**Known Issues – Immunization Messaging\_1.9.13 December 16, 2020**

| **Issue** | **Status** |
| --- | --- |
| **User Issue:** “The validator is not accepting the note repeats which are available to be sent in RXA-9.  We are sending RXA-9 as “00^New immunization record^NIP001~^New immunization record”, however, this gives the following errors: “RXA[1].9[2].1 is missing” and “RXA[1].9[2].3 is missing”.”  **Clarification:** The test tool is validating all occurrences of RXA-9 as being defined with the CE\_IZ data type requirements. Use of a different data type for this element is not standard practice. It is anticipated that the use for the second occurrence will be considered for the next release of the implementation guide. | Due to lack of clarity in the implementation guide on the use and purpose of this element, the test tool will only validate the first occurrence of RXA.9. Any errors related to RXA.9 repetitions should be ignored. |
| A conflict exists in the implementation guide regarding Acknowledgement processing requests in the outbound message. The implementation guide prescribes the use of original acknowledgement processing mode, which implies that MSH-15 is to be “NE” and MSH-16 is to be “AL”. However, this declaration can also imply that both MSH-15 and MSH-16 are left empty, and the implication is that the request is for an application type acknowledgement message to be returned (i.e., “MSH-15 = NE” and “MSH-16 = “AL” is implied).  The implementation guide also specifies MSH-15 and MSH-16 as required and includes conformance statements indicating that MSH-15 SHALL BE ‘ER’ and MSH-16 SHALL be ‘AL’. This is a direct conflict with the requirement to use “original acknowledgement processing mode” described above. | Currently, the test cases in the tool validate as prescribed in the conformance statements (MSH-15 SHALL BE ‘ER’ and MSH-16 SHALL be ‘AL’); however, given the conflict in the requirements, “MSH-15 = NE” should also be allowed until the issue is resolved in a subsequent release of the implementation guide or an erratum is issued.  The test cases in the tool will remain as they are; however, the vendor may also satisfy the requirement by valuing MSH-15 = “NE” and MSH-16 = “AL” of all outbound messages (i.e., submit and query). The ATL can ignore the error reported for MSH-15 if the vendor is choosing to implement with MSH-15 = NE”. |
| The Test Data Category for QPD-3.1 (Patient ID Number) is “Value-Test Case Fixed”, meaning the Tool is validating for the presence of the exact value provided in the test data and generates an error notification if this requirement is not met by the HIT Module being tested | If the HIT Module being tested is unable to control the Patient ID Number value that it creates   * QPD-3.1 in the Query message can be populated with a different value than the one provided in the test data * The Tester can ignore the error notification generated by the Tool * The Response message also will have to be modified accordingly   NIST has no plan to change the Test Data Category for QPD-3.1. One reason for designating “Test Case Fixed” for this field was to ensure that the querying system (1) would contain the Patient ID Number that matches the Patient ID Number in the NIST response system and (2) would create a Query message with this value in QPD-3.1 in order for the Tester to be able to perform Display Verification for the Response message.  Explanatory information has been added to the Tool in the **Notes for Testers** section of the **Test Story** tab for each Query Test Step in the Evaluated History and Forecast Group |
| In the Administration Group, for V04\_Z22 messages in all Test Cases except IZ-AD-7\_Historical\_IIS-Error and IZ-AD-10\_Historical\_IIS-SysError: based on guidance from the authors of the Immunization IG R1.5, the Test Suite validates the immunization messages for an OBX segment containing **Vaccine Funding Source** information; Usage for this segment in the Test Suite is “R” = Required. | ONC has determined that, from a regulatory/program perspective, an HIT Module cannot be required to be able to generate messages with the **Vaccine Funding Source** OBX segment for 2015 Edition certification testing.  For certification purposes, ONC permits Testers to ignore the error notification generated by the NIST Immunization Test Suite when this segment is missing.  Since the product under test will have to meet state reporting requirements when implemented, and many states require this information, it may be beneficial for HIT Modules to demonstrate support for the Vaccine Funding Source OBX segment during 2015 Edition certification testing.  Explanatory information has been added to the Tool in the **Notes for Testers** section of the **Test Story** tab for each affected V04\_Z22 Test Step in the Administration Group. |
