Overview of NIST Message Validation Tools
Compiled by AIRA And CDC Staff
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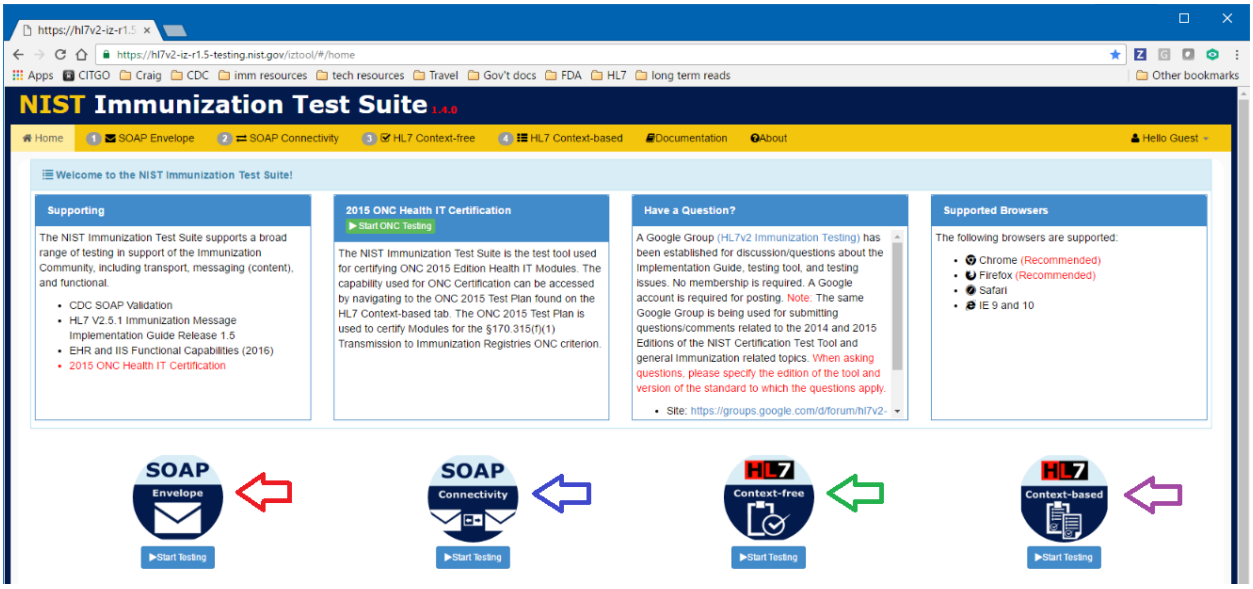
IIS Use of the NIST Immunization Test Suite

