



## Table of Contents

Introduction .....	2
Submission/Acknowledgment .....	3
Methods.....	3
Measures .....	4
Results .....	5
<b>Map: Submission/Acknowledgment Validation, complete level 2023</b> .....	5
<b>Table: Submission/Acknowledgment Validation, complete level 2023</b> .....	6
Conclusion.....	7
Appendix A: Glossary of Terms and Acronyms.....	8

## Introduction

The American Immunization Registry Association ([AIRA](#)) launched its community-driven immunization information system (IIS) [Measurement and Improvement \(M&I\) Initiative](#) in mid-2015. The M&I Initiative provides IIS with information and guidance to align with the [IIS Functional Standards](#). These standards are a set of specifications that describe the operations, data quality, and technology needed by IIS to support immunization programs, vaccination providers, and other immunization stakeholders.

M&I connects AIRA testing processes with IIS preproduction (or test) systems and/or analyzes de-identified data then shares results through the Aggregate Analysis Reporting Tool ([AART](#)). AIRA continues to test with a growing number of IIS interfaces, with over 90% of IIS programs currently participating. The initiative is demonstrating significant improvements in interoperability between IIS and electronic health record (EHR) systems across the community, as well as improvements in standards-based functionality.

M&I is a three-stage process for IIS to measure their alignment with current standards:

- [Testing and Discovery](#) gathers preliminary information on community alignment with standards.
- [IIS Assessment](#) involves more formal testing to measure individual IIS using IIS community-selected measures and tests.
- [Validation](#) is a summary stage to acknowledge and share results for IIS that are progressing toward or achieving alignment with community-selected measures and tests.

Each content area for measuring IIS functionality and capability progresses through each stage. M&I stages and content areas are developed by the Measurement for Assessment and Certification Advisory Workgroup ([MACAW](#)), a panel of IIS subject matter experts.

M&I's third and final stage, Validation, uses the same measures and tests, or a subset thereof, that have been developed, vetted, and approved by the IIS community for IIS Assessment, the second stage of M&I. Validation is measured at two levels: basic and complete. No new measures or tests are introduced in the Validation stage that are not already measured and visible in the Assessment stage. An [overview](#) is available that details the M&I Initiative, its content areas, and associated stages of measurement.

The following table presents an overview of M&I content areas and their respective progress across M&I stages.



	Pre-Measurement	Testing & Discovery	Assessment	Validation
Transport	☑	☑	☑	🏅
Submission/Acknowledgment	☑	☑	☑	🏅
Query/Response	☑	☑	☑	🏅
Clinical Decision Support	☑	☑	☑	🏅
Data Quality Incoming/Ongoing	☑	☑	☑	🏅
Data at Rest	☑	☑	📅 2023	
Provider Participation	☑	📅 2023		
Patient Matching	☑	📅 2023		
Onboarding	☑			
Patient Saturation	☑			
Security	☑			
Vaccine Matching	☑			
Vaccine Saturation	☑			

### Submission/Acknowledgment

The measurement process for Submission/Acknowledgment uses the National Institute of Standards and Technology (NIST) Immunization Test Suite Validation Tool.<sup>1</sup> This tool provides consistent conformance-based results for all measured IIS. In addition, the technical requirements for data submission and acknowledgment are documented in the HL7 Version 2.5.1: Implementation Guide for Immunization Messaging, Release 1.5<sup>2</sup> and addendum.<sup>3</sup> This is referred to as the “National IG.”

### Methods

Measures and tests are based on the CDC’s [IIS Functional Standards](#). All measures and tests are developed by [MACAW](#) and informed by the IIS community. Before 2021, measures required AIRA board of directors’ approval, and Submission/Acknowledgment Validation measures were approved in March 2018. Visit the [AIRA repository](#) for more detailed information about Submission/Acknowledgment measures and tests.

<sup>1</sup> <https://hl7v2-iz-r1-5-testing.nist.gov/iztool/#/cf>

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

<sup>3</sup> <https://www.cdc.gov/vaccines/programs/iis/technical-guidance/downloads/hl7guide-addendum-7-2015.pdf>

For Submission/Acknowledgment, the Functional Standards and operational guidance statements referenced include:

**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.

AIRA technical staff are responsible for implementing and conducting all M&I testing efforts. Current test methodology involves connecting with IIS preproduction systems through a web services interface, submitting test messages, and receiving back and analyzing test results.

Validation reports are run quarterly, and an IIS can achieve Validation status during any quarter of the year. Once achieved, Validation is considered “active” for the calendar year. Validation will be retested and renewed in the first quarter of each subsequent calendar year.

This report provides results for the **complete** level of Submission/Acknowledgment Validation; results for the **basic** level can be found [here](#). Summary information is presented for all measured IIS; individual results are available to authorized users in [AART](#).

## Measures

The **complete** level of Submission/Acknowledgment Validation contains 16 measures<sup>4</sup>:

1. The IIS processes an administered vaccine for a patient.
2. The IIS processes a historical vaccine for a patient.
3. The IIS processes the submission of a full immunization record for a patient.
4. The IIS processes an update to a previously submitted vaccination event.
5. The IIS processes a delete to a previously submitted vaccination event.
6. The IIS processes a submission where the patient does not give consent to share data (i.e., patient data are protected).
7. The IIS processes a refusal of a vaccination.
8. The IIS processes an adverse event.