| Test Case IZ-AD-8\_Admin\_IIS-Warning / Test Step IZ-AD-8.1\_Send\_V04\_Z22 requires component 1 (namespace), component 2 (OID), and component 3 (Type) be included in the message.  From an operational perspective, **either** component 1, **or** component 2, and component 3 can be sent. Both, however, must be supported (from an implementation perspective). Operationally, both may be sent depending on local implementation choices. NIST and the immunization SMEs decided that when an OID was sent the namespace also must be sent as best practice (also, future versions of the IG will likely require this). | When the error notification “Content - Expected content is missing. The empty value at PID-3.4.1 (Namespace ID) is expected to be present.” is generated, the Tester (ATL) can ignore it (for certification purposes).  The same principles apply for Namespace ID, Universal ID, and Universal ID Type elements in the following message segments for Administration Group Test Case #8, and the Tester can ignore the “Content - Expected content is missing...” error notification:   * MSH-3 * MSH-4 * MSH-5 * MSH-6 * MSH-22.6 * MSH-23.6 * PID-3.4 * ORC-10.9 * ORC-12.9 * RXA-10.9 * RXA-11 * ORC-2 * ORC-3 |
| Users have expressed confusion over why the error notification IZ-24 is being triggered in the validation tool:  IZ-24 - **If** RXA-20 is valued 'CP' or 'PA' **and** the first occurrence of RXA-9.1 is valued '00' **and** RXA-5.1 is valued with a CVX code from table PHVS\_VISVaccines\_IIS (See Appendix A) **then** for each vaccine information statement that was shared there SHALL be:  [one OBX segment with OBX-3.1 valued '69764-9' (bar coded) and one OBX with OBX-3.1 valued '29769-7' (presentation or delivery date) associated. Both OBX shall have the same value in OBX-4]  OR  [one OBX segment with OBX-3.1 valued '30956-7' (vaccine type) and one OBX segment with OBX-3.1 valued '29768-9' (version date) and one OBX with OBX-3.1 valued '29769-7' (presentation or delivery date) associated. All three OBX shall have the same value in OBX-4] | IZ-24 is being triggered because, per the Conformance Statement, the VIS can be messaged in **either** of 2 ways:   1. With one OBX segment with **OBX-3.1** valued with LN code **'29769-7'** (presentation or delivery date) and one OBX segment with **OBX-3.1** valued with LN code **'69764-9'** (bar coded document type) ***associated***.   **OR**   1. With one OBX segment with **OBX-3.1** valued with LN code **'29769-7'** (presentation or delivery date), one OBX segment with **OBX-3.1** valued with LN code **'30956-7'** (vaccine type) and one OBX segment with **OBX-3.1** valued with LN code **'29768-9'** (version date) ***associated***.   The pair of OBXs included in the message where **the first option** is chosen ***must have the same Observation Sub-ID (OBX-4) value and it must be distinct from all others***; and the triplet of OBXs included in the message where **the second option** is chosen ***must have the same Observation Sub-ID (OBX-4) value and it must be distinct from all others***.  Since LN code **'29769-7'** is in both options and the sub-ids have to be unique (for the set), the **OR** in the conformance statement **must** be seen as an exclusive OR; therefore, both options **cannot** be used in the same **Order Group** in a given message. Different options may be used in different Order Groups.  Also, any other OBXs in the message must have distinct Observation Sub-IDs. |
