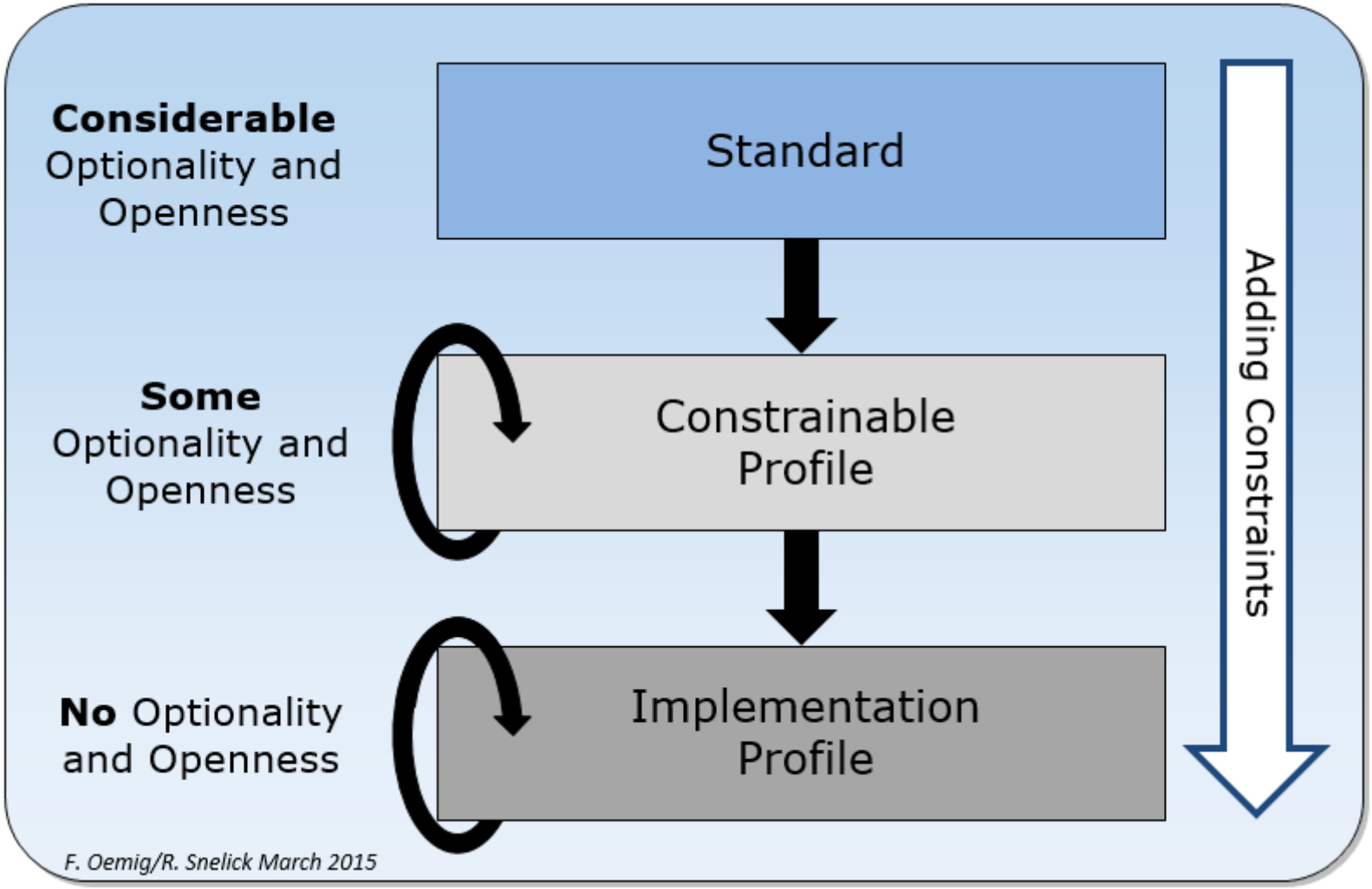
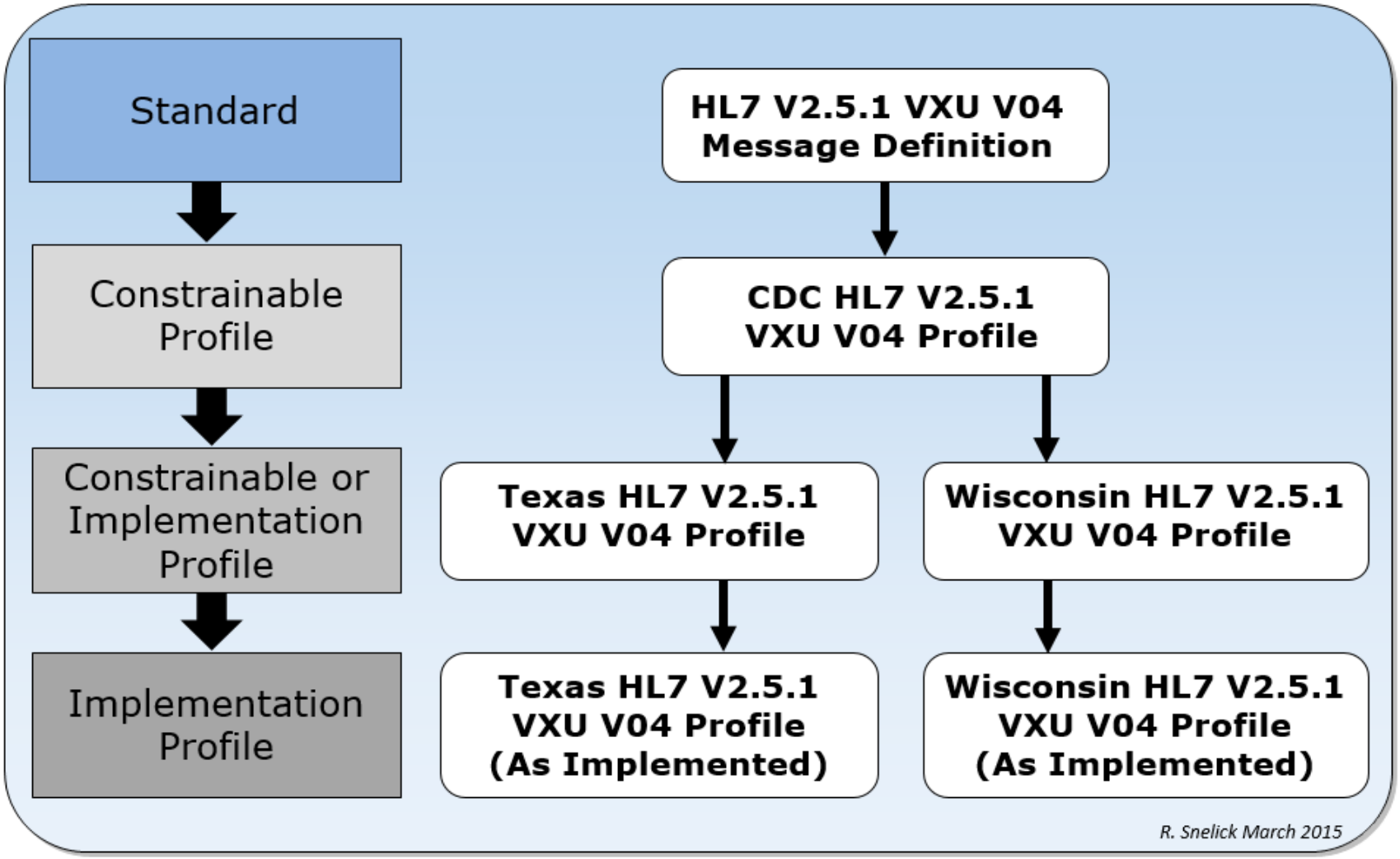
HL7 V2.x Profiling and Profile Hierarchy



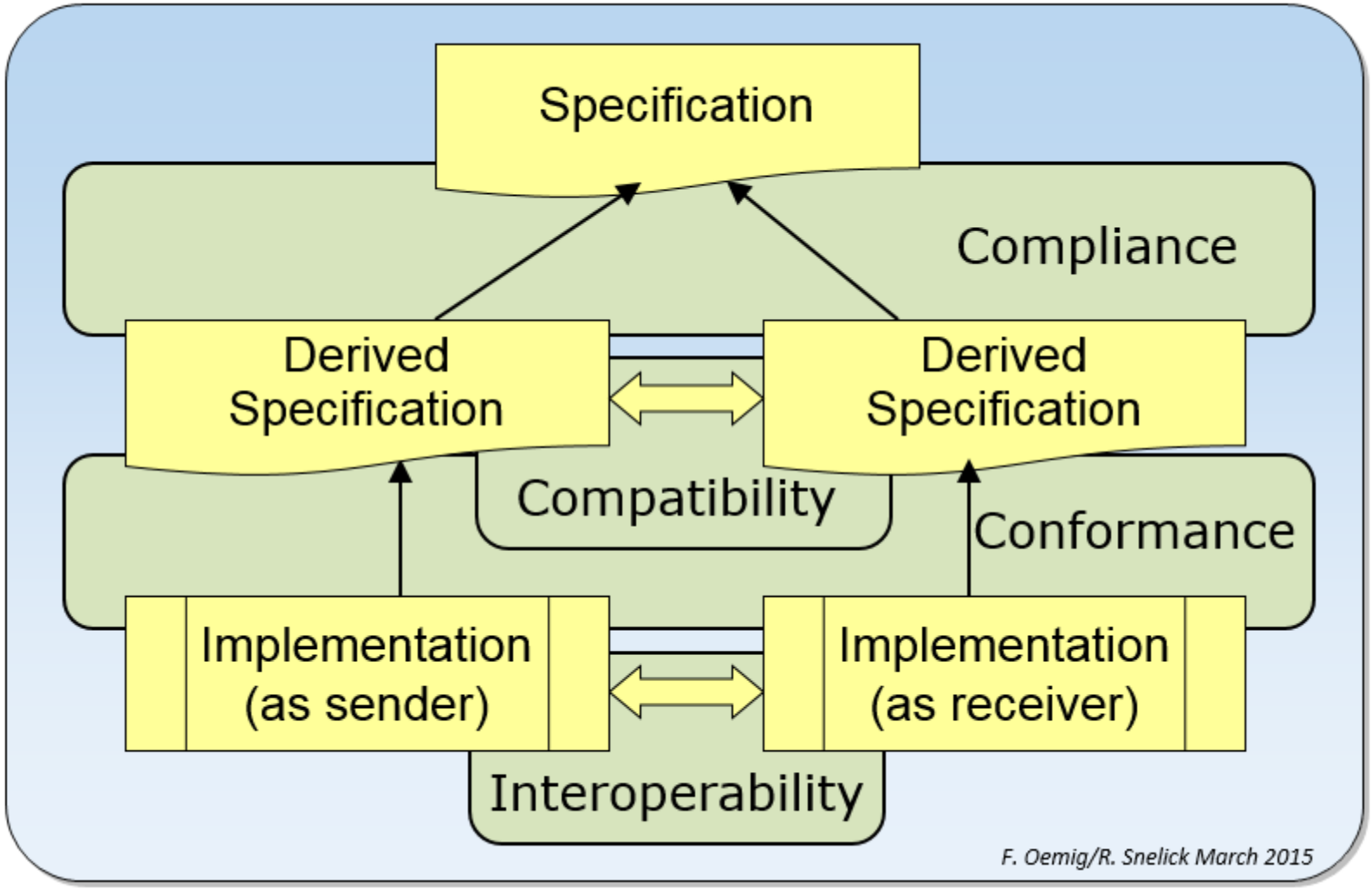
Applying Constraints

Constraint Type	Description	Examples
Usage	Indicates requirements for the presence (appearance) of an element. Also referred to as Appearance or Optionality indicator.	Constraint optional to required O → R
Cardinality	Indicates the number of occurrences for an element by specifying the minimum and maximum bounds.	Constrain the minimum cardinality from 0 (may be sent) to 1 (required to be sent) [0..1] → [1..1]
Data Type	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).	DT: Element 1 (R, 1..1); Element 2 (O, 0..*); Element 3 (O, 0..1); Element 4 (O, 0..*) → DT_IZ: Element 1 (R, 1..1); Element 2 (RE, 0..5); Element 3 (X, 0..0); Element 4 (O, 0..*)
Value	Defines the allowable values for a coded element (i.e., a list of values).	[M, F, U, O, A] → [M, F, U]
Length	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.	80 Element may have at most 80 characters. [2..4] Element may have at minimum 2 and at most 4 characters.
Predicate (Conformance Statement)	Provides an explicit normative statement expressed in text or a testable expression that defines a constraint. Also referred to as a "conformance statement".	PID.6.7 (Mother's Maiden Name – Name Type Code) SHALL be valued "M".