Overview

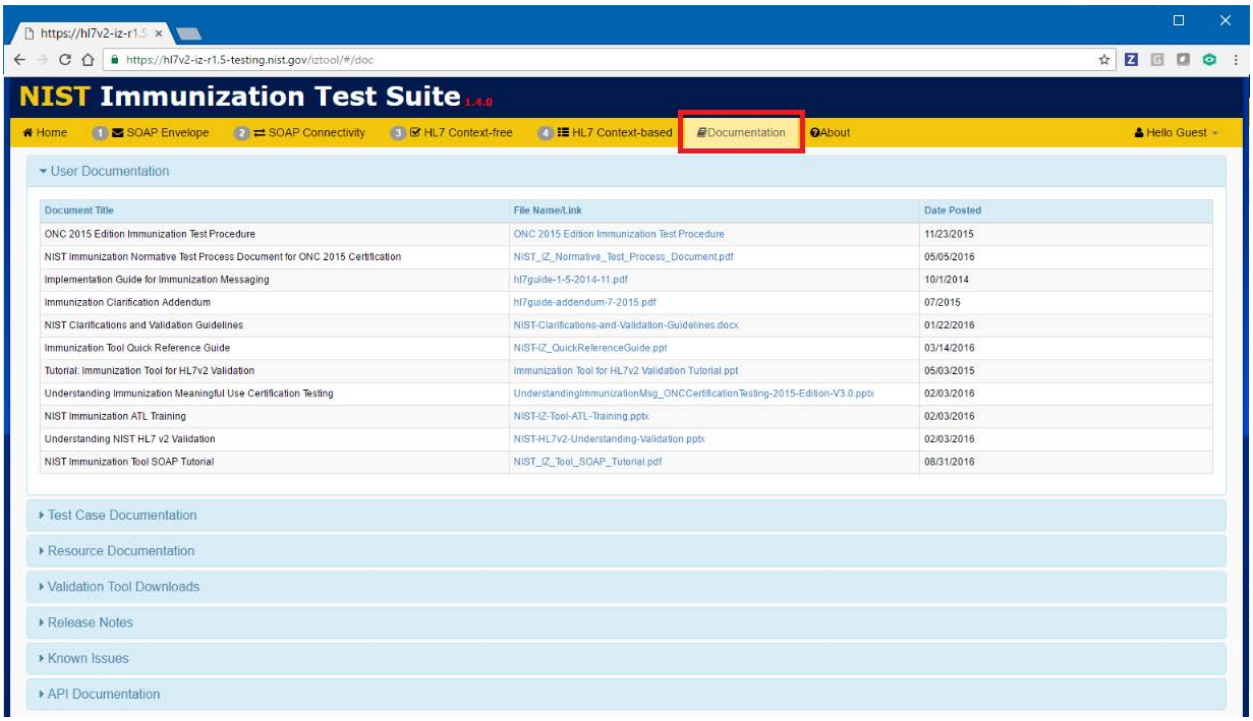
The National Institute of Standards and Technology (NIST) has been charged with developing tools to be used by the EHR certification program. NIST has created a testing tool suite which extends beyond EHR certification testing and is of considerable use to IIS looking to assess their support of Release 1.5. This Test Suite can be used to evaluate the conformance of IIS messages relative to Release 1.5 of the HL7 Implementation Guide (IG) for Immunization Messaging, which is the standard referenced by Meaningful Use and EHR certification regulations. IIS are highly encouraged to make use of the Test Suite to ensure that messages produced by the IIS are conformant to Release 1.5 of the IG.

The Test Suite can be used by an IIS in a number of different ways:

- SOAP/Web Services and CDC WSDL validation (red and blue arrows below)
    - Note that Meaningful Use and EHR certification requirements are silent on the transport method, but IIS are highly encouraged to implement the acknowledged transport standard of SOAP/Web Services and use of the CDC WSDL.
- Context-free validation (green arrow below)
    - This is the most useful feature for IIS and will be the focus of this document
- Context-based validation (purple arrow below)
    - This feature is used by for EHR certification



Also note that the NIST Immunization Test Suite has extensive documentation on the standards and methodology underlying the tool and well as detailed documentation on tool usage.



SOAP Interface

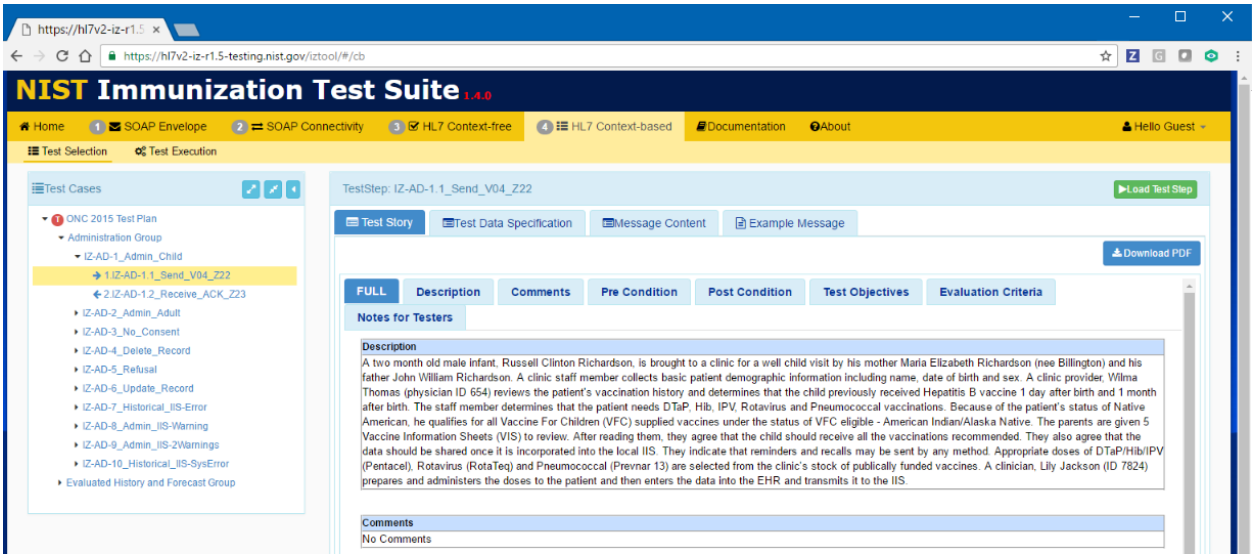
While Meaningful Use and EHR certification requirements are silent on the transport method, the adoption of a consistent transport method across IIS lowers the implementation burden for onboarding providers and EHR vendors. The NIST Test Suite offers tools for SOAP Envelope and Connectivity testing and should be utilized by IIS to ensure that the SOAP interface is conformant with the CDC specification. See the AIRA Technical Assistance web site for online training videos on this topic.

