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Health Information Technology (HIT)   
Standards Testing Infrastructure

HL7 Version 2.5.1 Implementation Guide for Immunization Messaging, Release 1.5

NIST Clarifications and Validation Guidelines

Version 0.3

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**DOCUMENT CHANGE HISTORY**

| **Version No.** | **Description of Change** | **Date Updated** |
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| 0.1 | Initial Review – R. Snelick/S. Martinez | March 19, 2015 |
| 0.2 | Correction on RCP-2 usage added | August 13, 2015 |
| 0.3 | Added clarifications for QPD-9, IZ-24/NDC and QPD-5.2. | November 4, 2015 |

**TABLE OF CONTENTS**

[1.0 Introduction 3](#_Toc430597749)

[2.0 Validation Policies 4](#_Toc430597750)

# Introduction

This document lists conformance testing issues and associated policies derived by NIST based on a review of the HL7 Version 2.5.1 Implementation Guide for Immunization Messaging, Release 1.5, 10/01/2014. The policies listed in section 2.0 of this document are implemented in the NIST immunization conformance test tool.

# Validation Policies

| **Issue** | **Policy** |
| --- | --- |
| The Implementation Guide for Immunization Messaging, Release 1.5, states that implementers who want to use optional message elements should refer to the HL7 V2.5.1 Base Standard to determine how these optional message elements are to be used. The IN1 segment is an exception, and implementers must follow the requirements indicated in the Implementation Guide for this segment. | The NIST test tool will validate optional elements against the HL7 Version 2.5.1 Base Standard; be aware that unexpected validation results may occur if immunization messages conformant to local requirements are submitted to the test tool.  For the optional IN1 segment, the test tool will validate conformance to the IN1 requirements as specified in Implementation Guide for Immunization Messaging, Release 1.5. |
| In many instances, the Implementation Guide for Immunization Messaging, Release 1.5, defines the length for complex elements; length is a concept that is meaningful only at the primitive element level. | All length requirements pertaining to complex elements are ignored by the NIST test tool, and this information is anticipated to be omitted in a future version of the Implementation Guide for Immunization Messaging. The NIST XML profiles do not include length for complex elements. |
| The Implementation Guide for Immunization Messaging, Release 1.5, defines MSH-21 with the EI data type and a conformance statement that allows for other values in the EI datatype.  For example the MSH-21conformance statement for Z22 is; IZ-43: The value of MSH.21 (Message Profile Identifier) SHALL be 'Z22^CDCPHINVS'. The IE.2 (Namespace ID) allows for values in HL70363, but the MSH-21 IZ-43 overrides the IE.2 (Namespace ID) with CDCPHINVS. | The NIST validation tool will confirm that the immunization message meets the requirement in the MSH-21conformance statement. |
| The Implementation Guide for Immunization Messaging, Release 1.5, has two conformance statements for the version ID, one at the data type level (IZ-7) and one at the profile level on MSH-12 (IZ-15):   * IZ-7: VID-1 (Version ID) SHALL be valued with the literal “2.5.1” * IZ-15: The MSH-12 (Version ID) SHALL be valued “2.5.1” | The NIST test tool will validate immunization messages only for the IZ-15 conformance statement. |
| The Implementation Guide for Immunization Messaging, Release 1.5, Addendum includes an erroneous clarification indicating that cdcgs1vis is not a valid entry in HL70396 and that the correct coding system to use is CDCPHINVS. | cdcgs1vis is a valid code system, and it will be added to the HL70396 base table. The NIST validation tool will accept the cdcgs1vis code system. |
| PHVS\_VISBarcodes\_IIS table is an evolving value set; the values in the Implementation Guide for Immunization Messaging, Release 1.5, might differ from the values in the PHVS\_VISBarcodes\_IIS CDC PHINVADS table. | The NIST validation tool will accept any value from the most current version of the PHVS\_VISBarcodes\_IIS CDC PHINVADS. |
| The Implementation Guide for Immunization Messaging, Release 1.5, requires that each immunization included in a Z42 message has a set of observations (OBX segments) in which one observation indicates whether the immunization was valid based on a standard set of recommendations provided by a clinical decision support (CDS) engine (typically ACIP). Some vaccines do not have validity recommendations. In addition, some CDS engines do not evaluate validity for certain vaccines. For instance, some of the vaccines that are not commonly given to the general population, such as rabies or yellow fever vaccines, are only evaluated by certain CDS engines. Smallpox vaccine is rarely given today, and most CDS engines do not evaluate its validity.  