| The NIST tool **Context-based validation** may generate an error notification when a test message is submitted in which Segments have been added and for which no test data have been provided for the Test Case.    E.g., if a Test Data Specification for a Test Case provides data for only one NK1 segment in the VXU message but the test message that is submitted includes two NK1 segments, the tool may generate an error notification (such as “Invalid content based on test case fixed data”) for an NK1 field, because the data provided for that field in the test message does not match the expected data for that field. | The **Context-based** validation in the NIST tool is designed to check for specific data in the test message associated with a Test Case. The tool does not account for all possible instances of valid messages, which would be overly complicated when the goal of Context-based validation is to ensure that the SUT supports a specific requirement in the Implementation Guide through correctly creating a message using the test data provided.  If this type of error notification is generated during certification testing, the test proctor may:   * Rearrange the order of the additional segment(s) involved and reload the test message * After ensuring that the SUT is capable of producing the message with the required fields populated as per the test data for the relevant segment, the error notification may be ignored   **When the NIST tool is being used for certification testing**, vendors are encouraged to have their HIT modules create messages that contain the test data as given in the Test Cases for **Context-based validation** — the testing is based on those data.  **When the NIST tool is NOT being used for certification testing**, vendors are encouraged to use **Context-free validation**, for which no test data are provided and, therefore, no checking for specific data is executed by the tool. |
| For VXU messages, the Conformance Statement IZ-24 states “If RXA-20 is valued 'CP' or 'PA' and the first occurrence of RXA-9.1 is valued '00' and RXA-5.1 is valued with a CVX code from table PHVS\_VISVaccines\_IIS…”; but the NIST Immunization Test Suite is only checking for the value of the RXA-5.1 code, regardless of the coding system (RXA-5.3).  Consequently, the NIST IZ testing tool is, under specific circumstances, issuing an error related to IZ-24 when it should not be. In such cases, the overall outcome of the message validation is still correct, but IZ-24 should not be listed as a failure. | A fix has been made in the supporting XML profile for IZ-24 to include checking for “CVX” in RXA-5.3 when RXA-5.1 is a CVX code.  The Context-**free** Validation in the NIST Immunization Test Suite now does not generate an error notification related to IZ-24 if RXA-5.3 is not “CVX”.  The verbiage of the IZ-24 error notification has not been changed. |
| The CDC uses the same NDC Unit of Use code – “58160-0828-01” – for both Shingrix and zoster vaccine subunit.  This NDC for zoster vaccine subunit was announced in October 2020 and was added to the NDC Unit of Use Value Set in the NIST 2015 Edition Immunization Test Suite.  This NDC for Shingrix was announced in November 2020.  If the Shingrix information is added to the NDC Unit of Use Value Set in the NIST Test Suite, then validation of any VXU message with “58160-0828-01” as the NDC in RXA-5.1 generates an error notification: “The value '58160-0828-01' at location Component RXA-5.1 (Identifier) is not member of the value set NDC\_Use or NDC\_Sale”. | The NDC Unit of Use Value Set in the NIST 2015 Edition Immunization Test Suite now contains the following entry:   * **Code**: 58160-0828-01 * **Code System**: NDC * **Description**: Shingrix or zoster vaccine subunit   This entry has been made to avoid generation of the error notification when RXA-5.1 is populated with the NDC Unit of Use “58160-0828-01”. |
| CVX code 213, “SARS-COV-2 (COVID-19) vaccine, UNSPECIFIED” has been added to the CVX Value Set in the NIST Immunization Test Suite.  Per the CDC, the CVX code 213, “SARS-COV-2 (COVID-19) vaccine, UNSPECIFIED”, is never to be used in VXU messages to populate RXA-5.1 when RXA-9.1 is “00”. | A NIST Conformance Statement has been added to the NIST Immunization Test Suite that causes generation of the following error notification when the CVX code 213 is used in VXU messages to populate RXA-5.1 when RXA-9.1 is “00”:   * **NIST-02**: The value CVX code 213 “SARS-COV-2 (COVID-19) vaccine, UNSPECIFIED” at location Field RXA-5 (Administered Code) is NOT RECOMMENDED by the CDC for newly administered (RXA-9.1 = “00”) COVID-19 vaccines. The CDC highly encourages sending a COVID-19 specified code; not doing so can affect ancillary systems and can negatively impact clinical outcomes. |