Context-based Validation

The Context-based tool within the Test Suite is used for 2015 EHR certification testing. Context-based testing allows comprehensive testing of all data elements with a Usage of Required (R), Required but Allowed to be Empty (RE) or Conditional (C) as well as testing for the inclusion of specific values for given fields.

Context-based testing is reliant upon the development of specific Test Cases. Note that currently the Immunization Test Suite only contains the Test Cases related to 2015 EHR Certification. However, these test cases may still be of use IIS.

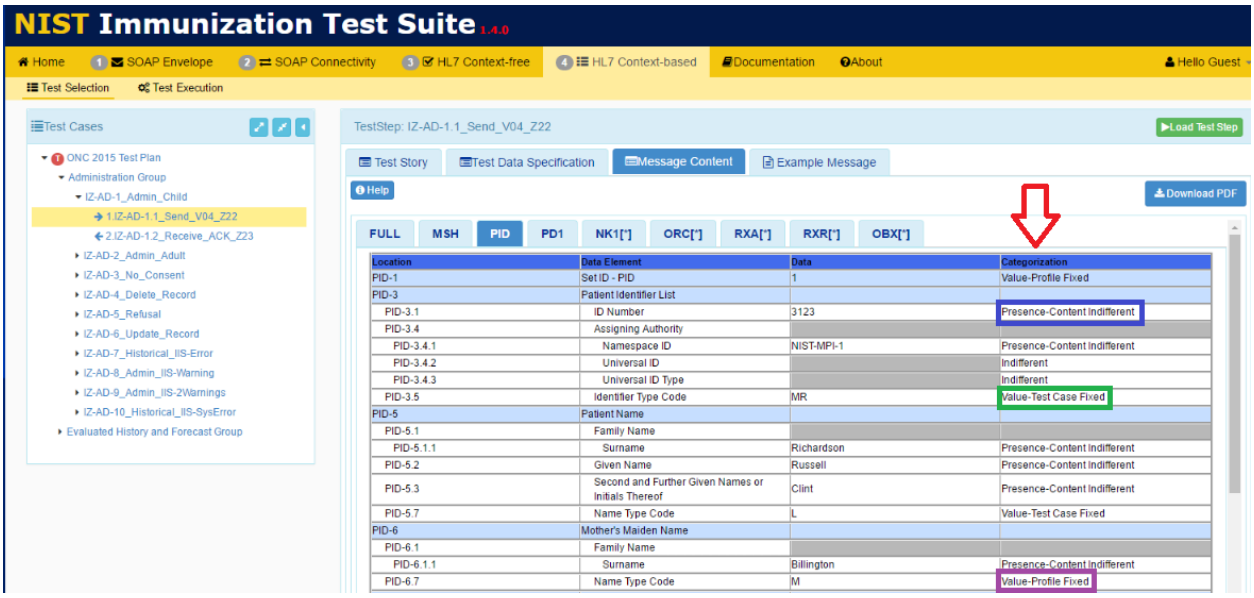
Each Test Plan is comprised of Test Groups where each group contains one or more Test Cases. In the example below, IZ-AD-1_Send_V04_Z22 is the Test Case related to a submitting new and historical immunizations for a child. For immunization test cases, both an originating message (either the VXU or QBP message) and a response message (either the ACK or RSP message) is documented. For each message a Test Story is provided to set the context for the Test Case. Also provided are Test Case data (in the Test Data Specification and Message Content tabs) as well as a sample message.



