Test Procedure for §170.314(f)(2) Transmission to immunization registries

This document describes the test procedure for evaluating conformance of EHR technology to the certification criteria defined in 45 CFR Part 170 Subpart C of the Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, Final Rule. The document[1] is organized by test procedure and derived test requirements with traceability to the normative certification criteria as described in the Overview document located at http://www.healthit.gov/certification (navigation: 2014 Edition Test Method). The test procedures may be updated to reflect on-going feedback received during the certification activities.

The Department of Health and Human Services (HHS)/Office of the National Coordinator for Health Information Technology (ONC) has defined the standards, implementation guides and certification criteria used in this test procedure. Applicability and interpretation of the standards, implementation guides and certification criteria to EHR technology is determined by ONC. Testing of EHR technology in the Permanent Certification Program, henceforth referred to as the ONC Health Information Technology (HIT) Certification Program[2], is carried out by National Voluntary Laboratory Accreditation Program (NVLAP) - Accredited Testing Laboratories (ATLs) as set forth in the final rule establishing the Permanent Certification Program (*Establishment of the Permanent Certification Program for Health Information Technology, 45 CFR Part 170; February 7, 2011*).

Questions or concerns regarding the ONC HIT Certification Program should be directed to ONC at ONC.Certification@hhs.gov.

CERTIFICATION CRITERIA

This certification criterion is from the Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, Final Rule issued by the Department of Health and Human Services (HHS) on September 4, 2012.

§170.314(f)(2) Transmission to immunization registries. EHR technology must be able to electronically create immunization information for electronic transmission in accordance with:

(i) The standard and applicable implementation specifications specified in §170.205(e)(3); and

(ii) At a minimum, the version of the standard specified in §170.207(e)(2)

[1] Disclaimer: Certain commercial products may be identified in this document. Such identification does not imply recommendation or endorsement by ONC.

[2] Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, Final Rule.

Per Section III.A of the preamble of the Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, Final Rule (September 4, 2012), the 2014 Edition of this certification criterion is classified as revised from the 2011 Edition. This certification criterion meets at least one of the three factors of revised certification criteria: (1) the certification criterion includes changes to capabilities that were specified in the previously adopted certification criterion, (2) the certification criterion has a new mandatory capability that was not included in the previously adopted certification criterion, or (3) the certification criterion was previously adopted as "optional" for a particular setting and is subsequently adopted as "mandatory" for that setting.

2014 Edition Preamble Language

Per Section III.A of the preamble of the Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, Final Rule where the transmission to immunization registries certification criterion is discussed:

- "We do not believe that permitting EHR technology to continue to be certified to HL7 2.3.1 as a means of meeting this certification criterion promotes improved exchanged and interoperability. Therefore, we are adopting only HL7 2.5.1 for the "transmission to immunization registries" certification criterion."
- "The CDC has worked to clarify ambiguities in Release 1.3 of the implementation guide and has published a new version of the implementation guide, Release 1.4, which reflects these clarifications. In particular, Release 1.4 clarifies the separate usage responsibilities for senders and receivers, provides conformance statements identifying core data elements that must be supported based on the National Vaccine Advisory Committee (NVAC) core data elements, adds support for messaging Vaccine Information Statement (VIS) data based on a 3D barcode, and provides HL7 version 2.7.1 usage guidance that improves clarity for conformance criteria and the requirements for HL7 message elements. Overall, these revisions do not establish additional substantive requirements in comparison to Release 1.3. Rather, the revisions improve the ability to test and certify EHR technology to the implementation guide and make it easier for EHR technology developers to implement the guide's requirements based on the corrections and clarifications."
- "Accordingly, in lieu of adopting Release 1.3 of the implementation guide as we had proposed, we have adopted Release 1.4 for the "transmission to immunization registries" certification criterion. For the reasons stated above, we are not adopting HL7 2.3.1."
- "Release 1.4 of the implementation guide reduces variability and standardizes the required data elements across public health jurisdictions. Release 1.4 also notes a standard format for states to indicate any variability."
- "The certification criteria do not address transport standards, as this is left to the receiving public health authority. However, an expert panel convened by CDC and American Immunization Registry Association (AIRA) has recommended a SOAP-based standard for transport of immunization data."

