IMMUNIZATION INTEGRATION PROGRAM: TEST PLAN REQUIREMENTS DOCUMENT

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Version 11.0 | **April** 2025

OVERVIEW

Project Overview

This document is intended for developers of clinical software used for patient management related to immunizations. The document presents immunization-related software requirement focused on end-to-end clinical workflow, functional and usability tests, and general guidance.

The Immunization Integration Program (IIP) presents this Test Plan companion document in partnership with the Centers for Disease Control and Prevention (CDC), (IDAB (Informatics and Data Analytics Branch)), the American Immunization Registry Association (AIRA), the Healthcare Information and Management Systems Society (HIMSS) and Drummond Group.

IIP Executive Council

The IIP is supported by an Executive Council comprised of leaders representing key partner groups and provide technical expertise to both the IIP Testing and Recognition initiative and the IIP Collaborative. The Executive Council considers changes in the environment, immunization community input and test findings through a series of meetings and recommends additional updates to the tests, capabilities, and guidance to ensure success. This document reflects those changes to the capabilities and guidance.

Collaboration with NIST

NIST makes the Immunization Integration Test Suite available for (a) testing whether public health immunization information systems (IIS) conform to standards and (b) to prepare for ONC Certified EHR Technology (CEHRT) 2015 requirements. Coordination of the EHR functional testing using the Immunization Integration Test Suite means that the scenarios include the same detailed data requirements expected of the IIS.

IIP Modular Approach

The initial IIP recognition program addressed clinical workflow with several patient-specific workflows with recognition of five clinical software products. The current program streamlines the testing process while addressing maintenance and sustainability. The result is a modular methodology to evaluating immunization management capabilities. The new approach includes a set of fundamental requirements expected for all IIP recognized immunization management software. This Essential Interoperability and Data Quality Module (Essential Module) incorporates all required immunization-related components of the ONC 2015 Certified EHR Technology (CEHRT) program to address interoperability plus critical software-specific data quality and patient safety issues. This Essential Module incorporates some concepts from each of the eight initial general user workflows. The IIP envisions future modules to allow software systems to achieve recognition for more comprehensive competence in specific areas of focus. Potential advanced modules include Clinical Decision Support, Error Checking and Advanced Data Quality, Publicly Provided Vaccine Processing, and Business Intelligence, Reporting, and Data Export

Test Development Process

The IIP team reviewed previous test plans and based on testing experience and IIP Executive Council and CDC sponsor feedback, selected essential elements to include in the Essential

Interoperability and Data Quality module. The team also updated testing element classification to assure consistent use of internal terminology and to provide clarity for transparency. The highest classification for each module is a set of capabilities. Capabilities are workflow related concepts that group together specific actions, for example, Care Provision and Documentation (i.e., vaccine order or administration), Interoperability (i.e., query the IIS), or some basic clinical decision support (i.e., immunization forecasting). Each capability contains one or more functions, each of which fulfills a requirement, or reason for performing evaluation. Each functional requirement includes one or more test steps with discrete data-specific pre-conditions, post-conditions, and evaluation criteria. Evaluating standards-based interoperability is relatively straightforward as standards have defined conformance criteria that must be satisfied. IIP testing avoids prescriptive software performance expectations as the proctor first requests detail from the SUT about how the system addresses user awareness of potential reasons to avoid an action. To successfully conform to expected activity during a test step, the proctor reviews if the SUT provides one of its stated methods to inform users about potential risks that may result from specific scenarios provided in the test.

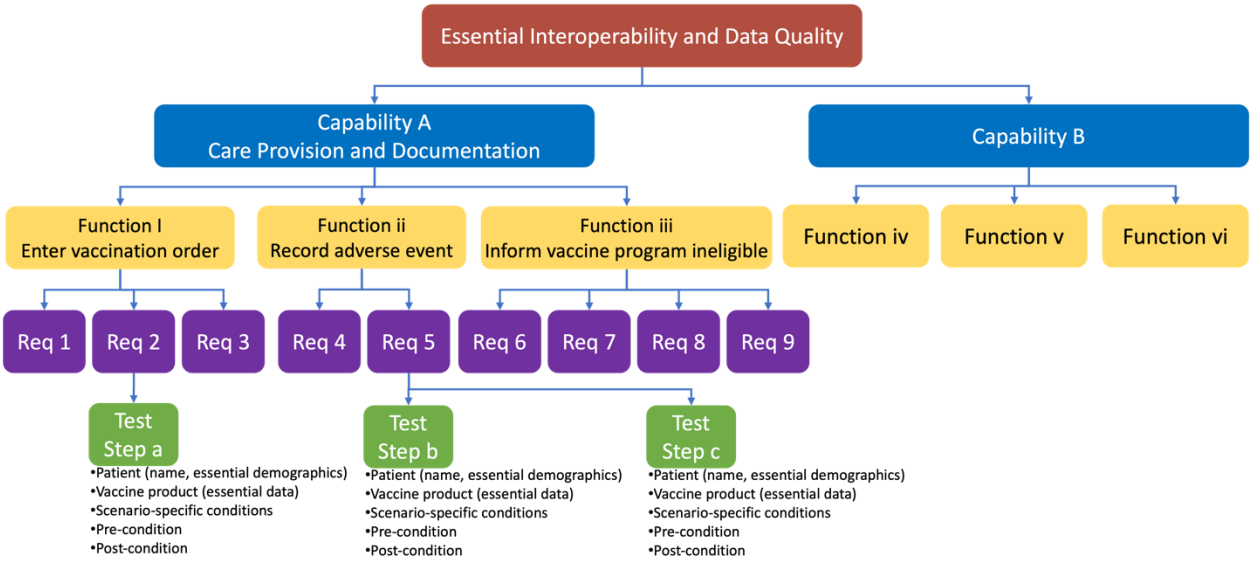

Figure 1. IIP Essential Module example of test development process

CAPABILITIES

The current IIP test plan includes eight capabilities. Each of these capabilities describes workflow-related concepts that group together with respect to common testable actions. The change from prior versions of the IIP test plan provides greater clarity regarding the intent and purpose of each grouping. Current capabilities include:

