



AIRA
AMERICAN IMMUNIZATION
REGISTRY ASSOCIATION

Measures and Tests for IIS Validation

Submission and Acknowledgment
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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 updated IIS Functional Standards v5.0 and Operational Guidance Statements (OGS) were developed through a consensus-based process by CDC's Informatics and Data Analytics Branch (IDAB), formerly known as Immunization Information Systems Support Branch (IISSB) with input from a variety of IIS managers and technical experts nationwide. These standards describe the core functionality an IIS should strive to achieve in support of programmatic and stakeholder immunization goals.

The following FS and OGS are applicable to Submission and Acknowledgment functionality and are included in the MACAW measures and tests defined in this document.

Measures and tests are based on the IIS Functional Standards v5.0.

Submission/Acknowledgement measures and tests are specifically based off the following:

Functional Standard B4.0: The IIS validates patient demographic and vaccination data.

Guidance Statement B4.2: The IIS monitors data quality within the IIS in accordance with policies and procedures.

¹ <https://www.cdc.gov/iis/about/?CDC>

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/>

Functional Standard C5.0: Manage interfaces for exchange and integration of data electronically between the IIS and other information systems in accordance with federal and jurisdictional standards.

Guidance Statement C5.1: The IIS exchanges data in accordance with current interoperability standards endorsed by CDC for message content, format, and transport.

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.⁴

Validation Stage

The *Immunization Information System (IIS) Measurement and Improvement: Testing and Discovery, Assessment and Validation Overview*⁵ 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.

⁴ <http://repository.immregistries.org/resource/submission-assessment-final-measures/>

⁵ <https://repository.immregistries.org/resource/iis-measurement-and-improvement-testing-and-discovery-assessment-and-validation-overview/>

http://www.immregistries.org/initiatives/measurement/IIS_Measurement_and_Improvement_-Validation_Overview_11-2017_Final.pdf

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

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*⁶.

Basic and Complete Level Requirements

Table 2: Basic and Complete Level Requirements

Validation Status	Assessment Outcome Requirements
 Complete Validated  Basic Validated	The IIS Meets all measures which are identified to be part of the Basic or Complete Level in Table 1 above.
 Complete Minor Difference  Basic Minor Difference	The IIS Meets all measures which are identified to be part of the Basic or Complete Level in Table 1 above, except for differences that 1) are allowed within the measures and test, or 2) are meeting requirements due to local law or policy.
 Major Difference - Validation Not Met	The IIS fails to meet the requirements for Basic or Complete Validated.
 Not Measured	The IIS has communicated willingness to be measured but is not able to be tested at this time.
 Not Participating	The IIS has chosen not to be measured.

⁶ <http://repository.immregistries.org/resource/submission-assessment-final-measures/>