- "…we continue to believe that the adoption of CVX is appropriate and that no other vocabulary standard needs to be expressly adopted for the purposes of certification."
- "We have established a process for adopting certain vocabulary standards, including CVX, which permits the use of newer versions of those standards than the one adopted in regulation. We refer readers to section IV.B for a discussion of "minimum standards" code sets and our new more flexible approach for their use in certification and upgrading certified EHR technology. Readers should also review § 170.555, which specifies the certification processes for "minimum standards" code sets."
- "The triggering event for reporting of an immunization is not part of the certification criteria. Certification focuses on the ability of EHR technology to properly create immunization information for electronic transmission according to the adopted standard and implementation specification."
- "The purpose of this certification criterion is to support interoperability between EHR technology and public health. Thus, any EHR technology that meets the certification requirements can be utilized to submit data to an Immunization Registry."
- "…we do not require EHR technology to be certified to any transport standard, including Direct, to meet this certification criterion. There is no consensus transport standard that states and public health agencies use for the reporting of immunization information. Therefore, we believe that it is appropriate for EHR technology developers to have the flexibility to include in their EHR technology and implement the transport standards that permit EPs, EHs, and CAHs to report in their states and to local public health agencies."

2011 Edition Preamble Language

Per Section III.D of the preamble of the Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, Final Rule (July 28, 2010) where the submission to immunization registries certification criterion is discussed:

- "We are primarily concerned with Certified EHR Technology's ability to transmit the immunization information in a standardized format, and do not believe that it is necessary to specify a particular recipient in the certification criterion."
- "The CDC maintains an openly available list of updated CVX codes as well as a mapping of CVX codes to CPT codes on their website."
- "NDC codes were not adopted as a standard to represent immunizations and we do not believe that requiring their use for the purposes of demonstrating compliance with this certification criterion would be appropriate."
- "…we have revised the certification criterion to replace the word "transmit" with "submit" to better align this certification criterion with the meaningful use objective and measure."

Changes from 2011 to 2014 Edition

Per Section III.A of the preamble of the Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 (September 4,

2012) Edition; Revisions to the Permanent Certification Program for Health Information Technology, Final Rule where the transmission to immunization registries certification criterion is discussed:

- "We proposed two certification criteria for immunization registries that were essentially a split of the 2011 Edition EHR certification criterion for submission to immunization registries (§170.302(k)).
    - We proposed one certification criterion that focused just on the capabilities to electronically record, change, and access immunization information (data capture) and another that focused on the capability to electronically create immunization information for electronic transmission in accordance with specified standards
    - For the certification criterion focused on electronically creating immunization information for electronic transmission, we clarified that this criterion focuses on the capability of EHR technology to properly create immunization information for electronic transmission in accordance with the applicable standards and implementation specifications.
    - We proposed the use of only the HL7 2.5.1 standard for formatting immunization information because immunization registries are rapidly moving to this standard."
- "Commenters supported our proposed 'two certification criteria approach'."

INFORMATIVE TEST DESCRIPTION

This section provides an informative description of how the test procedure is organized and conducted. It is not intended to provide normative statements of the certification requirements.

The test procedures are developed to be used by the ATLs in certification of EHR technology for the ONC. The term 'Tester', when used in the test procedure, refers to a person (such as an ATL employee) acting on behalf of an ATL for certification testing of a Vendor's EHR technology. In addition, an EHR Vendor may use the test procedures to test their own EHR technology in preparation for certification testing by an ATL.

This test evaluates the capability for a EHR technology to electronically generate immunization information for electronic transmission using the HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.4; and using the HL7 Standard Code Set CVX -- Vaccines Administered vocabulary standard.