- Test Preparation – Data Load and PH Configuration
- Care Provision and Documentation
- Query, Response and Reconciliation
- Transmission and Acknowledgment

- Patient Access
- Clinical Configuration
- Transport
- Data Quality

2.0.0 Test Preparation – Data Load

Attestation: Test Preparation – Data Load represents SUT preparation for IIP testing. The IIP provides initial data including patients with respective demographics, patient-specific immunization histories, immunization products sourced with private and with public guarantee program funding with detailed metadata such as vaccine code (CVX), manufacturer code (MVX), national drug code (NDC), expiration date. The IIP provides such vaccine data in data matrix (2D bar code) and in text. The initial data load provides required information to support subsequent capabilities and functional requirements, the SUT participant should be diligent to enter or upload the provided information correctly to avoid impacting SUT performance on subsequent functional requirements. The SUT **SHALL** link standard codes (i.e., LOINC for tests or evaluation tools, NDC codes for current immunizations, CVX for historical immunizations, MVX manufacturer codes, VIS Codes, and appropriate codes for administration site, route, method, etc.) to discrete data elements associated with an immunization.

Information included in the initial data load includes:

2.1.0 Facilities

Attestation: The SUT **SHALL** enter details for facilities that should exist in the system under test before testing scenarios are performed.

2.2.0 People – Register New Patients

Attestation: SUT **SHALL** enter details for patients that should exist in the system under test before testing scenarios are performed. The SUT allows a user to enter and store distinguishing information about patients. This allows practitioner to uniquely identify patients who have similar sounding names or other similar identifying information. For example, twins living in the same household will have similar dates of birth, addresses, and may have similar names.

This information must also be stored to successfully match with patients in IIS if the information is available. This information allows the practitioner to correctly identify the patient and also helps ensure a match when SUT sends the patient's information to external systems such as IIS.

2.3.0 Vaccine Inventory

Attestation: The SUT **SHALL** enter details for vaccine inventory that should exist in the system under test before testing scenarios are performed.

2.4.0 Public Health Configuration

Attestation: The SUT **SHALL** add vaccine program eligibility that may be new or unique to the local jurisdiction and these should exist in the system under test before testing scenarios are performed. Various jurisdictions are establishing new programs to provide vaccines and their administration to defined patient population for some or all vaccines. Many are state-specific programs.

2.4.1 PH Configuration

The SUT **SHALL** be required to capture the respective vaccine program applicable to the vaccine administered.

3.0.0 Care Provision and Documentation

This capability includes basic functionality that allows SUT users to prepare, administer, and record care provision. Advanced functionality is excluded from this capability. Advanced functionality excluded from the "Care Provision and Documentation" capability includes query, response, and reconciliation; display IIS immunization forecast; system configuration; display immunization forecast, submission and acknowledgment; display immunization history; basic data quality; patient access; configuration; and transport.

Functional Requirements Associated with Capability

3.1.0 Select Patient

The SUT allows a user to enter and store distinguishing information about patients. The stored data allows a practitioner to uniquely identify patients with similar demographic information such as similar sounding names. For example, twins living in the same household will have similar dates of birth, addresses, and may have similar names.

3.1.1 Select patient

This function allows a provider to look up and then select a patient's local medical record using the SUT software to perform subsequent actions such as view or update information or initiate a query for information to an IIS for the selected patient(s).

The SUT demonstrates its patient selection and patient matching processing and the SUT **SHALL** allow users to select a patient from a list of active patients.

3.2.0 Enter patient-provided immunization-related information

The SUT allows a practitioner to enter patient-provided immunization history data that is stored in the SUT as structured data in the patient's medical record identifiable as the patient's immunization history obtained from a secondary source (i.e., not administered at the practice location). Ideally, patient-provided information includes documented evidence such as a copy of a pharmacy or a clinic visit summary; such cases often represent valid data. Patient-reported information may also be entirely verbal and not verifiable. While IIP has considered requiring verified status for patient-reported data, many practitioners fail to document such metadata. Therefore, IIP does not currently require verified status as part of test data.

3.2.1 Enter patient-provided immunization-related information

The SUT **SHALL** allow a practitioner to enter patient-provided immunization data into the SUT-provided immunization history and indicate the source as patient-provided.

3.3.0 Display patient's updated immunization history

The SUT displays the patient-provided immunization data entered by the practitioner within the patient's SUT immunization record. Historical immunization frequently contains limited

metadata even if present on the documentation provided. Captured data elements should be sufficient to allow a forecasting engine to recognize the patient-provided immunization event in creating a future forecast.

3.3.1 Display patient's updated immunization history

The SUT **SHALL** display the patient's immunization history that includes the patient-provided immunization with the metadata detail provided (product name, date administered, patient-provided as source).