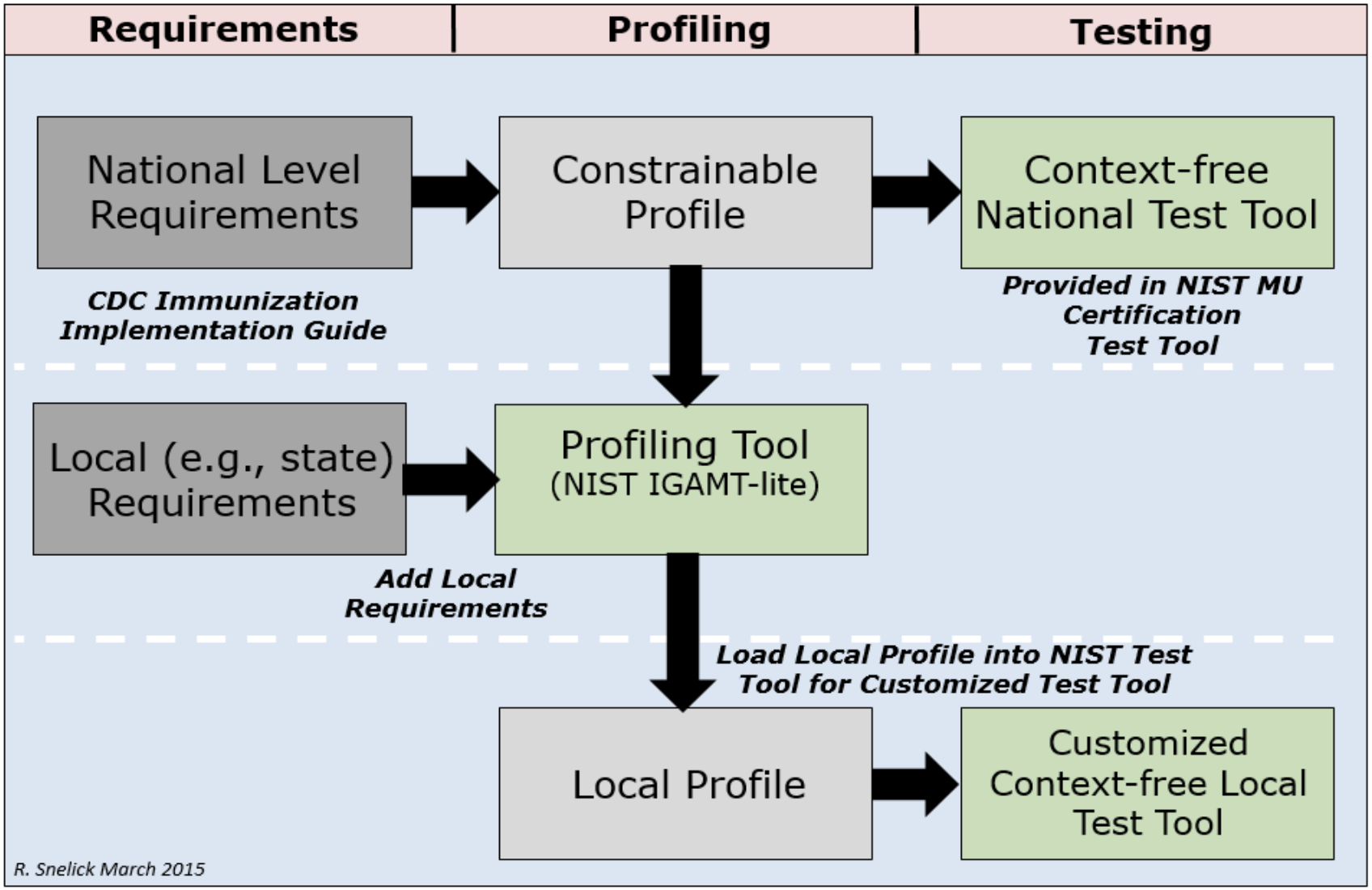
Creating Local Profiles



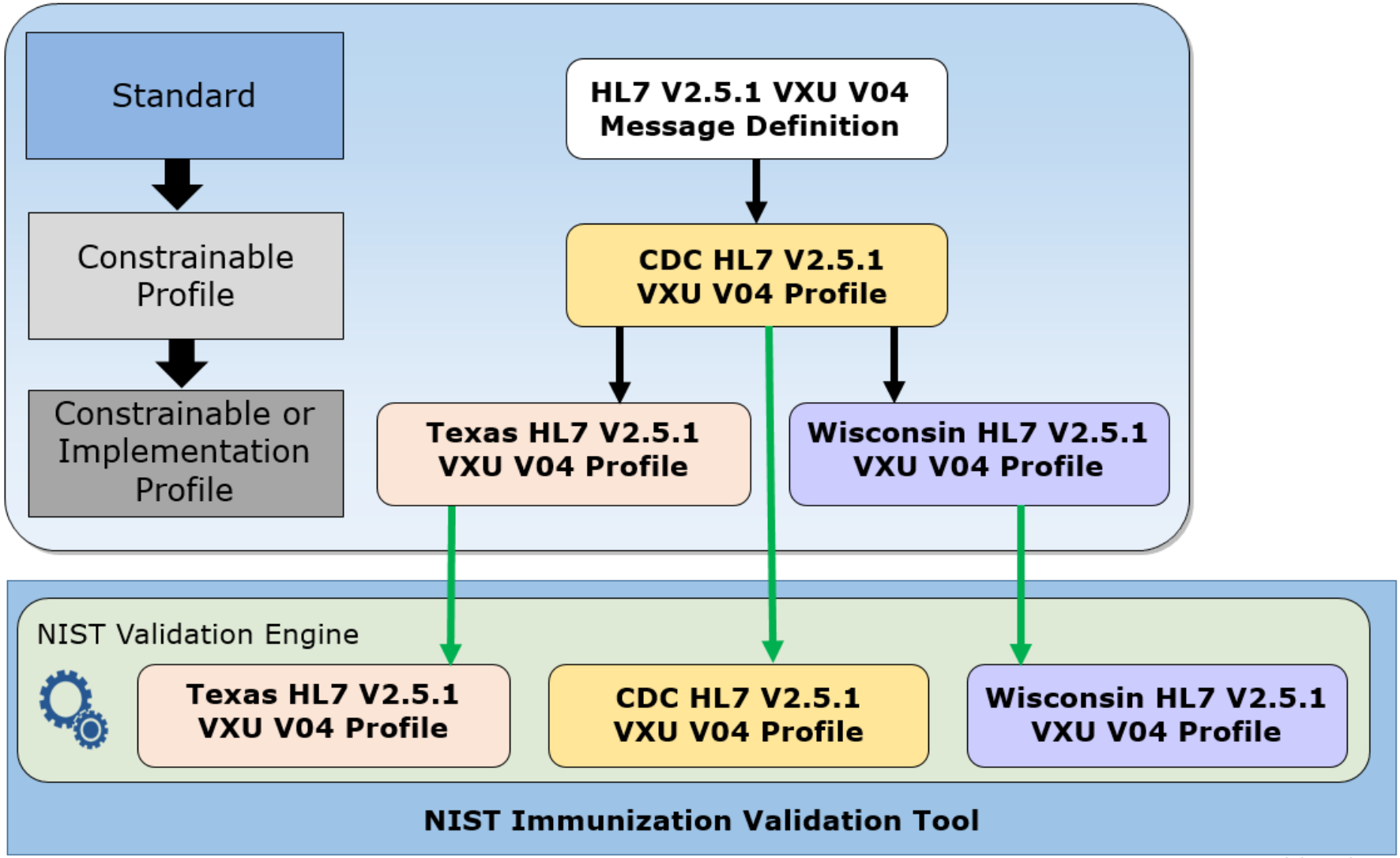
Understanding Profiling Terms



Profiling and Testing



Conformance Testing of Local Profiles



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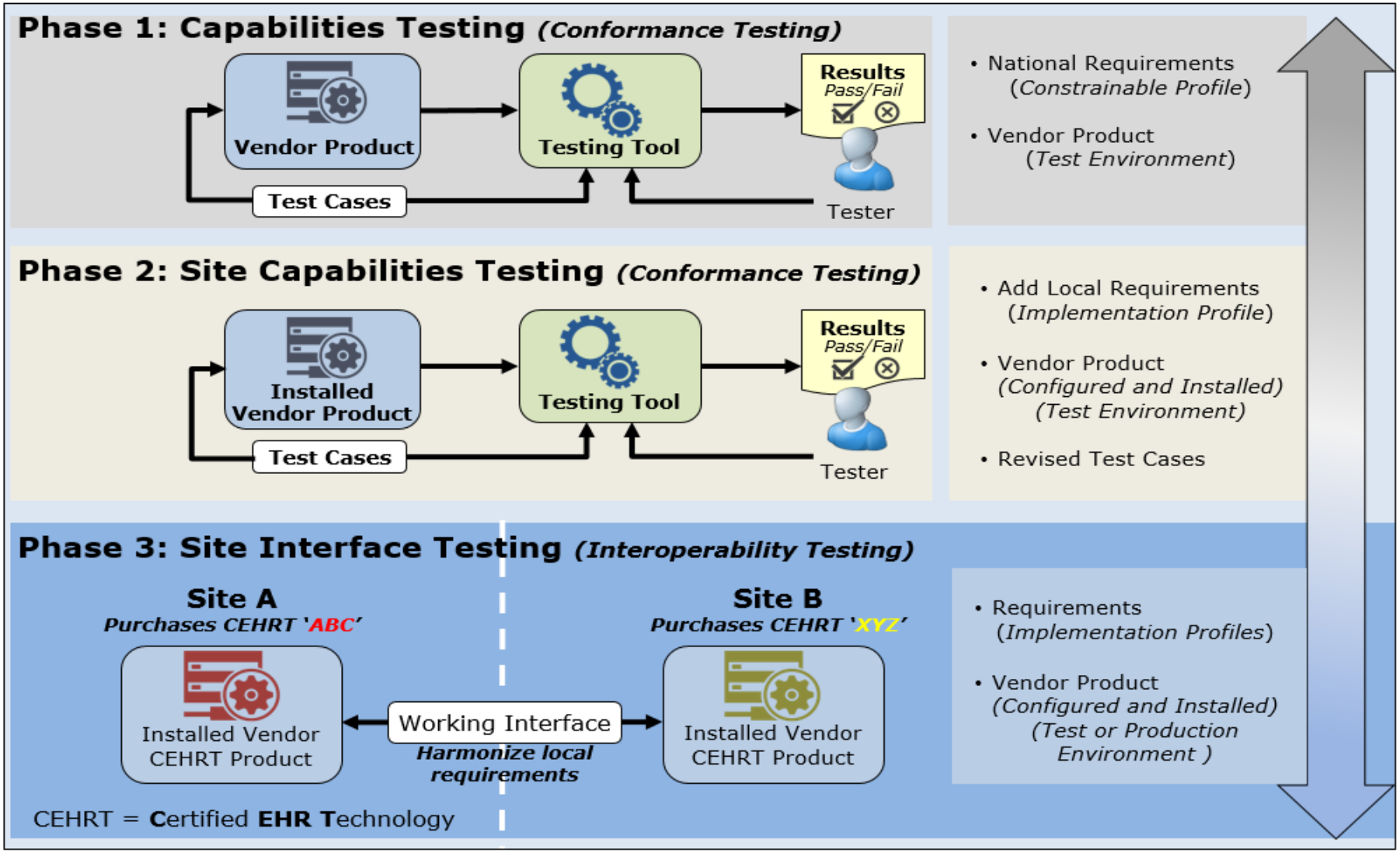
Testing Tiers



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HEALTH IT
STANDARDS TESTING INFRASTRUCTURE

Tutorial

Part 1: Using NIST IGAMT-lite

Part 2: Context-free Validation

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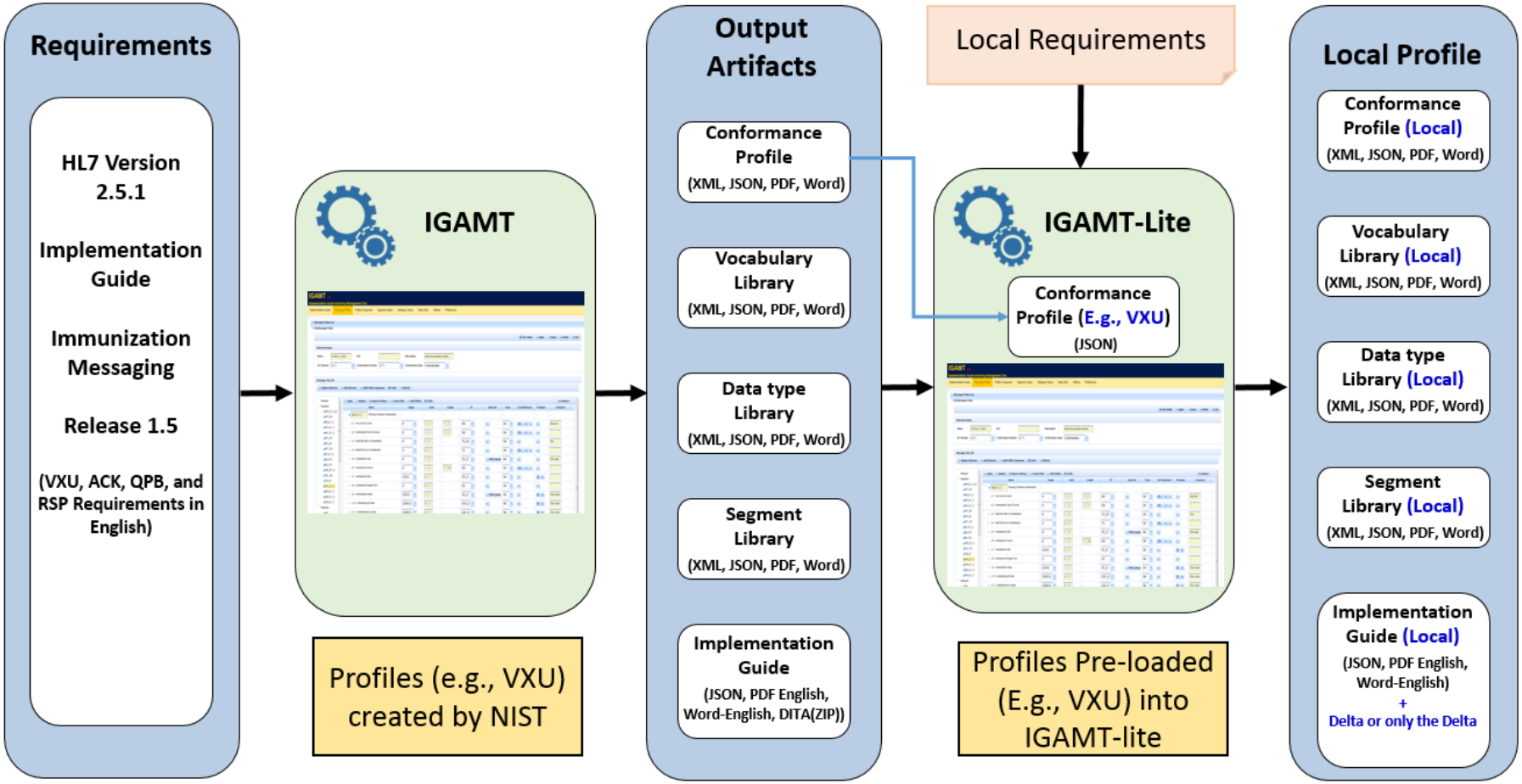
Overview of Profile Customization using IGAMT-lite



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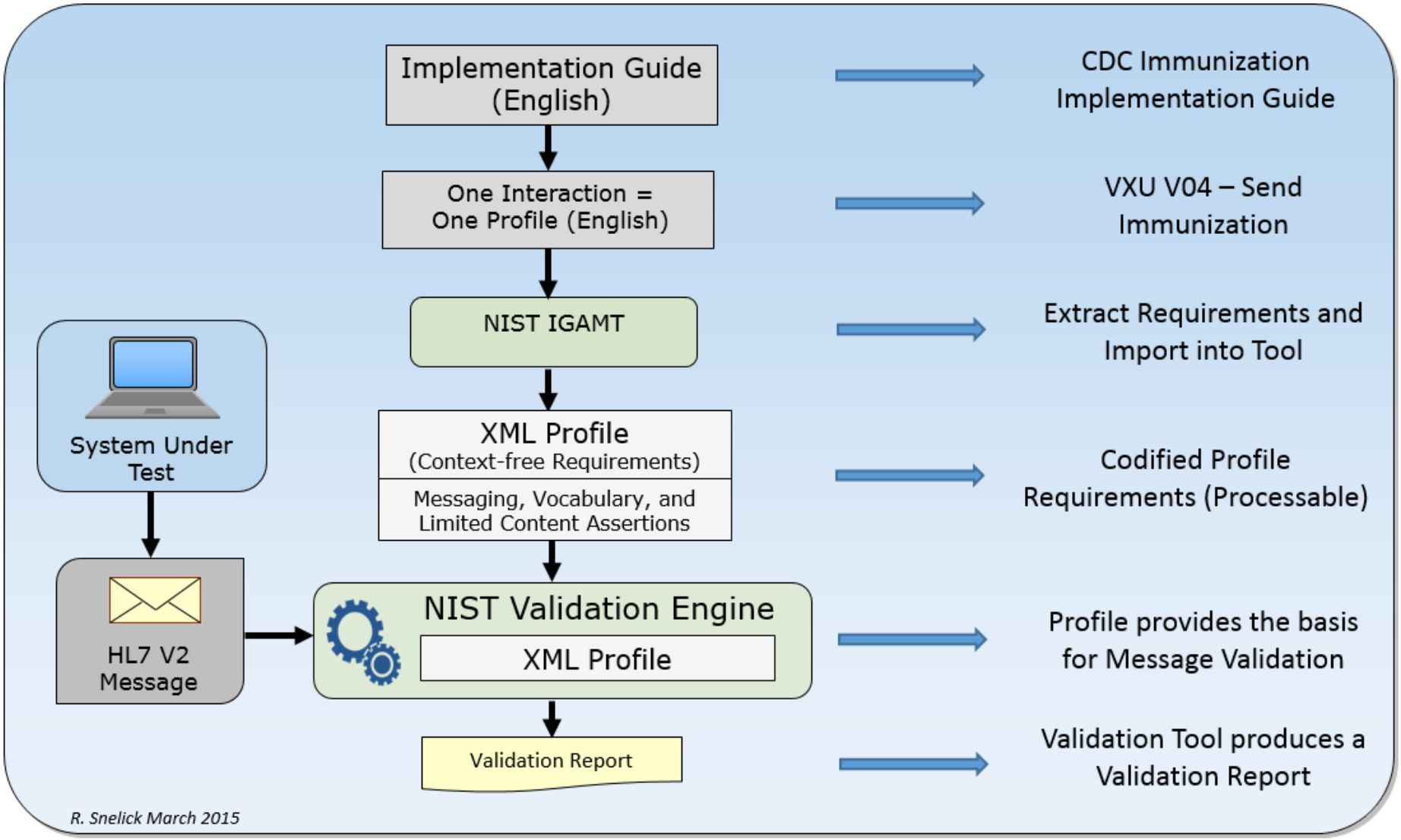
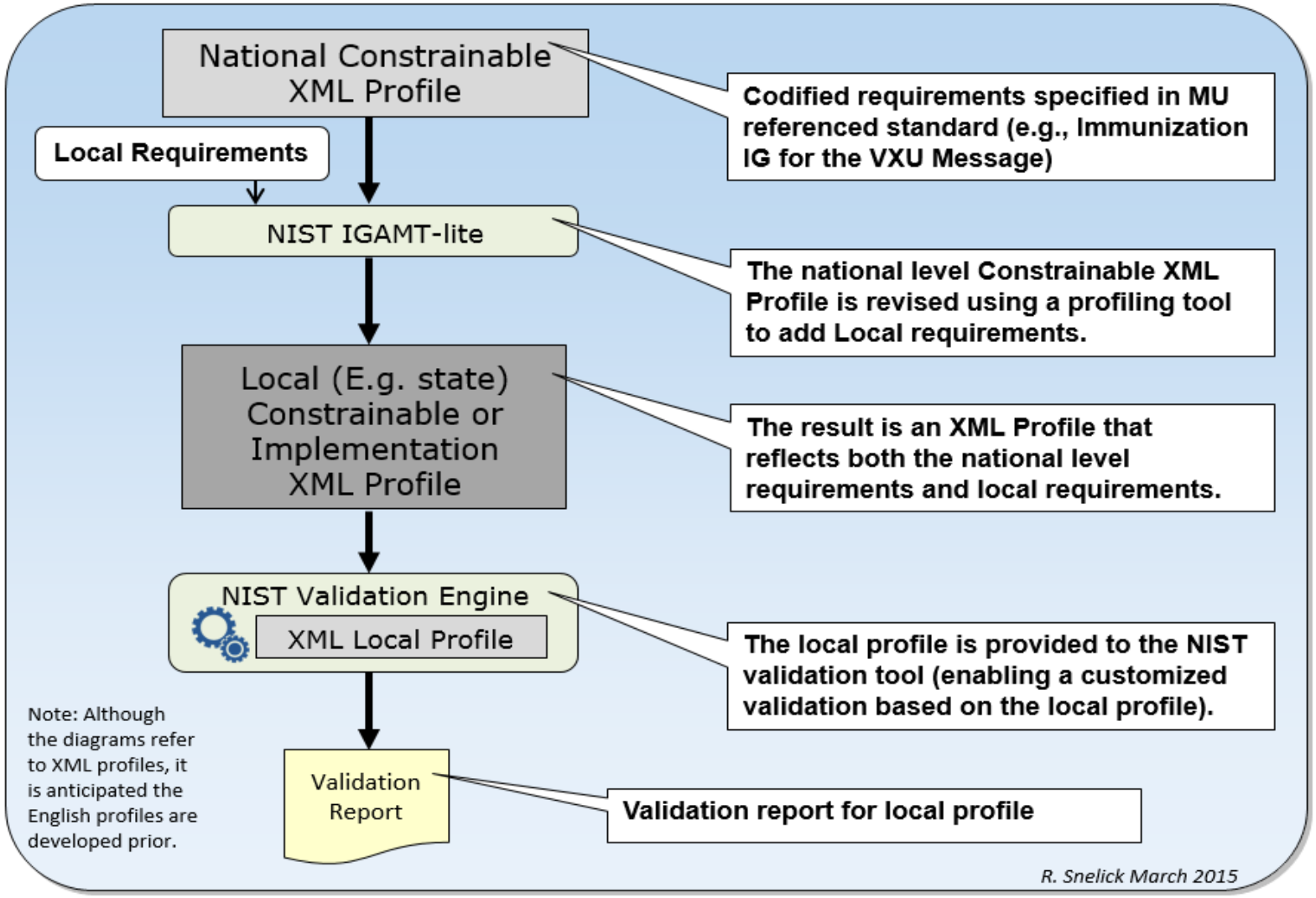
NIST Profile and Validation Process