During the process of building the HL7v2 Immunization Information System Reporting Validation Tool, additional errata as well as conformance requirements that were either conflicting or unclear in the named standards documents were discovered. The "*Conformance Clarification for EHR Certification of Immunization Messaging VXU MESSAGES V04 HL7 Version 2.5.1 Release 4 – November 27, 2012, Addendum to HL7 Version 2.5.1 Implementation Guide for Immunization Messaging (Release 1.4)*" clarifies these issues and indicates how they are interpreted in the test tool. This document can be accessed via the "Documentation" tab on the Conformance Test Tool.

Seven Test Scenarios are listed in the test data section for this test procedure, and each Test Scenario has three Test Cases. The test data for the Test Cases are provided in the Test Case PDF documents associated with this test procedure. For the certification test, the Tester shall select one Test Case from **each** of the seven Test Scenarios. Additional instructions for use of the provided test data are listed in the Normative Test Procedure and test data sections of this test procedure document.

ONC supplies the test data for this test procedure.

The test procedure is organized into one section:

- Create – evaluates the capability of the EHR technology to electronically generate conformant HL7 messages for immunization information
    - Using the Vendor-identified EHR function(s), the Tester inputs the provided immunization information test data for the test patients (input can be performed using a manual or automated process)
    - Using the Vendor-identified EHR function(s) and the provided test data, the Tester causes the EHR to generate the indicated immunization information message using the HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.4, and the HL7 Standard Code Set CVX -- Vaccines Administered vocabulary standard
    - Using the Vendor-identified EHR function(s), the Tester imports the message into HL7v2 Immunization Information System Reporting Validation Tool
    - Using the Validation Report produced by the HL7v2 Immunization Information System Reporting Validation Tool, the Tester verifies that the Implementation Guide conformance requirements tested are met and that the CVX codes are appropriate for the immunization information message

REFERENCED STANDARDS

§170.205 Content exchange standards and implementation specifications for exchanging electronic health information.	Regulatory Referenced Standard
The Secretary adopts the following content exchange standards and associated implementation specifications:	
(e)(3) Standard. HL7 2.5.1 (incorporated by reference in § 170.299). Implementation specifications. HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.4, (incorporated by reference in § 170.299).	
§170.207 Vocabulary standards for representing electronic health information.	**Regulatory Referenced Standard**
The Secretary adopts the following code sets, terminology, and nomenclature as the vocabulary standards for the purpose of representing electronic health information:	