3.4.0 Display patient's updated immunization local system (non-IIS) forecast

The SUT displays a single patient's immunization forecast report performed after entering the patient-provided historical immunization data. The SUT may contain valid immunization events received directly from pharmacies, from other practitioners, or from patient-reported history and a new forecast performed after entering a historical immunization should incorporate the new information into the forecast recommendation.

3.4.1 Display patient's immunization local system (non-IIS) forecast

The SUT **SHALL** perform and display an immunization forecast based on updated SUT history.

3.5.0 Enter vaccination order

The SUT allows practitioners to order the administration of immunizations to a patient by displaying vaccines, allowing the user to filter the display by antigen (agent for which the vaccine offers protection), including combination vaccines. Immunization-related workflow involves selecting an immunization to be administered to the patient during a specific encounter. The user interface can limit the time required to select an immunization from a list, filtering by desired antigen present in single agent and combination vaccines. This functionality also provides a comprehensive view of all products containing the respective antigen such that the ordering practitioner does not miss what might be an appropriate product for the patient. SUTs may have various methods to address the filtering option including sorting functions for a full list of products, and pre-filtered content based on selection of antigens from a patient-specific immunization schedule.

3.5.1 Enter vaccination order

The SUT **SHALL** allow a user practitioner to select and order an immunization to be administered to a patient by viewing vaccine options in a user interface in which the user can filter the display to show vaccines sorted by antigen which includes combination products containing a desired antigen.

3.6.0 Record vaccine administration data using 2D barcode scan found on vaccine vials and syringes to input the vaccine-specific information

The SUT supports the ability for a practitioner to record immunization administration for a patient by scanning the GS1 DataMatrix (2D barcode)[1] existing on vaccine vials and syringes including vaccine type, vaccine manufacturer, expiration date, and lot number to enter the respective data into the patient's record. CDC provides guidance about using the GS1 DataMatrix (2D barcode) for immunizations.[2] The 2D barcode content includes the products Global Trade Item Number (GTIN), Global Location Number (GLN) and over 100 additional data elements including batch/lot, expiration date, serial number. Vaccine 2D barcode scanning can replace manual entry of vaccine information to improve data accuracy and completeness and to support safe patient care.

Functional requirement 3.6.0 OBJ UoUUoU may represent a single dose item or a multidose vial. Similarly, vaccine packaging may contain multiple single dose items. Unit of Sale (UoS) references the 2D barcode on the packaging. This functional requirement does not address UoS; however, vaccine inventory may include both UoS and UoU content.

3.6.1 Save vaccine administration data using 2D barcode scan found on vaccine vials and syringes to input the vaccine-specific information

The SUT **SHALL** allow a practitioner user to scan 2D barcodes found on vaccine vials and syringes to input the vaccine information into the patient's immunization record at the time of vaccine administration.

3.7.0 Record vaccination administration data with manual data entry to input the vaccine-specific information

The SUT supports the ability for a practitioner to record immunization administration for a patient using manual data entry for vaccine product data such as vaccine type, vaccine manufacturer, expiration date, and lot number. Using the 2D barcode provides opportunity for practitioners to improve data accuracy and completeness; however, some SUT implementation sites, and some operational interruptions require availability for manual data entry.

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1 GS1. GS1 DataMatrix Guideline. Release 2.5.1, Ratified January 2018. Available at: https://www.gs1.org/standards/gs1-datamatrix-guideline/25. Accessed 29 February 2024.

2 Centers for Disease Control and Prevention. Vaccine Two-Dimensional (2D) Barcodes. January 19, 2021. Available at: https://www.cdc.gov/vaccines/programs/iis/2d-barcodes/index.html.Accessed January 19, 2024.

3.7.1 Record vaccine administration via manual entry (not scanned)

The SUT **SHALL** allow a practitioner to manually enter vaccine-specific information into the patient's immunization record at the time of vaccine administration.

3.8.0. Produce a printable version of a patient's immunization record that can be provided to a patient or a caregiver

The SUT supports the ability for the practitioner to provide a printed immunization record to the patient or caregiver. Patients may require practitioners or provider organizations to generate immunization records for access to vocational or avocational activities or to provide documentation required for travel. Parents or guardians may require such records for minor children to access childcare, camp, community, or other activities. Various organizations may require specific formats for immunization records. SUTs may give customers the ability to configure printable formats to accommodate such requirements or honor requests for custom formats; IIP testing does not address such configurability.

3.8.1 Produce a printable version of a patient's immunization record

The SUT **SHALL** allow a practitioner to produce a printable version of the patient's immunization record that can be shared with the patient or caregiver.

3.9.0 Display a patient's local immunization forecast after adding vaccine administration events to the immunization history

The SUT provides an immunization forecast after completion of vaccine administration events; this functional requirement assures the new forecast shows evidence of the newly administered doses. Immunization forecasts evaluated with the most recent vaccine administration data should be up to date to assure patients and practitioners have accurate information about immunization-related preventive care expectations.

3.9.1 Display a patient's local immunization forecast after adding vaccine administration events to the immunization history

The SUT **SHALL** provide a new forecast post-immunization administration, and that new forecast **SHALL** show evidence of the newly administered doses.

3.10.0 Vaccine dose expiration is visually apparent to administering practitioner

The SUT provides sufficient information about expiration dates of available vaccine products to enable practitioner selection of non-expired products to administer to patients.

3.10.1. Select patient for expired vaccine

(Not evaluated) This step represents set up for the subsequent steps and it must occur for the subsequent steps to successfully occur.