NIST Customized Profile and Validation Process



Profile Rendering

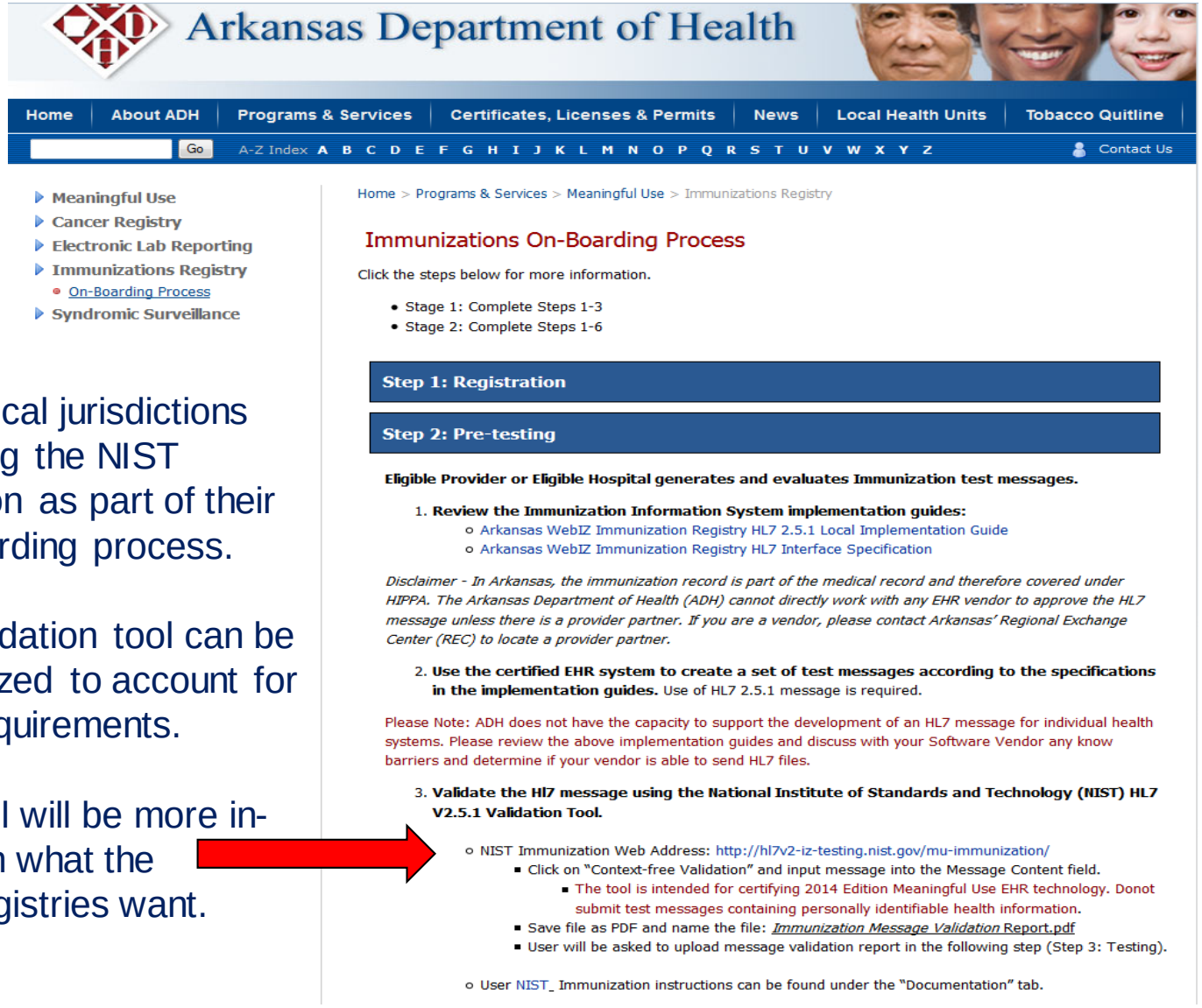
- Formats/Displays
  - JSON
  - XML
  - Browse-able
  - Excel
  - PDF
  - Word
  - And More…


```
    - <Assertion>
        <Custom id="2" className="gov.nist.healthcare.mu.iz.custom.RXA"/>
      </Assertion>
  </ConformanceStatement>
- <ConformanceStatement id="IZ-23" Profile="Base">
    <EnglishDescription>If RXA-20 is valued "CP" or "PA" and the first occurrence of RXA-9.1 (Administration Note code) is valued "00" then the message
      SHALL include an OBX segment associated with the RXA with OBX-3.1 shall equal "64994-7" . This OBX will indicate the Patient Eligibility Category
      for Vaccine Funding Program.</EnglishDescription>
  - <Assertion>
      <Custom id="1" className="gov.nist.healthcare.mu.iz.custom.RXA"/>
    </Assertion>
  </ConformanceStatement>
- <Field Name="Give Sub-ID Counter" Usage="R" Min="1" Max="1" MinLength="1" MaxLength="4" Datatype="NM">
  - <ConformanceStatement Id="IZ-28" Profile="Base">
      <EnglishDescription>RXA-1 ( Give Sub-id counter) ) SHALL be valued "0" Note that "0" is zero.</EnglishDescription>
    - <Assertion>
        <PlainText value="0" location="."/>
      </Assertion>
    </ConformanceStatement>
  </Field>
- <Field Name="Administration Sub-ID Counter" Usage="R" Min="1" Max="1" MinLength="1" MaxLength="4" Datatype="NM">
  - <ConformanceStatement id="IZ-29" Profile="Base">
      <EnglishDescription>RXA-2 (admin Sub-id) SHALL be valued "1"</EnglishDescription>
    - <Assertion>
        <PlainText value="1" location="."/>
      </Assertion>
    </ConformanceStatement>
  </Field>
- <Field Name="Date/Time Start of Administration" Usage="R" Min="1" Max="1" MinLength="1" MaxLength="26" Datatype="TS_IZ">
    <Component Name="Time" Usage="R" MinLength="4" MaxLength="24" Datatype="DTM"/>
    <Component Name="Degree of Precision" Usage="X" MinLength="1" MaxLength="15" Datatype="ID"/>
  </Field>
- <Field Name="Date/Time End of Administration" Usage="RE" Min="0" Max="1" MinLength="1" MaxLength="26" Datatype="TS_IZ">
  - <ConformanceStatement id="IZ-30" Profile="Base">
      <EnglishDescription>If RXA-4 (Date time of admin end ) is populated, then it SHALL be the same as Start time (RXA-3)</EnglishDescription>
```


FULL | MSH | PID | PD1 | NK1 | ORC | RXA | RXR | OBX | NTE

Location	Usage	Cardinality	Data Type	Length	Table	Predicate	Conformance Statement
RXA.1 : Give Sub-ID Counter	R	[1,1]	NM	[1,4]			IZ-28:RXA-1 (Give Sub-id counter)) SHALL be valued "0" Note that "0" is zero.
RXA.2 : Administration Sub-ID Counter	R	[1,1]	NM	[1,4]			IZ-29:RXA-2 (admin Sub-id) SHALL be valued "1"
RXA.3 : Date/Time Start of Administration	R	[1,1]	TS_IZ	[1,26]			
RXA.4 : Date/Time End of Administration	RE	[0,1]	TS_IZ	[1,26]			IZ-30:If RXA-4 (Date time of admin end) is populated, then it SHALL be the same as Start time (RXA-3)
RXA.5 : Administered Code	R	[1,1]	CE_IZ	[1,483]	CVX		
RXA.5.1 : Identifier	R	[1,1]	ST	[1,50]			
RXA.5.2 : Text	RE	[1,1]	ST	[1,999]			
RXA.5.3 : Name of Coding System	R	[1,1]	ID	[1,20]	0396		
RXA.5.4 : Alternate Identifier	RE	[1,1]	ST	[1,50]			
RXA.5.5 : Alternate Text	RE	[1,1]	ST	[1,999]			
RXA.5.6 : Name of Alternate Coding System	C(R/X)	[1,1]	ID	[1,20]	0396	If CE.4 (Alternate Identifier) is valued.	
RXA.6 : Administered Amount	R	[1,1]	NM	[1,20]			
RXA.7 : Administered Units	C(R/O)	[0,1]	CE_IZ	[1,483]	UCUM	If Administered Amount is not valued "999	

Improve On-Boarding



- Many local jurisdictions are using the NIST validation as part of their On-Boarding process.
- The validation tool can be customized to account for local requirements.
- Test tool will be more in-line with what the local registries want.

Understanding Results From NIST MU HL7 V2 Test Tools

		National Level		State/Local Level		State/Local Level	
	Usage Requirement of Element	RE	RE	R	R	R	R
	Data Present in Element in Submitted	Yes	No	Yes	No	Yes	No
Test Tool Mode	Context-free	Not Evaluated	Not Evaluated	Not Evaluated	Not Evaluated	Evaluated: No Error	Evaluated: Error
Test Tool Mode	Context-based (Test Data Provided)	Evaluated: No Error	Evaluated: Error	Evaluated: No Error	Evaluated: Error	Evaluated: No Error	Evaluated: Error
Test Tool Mode	Context-based (Test Data Not Provided)	Not Evaluated	Not Evaluated	Not Evaluated	Not Evaluated	Evaluated: No Error	Evaluated: Error
		NIST Test Tool Actual Results				User's Desired Results	

- NIST MU Certification Tools test to national level requirements (constrainable profiles)
- This testing specifically targets the capabilities of Vendor products
- When the tool is used at site-installations, users must recognize the implications of testing local requirements using a tool designed to test national level requirements
- The table above illustrates one example of results the tool will report when validating a message implemented to meet local requirements that differ from national level requirements; the tool will report results based on what it knows (per the national level conformance profile), not on what a local user wants it to know
- Site-based operators can provide a revised local level conformance profile to the validation engine to obtain validation results in accordance with local requirements. OUR GOAL IN THIS WORKSHOP!

Usage	Data Provided	Conformity Assessment
RE	Yes	Required
RE	No	Indifferent

Case Study

- California Immunization Registry (CAIR)
- 38 page guide documenting local requirements
- Local Profiling Process
  - Export base CDC VXU Profile template
  - Identify the differences
  - Use IGAMT-lite to document the differences
  - Address each the different type of constraints
  - Export Artifacts
    - Complete Profile, Segments, etc.
    - Various Formats (PDF, Word, XML)
- Load XML Profile into Validation Tool
  - Next part of presentation

Profiling: Message Definition Level

As Specified in CAIR

VXU Message Structure (Ignored segments not shown)

Segment	Cardinality	Description	Usage	Notes
MSH	[1..1]	Message Header	**R**	Every message begins with an MSH.
PID	[1..1]	Patient Identification	**R**	Every VXU requires one PID segment.
PD1	[1..1]	Patient Additional Demographics	**R**	Every PID segment must have one PD1 segment. Required for CAIR Disclosure information.
NK1	[0..*]	Next of Kin/Associated Parties	RE	PID segment in a VXU may have zero or more NK1 segments.
PV1	[0..1]	Patient Visit	RE	The PID segment in a VXU may have zero or one PV1 segments. CAIR requires if OBX segment is not sent.
ORC	[1..*]	Order Request	**R**	The order group in a VXU may have one or more ORC segments. ORC segments are required for each RXA segment.
RXA	[1..1]	Pharmacy/Treatment Administration	**R**	Each ORC segment in a VXU must have one RXA segment. Every RXA requires an ORC segment.
RXR	[0..1]	Pharmacy/Treatment Route	RE	Every RXA segment in a VXU may have zero or one RXR segment.
OBX	[0..*]	Observation/Result	RE	Every RXA segment in a VXU may have zero or more OBX segments.

IGAMT-lite: Use Usage and Cardinality constraint modifier to change “RE” to “R” and [0..1] to [1..1].

As Specified in IGAMT-lite

VXU Message Structure (optional segments not shown)

Segment	Cardinality	Usage	CAIR	Comment
MSH	[1..1]	R	R	Every message begins with an MSH.
PID	[1..1]	R	R	Every VXU has one PID segment.
[PD1]	[0..1] **[1..1]**	RE	**R**	Every PID segment in VXU may have one or less PD1 segment Every PID segment must have one PD1 segment. Required for CAIR disclosure information.
{[NK1]}	[0..*]	RE	RE	The PID segment in a VXU may have zero or more NK1 segments.
{[Begin Order group	[0..*]	RE	RE	Each VXU may have zero or more Order groups
ORC	[1..1]	R	R	The order group in a VXU must have one ORC segments.
RXA	[1..1]	R	R	Each ORC segment in a VXU must have one RXA segment. Every RXA requires an ORC segment.
[RXR]	[0..1]	RE	RE	Every RXA segment in a VXU may have zero or one RXR segments.
{[Begin Observation Group	[0..*]	RE	???	Every RXA segment in a VXU may have zero or more observation groups.
OBX	[1..1]	R	**RE**	**Define as RE in CAIR and when combined with the group it is essentially an RE.**
[NTE]	[0..1]	RE	???	Every OBX segment in a VXU may have zero or one NTE segment.
End Observation Group]}				
End Order Group]}				

Profiling: Segment Level

Master Field List – Comparison of National Standard to Local Specification

The Master Field List shows all of the fields that are expected to be populated in the VXU Message based on the *HL7 v2.5.1 Implementation Guide: Immunization Messaging Release 1.5*. Red text indicates Local Specification. Black italics are additional comments from Implementation Guide.