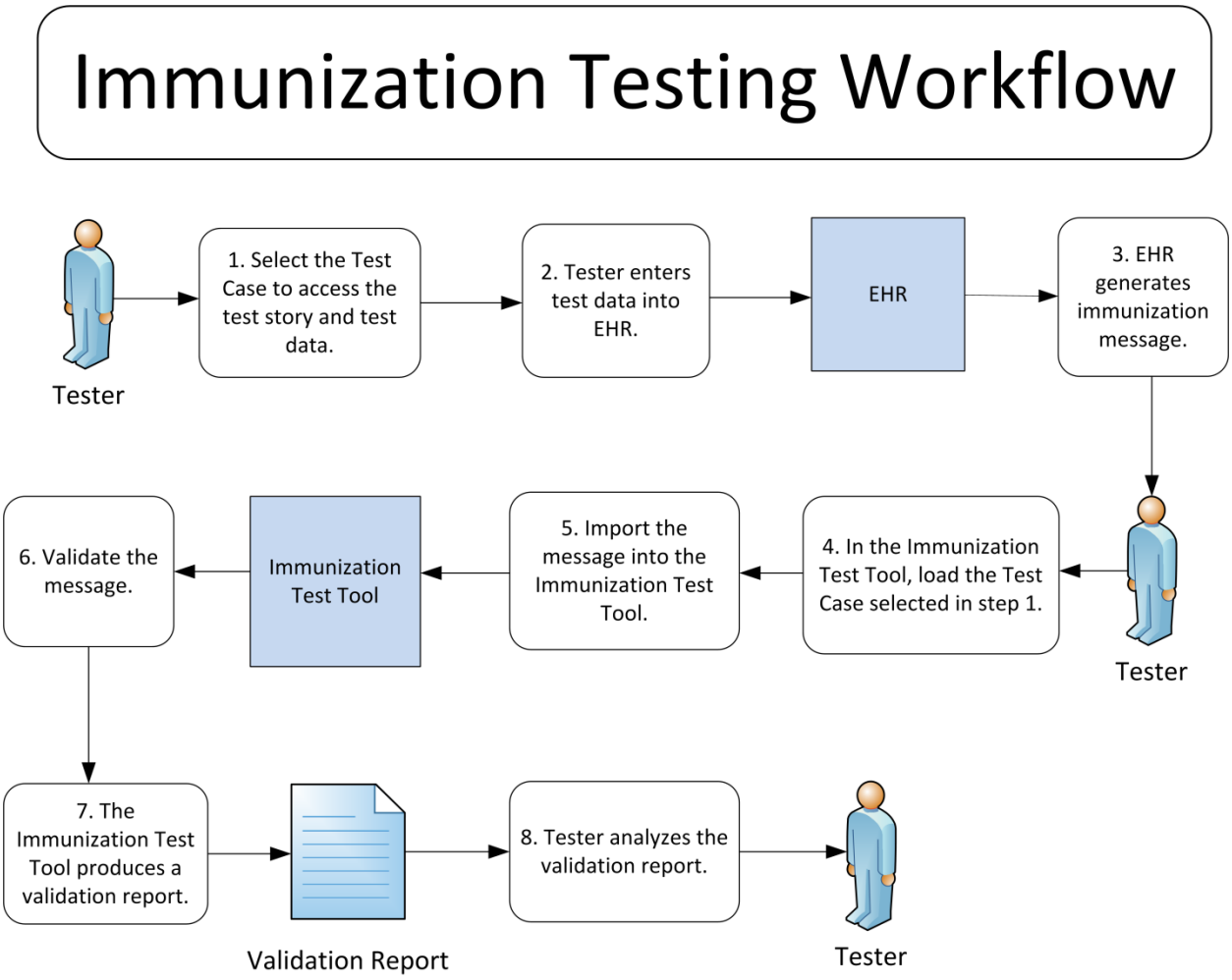
§170.205 Content exchange standards and implementation specifications for exchanging electronic health information.	Regulatory Referenced Standard
(e)(2) Standard. HL7 Standard Code Set CVX -- Vaccines Administered, updates through July 11, 2012 (incorporated by reference in § 170.299).	

NORMATIVE TEST PROCEDURES

Derived Test Requirements

DTR170.314(f)(2) - 1: Electronically Create Immunization Information

Figure 1



The instructions in the derived test procedure listed below reference the numbered test steps in Figure 1 above.

DTR170.314(f)(2) - 1: Electronically Create Immunization Information

Required Vendor Information

VE170.314(f)(2) – 1.01: Vendor shall identify the EHR function(s) that are available to 1) input the test data into the EHR for the test patients, 2) create immunization information messages using the test data, 3) import the immunization information messages to the HL7v2 Immunization Information System Reporting Validation Tool, and 4) demonstrate support for the named standard vocabulary value sets

VE170.314(f)(2) – 1.02: Vendor shall provide the mechanism necessary to capture and import immunization messages into the HL7v2 Immunization Information System Reporting Validation Tool

Required Test Procedures

For each of the seven Test Scenarios provided in the test data section of this test procedure, follow the steps below:

TE170.314(f)(2) – 1.01: Tester shall select a Test Case consisting of immunization information [Figure 1, Step 1]

TE170.314(f)(2) – 1.02: Using the Vendor-identified EHR function(s), the Tester shall input the provided immunization information test data selected in TE170.314(f)(2) – 1.01 (input can be performed using a manual or automated process) [Figure 1, Step 2]