3.10.2 Order vaccine

(Not evaluated) This step represents set up for the subsequent steps and it must occur for the subsequent steps to successfully occur. Practitioners do not generally have access to vaccine product and expiration dates at the time of ordering; thus,

the IIP does not expect any action at this point in the test to address expiration date.

3.10.3 Make vaccine dose expiration date prominently available to the user

The SUT **SHALL** provide sufficient information to allow a practitioner to distinguish between available vaccine products that have past their expiration dates and those that have not yet expired.

3.11.0 Identify and record publicly provided-vaccine program eligibility

The SUT enables the user to match, identify, and record publicly provided vaccine program dose-level eligibility for a patient when administering vaccines. Vaccines for Children (VFC) is the most common guarantee program. VFC requires that the patient meets specific criteria to receive vaccine products the program provides to the practitioners and that the specific vaccine dose is indicated by the program (i.e., *dose-level eligibility*).

3.11.1 Inform user of patient-specific vaccine product eligibility status

The SUT **SHALL** inform the individual planning to administer a vaccine product to a patient that the selected product funding source does not match the patient's eligibility status.

3.12.0 Record adverse events

The SUT enables local capture of structured data regarding vaccine-related adverse events. Capturing information about allergies and adverse events potentially caused by immunizations supports patient safety by making the information available when practitioners consider ordering or administering such products to the same patient in the future. However, out of scope for the IIP is transmission of adverse event data to the IIS because of immaturity of standards and inconsistent willingness of IIS to receive information regarding adverse events. Also, reporting adverse events to the Vaccine Adverse Event Reporting System (VAERS) is considered out of scope as it addresses a unique workflow initiated at the time a clinician identifies and records a potential vaccine-associated adverse event. Such occurrence may be within minutes to days after transmission of vaccine administration data to the IIS. Further, a consensus-based interoperability standard is not evident to require consistent interoperability method for VAERS reporting.

3.12.1. Select patient

(Not evaluated) This step represents set up for the subsequent steps and it must occur for the subsequent steps to successfully occur.

3.12.2 Enable local capture of structured data regarding adverse events

This step supports functional requirement 3.13.0 (inform users of risks due to previous adverse events within the ordering or administering workflows for potential causative agents). The SUT **SHALL** allow capture of structured data regarding adverse events potentially due to previously recorded administered vaccines.

3.13.0 Inform users of risks due to previous adverse events within the ordering or administering workflows for potential causative agents

The SUT informs practitioner users about previously documented immunization-related adverse events within the workflow for ordering or administering an immunization containing the same antigen suspected as the causative agent of the adverse event. The method for informing the user should be consistent with methodology the SUT uses to inform users of other potentially critical clinical risks. It may take the form of passive presentation such as user interface indicators in a vaccine schedule, in ordering screens, in product selection screens, or active presentation such as alerting within the workflow. The IIP is not prescriptive with respect to how the SUT displays the information.

3.13.1. Inform users ordering vaccines containing antigens previously identified as potential causative agents of an adverse event

The SUT **SHALL** inform a practitioner ordering an immunization for a patient with a previous adverse reaction to an antigen included in that product.

3.13.2 Inform users administering vaccines containing antigens previously identified as potential causative agents of an adverse event

The SUT **SHALL** inform a practitioner of a previous adverse reaction to an antigen about to be administered.

3.14.0 Record vaccine administration refusal

The SUT allows practitioner users to enter patient or caregiver refusals to receive specific immunizations and to transmit the refusal documentation to the IIS.

3.14.1. Select patient

(Not evaluated) This step represents set up for the subsequent steps and it must occur for the subsequent steps to successfully occur.

3.14.2. Enter order for Hepatitis A vaccine

(Not evaluated) The SUT **SHALL** allow a practitioner to enter an order for a vaccine. This step represents set up of the subsequent steps and it must occur for the subsequent steps to successfully occur.

3.14.3 Record vaccine administration

(Not evaluated) This step enters vaccine administration information to set up subsequent information flow. In this scenario, the administering practitioner records vaccine administration and the record will be transmitted to the IIS prior to the practitioner entering the patient's examination room and administering the vaccine. This functional requirement sets up the scenario that results in transmitting the message to the IIS and a transmitting a delete message to the IIS (test steps 5.5.1 and 5.5.3, respectively, part of the Transmission and Acknowledgement IIP capability). The next functional requirement (3.14.4) indicates recording the patient or caregiver refusal of vaccine administration.

3.14.4. Record vaccine administration refusal

The SUT **SHALL** allow a practitioner to record patient or caregiver refusal of vaccine administration.

3.15.0 Produce cohort reports

The SUT enables users to generate aggregate, cohort (clinic or health system level) reports based on known patient immunization data. While there are many examples of cohorts, common ones include patients who received vaccine products that were subsequently recalled, patients who have no indication of expected immunizations by a specified date or age, patients who have no history of immunization for a vaccine-preventable condition for which the local community is experiencing an outbreak, etc.

3.15.1 Generate aggregate, cohort patient immunization data reports

Attestation: The SUT **SHALL** attest to the ability of a user organization or practitioner to generate an aggregate, cohort patient immunization data report. At a minimum, the SUT **SHALL** support creating a report of patients with defined characteristics (a) with no record of expected immunizations as of a specific age or date (e.g., children seen at least twice in the practice with no evidence of MMR vaccination by age 2), and (b) with evidence of immunization with a vaccine product identifiable with a specific lot number. As part of pre-testing your organization **SHALL** be required to provide additional information on the reporting functionality.