Red indicates differences in CAIR

ces in CAIR	Element	Element Name	Data Type	Usage	CAIR	Card	Len	Conditional Predicate	Value Set	Description/ Comment	Differen
	MSH-1	Field Separator	ST	R		[1..1]	1..1				
	MSH-2	Encoding Characters	ST	R		[1..1]	4..4				
l Registry	MSH-3	Sending Application	HD	RE		[0..1]			HL70361	*No suggested values defined. The values are locally defined by the IIS or by mutual agreement*	Optional for Loca
ID that is assigned by ling facility is supplied anage value set.	MSH-4	Sending Facility	HD	RE	R	[0..1] [1..1]			~~HL70362~~ Constant for sender	*No suggested values defined. The values are locally defined by the IIS or by mutual agreement*	Populated with an the Registry. Send by CAIR. Receiver could ma
Registry	MSH-5	Receiving Application	HD							*uggested values ed. The values are y defined by the IIS mutual agreement*	Ignored by Local

IGAMT-lite: Use Usage and Cardinality constraint modifier to change "RE" to "R" and [0..1] to [1..1].

Profiling: Creating Local Value Sets

Segment / Field	Data Element	Usage	HL7 Code Table	Comment
MSH-4	Sending Facility	R		Required in MSH segment. Sending facility ID supplied by CAIR.
MSH-6	Receiving Facility	R		This is used for the CAIR Region Code; **See Appendix A for value.**
MSH-7	Date/time of message	R		

APPENDIX A - CAIR Receiving Facility Codes for MSH-6

County	CAIR Regional Registry	HL7 Code (MSH-6)
ALAMEDA	BAY AREA	CAIRBA
BUTTE	NORCAL	CAIRNC
COLUSA	NORCAL	CAIRNC
CONTRA COSTA	BAY AREA	CAIRBA
DEL NORTE	NORCAL	CAIRNC
EL DORADO	GREATER SACRAMENTO	CAIRGS
FRESNO	CENTRAL VALLEY	CAIRCV

IGAMT-lite: Use the Value Set utility to create local value set and bind to MSH.6

Profiling: Constraining a Value Set

	Acknowledgement Type			
PID-3	Patient ID	R		This is the patient ID from the provider's system, commonly referred to as medical record number. CAIR only accepts type codes, '**MR**', '**PI**', or empty.
PID-5	Patient Name	R		Each name field has a 20 character length limit in CAIR

This is the patient ID from the provider's system, commonly referred to as the medical record number.

Warning: The sending system's patient id is a required field. The message will be rejected if this id is not sent or cannot be found in this field.

Position	Field Name	Status
1	id	required
2	check digit	ignored
3	code identifying the check digit scheme employed	ignored

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4	assigning authority	required but may be empty
5	identifier type code	required, but may be empty
6	assigning facility	ignored

NOTE: CAIR only accepts identifier type codes **MR** (medical record number), **PI** (patient identifier), or empty string in PID-3.5

IGAMT-lite: Use the Value Set utility to clone, constrain, and bind to PID-3.5 (Patient Identifier-identifier type code).

Note: PID-3.5 is a required element in the standard and in the CDC guide. IGAMT-lite will not allow for "weakening" of requirements. Therefore, a code to indicate "undetermined" should be added to the constrained value set.

Profiling: Length Elements (with Data Type Flavor)

	Acknowledgement Type			
PID-3	Patient ID	R		This is the patient ID from the provider's system, commonly referred to as medical record number. CAIR only accepts type codes, '**MR**', '**PI**', or empty.
PID-5	Patient Name	R	→	Each name field has a 20 character length limit in CAIR

PID-5	Patient Name	XPN XPN_CA	R		[1..*]				The first repetition shall contain the legal name. Multiple given names or initials are separated by spaces.	Each name field has limit of 20 characters in CAIR. Assuming this applies to first, middle, and last name.

XPN

Table 4-31 Extended

SEQ	COMPONENT NAME	Data Type	Usage	LEN	CAIR LEN
1	Family Name	FN	R		
2	Given Name	ST	R	30	20
3	Second and Further Given Names or Initials Thereof	ST	RE	30	20

FN

Table 4-12 Family Name

SEQ	COMPONENT NAME	Data Type	Usage	LEN	CAIR LEN	Value Se
1	Surname	ST	R	1..50	1..20	
2	Own Surname Prefix	ST	O			

IGAMT-lite: Create XPN and FN data type flavors and set the length limits accordingly. Bind FN flavor to XPN and then XPN flavor to PID-5 (Patient Name).

Profiling: Conformance Statements

		inserted
PID-5	Patient's last name exceeds maximum length	Truncated at max length and inserted
PID-6, NK1-2	Mother's first name exceeds maximum length	Truncated at max length and inserted
PID-11	Invalid state code	'CA' value inserted
RXA-5	Tdap given before age 7	Vaccine inserted

This is a somewhat fabricated, but is for demonstration purposes.

IGAMT-lite: Use the conformance statement utility to create a conformance statement.

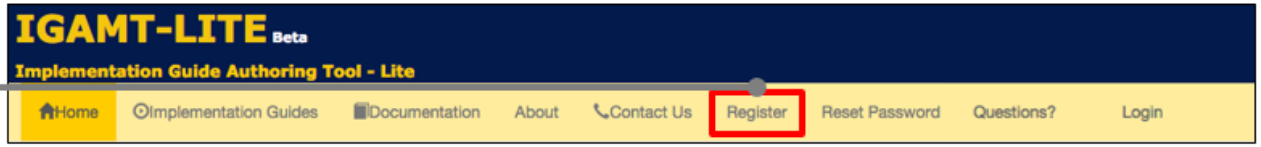
CA-01: PID-11.4 (State or Province) SHALL be valued with the constant code "CA" drawn from US Postal Service State code system.

IGAMT-lite Walk-Through

- Slides for reference
- Some features have been updated since this slides were created

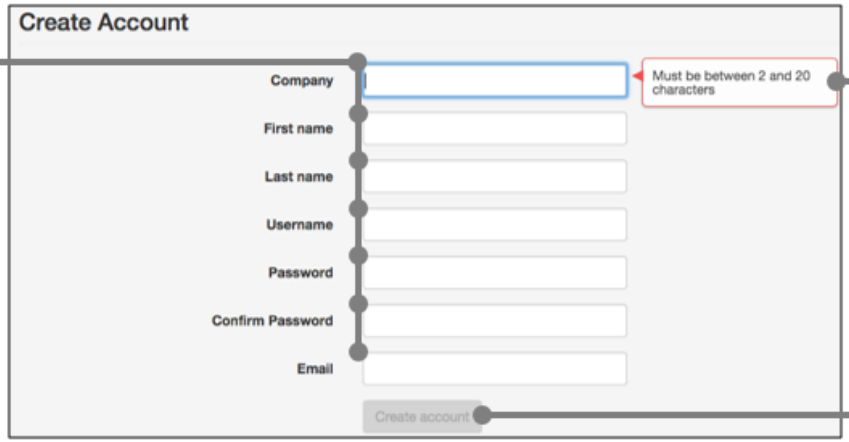
User Registration

1 From the IGAMT-lite '**Home**' screen, click the '**Register**' tab.



2 The Tester is prompted on the '**Create Account**' unique account information.

Required account registration fields are indicated with an ''. Unless specifically noted, all fields without an '*' are optional.*



2a IGAMT-lite provides the Tester with account registration field requirements in pop-out boxes.

2b Once all fields are complete and meet field requirements, the Tester clicks '**Create Account**'.

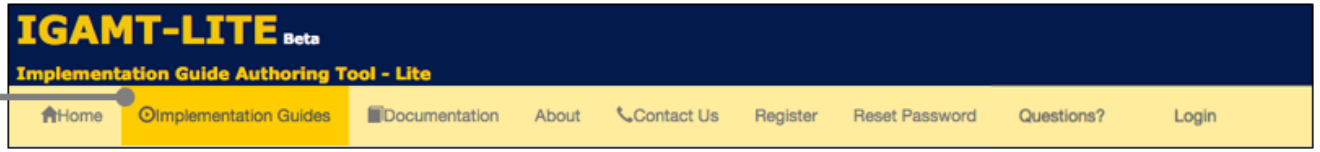
A prompt is sent the an IGAMT-lite administrator (NIST) and manual authorization occurs. The Tester receives and email notification when their account has been activated.

3 All Testers must '**Login**' to IGAMT-lite with their credentials before initiating a testing session within the tool.

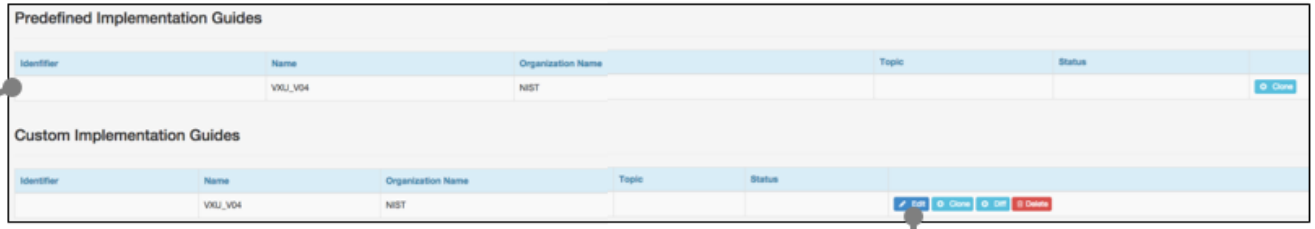
Tester loaded and created Implementation Guides are saved within tool user accounts.

Creating an Implementation Guide

1. From the IGAMT-lite '**Home**' screen, click the '**Implementation Guides**' tab.



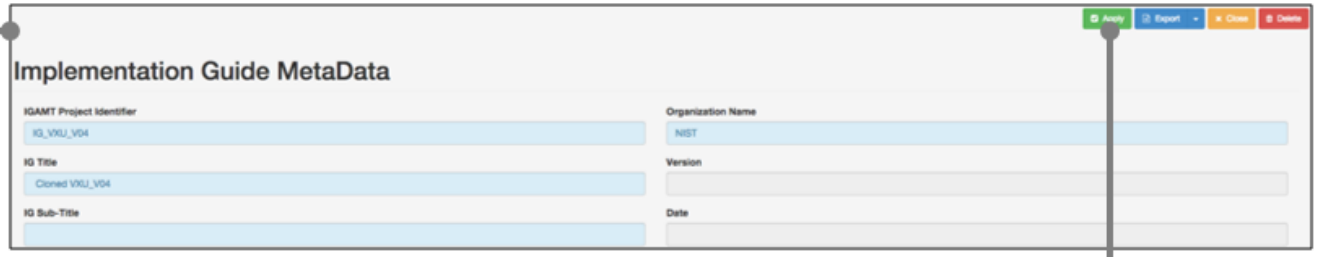
2. The Tester can import board level immunization Implementation Guides (e.g., National-level) and/or local jurisdiction requirement Implementation Guides (e.g., State-level) into the '**Predefined Implementation Guides**' library table.



2a. Click the '**Edit**' button to access a custom Implementation Guide's metadata content and detailed data/component constraint modification options.

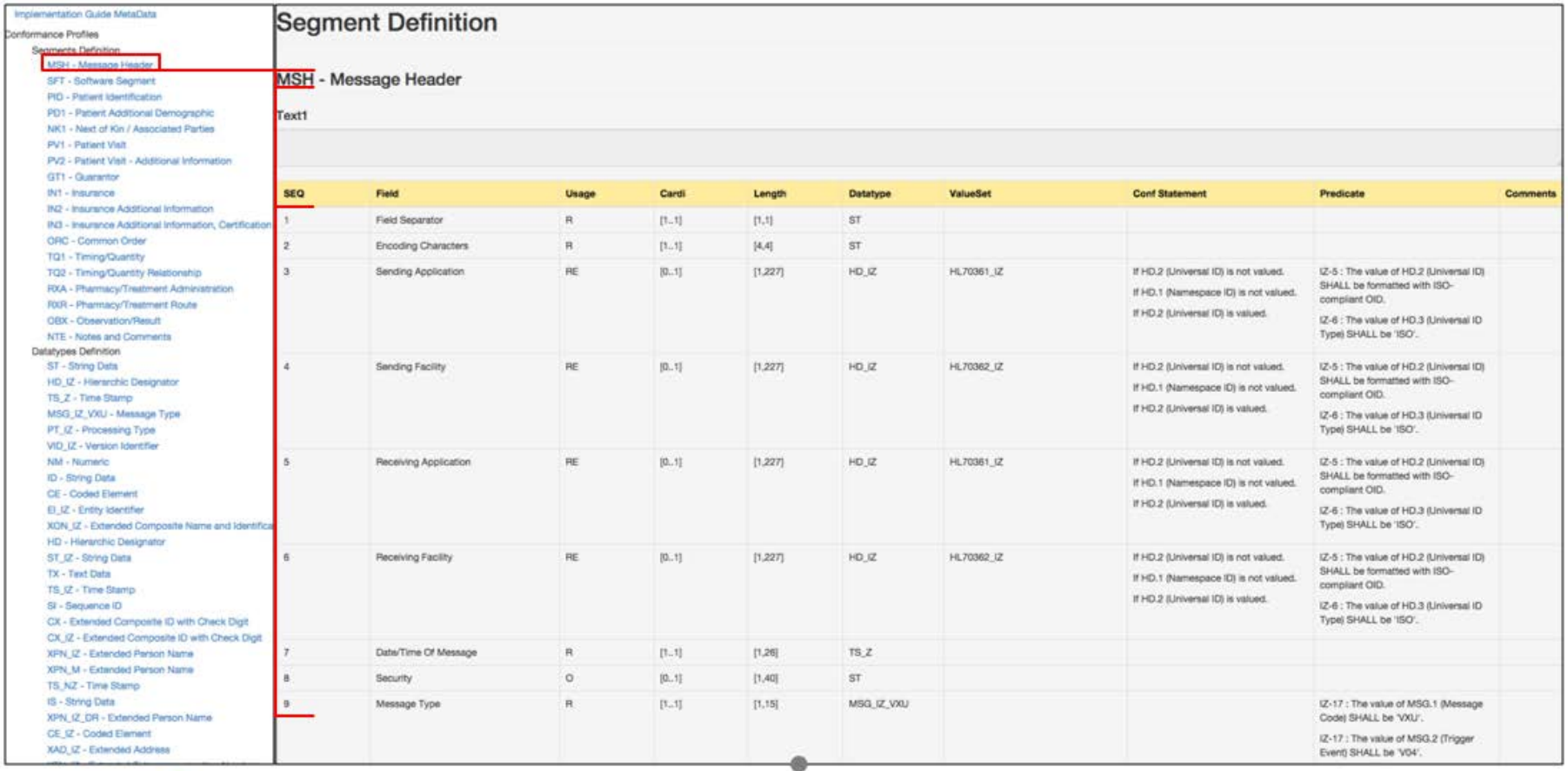
3. Select the '**Document**' tab.

4. The Tester can input uniquely identifiable information for the custom Implementation Guide in the '**Implementation Guide MetaData**' data fields.



4a. Clicking the '**Apply**' button saves the changes and updates the '**Custom Implementation Guide**' library table.