TE170.314(f)(2) – 1.03: Using the Vendor-identified EHR function(s) and the selected immunization information test data, the Tester shall

- Cause the EHR to generate the indicated immunization information message for the test patient based on the HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.4 interoperability standard, and the HL7 Standard Code Set CVX -- Vaccines Administered vocabulary standard [Figure 1, Step 3]
- Import the immunization information message to the HL7v2 Immunization Information System Reporting Validation Tool identified in the Conformance Test Tools section of this test procedure [Figure 1, Steps 4 & 5]

TE170.314(f)(2) – 1.04: Using the Inspection Test Guide, the Tester shall verify that the immunization message is conformant to the named standards and is generated with the appropriate immunization information

Inspection Test Guide

IN170.314(f)(2) – 1.01: Using the Validation Report produced by the HL7v2 Immunization Information System Reporting Validation Tool identified in the Conformance Test Tools section of this test procedure**,** the Tester shall verify that the Immunization Implementation Guide conformance requirements tested are met [Figure 1, Step 6, 7 & 8]

IN170.314(f)(2) – 1.02: Once during the certification testing for this criterion, the Tester shall inspect the EHR to verify the capability of the Vendor to support the named HL7 Standard Code Set CVX -- Vaccines Administered vocabulary standard and the value sets

specified in the HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.4 interoperability standard

- Using the Vendor-identified EHR function(s) and the HL7v2 Immunization Information System Reporting Validation Tool, the Vendor shall demonstrate to the Tester that their EHR supports the HL7 Standard Code Set CVX -- Vaccines Administered vocabulary standard
- Using the Vendor-identified EHR function(s) and the HL7v2 Immunization Information System Reporting Validation Tool, the Vendor shall demonstrate to the Tester that their EHR supports the CDC-defined NIP001 – Immunization information source value set
- At their discretion, the Tester may select another value set specified in the HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.4 interoperability standard and, using the Vendor-identified EHR function(s) and the HL7v2 Immunization Information System Reporting Validation Tool, the Vendor shall demonstrate that their EHR supports that selected value set

TEST DATA

ONC supplied test data are provided with the test procedure to ensure that the applicable requirements identified in the criteria can be adequately evaluated for conformance, as well as to provide consistency in the testing process across multiple National Voluntary Laboratory Accreditation Program (NVLAP) - Accredited Testing Labs (ATLs). The provided test data focus on evaluating the basic capabilities of required EHR technology, rather than exercising the full breadth/depth of capability that installed EHR technology might be expected to support. The test data are formatted for readability of use within the testing process. The format is not prescribing a particular end-user view or rendering. No additional requirements should be drawn from the format.

The Tester shall use and apply the provided test data during the test, without exception, unless one of the following conditions exists:

- The Tester determines that the Vendor product is sufficiently specialized that the provided test data needs to be modified in order to conduct an adequate test. Having made the determination that some modification to the provided test data is necessary, the Tester shall record the modifications made as part of the test documentation. See Table 2 below for guidance on allowable changes to data.
- The Tester determines that changes to the test data will improve the efficiency of the testing process; primarily through using consistent demographic data throughout the testing workflow. The Tester shall ensure that the functional and interoperable requirements identified in the criterion can be adequately evaluated for conformance and that the test data provides a comparable level of robustness.

Any departure from the provided test data shall focus on meeting the basic capabilities required of EHR technology relative to the certification criterion rather than exercising the full breadth/depth of capability that installed EHR technology might be expected to support.

The test procedures require that the Tester enter the applicable test data into the EHR technology being evaluated for conformance. The intent is that the Tester fully controls the process of entering the test data in order to ensure that the data are correctly entered as specified in the test procedure. If a situation arises where it is impractical for a Tester to directly enter the test data, the Tester, at the Tester's discretion, may instruct the Vendor to enter the test data, so long as the Tester remains in full control of the testing process, directly observes the test data being entered by the Vendor, and validates that the test data are entered correctly as specified in the test procedure.