4.0 Query, Response, and Reconciliation

This capability includes basic functionality that allows SUT users query an immunization registry (IIS) for a patient's evaluated immunization history and vaccine forecast, to reconcile the immunization history with data pre-existing in the SUT, and to view an updated vaccine forecast based on the reconciled data. Advanced functionality excluded from the "Query, Response, and Reconciliation" capability includes full evaluation of SUT-enabled forecasting engine conformance with CDSi requirements, user interface details with respect to reconciliation screen display, or configuration capabilities related to managing patient opt-in or opt-out decisions. Functional requirements included in this capability address and exceed some §170.315(f)(1) Transmission to immunization registry criteria.

Functional Requirements Associated with Capability

4.1.0 Display local forecast

The SUT includes the limited immunization history provided in the data load for a specified patient. The immunization forecast, represented in some systems as a vaccine schedule indicating immunizations and expected timing of doses the patient requires. The forecast includes age-appropriate immunizations based on the limited history available to the SUT.

4.1.1 Display local forecast

(Not evaluated, Pre-Test Step) The SUT displays an immunization forecast for the respective patient. This functional requirement sets up an initial forecast for comparison with a subsequent forecast performed after importing date received in

response to a query for evaluated immunization history and forecast from the IIS. This is a supporting step that must be performed.

4.2.0 Transmit query to the IIS and receive response

The SUT requests an evaluated immunization history and forecast from the local IIS using an HL7 version 2.5.1 Z44 profile message. The IIP expects the SUT to display the IIS evaluated immunization history to allow a user to reconcile information from the IIS with data existing in the SUT (functional requirement 4.3.0); the SUT will also receive the IIS forecast as part of the response to the query, but the SUT may only display a forecast performed after it requests a new forecast post-reconciliation (functional requirement 4.5.0).

4.2.1 Request a patient's evaluated immunization history and forecast from an IIS using an HL7 version 2.5.1 Z44 profile message

The SUT **SHALL** trigger a Z44 profile message (request for evaluated immunization history and forecast) to the IIS meeting criteria for a patient who is a twin, including patient name (first, middle, last), mother's maiden name, ID number, date of birth, administrative sex, address, phone number, multiple birth indicator, birth order.

4.2.2 Receive IIS history and forecast

The SUT **SHALL** receive an evaluated immunization history and forecast from the IIS as a response to the query just submitted. This item assures that immunization history includes vaccine name, CVX code, date administered (given), source, and validity. The latter two elements require some explanation:

a) Source is an element that helps differentiate previous immunizations administered by the practice using the SUT from those received from the IIS or from data provided by a patient or a different practice or pharmacy. The IIP uses the HL7 2.5.1 NIP001 table to identify source terminology. Detailed provenance is out of scope for the IIP due to the complexity of sharing required data with each interoperable message detailing a vaccination instance. The level of provenance supported in interoperability standards supported by the Office of the National Coordinator for Health Information Technology (ONC) in USCDI publications is limited and identifying the administering practice is further challenged by changes in location, practice identifiers, and organizational mergers. The IIP focus on source represents a general description of the entity from which the SUT receives the information. Policy issues are out of scope for the tests for example, policies addressing whether the practice should record patient provided history without viewing documented evidence.

b) Validity is an element indicating the vaccine record has been verified as appropriate. The IIP assures the SUT can support the validity status if received from another organization. Examples of invalid vaccine doses are those given too early with respect to the ACIP recommended vaccination schedule and those for which the vaccine product has been identified as non-potent due to product storage issues. The example provided in the test is

a vaccine administered when the patient is too young such that the dose may have been clinically appropriate due to disease exposure, but it does not count to fulfill the recommended vaccination schedule. Policy issues and vaccine storage requirements are out of scope for IIP testing which only assure the SUT can store validity status for invalid if such exists in a record received from another source.

4.3.0 Compare IIS-provided information

The SUT displays the evaluated immunization history received from the IIS and the immunization history previously known to the SUT and allows the user to reconcile the information from the two sources. Reconciliation includes accepting new immunization data known only to the IIS, retaining immunization data known only to the SUT, and choosing which of the two immunization events to retain for those events present in both the IIS and the SUT histories.

4.3.1 The SUT enables a user to reconcile immunization data to update the immunization record

The SUT **SHALL** display all immunization history indicating each item as present in the original SUT history, each item present only in the newly imported IIS history, and each item present in both original sources. The SUT **SHALL** also provide the user to retain the SUT record of a vaccine or to import the IIS record of a vaccine resulting in an updated local SUT vaccine history and that history **SHALL** include vaccine source and validity status.

4.4.0 Display SUT vaccination history including the user-reconciled IIS-provided history

The SUT displays the updated post-reconciliation immunization history.

4.4.1 The SUT displays the post-reconciliation SUT vaccination history

The SUT **SHALL** display the updated vaccination history that incorporates the local data, and the data provided from the IIS as reconciled by the user. The SUT display **SHALL** include data indicating vaccine source and validity status.

4.5.0 Re-evaluate patient's immunization forecast

The SUT performs a new immunization forecast based on the new immunization history resulting from users' new reconciliation of data from the IIS with pre-existing SUT data.

4.5.1 The SUT provides a new immunization forecast based on the post-reconciliation vaccination history

The SUT **SHALL** provide a new immunization forecast based on the post-reconciliation vaccination history. The updated forecast **SHALL** match the expected vaccines and recommended dates based on CDSi criteria; one vaccine **SHALL** reference earliest date, recommended date, and past-due date.