On the Message Content tab, a Categorization is given for each data element. The Categorization element defines the latitude allow when populating the element during execution of the Test Case.

Elements with a Categorization beginning with “Value” must be populated with the exact value from the Test Case (green and purple boxes). For example, below PID-3.5 must be populated with the exact value “MR”. Categorizations of “Value” are typically fixed at either the Profile or Test Case level, that is, the required value is defined by the specification itself (Profile) or by the authors of the Test Case to test specific functionality (Test Case).

Elements with a Categorization beginning with “Presence” must be populated in the test message, but the exact value is not evaluated (blue box). For example, below, PID-3.1 must be populated, but the exact value may be the sample value (3123) or some other value.



An IIS may use these 2015 EHR Certification Test Cases by downloading the sample messages EHR systems are expected to produce (that is all of the VXU_V04 and QBP^Q11 messages) and process them

through the incoming IIS interface. IIS should expect to be able to consume these test messages. A couple of things to note:

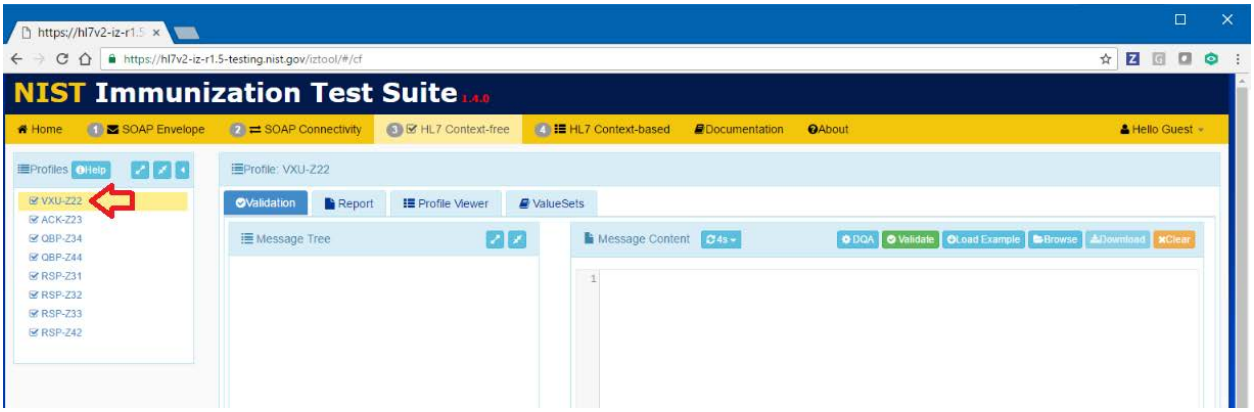
- Some functionality being asked of the EHR systems may not apply to all IIS. For example, Test Case IZ-AD_5_Refusal tests the ability of the EHR to document and transmit the refusal of a vaccination. Not all IIS support the ability to receive refusal information.
- An IIS testing with these messages have some latitude to edit the message before testing. For example, the IIS may need a specific value in MSH-4 before they can consume the message. Testers should be wary of manipulating any element with a Categorization of "Value-Profile Fixed" as these are values required for the Test Case by Release 1.5.
- The response messages (ACK and RSP^K11 messages) produced by the IIS upon consumption of the Test Case message should be compared to the response messages documented in the Test Case. The next section on Context-free validation documents how to use the Test Suite to validate the IIS produced response message against Release 1.5.