For ONC EHR certification testing, the primary purpose of the provided test data is to assist the Tester in verifying that the vendors' EHR technologies are capable of supporting the required functions; verifying the ability to support the specific content is not the purpose of the test data. Such testing and verification is more appropriate for local installations of the EHR technologies. The clinical test data are relevant for the given test stories; however, these data should not be expected to represent standards of practice.

Test data for §170.314(f)(2) Transmission to immunization registries is available through the conformance tool (reference Conformance Tool Section for tool access).

For this test procedure the Tester shall select one Test Case from **each** of the seven Test Scenarios listed (the Test Cases provide data that may be used for an ambulatory or an inpatient setting):

1. Admin for Child
2. Admin for Adult
3. Historical for Child
4. Consented Child
5. Refused Toddler
6. Varicella History Child
7. Complete Record

The Tester shall follow the normative test procedure to conduct these tests. Table 1 (Immunization Test Scenarios and Associated Test Cases) lists the **seven** Test Scenarios and identifies **three** Test Cases for each scenario. Details of the Test Cases, including the test story, test objectives, and test data, are provided in PDF files and are also accessible in the test tool (See the Context-based Validation tab).

Table 1: Immunization Test Scenarios and Associated Test Cases

Test Scenarios	Test Case 1	Test Case 2	Test Case 3
Administration for Child	IZ_1_1.1_Max	IZ_1_1.2_Max	IZ_1_1.3_Max
Administration for Adult	IZ_2_1.1_Typ	IZ_2_1.2_Typ	IZ_2_1.3_Typ

Historical for Child	IZ_3_1.1_Typ	IZ_3_1.2_Typ	IZ_3_1.3_Typ
Consented Child	IZ_4_1.1_Typ	IZ_4_1.2_Typ	IZ_4_1.3_Typ
Refused Toddler	IZ_5_1.1_Typ	IZ_5_1.2_Typ	IZ_5_1.3_Typ
Varicella History Child	IZ_6_1.1_Typ	IZ_6_1.2_Typ	IZ_6_1.3_Typ
Complete Record	IZ_7_1.1_Typ	IZ_7_1.2_Typ	IZ_7_1.3_Typ

NAVIGATING A TEST CASE

A test case consists of a test story and a test data specification. The test story gives a real world scenario that provides the context for the test case. The test data specification provides the data associated with the test story and is what is typically available in the clinical setting. Together the test story and the test data specification provide sufficient information that is to be entered into the EHR for a particular test case. Using this data and the EHR functions, a message is to be generated.

Another artifact called the message content data sheet is provided that shows a conformant message instance for the test case. The message content is organized in a table format that provides the HL7 V2 message elements and the data associated with the message elements for a given test case. If necessary the message content may be used to help the Vendor select the correct option provided by the EHR technology. It may also be used to provide assistance to the Tester and Vendor to resolve issues discovered in conformance testing. In short, the message content data sheet can be thought of as the "answer" to the scenario ("question") provided by the test story and the test data specification.

HOW TO INTERPRET THE MESSAGE CONTENT DATA SHEET

The message content data sheet indicates the location and data of the message for a particular test case. The message content data sheet can be used to assist the Tester in loading the EHR with the test case data and provides a classification of the data. This classification indicates the type and the expected source of the data. How the data is classified is directly related to how the message content is validated. In some cases the validator is examining the message element for the presence of data whereas in other cases it is examining the message element for the presence of data and for exact content.

The information in the ***Location*** column indicates the canonical element location in the HL7 V2 message. For example, MSH-9.3 represents the 3rd component in the 9th field of the MSH segment. The ***Data Element*** column indicates the name of the data element as specified by the HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.4.

The ***Test Data*** column provides the expected data (if applicable) for that message element. The ***Data Classification*** column indicates the classification of the data. See the table below for a description of the data classification and how it is being validated.