Creating an Implementation Guide



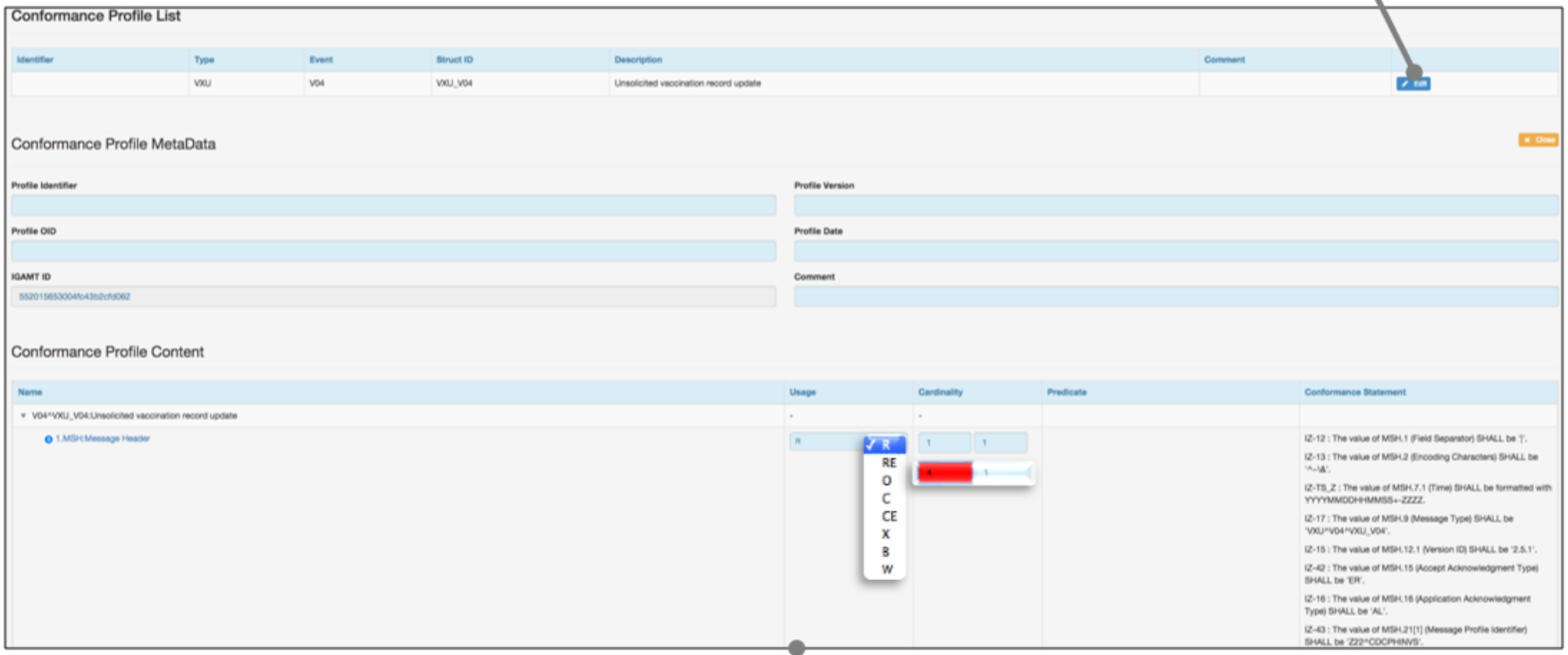
5 From the '**Conformance Profiles**' listed, selecting a '**Segment Definition**' or '**Datatype Definition**' displays the specific metadata for that element.

*Data is not editable (e.g., read only) within the '**Documentation**' tab of the custom Implementation Guide viewer window.*

Creating a Conformance Profile

6 Select the '**Conformance Profiles**' tab.

7 The '**Conformance Profile List**' displays the library table of the available and crated Conformance Profiles. Clicking '**Edit**' expands the MetaData and Content editable options.

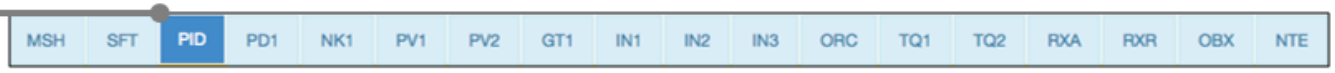


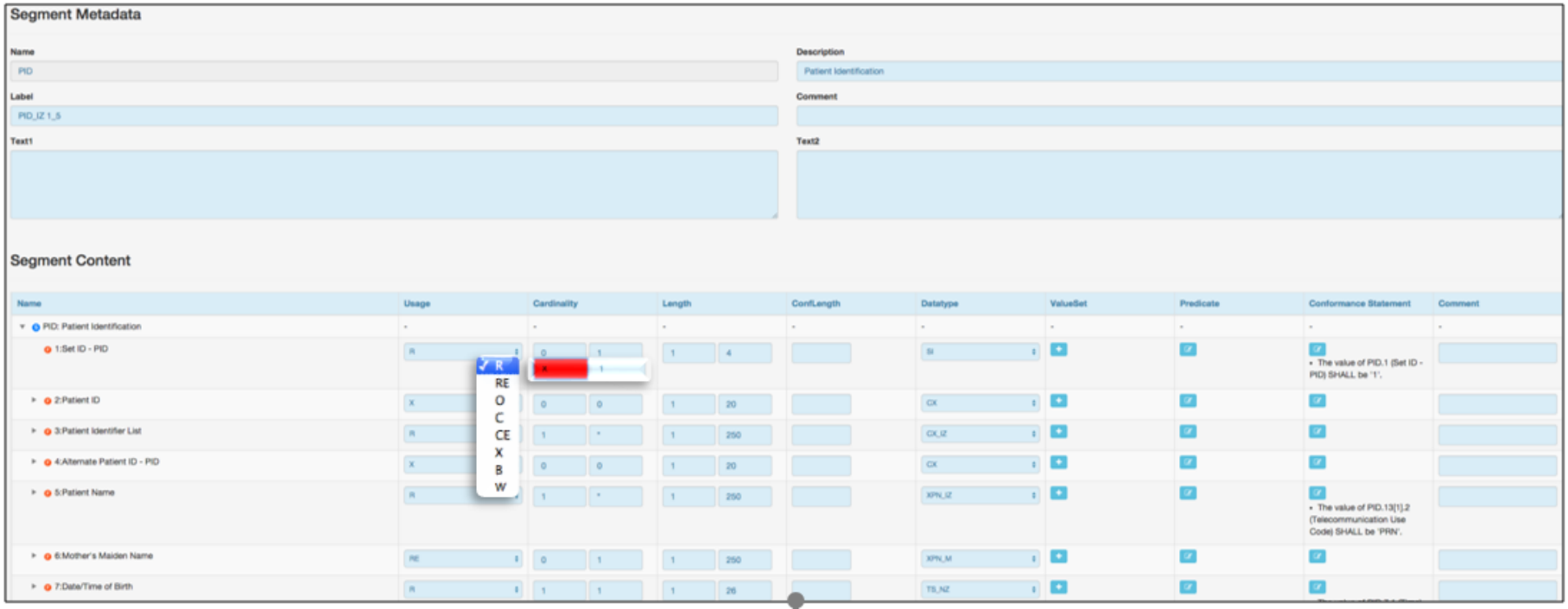
8 For a selected '**Conformance Profile**', the Tester can edit identifiable information for the custom Conformance Profile in the '**Conformance Profile MetaData**' and '**Conformance Profile Content**' fields. The available HL7 immunization conformant '**Usage**' options are '**R**', '**RE**', '**C**', '**CE**', '**X**', '**B**', and '**W**'. Invalid or incorrectly entered '**Cardinality**' values are indicated in RED.

Profiling Fields

9 Select the '**Segments**' tab.

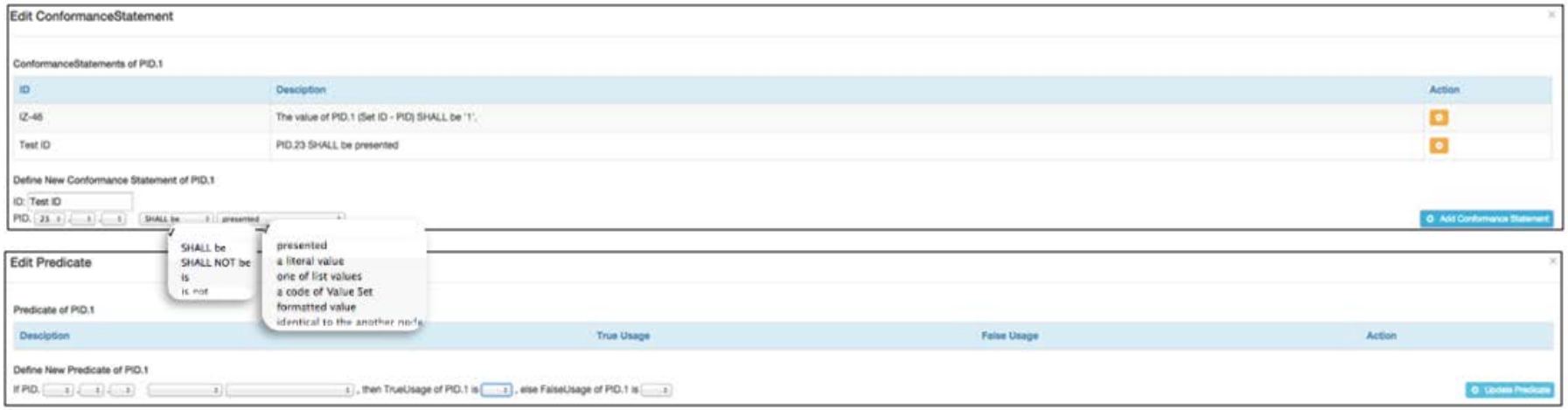
10 Select the target HL7 message '**Segment**' from the available options.





11 For a selected HL7 message '**Segment**', the Tester can edit identifiable information in the '**Segment MetaData**' and '**Segment Content**' fields. The available HL7 immunization conformant '**Usage**' options are '**R**', '**RE**', '**C**', '**CE**', '**X**', '**B**', and '**W**'. Invalid or incorrectly entered '**Cardinality**' values are indicated in RED. '**Datatype**' elements are constrained by the Conformance Profile.

Profiling: Predicates and Conformance Statements



Profiling: Data Types

13 Select the '**Datatypes**' tab.

14 The '**Datatypes List**' displays the library table of '**Datatypes**' organized by '**Flavor**', '**Base**', and '**Description**'.

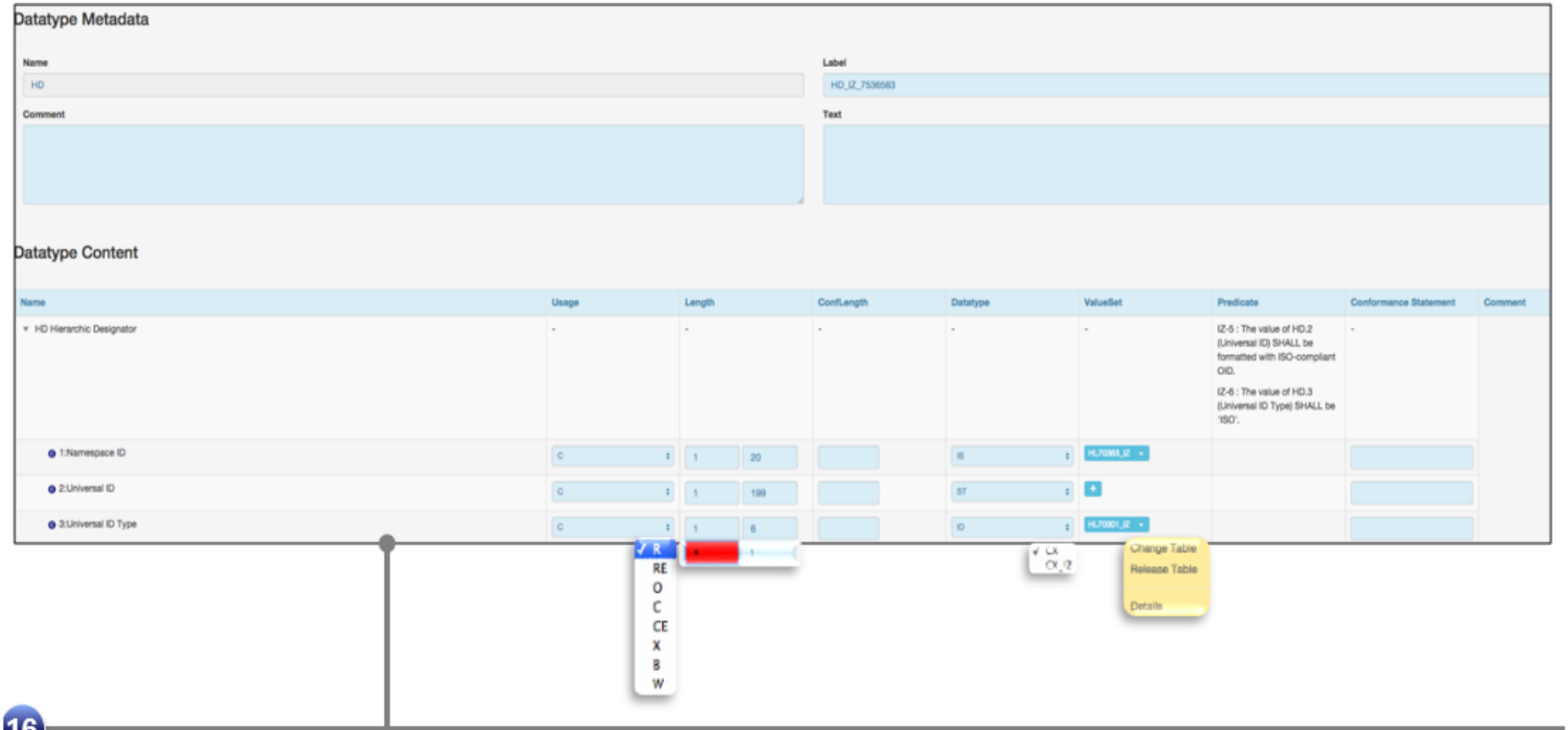
These represent the datatypes available for the Conformance Profile and custom Implementation Guide.