4.6.0 Not an exact match response (RSP)

The SUT addresses IIS responses to queries that indicate the IIS found too many matches or no matches.

4.6.1 Select patient

(Not evaluated) This step represents set up for the subsequent steps and it must occur for the subsequent steps to successfully occur.

4.6.2 Request evaluated immunization history and forecast from IIS

(Not evaluated) This step represents set up for the subsequent steps and it must occur for the subsequent steps to successfully occur. The SUT requests an evaluated immunization history and forecast from the IIS using an HL7 version 2.5.1 Z44 profile message.

4.6.3 Receive and process IIS response indicating too many matches

The SUT **SHALL** receive an acknowledgement (ACK – Z33 profile) indicating too many matches and displays that the query has completed but too many matching records were found for the person in the query.

4.6.4 Select patient

(Not evaluated) This step represents set up for the subsequent steps and it must occur for the subsequent steps to successfully occur.

4.6.5 Request evaluated immunization history and forecast from IIS

(Not evaluated) This step represents the set up for the subsequent steps and it must occur for the subsequent steps to successfully occur. The SUT requests an evaluated immunization history and forecast from the IIS using an HL7 version 2.5.1 Z44 profile message.

4.6.6 Receive and process IIS response indicating no matches

The SUT **SHALL** receive an acknowledgement (ACK – Z33 profile) indicating no matches and displays that the query has completed but no matching records were found for the person in the query.

5.0 Transmission and Acknowledgement

This capability includes transmission of newly documented patient immunization records to the immunization registry (IIS). Functional requirements included in this capability address the SUT submitting historical data new to the SUT, submitting newly administered immunizations, and submitting corrected data regarding previously reported immunizations. The IIP program limits testing of complex indicators to primarily address data submission and avoid confusion about potential responses. For example, some jurisdictions have distinct rules for handling the protection indicator that signifies whether the patient gives consent to sharing immunization data with the registry or other practitioners. [See 5.4.0.] Functional requirements exceed some §170.315(f)(1) Transmission to immunization registry criteria. Refer to Table xxx for a direct mapping of test elements to ONC (f)(1) criteria.

Functional Requirements Associated with Capability

5.1.0 Transmit newly recorded immunization records to IIS and Receive and process acknowledgement messages

The SUT supports the ability to send newly documented patient information to the IIS using the unsolicited vaccine update (VXU-Z22 profile message) correctly and includes all required (R) and required if known (RE) data elements per the HL7 version 2.5.1 Implementation Guide: Immunization Messaging (Release 1.5) and addendum. The data transmitted originates in functional requirement 3.7.0.

The SUT receives acknowledgement messages from the IIS in response to the submission of newly recorded immunization records and must be capable of receiving and processing the following type of acknowledgement (ACK) responses from an IIS: Fatal System Error (AR), Fatal Error (AE), Warning (AE), Multiple Warnings (AE), Informational (AA), and No Errors (AA). The responses must be visible in the system responsible for the content of the administration message (e.g., error log file, pop-up or display on screen).

5.1.1 Transmit newly recorded administered vaccine to the IIS

The SUT **SHALL** generate an unsolicited vaccine update (VXU-Z22 profile message) correctly and without omitting supplied test data.

5.1.2 Acknowledgement Error "E" (AR)

Receive and process acknowledgement messages from IIS indicating fatal system error due to the inability to process the entire message.

5.1.3 Acknowledgement Error "E" (AE)

Receive and process acknowledgement messages from IIS indicating fatal errors; single immunization record rejected from within a larger message.

5.1.4 Acknowledgement Error Warning "W" (AE)

Receive and process acknowledgement messages from IIS indicating warnings.

5.1.5 Acknowledgement Error Multiple Warnings "W" (AE)

Receive and process acknowledgement messages from IIS indicating multiple warnings.

5.1.6 Acknowledgement Informational "I" (AA)

Receive and process acknowledgement messages from IIS indicating an informational message.

5.1.7 Acknowledgement (AA)

Receive and process acknowledgement messages from IIS indicating no errors.

5.2.0 Update vaccine record previously submitted to IIS

The SUT supports the ability to send updated records to add or correct information sent during previous vaccine administration submissions to the IIS. This functional requirement supports sites for which local practice or IIS policy do not limit the SUT's ability to submit updated information.

5.2.1 Update vaccine record to correct previously submitted data sent to IIS

The SUT **SHALL** allow update to data entered in an immunization record. In this scenario, the user manually entered a vaccine lot number with the wrong number; the user re-opens the record and corrects the lot number. The scenario supporting this item indicates the manual entry of the vaccine lot number (functional requirement 3.7.0) and submitted in functional requirement 5.1.0 was incorrect and the SUT corrects the error followed by the next step, transmitting the updated record to the IIS.

5.2.2 Transmit updated immunization information to the IIS

The SUT **SHALL** transmit updated vaccine administration data to the IIS using unsolicited vaccination update (VXU) segment. In this scenario, the SUT sends the updated information with the corrected lot number entered in the previous step.

5.2.3 Receive acknowledgement message from IIS in response to updated vaccination record

(Not evaluated) The SUT receives an acknowledgement message from an IIS that indicates receipt of the updated vaccination record. This is a supporting step that must be performed.