Systems receiving RSP response messages may encounter records where the validity observation is not present. Ideally, these systems would accept these responses gracefully. In the case where the received response is displayed to an end-user, immunizations that do not have a validity observation should be included in the display. The display may indicate that these immunizations were not validated. | The NIST validation tool tests to requirements as stated in the Implementation Guide for Immunization Messaging. When a Z42 response message includes a record in which the validity observation is not present, an error notification (per the specification) will be generated by the immunization messaging test tool. The Tester must inspect the message and the error notification to determine if the particular instance involves a vaccine that is an exception to the implementation guide requirement – i.e., that vaccine would never have a validity recommendation – and the Tester shall ignore the error notification in this case. This exception does not apply to ONC 2015 Certification Testing since no test cases provided with the Context-based feature contain this exception.  In a production setting, the Z42 messages are generated by Immunization Information Systems (IIS) and this issue is being included in this NIST Clarifications and Validation Guidelines document to alert IIS vendors who may use the Context-free feature in the NIST tool to validate messages.  Future releases of the implementation guide will address this vaccine validity recommendation issue. The exact mechanism for dealing with it is yet to be determined. |
| The Implementation Guide for Immunization Messaging, Release 1.5, does not allow the set id numbering to be restarted within a message. The addendum includes a clarification that allows the set id to restart within a message. The Implementation Guide for Immunization Messaging, Release 1.6, will only allow the set id to restart within a message. | The NIST validation tool will allow restarting and not restarting the set id numbering within a message, but all of the Context-based test cases were developed using the restart approach specified in the Implementation Guide for Immunization Messaging, Release 1.6. |
| The Implementation Guide for Immunization Messaging, Release 1.5, Addendum has updated the Immunization Funding Source value set, and has added codes to the Immunization Profile Identifiers value set– IIS and the user defined Table 0064. | The NIST validation tool will enforce the value set updates as stated in the Implementation Guide for Immunization Messaging, Release 1.5, Addendum. |
| The 0396 table is an evolving value set; the values in the Implementation Guide for Immunization Messaging, Release 1.5, might differ from the values in the 0396 value set maintained by HL7. For example, ISOnnnn and HL7nnnn are listed in the Implementation Guide but are obsolete in the HL7 table; cdcgs1vis is missing in the Implementation Guide. | The NIST validation tool will support the 0396 table maintained by HL7, <https://www.hl7.org/Special/committees/vocab/table_0396/index.cfm>. |
| ONC did not adopt MVX (Manufacturers of Vaccines) codes for vaccine manufacturers in the 2015 Edition Health IT Certification Criteria Final Rule and did not include MVX codes in their list of code sets. For the purposes of administered vaccines, ONC requires that the NDC (National Drug Code) be sent in the VXU message [RXA-5] when an immunization is reported at the time it is administered when the actual product is known; and states that CVX (Vaccines Administered) codes are to be sent [RXA-5] when reporting historical vaccines. | The NIST Context-based feature in the 2015 Edition Immunization Test Suite used for ONC certification testing will verify that the Health IT Module supports NDC for new immunization records and CVX for historical immunization records in HL7 immunization messages, and the Test Cases in the Test Suite (ONC 2015 Test Plan) will reflect this requirement. |
| A question has arisen regarding whether the MVX code should be included in the VXU message [RXA-17] when an immunization is reported at the time it is administered, since the NDC is required to be sent and an NDC typically includes the identification of the vaccine manufacturer (Note: if the NDC identifies the re-packager of the vaccine, the identification of the actual vaccine manufacturer may not be readily available or apparent via that NDC).    The Implementation Guide for Immunization Messaging, Release 1.5, requires the MVX code be sent conditionally in RXA-17 of the VXU. The Condition Predicate that triggers populating RXA-17 with the MVX code is the first occurrence of RXA-9.1 (Administration Notes-Identifier) being valued "00" (New Immunization Record, i.e., newly administered vaccine) and RXA-20 (Completion Status) being valued "CP" (Complete) or "PA" (Partially Administered).    Though ONC does not require use of MVX codes in the VXU messages created by certified Health IT Modules, the Immunization Messaging Guide does require use of MVX codes if the Condition Predicate is met. | Immunization registries (IIS), which are not included in CMS Meaningful Use and are not incented to conform to the ONC health IT certification requirements, are likely to be following the Guide rather than the ONC 2015 Edition Final Rule regarding use of MVX codes. To facilitate interoperability, the NIST test cases include MVX codes in accordance with the requirement in the Implementation Guide for Immunization Messaging, Release 1.5; therefore, the NIST Immunization Test Suite verifies that the Health IT Module being tested supports MVX codes for RXA-17 as well as NDC for RXA-5 (for New Immunization Records) even though certain data available via the NDC and MVX code may be redundant. |