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<sup>4</sup> Measures 15 and 16 were moved into complete Validation in Q1 2021.



The 61<sup>5</sup> IIS participating<sup>6</sup> in AIRA’s M&I Initiative were encouraged to be formally measured in Submission/Acknowledgment Validation. Of the 61 IIS, **57 (93%)** were connected to the testing process and measured. Of those measured, **30 (53%) Validated** or **Validated with Minor Differences** at the complete level for Submission/Acknowledgment, meaning they met all 16 measures. Another 27 IIS were measured but displayed major differences with the standard. One IIS was not able to be measured at this time, while three opted not to be measured in Submission/Acknowledgment Validation.

Below are results for Submission/Acknowledgment Validation for 2023 in tabular form.

**Table: Submission/Acknowledgment Validation, complete level 2023**

Validation Status and Definition	IIS
<b>Validated:</b> The IIS meets Measures 1–16.	Arkansas, Connecticut, Delaware, Guam, Illinois, Kansas, Kentucky, Missouri, Nebraska, Nevada, New Hampshire, New Mexico, Oklahoma, Philadelphia, Puerto Rico, Rhode Island, South Carolina
<b>Validated with Minor Differences:</b> The IIS deviates in one or more measures.	Alaska, American Samoa, Arizona, Colorado, Indiana, Louisiana, Marshall Islands, Massachusetts, Micronesia, N. Mariana Islands (CNMI), Oregon, Palau, Washington
<b>Major Differences:</b> The IIS does not meet one or more measures.	Alabama, California, Georgia, Hawaii, Idaho, Iowa, Maine, Maryland, Michigan, Minnesota, Mississippi, Montana, New Jersey, New York City, North Carolina, North Dakota, Ohio, Pennsylvania, South Dakota, Tennessee, Texas, Utah, Virgin Islands, Virginia, West Virginia, Wisconsin, Wyoming
<b>Not Measured:</b> The IIS is not able to be tested at this time.	District of Columbia

<sup>5</sup> Note that the denominator for M&I participation decreased from 62 to 61 in Q2 2022, due to San Diego IIS’s merge with California’s state IIS.

<sup>6</sup> Includes all 50 states, American Samoa, the Commonwealth of the Northern Mariana Islands, the District of Columbia, the Federated States of Micronesia, Guam, New York City, Philadelphia, Puerto Rico, the Republic of the Marshall Islands, the Republic of Palau, and the Virgin Islands.

**Opted Out:** The IIS has chosen not to be measured.

Florida, New York state, Vermont

## Conclusion

Many IIS are continuing to implement functionality to fully conform with the IIS Functional Standards, particularly as relates to full implementation of HL7 2.5.1, release 1.5. For the complete level of Validation for Submission/Acknowledgment, the bar is set high, as IIS must meet all 16 measures to be Validated. We look forward to seeing continued progress in this area of testing for Submission/Acknowledgment. Published Validation reports offer transparency into the progress IIS are making to come into full alignment with our community-driven standards. AIRA staff are also available to provide technical assistance to IIS programs and vendors as requested.

Please visit AIRA's [website](#) for more background or other information on the M&I Initiative. Please direct questions and/or comments via AIRA's online technical assistance [form](#).

## Appendix A: Glossary of Terms and Acronyms

**AART:** The Aggregate Analysis Reporting Tool, an application used to display and share results from the Measurement and Improvement process.

**Assessment Stage:** A more formal testing step to measure IIS using IIS community-selected measures and tests, to share those results for quality improvement, and to provide technical assistance to accelerate improvement. This is the second of three stages.

**Basic Level:** A level of Validation measurement that includes only essential measures to functionally meet this content area.

**Complete Level:** A level of Validation measurement that includes conformance to all measures approved for Validation.

**Content Area:** A category for measuring IIS functionality and capability within a specific functional area, made up of distinct measures and tests. Measures and tests will become more formalized as they progress into different stages.

**MACAW:** Measurement for Assessment and Certification Advisory Workgroup.

**Major Differences Status:** The IIS cannot support the measures because of additional requirements that conflict with the national standard; the IIS must make significant changes in one or more measures to align with standards.

**Measure:** A metric developed to measure how well an IIS aligns with IIS Functional Standards/operational guidance statements or another recognized standard.

**Stage:** A distinct period of testing in the Measurement and Improvement process.

**Testing and Discovery Stage:** A step in testing IIS to gather preliminary and general information on community alignment with standards. Testing and Discovery is the first of all the stages.

**Validated Status:** The IIS has achieved full alignment with community-selected measures.

**Validated with Minor Differences Status:** The IIS has achieved full alignment with community-selected measures except for differences that (1) are allowed by the standard (e.g., constraints) or (2) are meeting requirements of local policy/law that do not conflict with standard requirements.

**Validation Stage:** A summary step to acknowledge IIS that are progressing toward or achieving alignment with community-selected measures and tests. A Validation designation

is automatically achieved when an IIS meets the designated measures and tests in a specific content area (e.g., Transport, Submission/Acknowledgment, Query/Response, etc.).