Datatypes List

Flavor	Base	Description	
ST	ST	String Data	Flavor Edit Delete
HD_IZ	HD	Hierarchic Designator	Flavor Edit Delete
IS	IS	String Data	Flavor Edit Delete
ID	ID	String Data	Flavor Edit Delete
TS_Z	TS	Time Stamp	Flavor Edit Delete
DTM	DTM	Date/Time	Flavor Edit Delete
MSG_IZ_VXU	MSG	Message Type	Flavor Edit Delete
PT_IZ	PT	Processing Type	Flavor Edit Delete
VID_IZ	VID	Version Identifier	Flavor Edit Delete
CE	CE	Coded Element	Flavor Edit Delete
NM	NM	Numeric	Flavor Edit Delete

15 To modify a target '**Datatype**' from the library list, click the '**Edit**' button.

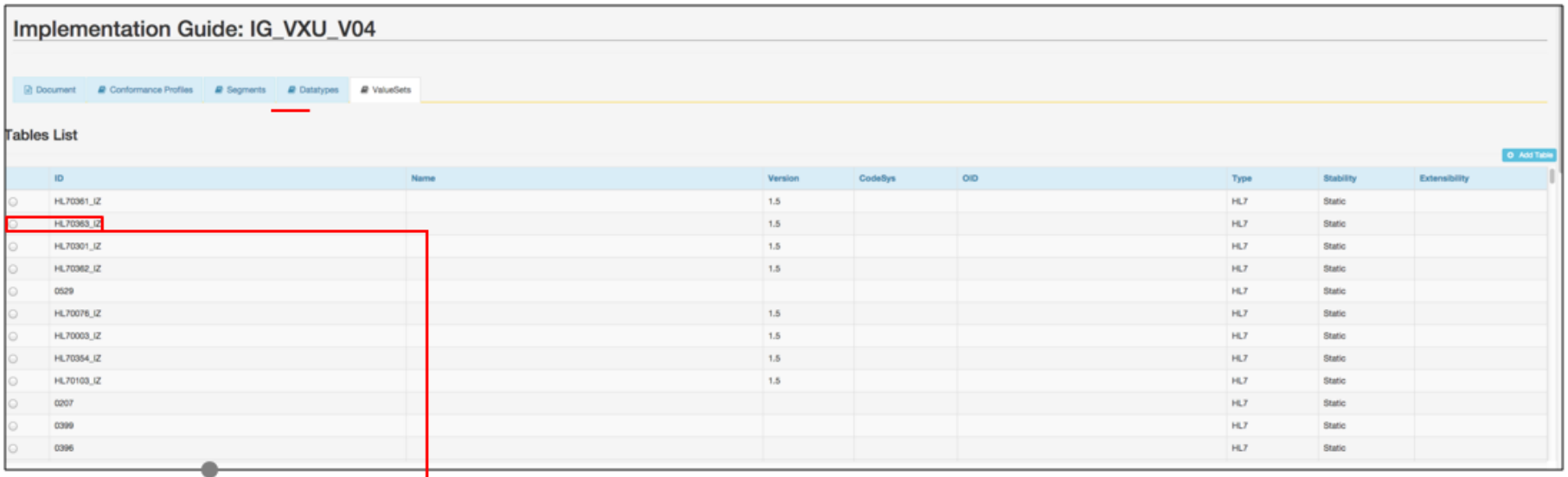
Profiling: Data Types



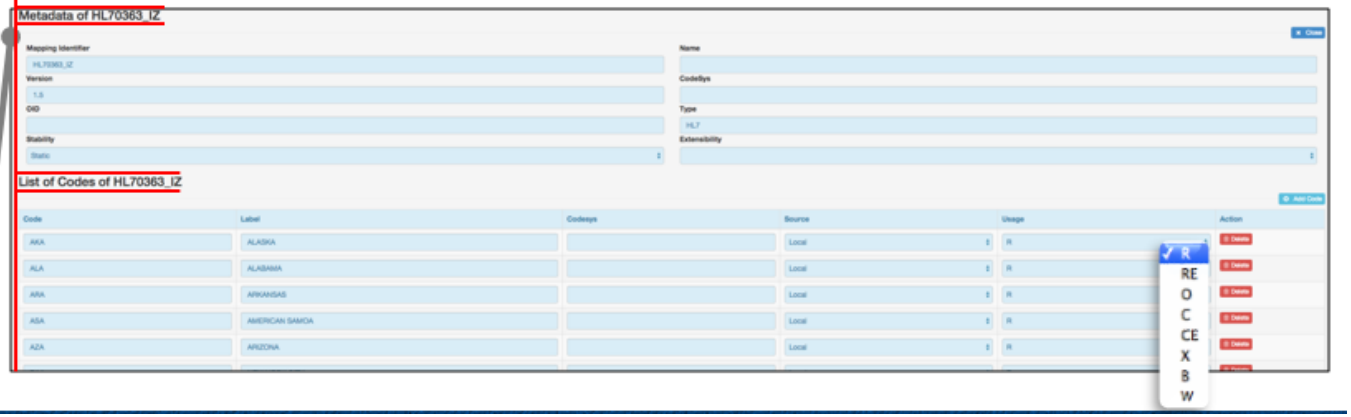
16 For a selected '**Datatype**', the Tester can edit identifiable information in the '**Datatype MetaData**' and '**Datatype Content**' fields. The available HL7 immunization conformant '**Usage**' options are '**R**', '**RE**', '**C**', '**CE**', '**X**', '**B**', and '**W**'. Invalid or incorrectly entered '**Cardinality**' values are indicated in RED. '**Datatype**' and '**ValueSet**' elements are constrained by the Conformance Profile.

Profiling: Value Sets

17 Select the '**ValueSets**' tab.



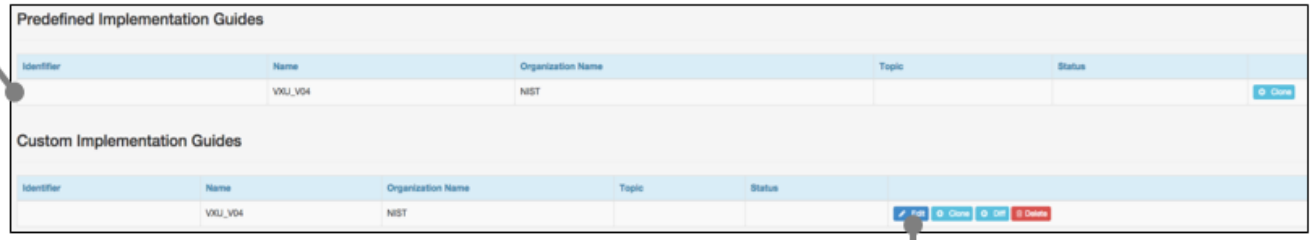
18 The '**ValueSet**' tab displays all the available and created '**ValueSet Table Lists**' for use by the Tester for the constrainable Conformance Profile and custom Implementation Guide.



18a For a selected '**ValueSet Table List**' element, the Tester can edit identifiable information in the '**Value MetaData**' and '**List of Codes**' fields. The available HL7 immunization conformant '**Usage**' options are '**R**', '**RE**', '**C**', '**CE**', '**X**', '**B**', and '**W**'

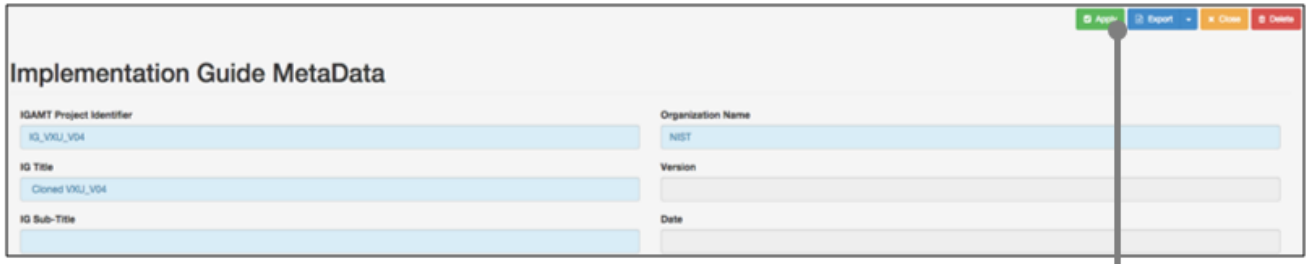
Export Artifacts

1 From the '**Custom Implementation Guides**' library table, identify a target Implementation Guide.



1a Click the '**Edit**' button to access a custom Implementation Guide's metadata content and detailed data/component constraint modification options.

2 Select the '**Document**' tab.



3 Click the '**Export**' button. The Tester export a custom created Implementation Guide into human and machine readable formats (e.g., .JSON, .XML, .PDF, Microsoft Word and Excel).

This provides a mechanism by which a Tester can manage and publish local jurisdiction requirements and standards (e.g., State-level).

HEALTH IT
STANDARDS TESTING INFRASTRUCTURE

Tutorial

Part 1: Using NIST IGAMT-lite

Part 2: Context-free Validation

Robert Savage

Centers for Disease Control (CDC)

Robert Snelick

National Institute of Standards and Technology (NIST)

April 21st, 2015

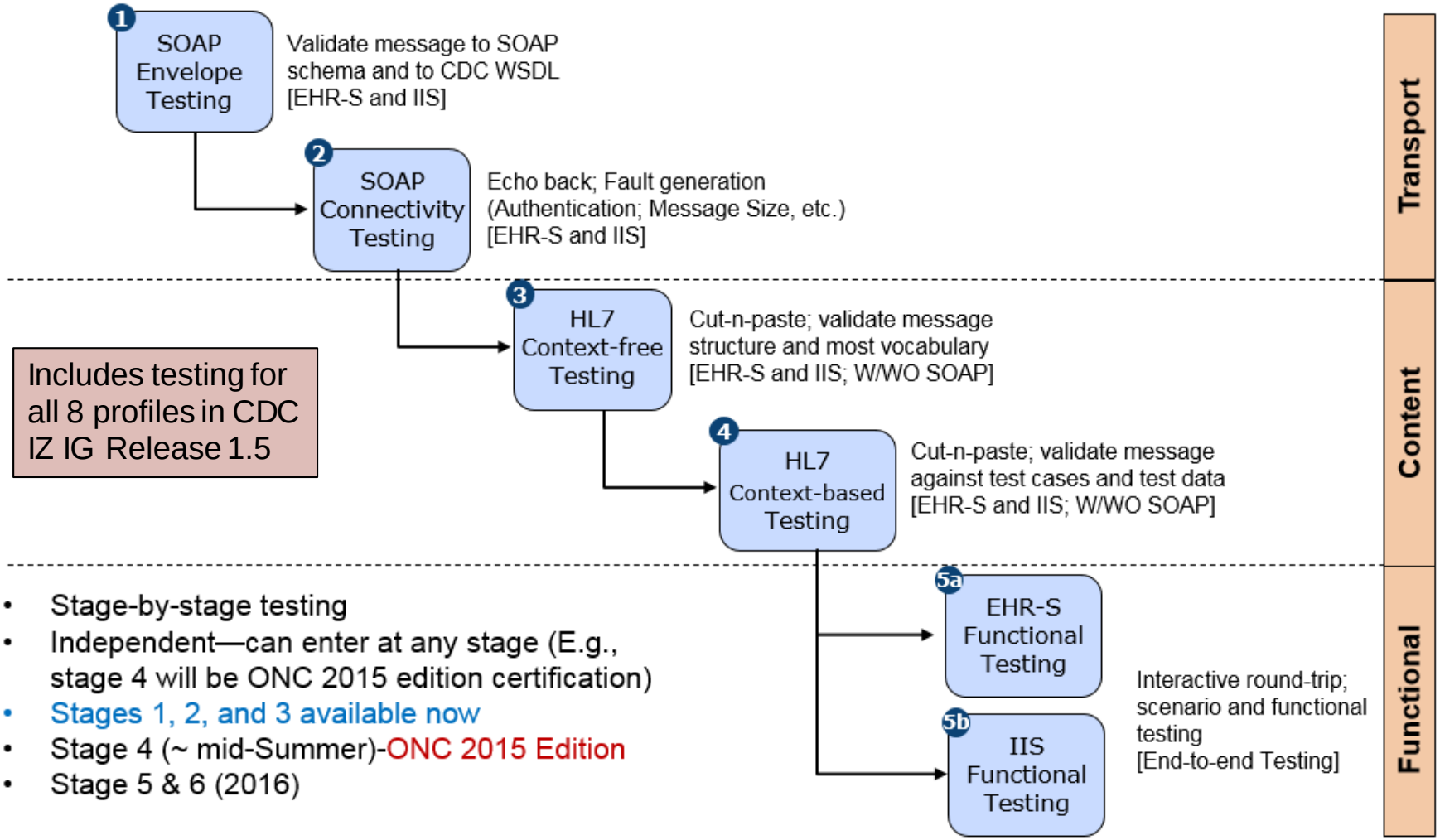
Contact: robert.snelick@nist.gov

AIRA AMERICAN IMMUNIZATION REGISTRY ASSOCIATION
Immunization Information Systems for a New Era

CDC

NIST
National Institute of Standards and Technology

Immunization Test Suite

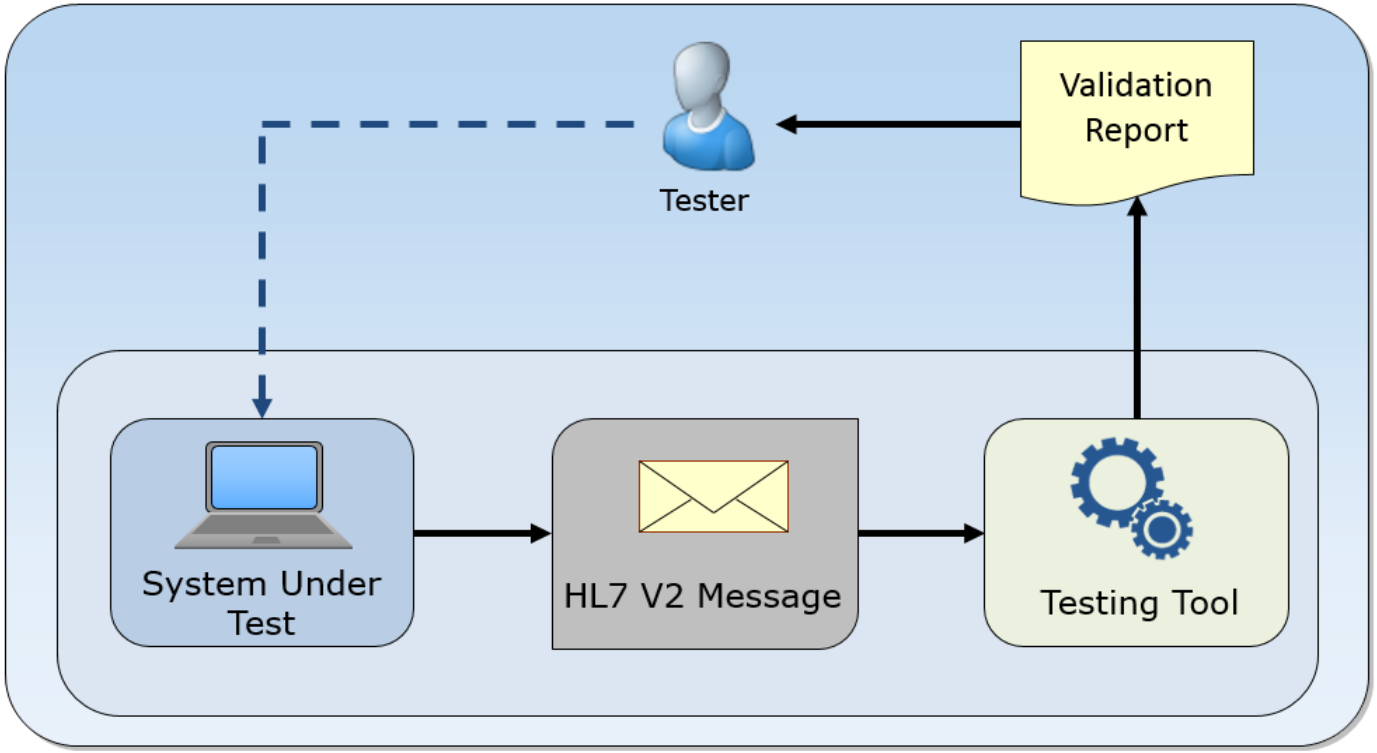


Includes testing for all 8 profiles in CDC IZ IG Release 1.5

- Stage-by-stage testing
- Independent—can enter at any stage (E.g., stage 4 will be ONC 2015 edition certification)
- Stages 1, 2, and 3 available now
- Stage 4 (~ mid-Summer)-ONC 2015 Edition
- Stage 5 & 6 (2016)

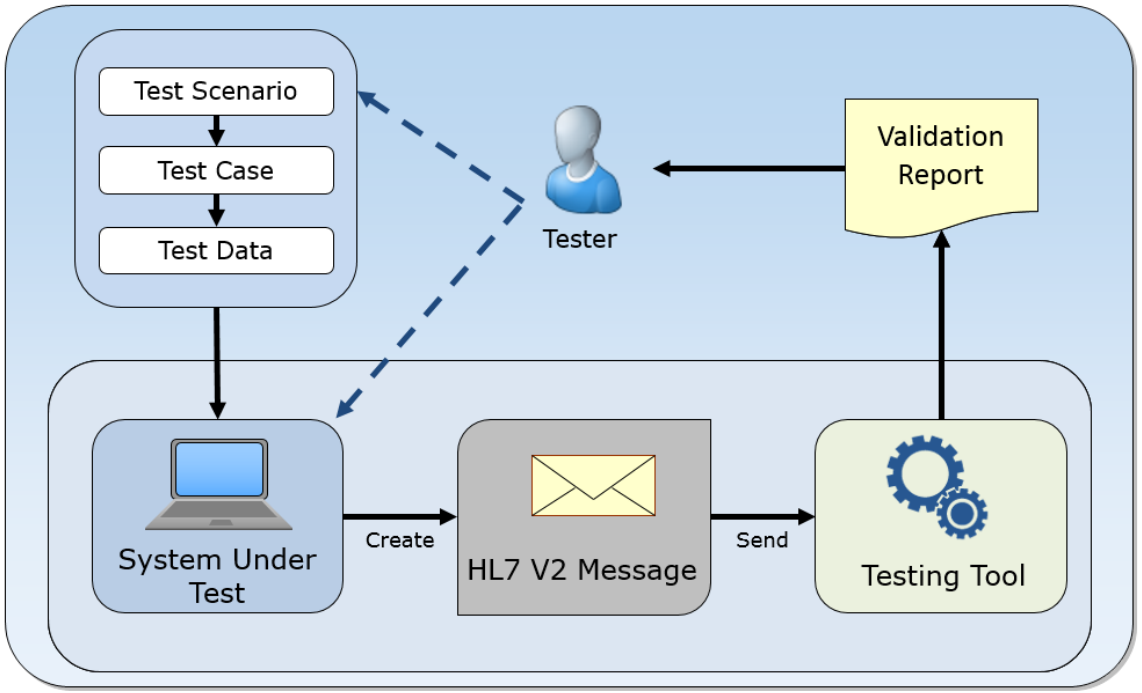
AIRA, CDC, and NIST Collaboration

Context-Free Testing



- 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*

Context-based Testing



- Context (specific scenario, data, etc.) is known to validation tool
  - The EHR creates a message that corresponds to the test data provided
  - Testing will include the technical requirements and content-specific requirements specified in the test case
- Used for ONC EHR technology certification testing
- Expands the scope of testing (e.g., support for RE elements)

IZ-tool Context-free Testing Walk-Through

Purpose: The main objective of the tool is to establish a powerful and interactive environment in which a Tester can perform validation on created SOAP messages, HL7 Version 2.5.1 data, and Center for Disease Control's (CDC) Web Service Description Language (WSDL) specifications.