| There is a typo in the “Code Tables, HL7 - defined Table 0301 - Universal ID type” section of the Implementation Guide for Immunization Messaging, Release 1.5. There is an erroneous constraint to “OID” instead of “ISO”. This correction was not captured in the Implementation Guide for Immunization Messaging, Release 1.5, Addendum | The NIST validation tool will only accept the value ISO. |
| The Implementation Guide for Immunization Messaging, Release 1.5, indicates the use of the NCIT (Route of administration) value set for RXR-1. The IG also provides a mapping to Table 0162 with specifications for using the NCIT values. | The intent of the IG is only to support NCIT; therefore, the NIST validation tool will evaluate only the NCIT codes. |
| In the Implementation Guide for Immunization Messaging, Release 1.5, the Observation Segment table (Table 8-8) names UCUM as the Value Set for OBX.6, but then allows the value “NA” (from HL7 table 0353) to be used when a unit of measure is not available. | As a result of this allowance, UCUM becomes just a coding system that is part of a value set drawn from two sources (UCUM and table 0353). For the purpose of validation, NIST created a value set UCUM\_0353\_IZ that contains the set of UCUM codes with UCUM as the code system and also includes the value “NA” with HL70353 as the code system. |
| The Implementation Guide for Immunization Messaging, Release 1.5, Addendum adds the following clarification to the PID-10 value set:  “The Value Set of Race (PID-10) is CDCREC. The coding system shall be CDCREC from the most recent version of HL70396. The values listed in Appendix A for HL70005 are still valid for CDCREC”.  The addendum clarification basically combines the value set of race (HL70005), which is used in PID-10 (Race), with the value set of Ethnicity Group (CDCREC), which is used in PID-22 (Ethnic Group). A clear distinction is needed between the two value sets. | For the purpose of validation NIST created two value sets:   * CDCREC\_R\_IZ with the set of race codes, used in PID-10 and code system CDCREC. * CDCREC\_E\_IZ with the set of ethnicity codes, used in PID-22 and code system CDCREC.   Note: the NIST validation tool will allow “CDCREC” as the code system for both PID-10.3 and PID-22.3; but, for PID-10.1 the tool will only accept race code values, and for PID-22.1 the tool will only accept the ethnicity code values. |
| The Implementation Guide for Immunization Messaging, Release 1.5, defines the RCP-2 (Quantity Limited Request) usage as “X” in the “Request Evaluated Immunization History and Forecast Query” profile (Z44) and as “RE” in the “Request a Complete Immunization History” profile (Z34). | A clarification will be added. The next version of the Implementation Guide IG will correct the current Usage for RCP-2 so both Z44 and Z34 will have “R” as the Usage. |
| The Implementation Guide for Immunization Messaging, Release 1.5, Addendum adds a clarification that requires the QBP-9 cardinality to be [0..1] which means that in any given query you can only query for a phone number or email. | Based on the SMEs feedback, support is needed only for phone numbers in QPD-9. Therefore, only support for phone numbers is being tested in the query message for the Evaluated History and Forecast test cases. |
| The NIST validation tool is supporting multiple value set binding on RXA-5, accepting both NDC and CVX codes. The IZ-24 conformance statement is not triggered when and NDC code is used. | The NIST validation tool will support the Implementation Guide for Immunization Messaging, Release 1.5 and only trigger an IZ-24 conformance statement when a CVX code is used. Support of NDC codes are a requirement for the ONC 2015 Edition Certification. IZ-24 is not related to the NDC codes. |
| The Implementation Guide for Immunization Messaging, Release 1.5, Table 11-8 for the Z44- Request Evaluated History and Forecast defines Mother’s Maiden Name with the data type XPN\_MDN and includes an entry for “given name”, which is currently “RE-required, but may be empty” but is now “O-optional” (based on the XPN\_M data type definition in the Addendum). | The HL7 Version 2.5.1 Implementation Guide for Immunization Messaging (Release 1.5)—Addendum makes a correction to change the datatype to XPN\_M. The next version of the Implementation Guide IG will incorporate this correction and remove the given name entry from table 11-8. The NIST profile sets QPD-5.2 as “O-optional” |