5.3.0 Transmit newly recorded historical immunization record

The SUT supports the ability to transmit a message to the IIS containing a newly recorded historical immunization record including all required (R) and required if known (RE) data element as per the HL7 version 2.5.1 Implementation Guide: Immunization Messaging (release 1.5) and addendum.

5.3.1 Transmit newly recorded historical immunization records to IIS

The SUT **SHALL** transmit an unsolicited vaccine update (VXU-Z22 profile message) containing the newly recorded historical immunization record documented in step 3.2.1.

5.3.2 Receive acknowledgement message from IIS as response to submitted immunization message

(Not evaluated) The SUT receives an acknowledgement message from an IIS that indicates receipt of the vaccination record. This is a supporting step that must be performed.

5.4.0 Transmit and delete record and for immunization

The SUT supports the ability to transmit a message to the IIS to delete a previously submitted immunization. This functional requirement supports sites for which local practice or IIS policy do not limit the SUT's ability to delete previously submitted immunization records.

5.4.1 Transmit VXU for newly administered vaccine documented prematurely

The SUT **SHALL** submit an updated vaccine administration record message to the IIS. This transmission includes the data entered prematurely (before the vaccine

administration event occurred) in functional requirement 3.14.0. This step provides the record subsequently deleted.

5.4.2 Receive acknowledgement message from IIS as response to submitted immunization message

(Not evaluated) The SUT receives an acknowledgement message from an IIS that indicates receipt of the vaccination record. This is a supporting step that must be performed.

5.4.3 Transmit delete message to IIS

The SUT **SHALL** submit a vaccine record delete message to the IIS (a single VXU message with RXA segment containing action code "D") for a recently submitted vaccine administration record. In this scenario, the SUT sent the message based on clinician entering data prior to actual vaccine administration and the patient refuses the vaccine. This transmission deletes the immunization record entered previously in functional requirement 5.5.0.

5.4.4 Receive acknowledgement message from IIS as a response to submitted immunization delete record

(Not evaluated) The SUT receives an acknowledgement message from an IIS that indicates receipt of the message to delete the vaccination record. This is a supporting step that must be performed.

5.5.0 Transmit refusal for immunization

The SUT supports the ability to transmit a message to the IIS indicating patient refusal of vaccination and the reason for the refusal.

5.5.1 Transmit refusal of individual vaccination

The SUT **SHALL** transmit an unsolicited vaccine update (VXU-Z22 profile message, RXA segment with Substance/Refusal Reason = Parent Decision (NIP002 00)) indicating parent refusal of vaccine using data from functional requirement 3.15.0.

5.5.2 Receive acknowledgement message from IIS as response to submitted immunization message

(Not evaluated) The SUT receives an acknowledgement message from an IIS that indicates receipt of the vaccination record. This is a supporting step that must be performed.

5.6.0 Transmit patient consent (protection status)

The SUT supports transmission of a patient's consent information (protection indicator) which signifies whether the patient gives consent to sharing immunization data with the registry or other practitioners. The data supporting this activity includes immunization data entered in in the SUT in functional requirement 3.11.0.

5.6.1 Transmit protection indicator to IIS

The SUT **SHALL** generate an unsolicited vaccine update (VXU-Z22 profile message) correctly and include the protection indicator.

5.6.2 Receive acknowledgement message from IIS as response to submitted immunization message

(Not evaluated) The SUT **SHALL** receive an acknowledgement message from an IIS that indicates receipt of the vaccination record. This is a supporting step that must be performed.

6.0 Patient Access

This capability addresses basic functionality allowing patients or their caregivers to access immunization records most frequently using a patient portal. This IIP Essential Interoperability and Data Quality module limits requirements to basic access to view and print a list of a patient's previous immunizations known to the SUT. More robust features supporting patient empowerment are not in scope for this basic module due to diverse privacy, policy, and procedural issues specific to jurisdictional regulation and patient and practice preferences. For example, some SUTs allow patients to enter information with supporting attachments regarding immunizations administered in pharmacies or other practices; however, most practices require review of such information prior to adding it to the patient's validated immunization history record. Such practices depend on local process decisions and third-party portal application capability and interoperability of which the SUT cannot control. The practitioner must review and provide recommendations regarding the next immunization(s) the patient requires. A SUT can provide configurable templates for each implementation site, but it requires clinician intervention to determine details regarding future patient care. Some IIS provide patients with access to immunization histories and forecasts as well.

Functional Requirements Associated with Capability

6.1.0 Provide patient or a designated individual electronic access to the patient's immunization record.

The SUT provides the patient or a designated individual with access to electronically view the patient's immunization record. The functional requirement assumes the SUT provides privacy and security functionality and that implementation sites have processes in place to assure assignment of designated individuals and their access to the record. Such processes are ubiquitous; they are not necessarily specific to immunization management.

6.1.1 Patient electronic access to immunization records.

Attestation: The SUT **SHALL** allow a patient or a designated individual to electronically access the patient's immunization record.

7.0 Clinical Configuration

This capability addresses adding a new vaccine to the SUT. The testing workflow expects that a practitioner can place an order for that vaccine, allowing another user to select that vaccine

from available inventory, administer it to a patient, and submit an unsolicited vaccination record to an IIS. Further, the SUT will receive an acknowledgement from the IIS, and it will update the patient's forecast or vaccination schedule accounting for the dose administered.