Context-free Validation

The Test Suite's Context-free validation activity allows IIS to evaluate messages they produce against the Release 1.5 specification. Unlike Context-based validation, Context-free validation is independent of any test story and can be used on any message.

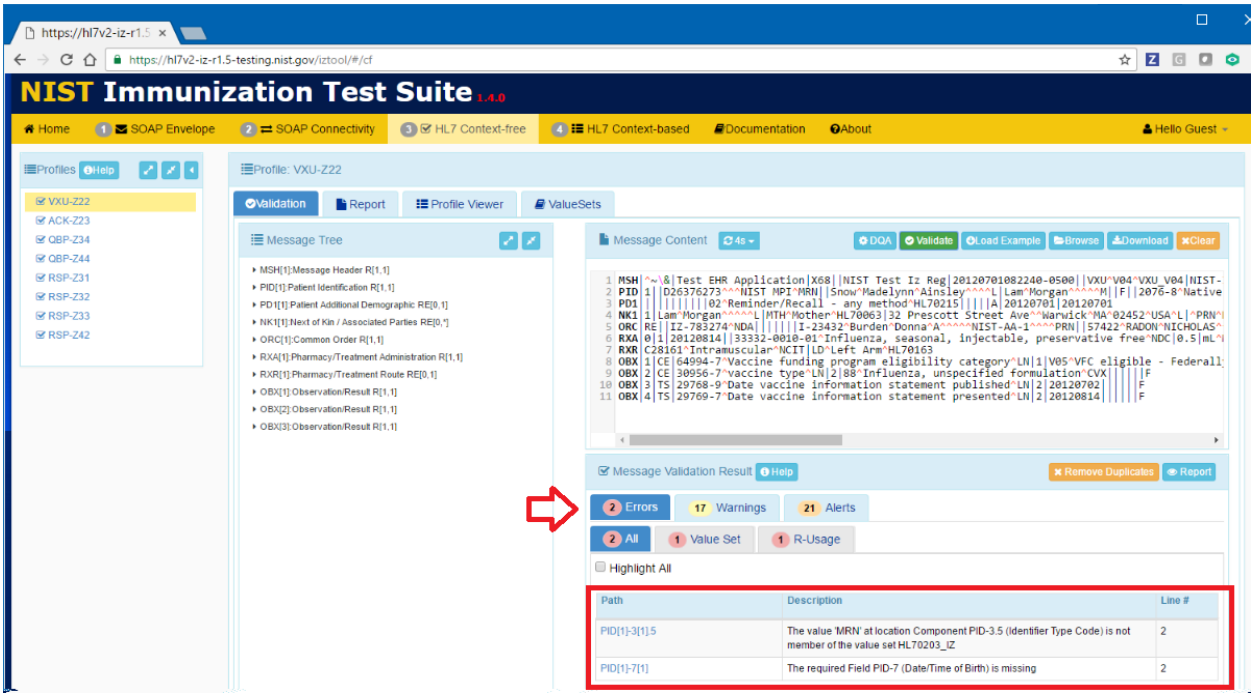
After completing interface development, all IIS should validate their messages against Release 1.5 to ensure that the interface produces messages compliant with Release 1.5.

The first step is to select the Profile used to validate against (red arrow below). All profiles documented in Release 1.5 are available to validate against, even those not included by the 2015 EHR certification requirements.