Table 2 Description of Data Classification and Validation

Data Classification	Description	Validation
Configurable	Data typically that is configured by the system (customer-definable). Example data is provided.	Validate for the presence of data
System Generated	Data typically generated automatically by system, e.g., message time. Example data is provided.	Validate for the presence of data
IG Fixed	Data that is fixed by the implementation guide; data can't be changed. Specific data is provided.	Validate for the presence and data content
Test Case Fixed	Data that is specific and fixed by the test case; data should not be changed. Specific data is provided.	Validate for the presence and selectively validate for data content
Changeable	Data where the exact content is not relevant for the test case and can be changed for the purposes of testing. Example data is provided.	Validate for the presence of data

The test cases and the context-based validation test tool are tightly-coupled. In addition to validating message conformance, the test tool performs selective content validation based on the test story and test data provided, and deviation from the test data may cause the test tool to issue Errors. For this reason, the Tester should use the test data as specified.

The HL7v2 standard provides flexibility in messaging—many different message instances for a given test case step can be considered conformant. The test tool is designed to support such instances; however, it is not a certainty. If the test tool issues an error for a message instance, the Vendor shall provide evidence of equivalency to the Tester.

CONFORMANCE TEST TOOLS

The following testing tools are available to evaluate conformance to the standards referenced in this test procedure:

- HL7v2 Immunization Information System Reporting Validation Tool – an HL7v2 validation tool is designed specifically to support this test procedure
- The tool is available as a Web Application
- The application can be downloaded for local installation
- The web application validation service is available at: http://hl7v2-iz-testing.nist.gov

Support for these tools is available by submitting questions to the following user's group: https://groups.google.com/d/forum/hl7v2-immunization-testing.

Inquiries may also be sent to this user group via email: hl7v2-immunization-testing@googlegroups.com.

Multiple browsers may be used to access this tool; if the tool does not load completely using Internet Explorer 8 or Internet Explorer 9, alternative browsers such as Firefox, Google Chrome, or Safari are recommended. The HL7v2 Immunization Information System Reporting Validation Tool uses non-standard ports. If your firewall blocks HTTP traffic on non-standard ports, this tool may not be accessible. Please retry access from a location without a firewall that blocks non-standard ports. Alternatively users may download and run a local version of the tool.

The following information is provided to assist the Tester in interpreting the conformance reports generated by HL7v2 Immunization Information System Reporting Validation Tool.

The HL7v2 Immunization Information System Reporting Validation Tool evaluates conformance requirements which are specified or have been derived from the standards and implementation guides identified in the Final Rule and the test data provided in this test procedure. The HL7v2 Immunization Information System Reporting Validation Tool evaluates the submitted HL7 message for each conformance requirement, and then produces a conformance report. The Tester should consider that a report containing only Affirmative and Warning messages indicates a sufficient level of conformance to the standard and test data expectations. If reported, Errors should be considered as significant departures from the standard or test data requirements which need to be corrected in order to claim conformance. ATLs will need to further analyze each error to determine if, in the context of meeting the criterion and overall meaningful use objective, the error results in a failure of the test procedure by the EHR technology.

Document History

Version Number	Description of Change	Date Published
1.0	Released for public comment	November 19, 2012
1.1	Delivered for National Coordinator Approval	December 3, 2012
1.2	Posted Approved Test Procedure	December 14, 2012
1.3	Posted Updated Approved Test Procedure Updates: • Conditions for test data modification added to Test Data section • Added paragraph to Test Data section about primary purpose of test data • Paragraph 3 of Test Data section reworded to indicate the instructions pertain to departure from provided test data • Final Test Data section paragraph updated to indicate that the Hl7v2 standard provides flexibility in messaging rather than the Hl7v2 Immunization Information System Reporting Validation Tool • Link to Google Group and email address changed to hl7v2-immunization-testing from hl7v2-lab-testing in Conformance Tools section	January 16, 2012