Key Capabilities of the Tool	
HL7 Context-free Testing	A simple and convenient Test Case independent environment in which any HL7 message created by an EHR can be tested against adherence to structure and vocabulary within requirement based conformance profiles.
Conformance Profiles	A versatile testing capability leverages standards defined within the CDC HL7 Version 2.5.1 Implementation Guide for Immunization Messaging (Release 1.5 10/1/2014) to analyze HL7 message data being transmitted between an Immunization Information Systems (ISS) and a Electronic Health Record system (EHR-S).
Message Validation Engine	A Test Case independent environment in which an EHR-S or IIS created HL7 message can be loaded into a test environment, interactively viewed and modified in real-time, and validated against a selected Conformance Profile.
Validation Testing Report	Delivers a detailed report based on HL7 message segment validations against a selected Conformance Profile. Notifications are received for validation successes (i.e., Affirmatives), failures (i.e., Errors), and general notices (i.e., Warnings, Alerts, and Informational).

Current Build:

- **Version:** Beta v0.1
- **Environment**: The IZ ISS Test Suite is currently only accessible as a web application. The recommended method of access is using Chrome (latest stable build), Firefox (latest stable build), and Internet Explorer Version 9 web browsers.
- **URL**: http://hl7v2-iz-r1.5-testing.nist.gov/

Tool Access and Navigation

Objectives

- Establish access to the IZ ISS Test Suite tool (web application).
- Locate the Navigation Bar.
- Locate relevant documentation.
- Locate the Test Suite.

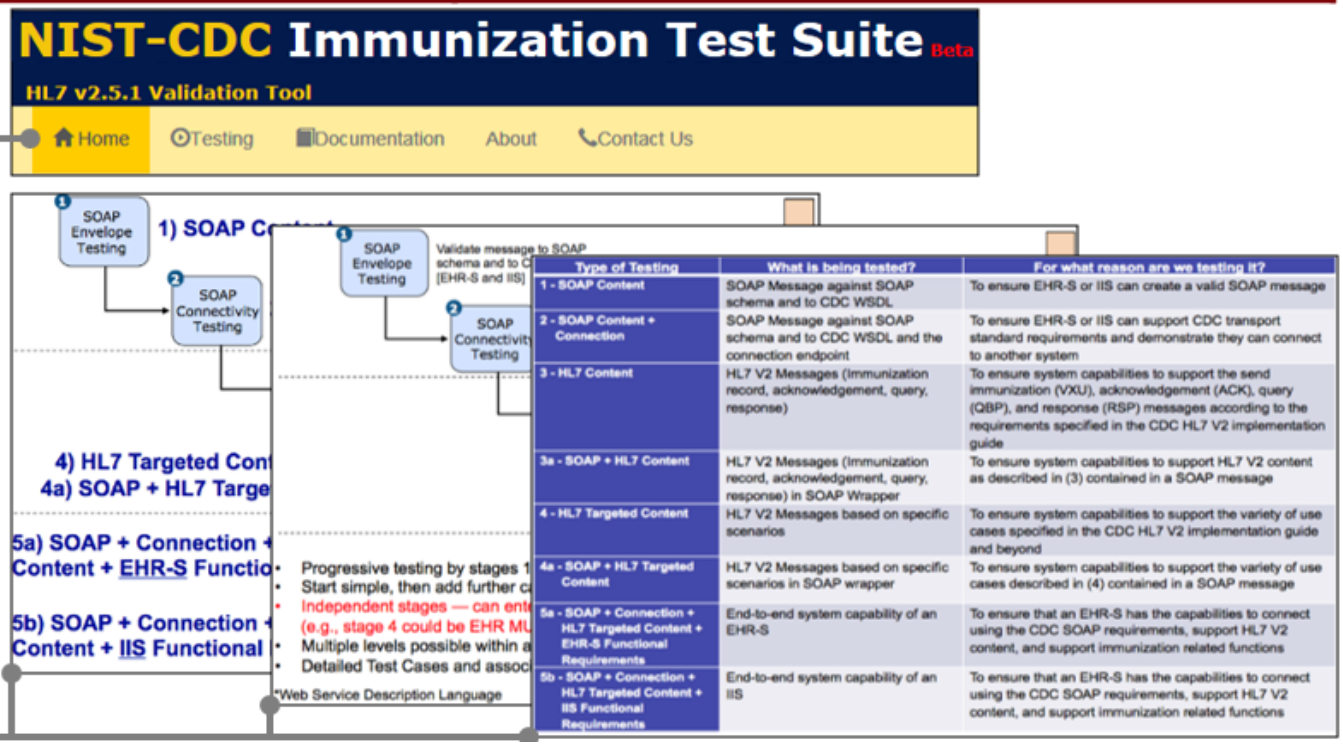
Informative Reference

- The IZ ISS Test Suite is accessible through the following URL: http://hl7v2-iz-r1.5-testing.nist.gov/.
- This displays the IZ ISS Test Suite's Welcome Screen, which is indicated by the '**Home**' tab.
- The '**Testing**' tab contains the Test Suite tools and validation engine.
- The '**Documentation**' tab contains relevant downloadable User, Documentation, Resources/Artifacts, and Notations.

1. The tool's Navigation Bar is located along the top. The options are '**Home**', '**Testing**', '**Documentation**', '**About**', and '**Contact Us**'.

   The Welcome Screen is located under the '**Home**' tab.

2. Scrolling down the Welcome Screen gives other useful information, such as the IZ ISS Test Suite:
   - Components;
   - Focus of Each Testing Stage;
   - Testing Stage Benefits; and
   - Testing Types.



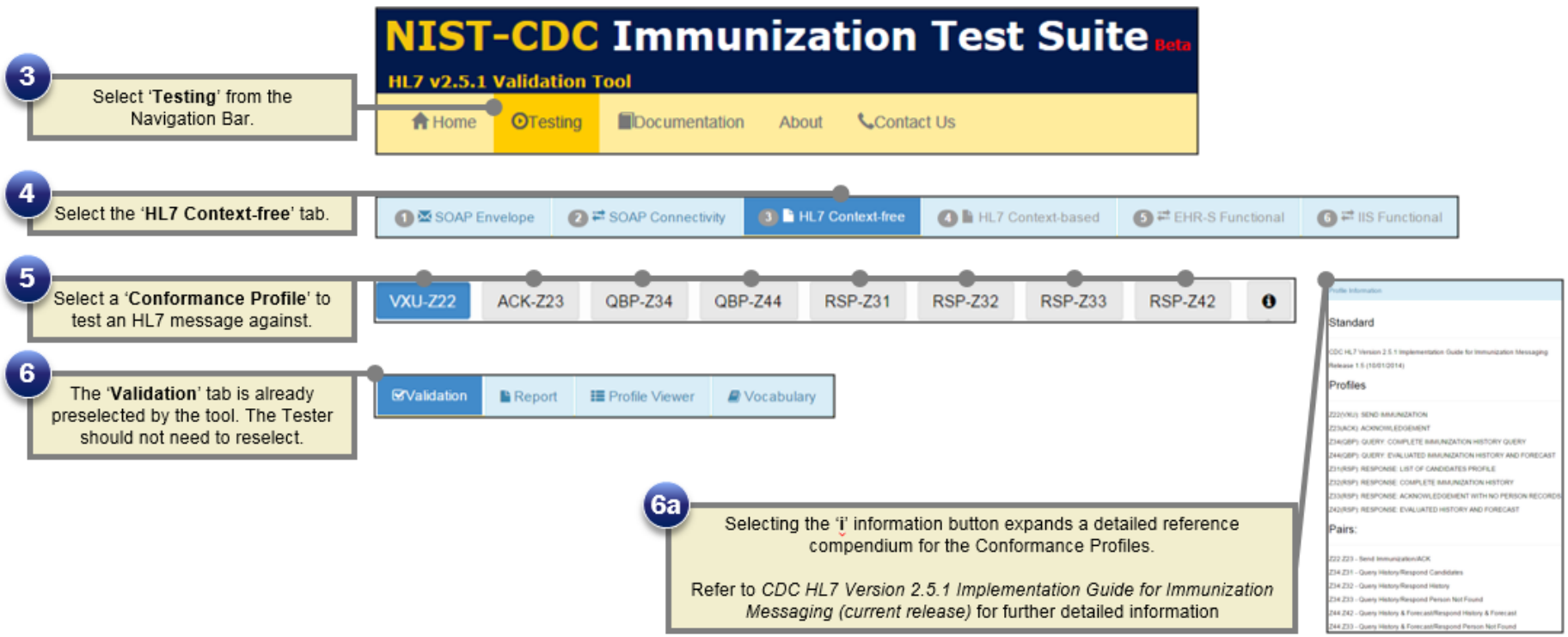
Conformance Profile Selection

Objectives

- Locate the '**Testing**' tab on the Navigation Bar.
- Locate the '**HL7 Context-free**' tab.
- Locate the IZ ISS Test Suite's available '**Conformance Profiles**'.
- Access additional information on standard / implementation guide documentation and profile linkages.

Informative Reference

- The '**Testing**' tab contains the target HL7 Context-free testing elements and associated HL7 message validation engine.
- The '**Conformance Profiles**' are derived from the *CDC HL7 Version 2.5.1 Implementation Guide for Immunization Messaging (current release)* document.



Load HL7 Message

Objectives

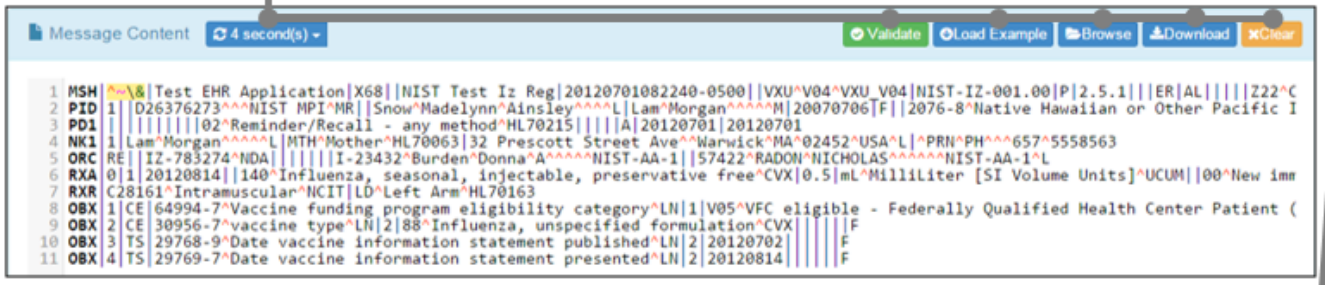
- Locate the '**Testing**' tab on the Navigation Bar.
- Locate the '**HL7 Context-free**' tab.
- Locate and select a profile from the IZ ISS Test Suite's available '**Conformance Profiles**'.
- Load an HL7 message into the IZ ISS Test Suite (either from local storage or by example).

Informative Reference

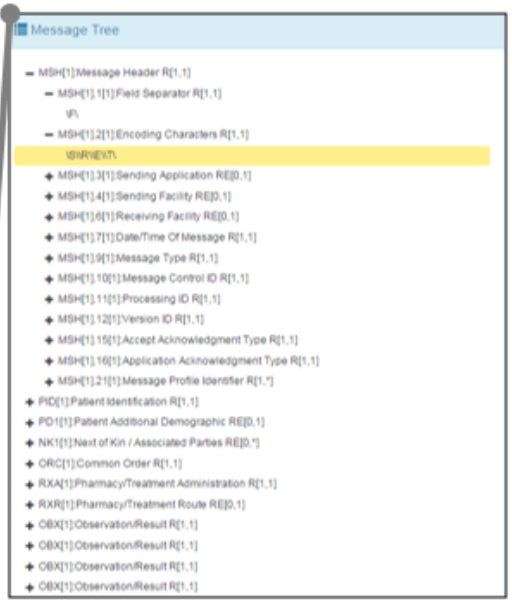
- An HL7 message can be loaded directly into the tool's '**Message Content**' field by copy/paste, direct from local file, or by default (preloaded and built-in) example.
- Clicking the '**Validate**' button performs instant message validation. The Tester can also elect to set an automatic message validation refresh frequency (Disable or 1 to 8 second delay).

7 With a Conformance Profile selected, an HL7 message can be loaded into the '**Message Content**' field by:
- Clicking the '**Browse**' button to load an existing HL7 message from the Tester's local machine; or
- Clicking the '**Load Example**' button to populate the a sample HL7 message based upon the Conformance Profile selection.

The validation frequency can be manipulated from '**1 to 8 seconds**'. Clicking the '**Validate**' button manually performs message validation against the selected Conformance Profile.
Selecting '**Download**' saves the viewable HL7 message in a .TXT' formatted file on the Tester's local machine.
Selecting '**Clear**' clears all HL7 related message data from the Message Content field.



8 When an HL7 message is loaded into the Message Content field, the '**Message Tree**' is automatically populated with the relevant HL7 message instance segments. Clicking the '+' and '-' arrows expand and contract the segments. Selecting an individual item shows its exact path with the Message Content field and viewable HL7 message (highlighted in yellow).



HL7 Message Validation

Objectives

- Locate the '**Testing**' tab on the Navigation Bar.
- Locate the '**HL7 Context-free**' tab.
- Locate and select a profile from the IZ ISS Test Suite's available '**Conformance Profiles**'.
- Load and validate an HL7 message within the IZ ISS Test Suite.

Informative Reference

- Performing HL7 message validation generates notifications for the Tester about the test and validation successes/failures. These are indicated as '**Errors**', '**Warnings**'/'**Alerts**'/'**Informational**', and '**Affirmatives**'.