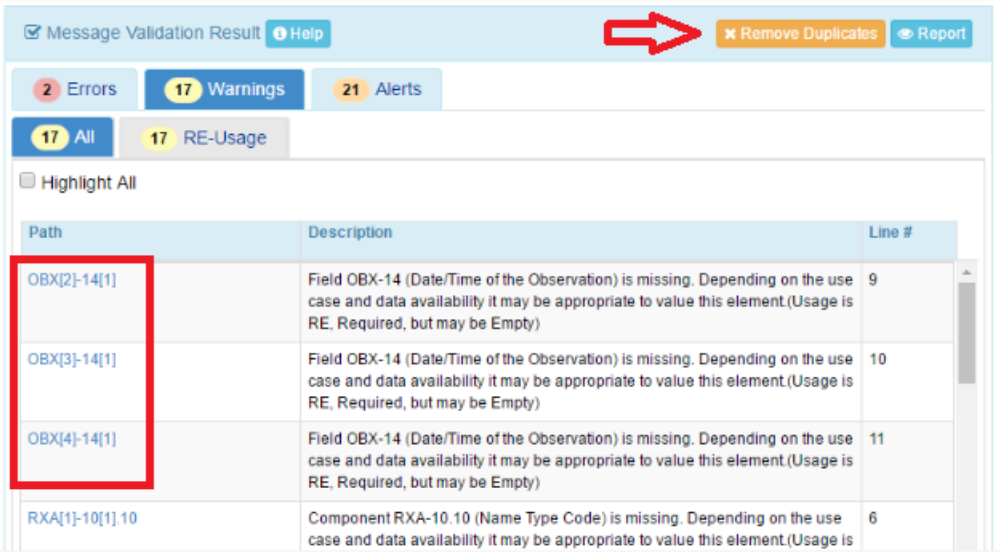
Once the profile has been selected, the message must be entered into Message Content box on the right-hand side of the tool. A message may be entered by browsing for a file (green box) or by a simple cut-and-paste. For testing purposes, a sample message can also be loaded into the box or downloaded (purple boxes). Once loaded, the structure of the message is represented in the Message Tree to the left of the message. To validate the message against the Release 1.5 profile, click the "Validate" button (red arrow). Note that the tool has a tendency to automatically run validation, but you can also trigger a validation manually via the button.

Once the message has been validated, the tool provides a list of issues found. Issues are categorized as either an error, a warning or an alert. Clicking on the appropriate tab displays the relevant issues in the pane below. Errors are the most significant and represent violations of Release 1.5. That is the message (and by extension, the system) would be considered non-conformant. In the example below, the message was modified to include an invalid value for a value set and to remove a required data element.



Warnings are less severe and would not result in a message or system being declared non-conformant. Warnings are often related to the absence of data with a Usage of RE (Required but Allowed to be Empty). One thing to keep in mind with Context-free testing is that it cannot know when an RE data element should be populated, so these warnings often crop up. However, when testing an interface, all warnings should be reviewed to ensure that the message is legitimately missing the RE data elements. Note that the same issue may be reported multiple times when a segment occurs repeatedly in a message. In the example below, the same warning regarding OBX-14 is repeated for each OBX in the

message which is missing the data element. Duplicate issues can be removed using the “Remove Duplicate” button.



Alerts are the least critical issue and usually relate to notifications about the behavior of the tool and usually do not require fixes to the interface or message.

Integrating the NIST Tool into a Testing Plan

After completing interface development and build, an organization should develop a comprehensive testing plan to exercise all the functionalities expected to be used in real world usage. The testing plan should include all test cases that could occur in a production setting. For example, a test plan may include some or all of the following test cases:

- Submission of Immunization Events
    - Receiving a new administration including some or all of:
        - VIS data
        - VFC eligibility
        - Funding source
        - Next of kin
        - Insurance data
    - Receiving an update to a new administration
    - Receiving a delete of a new administration
    - Receiving a historical (reported) administration
    - Receiving a refused administration
- Query for Evaluated History and Forecast
    - Receiving a valid query resulting in:
        - One high threshold match
        - Multiple high threshold matches
        - No high threshold matches
        - One high threshold match where patient data is protected
        - One high threshold match where the patient has no immunization history

- One high threshold match where the evaluation and forecast contains some or all of:
    - Contraindicated doses
    - Completed series
    - Invalid doses

As test cases are executed, the resulting messages should be validated against the appropriate profile using the NIST Test Suite. When testing an interface, any errors found must be addressed. Correcting an error may involve additional build/mapping in the system, code corrections and/or changes in workflow. Note that in the real world, some errors would be due to data quality, but during testing this should be rare. Once all test cases can be executed and validated without errors, the system should be in good shape, but keep in mind that it is impossible to test every situation which may occur in the real world and that the use of the Test Suite can only pinpoint errors in tested workflows and that it is not possible to validate that a system will be conformant in all situations.