



AIRA

AMERICAN IMMUNIZATION
REGISTRY ASSOCIATION

IIS Validation

Submission and Acknowledgment

Updated June 11, 2021

Background and Context

The consolidation of immunization records from multiple sources is a primary function of Immunization Information Systems (IIS)¹. To ensure complete, accurate and timely consolidated records, IIS must receive data from a high proportion of immunizers within their catchment area through standardized reporting channels. Messaging standards have been present across the IIS community for more than twenty years, and have increasingly gained importance as Electronic Health Record (EHR)-IIS interoperability has grown in necessity across health care. The primary standard for IIS messaging is the HL7 Version 2.5.1 Implementation Guide for Immunization Messaging, Release 1.5².

In 2016, AIRA convened the Measurement for Assessment and Certification Advisory Workgroup (MACAW) to develop and propose measures for IIS Assessment. These measures and tests were shared with the full AIRA community for input and consensus. Finally, these measures were approved by the AIRA Board of Directors in December 2016. A baseline measurement was taken during the first quarter of 2017 with remeasurements in each subsequent quarter. Aggregate results are published on the AIRA Repository³. MACAW is now recommending these measures be used for Validation.

Functional Standards and Operational Guidance Statements

The use of standardized messaging is referenced throughout the IIS Functional Standards, v4.0⁴. The revised IIS Functional Standards were developed by the Immunization Information Systems Support Branch, CDC/NCIRD, through a consensus-based process involving input from a variety of IIS managers and technical experts from across the U.S. They reflect the functionality an IIS should strive to attain to fully support program and stakeholder immunization-related goals. The following Functional Standards are included – at some level – in the MACAW measures and tests defined in this document.

Functional Standard 1.5: The IIS ensures that submitted vaccination and demographic data are processed and viewable in a timely manner.

Functional Standard 1.6: The IIS assures the receipt, processing, and storage of demographic and vaccination data elements as endorsed by CDC.

Functional Standard 8.2: The IIS receives submissions and returns acknowledgments consistent with the current CDC-endorsed HL7 Implementation Guide.

¹ <http://www.cdc.gov/vaccines/programs/iis/about.html>

² <http://www.cdc.gov/vaccines/programs/iis/technical-guidance/downloads/hl7guide-1-5-2014-11.pdf>

³ <http://repository.immregistries.org/resource/iis-measurement-and-improvement-message-submission-and-acknowledgement-assessment-aggregate-status-r/>

⁴ <https://www.cdc.gov/vaccines/programs/iis/functional-standards/func-stds-v4-0.html>

Approved Assessment Measures

The Assessment measures for Submission and Acknowledgment were approved in December 2016 and will be used for Validation. For more information on the Assessment measures, please see the Submission and Acknowledgment Assessment document on the AIRA website.⁵

Validation Stage

The *Immunization Information System (IIS) Measurement and Improvement: Testing and Discovery, Assessment and Validation Overview*⁶ document describes the Validation stage in detail and should be referenced for more information. At the highest level, the Validation stage uses the same (or a subset of) measures and tests which have been developed, vetted, and approved by the IIS community and AIRA Board for IIS Assessment. No new measures are introduced at Validation that have not already been measured in IIS Assessment.

Validation Levels

Submission and Acknowledgment will contain two Validation Levels (Basic and Complete). Measures selected for Validation are reviewed and assigned a Level based on the following definitions.

- **Basic Level:** A level of Validation measurement that includes only essential measures to functionally meet the content area.
- **Complete Level:** A level of Validation measurement that includes conformance to all measures approved for Validation.

The following table defines the requirements for both Basic and Complete levels of Validation.

⁵ <http://repository.immregistries.org/resource/submission-assessment-final-measures/>

⁶ <https://repository.immregistries.org/resource/iis-measurement-and-improvement-testing-and-discovery-assessment-and-validation-overview/>

Table 1: Submission and Acknowledgment Validation Levels

Assessment Measure	Basic Level	Complete Level
1 - The IIS processes an administered vaccine for a patient.	X	X
2 - The IIS processes a historical vaccine for a patient.	X	X
3 - The IIS processes the submission of a full immunization record for a patient.	X	X
4 - The IIS processes an update to a previously submitted vaccination event.	X	X
5 - The IIS processes a delete to a previously submitted vaccination event.	X	X
6 - The IIS processes a submission where the patient does not give consent (i.e., patient data is protected) to share data.	X	X
7 - The IIS processes a refusal of a vaccination.		X
8 - The IIS processes an adverse event.		X
9 - The IIS processes an observation about a patient which results in a contraindication or immunity to a vaccine preventable disease.		X
10 - The IIS processes messages with only minimally required data elements populated per the HL7 2.5.1, release 1.5 guide and addendum.		X
11 - The IIS processes both complete and incomplete/partially administered doses.		X
12 - The IIS responds to a correctly formatted message with no errors.		X
13 - The IIS responds to a submission that has an error.		X
14 - The IIS responds to a submission with an ACK within 5 seconds or less for 95% of the records		X
15 - The IIS processes an administered vaccine using the preferred NDC format.	X	X
16 – The IIS processes an administered vaccine using two alternative, but standardized NDC formats		X






Validation Statuses

Validation statuses are assigned based on the Assessment outcomes for the measures of interest (e.g., Meets, Deviates, Does Not Meet). More information on Assessment outcomes can be found in the *Measures and Tests for Assessments: Message Submission and Acknowledgment*⁷.

⁷ <http://repository.immregistries.org/resource/submission-assessment-final-measures/>






Basic Level Requirements

Table 2: Basic Level Requirements

Validation Status	Assessment Outcome Requirements
	The IIS Meets all measures which are identified to be part of the Basic Level in Table 1 above.
	The IIS Deviates on one or more measures and Meets on all remaining measures which are identified to be part of the Basic Level in Table 1 above.
	The IIS fails to meet the requirements for Validated and Minor Differences.
	The IIS has communicated willingness to be measured but is not able to be tested at this time.
	The IIS has chosen not to be measured.

Complete Level Requirements

Table 3: Complete Level Requirements

Validation Status	Requirements
	<p>The IIS Meets all measures which are identified to be part of the Complete Level in Table 1 above.</p>
	<p>The IIS Deviates on one or more measures and Meets on all remaining measures which are identified to be part of the Complete Level in Table 1 above.</p>
	<p>The IIS fails to meet the requirements for Validated and Minor Differences.</p>
	<p>The IIS has communicated willingness to be measured but is not able to be tested at this time.</p>
	<p>The IIS has chosen not to be measured.</p>