Functional Requirements Associated with Capability

7.1.0 Add new vaccine codes

The SUT enables updates to vaccine code sets including vaccine codes (CVX), National Drug Codes (NDC), the Manufacturer (MVX) when CDC releases such code sets, and the Vaccine Information Statements (VIS) associated with the new vaccine code. This function allows clinician users to order and administer newly enabled vaccines such as those developed and released for emerging infectious diseases. The first set of COVID vaccines available are good examples of this type of new vaccine product.

7.1.1 Add new vaccine codes

The SUT **SHALL** allow updates to vaccine code sets including at least CVX, NDC, VIS codes. The SUT SHOULD also include the Manufacturer code (MVX), vaccine manufacturer name.

7.1.2 Enter new vaccine inventory

(Not evaluated) The SUT adds new vaccine product to the inventory of products users have available to administer. The inventory data **SHALL** include product name, Unit-of-Use (syringe or vial) NDC code, manufacturer, lot number, expiration date, and the product's funding source of the product. This is a supporting step that must be performed.

7.1.3 Order new vaccine product

(Not evaluated) The SUT allows a user to order a vaccine represented by the new vaccine code. This is a supporting step that must be performed.

7.1.4 Administer new vaccine product

The SUT **SHALL** allow a user to select and administer the vaccine represented by the new vaccine code.

7.1.5 Transmit new vaccine administration containing new vaccine codes

The SUT **SHALL** submit an unsolicited vaccine update with the new vaccine codes including any new applicable eligibility code to the IIS.

7.1.6 Receive acknowledgment from IIS for VXU

(Not evaluated) The SUT receives acknowledgement message from the IIS for the vaccine update. This is a supporting step that must be performed.

7.2.0 Update immunization schedule to reflect changes in ACIP recommendations

The SUT updates the vaccine forecast or schedule based on new ACIP recommendations associated with the newly available vaccine product.

7.2.1 Update Vaccine Schedule

Attestation: The SUT **SHALL** attest to the ability to update a vaccine forecast or schedule based on new changes to the forecasting engine that address the newly available vaccine product.

8.0 Use of the CDC WSDL for Transport

This capability addresses the ability of the SUT to send and receive immunization messages with an IIS using the CDC WSDL (Web Services Definition Language). The CDC WSDL uses a Simple Object Access Protocol (SOAP) for transmitting HL7 immunization messages. The SOAP-CDC WSDL is the preferred data transport method for transmitting messages to an IIS.

Attestation: The SUT **SHALL** attest that the product has been connected to one or more IIS using the CDC WSDL 1.0 or **SHALL** attest that the SUT has used the NIST IIP Test Suite to meet the functional requirements associated with 8.0 Use of the CDC WSDL for Transport.

Functional Requirements Associated with Capability

8.1.0 Generate a conformant CDC WSDL message Submit immunization records to an IIS using the CDC WSDL with messages conforming to the SOAP Standard.

The SUT has the ability to generate a message envelope and a message body containing both the credentialing requirements and the message content to be delivered using the SOAP 1.2 transport standard using the CDC WSDL 1.0 web service standard.

8.1.1 Generate a conformant message Envelope

Attestation: The SUT **SHALL** have the ability to generate a message envelope with a basic message conforming to the SOAP 1.2 transport standard and CDC WSDL 1.0 web services

8.1.2 Generate a conformant message with credentialing

Attestation: The SUT **SHALL** have the ability to generate a submitSingleMessage contained within the message envelope which supports both the authentication information and the HL7 immunization message payload in according to the CDC WSDL 1.0 standard.

8.2.0 Send an HL7 Immunization Message using the CDC WSDL 1.0

The SUT has the ability to connect to a Web Service using with a basic message (used for testing connectivity) or to send an HL7 Immunization message using the SOAP 1.2 transport standard and the CDC WSDL 1.0 web service standard.

8.2.1 Connect to a Web Service

Attestation: The SUT **SHALL** have the ability to connect to a Web Service and send a basic message which conforms to the SOAP 1.2 transport standard and CDC WSDL 1.0 web services for the purpose of testing connectivity.

8.2.2 Generate a conformant message with credentialing

Attestation: The SUT **SHALL** have the ability to connect to a Web Service and send an H7 immunization message using the submitSingleMessage with authentication information in accordance with the SOAP 1.2 transport standard and the CDC WSDL 1.0 standard.

9.0 Data Quality

This capability addresses basic quality checks to evaluate the SUT regarding fundamental data error prevention. Examples include a patient's birth date in the future compared to the test date, a patient's date of death earlier than the birth date, a vaccine administration event occurring prior to the patient's birth date, a patient's birthdate greater than 150 years before the test date. Some data quality concerns require further discovery to determine the value and feasibility of testing in future versions of the IIP, for example, how a SUT addresses agreement of vaccine administration body site and route expected based on the vaccine product given, and the enforcement of timing the interval between different live vaccines.

Functional Requirements Associated with Capability

9.1.0 Prevention of critical date data entry errors

The SUT prevents data entry errors of critical dates including patient birth dates in the future, patient birth dates too far in the past (e.g., over 150 years ago), vaccine administration dates in the future and vaccine administration dates earlier than the patient's birth date.

9.1.1 Patient DOB in the future

Attestation: The SUT **SHALL** attest to the ability to inform or prevent a user from entering a birth date in the future compared to the test date.

9.1.2 Patient DOB too old

Attestation: The SUT **SHALL** attest to the ability to inform or prevent a user from entering a birth date greater than 150 years before the test date.

9.1.3 Patient vaccination date is before DOB

The SUT **SHALL** inform or prevent a user from entering a vaccine administration date that is earlier than the patient's birth date.