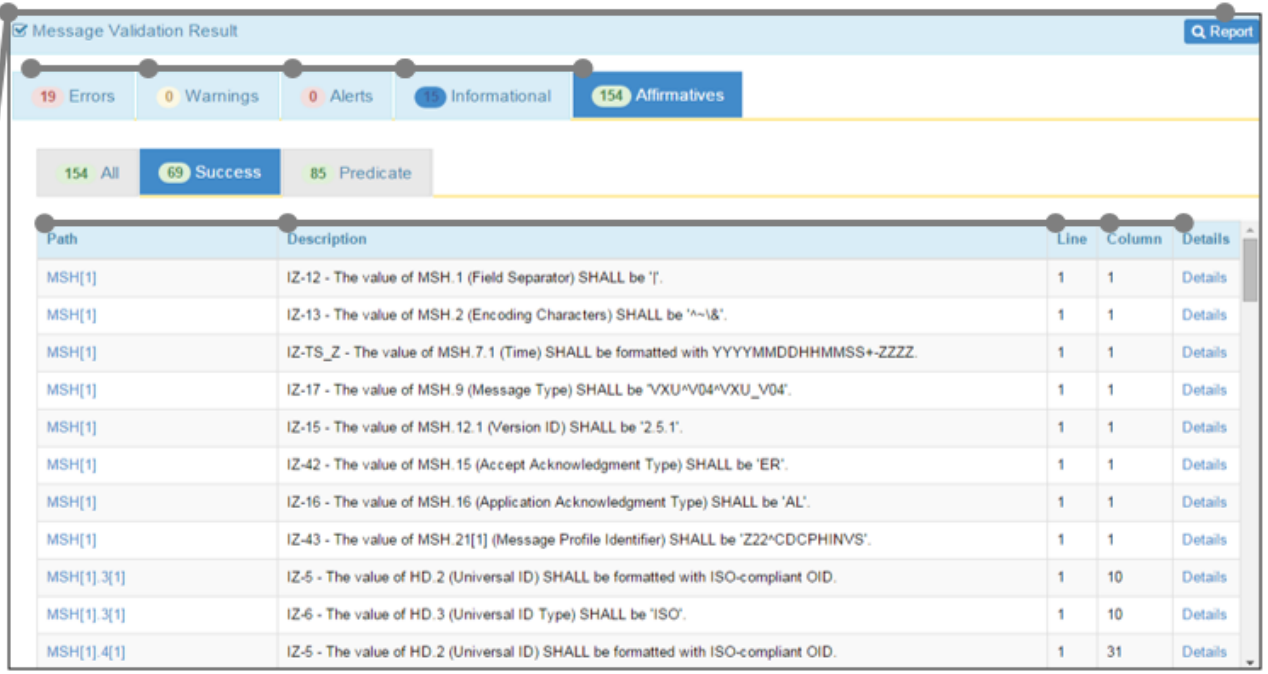
9

The HL7 message validation results are displayed within the '**Message Validation Result**' field. Various testing notifications are generated for the Tester. The types of notifications are:

- '**Errors**' – HL7 message elements that failed validation testing.
- '**Warnings**', '**Alerts**', and '**Information**' – 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.

The exact HL7 message '**Line**' and '**Column**' location where the notification was discovered is displayed, as well as '**Description**' for why the notification was flagged. Clicking the '**Path**' highlights in the Message Tree and Message Content fields the HL7 message notification data element. Clicking '**Details**' displays a popup with additional constraint/code metadata.

Clicking the '**Report**' button presents the Tester with a consumable Message Validation Report that captures the totality of HL7 Context-free validation for the given HL7 message under test.



Path	Description	Line	Column	Details
MSH[1]	IZ-12 - The value of MSH.1 (Field Separator) SHALL be '|'.	1	1	Details
MSH[1]	IZ-13 - The value of MSH.2 (Encoding Characters) SHALL be '^~\&'.	1	1	Details
MSH[1]	IZ-TS_Z - The value of MSH.7.1 (Time) SHALL be formatted with YYYYMMDDHHMMSS+-ZZZZ.	1	1	Details
MSH[1]	IZ-17 - The value of MSH.9 (Message Type) SHALL be 'VXU^V04^VXU_V04'.	1	1	Details
MSH[1]	IZ-15 - The value of MSH.12.1 (Version ID) SHALL be '2.5.1'.	1	1	Details
MSH[1]	IZ-42 - The value of MSH.15 (Accept Acknowledgment Type) SHALL be 'ER'.	1	1	Details
MSH[1]	IZ-16 - The value of MSH.16 (Application Acknowledgment Type) SHALL be 'AL'.	1	1	Details
MSH[1]	IZ-43 - The value of MSH.21[1] (Message Profile Identifier) SHALL be 'Z22^CDCPHINVS'.	1	1	Details
MSH[1].3[1]	IZ-5 - The value of HD.2 (Universal ID) SHALL be formatted with ISO-compliant OID.	1	10	Details
MSH[1].3[1]	IZ-6 - The value of HD.3 (Universal ID Type) SHALL be 'ISO'.	1	10	Details
MSH[1].4[1]	IZ-5 - The value of HD.2 (Universal ID) SHALL be formatted with ISO-compliant OID.	1	31	Details

HL7 Message Validation Report

Objectives

- Locate the '**Testing**' tab on the Navigation Bar.
- Locate the '**HL7 Context-free**' tab.
- Locate and select a profile from the IZ ISS Test Suite's available '**Conformance Profiles**'.
- Load and validate an HL7 message within the IZ ISS Test Suite.
- Generate and review the '**Message Validation Report**'.

Informative Reference

- The '**Message Validation Report**' gives a Tester the complete narrative for a single validation test. Multiple tests cannot be combined together within the report.

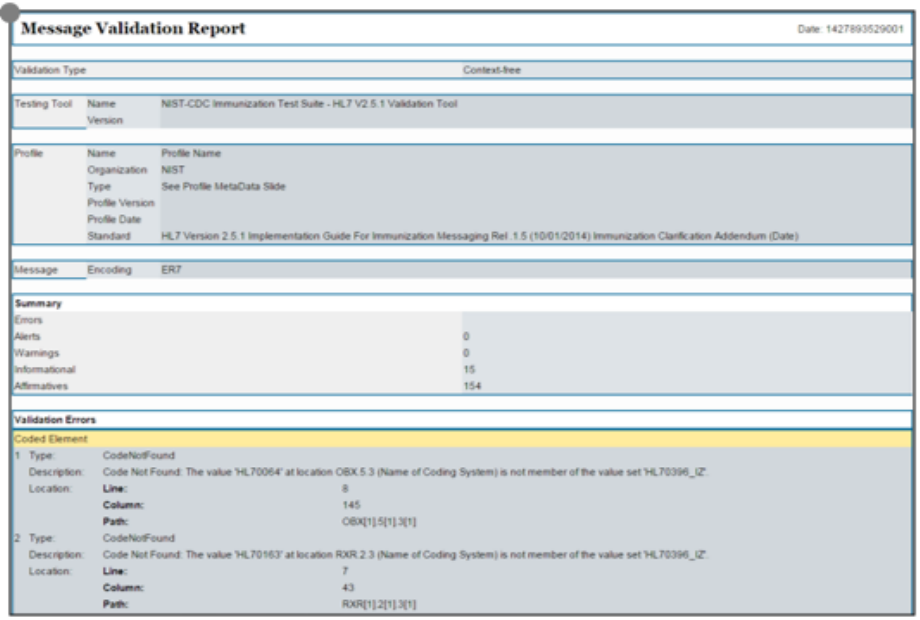
10 Select the '**Report**' tab.

11 The '**Message Validation Report**' presents the complete results of HL7 message validation testing in an easily consumable format.

Meta such as validation testing type, tool used, and profile used to validate against are included in the report.

A detailed summary of '**Errors**' (i.e., validation fails), '**Alerts**', '**Warnings**', '**Information**' elements, and '**Affirmatives**' (i.e., validation successes and condition predicate satisfactions) are also presented in the report.

*The '**Message Validation Report**' for a HL7 message validation test can also be viewed by clicking the '**Report**' button within the '**Message Validation Result**' field (*see Step 9*).



Message Validation Report

Date: 1427893529001

Validation Type		Context-free
Testing Tool	Name	NIST-CDC Immunization Test Suite - HL7 V2.5.1 Validation Tool
	Version	
Profile	Name	Profile Name
	Organization	NIST
	Type	See Profile MetaData Slide
	Profile Version	
	Profile Date	
	Standard	HL7 Version 2.5.1 Implementation Guide For Immunization Messaging Rel .1.5 (10/01/2014) Immunization Clarification Addendum (Date)
Message	Encoding	ER7

Summary

Errors	
Alerts	0
Warnings	0
Informational	15
Affirmatives	154

Validation Errors

Coded Element

1 Type: CodeNotFound
Description: Code Not Found: The value 'HL70064' at location OBX.5.3 (Name of Coding System) is not member of the value set 'HL70396_IZ'
Location: Line: 8
Column: 145
Path: OBX[1].5[1].3[1]

2 Type: CodeNotFound
Description: Code Not Found: The value 'HL70163' at location RXR.2.3 (Name of Coding System) is not member of the value set 'HL70396_IZ'
Location: Line: 7
Column: 43
Path: RXR[1].2[1].3[1]

Conformance Profile Data Elements

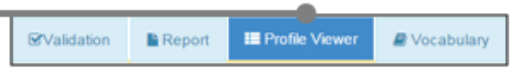
Objectives

- Locate the '**Testing**' tab on the Navigation Bar.
- Locate the '**HL7 Context-free**' tab.
- Locate and select a profile from the IZ ISS Test Suite's available '**Conformance Profiles**'.
- Load and validate an HL7 message within the IZ ISS Test Suite.
- Generate and review the '**Message Validation Report**'.
- Review HL7 message data type and element requirements.

Informative Reference

- The '**Profile Viewer**' gives a Tester the complete standard / implementation guide metadata components that is needed to perform supplemental message validation, error remediation, and troubleshooting.

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

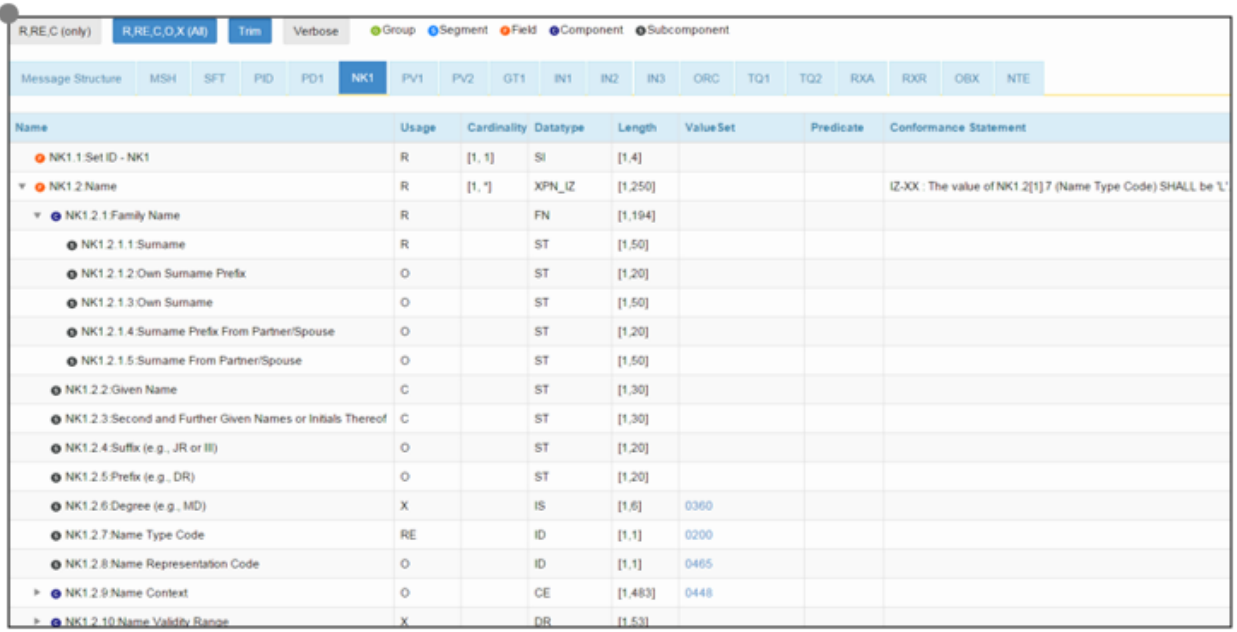


13 This display presents an interactive interface in which to view data elements and table values for a selected Conformance Profile. The '**Message Structure**' tab displays all data segments for a selected Conformance Profile. Each segment can be filtered by selecting the corresponding tab. Data types are organized based on message '**Group**', '**Segment**', '**Field**', '**Component**', and '**Subcomponent**'.

Data elements may be filtered according to Usage by selecting either:

- '**R, RE, C (only)**' – Required, Required but may be empty, and Conditional; or
- '**R, RE, C, O, X (All)**' – Required, Required but may be empty, Conditional, Optional, and Not supported.

'**Cardinality**', '**Data Type**', '**Length**' (minimum/maximum valid data element length), '**Value Set**', '**Condition Predicate**', and '**Conformance Statement**' fields are also represented for each data element.



View Conformance Profile Vocabulary

Objectives

- Locate the '**Testing**' tab on the Navigation Bar.
- Locate the '**HL7 Context-free**' tab.
- Locate and select a profile from the IZ ISS Test Suite's available '**Conformance Profiles**'.
- Load and validate an HL7 message within the IZ ISS Test Suite.
- Generate and review the '**Message Validation Report**'.
- Review HL7 message data type and element requirements.
- Browse HL7 message vocabulary requirements.

Informative Reference

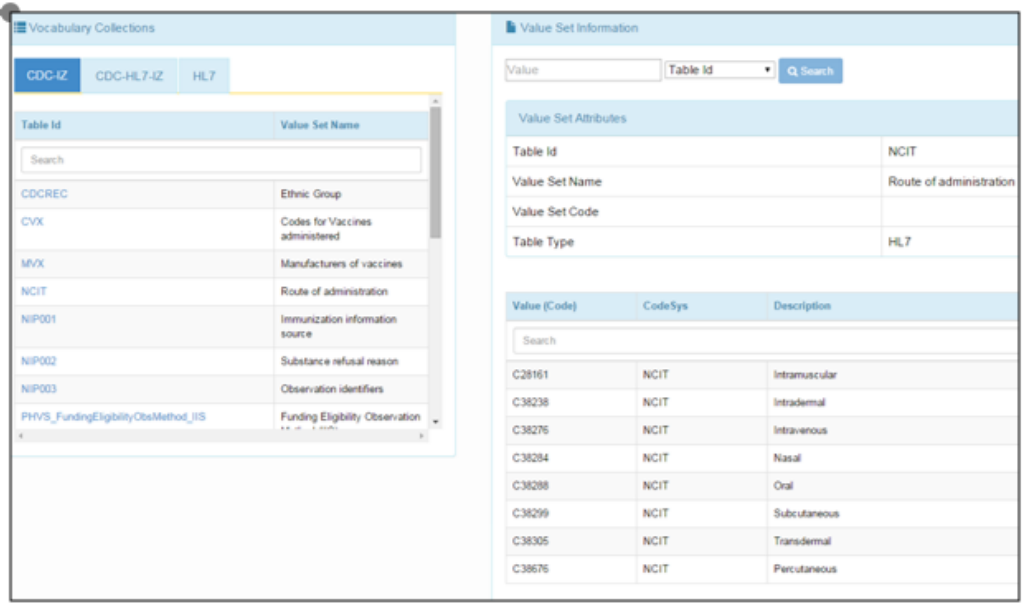
- The '**Vocabulary**' tab provides the Tester a reference repository for HL7 message and standard / implementation guide driven vocabulary requirements.

14 Select the '**Vocabulary**' tab.

15 This display presents a functional way to browse Conformance Profile vocabulary requirements.

The search feature includes the capability to search based on vocabulary '**Table ID**', '**Value Set Code**', '**Value Set Name**', and '**Description**'.

Clicking a '**Table ID**' in the '**Vocabulary Collections**' field populates the '**Value(Code)**', '**CodeSys**', and '**Description**' table fields.



Hands-on Activities and Tool URLs

1. Determine and document local requirements
2. Using IGAMT-lite modify CDC Profile, add constraints for:
    1. Usage
    2. Cardinality
    3. Length
    4. Data Type
    5. Value Sets
    6. Conformance Statements
3. Export Local Profile

- IGAMT-lite

  hl7v2.igamt.nist.gov

- Immunization Test Suite

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

Status

- IGAMT-lite
  - IGAMT-lite Prototype Today
  - Seeking pilot testers
  - Webinar to be presented when finished
  - Send interest to:

Rob Snelick (robert.snelick@nist.gov)

- Immunization Test Suite
  - SOAP and HL7 Context-free testing is available
  - MU 2015 Edition (Summer)
    - VXU, ACK, QBP, RSP
    - Test Cases
  - Add data quality
  - EHR-S and IIS Functional Requirement Testing (2016)